

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 801, 803, 804, 807, 820, and 897****[Docket No. 95N-0253]****RIN 0910-AA48****Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing regulations governing access to and promotion of nicotine-containing cigarettes and smokeless tobacco to children and adolescents.

The regulations prohibit the sale of nicotine-containing cigarettes and smokeless tobacco to individuals under the age of 18; require manufacturers, distributors, and retailers to comply with certain conditions regarding the sale and distribution of these products; require retailers to verify a purchaser's age by photographic identification; prohibit all free samples and prohibit the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time; limit the advertising and labeling to which children and adolescents are exposed to a black-and-white, text-only format; prohibit the sale or distribution of brand-identified promotional nontobacco items such as hats and tee shirts; prohibit sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permit such sponsorship in a corporate name; and require manufacturers to provide intended use information on all cigarette and smokeless tobacco product labels and in cigarette advertising.

These regulations will address the serious public health problems caused by cigarettes and smokeless tobacco products. They will reduce children's and adolescents' easy access to cigarettes and smokeless tobacco and will significantly decrease the amount of positive imagery that makes these products so appealing to that age group.

The regulations are predicated on the agency's assertion of jurisdiction under the Federal Food, Drug, and Cosmetic Act over cigarettes and smokeless

tobacco as delivery devices for nicotine, incorporated as part of the regulations for purposes of, and to facilitate, congressional review under the Small Business Regulatory Enforcement Fairness Act of 1996.

**DATES:** *Effective date.* The regulation is effective August 28, 1997, except that § 897.14(a) and (b) are effective February 28, 1997 and § 897.34(c) is effective February 28, 1998.

*Compliance dates.* Manufacturers and distributors are required to comply with the requirements of 21 CFR parts 803 and 804 August 28, 1997; manufacturers are required to comply with the requirements of 21 CFR parts 807 and 820 February 28, 1998.

**ADDRESSES:** References listed in the footnotes of this document have been placed on public display at the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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## I. Introduction

### A. Purpose and Overview of the Rule

This rule establishes regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents, implementing FDA's determination that it has jurisdiction over these products under the Federal Food, Drug, and Cosmetic Act (the act). As described in "Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination" (the 1996 Jurisdictional Determination), annexed hereto, FDA has determined that cigarettes and smokeless tobacco are intended to affect the structure or function of the body, within the meaning of the act's definitions of "drug" and "device." The nicotine in cigarettes and smokeless tobacco is a "drug," which produces significant pharmacological effects in consumers, including satisfaction of addiction, stimulation, sedation, and weight control. Cigarettes and smokeless tobacco are combination products consisting of the drug nicotine and device components intended to deliver nicotine to the body.

FDA has chosen to regulate cigarettes and smokeless tobacco under the act's device authorities. This rule allows the continued marketing of these products, while employing measures to prevent future generations of Americans from becoming addicted to them. As discussed in section I.B. of this document, most people who use cigarettes and smokeless tobacco begin their use before the age of 18 and, therefore, before they fully understand the addictive nature and serious health risks of these products. Even though the sale of tobacco products to minors is illegal in 50 States, the tobacco industry has adopted extensive marketing campaigns which appeal to children and adolescents. Therefore, the rule effects measures that would both complement the existing State restrictions on access and prevent

tobacco companies from marketing their products to children and adolescents.

In determining the best course of action, the agency considered the highly addictive nature of cigarettes and smokeless tobacco and the fact that these products have previously been lawfully marketed to millions of adult Americans. The agency has determined that the approach outlined in this document—restrictions to reduce the use of cigarettes and smokeless tobacco by individuals under the age of 18 while leaving these products on the market for adults—is the available option that is the most consistent with both the act and the agency's mission to protect the public health.

The agency intends to assist affected entities, including retailers, distributors, and manufacturers, in complying with the rule. The agency also will issue a small entities guide in easy to understand language. In addition, the agency will conduct workshops throughout the country to assist affected entities in complying with the rule.

#### B. Background

Approximately 50 million Americans currently smoke cigarettes and another 6 million use smokeless tobacco.<sup>1</sup> In the Federal Register of August 11, 1995 (60 FR 41314), FDA published a proposed rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents" (the 1995 proposed rule). As stated in the preamble to the 1995 proposed rule, tobacco use is the single leading cause of preventable death in the United States.<sup>2</sup> More than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths.<sup>3</sup> Tobacco alone kills

more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined.<sup>4</sup>

Tobacco products have historically been legal and widely available in this country. It was only after millions of people became addicted to the nicotine in cigarettes and smokeless tobacco that health experts became fully aware of the extraordinary health risks involved in the consumption of these products. Consequently, tobacco use has become one of the most serious public health problems facing the United States today. Because of the grave health consequences of the use of tobacco products, some have argued that they should be removed from the market.

However, a ban would have adverse health consequences and would not be likely to prevent individuals from gaining access to these products. Of the 50 million people who use cigarettes, 77 to 92 percent are addicted.<sup>5</sup> Data suggest that almost as many smokeless tobacco users may be addicted.<sup>6</sup> Adverse health consequences could result if these people were suddenly deprived of the nicotine these products deliver. As stated in the preamble to the 1995 proposed rule:

Because of the high addiction rates and the difficulties smokers experience when they attempt to quit, there may be adverse health consequences for many individuals if the products were to be withdrawn suddenly from the marketplace. Our current health care system and available pharmaceuticals may not be able to provide adequate or sufficiently safe treatment for such a precipitous withdrawal.

(60 FR 41314 at 41348)

A similar situation would exist for addicted smokeless tobacco users.

It is probable also that a black market and smuggling would develop to supply addicted users with these products. As stated in the preamble to the 1995 proposed rule, and discussed further in section II.C.5. of this document, "[t]he products that would be available through a black market could very well be more dangerous (e.g., cigarettes containing more tar or nicotine, or more toxic additives) than products currently on the market" (60 FR 41314 at 41349). Thus, the agency has concluded that, while taking cigarettes and smokeless tobacco off the market could prevent some people from becoming addicted and reduce death and disease for others,

the record does not establish that such a ban is the appropriate public health response under the act.

To effectively address the death and disease caused by tobacco products, addiction to cigarettes and smokeless tobacco must be eliminated or substantially reduced. The evidence demonstrates that this can be achieved only by preventing children and adolescents from starting to use tobacco. Most people who suffer the adverse health consequences of using cigarettes and smokeless tobacco begin their use before they reach the age of 18, an age when they are not prepared for, or equipped to, make a decision that, for many, will have lifelong consequences. These young people do not fully understand the serious health risks of these products or do not believe that those risks apply to them. They are also very impressionable and therefore vulnerable to the sophisticated marketing techniques employed by the tobacco industry, techniques that associate the use of tobacco products with excitement, glamour, and independence. When cigarette and smokeless tobacco use by children and adolescents results in addiction, as it so often does, these youths lose their freedom to choose whether or not to use the products as adults.

The facts on underage use confirm this pattern. As stated in the preamble to the 1995 proposed rule, approximately 3 million American adolescents currently smoke and an additional 1 million adolescent males use smokeless tobacco.<sup>7</sup> Eighty-two percent of adults who ever smoked had their first cigarette before the age of 18, and more than half of them had already become regular smokers by that age.<sup>8</sup> Among smokers ages 12 to 17 years, 70 percent already regret their decision to smoke and 66 percent say that they want to quit.<sup>9</sup>

Moreover, children and adolescents are beginning to smoke at younger ages than ever before. Despite a decline in smoking rates in most segments of the American adult population, the rates among children and adolescents have recently begun to rise.<sup>10</sup> Data reported

<sup>1</sup> "National Household Survey on Drug Abuse: Population Estimate 1993, Department of Health and Human Services (DHHS), Public Health Service (PHS), Substance and Mental Health Services Administration (SAMHSA), Office of Applied Studies, Rockville, MD, Pub. No. (SMA) 94-3017, pp. 89 and 95, 1994.

<sup>2</sup> "Cigarette Smoking—Attributable Mortality and Years of Potential Life Lost—United States, 1990," *Mortality and Morbidity Weekly Report*, (MMWR) CDC, DHHS, vol. 42, No. 33, pp. 645-649, 1993; Lynch, B. S., and R. J. Bonnie, editors, *Growing Up Tobacco Free—Preventing Nicotine Addiction in Children and Youths*, Committee on Preventing Nicotine Addiction in Children and Youths, Division of Biobehavioral Sciences and Mental Disorders, Institute of Medicine, National Academy Press, Washington, DC, p.3, 1994, (hereinafter cited as "IOM Report").

<sup>3</sup> "Cigarette Smoking—Attributable Mortality and Years of Potential Life Lost—United States, 1990," *MMWR*, CDC, DHHS, vol. 42, No. 33, pp. 645-649, 1993.

<sup>4</sup> IOM Report, pp. 3-4.

<sup>5</sup> See authorities cited at 1996 Jurisdictional Determination, Section II(B)(2)(a).

<sup>6</sup> *Id.*

<sup>7</sup> "Preventing Tobacco Use Among Young People: A Report of the Surgeon General," DHHS, PHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, the Office on Smoking and Health (OSH), Atlanta, GA, p. 5, 1994, (hereinafter cited as "1994 SGR").

<sup>8</sup> 1994 SGR, p. 65.

<sup>9</sup> "Teen-Age Attitudes and Behavior Concerning Tobacco," The George H. Gallup International Institute, p. 54, September 1992.

<sup>10</sup> "Cigarette Smoking Among Adults—United States, 1991," *MMWR*, DHHS, CDC, vol. 42, No. 12,

in December 1995, after publication of the 1995 proposed rule, showed increases in 30-day prevalence rates of cigarette smoking for 4 consecutive years for 8th- and 10th-graders, and 3 consecutive years for high school seniors.<sup>11</sup> Daily use of cigarettes by 8th-, 10th-, and 12th-graders has also increased in each of the last 3 years.<sup>12</sup> The percentage of 8th- and 10th-graders who reported smoking in the 30 days before the survey had risen by one-third since 1991 to about 19 percent and 28 percent, respectively.<sup>13</sup> Similarly, the percentage of high school seniors saying that they had smoked in the 30 days before the survey had increased by more than one-fifth since 1991, to about 33.5 percent or one in three.<sup>14</sup>

An adolescent whose cigarette use continues into adulthood increases his or her risk of dying from cancer, cardiovascular disease, or lung disease.<sup>15</sup> Moreover, the earlier a young person's smoking habit begins, the more likely he or she will become a heavy smoker and therefore suffer a greater risk of diseases caused by smoking.<sup>16</sup>

pp. 230–233, 1993; Johnston, L. D., P. M. O'Malley, and J. G. Bachman, "National Survey Results on Drug Use from the Monitoring the Future Study 1975–1993, vol. I: Secondary School Students," Rockville, MD, DHHS, PHS, National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), NIH Pub. No. 94–3809, pp. 9 and 19, 79, 80, and 101, 1994; "Smoking Rates Climb Among American Teen-agers, Who Find Smoking Increasingly Acceptable and Seriously Underestimate the Risks," The University of Michigan News and Information Service, Table 1., July 17, 1995.

<sup>11</sup> "Results from the 1995 Monitoring the Future Survey," National Institute on Drug Abuse Briefing for Donna E. Shalala, Ph.D., Secretary of Health and Human Services, December 13, 1995.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> McGinnis, J. M., and W. H. Foege, "Actual Causes of Death in the United States," *Journal of the American Medical Association (JAMA)*, vol. 270, No. 18, pp. 2207–2212, 1993; "Reducing Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General," DHHS, PHS, CDC, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), OSH, DHHS Pub. No. 89–8411, p. 5, 1989, (hereinafter cited as "1989 SGR"); See generally "The Health Consequences of Smoking: Chronic Obstructive Lung Disease: A Report of the Surgeon General," DHHS, PHS, OSH, 1984, (hereinafter cited as "1984 SGR"); "The Health Consequences of Smoking: Cardiovascular Disease—A Report of the Surgeon General," DHHS, PHS, OSH, 1983 (hereinafter cited as "1983 SGR"); "The Health Consequences of Smoking: Cancer—A Report of the Surgeon General," DHHS, PHS, OSH, 1982, (hereinafter cited as "1982 SGR").

<sup>16</sup> Taioli, E., and E. L. Wynder, "Effect of the Age at Which Smoking Begins on Frequency of Smoking in Adulthood," *The New England Journal of Medicine*, vol. 325, No. 13, pp. 968–969, 1991; Escobedo, L. G., et al. "Sports Participation, Age at Smoking Initiation, and the Risk of Smoking Among

Approximately one out of every three young people who become regular smokers each day will die prematurely as a result.<sup>17</sup>

Similar problems exist with underage use of smokeless tobacco. As stated in the 1995 proposed rule, the market for smokeless tobacco has shifted dramatically toward young people since 1970 (60 FR 41314 at 41317). School-based surveys in 1991 estimated that 19.2 percent of 9th to 12th-grade boys use smokeless tobacco.<sup>18</sup> Among high school seniors who had ever tried smokeless tobacco, 73 percent did so by the 9th grade.<sup>19</sup>

As long as children and adolescents become addicted to cigarette and smokeless tobacco use in these numbers, there is little chance that society will be able to reduce the toll of tobacco-related illnesses. If, however, the number of children and adolescents who begin tobacco use can be substantially diminished, tobacco-related illness can be correspondingly reduced because data suggest that anyone who does not begin smoking in childhood or adolescence is unlikely to ever begin.<sup>20</sup>

On the basis of this evidence, the agency has determined that establishing restrictions to substantially reduce the number of children and adolescents who become addicted to cigarettes and smokeless tobacco best serves its public health obligations. Because such a small percentage of the U.S. population begins tobacco use after the age of 18, limiting the use of these products to the adult population would substantially reduce the principal source of new users. Thus, the appropriate emphasis is on reducing the use of tobacco products by children and adolescents.

Evidence in the administrative record demonstrates that the most effective

U.S. High School Students," *JAMA*, vol. 269, No. 11, pp. 1391–1395, 1993; see also 1994 SGR, p. 65.

<sup>17</sup> Memorandum from Michael P. Eriksen (CDC) to Catherine Lorraine (FDA) August 7, 1995 and CDC Fact Sheet (based on J. P. Pierce, M. C. Fiore, T. E. Novotny, E. J. Hatzianandreu, and R. M. Davis, "Trends in Cigarette Smoking in the United States: Projections to the Year 2000," *JAMA*, vol. 261, pp. 61–65, 1989; Unpublished data from the 1986 National Mortality Followback Survey, CDC, OSH; Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, Jr., "Mortality from Smoking in Developed Countries, 1950–2000: Indirect Estimates from National Vital Statistics," Oxford University Press, Oxford, 1994).

<sup>18</sup> Kann, L., W. Warren, J. L. Collins, J. Ross, B. Collins, and L. J. Kolbe, "Results from the National School-Based 1991 Youth Risk Behavior Survey and Progress Toward Achieving Related Health Objectives for the Nation," *Public Health Reports*, vol. 108, (Supp. 1), pp. 47–54, 1993.

<sup>19</sup> 1994 SGR, p. 101.

<sup>20</sup> *Id.*, pp. 5, 58, and 65–67.

way to achieve such a reduction is by limiting the access to, and attractiveness of, cigarettes and smokeless tobacco to young people. FDA concludes that the act provides sufficient authority to issue regulations that, while leaving these products on the market for adult use, restrict access to and promotion of cigarettes and smokeless tobacco to those under 18 years of age.

### C. Provisions of the Rule

After considering numerous comments submitted in response to the 1995 proposed rule, the agency is adopting the rule in modified form. New part 897 is being added to Title 21 of the Code of Federal Regulations and contains the regulations governing the labeling, advertising, sale, and distribution of cigarettes and smokeless tobacco to children and adolescents.

FDA is regulating nicotine-containing cigarettes and smokeless tobacco as restricted devices within the meaning of the section 520(e) of the act (21 U.S.C. 360j(e)). While leaving these products on the market for adults, the final rule prohibits the sale of nicotine-containing cigarettes and smokeless tobacco to individuals under the age of 18 and requires manufacturers, distributors, and retailers to comply with certain conditions regarding access to, and promotion of, these products. Among other things, the final rule requires retailers to verify a purchaser's age by photographic identification. It also prohibits all free samples and prohibits the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time. The rule also limits the advertising and labeling to which children and adolescents are exposed. The rule accomplishes this by generally restricting advertising to which children and adolescents are exposed to a black-and-white, text-only format. In addition, billboards and other outdoor advertising are prohibited within 1,000 feet of schools and public playgrounds. The rule also prohibits the sale or distribution of brand-identified promotional, nontobacco items such as hats and tee shirts. Furthermore, the rule prohibits sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permits such sponsorship in a corporate name. This rule is intended to complement the regulations issued by SAMHSA implementing section 1926 of the Public Health Service Act (42 U.S.C. 300x–26) regarding the sale and

distribution of tobacco products to individuals under the age of 18 (the SAMHSA rule).

In this document, FDA: (1) Presents its analysis of its authority to issue regulations that impose the enumerated restrictions on the sale and promotion of cigarettes and smokeless tobacco to those under the age of 18, while leaving cigarettes and smokeless tobacco on the market for adults; and (2) responds to comments on the proposed rule.

## II. Legal Authority

In the 1996 Jurisdictional Determination, annexed hereto, the Food and Drug Administration (FDA) <sup>21</sup> has determined that cigarettes and smokeless tobacco are combination products consisting of a drug (nicotine) and device components intended to deliver nicotine to the body. The agency may regulate a drug/device combination product using the Federal Food, Drug, and Cosmetic Act's (the act's) drug authorities, device authorities, or both. The agency exercises its discretion to determine which authorities to apply in the regulation of combination products to provide the most effective protection to the public health. FDA has determined that tobacco products are most appropriately regulated under the device provisions of the act, including the restricted device authority in section 520(e) of the act (21 U.S.C. 360j(e)).

### A. Legal Principles Applicable to Combination Drug/Device Products

The agency's discretion to choose the appropriate regulatory tools under the act is based, in part, on the authority provided under the Safe Medical Devices Act of 1990 (the SMDA). FDA's interpretation, supported by the language of the statute and its legislative history, is embodied in the agency's implementing regulations codified at part 3 (21 CFR part 3), the delegations of premarket approval authority to FDA's Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and Center for Biologics Evaluation and Research (CBER) that enable all three Centers to administer statutory authority for drugs, devices, and biologics (56 FR 58758, November 21, 1991), and the "intercenter agreements" that guide the agency in allocating Center

responsibility for various categories of combination products (56 FR 58760, November 21, 1991). In addition to the authority provided by the SMDA, the agency's discretion is also based on the principles recognized by the Supreme Court in cases such as *United States v. An Article of Drug* \* \* \* *Bacto-Unidisk*, 394 U.S. 784 (1969). In *Bacto-Unidisk*, for example, the Supreme Court upheld the agency's decision to regulate a diagnostic test kit under its drug authorities on the grounds that "[i]t is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that such regulation is desirable for the public health \* \* \*." (*Bacto-Unidisk* 394 U.S. at 791-792.)

The discussion that follows describes in more detail FDA's interpretation of the combination product provisions of the SMDA, the agency's understanding of combination products, and the way in which the agency has exercised its discretion in determining the most appropriate authorities to apply to regulate combination products.

#### 1. The SMDA Recognized Combination Products for the First Time

Congress enacted the SMDA's combination product provisions to recognize combination products as distinct entities subject to regulation under the act and to alleviate the difficulty the agency had experienced in regulating such products, especially those consisting of components of both a drug and a device. First, the SMDA explicitly recognized the existence of products that "constitute a combination of a drug, device, or biological product" (section 503(g)(1) of the act (21 U.S.C. 353(g)(1))). Second, the statute provided a mechanism for determining which agency component would be assigned the administrative responsibility of regulating a particular combination product (*Id.*).

In accordance with its recognition of combination products, the SMDA changed the statutory definitions of "drug" and "device" at section 201(g) and (h) of the act (21 U.S.C. 321(g) and (h)). Before the enactment of the SMDA, section 201(g) of the act provided that a drug "does not include devices or their components, parts, or accessories." The SMDA removed this language from the definition of "drug" so that the terms "drug" and "device" were no longer mutually exclusive, thereby making it possible for a combination product consisting of both a drug and device to be regarded as an independent entity subject to regulation. The legislative history indicates that this

definitional change was made "to accommodate the principle of [combination products in] section 20" (S. Rept. 101-513, 101st Cong. 2d sess., at 30 (1990)). For the first time it was possible, as a legal matter, for a single product to have both drug and device components.

The SMDA also permitted a wider range of products to meet the definition of a device. Prior to its amendment by the SMDA, section 201(h) of the act defined a "device" as an instrument or other item that, among other things, "does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes." The SMDA changed the phrase "any of its principal intended purposes" in the definition to read, "its primary intended purposes." This change broadened the definition of device and allowed more products to be categorized as devices.

#### 2. The SMDA Leaves to FDA's Discretion the Determination of Which Regulatory Authorities to Apply to Particular Combination Products

Having recognized combination products, the SMDA also provided a clear mechanism for determining which agency component a particular combination product should be directed to for review. Under the SMDA, the agency must:

[d]etermine the primary mode of action of the combination product. If the [agency] determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

(Section 503(g)(1) of the act)

This section of the SMDA "provide[d] the [agency] with firm ground rules to direct products promptly to that part of FDA responsible for reviewing the article that provides the primary mode of action of the combination product" (S. Rept. 101-513, 101st Cong., 2d sess., 30 (1990)).

Although the SMDA provided a mechanism for determining which agency component, i.e., a Center, should review a particular combination product, the legislation left to FDA the discretion to decide which statutory authorities it would use in regulating a particular combination product. The

<sup>21</sup> The Secretary of the Department of Health and Human Services (DHHS) (the Secretary) has the authority to carry out functions under the act through the Commissioner of Food and Drugs (the Commissioner). (See section 903 of the act (21 U.S.C. 393); 21 CFR 5.10 and 5.11.) Throughout this document, references to FDA include the Secretary and the Commissioner.

language of the SMDA makes this clear, as does the legislative history of the statute. Indeed, an earlier version of the bill, S. 3006, would arguably have removed this discretion by requiring the agency to regulate a product based only on its Center assignment. Thus, for example, if the primary mode of action were that of a drug, the product would be subject to regulation by CDER under the act's drug authorities. The earlier version's language, which Congress chose to strike from the final enactment, provided in relevant part:

The [agency] shall require only one market clearance route for an article that constitutes a combination of a device, drug, or biological product. If the [agency] determines that the primary mode of action of the combination article is that of—

(A) a drug (other than a biological product), neither the combination article nor any part of the article shall be treated as a device or as a biological product for market clearance purposes;

(B) a device, neither the combination article nor any part of the article shall be treated as a drug or a biological product for market clearance purposes; or

(C) a biological product, neither the combination article nor any part of the article shall be treated as a drug or a device for market clearance purposes.

(136 Congressional Record, S.12493, 101st Cong., 2d sess., August 4, 1990)

The omission of this language from the statute indicates that while Congress considered dictating which regulatory authority must be applied to particular combination products, and knew how to craft language to accomplish such a result, Congress ultimately chose to rely on FDA's expertise in determining the most appropriate regulatory tools needed to ensure the safety and effectiveness of the combination products that it regulates.

Moreover, Congress enacted language that recognizes that the agency may choose the appropriate regulatory authority for a particular combination product. Section 503(g)(2) of the act provides that nothing "shall prevent the [Agency] from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article." Since the enactment of the SMDA, the agency has interpreted the phrase "any agency resources" to include administrative resources and all applicable statutory authorities. See Drug/Device Intercenter Agreement, p. 2, contemporaneous interpretation that:

[u]nder the provisions of the Safe Medical Devices Act of 1990 and regulations promulgated to implement the combination product provisions of the Act, [the Center for

Drug Evaluation and Research] and [the Center for Devices and Radiological Health] each may use both the drug and device provisions of the Federal Food, Drug, and Cosmetic Act as appropriate to regulate a combination product.

(See 21 CFR Part 3).

(See also 56 FR 58754 at 58759, November 21, 1991 (FDA amending its procedural regulations at part 5 by adding delegations of authority relating to the premarket review of combination products to state that those specified officials in CBER, CDRH, or CDER "who currently hold delegated premarket approval authority for biologics, devices, or drugs, respectively, are hereby delegated all the authorities necessary for premarket approval of any product that is a biologic, a device, or a drug, or any combination of two or more of these products: \* \* \*" (21 CFR 5.33).) Thus, when a combination product, a single entity, consists of a component that may be regulated as a drug, the act's drug provisions and device provisions are "resources" available to the agency for regulating the product.

(1) One comment disputed the agency's interpretation of section 503(g)(2) of the act, stating that the language of section 503(g)(2) can be construed to mean only "people, laboratories, and other agency support. The term 'Agency resources' does not mean 'legal authorities' as FDA would like to believe."

FDA disagrees with this comment. The agency notes that there is nothing in the statute itself or the legislative history that suggests any reason that the expansive phrase "any FDA resources" should be narrowly interpreted given the important public health benefit ("ensuring an adequate premarket review") that is the goal of this section of the SMDA. The agency's interpretation of this language is supported by the SMDA's legislative history, which is discussed more fully in section II.A.2. of this document. More importantly, as discussed previously, the agency has the discretion under the statute as enacted to choose the regulatory authorities most appropriate to the specific product at issue.

3. Interpreting the SMDA to Allow the Agency to Determine Which Regulatory Scheme Best Serves the Public Health is Consistent With 50 Years of Case Law

Construing the act as allowing the agency discretion to choose the most appropriate regulatory tools for a particular combination product is consistent with over 50 years of judicial precedent. The importance of

interpreting the act in a manner that is consistent with the public health purposes of the act was recognized by the Supreme Court in *United States v. Dotterweich*, 320 U.S. 277 (1943). This case, decided shortly after substantial changes were made to expand the agency's authority by the 1938 act, addressed the breadth of the term "person" in determining who was subject to prosecution for violations of the act. The Court described the spirit in which the statute should be interpreted:

By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

(*Id.* at 280)

The approach in *Dotterweich* was followed by a number of cases in which FDA's interpretation of the statute, especially in the area of selecting how to regulate a product to achieve a public health purpose, has been granted deference and has been upheld. In *United States v. An Article of Drug* \* \* \* *Bacto-Unidisk*, 394 U.S. 784 (1969), FDA's interpretation of the definition of the term "drug" and the applicability of the premarket review requirements were at issue. The Court upheld the agency's expansive interpretation of the definition of "drug" to include a laboratory screening product, in large part because this interpretation resulted in greater protection of the public health by virtue of the premarket review that the product would be subject to as a drug. As the Court reasoned:

It is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that such regulation is desirable for the public health, for we are hardly qualified to second-guess the Secretary's medical judgment.

(*Bacto-Unidisk*, 394 U.S. at 791-792)

The Court further stated:

The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow \* \* \*. But we are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is

to be given a liberal construction consistent with the Act's overriding purpose to protect the public health, and specifically, § 507's purpose to ensure that antibiotic products marketed serve the public with 'efficacy' and 'safety.'

(*Id.* at 798); (See also *U.S. v. 25 Cases, More or Less, of An Article of a Device*, \* \* \* *Sensor Pads*, 942 F.2d 1179 (7th Cir. 1991) (upholding FDA's determination that a latex bag filled with a layer of silicone lubricant that was intended to aid women in self-examinations for early detection of breast cancer was a device, because, among other reasons, the court deferred to the agency's discretion to interpret its own statute based on the legislative history of the act and on the principles announced in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)); *AMP, Inc. v. Gardner*, 389 F.2d 825, 830 (2d Cir.), *cert. denied, sub nom. AMP, Inc. v. Cohen*, 393 U.S. 825 (1968) (upholding FDA's classification of appellant's product for tying off severed blood vessels as a drug because, in part, the court was reluctant to give a narrow construction to the act, "touching the public health as it does").

These cases stand for two principles: (1) FDA's interpretations of its own statute should be given deference, and (2) the act should be interpreted expansively to achieve its primary purpose, protecting the public health. These principles support the agency's determinations, carefully made after applying its considerable scientific expertise to the evaluation of the evidence before it, that cigarettes and smokeless tobacco are drug delivery devices and that these combination products are most appropriately regulated using the device authorities of the act. The agency's decision regarding tobacco products is consistent with other determinations that the agency has made, which have been upheld and endorsed by the courts, to regulate products in the most reasonable manner that will result in the best protection of the public health.

#### 4. The Implementing Regulations and the Delegations of Authority Reflect FDA's Interpretation That Section 503(g) of the Act Authorizes the Agency to Determine the Appropriate Regulatory Authorities

FDA's implementing regulations and delegations of authority, adopted shortly after passage of the SMDA, reflect the agency's contemporaneous interpretation of section 503(g) of the act as authorizing the agency to apply the most appropriate regulatory authorities to any given combination product. In

§ 3.2(e)(1), FDA defined a combination product to include, in relevant part:

A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity[.]

In a final rule that published in the Federal Register of November 21, 1991 (56 FR 58754), the agency explained that "the term combination product means a product comprised of two or more different regulated entities, e.g., drug, device, or biologic \* \* \*" or that are produced together as a single entity, packaged together, or used together to achieve the intended effect. Thus, the fact that a single product contains elements of two or more regulated entities does not change the regulatory status of the individual elements. Each "different regulated entity[y]" of the combination continues to satisfy the criteria of its relevant statutory definition; that is, a drug component must satisfy the definition in section 201(g) of the act, and a device component must comply with the definition in section 201(h) of the act. Because the elements of a combination product meet more than one jurisdictional definition, the agency may apply one or more sets of regulatory provisions to the product.

In the same issue of the Federal Register in which the agency published the final regulations governing combination products, the agency published delegations of authority that allow the officials in CDER, CDRH, and CBER to utilize the premarket approval authorities for any product that is a drug, device, biologic, or any combination of two or more of these (56 FR 58758, November 21, 1991 (21 CFR 5.32)). These delegations allow the officials of one Center to conduct a premarket review of a product under another Center's regulatory authority, thereby making it possible, for example, for CDER to review a drug/device combination product under the device authorities. While the combination product regulations created the procedure for making the proper Center assignment, the delegations were necessary in order for FDA to exercise its discretion to determine which regulatory authority is most appropriate and to make it possible to apply that authority to review a particular product. If the primary mode of action of a combination product having drug and device components resulted in the assignment of the product to CDER, for example, but the agency determined

that the device component of the product presented the most important regulatory and scientific questions, the delegations make it possible for CDER officials to conduct the premarket review of the product under the device provisions of the act.

The regulations and the delegations of authority constitute the agency's contemporaneous interpretation of section 503(g) of the act as granting the agency discretion to choose the premarket approval authority that provides the best public health protection. Such contemporaneous interpretations by an agency are entitled to considerable deference by the courts. (See *Young v. Community Nutrition Institute*, 476 U.S. 974 (1986).)

#### 5. The Intercenter Agreements and Administrative Precedent Recognize That FDA May Determine Which Regulatory Authority to Apply to a Particular Product

In addition to the regulations and delegations of authority implementing section 503(g) of the act, FDA has also adopted and made public three guidance documents, entitled "Intercenter Agreements," that describe the agreements reached among the Centers about regulatory pathways for specified products or classes of products as of October 31, 1991. (See Intercenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health; Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health (the Drug/Device Agreement); and Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research.)

These documents detail which Center generally will have the lead responsibility for regulating particular types of products. The Intercenter Agreements also state which regulatory authority usually will be applied to specific products. For example, the Drug/Device Agreement provides that a device with the primary purpose of delivering or aiding in the delivery of a drug and distributed containing a drug (i.e., "prefilled delivery system") will be regulated by "CDER using drug authorities and device authorities, as necessary" (Drug/Device Agreement, p. 6). Examples given of such combination products include a nebulizer, prefilled syringe, and transdermal patch (Drug/Device Agreement, p. 6). The Drug/Device Agreement specifically provides that such combination products may be regulated under either the drug or



device authorities, whichever is more appropriate for a particular product.<sup>22</sup>

FDA's implementation of the Intercenter Agreement reflects these understandings. For example, one drug delivery product that has been regulated under the device authorities under the Drug/Device Agreement is the prefilled, intravenous infusion pump, manufactured by two companies. These are pumps designed to be sold prefilled with a diluent, either a sodium chloride solution or a dextrose solution. FDA regulates the diluents in the pumps as drugs under section 201(g)(1)(B) of the act because they are intended for use in the treatment of disease. The pumps are combination products consisting of a device component, the pump, and a drug component, the diluent; and the product's purpose is to deliver the diluent to be mixed by the doctor or other health care provider attending the patient with another drug substance for infusion into the patient. These pumps prefilled with diluents are clearly "a device containing a drug substance as a component with the primary purpose of the combination product being to fulfill a drug purpose" that would be regulated as a drug according to the general principle stated in the Drug/Device Agreement (Drug/Device Agreement, p. 14). However, the agency exercised its discretion and determined that these drug delivery products should be regulated under the device authorities.

The agency based its determination on the fact that the drugs that were delivered by the products, saline and dextrose, are two ingredients very commonly used in intravenous infusions about which the agency had a wealth of scientific information and thorough regulatory experience. The pumps, the device component of this combination, however, operated on novel design principles. Because the device components of these combination products were new and raised significant regulatory questions, the agency determined that the products would receive the most appropriate premarket review if the device authorities were applied.

Another example of the agency's use of its discretion and its ability under the guidance in the Intercenter Agreements to make a sensible decision about product assignment is its decision regarding regulation of a catheter flush solution containing a blood-thinning drug and an antibiotic. The solution is intended as a flush solution to prevent the catheter (or tube) inserted into a patient's body from becoming clogged with blood and to prevent dangerous bacteria from growing in the catheter. Under the Drug/Device Agreement, this product would appear to fit into the category of a "liquid \* \* \* or other similar formulation intended only to serve as a component \* \* \* to a device with a primary mode of action that is physical in nature [and] will be regulated as a device by CDRH" (see Drug/Device Agreement, p. 13). The agency did determine that the product's premarket review would be conducted under the device authorities, but it assigned the review responsibility to CDER. The decision to follow an approach different from the one generally suggested in the Drug/Device Agreement was based on the fact that the inclusion of the blood-thinning and anti-infective drugs in the flush solution represented an innovation in such solutions and raised important scientific and regulatory questions that were most properly reviewed by the scientists in CDER. Because CDER was assigned the lead, the sponsor of this product was informed that the clinical investigations of this product should proceed under the investigational drug provisions of the act (section 505(i) of the act (21 U.S.C. 355(i))). This determination tailored the act's premarket review provisions, incorporating the most appropriate sections of both the drug and device authorities without being redundant, to the special features of this original product.

The agency has thus in the past made its jurisdiction decisions by determining the most reasonable course of action to protect public health given the scientific questions presented by each product. FDA considers essential its ability to continue to assess the individual circumstances of particular products. This will allow the agency to respond to technological developments, expanded scientific understanding, or additional factual information concerning a specific product or class of products.

### *B. Cigarettes and Smokeless Tobacco Have Both a Drug and a Device Component and Are Therefore Combination Products*

As discussed in detail in the 1996 Jurisdictional Determination, the agency has concluded that the nicotine in cigarettes and smokeless tobacco is a drug within the meaning of section 201(g)(1)(C) of the act. The agency has also concluded that cigarettes and smokeless tobacco contain, in addition to the drug nicotine, delivery device components that deliver a controlled amount of nicotine to the body. Thus, cigarettes and smokeless tobacco are combination products that contain both a "drug" and a "device."

The agency further concluded that processed loose cigarette tobacco, which is used by smokers who roll their own cigarettes, is a combination product.

### *C. FDA's Choice of Legal Authorities*

#### *1. FDA Will Regulate Cigarettes and Smokeless Tobacco Under the Act's Device Authorities*

Having established that cigarettes and smokeless tobacco are combination products consisting of both a drug component and device components, the agency has the discretion to choose whether it will regulate these products under the act's drug authorities, device authorities, or both if appropriate. Making this determination requires FDA to consider how the public health goals of the act can be best accomplished.

The act's drug and device provisions have a common objective: To ensure the safety and effectiveness of regulated products. They also provide the agency with similar authorities to regulate drugs and devices. In certain ways, however, the device provisions offer FDA more flexibility. The Medical Device Amendments of 1976 (the Medical Device Amendments) were enacted nearly 40 years after the act itself. During that period of time, Congress observed FDA's efforts to regulate devices under the authority of the act, noting that the agency's authority over devices became increasingly inadequate as the nature of the devices on the market changed (H. Rept. 94-853, 94th Cong., 2d sess., 6-10 (1976)).

In 1938 most of the devices in use were "relatively simple items which applied basic scientific concepts \* \* \*" (H. Rept. 94-853, 6). However, by the time the Medical Device Amendments were enacted, the universe of device products had evolved from primarily simple products, such as tongue depressors and bandages, to include a

<sup>22</sup> A later section of the Drug/Device Agreement states that a "device containing a drug substance as a component with the primary purpose of the combination product being to fulfill a drug purpose is a combination product and will be regulated as a drug by CDER." While this is the approach that FDA will usually take with such products, the earlier language of the Drug/Device Agreement expressly recognizes that FDA may use its device authorities where appropriate, and as discussed in the text, there are several examples of this type of prefilled delivery system being regulated using the device authorities.



variety of scientifically and technologically sophisticated products, such as cardiac pacemakers, lasers, and magnetic resonance imaging equipment. This wide range of technology posed many more varied regulatory concerns than those posed by drugs, which as a group of products are less diverse in nature.

Congress recognized the need for specific authority for devices that would take into account "the great diversity among the various medical devices and their varying potentials for harm as well as their potential benefit to improved health" (S. Rept. 94-33, 94th Cong., 1st sess., 10 (1975)). Thus, with the Medical Device Amendments, Congress enhanced FDA's authority to tailor regulatory controls, from an array of statutory tools, to fit the particular safety and effectiveness issues presented by individual devices.

Because of this additional flexibility, the agency has determined that the device authorities provide the most appropriate basis for regulating cigarettes and smokeless tobacco. Because millions of Americans are addicted to cigarettes and smokeless tobacco, regulation of these products presents unique safety problems that require careful, tailored solutions. The Medical Device Amendments provide the agency with regulatory options that are well suited to the unique problems presented by cigarettes and smokeless tobacco.

Although the agency has determined that the device authorities are the most appropriate authorities for regulating cigarettes and smokeless tobacco, the agency disagrees with the comments that suggest that the agency could not regulate cigarettes and smokeless tobacco as drugs. To the contrary, as discussed in section II.D. of this document, the agency could have used its drug authorities to implement similar types of controls on cigarettes and smokeless tobacco as it is imposing under the somewhat more flexible device authorities.

## 2. Cigarettes and Smokeless Tobacco Will be Subject to the Full Range of Device Authorities

In regulating cigarettes and smokeless tobacco, FDA will follow the regulatory scheme created by Congress for devices. Because the universe of devices is extremely diverse, presenting a broad spectrum of safety and effectiveness issues, the Medical Device Amendments include a wide range of regulatory controls. Some of these controls, such as the adulteration and misbranding requirements, are applicable to all

devices, while others, such as premarket approval and restrictions on sale, distribution, and use, are to be applied only where FDA concludes that they are necessary to provide reasonable assurance of safety and effectiveness for particular devices. The Medical Device Amendments are thus designed to allow the agency to regulate individual devices with controls that are tailored to address the safety and effectiveness problems raised by those devices.

As devices, cigarettes and smokeless tobacco will be subject to all mandatory provisions of the act, except where exemption is permitted by statute and is appropriate for these products. In addition, cigarettes and smokeless tobacco will be subject to other discretionary provisions of the act that the agency has concluded are necessary to address the special safety issues posed by these products.

The basic requirements of the act applicable to all devices include: Adulteration and misbranding provisions (sections 501 and 502 of the act (21 U.S.C. 351 and 352)), labeling requirements (section 502), establishment registration, device listing, and premarket notification (section 510 (21 U.S.C. 360)), recordkeeping and reporting requirements (section 519 (21 U.S.C. 360i)), and good manufacturing practice (GMP) requirements (section 520(f)). As described in more detail in section II.C.4. of this document, FDA intends to apply these requirements, where appropriate, to cigarettes and smokeless tobacco at a future time. In addition, the act requires the agency to classify devices into one of three classes. Depending on the class into which a product is classified, additional regulatory requirements may apply: Class I (general controls), class II (special controls), and class III (premarket approval). As described in more detail in section II.C.5. of this document, as the act contemplates, FDA intends to classify cigarettes and smokeless tobacco at a future time, and will impose any additional requirements that apply as a result of their classification.

The agency has determined that the safety of cigarettes and smokeless tobacco cannot be assured without restrictions on the sale, distribution, and use of these products to children and adolescents. Accordingly, FDA is imposing restrictions under the authority granted in section 520(e) of the act.

(2) Several comments argued that the regulatory requirements proposed by

FDA for cigarettes and smokeless tobacco distort the regulatory scheme for devices established by Congress. These comments contended that FDA has: (1) Selectively applied the provisions of the Medical Device Amendments; (2) inappropriately relied on section 520(e) of the act (restrictions on sale, distribution, or use) while ignoring other mandatory provisions of the act, such as classification; and (3) determined that cigarettes and smokeless tobacco are unsafe and yet failed to invoke provisions of the act that, according to the comments, require the agency to remove them from the market.

FDA disagrees with these comments. As already described, FDA intends to apply to cigarettes and smokeless tobacco all of the mandatory provisions of the Medical Device Amendments. Thus, FDA is neither selectively applying the provisions of the act nor ignoring mandatory provisions.

Although FDA intends to impose on cigarettes and smokeless tobacco all requirements applicable to devices, the act does not provide that these requirements should all be imposed immediately. Classification serves the purpose of identifying which devices need to be subject to special controls (class II) or premarket approval (class III) in addition to the general controls applicable to all devices. Classification requires FDA to institute a separate rulemaking proceeding. The act does not require the agency to classify a device before general controls become applicable to it. Rather, the general controls provisions of the act apply to all devices both before and after classification and irrespective of the class into which a device is ultimately classified. Because the classification process involves many steps and can take years to complete, FDA does not ordinarily complete the classification process before regulating the device under its general controls.

Moreover, the statute contains no requirement that the agency complete a classification rulemaking before invoking the general controls that apply to all devices. For example, each of the literally thousands of medical devices that have been classified by rulemaking under section 513 of the act (21 U.S.C. 360c) were subject to the general controls of the statute—such as the provisions on adulteration, misbranding, registration, investigational device controls, and GMP—in advance of the completion of the classification rulemaking proceedings. (See, e.g., *Contact Lens*

*Mfrs. Association v. FDA*, 766 F.2d 592, 603 (D.C. Cir. 1985), *cert. denied* 474 U.S. 1062 (1986).) Indeed, in some cases, the general controls provisions were applicable to marketed devices for many years before completion of classification.

Consistent with the agency's practice, FDA has made a decision to apply the general controls provisions of the act to cigarettes and smokeless tobacco, including restrictions on their distribution, sale, and use under section 520(e) of the act, before classifying cigarettes and smokeless tobacco. As described in section II.C.5. of this document, FDA will, in a future rulemaking, classify cigarettes and smokeless tobacco in accordance with the procedures in section 513 of the act. In the meantime, the general controls will apply.

FDA also disagrees that the act requires the agency to remove cigarettes and smokeless tobacco from the market. As described in the preamble to the 1995 proposed rule (60 FR 41314), although cigarettes and smokeless tobacco pose very grave risks, the agency cannot conclude that removing them from the market would most effectively meet the statutory goal of providing reasonable assurance of safety and effectiveness. Because millions of Americans are addicted to cigarettes and smokeless tobacco, the consequences of their removal from the market, as discussed in greater detail in section II.C.5. of this document, would include adverse health effects from sudden withdrawal, the likely development of a black market, and the possibility that the products that would be available through a black market would pose greater risks than those currently on the market. None of the statutory sections cited by the comments require the agency to remove products from the market where the agency concludes that such action would be contrary to the public health. Here, FDA has determined that the unique safety issues presented by highly addictive and long-marketed products like cigarettes and smokeless tobacco can most effectively be addressed by actions to prevent new users from becoming addicted to these devices.

In section II.C.3. of this document, FDA discusses its authority to impose restrictions on sale, distribution, and use to prevent children and adolescents from becoming addicted to cigarettes and smokeless tobacco. In section II.C.4 of this document, FDA discusses imposition of other general controls, and, in section II.C.5 of this document,

FDA discusses classification of cigarettes and smokeless tobacco.

### 3. The Restricted Device Provision Authorizes FDA to Establish Access and Advertising Restrictions

Congress provided FDA with authority to prevent the use of a device by those not competent to use it safely in the restricted device provision (section 520(e) of the act). Specifically, section 520(e) of the act states in part:

(1) The [agency] may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the [agency] may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the [agency] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

Section 520(e) is one of the act's "general controls" (see section 513(a)(1)(A) of the act). As a general control, section 520(e) of the act can be used by FDA to regulate any class of device (section 513(a) of the act). Because its applicability does not depend upon the outcome of the classification process, 520(e) of the act—like the other general controls—can be used by FDA to regulate a device prior to the classification of the device.

In applying section 520(e) of the act to restrict the sale, distribution, or use of a device, FDA must find that without the restriction "there cannot otherwise be reasonable assurance of its safety and effectiveness." This provision requires FDA to find that the restrictions in section 520(e) of the act are necessary to assure the safety and effectiveness of the device, but FDA does not have to find that the restrictions are sufficient to assure safety and effectiveness. During the classification process, FDA determines whether additional controls beyond section 520(e) of the act and the other general controls applicable to all devices are needed to assure the safety and effectiveness of the device.

The restricted device provision in section 520(e) of the act authorizes FDA to adopt regulations that ensure that children and adolescents, who by State law are not competent to use cigarettes and smokeless tobacco, will not be able to obtain them. In particular, FDA has determined that section 520(e) of the act authorizes the access and advertising restrictions in the final rule because without these restrictions "there cannot otherwise be reasonable assurance of \* \* \* safety \* \* \*."

As described more fully later in this section of this document, the agency's use of section 520(e) of the act in this rule is consistent with the plain language of section 520(e), the legislative history, and the agency's prior use of section 520(e) in, for example, restricting the sale, distribution, and use of hearing aids (42 FR 9285, February 15, 1977, as amended at 47 FR 9397 through 9398, March 5, 1982).

As discussed in section II.C.5. of this document, the agency intends to classify cigarettes and smokeless tobacco under the procedures contained in section 513 of the act. The classification process is the time at which the agency determines what degree of regulation is necessary to provide a "reasonable assurance of safety and effectiveness" for a particular product, such as tobacco products. However, the act does not specify the timing of the application of device authorities, and the agency is therefore able to issue restrictions under section 520(e) of the act prior to initiating the classification process. The agency also did so in its regulation of hearing aids. In 1977, FDA adopted regulations under section 520(e) of the act containing restrictions on the sale, distribution, and use of hearing aids (42 FR 9285, February 15, 1977, as amended at 47 FR 9397 and 9398, March 5, 1982), but did not classify these products until 1986 (51 FR 40378 at 40389, November 6, 1986).

FDA is following a similar course here. The agency has determined that unless measures are taken now to prohibit the sale and promotion of these products to young people under the age of 18, there cannot otherwise be reasonable assurance of safety. Therefore, FDA is acting under section 520(e) of the act to restrict the sale, distribution, and use of cigarettes and smokeless tobacco.

a. *The restricted device provision authorizes FDA to prevent access to persons who cannot use a device safely or effectively.* Section 520(e) of the act is in part the device counterpart to section 503(b), the act's prescription drug provision. Section 503(b)(1) of the act, for instance, authorizes FDA to restrict access to potentially dangerous drugs by requiring that they be dispensed "only upon a \* \* \* prescription of a practitioner licensed by law to administer such a drug \* \* \*." Similarly, section 520(e)(1)(A) of the act authorizes FDA to restrict access to potentially dangerous medical devices "only upon the \* \* \* authorization of a practitioner licensed

by law to administer or use such device \* \* \*."

The restricted device provision, however, is significantly broader than the prescription drug provision. Not only may FDA restrict sale, distribution and use by prescription, but it may do so upon "*such other conditions as [it] may prescribe in such regulation*" (section 520(e)(1)(B) of the act (emphasis added)). There is no counterpart to this "other conditions" authority in the prescription drug provisions.

Section 520(e) of the act was designed to deal with the risks that are created by improper use of a device. The legislative history of the Medical Device Amendments specifically states that section 520(e) of the act was intended to "supersede[]" and "add[]" to the prescription authority derived from section 503(b) of the act (H. Rept. 94-853, 94th Cong. 2d sess., 24-25 (1976)). This confirms that Congress intended to give FDA broad authority to restrict access to potentially dangerous devices. (See also "Medical Device Regulation: The FDA's Neglected Child," Report of the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, 98th Cong., 1st sess., 31 (1985).)

Congress' use of the phrase "could include" indicates that this discussion was intended to be illustrative rather than exhaustive. The examples of possible restrictions described in the legislative history demonstrate that Congress intended to give the agency authority to restrict access to devices in a variety of ways, depending upon the type of risk posed by the device and the measures needed to ensure that the device is not used inappropriately. In short, the legislative history supports the statutory language and establishes that Congress intended FDA's authority to restrict the sale, distribution, and use of devices "upon such other conditions as the [agency] may prescribe" to be a flexible authority that allows FDA to tailor restrictions on sale, distribution, and use according to the circumstances posed by the device being regulated.

b. *The restricted device provision also authorizes FDA to restrict promotional activities that encourage uses that are inconsistent with the regulatory scheme.* Section 520(e) of the act is a broad grant of authority. The Secretary, and by delegation FDA, is authorized to restrict the sale, distribution, or use of a device "upon such other conditions as the [agency] may prescribe in such regulation." This broad grant of

authority covers all aspects of the sale of a device, including the offer of sale.

How a device is sold involves many elements. It involves not only the circumstances surrounding the exchange of money for the device, but also whether the device must be sold only on the authorization of a practitioner, whether age limits on users are appropriately established, and how the device is represented to potential users. It is in the latter regard that advertising plays a role and may be restricted under section 520(e) of the act.

The Supreme Court cases on commercial speech recognize that a State's interest in regulating sales extends to advertising promoting the sale. In *Edenfield v. Fane*, 507 U.S. 761, 767 (1993), the Supreme Court said that commercial transactions are "linked inextricably" with the commercial speech that proposes the transaction, and that the State's interest in regulating the underlying transaction may give it a concomitant interest in the expression itself. Likewise, under section 520(e) of the act, the sale of a device is "linked inextricably" to the advertising that promotes the sale, giving FDA concomitant authority to impose necessary restrictions on the advertising.

FDA's regulation of hearing aids exemplifies this aspect of section 520(e) of the act. One of the most important purposes of the restrictions on sale, distribution, and use imposed on hearing aids was to respond to widespread inappropriate promotion of hearing aids to consumers for whom the devices are not effective (see 41 FR 16756 at 16757 (April 21, 1976)). In that regulation, in addition to restricting sales to persons who had been medically evaluated for hearing aids, FDA relied upon section 520(e) of the act to require that an instructional brochure be distributed to each prospective hearing aid user. These brochures described the adverse reactions and side effects associated with hearing aids and encouraged prospective users to seek medical evaluations. The distribution of the brochure was required as a means of ensuring that advertising for hearing aids did not inappropriately induce persons who had not been medically evaluated to purchase the hearing aids.

The agency's authority to use section 520(e) of the act to restrict advertising is especially strong when limits on advertising are necessary to ensure that advertising does not undermine the conditions on sale, distribution, or use

that the agency adopts under section 520(e). The agency should not be—and under section 520(e) of the act is not—powerless to prevent advertising that encourages sales that the agency has barred under section 520(e). Rather, the agency may use its authority to impose "such other conditions as the [agency] may prescribe" to restrict advertising that directly undercuts the agency's restrictions on sale, distribution, and use.

c. *The restricted device provision authorizes FDA's restrictions on youth access and on advertising designed to make cigarettes and smokeless tobacco appealing to youth.* The restricted device provision authorizes the restrictions on youth access and on advertising in this final rule. Section 520(e) of the act contemplates these types of restrictions on sale and distribution. Moreover, they are necessary if FDA ever were to be able to find that there is a reasonable assurance of the safety of cigarettes and smokeless tobacco under the act. As section 520(e) of the act provides, without these restrictions "there cannot otherwise be reasonable assurance of safety and effectiveness."

The provisions in the final rule that restrict the access of minors to cigarettes and smokeless tobacco are clearly restrictions on "sale, distribution, or use" of a device within the meaning of section 520(e) of the act. FDA's access restrictions are designed to ensure that children and adolescents are unable to have access to cigarettes and smokeless tobacco. These restrictions directly limit the sale of cigarettes and smokeless tobacco by, for instance, banning the sale of these products to persons under 18. They also directly limit the distribution of cigarettes and smokeless tobacco by, for instance, banning the distribution of free samples. Hence, these access restrictions are within the plain language of section 520(e) of the act.

The advertising restrictions in the final rule are also among the types of restriction that section 520(e) of the act authorizes. As in the case of the restrictions imposed on hearing aids, the advertising restrictions are designed to address inappropriate promotion of cigarettes and smokeless tobacco to individuals for whom the potentiality for harm is particularly great. The advertising restrictions are necessary to prevent advertising by the manufacturers of cigarettes and smokeless tobacco from undercutting the access restrictions. The effectiveness of the restrictions on youth access

would be substantially diminished if the manufacturers were free to entice children and adolescents to circumvent the access restrictions. In this circumstance, restrictions on advertising are properly treated as restrictions on "sale, distribution, or use" within the meaning of section 520(e) of the act.

The final requirement of section 520(e) of the act is that the agency establish that without the restrictions on the device "there cannot otherwise be reasonable assurance of its safety and effectiveness." This requirement is plainly met in the case of the access and advertising restrictions for cigarettes and smokeless tobacco. Without effective restrictions on sale and distribution of cigarettes and smokeless tobacco to children and adolescents under 18, young people will continue to become addicted to these products and, once addicted, will as adults continue to use them in spite of their potential for harmful effects. As stated in section I.B. of this document, the earlier tobacco use begins, the greater the risk of disease caused by, or associated with, the use of these products. Thus, there can be no doubt that without the access and advertising restrictions imposed in this final rule, no finding that there is a reasonable assurance of safety for cigarettes and smokeless tobacco would be possible.

Although FDA finds that the restrictions under section 520(e) of the act are *necessary* for providing a reasonable assurance of safety, FDA is not required under section 520(e) of the act to show that the restrictions are *sufficient* by themselves to provide a reasonable assurance of safety or effectiveness. Under section 520(e) of the act, all that FDA must establish is that without the section 520(e) restrictions, the device could not be found to be safe.

It is in the classification process—not in the application of section 520(e) of the act—that FDA must determine what controls are necessary if the agency is to find that there is a reasonable assurance that a device is safe and effective for its intended use. As discussed in section II.C.5. of this document, FDA intends to classify cigarettes and smokeless tobacco in a future rulemaking.

d. *Response to other comments.* FDA received several comments on whether section 520(e) of the act authorizes restrictions on youth access and advertising. Most of the comments were from tobacco trade associations, tobacco companies, and advertisers, arguing that section 520(e) of the act does not provide authority for either the access or

advertising restrictions. A comment from a public interest group, however, fully supported FDA's reliance on section 520(e). FDA also received a large number of comments from a broad cross-section of the public that expressed support for, or opposition to, the proposed restrictions without delving into the legal issues analyzed in the 1995 proposed rule.

(3) One comment said that FDA uses the term "conditions" in section 520(e)(1)(B) of the act to mean any regulatory imposition that the agency believes would bring about an improvement in safety in some way related to the device in question. The comment argued that FDA has used this term in such an overinclusive way that it would authorize FDA to impose many of the requirements that Congress imposed in other provisions of the act. For example, the comment argued that under FDA's interpretation it could require premarket approval of a device with a potentiality for harmful effect as a "condition" on the "sale, distribution, or use" of the device, on the theory that without premarket approval it would be impossible for there to be "reasonable assurance of its safety."

FDA disagrees with this comment. FDA's interpretation of section 520(e) of the act does not create any redundancy with the other provisions of the Medical Device Amendments. Most of the general controls authorized under the act, and the major thrust of the provisions on performance standards and premarket approval, are geared toward ensuring that finished devices, when ready for use, will be free from defects and will provide a reasonable assurance of safety and effectiveness for their labeled use. Restrictions under section 520(e) of the act, on the other hand, are imposed because the device's "potentiality for harmful effect or the collateral measures necessary to its use," and the determination that, without such restrictions, there cannot otherwise be a reasonable assurance of safety and effectiveness. The restrictions under section 520(e) of the act on cigarettes and smokeless tobacco focus on those who may *not* purchase and use these products rather than on those who will be using the products. Without successful restrictions on sale, distribution, and use of cigarettes and smokeless tobacco to children and adolescents under 18, there will never be reasonable assurance of the safety of these products because they would continue to be available to these young people, who, by State law, are not competent to use them.

(4) With regard to access, industry comments contended that FDA's authority under the provisions of the act relating to restricted devices was intended to be no broader than its prescription drug authority and, accordingly, could not extend to restrictions such as those in the 1995 proposed rule.

FDA disagrees with this view and believes that it is unsupported by the clear language of the act and the legislative history (see H. Rept. 94-853, 94th Cong., 2d. sess., 24-25 (1976)). Had Congress meant for the authority granted FDA under section 520(e) of the act to be no broader than the authority granted in section 503(b)(1) of the act to limit drugs to prescription use, it could simply have amended section 503(b)(1) of the act to add "or device" after "drug" each time the term is used. Indeed, as discussed in *Becton, Dickinson and Company v. Food and Drug Administration*, 589 F.2d 1175 (2d Cir. 1978) that approach was the one used in early versions of the legislation that became the 1976 amendments but was abandoned in favor of the broader "restricted device" approach that has been a part of the law for 20 years. The plain language of the enacted provision contains no limitation on the types of restrictions that can be imposed and certainly is not limited by its terms to restriction to prescription use. Moreover, as previously discussed, the legislative history specifically states that the agency's authority under section 520(e) of the act is broader than its authority under the prescription drug provisions (H. Rept. 94-853, 94th Cong., 2d sess., 24-25, 1976).

(5) An industry comment contended that "FDA uses what is merely the medical device version of prescription drug status as the sole legal justification for an elaborate system of controls far broader and more intrusive than is authorized even for true medical devices."

As discussed in section II.C.3. of this document, FDA's restricted device authority is significantly broader than suggested by this comment. Given the potentiality for harm from cigarettes and smokeless tobacco, FDA has ample authority to impose the conditions on their sale, distribution, and use that it is adopting.

As is the case with other medical devices, cigarettes and smokeless tobacco are subject to those regulatory controls that are appropriate for medical devices generally (e.g., registration, labeling, and inspection), along with those tailored to the product in question

and the risks that it presents (access restrictions and advertising controls). Thus, FDA is treating cigarettes and smokeless tobacco in a manner that is consistent with how it treats other medical devices.

(6) Turning to the advertising restrictions, several comments argued that section 520(e) of the act authorizes only restrictions on "sale, distribution, or use," and that it does not include the words "offer for sale." These comments pointed out that Congress used the words "offer for sale" elsewhere in the act (sections 301(m) and (o) (21 U.S.C. 331(m) and (o)) and 503(c)), and they therefore drew the inference that if Congress had intended section 520(e) of the act to authorize restrictions on how medical devices are offered for sale, it would have made this fact explicit.

FDA is not persuaded by this argument. In each of the instances cited in the comments where Congress has included the phrase "offer for sale" in the act, it was defining a prohibited act, that is, an act whose commission would violate the statute, in which the prohibition focused, at least in part, on the sale of a food, drug, or device. By including the phrase "offered for sale" in these provisions, Congress sought to ensure that the statutory objective of preventing the actual sale of products where advertising or labeling does not meet the statutory requirement would be met by including products merely "offered for sale" within the statute's coverage. The agency notes that, similarly, the words "offered for sale" appear in section 502(q) of the act, the provision that the agency would use to enforce section 520(e) of the act. Thus, Congress did in fact include "offer for sale" in the scope of conduct regulated under section 520(e) of the act and its enforcement clause, section 502(q). The comment's argument, however, misses the significance of section 520(e) of the act.

As discussed in section II.C.3. of this document, the authority to restrict the "sale, distribution, or use" of a device includes the authority to restrict the circumstances surrounding the sale and distribution of the device, including the device's advertising. The use of section 520(e) of the act to restrict advertising is particularly appropriate when the advertising restrictions are necessary to ensure that access restrictions issued under section 520(e) of the act are not undermined by a manufacturer's advertising. Here, FDA is restricting the sale of cigarettes and smokeless tobacco because of their potential harmful effects on individuals who start using

them before the age of 18 and who lack the competency to decide to do so. FDA has determined, as explained in sections VI.B. and D. of this document, that how cigarettes and smokeless tobacco are advertised plays a material role in the decision of children and adolescents under 18 to purchase and use these products. Thus, if the restrictions on how cigarettes are sold, distributed, and used that FDA is adopting under section 520(e) of the act are to be effective, they must include restrictions on how cigarettes and smokeless tobacco are advertised.

(7) The comments also argued that section 520(e) of the act on its face says nothing about advertising. Thus, according to these comments, FDA's authority to regulate the advertising of restricted devices is limited by section 502(q)(1) of the act, which prohibits false or misleading advertising, and section 502(r) of the act, which prescribes certain statements in the advertising for these devices. One comment implied that FDA's interpretation of section 520(e)(1) of the act had rendered section 502(q)(1) and (r) of the act superfluous.

FDA is not persuaded by these comments. The interpretation of section 520(e) of the act that FDA has adopted in this proceeding would not render either section 502(q)(1) or (r) of the act inoperative or superfluous. These sections impose requirements on advertising of the permissible sale, distribution, and use of restricted devices. They set out conditions on advertising to which manufacturers must adhere in offering these devices for sale. Section 520(e) of the act, on the other hand, is the means by which FDA demarcates permissible and nonpermissible conditions of sale, distribution, and use of these devices. In so doing, as has been explained in response to the previous comments, FDA may by regulation impose limits on advertising that it finds are necessary to ensure that advertising is not used to undermine the conditions on sale, distribution, or use that the agency adopts. This is what §§ 897.30, 897.32(a), and 897.34, the regulations that set out the restrictions on advertising, are designed to accomplish. In fact, section 502(q)(1) of the act reinforces this authority because any advertisement that promotes the sale of a device for a use that is inconsistent with a restriction established by FDA would be false and misleading because it would represent that the device is appropriate for that use, which would not be the case.

Thus, Congress clearly intended section 502(q)(1) and (r) of the act and any restrictions that FDA adopts under section 520(e) of the act to be complementary. This intent is further evidenced by the fact that section 502(q)(2) of the act provides that a restricted device is misbranded if it is sold, distributed, or used in violation of regulations prescribed under section 520(e) of the act. Section 502(q)(2) of the act thus complements sections 502(q)(1) and (r) of the act, which, as previously explained, address different aspects of the regulation of restricted devices than does section 520(e) of the act.

FDA's interpretation of section 520(e) of the act accordingly does not render either section 502(q)(1) or (r) of the act superfluous. Rather, the three provisions support and reinforce each other.

(8) An additional argument advanced by two tobacco trade associations was that the interpretation of section 520(e)(1)(B) of the act, which authorizes FDA to restrict the sale of a device upon such "other conditions" as it deems necessary, is governed and limited by the rule of *ejusdem generis*. This rule of statutory construction provides that, where general words follow an enumeration of persons or things of a particular and specific meaning, such general words are not to be construed in their widest extent but are to be held as applying to only persons or things of the same general kind or class as those specifically mentioned. Thus, the comment argued that here, *ejusdem generis* limits the scope of "other conditions" in section 520(e)(1)(B) of the act to restrictions similar in nature to the restriction to prescription use in section 520(e)(1)(A) of the act. The comment argued that it would be totally inconsistent with the rule of *ejusdem generis* to expand the scope of "other conditions" to include a provision as dissimilar to a prescription requirement as a restriction on advertising. FDA does not agree that *ejusdem generis* is controlling, or that it has any application here. In *Norfolk & Western v. American Train Dispatchers Ass'n*, the Supreme Court held that this canon does not control "when the whole context dictates a different conclusion" (499 U.S. 117, 129 (1991)). The context involving section 520(e) of the act does not support the application of *ejusdem generis* to it. There is no indication that Congress thought that it was providing a list of similar measures in section 520(e)(1)(A) and (e)(1)(B) of the act. In fact, the face of the act is to the contrary. After specifying one means of restricting

the sale, distribution, and use of a device, Congress granted the Secretary broad authority to impose "such other conditions as [she] may prescribe in such regulation." Congress, rather than limiting the Secretary's options, left it to the Secretary to decide what conditions are necessary for a particular device. Nor does the legislative history support the comments. As stated in section II.C.3.a. of this document, Congress intended section 520(e) of the act to add to the agency's authority beyond providing for use by prescription only (H. Rept. 94-853, 94th Cong., 2d sess., 24-25 (1976)).

Moreover, the "or" connecting section 520(e)(1)(A) of the act with section 520(e)(1)(B) is properly read here as disjunctive rather than conjunctive. (See *Garcia v. United States*, 469 U.S. 70, 73 (1984).) Section 520(e) of the act is intended to authorize such conditions on the sale, distribution, or use of a device as are necessary to ensure that the device is not improperly used and without which a reasonable assurance of its safety and effectiveness cannot be provided. There is no basis on the face of the act or in the legislative history to conclude that Congress was trying to limit the conditions that FDA could impose to achieve that end (other than the admonition not to base a physician restriction on board certification).

(9) One comment argued that the interpretation of section 520(e) of the act that FDA is advancing in this proceeding is contrary to the interpretation that the agency offered in imposing restrictions on hearing aids in 1977. The comment pointed out that FDA stated at that time: "The Commissioner notes, however, that the [Act] regulates the safety \* \* \* of the [device] itself" (42 FR 9286 at 9287, February 15, 1977). The comment asserted that, for this reason, FDA concluded that it could not prescribe competency standards for hearing health professionals, fix the price of hearing aids, or control the promotional practices of hearing aid dispensers, all matters that were being handled by the Federal Trade Commission (FTC) (42 FR 9286 at 9287). The comment argued that, for the same reasons, FDA may not, under section 520(e) of the act, regulate attire, contests, or athletic or cultural events.

FDA does not agree that the hearing aid proceeding provides any support for the view that the agency has been inconsistent in its interpretation of section 520(e) of the act. In that proceeding, FDA was aware that FTC had developed a proposed trade

regulation rule that included a prohibition of certain selling techniques (42 FR 9286 at 9287). FDA said that it was avoiding any duplication of effort with FTC. Thus, it was not necessary for FDA to consider the extent of its authority to specifically regulate selling techniques of hearing aid dispensers.

Contrary to the comment's assertion, this proceeding is consistent with the hearing aid proceeding. Although FDA did not duplicate FTC's effort and directly regulate selling techniques, FDA imposed various restrictions that were tailored to restrict inappropriate promotion of hearing aids including requiring a medical evaluation before purchase and distribution of a user instructional brochure. In the case of cigarettes and smokeless tobacco, FDA is imposing restrictions that are tailored to promotion of tobacco products to ensure that advertising does not induce the use of cigarettes and smokeless tobacco by children and adolescents under 18.

(10) Finally, several comments argued that FDA lacks statutory authority for the advertising restrictions that it is imposing. Some of these comments sought to analogize this rulemaking to *American Pharmaceutical Ass'n v. Weinberger*, 377 F. Supp. 824, 831 (D.D.C. 1974), *aff'd sub nom. American Pharmaceutical Ass'n v. Mathews*, 530 F.2d 1054 (D.C. Cir. 1976) (per curiam). That case involved an attempt by FDA to limit the distribution of methadone to certain designated facilities under the drug authorities of the act. The court held that the statutory drug authority did not authorize the agency to impose these limitations on the distribution of methadone, even though methadone posed unique problems of medical judgement, law enforcement, and public policy.

FDA regards the *American Pharmaceutical Ass'n* case as a questionable precedent. The case predates both the Supreme Court's decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), and the Medical Device Amendments. In *Chevron*, the Court stated that "considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer \* \* \*" (467 U.S. at 844). Moreover, when Congress enacted section 520(e) of the act, one of its objectives was to provide FDA with precisely the kind of authority over medical devices that the court found that the agency did not have over drugs in *American Pharmaceutical Ass'n*. Thus, FDA now has explicit

authority under section 520(e) of the act to impose conditions on the sale, distribution, and use of a medical device to prevent its misuse, including the access and advertising restrictions in the final rule. FDA is imposing controls on the sale of cigarettes and smokeless tobacco to ensure that individuals under 18 will not be able to purchase them. Further, to ensure that these controls on sale, distribution, and use are not undermined, FDA has found that they must include restrictions on how these products are advertised, so that individuals under 18 are not encouraged to purchase or use them. These actions are consistent with the language and purpose of section 520(e) of the act.

#### 4. Application of Other Device Authorities

As described in section II.C.2. of this document, FDA intends to follow its normal course and apply the "general controls" provisions of the Medical Device Amendments to cigarettes and smokeless tobacco pending classification of these products. The general controls authorized by the Medical Device Amendments include adulteration and misbranding (sections 501 and 502 of the act), establishment registration, device listing, and premarket notification (section 510), labeling requirements (section 502), recordkeeping and reporting requirements (section 519), and GMP (sections 501 and 520(f)).

(11) Tobacco industry comments claimed that FDA had ignored a number of mandatory provisions of the act applicable to devices, "presumably because they again recognize that those provisions would mean the prohibition of tobacco sales." The comments also asserted that FDA had picked and chosen among statutory provisions and had misinterpreted *Heckler v. Chaney*, 470 U.S. 821 (1985), as authorizing this selective regulatory approach. These comments also argued that FDA had ignored section 520(a) of the act, which provides that the adulteration, misbranding, and records and reports requirements are applicable to devices until the applicability of these requirements is changed by an action under the classification, premarket approval, standard-setting, or investigational device provisions of the act.

The agency disagrees with these comments. FDA is applying to cigarettes and smokeless tobacco the general controls applicable to all devices.

In the following discussion, the agency elaborates on the applicability of the general controls provisions to

cigarettes and smokeless tobacco, and on matters the agency has reconsidered in response to comments (the applicability of labeling requirements to cigarettes and smokeless tobacco is discussed in sections V. and VI. of this document). Overall, FDA believes that it has developed a regulatory system for cigarettes and smokeless tobacco that is consistent with the statutory scheme and the record of this rulemaking.

*a. Adulteration and misbranding.* Cigarettes and smokeless tobacco will be subject to the adulteration and misbranding provisions in sections 501 and 502 of the act, and the implementing regulations, with one exception that is permitted by statute. Section 502(f) of the act authorizes the agency to grant exemptions from section 502(f)(1) of the act under certain circumstances. As described in section V.E. of this document, FDA has determined that an exemption from section 502(f)(1) of the act is appropriate for cigarettes and smokeless tobacco. In addition, section VI.E.6. of this document also contains a more detailed description of the applicability of specific labeling requirements to cigarettes and smokeless tobacco.

The adulteration and misbranding provisions are largely self-executing and do not require the agency to impose requirements by regulation.

*b. Device registration and listing.* Section 510 of the act and part 807 (21 CFR part 807) of the regulations require that device manufacturers and importers register their establishments with the agency. Every year an annual registration form is sent to all registered establishments to be completed and returned to the agency (§ 807.22(a)). Any significant changes of information to the original must be reported to FDA within 30 days of the change (§ 807.26).

Manufacturers are also required to list their devices that are in commercial distribution in the United States (part 807). Foreign manufacturers may, but are not required to, register (§ 807.40). However, they are required to list their devices (§ 807.40(b)). Manufacturers are required to update their listing if there are significant changes to listing information.

Manufacturers of cigarettes and smokeless tobacco will be subject to the establishment registration and device listing requirements in section 510 of the act and part 807 of FDA's regulations. The application of these provisions to cigarettes and smokeless tobacco derives from their status under the device provisions of the act and

does not require rulemaking by the agency.

Section 510(k) of the act requires submission of a premarket notification to the agency whenever a manufacturer markets a device for the first time, whenever there is a major change in the intended use of an already marketed device, or whenever an already marketed device is to be modified in a way that could significantly alter its safety or effectiveness (§ 807.81). The device may not be commercially distributed unless the agency issues an order finding the device substantially equivalent to one or more predicate devices already legally marketed in the United States for which premarket approval is not required (section 513(i) of the act (§ 807.100)), or unless the agency approves a premarket approval application for a device subject to an approval requirement under section 515 of the act (21 U.S.C. 360(e)). Substantial equivalence means that a device has the same intended use and the same technological characteristics as the predicate device; or has the same technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and does not raise different questions regarding safety and effectiveness (section 513(i) of the act). The premarket notification submission must include either a summary of the safety and effectiveness information upon which a substantial equivalence determination may be based, or state that safety and effectiveness data will be made available to anyone upon request (section 513(i)(3)(A) of the act (21 U.S.C. 360c(i)(3)(A)), and §§ 807.87(h) and 807.92).

*c. Records and reports.* Section 519 of the act contains several requirements relating to the keeping of records and making of reports on devices. In addition to implementing the specific requirements of the act, the agency has used its authority under section 519 of the act to issue several regulations. As nicotine delivery devices, which are drug-device combination products that FDA is regulating under its device authorities, cigarettes and smokeless tobacco are subject to the requirements of section 519 of the act and the implementing regulations unless otherwise exempted.

Section 519(a) of the act requires manufacturers, importers, and distributors of devices to establish and maintain records, and make reports and other information available to the agency, to ensure that a device is not adulterated or misbranded and to

otherwise ensure its safety and effectiveness. Similarly, section 519(b) of the act requires medical device user facilities to make reports to device manufacturers and the agency when they become aware of information suggesting that a device has caused or contributed to a death, serious injury, or serious illness. Under this authority, the agency has issued part 803 (21 CFR part 803), on medical device reporting, and part 804 (21 CFR part 804), on medical device distributor reporting (the MDR requirements). These regulations were recently amended by a final rule published in the Federal Register of December 11, 1995 (60 FR 63578) (the 1995 reporting requirements final rule), reflecting changes in the reporting requirements of section 519 of the act that were mandated by the SMDA and the Medical Device Amendments of 1992.

The 1995 proposed rule would have amended parts 803 and 804 to exempt cigarettes and smokeless tobacco from the MDR requirements. These proposed exemptions were based on the fact that "the adverse health effects attributable to cigarettes and smokeless tobacco products are extensive and well-documented" (60 FR 41314 at 41342). The agency stated that it did not anticipate any real benefit in requiring manufacturers and distributors of these products to report such information (*Id.*).

(12) The agency received several comments criticizing this proposed exemption. One comment from a trade association stated that, although it disagreed with the agency's classification of cigarettes as medical devices, the agency had no authority to exempt manufacturers from this reporting requirement. This trade association also stated that, because the agency has concluded that cigarettes are not safe for individual users, this exemption cannot be reconciled with the standard under section 519(c) of the act for exempting this product. (Section 519(c)(3) of the act provides for exemptions upon a finding that compliance with recordkeeping and reporting is not necessary to ensure that a device is not adulterated or misbranded or to otherwise ensure its safety and effectiveness.) Another trade association claimed that the agency did not follow the proper exemption procedures under the act. A trade association also noted that the agency did not propose to require such user facility reports for cigarettes and also noted that such reports are not "suitable" for cigarettes.



In view of these comments, the agency has reconsidered its tentative position regarding the application of the MDR requirements in parts 803 and 804. The adverse health effects attributable to these products are extensive and well-documented. As a result, the cost of processing the enormously high volume of MDR reports related to the use of cigarettes and smokeless tobacco would likely be prohibitive in light of the small benefit to be gained from reports documenting adverse health effects already known to the agency.

Nevertheless, there would be a benefit to receiving information regarding adverse events that are not well-documented and thus, not well-known or anticipated. Therefore, the agency has determined that it will require MDR reporting in certain limited circumstances, and is amending §§ 803.19 and 804.25 of its regulations to make this clear.

In the preamble to the 1995 reporting requirements final rule, the agency clarified that it may grant a written exemption, variance, or alternative to some or all of the MDR requirements "when it determines compliance with all MDR requirements is not necessary to protect the public health" (60 FR 63578 at 63592). The agency cited, as an example for an appropriate exemption, devices for which "adverse events that are known and well documented, are occurring at a normal rate, and do not justify the initiation of remedial action \* \* \* (Id.).

To limit the volume of reports that could otherwise be required, the agency is modifying the MDR requirements for adverse events relating to tobacco. The agency has added § 803.19(f) to the regulation's "Exemption, variances, and alternative reporting requirements" section in order to limit the medical device reports concerning cigarettes and smokeless tobacco; specifically, new paragraph (f) requires reports from manufacturers only for those adverse events related to contamination, a change in any ingredient or any manufacturing process, or any serious adverse event that is not well-known or well-documented by the scientific community.

The agency notes that user facilities are not likely to have direct knowledge of even these limited adverse events required to be reported by manufacturers. Therefore, the agency is adding § 897.19(g) to exempt user facilities from the MDR requirements relating to cigarettes and smokeless tobacco.

For similar reasons, FDA is also modifying the MDR requirements for distributors of cigarettes and smokeless tobacco. Because distributors handle these products, break open cartons, and even affix the tax stamp, the agency believes that distributors could be responsible for, or aware of, contamination of these products. The agency does not believe, however, that distributors are likely to have direct knowledge of any change in ingredient or manufacturing process or any serious adverse event that is not well-known or well-documented by the scientific community. Therefore, the agency is limiting the MDR requirements for distributors to require reports concerning cigarettes and smokeless tobacco only for adverse events relating to contamination.

The agency notes that it has granted similar variances in the past for circumstances that justify modifications to the MDR requirements and has issued guidance that establishes criteria for modified reporting. Examples where reporting has been modified include events involving health care professionals being stuck by needles and certain events involving defibrillators. These modifications were made in order to clarify which events would provide valuable information to the agency given the inherently risky circumstances surrounding the use of these devices. A variance from the MDR requirements has also been granted to the manufacturers of breast implants in order to limit the frequency of reports for events already known to the agency.

(13) Industry comments also questioned why FDA had not proposed to apply device tracking and premarket surveillance provisions to cigarettes and smokeless tobacco. Section 519(e) of the act, governing device tracking, applies only to products that are permanently implantable, life-sustaining or life-supporting, or have been designated by the agency to be tracked. Cigarettes and smokeless tobacco do not fall within the first two categories, and the agency has not designated them for tracking.

For the reasons cited in the previous discussion of 519(e) of the act, postmarket surveillance will not be required unless, at a future date, the agency specifically designates these products under section 522 of the act (21 U.S.C. 360l).

Section 519(f) of the act, which requires FDA to issue regulations to require reports on device removals and corrections, will apply to manufacturers, importers, and distributors of cigarettes and smokeless

tobacco. To implement section 519(f) of the act, FDA issued a proposed rule in the Federal Register of March 23, 1994 (59 FR 13828), that would require manufacturers, importers, and distributors of devices to report promptly to FDA any corrections or removals of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. The agency expects that the final rule will publish in 1996. This rule will apply to removals and corrections of medical devices including cigarettes and smokeless tobacco.

d. *GMP*. In the preamble to the 1995 proposed rule, FDA specifically recognized that the GMP regulations may be appropriate for tobacco products (60 FR 41314 at 41352). In this final rule, FDA is requiring that the manufacturers of cigarettes and smokeless tobacco comply with GMP regulations in part 820 (21 CFR part 820), which the agency is currently revising. (See 58 FR 61952, November 11, 1993.) Application of GMP's to cigarettes and smokeless tobacco will assist the tobacco industry in avoiding such situations as the recall of Marlboros in 1995 because of a contamination mishap in processing and, in such cases, may advance public health by reducing to some degree the overall risk associated with these products.

(14) A comment from a tobacco trade association urged that FDA provide ample time for compliance with GMP and requested a 2-year period for compliance.

FDA recognizes that manufacturers will need an adequate amount of time to comply with GMP requirements and is accepting the suggestion in the comment by adopting a 2-year period for compliance. The tobacco industry already has a sophisticated approach to quality control with the production of their products. Thus, much of what is required to meet the requirements of part 820 appears to be in place already, and therefore, 2 years should be a sufficient time for compliance.

(15) In response to comments from tobacco distributors expressing concern about present or future applicability of the GMP regulations, FDA advises that it is exempting distributors from part 820. The agency has decided to amend part 820 by adding a new § 820.1(f) to exempt distributors from the requirement of complying with GMP regulations because it has concluded that compliance with GMP requirements

by distributors is not necessary to assure that these devices will be safe and effective or otherwise in compliance with the act.

#### 5. FDA Will Classify Cigarettes and Smokeless Tobacco Under Section 513 of the Act

In addition to applying the general device authorities previously described to cigarettes and smokeless tobacco, the agency will classify cigarettes and smokeless tobacco under section 513 of the act. The agency relies on classification to determine what level of control of the device is required to provide a reasonable assurance of safety and effectiveness. For devices classified into class I, general controls (sections 501, 502, 510, 516, 518, 519, and 520 of the act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j, respectively)) are sufficient to provide a reasonable assurance of safety and effectiveness. For devices classified into class II, special controls (such as performance standards under section 514 of the act (21 U.S.C. 360d)) are needed in addition to the general controls to provide a reasonable assurance of safety and effectiveness. For devices classified into class III (premarket approval), neither general nor special controls are sufficient to provide a reasonable assurance of safety and effectiveness, without the added safeguard of premarket approval. Therefore, these devices are subject to "premarket approval" under section 515 of the act.

The process of classification is an important component of device regulation, but it includes numerous procedural steps and thus cannot be part of this final rule. Under section 513 of the act, FDA is required to convene or use a classification panel, which should consist of experts who "possess skill in the use of, or experience in the development, manufacture, or utilization of," the device and who provide "adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions" (section 513(b)(2) of the act). The classification panel is required to "provide an opportunity for interested persons to submit data and views on the classification" and, after consideration of these data and views, to submit to FDA its "recommendation for the classification of the device" (section 513(c)(1) and (c)(2) of the act). Upon receipt of the panel recommendation, FDA must publish in the Federal Register "the panel's recommendation and a proposed regulation classifying

such device" and provide interested persons "an opportunity to submit comments on such recommendation and the proposed regulation" (section 513(d) of the act). After reviewing the comments, FDA must classify the device "by regulation" (*Id.*).

As required by section 513 of the act, FDA will, in a future rulemaking, classify cigarettes and smokeless tobacco in accordance with the procedures in section 513 of the act. Without prejudging that proceeding, the agency recognizes that it will involve consideration of both the known risks of tobacco products and the public health concerns that could be raised by withdrawal from the market of cigarettes and smokeless tobacco to which many adults are addicted. Moreover, the agency's restrictions on access and advertising in this final rule, which are carefully designed to help prevent young people from becoming addicted, will need to be factored in as well.

Consistent with the statute and the agency's normal practice, however, FDA is not postponing regulation of cigarettes and smokeless tobacco under its general authorities pending classification. Such a postponement would serve no useful purpose, because the general authorities will be applicable to cigarettes and smokeless tobacco regardless of the outcome of the classification proceeding. To the contrary, postponing application of FDA's general authorities would have adverse consequences for public health because, during the several years that it may require to complete classification, the applicability of the controls put in place by this final rule, as well as the registration, GMP, and other general controls discussed in this document, would be delayed with respect to cigarettes and smokeless tobacco. During this period, millions of children and adolescents would be likely to use cigarettes and smokeless tobacco for the first time and, in the absence of FDA regulation under its general authorities, become addicted to these dangerous products.

The tobacco industry argues that FDA cannot classify cigarettes and smokeless tobacco because, given "FDA's view of the health effects" of cigarettes and smokeless tobacco, classification would inevitably lead to a ban of the products. According to the industry, FDA cannot classify cigarettes under class I or class II because neither the general nor the special controls will provide what FDA will regard as a reasonable assurance of safety, leaving FDA with only one option: To classify cigarettes and

smokeless tobacco under class III. According to the industry, classifying cigarettes and smokeless tobacco under class III would lead to a ban of cigarettes and smokeless tobacco because FDA cannot grant premarket approval of a class III device until it is satisfied that there is reasonable assurance that the device is safe. The tobacco industry argues that the inability of FDA to classify cigarettes and smokeless tobacco without triggering a ban of the products demonstrates that the act was never intended to apply to cigarettes and smokeless tobacco.

It would not be appropriate for FDA to make a final determination at this time as to whether the application of all appropriate regulatory controls identified in a classification proceeding would result in a reasonable assurance of safety and effectiveness for cigarettes and smokeless tobacco for any users. This determination must await completion of the classification process and of any regulatory steps identified in the classification process (section 513 of the act). Nonetheless, it seems clear that the best public health result is one that prevents access to tobacco products by children and adolescents while allowing their continued availability for adults. Moreover, the agency disagrees with industry comments that argue that it does not have the authority to permit the sale of tobacco products to adults because the agency has found that tobacco products are unsafe.

In considering this issue, the agency reiterates that tobacco products are dangerous. As discussed more fully in section I. of this document and in the preamble to the 1995 proposed rule, cigarettes and smokeless tobacco cause great pain and suffering from illness, such as cancer, respiratory illnesses, and heart disease. More than 400,000 people die each year as a result of tobacco use.<sup>23</sup>

If the act required that the agency limit its consideration to the risks of tobacco products, then it could not find that there is a reasonable assurance of safety. To the contrary, tobacco products are unsafe, as that term is conventionally understood. However, as reflected in the act and in judicial decisions, the determination as to whether there is a "reasonable assurance of safety" involves consideration of not only the risks presented by a product but also any of the countervailing effects of use of that product, including the consequences of

<sup>23</sup> "Cigarette Smoking-Attributable Mortality and Years of Potential Life Lost—United States, 1990," *MMWR*, CDC, vol. 42, No. 33, pp. 645–649, 1993.

not permitting the product to be marketed. Thus, section 513(a)(2)(C) of the act declares that, with respect to safety and effectiveness, the agency must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use (see also 21 CFR 860.7(d)(1)). According to the legislative history of the Medical Device Amendments, "[the reasonable assurance of safety standard] is predicated upon the recognition that no regulatory mechanism can guarantee that a product will never cause injury" because "[r]egulation cannot eliminate all risks but rather must eliminate those risks which are unreasonable in relation to the benefits derived" (H. Rept. 94-853, 94th Cong., 2d sess., 16, 17 (1976); see also *United States v. Rutherford*, 442 U.S. 544, 555 (1979)).

An example of the balancing of risks of using a product against the risks of not using a product can be found in the agency's approval of a number of drugs used in the treatment of various cancers. These drugs are highly toxic to patients who receive them, and in approving these drugs for chemotherapy, FDA balances the seriousness of the diseases these drugs were intended to treat against the drugs' toxicity. In cases where the risks of not treating the cancer outweighed the risks of the drugs, FDA has approved these products.

Similarly, in the case of tobacco products, the agency must weigh the risks of leaving cigarettes and smokeless tobacco on the market against the risks of removing these products from the market. For children and adolescents, the serious health consequences of using tobacco products support an approach designed to reduce their use, as all 50 States and many of the tobacco companies themselves recognize. It is also relevant that many children who use tobacco products are in the period of initiation and are not addicted, and thus a prohibition of the sale and promotion to this segment of the population will effectively reduce their use of tobacco products. Although some children and adolescents are addicted to tobacco products, the agency has concluded that the approach that most effectively takes into account the health of young people is one that prohibits the sale and promotion of tobacco products to children and adolescents under 18 years of age.

The issue is more difficult with respect to adults, particularly adults who are addicted to cigarettes and other tobacco products. There are

approximately 50 million Americans who currently smoke and another 6 million who use smokeless tobacco.<sup>24</sup> It is particularly relevant that 77 to 92 percent of all smokers are addicted<sup>25</sup> and that a substantial number of all users of smokeless tobacco are addicted.<sup>26</sup>

The agency believes that these factors must be considered when developing a regulatory scheme that achieves the best public health result for these products. The sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous. First, there could be significant health risks to many of these individuals. Second, it is possible that our health care system would be overwhelmed by the treatment demands that these people would create, and it is unlikely that the pharmaceuticals available could successfully treat the withdrawal symptoms of many tobacco users. Third, the agency also believes that, given the strength of the addiction and the resulting difficulty of quitting tobacco use, a black market and smuggling would develop to supply smokers with these products.<sup>27</sup> It also seems likely that any black market products would be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives.<sup>28</sup>

Whether individuals who use these products have an opportunity to make an informed choice is also relevant. Most individuals who use these products begin as children and adolescents, at an age when they are not prepared for or equipped to make a

decision that for many will have lifelong consequences.

In contrast, adults generally have the capacity to make informed decisions. In the case of cigarette and smokeless tobacco, very few adults who have not used tobacco as children and adolescents choose to use these products as adults.<sup>29</sup> Unfortunately, for the many individuals who have become addicted, their capacity to choose whether to use cigarettes or smokeless tobacco in large measure no longer exists. Thus, the agency must take their addiction into consideration when developing its regulatory scheme.

Serious health consequences follow both from the option of leaving tobacco products on the market and from the option of banning tobacco products. However, on balance, an approach that prohibits the sale and promotion of cigarettes and smokeless tobacco to children and adolescents, while permitting the sale to adults seems most appropriate. It is consistent with the statutory standard of reasonable assurance of safety and is more effective in achieving public health goals than a ban on all tobacco products. Therefore, FDA is adopting this approach in this final rule.

There is also a basis for finding that these products are "effective" for adults who are addicted to tobacco products because such products sustain with great efficacy the individual's continued need for the active ingredient nicotine. Tobacco products are effective for preventing withdrawal symptoms in individuals addicted to nicotine in much the same way that methadone is effective in preventing withdrawal.

Section 516 of the act supports this analysis. Section 516 of the act is the provision that gives the agency the authority to ban medical devices. Under that provision, the agency "may" ban a device if it finds that the device presents "an unreasonable and substantial risk of illness or injury." There are two elements of discretion which plainly allow the agency to leave these products on the market—the word "may" which applies to the entire banned device authority; and the standard of "unreasonable \* \* \* risk of illness or injury," which gives the agency ample discretion to balance the unique circumstances surrounding this product.

<sup>24</sup> "National Household Survey on Drug Abuse: Population Estimate 1993," DHHS, PHS, SAMHSA, Office of Applied Studies, Rockville, MD, Pub. No. (SMA) 94-3017, pp. 89 and 95, 1994.

<sup>25</sup> 1996 Jurisdictional Determination, section II(B)(2)(a).

<sup>26</sup> *Id.*

<sup>27</sup> That a black market and smuggling will occur can be predicted by examining the current situation with illegal drugs in the United States and past experience with prohibition of respect to alcoholic beverages. In both situations, individuals continued using the products. Moreover, in the case of cigarettes, even increased cost due to tax disparities can lead to smuggling and black markets. S. Rept. 95-962, 95th Cong., 2d Sess., (June 28, 1978); Joossens, L., and M. Raw, "Smuggling and Cross Border Shopping of Tobacco in Europe," *British Medical Journal*, vol. 310, May 27, 1995.

<sup>28</sup> Such has been the case with illegally produced alcohol. See "Elevated Blood Lead Levels Associated with Illicitly Distilled Alcohol—Alabama, 1990–1991," *MMWR*, CDC, DHHS, vol. 41, No. 17, pp. 294–295, 1992; Pegues, D. A., B. J. Hughes, C. H., Woernle, "Elevated Blood Lead Levels Associated with Illegally Distilled Alcohol," *Archives of Internal Medicine*, vol. 153, pp. 1501–1504, 1993.

<sup>29</sup> 1994 SGR, pp. 5, 58, and 65–67.

*D. The Fact That the Act's Drug Authorities Authorize the Imposition of Similar Restrictions Supports the Reasonableness of the Restrictions That the Agency Has Imposed*

(16) At least one tobacco industry comment argued that the agency's proposed access and advertising restrictions were an affront to "common sense"—i.e., that the types of restrictions the agency had proposed, under the device provisions of the act, went well beyond what the plain language of the act could be read to support. The agency, however, could have chosen to impose similar restrictions using the act's drug authorities. As this section demonstrates, the agency has restricted the marketing of a number of drug products, using the adulteration, misbranding, and marketing provisions governing drug products. That similar restrictions can be invoked under either the act's device authorities or under the act's drug authorities supports the reasonableness of restrictions adopted in the final rule.

As discussed in the 1995 proposed rule and in sections II.A. and B. of this document, cigarettes and smokeless tobacco are drug delivery systems—i.e., they combine a drug component and a device component in a single combination product (60 FR 41314 at 41347 through 41349). As such, cigarettes and smokeless tobacco are subject to regulation under the device provisions of the act, the drug provisions of the act, or a combination of the two. The agency has determined that it should use the act's device authority to regulate these products because the device provisions of the act offer the agency greater regulatory flexibility than do the drug provisions of the act (see section II.B. of this document and the 1995 proposed rule at 60 FR 41314 at 41347 through 41349). However, if there were no device component to cigarettes and smokeless tobacco, or if the agency had chosen to regulate these combination products under the act's drug authorities, the agency nevertheless could have limited the access to and advertising of these products in order to protect children and adolescents.

Although the agency's authority to impose access restrictions on a drug product is not as explicit as it is under the device provisions of the act (see section 520(e) of the act authorizing controls over the "sale, distribution, or use" of a device to protect against a potentially harmful or unsafe use), the agency has in fact drawn from several

statutory sources to achieve some of the same regulatory results for a drug. The agency routinely imposes restrictions to protect against unsafe uses of drug products—even where those uses are otherwise unlawful, wholly irrational, or in contravention of express warnings. From the time of the product's development and manufacture through its retail sale, the agency is authorized to ensure that drug products are neither unsafe, misbranded, nor adulterated. (See sections 201(n), 301, 501, 502, 503 and 505 of the act; *United States v. Sullivan*, 332 U.S. 689, 696 (1948) (Congress intended "to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer").)

Consistent with this broad grant of authority, Congress also authorized the agency to issue regulations for the "efficient enforcement" of the act, such as regulations that set forth the conditions under which a drug must be marketed to ensure that it will not be deemed violative of the act (see section 701(a) of the act (21 U.S.C. 371); *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240, 246 (2d Cir. 1977); and *Pharmaceutical Manufacturers Association v. FDA*, 484 F. Supp. 1179, 1183 (D. Del. 1980) (FDA has broad authority to issue drug regulations reasonably related to the public health purposes of the act, so long as the regulations further congressional objectives evidenced elsewhere in the act)).

With this authority, the agency has imposed restrictions on the advertising, labeling, and packaging of drug products, as well as restrictions on access to drug products, without which the products could not be lawfully marketed. For example, the agency has used its authority to ensure that drug products are not adulterated to require special packaging requirements for over-the-counter (OTC) drugs, to protect against product tampering (see 47 FR 50442 at 50447, November 5, 1982); § 211.132 (21 CFR 211.132)). Thus, the agency has imposed industry-wide packaging requirements to protect against product contamination as well as unintended, unsafe uses of drug products. (Compare § 897.14(d) (prohibiting retailers from breaking open cigarette and smokeless tobacco packages to sell loose cigarettes or smokeless tobacco).)

Similarly, the agency has authority to control carefully the package size of drug products to protect persons who

fail to follow the directions from taking a lethal dose of the product (see 60 FR 52474 at 52491, 52502, and 52503, October 6, 1995, and § 355.20 (21 CFR 355.20) (final monograph setting package size limitations on OTC anticaries drugs to prevent individuals from ingesting an acutely toxic dose)). (Compare § 897.16(b) (setting minimum package size for cigarettes).)

Along the same lines, the agency has used its authority to ensure that drugs are not misbranded to restrict the marketing of certain drug products where consumers simply were unable or unwilling to heed the warnings on these products. In some instances, the agency has banned altogether the marketing of persistently misused drug products. (See, e.g., 47 FR 41716 at 41719, September 21, 1982 (camphorated oil products deemed misbranded because, despite label warnings, consumers continued to misuse the product); 47 FR 34636, August 10, 1982 (proposing withdrawal of all drugs containing phenacetin because of persistent abuse, and associated health risks, despite label warnings contained on those products).) In other instances, the agency has restricted the product to prescription use. (See, e.g., § 250.12 (21 CFR 250.12) (requiring prescription dispensing of OTC stramonium preparations because, despite package warnings, young people continued to abuse and misuse them); § 250.100 (21 CFR 250.100) (switching amyl nitrite inhalant from OTC to prescription dispensing because of persistent off-label use and abuse); see also 60 FR 38643, July 27, 1995 (proposing to restrict ephedrine drug products to prescription marketing because of the illicit use of OTC ephedrine in the manufacture of certain controlled substances).)

Finally, the agency has approved drug products with strict limits on distribution, to ensure that the drug will be safe for use under the conditions, prescribed, recommended, or suggested in the product's labeling. For example, the drug Clozaril® (clozapine), used in the treatment of schizophrenia, can cause the onset of a potentially fatal blood condition, agranulocytosis. However, early detection of agranulocytosis through routine blood testing can substantially reduce the risk of death. FDA, therefore, approved the drug with labeling that provides that the drug is available "only through a distribution system that ensures weekly [white blood cell] testing prior to delivery of the next week's supply of

medication.”<sup>30</sup> This labeling was intended to ensure that Clozaril® would not continue to be administered to those for whom it presents an unreasonable risk of harm. The marketing of Clozaril® in contravention of the labeling would result in the product being deemed misbranded and subject to regulatory action. More recently, the agency issued regulations authorizing generally restrictions on the distribution of drug products in instances where “a drug product shown to be effective can be safely used only if distribution or use is restricted \* \* \*” (see § 314.520 (21 CFR 314.520)). (Compare § 897.16 (setting conditions on the manufacture, sale, and distribution of cigarettes and smokeless tobacco); § 897.14(b)(1) (requiring retailers to verify the consumer’s age to ensure that the product will not be used by minors) § 897.16(c)(1) (prohibiting use of self-service displays at retail establishments).)<sup>31</sup>

These examples illustrate how the agency has interpreted sections 501, 502, 503, and 505 of the act (in conjunction with sections 201(n), 301, and 701(a) of the act) as authorizing an array of controls to prevent unsafe uses of drug products. The minimum age

requirement for cigarettes and smokeless tobacco (see § 897.14(a)), and the controls on packaging (see §§ 897.14(d) and 897.16(b) and (d)), vending machine sales (see §§ 897.14(b) and 897.16(c)), and self-service displays (see §§ 897.14(c) and 897.16(c)), follow this same path. Without these restrictions, cigarettes and smokeless tobacco as drug products could be deemed misbranded or adulterated drug products and could present too great a safety risk to be marketed at all.

The final rule also regulates the advertising used to promote cigarettes and smokeless tobacco (see §§ 897.30, 897.32, and 897.34). While the act’s device provisions provide the most direct and extensive basis for regulating the advertising of these products (see section VI. of this document), the drug provisions of the act also would have allowed the agency to regulate the advertising of these products.

Whether a drug is marketed on a prescription basis or OTC, the agency has authority to prohibit advertising that promotes the product for a use for which it would be unapproved or misbranded (see sections 201(n), 301, 502, and 505 of the act; see also § 201.128 (21 CFR 201.128) (advertising of a drug product may be used to establish that the product is being marketed for a use for which it is neither labeled nor approved)). Though the agency generally will defer to FTC with respect to the advertising of OTC drugs (see Food and Drug Administration and Federal Trade Commission Memorandum of Understanding (36 FR 18539, September 16, 1971)), the agency retains authority to take action against an OTC drug that is promoted for an unapproved use. (See § 330.1(d) (21 CFR 330.1(d)) (for an OTC drug to be generally recognized as safe and effective, and not misbranded, the advertising for the drug must not prescribe, recommend, or suggest its use under conditions not stated in the labeling); see, e.g., § 310.519 (21 CFR 310.519) (prohibiting the marketing of any OTC drug that is “labeled, represented, or promoted as an OTC daytime sedative (or any similar or related indication)”.)

The agency also has authority to require that a drug product not be advertised in a manner that would undercut or counteract the product’s labeling, including label-based warnings. (See *McNeilab, Inc. v. Heckler*, Food Drug Cosm. L. Rep. (CCH 1985) (Transfer Binder) ¶38,317, p. 39, 787 (D.D.C. 1985) (while FDA “cannot rely on advertising to make safe [an

OTC] drug which is deemed too dangerous to be sold with label warnings alone,” it would be “proper for the agency \* \* \* to ensure that ads do not undercut otherwise sufficient labeling”); see also 57 FR 13234 at 13237, April 15, 1992 (preamble to Accelerated Approval Regulations discussing requirement of submission of promotional materials to ensure that the drugs approved under this section will not be put to inappropriate or unsafe uses).) And, irrespective of whether a drug is marketed OTC or by prescription, the agency has authority to prohibit the distribution of “false or misleading” product “labeling” (see section 502(a) of the act).

Last, had the agency chosen to use the act’s drug authorities to regulate these products, one possible means of limiting their access would have been to require some form of prescription dispensing. In that case, the agency’s authority to regulate the advertising of cigarettes and smokeless tobacco would be extensive (see section 502(n) of the act; § 202.1 (21 CFR 202.1); § 314.81(b)(3)(i) (21 CFR 314.81(b)(3)(i))). The agency, for example, has discretion under the act to regulate both the presentation and format of prescription drug advertising. According to the House Conference Report on section 502(n) of the act, Congress contemplated that:

[I]n administering the requirement contained in the conference substitute that advertisements contain brief summaries of side effects, etc., the Secretary under the conference substitute has sufficient discretion to exercise due regard to *the size of the advertisement, the need for protecting the public health, and the conditions for which the drug is offered in the advertisement.*

(Report of the Committee of Conference, H. Conf. Rept. 2526, 87th Cong. 2d sess., (Oct. 3, 1962) reprinted in 1962 U.S. Code Cong. and Admin. News 2927, 2934 (emphasis added).)

Further, the agency may take action against a prescription drug advertisement to the extent it lacks “fair balance” or is otherwise “false or misleading” (see sections 201(n), 502(a), and (n) of the act; § 202.1 (21 CFR 202.1)). Thus, had the agency chosen to regulate these products as prescription drugs, the agency’s existing prescription drug advertising regulations themselves would require significant changes to the content and format of the tobacco industry’s advertising campaigns.

The final concern—had the agency regulated these products as drugs—is whether cigarettes and smokeless tobacco could continue to be marketed to adults. As discussed in greater detail

<sup>30</sup> Clozaril® (clozapine tablets) product labeling, Sandoz Pharmaceuticals, March 1994, in Physician’s Desk Reference, 50th edition, p. 2252, 1996.

<sup>31</sup> “The Federal Food, Drug, and Cosmetic Act provides authority for FDA to restrict the conditions for use, including the channels of distribution and use, of any drug, or withdraw approval of an NDA, if a drug cannot otherwise safely be used” (H. Rept. No. 93-884, 93d Cong., 2d Sess., p.4, 1974, reprinted in U.S. Cong. & Admin. News, pp. 3029-3032). But see *American Pharmaceutical Ass’n v. Weinberger*, 377 F.Supp. 824, 829 (D.D.C. 1974) (striking down an FDA regulation restricting the distribution of methadone), *aff’d per curiam sub nom. American Pharmaceutical Ass’n v. Mathews*, 530 F.2d 1054 (D.C. Cir. 1976). The *American Pharmaceutical Ass’n* case, however, was decided before the emergence of cases such as *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), in which the Court signaled the importance of deferring to an agency’s interpretation of its own statute, provided the interpretation is sufficiently rational. The case also involved some unique circumstances: the agency had withdrawn approval of the NDA for the drug (methadone), but nevertheless permitted the drug to be marketed under a regulation to certain treatment programs and pharmacies. Also, because methadone is a controlled substance within the provisions of the Controlled Substances Act, the district court concluded that issues regarding restrictions on the distribution of the drug were more properly within the jurisdiction of the Department of Justice than FDA. In most other instances, however, where a drug is not subject to the Controlled Substances Act, and where certain marketing restrictions are necessary to ensure that the drug will be used safely and effectively, under the conditions contemplated in a new drug application, the *American Pharmaceutical Ass’n* case is distinguishable.

in section II.C.5. of this document, there are compelling public health reasons for permitting the continued marketing of these products to adults. The same rationale would apply had these products been regulated as drugs. As is the case with respect to devices, there is a basis for concluding that an approach that prohibits the sale and promotion of cigarettes and smokeless tobacco to children and adolescents, yet allows these products to continue to be marketed to adults who are addicted to these products, could be found to be consistent with the statutory standard of "safe" and "effective" under section 505 of the act for these products.

It is, of course, essential to this analysis that the agency's youth access restrictions in new part 897 be implemented. These restrictions are necessary to help ensure that the most alarming safety issue associated with these products will have been contained. Absent these restrictions, the risks associated with the continued marketing of these products, even to adults, may be overwhelming. The close issue of whether the public health is better served by allowing adults to continue to use these products, such that the agency could find that cigarettes and smokeless tobacco are "safe" and "effective," depends heavily on the agency's ability to prevent the most alarming use of these products, namely, use by substantial numbers of children.

Moreover, the approach of allowing the continued marketing of these products to adults, so long as youth access is carefully controlled, would be consistent with the agency's inherent discretion to take enforcement action against some uses of a drug product, but not others. Such an exercise of discretion would be unreviewable (*Heckler v. Chaney*, 470 U.S. 821 (1985)).<sup>32</sup>

In resolving that there is a presumption against judicial review of agency determinations not to take enforcement action, the *Chaney* Court reasoned that an agency's nonenforcement policy generally

involves a complex weighing of factors "peculiarly" within the agency's expertise. (*Id.* at 831). These factors include, "whether agency resources are best spent on this violation or another," "whether the agency has enough resources to undertake the action at all," and "whether the particular enforcement action requested best fits the agency's overall policies." (*Id.* at 831-832).

A decision by the agency to focus its resources on youth access to cigarettes and smokeless tobacco involves the same "ordering of priorities"—i.e., the same balancing of agency-specific factors—on which the rule crafted in *Chaney* rests. Thus, were the agency to enforce the act only with respect to the promotion and sale of these products to children and adolescents, such a decision would enjoy the full force of the *Chaney* Court's presumption of nonreviewability.<sup>33</sup>

Thus, while the agency finds that cigarettes and smokeless tobacco are more appropriately regulated as restricted devices, as the discussion in section II.C. of this document demonstrates, the agency could have crafted a serviceable regulatory scheme for these products under the drug provisions of the act. Contrary to the comments that have argued that the act is inherently unfit for regulation of these products, or that the agency's proposed restrictions exceeded the common sense boundaries of the act, both the device provisions and the drug provisions of the act provide sound authority for controlling the access to and promotion of these drug delivery devices.

#### *E. Constitutional Issues Regarding Authority*

##### *1. Separation of Powers*

The doctrine of Separation of Powers refers to the distribution under the Constitution of the Federal Government's powers among the legislative, executive, and judicial

branches. In particular, under this scheme only Congress has the constitutional authority to make law.

(17) Numerous comments by industry, media, and retailer trade associations and by State legislators and individuals argued that FDA's assertion of jurisdiction over tobacco products supersedes Congress' legislative judgment, and, some argued, therefore violates the doctrine of Separation of Powers. The comments contended that Congress has provided statutory authority over tobacco products to the Executive Branch only under the statutes that it has enacted that expressly apply to tobacco products, such as the Comprehensive Smokeless Tobacco Health and Education Act (the Smokeless Act) (15 U.S.C. 4401 *et seq.*) and the Federal Cigarette Labeling and Advertising Act (the Cigarette Act) (15 U.S.C. 1331 *et seq.*) and not at all under the act. The comments cited the history of proposals in Congress further to regulate tobacco products, none of which came to fruition, as evidence that Congress has exercised its legislative will not to act further on tobacco regulation.

The agency does not agree that the rule violates the Separation of Powers Doctrine. The relevant legal standards are set out in *Youngstown Sheet and Tube Co. v. Sawyer*, 343 U.S. 579 (1952), and *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979), which are cited in the comments. Justice Black's opinion for the Court in *Youngstown* stands for the proposition that the Executive Branch may not act unless authorized by the Constitution or by statute to do so. In particular, lacking Constitutional authority, the Executive Branch may act only under the aegis of a statute passed by Congress under its "law making power" (see *Youngstown*, 343 U.S. at 585-586, 589).

Executive Branch agencies frequently act by rulemaking. In *Chrysler*, the Supreme Court considered the prerequisite for an agency's "legislative" or "substantive" rules to have the "force and effect of law" (see *Chrysler*, 441 U.S. at 301-302). "The legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes" (*Id.* at 302). Therefore, for legislative rules to have the "force and effect of law," they must be "reasonably within the contemplation of [the statutory] grant of authority" (*Id.* at 306). The "thread"

<sup>32</sup> See *Cutler v. Hayes*, 818 F.2d 879, 893 (D.C. Cir. 1987) ("The FDC act imposes no clear duty upon FDA to bring enforcement proceedings to effectuate either the safety or the efficacy requirements of the Act"); *Schering Corp. v. Heckler*, 779 F.2d 683, 686 (D.C. Cir. 1985) (FDA's agreement not to take enforcement action against an unapproved product for a period of 18 months was unreviewable); see also *Cutler v. Kennedy*, 475 F.Supp. 838, 856 (D.D.C. 1979) (while FDA may not formally authorize the sale of drugs that it has found do not comply with the safety and effectiveness provisions of the act, the agency may use its enforcement discretion not to move against these unapproved drug products).

<sup>33</sup> In a number of other contexts, the agency has declined to take enforcement action against particular uses of unapproved drug products. Indeed, the agency has on occasion set forth detailed guidelines outlining the conditions under which it will, as a general matter, refrain from taking regulatory action. (See, e.g., FDA Compliance Policy Guide, (CPG) 7132b.15 (stating that pending completion of the OTC Drug Review, FDA generally will not take regulatory action against unapproved or misbranded OTC drugs prior to completion of a final monograph); CPG 7125.06 (setting conditions exempting extra-label use of new animal drugs from regulatory action); Regulatory Procedures Manual 9-71 (setting conditions under which FDA generally will permit the import of small quantities of unapproved drugs for personal use which are not available domestically).)

between the regulations and the statute relied upon may not be "so strained that it would do violence to established principles of separation of powers to denominate the[] particular regulations 'legislative' and credit them with the 'binding effect of law'" (*Id.* at 307–308).

This is not to say that any grant of legislative authority to a Federal agency by Congress must be specific before regulations promulgated pursuant to it can be binding on courts in a manner akin to statutes. What is important is that the reviewing court reasonably be able to conclude that the grant of authority contemplates the regulations issued.

(*Id.* at 308.)

*Youngstown* therefore requires that FDA act under a statutory grant by Congress, while *Chrysler* demands a "nexus between [FDA's] regulations and some delegation of the requisite legislative authority by Congress" (see *Chrysler*, 441 U.S. at 304).

As discussed elsewhere in this document, Congress exercised its lawmaking power to provide FDA with the authority to regulate any product that is a drug or device as defined in section 201 of the act. The evidence cited in both the 1995 Jurisdictional Analysis and the 1996 Jurisdictional Determination annexed hereto demonstrates that cigarettes and smokeless tobacco meet the statutory definitions of drug and device. FDA may therefore act to regulate tobacco products, and in doing so, it is acting "pursuant to an express or implied authorization of Congress," and the executive branch's "authority is at its maximum \* \* \*" (see *Youngstown*, 343 U.S. at 635 (Jackson, J., concurring)). Moreover, *Chrysler* does not require that the act specifically refer to tobacco products, as the comments suggested (see *Chrysler*, 441 U.S. at 308). In fact, most products regulated by FDA are not specifically referred to in the act. In addition, as discussed in sections X.A. and X.B. of this document, neither the Smokeless Act nor the Cigarette Act precludes regulation under the act of cigarettes and smokeless tobacco as drug delivery devices. FDA's assertion of jurisdiction over cigarettes and smokeless tobacco is therefore reasonably contemplated by the laws as enacted by Congress. Consequently, in regulating tobacco products under the act, FDA is not asserting the lawmaking power reserved by the Constitution to Congress.

## 2. Nondelegation Doctrine

The Nondelegation Doctrine, broadly speaking, imposes constraints on Congress' authority to delegate to others

the legislative power vested in it by the Constitution.

(18) While maintaining that Congress has not granted FDA the authority to regulate tobacco products, an industry comment argued that FDA seeks to assume authority that, under the Nondelegation Doctrine, Congress could not have delegated to the Executive Branch. In particular, the comment argued that the act requires FDA to approve a new drug as safe and effective, or to ban it, and to classify a device into one of three categories in which it will be required to meet conditions that ensure that it is safe and effective. Because FDA proposed to do neither with respect to nicotine and cigarettes and smokeless tobacco, the comment contended, the agency is free to choose any course it wishes; and had Congress delegated to FDA such unlimited authority, it would have violated the Nondelegation Doctrine. The comment can also be read to suggest that, if FDA has the flexibility to regulate medical devices, and in particular tobacco products, as it proposed, then Congress provided the agency without a standard, that is, with too much discretion.

The agency disagrees with this comment. The act, while vesting FDA with broad discretion to regulate foods, drugs, and devices, does so by precisely defining the agency's jurisdictional ambit in section 201 of the act and by establishing a range of requirements and enforcement provisions—for example, in sections 301, 302, 303, 304, 501, 502, 505, 510, 513, 514, 515, 516, 517, 518, 519, 520, and 701 of the act (21 U.S.C. 331, 332, 333, 334, 351, 352, 355, 360, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, and 371 respectively)—for it to pursue when, in its discretion, *Heckler v. Chaney*, 470 U.S. 821 (1985), it has found the operative facts established by Congress. The act therefore involves no delegation of Congress' legislative power that violates the Nondelegation Doctrine, as the courts have repeatedly held. (See, e.g., *United States v. Shreveport Grain and Elevator Co.*, 287 U.S. 77, 85 (1932); *United States v. Garfinkel*, 29 F.3d 451, 457–59 (8th Cir. 1994); *White v. United States*, 395 F.2d 5, 9–10 (1st Cir.), *cert. denied*, 393 U.S. 928 (1968); *United States v. 62 Packages, More or Less, of Marmola Prescription Tablets*, 48 F. Supp. 878, 884 (W.D. Wis. 1943), *aff'd*, 142 F.2d 107 (7th Cir.), *cert. denied*, 323 U.S. 731 (1944).)

The Supreme Court has only infrequently invalidated a congressional delegation to the Executive Branch.

(See, e.g., *Panama Refining Co. v. Ryan*, 293 U.S. 388, 418 (1935) (holding statute authorizing the President to prohibit interstate shipment of "hot oil" determined by State law or regulation to be "excess" to be unconstitutional delegation because "Congress left the matter to the President without standard or rule, to be dealt with as he pleased"); *Schechter Poultry Corp. v. United States*, 295 U.S. 495, 541–542 (1935) (reversing convictions for violations of code of conduct for poultry suppliers because "the discretion of the President in approving or prescribing [such] codes, and thus enacting laws for the government of trade and industry throughout the country, is virtually unfettered").)

More recently, the courts have applied the Nondelegation Doctrine to reach, or require from an agency, a narrow interpretation of a statutory provision that would otherwise be too broad a delegation. (See, e.g., *Industrial Union Dep't., AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 646 (1980); *International Union, UAW v. OSHA*, 37 F.3d 665, 668–69 (D.C. Cir. 1994); *International Union, UAW v. OSHA*, 938 F.2d 1310, 1316–17 (D.C. Cir. 1991).)

Unlike the statutes under review in *Panama Refining* and *Schechter*, the act sets standards for FDA to follow. The agency need not narrowly interpret the act to avoid an otherwise over-broad delegation, and courts have repeatedly directed that the act be construed liberally in light of its public health purpose (see sections I.B. and II.A. of this document). The agency's rulemaking with respect to tobacco products is a legitimate application of those standards to the facts before the agency. The agency therefore concludes that neither the act nor this rulemaking violates the Nondelegation Doctrine.

## III. Overview of Comments, Smoking Prevalence Rates Among Minors, Scope, Purpose, and Definitions

### A. Overview of Comments

From the time the 1995 proposed rule was published on August 11, 1995 (60 FR 41314), until January 2, 1996, the Food and Drug Administration (FDA) accepted public comments. This comment period was the opportunity for the public to speak to FDA about the matter of regulating nicotine-containing tobacco products. On March 18, 1996, the agency reopened the comment period for 30 days to make additional information relevant to this rulemaking available for public comment.



The 1995 proposed rule generated more responses than the agency had received at any other time in its history on any other subject. Altogether, the agency received more than 700,000 pieces of mail, representing the views of nearly 1 million individuals. Most of the submissions were form letters or post cards. The agency identified more than 500 different types of form letters.<sup>34</sup> Others were petitions with sometimes hundreds of signatures. More than 95,000 submissions expressed individual comments on the 1995 proposed rule, including more than 35,000 from children who were overwhelmingly supportive. The individual comments included one from an industry trade association which delivered a single submission of some 45,000 pages on the last day of the announced comment period.

As may be expected, comments differed sharply on the overarching issues of whether FDA should regulate cigarettes and smokeless tobacco, and whether the 1995 proposed rule would have the desired effect of reducing the availability and attractiveness of these products to children and adolescents.

Several Government officials commented, including U.S. Senators and Congressmen, other Federal agencies, State governors and legislators, and law enforcement officials. Comments came from every corner of the country. FDA heard from smokers who could not understand why the Government was meddling in their lives, and from smokers who desperately wanted to quit, but could not. It heard from employers and employees in the affected industries, including tobacco farmers, wholesalers, cigarette manufacturers, and even laborers with the lowest paying jobs who feared that they might lose the only jobs they know. The agency even heard from school children who wanted to be protected from tobacco. "It is not fair," wrote one 13-year-old, "that the tobacco companies try to get kids to use tobacco."

Although many of the comments were addressed to specific portions of the tobacco regulation proposal, tens of thousands of letters commented in general. Thousands of general comments supported the rule. Some, like this one, came from surprising sources: "I support regulations restricting the sale, advertising,

promotion and distribution of cigarettes and chewing tobacco. I grow tobacco, but I know it is wrong to sell death. I really feel sorry for people who are 'hooked' on nicotine." Other supporting comments came from more traditional sources, especially the medical and public health communities. One letter from a coalition of medical associations that was addressed to President Clinton said: "We, the undersigned 125 organizations, representing more than 18 million members and volunteers, urge your strong support for Food and Drug Administration actions to protect children and teenagers from tobacco."

Many expressed strong overall opposition to the rule. One comment said: "I am taking the time to write this letter to express my overwhelming dissatisfaction with the action of the FDA in trying to rewrite the Constitution and take control of the Tobacco Industry."

Although many comments opposed FDA's regulation of tobacco products, there was nearly unanimous agreement—even from the tobacco companies and smokers—that children under the age of 18 should not be using nicotine-containing products, either cigarettes or smokeless tobacco. A few children, however, did write that, even if tobacco use is unhealthy, it should still be their choice, even if they are younger than 18. The agency received thousands of general comments about the addictive and harmful consequences of tobacco use, and they called on the agency to act.

A summary of the general issues reflected in the thousands of comments, and the agency's responses, follows:

(1) The agency received several thousand comments stating that FDA should focus on the products it already regulates. In addition, many comments said that FDA should not expand its responsibilities because the agency's resources already are inadequate. Others stated that the regulation of tobacco is a responsibility that Congress has reserved for itself.

In contrast, many supporters of the 1995 proposed rule argued that it was appropriate for FDA to take action on this issue. One woman wrote: "As the Federal agency designed to protect consumers from harmful consumer products, FDA clearly has both the right and the responsibility to take these actions against the most serious health threat to our young people."

The regulation of drugs and medical devices sold through interstate commerce is central to FDA's established role. Based on recently

available information, as stated in section II. and in the 1996 Jurisdictional Determination annexed hereto, FDA has determined that nicotine is an addictive drug, and that cigarettes and smokeless tobacco are drug delivery devices, which are combination products under section 503(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(g)). As such, these products fall within the traditional scope of FDA's jurisdiction. Therefore, by regulating these products, FDA is carrying out its traditional role.

(2) FDA received thousands of comments about how smoking was an issue of free choice for adults. Most of the comments focused either on the ideological issue of freedom to choose anything, even something dangerous, or on related economic issues, such as the freedom to receive discount or specialty tobacco products by mail. Many comments said the Government must not attempt to regulate human behavior, especially for adults, even when there are health consequences. Letters like this were typical: "As individuals we too have been promised the freedom of choice and this should continue to be. I don't want the government regulating my personal freedoms."

Supporters of the rule countered that because nicotine addiction is a pediatric disease, the choice to start smoking is not being made by adults, but by adolescents who constitute a most vulnerable population. Because they are not yet mature individuals, they are not really expressing a free choice, the comments said. In addition, supporters of the rule stated that adolescents, who are so impressionable, are being manipulated by the tobacco companies, especially through advertising, and therefore, are actually being denied a free choice. Instead, the comments urged that adolescents not be allowed to choose something addictive that may damage their health or shorten their lives.

FDA believes that adults should continue to have the freedom to choose whether or not they will use tobacco products. However, because nicotine is addictive, the choice of continuing to smoke, or use smokeless tobacco, may not be truly voluntary. Because abundant evidence shows that nicotine is addictive and that children are not equipped to make a mature choice about using tobacco products, the agency believes children under age 18 must be protected from this addictive substance.

(3) Numerous comments, many from adult smokers, expressed the fear that FDA's true goal is a total ban of all

<sup>34</sup> Opponents and proponents of the rule organized letter-writing campaigns. One, a massive tobacco company-orchestrated campaign, generated some 300,000 pieces of mail—nearly half of all of the mail received by the agency on this topic.

tobacco products. Some asserted that the 1995 proposed rule is a prelude to prohibition. One woman wrote: "The most insidious insight into this proposed regulatory act is the Federal Government's thinly veiled motive of the eventual prohibition of tobacco sales in the United States to appease a small minority of fanatical anti-smoking zealots."

FDA strongly disagrees with these comments and reiterates that it has no intention of banning cigarettes and smokeless tobacco. FDA is aware that at least one tobacco manufacturer, in letters sent to its customers encouraging them to submit comments opposing the rule, claimed that the "real agenda is Backdoor Prohibition of all tobacco products." These allegations are baseless and ignore statements made by the President and FDA to the contrary. For example, when the President announced the proposed FDA regulations on August 10, 1995, one reporter asked whether an outright ban would be more logical than a "regulatory partial step." The President replied:

I think it would be wrong to ban cigarettes outright because, number one, it's not illegal for adults to use them \* \* \* tens of millions of adults do use them. And I think it would be as ineffective as prohibition was. But I do think to focus on our children is the right thing to do.

(Transcript, "Press Conference by the President," dated August 10, 1995) The preamble to the 1995 proposed rule expressed a similar view that removing cigarettes and smokeless tobacco from the market would not be in the best interest of public health (60 FR 41314 at 41348 and 41349).

Rather than instituting prohibition, the agency's rule will inhibit the spread of smoking behavior from one generation to the next. As a result, fewer and fewer adolescents will become addicted to nicotine-containing products. As current smokers either quit or die, the total number of smokers will gradually decline as they are replaced by fewer and fewer new smokers. The agency wants to reassure those who fear that FDA is taking the first steps that would lead inexorably to a ban on the sale of these products to those 18 and over that FDA will not ban these products for adults. Thus, any claim that the rule is a prelude to or would lead to prohibition is totally without merit.

(4) FDA received many comments from politicians, industry representatives, and private citizens who argued that the agency does not need to regulate tobacco because the

product is already highly regulated. Many comments observed that all 50 States have passed their own laws prohibiting the sale of tobacco products to minors younger than 18. Comments on existing State enforcement programs primarily came from those opposed to FDA's proposed regulation, including legislators from more than a dozen States. These comments claimed that this should remain a State matter, that State laws are either sufficient or superior to the 1995 proposed rule, that State officials, unlike FDA, are responsive to the concerns of State citizens, and that States and private groups are more responsible and effective than a Federal agency. Comments like this were common: "Many states have strict restrictions on tobacco sales to minors already and in my State (Maryland) these regulations are being enforced with great success."

Many supporters of the 1995 proposed rule, however, pointed out that State rules generally have failed to stop minors from purchasing tobacco products. One individual wrote: "I currently live in a State where there is absolutely no enforcement of the laws banning sales of tobacco to minors," and numerous other comments referred to specific instances in which they said State laws were not observed. A joint letter sent by attorney generals from 25 States, as well as Guam and Puerto Rico, welcomed the 1995 proposed rule, saying:

Although every State bans the sale of tobacco to minors, studies show that children have easy access to tobacco. \* \* \* We believe the proposed rule, which emphasizes reducing access and limiting the appeal of tobacco products to children, should be a crucial component of a national effort by Federal, State and local officials to help our youngest generation of Americans avoid suffering preventable disease and premature death from the use of tobacco products.

Many comments stated that the tobacco industry has in place guidelines to prevent the sale of tobacco products to minors. Said one comment: "I fail to see why the government is so quick to dismiss voluntary action on the part of the industry." Other comments recommended that voluntary education programs aimed at retailers, or, more specifically, at retail sales clerks, would be sufficient. These educational programs would either be based on voluntary efforts by the affected industries or in-house, employee training programs.

Supporters of the rule, however, expressed widespread distrust of the industry and of its promise to use voluntary programs to prevent minors

from smoking. One woman wrote: "Thirty years of experience in compromising with the tobacco industry has proven that the industry can not be trusted. After the release of the Surgeon General's report in 1964, the tobacco industry promised to abide by a voluntary advertising code, but the code was quickly ignored after the threat of government regulation had passed." Another comment said: "When tobacco companies fear government regulation, they often adopt voluntarily the restrictions the government is considering. However, there is no penalty for violating a voluntary guideline. The tobacco industry has a track record that speaks for itself. Please don't play the tobacco industry's game!"

The agency believes that the comments opposing the rule on the basis that the States already have restrictions have misinterpreted its scope and application. FDA, under the act, regulates human and animal drug products, certain foods, and devices that are, or have been in interstate commerce. The fact that these products move across State lines makes their regulation a Federal matter.

Other statutes and regulations provide further evidence that tobacco regulation is not reserved to States. The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 *et seq.*) (Cigarette Act) and the Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. 4401 *et seq.*) (Smokeless Act), among other things, place federally-required statements and warnings on cigarettes and smokeless tobacco and require manufacturers to submit reports to the Federal Government. These products are also subject to Federal taxes (see, e.g., 26 U.S.C. 5701) and Federal, rather than State, laws and regulations intended to guard against contraband cigarettes (see 18 U.S.C. 2341 *et seq.*; 27 CFR part 296, subpart F). Thus, tobacco regulation is clearly both a Federal and State matter.

FDA also disagrees with those comments suggesting that States and private groups may be more responsible or efficient than FDA or that FDA may not be as responsive to citizens' concerns. Federal regulation of these products has several significant advantages over State or private group oversight alone; for example, the rule establishes minimum, national standards for the sale and distribution of these products whereas State or private group efforts may be limited to a specific locality or to group members. FDA's regulations also create enforceable obligations whereas private

group efforts, voluntary codes, and industry policies do not.

FDA notes that this regulation does not necessarily preclude States from enforcing their own laws. In fact, under section 1926 of the Public Health Service Act (the PHS Act) (42 U.S.C. 300x-26), States are expected to enact and to enforce laws to prohibit any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual under age 18.

Moreover, States may choose to regulate areas that are not addressed in this rule and not authorized by the act, such as requiring licenses for retailers. FDA agrees with the comments from State attorneys general that effective regulation of cigarettes and smokeless tobacco, in order to protect children and adolescents, will involve cooperation and joint efforts by Federal and State officials and FDA's rule will enhance, rather than hinder, State tobacco control efforts.

Moreover, States are not precluded from taking action in areas that are addressed in this rule. Although some of these requirements may be preempted, the State may petition the agency for an exemption from the act's preemptive effect under section 521(b) of the act (21 U.S.C. 360k(b)). A more detailed discussion of preemption can be found in section X. of this document.

Finally, regarding the comments questioning FDA's response to State or citizen concerns, mechanisms do exist for States and individual citizens to seek regulatory action or changes by FDA. FDA regulations permit any person to petition the agency to request an action (such as issuance, amendment, or revocation of a rule), to reconsider an action, or to stay an administrative action (see §§ 10.30, 10.33, and 10.35 (21 CFR 10.30, 10.33, and 10.35)). Less formal mechanisms for communicating with FDA, such as letters or meetings, exist as well.

(5) Many comments opposing this rule argued that the tobacco industry already is intensely regulated, and that more regulation is unneeded and unjustified. One person wrote: "As you know the tobacco industry is already one of the most heavily regulated industries in the United States. Current laws would accomplish the stated objective of the proposed FDA regulations." Others disagreed: "I believe that the tobacco industry has a long, sorry, and cynical record \* \* \*. It is an industry that greatly deserves to be regulated further."

While it is true that production of tobacco products is regulated, and the industry is heavily taxed, virtually none of these measures is aimed at the product's impact on the health of the individuals using them or on public health. FDA regulation of tobacco products is intended to have a completely different effect than any of the rules that currently applies to the tobacco industry. The agency's regulatory effort will attempt to reduce the number of young people who smoke or use tobacco products, consistent with FDA's mission to protect public health by existing laws.

(6) Many comments objected to the 1995 proposed rule, stating that cigarettes and smokeless tobacco are legal products and should be treated like any other legal consumer product.

FDA believes that the comments misunderstand the regulatory basis for the rulemaking. FDA has determined that these products contain both a drug and device component as defined in section 201(g) and (h) of the act (21 U.S.C. 321(g) and (h)), respectively, because the products, and the nicotine in the products, are intended to affect the structure and function of the body. The agency has further determined that these products should be regulated as devices. Thus, the issue is not merely whether the products themselves have been legally marketed, but how they may be most appropriately regulated to protect the public health, given their status under the act and potential to do harm.

(7) Some comments suggested that if the Government begins regulating tobacco, it will soon regulate many other consumer products that are now legal, but judged to be harmful to health, including alcohol and caffeine. They expressed fear that, once FDA begins to regulate one consumer product, it will be obligated to regulate others. Said one man: "The FDA thinks it is being sly by defining cigarettes as 'nicotine delivery devices.' A shot glass must then be described as a device for alcohol consumption. A coffee mug must be a device for caffeine consumption. Will the FDA be regulating my morning coffee by restricting the size of my cup?" Some supporters of the proposed rule said that FDA should regulate some of the other consumer products associated with medical disorders. Wrote one: "Bud frogs are no different than Joe Camel."

FDA strongly disagrees with these comments and believes that the concerns they express are misplaced. In no way does the agency's regulation of

cigarettes and smokeless tobacco as nicotine delivery devices justify or require the regulation of coffee cups and shot glasses.

First, the agency notes that currently it regulates both caffeine and alcohol under the authority of the act. Caffeine naturally occurs in coffee, tea, and other foods. It is also used as an ingredient in soft drinks. The act defines "food" as "articles used for food or drink for man or other animals" (section 201(f)(1) of the act (21 U.S.C. 321(f)(1))). When caffeine naturally occurs in products that are foods, such as coffee, or when caffeine is used in soft drink products in accordance with section 402 of the act (21 U.S.C. 342), the product is a "food" under section 201(f)(1) of the act and thus explicitly excepted from the definition of "drug" in section 201(g)(1)(C) (21 U.S.C. 321(g)(1)(C)). Caffeine used in soft drinks in accordance with section 402 of the act is appropriately regulated as a food under 201(f)(1) of the act. Caffeine is also used as an active ingredient in several products regulated as drugs by the agency, including over-the-counter stimulants, internal analgesics and menstrual discomfort relief products.

Likewise, alcohol is used as an ingredient in products regulated as drugs under the act, including over-the-counter cough and cold preparations. There is no evidence to suggest that the agency's current regulation of these substances is inappropriate or inadequate to protect the public health. Therefore, there is no factual or scientific basis for the agency to change the manner in which these substances are now being regulated.

FDA's attention was drawn to tobacco rather than caffeine and alcohol because of certain fundamental differences among the substances. Nicotine is a highly addictive drug. As discussed in section I.B. of this document, studies estimate that as many as 92 percent of all smokers are addicted to the nicotine in cigarettes. There is no evidence that either caffeine or alcohol pose this kind of health problem. Moreover, cigarettes and smokeless tobacco are dangerous products that are associated with lung cancer, heart disease, and many other serious illnesses and conditions.

Yet these factors only served to draw FDA's attention to the tobacco problem. What ultimately separates caffeine and alcohol from nicotine and tobacco products is that caffeine and alcohol are currently being appropriately regulated as foods or drugs based on their intended use. Nicotine and tobacco products, on the other hand, are drugs

and medical devices, respectively, that, in large measure, are not being appropriately regulated. FDA is moving to correct this situation, and the public health will undoubtedly benefit as a result.

(8) Several comments argued that it is the responsibility of parents and teachers, not the Federal government, to educate young people about cigarette and smokeless tobacco use. Some comments feared that FDA's effort to reduce the use of nicotine-containing cigarettes and smokeless tobacco by youth might interfere with the relationship between parents and their children. Many comments voiced the argument that this rule is a sign of big Government getting in the way of parents educating their children. One comment stated, "This is obviously a case of misplaced priorities \* \* \*. The battle will really be won on the home front. Parental guidance will go a long way in curbing underage smoking."

Other parents, however, were grateful for any assistance they could get to help protect their children from nicotine addiction. One person said: "The parents cannot do it all alone." Furthermore, most parents who submitted comments stated that a strong national approach to reducing these products' accessibility and appeal would reinforce messages that their children get at home. One comment stated, "While I am in no way an advocate of government in my life, this to me is a totally different circumstance \* \* \* children should not be expected to make these choices." One comment from a middle school student said, "Giving school age children the opportunity to purchase things that will endanger them is inexcusable."

The agency recognizes the unique role that parents and teachers have in educating young people and has no intention of intervening in that relationship. Rather, FDA expects the rule to complement parental and educational efforts by reducing the availability and appeal of tobacco products. The preamble to the 1995 proposed rule contained ample evidence as to how these products are easily accessible to and appeal to young people and how a comprehensive approach, aimed at reducing both access and appeal, will be more effective than an educational approach alone. Educating young people about health risks may deter some young people from trying cigarettes and smokeless tobacco, but educating them and simultaneously reducing their ability to acquire the products, as well as reducing the appeal

of the products themselves, will prevent more young people from using the products.

FDA also emphasizes that cigarettes and smokeless tobacco are combination drug-device products that are subject to regulation under the act. Consequently, the rule properly addresses issues relating to the sale, distribution, and use of these products by children and adolescents. The rule does not adversely affect a parent's or teacher's ability to discuss cigarette and smokeless tobacco use with young people.

(9) Comments suggested that, for some, illegal drugs and crime evoke stronger emotions than tobacco use. Many comments stated that the Government, although not FDA specifically, should spend more of its resources on fighting crime instead of trying to regulate a legal product such as tobacco. One of the form letters stated it this way: "Federal dollars would be much better spent addressing inner-city violence, illegal drug sales, and this country's deteriorating education system."

FDA's authority is defined by the act. FDA lacks the authority to help with other social ills such as crime and illicit drug sales.

(10) One comment urged FDA to institute policies that would facilitate "whistleblowing." The comment said that FDA should encourage tobacco company employees to disclose allegedly illegal or dishonest practices.

Any person, regardless of the industry that employs that person, can provide records and information to FDA for law enforcement purposes with the assurance that his or her identity, and the information and records that he or she provides, will not be publicly disclosed. Current Federal statutes and FDA regulations already protect records or information compiled for law enforcement purposes from public disclosure. For example, the Freedom of Information Act exempts law enforcement records and information from public disclosure. FDA's regulations governing public disclosure elaborate on this exemption, stating, among other things, that the agency may withhold from public disclosure records or information compiled for law enforcement purposes to the extent that disclosure of such records or information could reasonably be expected to disclose the identity of a confidential source and information furnished by a confidential source in the case of a record compiled by FDA or any other criminal law enforcement

authority in the course of a criminal investigation (§ 20.64 (21 CFR 20.64(a))).

#### *B. Smoking Prevalence Rates Among Minors*

The agency received some comments stressing the importance of accurately measuring youth consumption of tobacco products, reiterating the problem of growing use among young people, and stressing the need to curb such growth to improve health and to reduce the tremendous health care costs attributable to tobacco-related illnesses. However, several disputed the statistics FDA cited on the number of youth smokers and challenged the data sources used. These comments are discussed below.

(11) One comment objected to FDA's description of smoking as a "pediatric problem," arguing that "TAPS II [Teenage Attitude and Practice Survey II] demonstrates that smoking in any meaningful sense is a phenomenon that occurs in the later teenage years, not in the pre-teen or early teen years." It further charged that the agency's use of the term "pediatric" is intended to serve "emotive and/or political purposes, not to describe the problem of underage smoking in scientific or medical terms."

A comment from a public health association, however, cited the TAPS II survey as showing that "the average teen smoker initiates smoking at age 13, and becomes a regular smoker by age 14.5." It also referred to the Center for Disease Control and Prevention (CDC's) 1992 Youth Risk Behavior Survey, which showed "similar patterns of early initiation rates, with smoking initiation rates rising rapidly between 10 and 14 years of age."

The agency maintains its position that smoking is a pediatric disease. It agrees with the comment citing TAPS II and Youth Risk Behavior Survey data showing that the average teen smoker begins smoking in the early teens or even preteens, rather than later years.

Furthermore, the American Academy of Pediatrics' Council on Child and Adolescent Health states that the purview of pediatrics includes the physical and psychosocial growth, development, and health of the individual beginning before birth through early adulthood, and that "[t]he responsibility of pediatrics may therefore begin with the fetus and continue through 21 years of age." This definition of pediatrics obviously includes the age group FDA has targeted to reduce smoking.

(12) One comment from the tobacco industry charged that FDA's assertion

that smoking has increased among 8th- and 10th-grade students ignored CDC's TAPS II data showing that the incidence of underage smoking declined between 1989 and 1993. TAPS II, the comment maintained, showed that "[a]lthough total smoking in the interview sample [1993] has increased as minors have aged since 1989, comparing the results for minors of a given age indicates that the incidence of underage smoking declined between the two surveys" and that "between the two surveys both daily smoking and any smoking in the past 30 days declined among minors."

The introduction to TAPS II stated that its prevalence findings were comparable to or lower than those of other national surveys. It explained that the survey method used in TAPS II, computer-assisted telephone interviews, had several limitations that may have led to the lower estimates. For example, young people may be fearful of disclosing smoking behavior if a parent is present in the room during the telephone interview. Further, telephone interviews do not afford the same opportunity for building a rapport between the interviewer and the respondent as do in-person interviews. As a result, young people being interviewed in this manner may be less likely to disclose their real smoking behavior. For these reasons, the introduction stated, "prevalence estimates from TAPS II may be lower than they would have been had the entire TAPS I cohort been successfully reinterviewed and therefore, should be interpreted with caution."<sup>35</sup>

(13) One comment challenged FDA's claim that 3,000 young people become new smokers every day. The comment maintained that "the study from which the '3,000 per day' number was derived did *not* refer to children at all," but to smokers "aged 20 years old" (Pierce et al., 1989) (emphasis from original).<sup>36</sup>

The agency agrees that the study surveyed individuals who were 20-years-old, although the agency referred to these individuals in essentially the same terms used by the authors of the study—"young persons."

Any potential confusion is mitigated by the fact that subsequent surveys indicate that the vast majority of 20-year-olds begin smoking at a younger age. For example, according to the

Combined National Health Interview Surveys for 1987 to 1988, 92 percent of 20-year-old smokers started smoking by age 18. Taking into account the comment and these data, the agency believes that it is accurate to state that approximately 3,000 young people begin to smoke each day, regardless of whether young people is defined as under 18, or 20 years and under, although the agency would note that of the 3,000 young people who begin smoking each day, 2,722 are under age 18.

### C. Scope

Proposed § 897.1(a) would have stated that "[t]his part is intended to establish the conditions under which cigarettes and smokeless tobacco products that contain or deliver nicotine, because of their potential for harmful effect, shall be sold, distributed, or used under the restricted devices provisions of the Federal Food, Drug, and Cosmetic Act." Proposed § 897.1(b) would have stated that "[r]eferences in this part to regulatory sections to the Code of Federal Regulations are to chapter I of Title 21, unless otherwise noted." The final rule is being amended to explicitly state that failure to comply with any applicable provision would render the product misbranded.

The preamble to the 1995 proposed rule stated that "[t]he proposed rule would not apply to pipe tobacco or to cigars because the agency does not currently have sufficient evidence that these products are drug delivery devices under the act" (60 FR 41314 at 41322). The preamble stated that "FDA has focused its investigation of its authority over tobacco products on cigarettes and smokeless tobacco products, and not on pipe tobacco or cigars, because young people predominantly use cigarettes and smokeless tobacco products" (*Id.*).

(14) A comment opposing this provision stated that FDA does not have authority to regulate cigarettes under the restricted device (or any other) provision of the act.

The agency disagrees. A full discussion of the agency's authority can be found in section II. of this document.

(15) Several comments supported the provision. Some comments recommended that the scope of the rule should also apply to adult smokers. One comment stated that:

[I]t is evident from the FDCA [the Federal Food, Drug, and Cosmetic Act] that the FDA has clear and unambiguous authority to regulate and restrict the sale of the subject products not only to minors but also to adults, who suffer equally from the mortality

and morbidity effects of the toxic components of cigarette smoke and tobacco.

As discussed in section I.B. of this document, the agency believes that, on balance, it is better for cigarettes and smokeless tobacco to remain available for use by adults.

(16) Several comments urged that the scope should be expanded to include all nicotine containing products, including cigars and pipes. Another comment expressed concern that the sale and use of big cigars and pipe tobacco by youth may be increasing, and therefore recommended that FDA expand the scope "to include all presently marketed nicotine delivery devices," or to "include regular monitoring of youth's use of these products, and should that use increase, provide a means to extend the FDA's rulings to include those products."

Another comment stated that since "federal regulations often take seven to ten years to enact and enforce, it is essential that the regulation be written pro-actively to adequately address the problem at the outset." The comment stated that "[i]t is therefore, important to write regulations to protect the public from all 'nicotine delivery devices' that in the future, might be placed in something other than tobacco" because "[a]ny product containing the addictive substance of nicotine has a future market because of its addictive nature."

Finally, this comment asserted that FDA should broaden the scope of the rule to include all products that deliver nicotine, because the comment stated that smoking mothers are at greatest risk for reproductive hazards, such as low birth weight babies. The comment stated that "[c]onsidering that over 50% of births are unplanned, and that people believe they can always quit smoking, it is too late to avoid damage by smoking mothers by the time they realize they are pregnant."

The preamble to the 1995 proposed rule stated that "[t]he proposed rule would not apply to pipe tobacco or to cigars because the agency does not currently have sufficient evidence that these products are drug delivery devices under the act" (60 FR 41314 at 41322). The preamble stated that "FDA has focused its investigation of its authority over tobacco products on cigarettes and smokeless tobacco, and not on pipe tobacco or cigars, because young people predominantly use cigarettes and smokeless tobacco products" (60 FR 41314 at 41322).

The agency advises that, at this time, there is insufficient evidence of cigar or pipe tobacco use by children and

<sup>35</sup> "1993 Teenage Attitudes and Practices Survey, Public Use DataTape," CDC, OSH, p. 3, 1993 (unpublished data).

<sup>36</sup> Pierce, J. P., M. C. Fiore, T. E. Novotny, E. J. Hatziandreu, and R. M. Davis, "Trends in Cigarette Smoking in United States: Projections to the Year 2000," *JAMA*, vol. 261, pp. 61-65, January 6, 1989.

adolescents to support the inclusion of cigar, pipe tobacco, or "all presently marketed nicotine delivery devices" within the scope of the final rule (section III.E. of this document).

In response to the comment stating that the agency should monitor youths' use of products such as cigars or pipe tobacco, and that the agency should provide a means to "extend FDA's rulings to include these products," the agency advises that, as stated in the 1995 proposed rule, the objective of the final rule is to meet the goal of the report "Healthy People 2000," by reducing roughly by half children's and adolescents' use of tobacco products. The agency is not asserting jurisdiction over pipes and cigars at this time because it does not have sufficient evidence that these products satisfy the definitions of drug and device in the act. However, the agency will consider any additional evidence that becomes available, including any new evidence that these products meet the statutory definitions as well as evidence that indicates that cigars and pipe tobacco are used significantly by young people.

FDA also disagrees with the comment claiming that Federal regulations take 7 to 10 years to enact and enforce. While it may be true that rulemaking, in general, can be a time-consuming task, the agency can and has taken prompt action to issue rules with significant public health implications. For example, the proposed rule for this final rule appeared in the Federal Register of August 11, 1995 (60 FR 41314). (See also 56 FR 60366 et al., November 27, 1991, and 58 FR 2066 et al., January 6, 1993 (15 months to issue Nutrition Labeling and Education Act regulations); 60 FR 5530, January 27, 1995, and 60 FR 63372, December 8, 1995 (11 months to issue regulations to facilitate communications between FDA and State and foreign governments in order to enhance regulatory cooperation).) If it is necessary to amend this regulation, the agency will also be able to do so expeditiously.

The agency agrees with the comment stating that smoking mothers are at risk for certain reproductive hazards. FDA has chosen to tailor its regulation to address only children and adolescents. However, other agencies within the Department of Health and Human Services (DHHS) have programs that currently address tobacco use by persons of all ages.

FDA, on its own initiative, has revised § 897.1 to simplify and to clarify the scope of the rule. As revised, § 897.1(a) states that part 897 "sets out the

restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine." This sentence is comparable to proposed § 897.1(a), but more accurate because the 1995 proposed rule only referred to FDA's restricted device authority. FDA has also added a new § 891.1(b) stating that "[t]he failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act." This sentence is intended to remind parties that violations of a regulation for a restricted device and other actions relating to the sale of a device may cause a device to be "misbranded" under the act. Proposed § 897.1(b), which would have stated that regulatory references are to title 21 of the Code of Federal Regulations, has been renumbered as § 891.1(c) in the final rule and has not been changed.

#### *D. Purpose (§ 897.2)*

Proposed § 897.2(a) would have stated that:

[t]he purpose of this part is to establish conditions for the sale, distribution, and use of cigarettes and smokeless tobacco products in order to: \* \* \* [r]educe the number of people under 18 years of age who become addicted to nicotine, thus avoiding the life-threatening consequences associated with tobacco use and to provide important information regarding the use of these products to users \* \* \*

The agency has modified the final rule to provide information regarding the use of these products only to users; it has deleted potential users because the final rule no longer includes an education program for young people. Proposed § 897.2(b) stated that this part of the provision is intended to "[p]rovide important information regarding the use of these products to users and potential users." The agency's response to more specific comments follows.

The preamble to the 1995 proposed rule stated that the proposed rule would reduce "the appeal of and access to cigarettes and smokeless tobacco products by persons under 18 years of age," but "would preserve access to cigarettes and smokeless tobacco products by persons 18 years of age and older" (60 FR 41314 at 41322).

This rule is designed to complement the regulations (sometimes referred to as "the Synar regulations") issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) (the SAMHSA rule) implementing section 1926 of the PHS Act regarding the sale and distribution of tobacco products to

individuals under the age of 18. The SAMHSA rule contains standards for determining State compliance with section 1926 relating to the enactment and enforcement of State laws prohibiting the sale and distribution of tobacco products to individuals under the age of 18. Both sets of regulations are designed to help address the serious public health problem caused by young people's use of nicotine-containing tobacco products. By approaching this pediatric disease from different perspectives, these regulations together will help achieve the Administration's goal of reducing the number of young people who use tobacco products by 50 percent.

(17) One comment opposing this provision stated that "it will have little effect on tobacco use by young people, is beyond FDA'S statutory authority, is unjustified as a matter of policy, and would violate the Constitution."

The agency believes that the comment opposing this provision misinterprets § 897.2. This particular provision merely states the purpose of the entire rule and is not intended, in and of itself, to impose any new restrictions. The agency disagrees that the entire rule will have little effect on tobacco use by young people; that it is beyond the agency's statutory authority; that it is unjustified as a matter of policy; and that it violates the Constitution. All of these issues are discussed in detail elsewhere in this document.

(18) Several comments supported the provision, stating that a national policy is essential because State laws are ineffective and inconsistent.

The agency agrees with these comments and advises that the final rule complements the existing efforts by States to enforce restrictions on young people's access to cigarettes and smokeless tobacco. As stated in the comments, all States currently have laws prohibiting the sale of tobacco products to minors. Section 1926 of the PHS Act creates an incentive for the States to reduce the unlawful sales of tobacco products to young people by "requiring States to have in effect laws which prohibit the sale of tobacco products to minors as a condition of receipt of substance abuse grants." This rule would only preempt individual State requirements that are different from or in addition to these regulations (see section 521(a) of the act (21 U.S.C. 360k(a))). Thus, a State restriction on the sale of cigarettes and smokeless tobacco to individuals under the age of 18 will continue to be enforced by the State. (See preemption discussion,

section X. of this document.) While the agency expects the State laws to reduce smoking among young people, those laws unlike FDA's rule, only reduce access and not the appeal of smoking to young people. Thus, the agency believes that the rule will help States achieve their goals under the substance abuse programs.

(19) One comment supporting the provision stated that although the focus of the rule should be on children, "the needs of adult smokers should not be abandoned." Another comment stated that:

Cigarettes and smokeless tobacco products are nicotine delivery devices and they regularly cause addiction in their users. Because addiction often leads to serious illness and death, it is important to reduce the number of people under 18 years of age who become addicted to nicotine. Similarly, it is important to provide accurate information about the use of these products to users and to potential users.

The agency appreciates the comment's suggestion, but advises that, for reasons explained in section I.B. of this document, the final rule focuses principally on children and adolescents.

FDA, on its own initiative, has revised § 897.2 to state that the purpose of part 897 is "to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use." FDA believes this revision is a simpler and more accurate statement of the rule's purpose.

#### *E. Definitions (§ 897.3)*

Proposed § 897.3 would have contained definitions for the terms "cigarette," "cigarette tobacco," "distributor," "manufacturer," "nicotine," "package," "point of sale," "retailer," and "smokeless tobacco." The agency received several comments on the definition section of the proposal, regarding either the specific definitions provided or requesting definitions for additional terms. In response to the comments, the agency has clarified several terms, including "distributor" and "retailer," and has modified the term "cigarette" to exclude little cigars.

Proposed § 897.3(a)(3) would have provided a definition of "cigarette" which included the following language, modeled after the definition of "little cigar" contained in the Cigarette act:

(a) *Cigarette* means \* \* \*

(3) [a]ny roll of tobacco wrapped in leaf tobacco or any substance containing tobacco

\* \* \* and as to which 1,000 units weigh not more than 3 pounds.

(20) Several comments supported the inclusion of "little cigars" in the definition of "cigarette" and suggested that the definition be broadened to include other tobacco products as well. These comments argued that all tobacco, including "snuff," chewing tobacco, cigars, and pipes, should be regulated in the same manner as cigarettes, as these products are also nicotine delivery systems. These comments further stated that there is evidence to show that cigar smoking is becoming increasingly popular among young adults and adolescents.

In contrast, several comments from industry indicated that little cigars are unique products which should not be regulated as cigarettes. One comment stated that the agency has no studies to support the inclusion of little cigars in the rule. Moreover, the U.S. Treasury Department's Bureau of Alcohol, Tobacco and Firearms (BATF) submitted a comment opposing the inclusion of little cigars in the "cigarette" definition, as this would require little cigars to be labeled and advertised as a cigarette under the FDA regulations, but taxed and labeled as a "cigar," under the Internal Revenue regulations enforced by BATF.

The agency has decided, based upon the comments and the record of this proceeding, not to include little cigars in the definition of "cigarettes" for the purposes of the regulation. The differences between little cigars and cigarettes are significant—the products are easily distinguishable, taxed at different levels, and marketed to different consumers. Moreover, little cigars are neither advertised extensively nor sold in vending machines. Most importantly, the agency is not currently aware of sufficient evidence of use of little cigars by children or adolescents to support inclusion of such products in the rule. Therefore, FDA has deleted little cigars from the definition of "cigarette" in § 897.3(a). Moreover, FDA will continue to coordinate definitions with BATF as appropriate.

Additionally, FDA has deleted "components, accessories, or parts" from § 897.3(a). The reference to "components, accessories, or parts" was unnecessary because the statutory definition of "device" includes "any component, part, or accessory."

Proposed § 897.3(b) would have defined "cigarette tobacco" as "any loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette." The proposed

definition also would have stated that "[u]nless otherwise stated, the requirements pertaining to cigarettes shall also apply to cigarette tobacco."

(21) One comment by manufacturers of "roll-your-own" (RYO) cigarette tobacco argued that the inclusion of RYO cigarette tobacco under the 1995 proposed rule was arbitrary and capricious, as the agency had no factual information about RYO's composition, marketing, and usage. This comment also asserted that there is no evidence of RYO tobacco usage by minors.

The agency disagrees that the inclusion of cigarette tobacco in the rule is arbitrary and capricious. RYO tobacco is nothing less than cigarettes that have not yet been assembled.

Unquestionably, RYO cigarettes contain tobacco and are smoked. The comment did not challenge the agency's proposed finding that the smoke from RYO cigarettes is inhaled, that the RYO tobacco is processed, and that RYO cigarettes deliver nicotine. Unlike "little cigars," discussed in paragraph 1 of this section of the document, the agency believes that there is no significant difference in the composition of RYO tobacco or in the reason consumers use it (to deliver nicotine) from cigarettes. The agency believes that, because a RYO cigarette is fundamentally the same product as a commercially manufactured cigarette posing the same risks, it should be subject to the restrictions in this rule in order to protect the public health.

Furthermore, it is important to include RYO tobacco because to exclude it would provide a simple and obvious way to avoid the restrictions in this regulation. If such an exception existed, cigarettes could be packaged and sold in such a way as to be considered RYO products. Tobacco companies would then be free to sell these products using all the marketing and promotion techniques currently used for cigarettes, techniques that are particularly successful with young people. An exception so broad would quickly undermine the entire purpose of the rule. Additionally, FDA has made a minor change to § 897.3(b) to have "cigarette tobacco" mean "any product that consists of loose tobacco \* \* \*." The addition of the words "any product" is intended to make § 897.3(b) conform with the format used for other definitions.

(22) In proposed § 897.3(c), "distributor" would have been defined as "any person who furthers the marketing of cigarettes or smokeless tobacco products \* \* \* from the



original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the \* \* \* products."

Several comments stated that the definition of "distributor" is vague and over broad, because:

[P]ersons 'who further the marketing of cigarettes or smokeless tobacco' [may include] literally everyone involved in the production, shipping, advertising, or promotion of cigarettes. Such 'distributors' could thus include, for example, cigarette manufacturers and their employees; truckers and shipping clerks involved in the physical movement of the product; advertising agencies; people involved in promotional activities and the manufacture of promotional materials; retailers and their employees; and conceivably even individuals who 'deliver' cigarettes to social acquaintances or family members as 'ultimate users.' Including such persons and entities within the definition of 'distributor' would, in turn, render them 'responsible,' \* \* \* for ensuring that the cigarettes the 'marketing' of which they 'further' comply with 'all applicable requirements' of part 897.

(23) One comment suggested that an individual advocating a particular brand of cigarette would fall within the definition of "distributor."

The agency recognizes the concerns expressed about the proposed definition of "distributor." Therefore, based upon the comments received, the agency has determined that the definition should be modified to clarify the term. The definition of "distributor" has been modified to mean "any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption." The term does not include persons who do not manufacture, fabricate, assemble, process, or label a finished cigarette or smokeless tobacco product, and does not repackage or otherwise change the container, wrapper, or labeling of the cigarette or smokeless tobacco product, because such persons would be "manufacturers" under § 897.3(d).

Under this modified definition, one who manufactures cigarettes or smokeless tobacco is not considered a distributor, but is subject to the requirements applicable to manufacturers (see § 897.3(d), definition of "manufacturer"). Similarly, one who "sells or distributes the product to individuals for personal consumption" is not a distributor, but is subject to the requirements applicable to retailers (see § 897.3(h), definition of "retailer").

Furthermore, the modified definition clearly does not apply to advertising agencies. Although advertising agencies may be said to further the "marketing" of a product they advertise, they do not further the "distribution" of that product. As for truckers and other carriers, section 703 of the act only requires "carriers engaged in interstate commerce" and persons receiving or holding devices in interstate commerce to provide access to records showing the devices' movement or holding in interstate commerce. Thus, such carriers would not be subject to the requirements applicable to distributors under this part.

(24) Proposed § 897.3(d) would have defined "manufacturer," in part, "as any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product." One comment suggested that this definition be modified to exclude foreign manufacturers and manufacturers of products that make up less than 1 percent of the total U.S. cigarette market.

The agency disagrees that foreign manufacturers and "small" manufacturers should be excluded from the definition. A company that manufactures a small amount of a product is, nevertheless, a manufacturer. Thus, small manufacturers and foreign manufacturers of products marketed in the United States are included in the definition of "manufacturer" and are subject to the provisions of this rule. Furthermore, as discussed in more detail later, FDA regulates devices as a class without making exceptions for small market share.

Additionally, FDA, on its own initiative, has deleted the part of the definition which would have stated that a "manufacturer" "does not include any person who only distributes finished cigarettes or smokeless tobacco products." FDA believes this text was unnecessary given the definition of "distributor" in § 897.3(c).

Proposed § 897.3(e) would have defined "nicotine" by its chemical formula, 3-(1-Methyl-2-pyrrolidinyl) pyridine, and would have included any salt or complex of nicotine. FDA did not receive any comments that would warrant a change to § 897.3(e), and has finalized this definition without change.

Proposed § 897.3(f) would have defined "package" as a pack, box, carton, or container of any kind in which cigarettes or smokeless tobacco

are offered for sale, sold, or otherwise distributed to consumers.

FDA did not receive any comments that would warrant a change to § 897.3(f) but has, on its own initiative, deleted the word "products" from "smokeless tobacco products" to correspond to similar changes throughout the rule.

(25) Proposed § 897.3(g) would have defined "point of sale" to mean "any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco products for personal consumption." One comment stated that this definition is unconstitutionally vague and over broad, because "a person can 'obtain' cigarettes from a social acquaintance or family member \* \* \* in any number of \* \* \* settings." The comment suggested that "point of sale" be limited to "commercial establishments where tobacco products are sold in arm's-length commercial transactions."

The agency agrees that obtaining a cigarette from a social acquaintance or family member should not render the venue of this "transaction" a "point of sale." However, the agency does not believe that the definition of "point of sale" is vague or overly broad, or that it needs to be modified. The definition, as proposed, makes it clear that "point of sale" does not contemplate venues where cigarettes are lent or offered to social acquaintances or family members. The definition in § 897.3(d) refers to the "location at which a consumer can purchase or otherwise obtain" the product (emphasis added). The term "consumer," means "a person who buys goods or services for personal needs and not for resale or to use in the production of other goods for resale."<sup>37</sup> Thus, in its normal use, the term "consumer" implies a commercial relationship and precludes the possibility that, for example, the act of providing a cigarette to a travel partner would render the vehicle in which both are traveling the "point of sale" for that product.

(26) Proposed § 897.3(h) would have defined "retailer" to mean "any person who sells or distributes cigarettes or smokeless tobacco products to individuals for personal consumption." One comment stated that this definition is unconstitutionally vague and over broad, because a "manufacturer or wholesaler that 'distributes' complimentary cigarettes to its employees, or to guests at a private function, would be a 'retailer,' as would

<sup>37</sup> Webster's New World Dictionary, edited by V. Neufeldt, Third College Edition, Prentice Hall, New York, p. 299, 1991.

be any individual who gives any other individual a cigarette."

The agency agrees that, although the intended meaning of the term is clear, a "person who \* \* \* distributes \* \* \* [a product] to individuals for personal consumption" may include transactions that the agency does not intend to regulate (i.e., noncommercial transactions). Therefore, the definition is modified to mean "any person who sells cigarettes or smokeless tobacco to individuals for personal consumption."

Additionally, under § 897.3(h) as revised, a retailer can be any person "who operates a facility where vending machines and self-service displays are permitted under this part." This change complements a change to § 897.16(c) which permits vending machines and self-service displays in facilities where no person under age 18 is present, or permitted to enter, at any time. The agency addresses § 897.16(c) in greater detail below.

Proposed § 897.3(i) would have defined smokeless tobacco as "any cut, ground, powdered, or leaf tobacco that contains or delivers nicotine and that is intended to be placed in the oral cavity."

FDA did not receive any comments that would warrant a change to § 897.3(i). However, FDA has revised the definition to refer to "any product that consists of cut, ground, powdered, or leaf tobacco \* \* \*." The agency made this change because the words "smokeless tobacco" are often understood as meaning a "smokeless tobacco product" or products. Additionally, elsewhere in this rule, FDA has replaced "smokeless tobacco product" with "smokeless tobacco."

(27) Several comments requested definitions for additional terms. Specifically, one comment requested that "advertising" be defined to distinguish between trade and consumer advertising; several comments requested that "vending machine" be defined to exempt machines which dispense cigarettes to cashiers, machines that dispense individual cigarettes, or machines that scan a driver's license or age of majority card before dispensing cigarettes; and several comments requested that "playground" be defined for clarity.

The agency disagrees that additional definitions are necessary for the terms "advertising" and "vending machine." However, the agency has clarified the use of those terms in the relevant sections of the preamble. The agency has determined that a definition for the term "playground" is necessary, and has

added some examples to § 897.30. A discussion of the comments regarding the definition of "playground" can be found in section VI. of this document.

#### IV. Access

Subpart B of part 897 (now retitled as "Prohibition of Sale and Distribution to Persons Younger than 18 Years of Age") contains the restrictions on access to cigarettes and smokeless tobacco by individuals under the age of 18. This subpart, by imposing restrictions on manufacturers, distributors, and retailers, is intended to ensure that children and adolescents cannot purchase these products.

In support of proposed subpart B, the preamble to the 1995 proposed rule cited studies showing that the majority of junior high and high school students—from 67 percent of 9th grade students in a 1990 survey to 94 percent of junior high and high school students in a 1986 survey—believed that purchasing cigarettes and smokeless tobacco was easy (60 FR 41314 at 41322, August 11, 1995). Other studies supported that belief. As noted in the preamble to the 1995 proposed rule, the 1994 Surgeon General's Report entitled "Preventing Use Among Young People: A Report of the Surgeon General" (the 1994 SGR) examined 13 studies of over-the-counter (OTC) sales and determined that approximately 67 percent of minors are able to purchase cigarettes illegally. The 1994 SGR examined nine studies and found that the weighted average rate of illegal sales to children and adolescents from vending machines was 88 percent.<sup>38</sup>

Significant numbers of children and adolescents successfully purchased smokeless tobacco as well, with the success rate ranging from 30 percent for junior high school students to 62 percent for senior high school students (60 FR 41314 at 41322). Ninety percent of smokeless tobacco users in junior high and high school in a 1986 survey said they bought their own smokeless tobacco (60 FR 41314 at 41322).

Studies indicate that a comprehensive approach to reducing young people's access to cigarettes and smokeless tobacco would be more effective than relying primarily on retailer education programs about the need to prevent sales to underage persons. For example, the preamble to the 1995 proposed rule cited a comprehensive community intervention in Woodridge, IL, involving retailer licensing, regular compliance checks, and penalties for merchant

violations. The Woodridge program reduced illegal sales from 70 percent to less than 5 percent almost 2 years later (60 FR 41314 at 41322). Rates of both experimentation and regular smoking decreased more than 50 percent among seventh and eighth grade students (60 FR 41314 at 41322).

In contrast, another study cited in the 1995 proposed rule indicated that retailer education programs, alone, may have limited utility. In the study, retailers received informational packages on preventing illegal sales to young people, yet despite these informational packages, young people were able to buy cigarettes in 73 percent of the stores that received these informational packages, and, after a comprehensive retailer educational program was conducted, illegal sales were still found to occur in 68 percent of the stores (60 FR 41314 at 41322). When the program began issuing citations to violative establishments, the illegal sales rate dropped to 31 percent (*Id.*). This study, as well as other studies reviewed by the agency in the 1995 proposed rule and made available for public comment and review, led the Food and Drug Administration (FDA) to draft a comprehensive proposal to reduce young people's access to cigarettes and smokeless tobacco and to make explicit the responsibility of manufacturers, distributors, and retailers to prevent cigarette and smokeless tobacco product sales to persons under 18 years of age.

Subpart B to part 897 consists of four provisions. Section 897.10 establishes the general responsibilities of manufacturers, distributors, and retailers to ensure that the cigarettes and smokeless tobacco that they manufacture, label, advertise, package, distribute, sell, or otherwise hold for sale comply with the requirements in this subpart. The agency made one minor change to this provision, to change "smokeless tobacco products" to "smokeless tobacco."

Section 897.12 sets forth additional responsibilities of manufacturers. Proposed § 897.12(a) would have required manufacturers to remove from point of sale all violative self-service displays, advertising, labeling, and other manufacturer-supplied or manufacturer-owned items. In response to comments from manufacturers and sales representatives objecting to their responsibility for items not owned by them, the agency has amended this provision to require manufacturers only to remove from point of sale all violative self-service displays, advertising,

<sup>38</sup> 1994 SGR, p. 249.

labeling, and other items owned by the manufacturer.

Proposed § 897.12(b) would have required manufacturers' representatives who visit a point of sale in the normal course of business to visually inspect and ensure that products are labeled, advertised, and distributed in accordance with this subpart. In response to comments questioning the need for and operation of this requirement, FDA has deleted this provision.

Section 897.14 sets forth additional responsibilities of retailers. Many of the comments supported the requirements to verify age and to ban the sale of single cigarettes. Comments were divided on the requirement for a direct transaction. The comments opposing the 1995 proposed rule were taken into account in the modifications to the final rule.

The final rule contains a new § 897.14(a), which states that no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. This new paragraph codifies a concept that was implicit in the 1995 proposed rule.

Proposed § 897.14(a) (now renumbered as § 897.14(b)) would have required that the retailer or an employee of the retailer verify by means of photographic identification showing the bearer's date of birth that no purchaser is younger than 18 years of age. In response to changes made to § 897.16 regarding mail-order and vending machine sales and self-service displays in facilities inaccessible to children and adolescents, the final rule excepts the requirements for proof of age under these limited circumstances. New § 897.14(b)(2) eliminates the verification requirement for consumers 26 years of age or older.

Proposed § 897.14(b) (now numbered as § 897.14(c)) would have required that cigarettes or smokeless tobacco be provided to the purchaser by the retailer or an employee of the retailer, without the assistance of an electronic or mechanical device, such as a vending machine. The final provision has been modified to reflect changes made to § 897.16 permitting vending machines and self-service displays in certain limited circumstances and to correspond more closely to the requirements in § 897.16(c)(1).

Proposed § 897.14(c) (now renumbered as § 897.14(d)) would have prohibited the retailer or an employee from opening any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or any quantity of the product that is smaller than the

quantity in the unopened products. In order to clarify the intent of this provision, the final rule prohibits retailers from breaking or otherwise opening "any cigarette or smokeless tobacco product package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use."

The final rule also adds § 897.14(e) to clarify that each retailer is responsible for removing all violative self-service displays, advertising, labeling, and other items located in the retailer's establishment or for bringing those items into compliance with the requirements in this rule. This provision complements § 897.12 which requires manufacturers to remove manufacturer-owned, violative items from retail establishments.

Section 897.16 establishes the conditions of manufacture, sale, and distribution. Proposed § 897.16(a) would have prohibited the use of a trade or brand name for a nontobacco product as the trade or brand name for a tobacco product "except for tobacco products on which a trade or brand name of nontobacco product was in use on January 1, 1995." The only change to § 897.16(a) has been to clarify the agency's intent by amending the language to restrict manufacturers to those product names "whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995."

Section 897.16(b) would have established a minimum package size of 20 for cigarettes. The final rule was amended only to provide a very limited exception consistent with the changes made to § 897.16(c)(2)(ii), discussed below.

Proposed § 897.16(c) would have prohibited vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale and required direct, face-to-face exchanges between retailers and consumers. In response to comments criticizing the restrictions as inconveniencing adults, the agency has amended this section. The final rule allows mail-order sales (except for mail-order redemption of coupons and the distribution of free samples through the mail). The final rule also allows vending machines (even those selling packaged, single

cigarettes), and self-service displays (merchandisers) in facilities that are inaccessible to persons under the age of 18.

Proposed § 897.16(d) would have prohibited manufacturers, distributors, and retailers from distributing any free samples of cigarettes or smokeless tobacco. FDA made one minor change to this provision, changing the words "manufacturers, distributors, and retailers may not distribute" to "no manufacturer, distributor, or retailer may distribute" free samples.

The final rule adds a new § 897.16(e) to prohibit manufacturers, distributors, and retailers from selling, distributing, or causing to be sold or distributed cigarettes or smokeless tobacco with advertising or labeling that does not comply with the rule's advertising and labeling requirements. This provision is intended to clarify that the rule's advertising and labeling requirements are conditions on the sale, distribution, and use of these products.

#### *A. General Comments*

The agency received many general comments both in support of and in opposition to proposed subpart B of part 897. Comments supporting the 1995 proposed rule often stated that the rule, if finalized, would help prevent young people from obtaining or using cigarettes and smokeless tobacco and would eventually lead to a healthier population and lower health care costs. The agency also received comments from attorneys general of more than 25 States concluding that, overall, the 1995 proposed rule "should be a crucial component of a national effort by Federal, State, and local officials to help our youngest generation of Americans avoid suffering preventable disease and premature death from the use of tobacco products."

Comments opposing the 1995 proposed rule, in general, asserted that FDA regulation was unnecessary or unauthorized or that the proposed requirements would be ineffective. The following is an analysis of and response to these general comments.

(1) Several comments stated that the 1995 proposed rule violates the Commerce Clause of the Constitution. The comments argued that there is no equivalent to a congressional finding that the regulated activity at issue—the sale of tobacco products to children and adolescents—affects interstate commerce, nor is the regulation reasonably adapted to an end permitted by the Constitution. They argued that the regulation of tobacco products by

the Federal Government is impermissible based on *United States v. Lopez*, 115 S.Ct. 1624 (1995) (Congress lacked power under Commerce Clause to criminalize possession of a gun within 1,000 feet of a school).

The agency disagrees with these comments. The Constitution gives Congress the power "[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes." Under the Commerce Clause, Congress may "regulate those activities having a substantial relationship to interstate commerce, i.e., those activities that substantially affect interstate commerce" (*Lopez*, 115 S.Ct. at 1629–30 (citation omitted)). The Supreme Court has consistently held that Congress acted within its powers under the Commerce Clause when it enacted and subsequently amended the Federal Food, Drug, and Cosmetic Act (the act). (See *United States v. Sullivan*, 332 U.S. 689, 697–98 (1948); *United States v. Walsh*, 331 U.S. 432, 437–38 (1947); *Weeks v. United States*, 245 U.S. 618, 622 (1918); *Seven Cases of Eckman's Alternative v. United States*, 239 U.S. 510, 514–15 (1916); *McDermott v. Wisconsin*, 228 U.S. 115, 128 (1913); *Hipolite Egg Co. v. United States*, 220 U.S. 45, 58 (1911).) Regulation of tobacco products is a legitimate exercise of FDA's authority under the act to regulate drugs and devices and is therefore within the scope of Congress' power under the Commerce Clause.

The Supreme Court's recent opinion in *Lopez* does not affect this analysis. As the Court noted, "[t]he possession of a gun in a local school zone is in no sense an economic activity that might, through repetition elsewhere, substantially affect any sort of interstate commerce." (See *Lopez*, 115 S.Ct. at 1634; see also *Id.* at 1640 (Kennedy, J., concurring) ("[H]ere neither the actors nor their conduct have a commercial character, and neither the purposes nor the design of the statute have an evident commercial nexus.").)

By contrast, this tobacco regulation affects conduct that is distinctly commercial in character. In particular, the access restrictions—the national minimum age for purchase of tobacco products and the restrictions on hand-to-hand sales, sales from opened packages, package size, vending machine sales, and self-service displays—all involve actors (manufacturers, vendors, and consumers) and conduct (the marketing, sale, and purchase of products that are themselves in interstate commerce) that are quintessentially commercial (see,

e.g., *Katzenbach v. McClung*, 379 U.S. 294, 298–304 (1964) (under the Commerce Clause, Congress may regulate activities of restaurants that serve food, a substantial portion of which has moved in interstate commerce)). In addition, the purpose and design of the regulation—to deter this commercial activity directed at persons under the age of 18 in order to reduce addiction to the nicotine in these products—has the requisite commercial nexus. (See, e.g., *Heart of Atlanta Hotel, Inc. v. United States*, 379 U.S. 241 (1964); *Perez v. United States*, 402 U.S. 146 (1971).) Moreover, because youths alone purchase an estimated \$1.26 billion of tobacco products annually, the regulated activity—sales of tobacco products—substantially affects interstate commerce.<sup>39</sup>

As noted, tobacco products are in interstate commerce as defined in section 201(b) of the act (21 U.S.C. 321(b)). Cigarettes manufactured in the United States include myriad components that are in interstate commerce. For example, American-type blended cigarettes contain oriental tobacco imported from Greece, Turkey, Russia, Yugoslavia, or Bulgaria, and they may also contain imported flue-cured tobacco from, for example, Zimbabwe or Brazil. In addition, they contain other tobacco and tobacco products, filters, paper, ammonia, sugars, humectant, licorice, and cocoa, among nearly 600 other possible ingredients. (See generally Brown, C. L., *The Design of Cigarettes*, Hoechst Celanese Corp., Charlotte, NC (3d ed. 1990); "Ingredients Added to Tobacco in the Manufacture of Cigarettes by the Six Major American Cigarette Companies," (April 12, 1994)). Similarly, smokeless tobacco is made from tobacco grown in Pennsylvania and Wisconsin or in Kentucky and Tennessee and contains other ingredients from a list of over 560, such as sugar, molasses, and licorice, which are in interstate commerce. (See *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General*, DHHS, PHS, p. 5, 1986; "Smokeless Tobacco Ingredient List as of April 4, 1994, attached to letter of May 3, 1994, from Stuart M. Pape to the Hon. Henry A. Waxman and the Hon. Thomas J. Bliley, Jr.)

(2) The comments also suggested that Congress' Commerce Clause powers do not allow imposition of a national

minimum age for the purchase of tobacco products.

The agency disagrees. The cases cited in these comments, *South Dakota v. Dole*, 483 U.S. 203 (1987) and *Oregon v. Mitchell*, 400 U.S. 112 (1970), do not address the Commerce Clause, and there is no case law suggesting that an agency may not impose regulations on commerce based on the age of people involved, under a statute passed pursuant to Congress' Commerce Clause power, and in particular that an agency may not set a national minimum age for sales of cigarettes and smokeless tobacco in order to reduce the risks of addiction and to health associated with their use by individuals under age 18. In fact, under its authority to regulate commerce, Congress may exclude from interstate commerce goods produced by children workers, *United States v. Darby*, 312 U.S. 100, 115–17 (1941) (overruling *Hammer v. Dagenhart*, 247 U.S. 251 (1918), which held that Congress lacked power to exclude products of child labor from interstate commerce), and criminalize, for example, the transportation in interstate commerce of pornography involving children (18 U.S.C. 2251 through 2259), or the sale of firearms and ammunition to individuals under the age of 18 (18 U.S.C. 922(b)(1)).

Moreover, "[t]he authority of the Federal government over interstate commerce does not differ \* \* \* in extent or character from that retained by the states over intrastate commerce." (See *Heart of Atlanta Hotel*, 379 U.S. at 260 (quoting *United States v. Rock Royal Co-op., Inc.*, 307 U.S. 533, 569–70 (1939)).) States may set a minimum age for sales of cigarettes and smokeless tobacco, and these products are in interstate commerce (and as devices, are presumed under section 709 of the act to be in interstate commerce for the purpose of jurisdiction under the act). Thus, it follows that the Federal Government may establish a national minimum age for sales of tobacco products.

In summary, the imposition of a national minimum age for purchase of tobacco products and restrictions on hand-to-hand sales, sales from opened packages, package size, vending machine sales, and self-service displays is within Congress' authority under the Commerce Clause.

(3) Several comments argued that the regulation's imposition of a national minimum age for purchase of tobacco products and its restrictions on impersonal sales, sales from opened packages, package size, vending

<sup>39</sup> DiFranza, J. R., and J. B. Tye, "Who Profits from Tobacco Sales to Children?" *JAMA*, vol. 263, No. 20, pp. 2784–2787, 1990.

machine sales, and self-service displays violate the Tenth Amendment to the Constitution. In particular, the comments argued that the regulation of tobacco products and decisions about eligibility and maturity are traditionally State functions, and that this fact required Congress to have made it unmistakably clear by statute that it intended FDA to regulate tobacco products.

The agency believes that this regulation does not violate the Tenth Amendment. The Tenth Amendment provides that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." It follows that, "[i]f a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States." (See *New York v. United States*, 505 U.S. 144, 156.) Because FDA is acting under the act, which Congress enacted under its Commerce Clause authority, there is no Tenth Amendment violation.

FDA disagrees that regulation of tobacco sales or decisions about eligibility and maturity are traditional State functions. Even if they were, however, that fact would not implicate the Tenth Amendment. "As long as it is acting within the powers granted it under the Constitution, \* \* \* Congress may legislate in areas traditionally regulated by the States" (*Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991)). Because the agency is acting to regulate cigarette and smokeless tobacco sales in order to eliminate the health risks of those products, and is doing so under a statute passed under Congress' Commerce Clause power, these provisions do not violate the Tenth Amendment.

Further, Congress need not make its intention to regulate in such areas "unmistakably clear in the language of [a] statute," *Will v. Michigan Dept. of State Police*, 491 U.S. 58, 65 (1989) (quotations omitted), as suggested in the comments. This requirement only applies to Federal statutes that "go[] beyond an area traditionally regulated by the States" to affect "decision[s] of the most fundamental sort for a sovereign entity," *Gregory*, 501 U.S. 460, because such statutes "alter the usual constitutional balance between the States and the Federal Government," *Will*, 491 U.S. 65 (quotations omitted); see also *Seminole Tribe of Florida v. Florida*, 116 S.Ct. 1114, 1123-1132 (1996) (holding that, even if Congress,

acting under the Commerce Clause, makes its intention to subject unconsenting States to Federal suits by private parties absolutely clear, the Eleventh Amendment bars such suits). Regulation of the sale of cigarettes and smokeless tobacco does not fundamentally affect the States' prerogatives under the Constitution (such as abrogating the States' sovereign immunity), and so Congress need not have made it unmistakably clear by statute that it intended FDA to regulate their sale.

In summary, the agency is imposing a national minimum age for purchase of tobacco products and restrictions on impersonal sales, sales from opened packages, package size, vending machine sales, and self-service displays in order to eliminate the health risks to young people associated with products in interstate commerce. These provisions therefore do not violate the Tenth Amendment.

(4) A comment from an industry trade association stated that the Ninth Amendment to the Constitution is a "barrier to federal laws that would restrict freedom of adults as well as others to use tobacco products." Several comments from adults expressed similar arguments regarding an adult's "freedom" to purchase or use tobacco products.

The agency disagrees that its imposition of a national minimum age for purchase of tobacco products and its restrictions on hand-to-hand sales, sales from opened packages, package size, vending machine sales, and self-service displays impinge on unenumerated rights protected by the Ninth Amendment.

The Ninth Amendment provides that "[t]he enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people." Although not a source of rights itself, the Ninth Amendment nevertheless "show[s] the existence of other fundamental personal rights" and that 'liberty' protected by the Fifth \* \* \* Amendment[] from infringement by the Federal Government \* \* \* is not restricted to rights specifically mentioned in the first eight amendments." *Griswold v. Connecticut*, 381 U.S. 479, 493 (1965) (Goldberg, J. concurring).

The final rule regulates commercial transactions involving tobacco products to limit young people's access to them. Young people do not have an unenumerated, fundamental right protected by the Constitution to have commercial access to tobacco products.

(See *Bowers v. Hardwick*, 478 U.S. 186, 190 (1986).) Nor does the agency believe that it is merely a specific manifestation of a broader right, *Id.* at 199 (Blackmun, J., dissenting), whether styled as the right to privacy, *Griswold*, 381 U.S. at 484-485, or to be let alone, *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting), or to individual autonomy, *Carey v. Population Services Int'l*, 431 U.S. 678, 687 (1977).

In particular, the right to privacy does not protect commercial access to tobacco products for young people, because restricting sales of addicting tobacco products to young people "is within the area of governmental interest in protecting public health." (See *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir.), (right to privacy does not include access to laetrile) *cert. denied*, 449 U.S. 937 (1980); see also *Carnohan v. United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) ("Constitutional rights of privacy and personal liberty do not give individuals the right to obtain laetrile free of the lawful exercise of government police power"); *United States v. Horsley*, 519 F.2d 1264, 1265 (5th Cir. 1975), (holding that right of privacy does not protect possession of marijuana with intent to distribute) *cert. denied*, 424 U.S. 944 (1976); *United States v. Kiffer*, 477 F.2d 349, 352 (2d Cir.) (same), *cert. denied*, 414 U.S. 831 (1973).) The agency therefore concludes that this rule does not abridge an unenumerated, fundamental right reserved to the people by the Ninth Amendment to the Constitution.

(5) Several comments suggested that comprehensive regulations were unnecessary. Instead, these comments advocated training programs for retailers and, more specifically, for retail sales clerks. These training programs would be based either on voluntary efforts by the affected industries or on in-house, employee training programs. A few comments argued that any regulations to restrict access to cigarettes and smokeless tobacco would be futile because young people "would get the products anyway."

The agency disagrees with these comments. The preamble to the 1995 proposed rule indicated that informational or training programs, alone or without any enforcement mechanisms, have limited success (60 FR 41314 at 41322). Given the health risks caused by or associated with these products and the evidence that current, voluntary restrictions on youth access are ineffective, FDA believes that it

needs to develop an effective, mandatory program under the act to restrict young people's access to cigarettes and smokeless tobacco. The agency cannot and should not abdicate its public health responsibilities in deference to voluntary efforts to inform employees or other parties on the sale and distribution of these products, given the evidence cited in the preamble to the 1995 proposed rule that such programs must be bolstered by government sanctions and measures like those in subpart B of part 897 in order to be effective.

(6) Other comments, particularly those submitted by a few State legislators, claimed that States should be free to allocate their resources as they wished so that, if a State decided not to address a particular issue, such as access to tobacco products, that decision would be within the State's purview.

In contrast, comments submitted by State and local public health officials were unanimous in recommending strong Federal leadership in reducing young people's access to cigarettes and smokeless tobacco.

The agency believes that the comments opposing the rule misinterpret the rule's scope and application. The rule does not require States to enforce any provision, nor does it require States to allocate resources in any manner. FDA will enforce the rule as it does any other rule, by using FDA's own resources or, where appropriate and with cooperation from State officials, by "commissioning" State officials to perform specific functions on the agency's behalf. FDA is authorized, under section 702(a) of the act (21 U.S.C. 372), to conduct examinations and investigations through any health, food, or drug officer or employee of any State, territory, or political subdivision commissioned as an officer of DHHS. In most cases, a commissioned State or local government official is authorized to perform one or more of the following functions: (1) Conduct examinations, inspections, and investigations under the act; (2) collect and obtain samples; (3) copy and verify records; and (4) receive and review official FDA documents.<sup>40</sup> The scope of the official's authority depends on his or her qualifications, and the commissioning process involves active and voluntary participation by States in identifying suitable candidates for commissioning

and establishing the scope of the commissioned official's duties.

(7) A few comments claimed that the rule would create friction between States and the Federal Government because, according to these comments, FDA would be interfering in State affairs. Some comments also claimed that the rule would make State efforts less effective because State regulatory or police agencies would defer to FDA.

In contrast, as noted above, several State attorneys general expressed a different view, stating that the rule would strengthen State efforts to reduce cigarette and smokeless tobacco use among young people.

The agency respectfully disagrees with those comments that claim FDA will be interfering in State affairs or that the rule will create friction or undermine the effectiveness of State officials. The agency has a history of cooperative relations with State regulatory officials. For example, as mentioned earlier, section 702(a) of the act authorizes FDA to commission State officials to perform specific functions on FDA's behalf. FDA also works with State officials in implementing statutes such as the Prescription Drug Marketing Act of 1987, the Nutrition Labeling and Education Act of 1990, and the Mammography Quality Standards Act of 1992. Given this history of cooperation between FDA and State regulatory agencies, FDA does not agree that the rule will create friction between FDA and State authorities or undermine the effectiveness of State officials.

(8) Many comments argued that the 1995 proposed rule would restrict an adult's ability to purchase or select cigarettes and smokeless tobacco. Several asserted that regulations would be ineffective because young people would obtain cigarettes and smokeless tobacco anyway. Hence, these comments would eliminate all provisions intended to reduce a young person's access to these products.

In contrast, many comments supported the rule, stating that it would reduce a young person's easy access to and opportunity for early experimentation with cigarettes and smokeless tobacco, help reduce the use of those products by young people, and prevent young people from suffering adverse health effects associated with using these products.

The agency agrees that the rule may have an incidental effect on an adult's ability to purchase cigarettes or smokeless tobacco, but FDA emphasizes that the rule's benefits far outweigh any inconvenience to adults. FDA has

narrowly focused the rule to address those activities and practices that are especially appealing to, or used by, young people and to preserve, to the fullest extent practicable, an adult's ability to purchase these products. Any inconvenience to adults should be slight. For example, although the final rule eliminates self-service displays for cigarette packages in facilities that are accessible to young people, the limited amount of time spent in requesting and receiving a cigarette pack from a retail clerk should not result in hardship on adults. The agency has also amended the rule, as discussed in section IV.E. of this document to retain specific modes of sale that are restricted to—or used almost exclusively by—adults. These amendments respond to comments from adult consumers and retailers that young people cannot or do not use certain modes of sale and so those modes of sale should remain available to adults.

(9) Several comments argued that the 1995 proposed rule "intruded" on private life or "discriminated" against adult cigarette and smokeless tobacco users.

In contrast, other comments agreed that FDA has jurisdiction over cigarettes and smokeless tobacco and that the rule was an appropriate exercise of FDA's authority and properly focused on curtailing access by young people. Several comments suggested amending the rule to add restrictions for adults, to ban smoking, or to provide information to help all smokers to stop smoking.

As stated earlier, the agency has drafted the rule as narrowly as possible to restrict the sale and distribution of these products to children and adolescents, while preserving adults' ability to purchase the products.

As for extending the rule to include adults or to ban smoking, FDA declines to adopt the comments' suggestion. As discussed in section III.A. of this document, the President, and the agency in its preamble to the 1995 proposed rule, have stated that removing cigarettes and smokeless tobacco from the market would not be in the best interests of the public health. The agency adheres to this position.

(10) Many comments urged FDA to refrain from rulemaking and instead rely on voluntary, manufacturer-developed or retailer-developed programs, such as "Action Against Access," "It's the Law," and "We Card," to prevent sales to young people. Some would require retailers and their employees to be trained to comply with existing State and local laws. Several large retail

<sup>40</sup> FDA Regulatory Procedures Manual, DHHS, PHS, Office of Regulatory Affairs, Office of Enforcement, Division of Compliance Policy, Chapter 3, p. 45, August 1995.

chains described the programs they already have in place.

Other comments expressed skepticism about such programs and, therefore, strongly supported FDA's rulemaking activities.

The agency declines to rely solely on voluntary, manufacturer- or retailer-developed programs to prevent sales to young people. The agency is regulating cigarettes and smokeless tobacco as devices under the act. Voluntary programs cannot serve as a substitute for such regulation and do not provide many of the safeguards that the act provides.

As for retailer programs to train employees not to sell cigarette and smokeless tobacco to young people, FDA believes that such training efforts will help retailers comply with their obligations under § 897.14. However, retailer training programs, alone, will not be as effective as the rule's comprehensive approach because such training would not affect certain activities (such as free samples and advertising) that are used by or appeal to young people.

Similarly, voluntary, manufacturer-developed programs are not sufficient to prevent sales to young people. Such programs purport to deter young people from using cigarettes or smokeless tobacco until they reach legal age, but often omit retail activities or impose no sanctions if a voluntary code or provision is violated. For example, one comment supported the rule, in part, because a retailer gave the author, when he was 15 years old, and other children free cigarettes. A manufacturer-developed program might not be effective at curtailing such practices by retailers, whereas the rule bars distribution of free samples by manufacturers, distributors, and retailers.

(11) One comment suggested amending the rule to include advertisers.

FDA declines to amend the rule as suggested by the comment. The agency's authority attaches to the product and those responsible for its manufacture, distribution, or sale in interstate commerce. Advertisers do not have control over the products and presumably act at the direction of manufacturers, distributors, and retailers. If an advertisement violated the requirements of this part, the agency would hold the appropriate manufacturer, distributor, or retailer responsible for the violative advertisement.

(12) One comment argued that cigarettes should be sold by prescription only. Other comments opposing the rule predicted that the agency would require prescriptions.

The agency declines to amend the rule to require prescriptions. Such a requirement would unduly affect adults and retailers and, FDA expects that the more narrowly tailored provisions in subpart B of part 897 will adequately restrict young people's access to these products.

(13) One comment criticized the 1995 proposed rule for not restricting where cigarettes and smokeless tobacco may be sold. The comment said that pharmacies and health care facilities often sell these products and that such sales undermine the credibility of health warnings related to these products. The comment suggested that FDA prohibit "inappropriate places" from selling these products.

FDA declines to amend the rule as suggested by the comment. The agency has no information or criteria that would permit it to determine whether certain places or types of establishments are not "appropriate" for selling cigarettes and smokeless tobacco.

#### *B. General Responsibilities of Manufacturers, Distributors, and Retailers (§ 897.10)*

Proposed § 897.10 would have required each manufacturer, distributor, and retailer to be responsible for ensuring that the cigarettes or smokeless tobacco that it "manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale" comply with the requirements in part 897. FDA proposed this provision setting forth these general responsibilities as part of the agency's comprehensive program to reduce young people's access to cigarettes and smokeless tobacco. Through this provision FDA intended to ensure that these products, from the time of their manufacture to the time of their purchase, comply with part 897 and that manufacturers, distributors, and retailers appreciate their roles, and carry out their legal responsibilities to reduce the accessibility and appeal of these products to young people. The final rule retains § 897.10 without any significant changes.

(14) Many comments interpreted proposed § 897.10 as imposing strict liability on manufacturers, distributors, and retailers. Generally, these comments interpreted the 1995 proposed rule as making a party responsible for violations committed by another party, even if the former was unaware that the

violation had been committed by the latter. Some comments asserted that the agency cannot impose such vicarious liability, under these comments' interpretation of *United States v. Dotterweich*, 320 U.S. 277 (1943), and *United States v. Park*, 421 U.S. 658 (1975). One comment acknowledged that proposed § 897.10, when read literally, would not hold parties responsible for acts committed by other parties, but nevertheless claimed that, despite such language, FDA would hold manufacturers, distributors, and retailers liable for any action committed by any party.

The agency believes that the comments have misinterpreted § 897.10. Section 897.10 holds manufacturers, distributors, and retailers responsible for their own actions; it does not require any party to ensure that another party complied with the regulations, nor does it hold a party responsible criminally or civilly for actions that it did not commit or about which it had no responsibility under the act and no knowledge. This is the most logical and straightforward interpretation of § 897.10, and, as stated earlier, the provision states that "each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes and smokeless tobacco it manufactures, labels, advertises, packages \* \* \* comply with all applicable requirements under this part" (emphasis added). The word "it" refers to the individual manufacturer, distributor, or retailer, while the word "applicable" signifies that a party, depending on the circumstances, is subject only to those requirements for which that party is responsible. This issue is discussed in greater detail later in this section of the document.

In determining which party may be responsible for a regulatory violation, FDA will examine where and when the violation occurred. For example, § 897.14(d), among other things, prohibits retailers from opening any cigarette package and selling individual cigarettes. If a retailer, on its own initiative, opened a package and sold single cigarettes, without the knowledge of a manufacturer or distributor, only the retailer would be responsible because only the retailer engaged in actions that violated the requirements in this part. However, if the manufacturer or distributor supplied single cigarettes to the retailer—contrary to § 897.16(b) which establishes a minimum package size for cigarettes—and the retailer sold the single cigarettes, or if the manufacturer or distributor knew or had reason to know that the retailer sold



single cigarettes and continued to provide cigarettes to the retailer, the manufacturer or distributor, as well as the retailer, would be subject to regulatory action. The manufacturer or distributor would have violated § 897.16(b) and assisted in violating § 897.14(d), while the retailer would be in violation of § 897.14(d). In sum, each manufacturer, distributor, and retailer is responsible for ensuring that *its* products (whether it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds them for sale) comply with all requirements *applicable* to it and its products. As such, § 897.10 does not create the problems that the comments suggested it does.

(15) Several comments objected to proposed § 897.10 because it would have each manufacturer, distributor, and retailer responsible for ensuring compliance with the regulatory requirements in part 897. These comments interpreted the provision as having the affected industries, rather than Federal or State Governments, determine compliance. One comment also asserted that the imposition of such responsibility on private persons is a violation of the Due Process Clause of the Fifth Amendment, which prevents unreasonable delegations of governmental authority. Several comments added that manufacturers, distributors, and retailers should not “spy” on each other to ensure compliance. One comment said that the rule would create a “hidden enforcement tax.”

FDA believes that the comments objecting to § 897.10 have misinterpreted its application. Section 897.10 does not make manufacturers, distributors, or retailers solely responsible for ensuring compliance with the regulations nor does it alter or affect any Federal or State enforcement mechanism. Section 897.10 is intended to remind manufacturers, distributors, and retailers that they are responsible for complying with the regulations that are applicable to them. FDA remains primarily responsible, as it does for most FDA regulations, for determining whether parties comply with the regulations. States, of course, remain free to enforce applicable State laws relating to these products.

(16) One comment asserted that proposed § 897.10 would impose vicarious liability in violation of the Eighth Amendment’s Excessive Fines Clause.

As previously discussed, § 897.10 does not impose the sort of vicarious

liability on manufacturers or distributors that the comments suggested it does. The Excessive Fines Clause of the Eighth Amendment states that “excessive fines [shall not be] imposed.” Here, neither § 897.10 nor any other provision of the final rule imposes an excessive fine or any fine at all. Moreover, whether a fine is excessive in a particular case requires a close analysis of the facts of that case. (See, e.g., *United States v. One Parcel Property Located at 427 and 429 Hall Street, Montgomery, Montgomery County, Alabama*, 74 F.3d 1165, 1170–73 (11th Cir. 1996) (adopting and applying proportionality test to *in rem* civil forfeiture); *United States v. Chandler*, 36 F.3d 358, 365–66 (4th Cir. 1994) (adopting and applying three-part instrumentality test to *in rem* civil forfeiture) *cert. denied*, 115 S.Ct. 1792 (1995).)

(17) A few comments implied that manufacturers should be excluded from § 897.10, stating that retailers, rather than manufacturers, should be responsible for preventing sales to young people.

The agency declines to amend the rule to exclude manufacturers. The preamble to the 1995 proposed rule demonstrated how certain practices by manufacturers, such as the distribution of free samples, offer young people easy and inexpensive access to cigarettes and smokeless tobacco. (See 60 FR 41314 at 41326 (free samples).) FDA received several comments that reinforced these views, such as comments from a 12-year old recounting how his classmate acquired free cigarettes from a manufacturer, and a mother whose 14-year old daughter and friends attributed their cigarette use to free samples obtained from manufacturers. Thus, manufacturers play a critical role in making cigarettes and smokeless tobacco accessible and appealing to young people.

In addition, because cigarettes and smokeless tobacco are products subject to the act, regulation of these products properly follows them from the time of their manufacture to their sale to the consumer. Focusing solely on the sale of these products to consumers would deprive the agency of any ability to address problems that may exist at the manufacturer or distributor level. For example, if products were incorrectly packaged or labeled, a rule that concentrated solely on retail sales might permit FDA to restrict sales of those products, but might not permit FDA to require the manufacturer to package or label those products correctly.

(18) Two comments would amend the rule to exempt manufacturers that had 1 or 2 percent of the cigarette or smokeless tobacco product market. One comment came from an association of specialty tobacco companies that either manufacture or import specialty cigarettes and other tobacco products. The comment claimed that specialty cigarettes account for a very small fraction (approximately 400 million cigarettes) of the total cigarettes market, are sold at higher retail prices compared to domestic cigarettes (from \$1.75 for 10 Indonesian cigarettes to \$4.00 for 20 German cigarettes), and are sold in shops that young people normally do not frequent. The comment also stated that the rule would have an adverse effect on foreign products (particularly products in packages containing less than 20 cigarettes), that the companies had little control over foreign manufacturers, and that companies would go out of business or be adversely affected by the rule. The comment sought an exemption either for firms or brands that have 1 percent or less of the total cigarette market in the United States. The comment explained that an exemption would be equitable because, the comment asserted, there is no evidence that specialty cigarettes contribute to underage smoking, and would also be consistent with an exemption granted by the Federal Trade Commission (FTC) for rotating cigarette label warnings and regulations by the U.S. Department of Agriculture (USDA) defining a “domestic manufacturer of cigarettes” for assessing payments under the Agricultural Adjustment Act of 1938.

The other comment came from a firm whose sales focused primarily on smokeless tobacco, with the remainder devoted to cigars and “smoking tobaccos.” The company said that it had approximately 1 percent of the smokeless tobacco market and is the sixth largest smokeless tobacco product manufacturer. The comment sought an exemption for companies with market shares under 2 percent because it claimed the rule would “sound the death knell” for small, family-owned businesses.

Both comments indicated that 80 to 90 percent of their sales occurred through the mail.

The agency declines to accept the comments’ suggestions to create an exemption based solely on market share. The agency believes that subjecting similar or identical products to the same statutory and regulatory standards is both practical and fair to manufacturers

and consumers. A consumer should be able to expect that similar or identical products made by different manufacturers will be regulated in the same fashion. Similarly, manufacturers will not be unfairly advantaged or disadvantaged if they are all subject to the same statutory and regulatory requirements. For example, the final rule prohibits the distribution of free samples. This restriction applies regardless of a manufacturer's market share and, aside from eliminating a free source of cigarettes and smokeless tobacco that people use, also treats manufacturers equally.

FDA is not persuaded by one comment's suggestion that an exemption would be consistent with actions taken by other agencies. FTC's exemption is based on statutory language at 15 U.S.C. 1333(c)(2)(A)(i) and is limited to changes in the label rotation sequence; in other words, the exemption does not relieve the manufacturer from placing warning statements on its packages. USDA's regulation pertaining to "domestic" manufacturers is based on statutory language at 7 U.S.C. 1301(b)(17) as part of the Agricultural Adjustment Act of 1938 that was designed, among other things, to create an incentive for domestic manufacturers to use domestic tobacco leaf. Thus, neither the FTC nor USDA statutes or regulations were intended to relieve foreign products from substantive requirements or to regulate foreign manufacturers.

As for the comments' assertions that their products are either not used by or accessible to young people, the agency has amended the rule to permit specific modes of sale, including mail order sales, that young people cannot or do not use. The agency did not amend the rule, however, to exclude cigarettes and smokeless tobacco or brands that young people do not appear to use or purchase. It would be inappropriate to exempt a particular brand or specialty product simply because a manufacturer claims young people do not purchase that product. (The agency also notes that the \$1.75 price charged for 10 Indonesian cigarettes is lower than the price charged for some domestic brands and creating an exemption for a low cost cigarette product in a "kiddie pack" size would be contrary to the rule's purpose.)

Additionally, FDA traditionally classifies, as a group, device products that are sufficiently similar so that they can be considered the same type of device for purposes of applying the regulatory controls in the act (see

§ 860.3(i) (21 CFR 860.3(i)) (definition of "generic type of device"), using the cumulative evidence from several manufacturers. Reclassification of one product of a particular type results in the reclassification of the entire group. (See 42 FR 46028, September 13, 1977; and 43 FR 32988 July 28, 1978.) The alternative would require FDA to classify individually each manufacturer's device, and to undertake the classification process whenever a new manufacturer marketed a product within an already identified device type. Thus, FDA applies the same regulatory requirements to all devices within an identified device type that are substantially equivalent to one another. This approach is necessary to provide similar regulatory treatment for essentially identical products of different manufacturers and distributors (42 FR 46028 at 46031; and 43 FR 32988 at 32989).

Additionally, assuming that the rule effectively restricts a young person's access to cigarettes and smokeless tobacco, it is reasonable to assume that a young person would turn to alternative products, such as foreign cigarettes that the comment would exempt. Consequently, the agency declines to exempt products with small market shares from the rule.

(19) FDA received several comments from wholesalers or distributors arguing that they should be exempt from the 1995 proposed rule, particularly proposed § 897.10, because they are unable to affect the actions of manufacturers and retailers. Several comments asserted that wholesalers and distributors are "merely a conduit" for transferring products from manufacturers to retailers and have small staffs that would be unable to comply with all requirements in part 897. According to these comments, a wholesaler or distributor would either have to hire additional staff to ensure that products complied with all applicable requirements or be without sufficient staff to ensure that all products supplied to all retailers complied with the regulations. Several comments added that requiring wholesalers and distributors to maintain records, submit reports to FDA, and be subject to inspection by FDA would waste the wholesaler's or distributor's resources and provide FDA with little or no useful information. A minority expressed confusion as to their obligations if they relabel cigarettes or smokeless tobacco.

The agency believes that the comments misinterpret § 897.10. The

provision states that a distributor would be responsible for ensuring that the cigarettes or smokeless tobacco that *it* manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale complies with all *applicable* requirements. For example, the reporting requirement in proposed § 897.40 was directed at manufacturers. Consequently, distributors would not have been required to submit reports to FDA under § 897.40. (Moreover, as discussed in section VIII. of this document, FDA has deleted § 897.40 and exempted distributors from the registration and listing requirements in part 807. Distributors are, however, subject to other reporting requirements, such as medical device distributor reports under part 804.) However, if a distributor acts in a manner that is outside the definition of distributor in § 897.3, it may alter its regulatory status and become subject to other provisions in this part. For example, a distributor who relabels cigarettes would, for those relabeled products, become a "manufacturer" under this rule and be subject to those provisions pertaining to manufacturers. Section 897.3 defines a manufacturer, in part, as any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels finished cigarettes or smokeless tobacco.

(20) Several comments would exempt distributors from the rule because, the comments claimed, the 1995 proposed rule set forth little or no evidence to justify regulating distributors.

FDA declines to exempt distributors from the rule. The agency reiterates that it is regulating cigarettes and smokeless tobacco under its drug and device authority, and that, as it does for other FDA regulated products, FDA's rule follows the products from the time of their manufacture to the time of their sale. Wholesale or distribution operations must be included in any effective regulatory system because products can be contaminated, diverted into illegal channels, or otherwise adulterated or misbranded at the wholesale or distribution level just as they can at the manufacturing and retail levels.

(21) Many comments asserted that, rather than impose responsibilities on manufacturers and distributors, FDA should limit the rule to requiring that retailers verify the age of persons purchasing cigarettes and smokeless tobacco. These comments claimed that no other regulatory provisions would be necessary if retailers, or their sales clerks, verified the purchaser's age.

FDA declines to exclude manufacturers and distributors from the rule. As stated earlier in section IV.B. of this document, cigarettes and smokeless tobacco are products subject to regulation under the act, and, as a result, the rule follows the products from the time of their manufacture, through storage and distribution, to product sale at the consumer level. Excluding manufacturers and distributors would compromise FDA's ability to ensure that these products are not accessible or appealing to young people. Manufacturers engage in activities, such as advertising, labeling, and distributing samples, that make cigarettes and smokeless tobacco accessible and/or appealing to young people. Distributors channel products from manufacturers to retailers, and so the rule includes distributors to ensure, among other things, that the products do not become adulterated or misbranded while held by distributors.

(22) FDA received many comments from retailers stating that FDA regulation was unnecessary because retailers train their staffs to request proof of age or have taken other steps to prevent sales to young people.

The preamble to the 1995 proposed rule provided reasons for not relying on retailer training programs alone. The preamble to the 1995 proposed rule cited a report by 26 State attorneys general stating that industry training films and retailers' programs have not, on their own, prevented illegal sales to young people and that, in some retail sectors, high employee turnover rates complicated training efforts (60 FR 41314 at 41323). The preamble to the 1995 proposed rule also cited studies showing that significant numbers of young people are not asked to verify their age when purchasing cigarettes or smokeless tobacco and that, in some cases, retail clerks even encouraged the young person's purchase by suggesting cheaper brands or offering to make up the difference in the purchase price if the young person lacked sufficient funds (60 FR 41314 at 41323). FDA received some comments that further illustrated the ease with which young people can purchase these products; for example, one comment reflected on the author's own practice, at age 11, of purchasing cigarettes by saying "They are for my Mom." Thus, while training retail clerks to request proof of age should help curtail a young person's access to cigarettes and smokeless tobacco, the reports and studies cited in the 1995 proposed rule, as well as the personal experiences reflected in some

comments, suggest that additional measures are necessary to reduce a young person's access to these products.

(23) Several comments from retailers claimed that the 1995 proposed rule violated their "right" to sell products or arrange their stores in any manner they wished. Many comments added that, if retailers are subject to the rule, many retailers will lose sales and fees associated with cigarettes and smokeless tobacco and could be forced to fire staff. One comment further stated that this would actually harm young people because the retailer would fire its newest staff, and such staff employees are usually young people. Conversely, some comments claimed that, in order to comply with the rule, retailers would be obliged to hire additional staff.

In contrast, FDA received two comments denying that retailers would lose slotting or promotional fees. (Some manufacturers pay retailers to display their products (often referred to as "slotting fees") in a specific fashion or to display signs or other materials provided by the manufacturer.) One comment, based on experience in an area in northern California where self-service displays were prohibited, stated that retailers did not suffer significant economic losses after the displays were banned. Another comment opined that manufacturers would still have an incentive to offer slotting fees or allowances to retailers to ensure advantageous placement of their products behind the counter.

FDA disagrees with the comments asserting an unrestricted "right" to sell products. Section 520(e) of the act (21 U.S.C. 360j(e)) states, in part, that the agency may require that a device be restricted to sale, distribution, or use upon such conditions as the agency may prescribe by regulation. Because FDA has determined that these products should be regulated as restricted devices, the act authorizes FDA to impose controls on their sale and distribution. The agency further notes that, in addition to restrictions authorized under the act, other consumer products are sold subject to various restrictions. For example, under 23 U.S.C. 158(a)(1), the "national minimum drinking age" is 21 years, and the Secretary of Transportation is authorized to withhold certain highway funds from States that have a lower minimum age. Federal law expressly prevents licensed importers, manufacturers, dealers, and collectors from selling firearms and ammunition to any individual that the licensee knows or has reasonable cause to believe to be

under 18 years old (except in specific, limited cases), or, if the firearm is not a shotgun or rifle, prohibits sales to individuals under 21 years of age (18 U.S.C. 922(b)).

Thus, there is no unfettered or unrestricted "right" to sell consumer products. Instead, products are often sold subject to conditions or restrictions, including those based on age, that are designed to protect the integrity of the product, to protect users or other members of the public, or to prevent the product from reaching certain groups of people.

FDA also disagrees with those comments predicting that the rule will result in lower sales and fees and compel retailers to lay off staff. Insofar as retailers are concerned, the rule does not affect sales to adults. It is intended to eliminate illegal sales to young people. Thus, for a retailer to assert that the rule will reduce its sales revenue so much as to require staff reductions, illegal sales would necessarily have to play a significant role in funding staff positions.

With respect to fees, the agency cannot determine whether manufacturers will discontinue paying slotting fees or other allowances to retailers as a result of the rule. The preamble to the 1995 proposed rule did estimate that industry promotional allowances totaled approximately \$1.6 billion in 1993, or \$2,600 per retailer if the sum is evenly distributed among the estimated 600,000 retail outlets (60 FR 41314 at 41369). FDA does note, however, that some comments supported the agency's position that retailers will not suffer significant economic losses. One study cited in the preamble to the 1995 proposed rule stated that, "in the absence of advertising and promotion outlets \* \* \* the cigarette industry may be expected to provide greater incentives to retailers to provide more and better shelf space for their brands in order to provide availability to the buyer in the store" (60 FR 41314 at 41369). Thus, while some manufacturers might stop paying slotting fees, others might continue paying those fees or even increase the fees to obtain favorable placement of their products behind the counter.

Furthermore, as described in greater detail in section IV.E.4.b. of this document, FDA has amended the rule to permit self-service displays (or, more specifically, merchandisers) in facilities that are inaccessible to young people.

As for those comments stating that retailers would have to hire additional staff, it is possible that some retailers

who have relied on modes of sale that the rule will now prohibit or restrict may need to hire additional staff. For example, if a retailer derived a substantial portion of its revenue from vending machines and those machines would not be available under the rule, the retailer might decide to hire staff in order to continue selling cigarettes or smokeless tobacco. However, the comments did not provide sufficient information to enable FDA to determine the number of retailers who might be affected or the extent to which they might be affected.

(24) A few comments challenged the validity of the 1995 proposed rule because it did not impose responsibilities on young people who purchase cigarettes and smokeless tobacco. These comments claimed that omitting young people from the rule, while requiring retailers to comply, was unfair, arbitrary, and capricious. One comment stated, "any effective public policy to restrict sales of tobacco products to minors must go beyond the discouragement of promotion, advertising and merchandising to minors. It must be accompanied by realistic penalties for minors who purchase and possess cigarettes and for adults who purchase for them."

It would be inappropriate for FDA to amend the rule to impose penalties or sanctions on young people who purchase or possess cigarettes or smokeless tobacco or adults who purchase such products for young people. The main focus of the act is on the introduction, shipment, holding, and sale of goods in interstate commerce. Thus, the actions of minors who purchase cigarettes and smokeless tobacco are appropriately a matter for State or local law.

(25) One comment stated that FDA should prohibit young people under 18 years of age from selling tobacco products.

The agency declines to amend the rule to place age restrictions on those who sell these products. FDA has little evidence to suggest that manufacturers', distributors', or retailers' young employees play a significant role in making cigarettes and smokeless tobacco accessible or appealing to young people. Although some evidence indicates that, in certain settings, a young employee might be less likely to check age or to challenge his or her peers (as in situations where the young employee distributed free samples (60 FR 41314 at 41326)), other provisions in this subpart, such as the elimination of

free samples, should reduce the need to place age restrictions on employees.

The agency does note, however, that in response to comments requesting that vending machines and self-service displays be permitted in "adult-only" facilities, FDA has amended the final rule to allow vending machines and self-service displays in facilities that are totally inaccessible to people under 18 and employ no persons below age 18. This is to ensure that an "adults-only" facility is truly restricted to adults rather than to create an age restriction on sellers. These changes to the rule are described in greater detail elsewhere in this document.

The agency is aware that several local governments have statutes or regulations that establish minimum age requirements for persons who sell tobacco products. Because this rule does not contain a minimum age requirement for persons who sell these products, those statutes or regulations are not preempted. The rule's preemptive effect on other State or local statutes or regulations and federalism issues are discussed elsewhere in this document.

(26) Several comments suggested that, instead of issuing regulations, the Federal Government should transfer funds to States for use in preventing cigarette and smokeless tobacco sales to young people.

FDA must decline to accept the comments' suggestion. Federal funding of State prevention efforts is beyond the scope of the rule. The agency does intend to work with State officials and cooperate in enforcement activities where appropriate and to the extent that its resources permit.

(27) Several comments suggested that FDA amend the rule so that the restrictions on the sale and distribution of cigarettes and smokeless tobacco do not apply to locations where young people do not enter or where entry is restricted, such as bars, liquor stores, factories, and prisons.

After consideration of these comments, the agency has amended the rule to allow certain retail practices to continue because those practices are not used by young people or are inaccessible to them. For example, the final rule permits mail-order sales to occur because the evidence does not establish that young people use mail-order sales to acquire these products. The final rule also permits vending machines and self-service displays (merchandisers only) to be used in locations where young people cannot enter, such as locations where proof of age is required in order to enter the

premises or facilities that employ only adults. These changes are described in detail in the discussion of § 897.16 and elsewhere in this document.

### *C. Additional Responsibilities of Manufacturers (§ 897.12)*

#### **1. Removal of Manufacturer-Supplied or Manufacturer-Owned Items That Do Not Comply With the Regulations**

Proposed § 897.12(a) would have required manufacturers, in addition to their other obligations under part 897, to remove, from each point of sale, "all self-service displays, advertising, labeling, and other manufacturer-supplied or manufacturer-owned items" that do not comply with the requirements in part 897. In response to comments, the agency has amended the final rule to require the manufacturer to remove only those violative items that the manufacturer owns.

(28) Many comments, including comments from manufacturers' sales representatives and retailers, strongly objected to this provision, particularly as it would apply to self-service displays. In general, the comments claimed that retailers, rather than manufacturers, own the self-service displays. The comments also expressed concern that manufacturers' representatives or retailers' employees might be physically harmed if a manufacturer's representative attempted to remove a self-service display from a retailer. Several comments also interpreted proposed § 897.12(a) as requiring a manufacturer's sales representative to remove self-service displays supplied by another manufacturer; these comments said removing a competitor's self-service display would be unethical and could result in the sales representative being barred from reentering the retail establishment in the future.

In contrast, a few comments supported proposed § 897.12(a) because manufacturers provide the displays to retailers and visit retailers often. One comment added that the burden of removing displays should not rest on retailers alone, but added that retailers should remain ultimately responsible for displays they use or have on site. This comment suggested that retailers be responsible for removing displays if the manufacturer fails to do so.

The agency agrees, in part, with the comments critical of the proposed provision and has amended § 897.12 to clarify that a manufacturer is responsible for removing all self-service displays (which the final rule also clarifies as referring to merchandisers),

advertising, labeling, and other items that it owns that do not comply with the requirements in part 897. FDA has also amended § 897.14 to clarify the obligation of retailers with respect to all other violative items in the retailer's establishment. These changes should eliminate potential conflicts between manufacturers' sales representatives and retailers.

Additionally, § 897.12 requires a manufacturer to be responsible only for the removal of the items it owns. The agency does not expect manufacturers to remove items owned by another manufacturer, but encourages manufacturers to inform another manufacturer and FDA if another manufacturer's items violate the requirements in part 897. However, the agency advises manufacturers who know or have reason to know that a distributor or retailer is misbranding that manufacturer's products, or causing its products to violate these regulations or the act, to take action, such as discontinuing sales, incentives, and supplies, to halt the violation. Manufacturers might be held liable for subsequent violations by the distributor or retailer, if the manufacturer knew or should have known about the violation and continued to supply its product to such parties.

Liability, both criminal and civil, under the act is very broad. Section 301 of the act (21 U.S.C. 331) prohibits certain acts "and the causing thereof." *United States v. Dotterweich*, 320 U.S. 277 (1943), and *United States v. Park*, 421 U.S. 658 (1975) elaborate on the meaning of "causing" in section 301 of the act (see *Park*, 421 U.S. at 673). These cases stand for the proposition that a corporate official can be held criminally liable as having caused the corporation's violations of the act of which he had no knowledge, so long as he stood in a "responsible relationship" to the violations (*Id.* at 672).

Under the act, "all who \* \* \* have \* \* \* a responsible share in the furtherance of the transaction which the statute outlaws" have caused the violation and are subject to civil and criminal liability (*Dotterweich*, 320 U.S. at 284). Indeed, a corporate employee and the corporation itself can have a responsible share in the furtherance of a violation of the act committed by another corporation or a person who is not an employee of the corporation. (See, e.g., *United States v. Parfait Powder Puff Co.*, 163 F.2d 1008, 1009-10 (7th Cir. 1947) (holding defendant corporation criminally liable for violations committed without its

knowledge by second corporation that defendant had contracted with to manufacture, package, and distribute its cosmetic product), *cert. denied*, 332 U.S. 851 (1948); *United States v. Articles of Drug*, 601 F. Supp. 392 (D. Neb. 1984) (enjoining drug distributor that induced its customers to pass off its drugs as controlled substances), *aff'd* in part, *rev'd* in part on other grounds, 825 F.2d 1238 (8th Cir. 1987); *cf. Inwood Lab., Inc. v. Ives Lab., Inc.*, 456 U.S. 844, 853-54 (1982) (manufacturer or distributor who "intentionally induces another" to violate trademark law or who "continues to supply its product to one whom it knows or has reason to know" will violate trademark law is itself responsible for violation).) And it is a "settled doctrine[] of criminal law" (*Park*, 421 U.S. at 669) that a person who knows or has reason to know that goods that he sells will be used unlawfully may be criminally liable as aider and abettor under 18 U.S.C. 2; *Bacon v. United States*, 127 F.2d 985, 987 (10th Cir. 1942) (discussing former 18 U.S.C. 550, precursor to 18 U.S.C. 2(a)).

For example, a manufacturer or distributor that continues to supply its product to a retailer whom it knows or has reason to know sells cigarettes or smokeless tobacco to young people (or who breaks open packages and sells single cigarettes) might be liable for subsequent violations by that retailer. Likewise, a manufacturer who paid a retailer a fee for the retailer to use an illegal self-service display in a store might be liable for the retailer's violation.

These examples are, however, only by way of illustration because, as the Supreme Court stated in *Dotterweich*, "[t]o attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress \* \* \* would be mischievous futility" (320 U.S. at 285). It added that, "[i]n such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted" (*Id.*).

(29) One comment challenged FDA's authority to require manufacturers to remove items that fail to comply with the regulations. The comment explained that FDA, rather than manufacturers, is responsible for compliance activities and a manufacturer's representative is not deputized or authorized to act on the agency's behalf. The comment added that sales representatives are not trained to perform investigative or law enforcement functions and, unlike

Government employees, would not enjoy the same legal protections accorded to the agency's inspectors. The comment also argued that FDA lacks authority to require manufacturers, or any other party, to remove any materials that would violate the regulations. The comment asserted that the agency has no general recall authority and that the recall authority in the act for devices requires the agency to find that a reasonable probability of serious adverse health consequences or death exists and, when exercising that recall authority, to provide an opportunity for a hearing. Thus, according to the comment, the 1995 proposed rule is deficient because it makes no findings and fails to provide for a hearing.

The agency believes that the comment misinterprets the provision. Section 897.12 would not "deputize" manufacturers' representatives nor confer any official responsibility on them. FDA intends to enforce the act and regulations itself and, where appropriate, will consider commissioning State officials, under its authority in section 702(a) of the act, to perform specific functions on FDA's behalf. Section 702(a) of the act does not extend to commissioning private parties, and the agency has no intention of commissioning manufacturers' representatives.

FDA also disagrees with the comment's claim that FDA has no authority to require manufacturers to remove materials that violate FDA regulations. FDA is issuing this provision, as well as part 897 generally, under its authority under section 520(e) of the act, which expressly declares, in part, that the agency may, by regulation, require that a device be restricted to sale, distribution, or use "upon such other conditions as the Secretary may prescribe in such regulation." Section 897.12, as amended, is a logical and necessary complement to the restrictions on the devices' sale, distribution, and use because it requires the manufacturer to assume responsibility for removing items that it owns that do not comply with the restrictions. Furthermore, as the Supreme Court stated in *United States v. Park*, 421 U.S. 658, 672 (1975), "the act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur."

The comment's argument with respect to the agency's recall authority is also misplaced. Section 897.12 applies in situations where a manufacturer knows,

either acting on its own or on the basis of information supplied to it, that one of its items does not comply with the regulations. Knowing that the item does not comply with the requirements in part 897, the manufacturer is then obligated to remove the violative item. Notice of an opportunity for a hearing or other due process considerations associated with recalls under section 518 of the act (21 U.S.C. 360h) are inapplicable because the manufacturer, rather than the government, would be the principal party during this process, using information it has to act on its own items. In any case, section 518 of the act applies to the recall of a device, not its advertising.

FDA fully expects manufacturers to comply with § 897.12. For example, if the manufacturer provided advertising that used colors and photographs, contrary to § 897.32, which requires black and white text only, the manufacturer is deemed to know that the advertising does not comply with § 897.32 and should remove that advertising. In this situation, where the manufacturer's advertising clearly does not comply with the regulations, requiring FDA to provide notice and an opportunity for a hearing (as the comment would apparently require) would simply waste FDA's and the manufacturer's resources.

FDA will take regulatory action against manufacturers who fail to comply with this provision or any other applicable provision. The nature of the regulatory action will depend, in large part, on the violation, but could range from issuance of a warning letter, to an injunction under section 302 of the act (21 U.S.C. 332), the imposition of civil penalties, criminal fines, and/or imprisonment under section 303 of the act (21 U.S.C. 333), and seizures under section 304 of the act (21 U.S.C. 334).

## 2. Visual Inspections by a Manufacturer's Representative at Each Point of Sale

Proposed § 897.12(b) would have required a manufacturer's representatives to visually inspect each point of sale that they visit during the normal course of business to ensure that cigarettes and smokeless tobacco are "labeled, advertised, and distributed in accordance with this part." The preamble to the 1995 proposed rule indicated that manufacturers keep extremely detailed records about each retailer and that some records noted whether the retailer should be visited weekly, biweekly, etc. and noted the types of displays in the retailer's

establishment (60 FR 41314 at 41323). The preamble to the 1995 proposed rule also stated that this provision would not impose a new responsibility or burden on companies that did not visit retailers as part of their ordinary business practice and, for those manufacturers that would be expected to comply, estimated that these visual inspections would take no more than 2 to 3 minutes per visit (60 FR 41314 at 41323 and 41365). Based on the comments received in response to this proposal, the agency has deleted § 897.12(b) from the final rule.

(30) Several comments opposed proposed § 897.12(b). One comment argued that proposed § 897.12(b) is unconstitutional because it would hold manufacturers vicariously liable for the acts of others in violation of the Due Process Clause, and would violate Article I, Section 8 of the Constitution, which implicitly reserves to States the authority to raise militias. One comment asserted that the number of manufacturers' representatives varies among manufacturers and that there are too many retail establishments for those representatives to inspect. The comment added that any inspection would require more than 3 minutes to be effective, so that conducting inspections at each retailer would be labor intensive and costly. Another comment, notwithstanding the statement in the preamble to the 1995 proposed rule that the provision applied only to those firms that visit retailers in the ordinary course of business, asserted that its entire staff would be too small to visit all the retailers that it services. A small number of comments added that such responsibilities would, in effect, constitute a hidden "tax" on manufacturers.

Other comments, many submitted by sales representatives, objected to proposed § 897.12(b), stating that the representatives have no power over a retailer's actions and cannot take any adverse action, such as discontinuing supplies, to retailers who sell cigarettes and smokeless tobacco to young people. Some comments explained that, even if a sales representative could ask a distributor to stop supplying certain retailers, the retailer could simply switch distributors and continue to obtain products. Other comments argued that the responsibility to prevent sales to young people rests solely with the retailer.

In contrast, several comments supported proposed § 897.12(b) because sales representatives frequently visit retailers or because manufacturers

deliver materials, such as self-service displays and promotional materials, to retailers. One comment even suggested amending the rule to require manufacturers to enter into contracts with retailers and distributors to comply with FDA regulations and to state that failure to comply would result in termination of the retailer's or distributor's ability to obtain the manufacturer's cigarettes or smokeless tobacco.

After consideration of the comments, the agency has removed § 897.12(b). FDA intends to examine this matter further and to develop a guidance describing how manufacturers may be able to assist retailers to comply with this subpart. Possible options might include methods suggested by the comments, such as contractual agreements between retailers and manufacturers including provisions on compliance and the consequences of noncompliance.

## D. Additional Responsibilities of Retailers (§ 897.14)

Proposed § 897.14 would have established additional responsibilities for retailers, stating that "[i]n addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes and smokeless tobacco to any person (other than a distributor or retailer)" comply with specific, listed requirements.

FDA, on its own initiative, has amended § 897.14 to delete the parenthetical text referring to a distributor or retailer because the evidence does not establish that retailers sell these products to such parties, and if a retailer did sell these products to a distributor or retailer, the retailer would be acting as a "distributor" as defined in § 897.3(c).

FDA, also on its own initiative, has amended § 897.14 to add a new paragraph (a) stating that, as one of the listed requirements, "[n]o retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age" and has renumbered proposed § 897.14(a) through (c) accordingly. The new paragraph codifies a concept that was present throughout the 1995 proposed rule, namely that retailers are not to sell cigarettes or smokeless tobacco to young people under 18 years of age.

### 1. Use of Photographic Identification to Verify Age

Under proposed § 897.14(a) (now renumbered as § 897.14(b)), each retailer, or an employee of the retailer,

would have been required to verify, by means of photographic identification containing the bearer's date of birth, that no person purchasing or intending to purchase cigarettes or smokeless tobacco is younger than 18 years of age.

The preamble to the 1995 proposed rule explained that studies indicate that young people who purchase cigarettes and smokeless tobacco from stores are often not asked to verify their age. For example, one study found that 67 percent of young people, whose mean age was 15 years, were asked no questions when they attempted to purchase cigarettes. In some cases, retail clerks even encouraged purchases by young people, suggesting less expensive brands or offering to make up the difference if he or she lacked sufficient funds (60 FR 41314 at 41323). The preamble to the 1995 proposed rule also noted that requiring proof of age to purchase cigarettes and smokeless tobacco could reduce cigarette and smokeless tobacco use among young people (60 FR 41314 at 41323). Consequently, the 1995 proposed rule would have required retailers to verify that persons who intend to purchase cigarettes or smokeless tobacco are legally entitled to do so.

The preamble to the 1995 proposed rule also indicated that a driver's license or college identification card would be acceptable forms of photographic identification, but the agency invited comment on whether the final rule should contain more specific requirements on the types of identification (60 FR 41314 at 41323).

FDA received many comments supporting a proof of age requirement. These comments came from law enforcement entities, drug abuse prevention groups, health care professionals, medical societies, public health organizations, and even some adult smokers who agreed that a proof of age requirement will reduce young people's access to cigarettes and smokeless tobacco. One comment from a coalition of State attorneys general said there "are many teenagers who look much older than they are, who can obtain tobacco products quite easily. When they are required to show age verification, they will not be mistaken for an older age. Therefore, they will not be permitted to acquire tobacco products." Another comment from a State public health department reported that, based on data analyzed from the State's own experience, illegal tobacco purchases occur less than 5 percent of the time when the retailer checks a photographic identification card to

verify age, as opposed to a 95 percent illegal sales rate when no photographic identification card is checked.

In response to comments and changes to § 897.16 regarding mail order and vending machine sales and self-service displays in facilities that are inaccessible to children and adolescents, the final rule excepts the proof of age requirement under these limited circumstances.

(31) Several comments objected to making retailers responsible for their employees' actions. These comments asserted that an employee's failure to verify a potential purchaser's age or an employee's error should not subject the retailer to any regulatory action. A few comments faulted the 1995 proposed rule for not holding sales clerks responsible or argued that the rule would be ineffective because it would not alter a sales clerk's behavior.

In contrast, many comments supported the requirements that hold retailers responsible for preventing illegal sales. Indeed, one comment suggested that there should be "significant penal[t]ies for sales to persons under 18, including the loss of the opportunity to sell tobacco \* \* \*." Another comment stated that the rule should contain penalties for illegal tobacco sales.

The agency declines to amend the rule to relieve retailers from responsibility. Retailers, in general, are responsible for the acts of their employees. (See *United States v. Park*, 421 U.S. 658, 672 (1975).) Relieving retailers from responsibility for their employees' actions would only invite abuse because retailers could continue to sell products to young people and, if caught making such sales, could blame their employees without suffering any adverse consequences themselves. To reflect its position that retailers are generally responsible for their employees' actions, FDA has amended § 897.14 to remove all references to "an employee of the retailer." Thus, § 897.14 now refers to a "retailer" and makes no distinction for the retailer's employees.

As for the comment claiming the rule contains no penalties for illegal tobacco sales, the agency believes that the comment misunderstands how the rule will operate. In general, FDA regulations implement and interpret the agency's statutory obligations under the act, including various criminal and civil penalties. Thus, a regulation need not specify what penalties are attached to a violation because the act provides this information.

FDA has, however, amended proposed § 897.14(a) (now renumbered as § 897.14(b)) to state that, "[e]xcept as otherwise provided in § 897.16(c)(2)(i) and in paragraph (a)(2) of this section," a retailer shall ensure compliance with the prohibition against sales to persons under 18 by verifying the purchaser's age. FDA made this amendment to correspond with the prohibition, in § 897.14(a), against sales to persons under 18 and because, as discussed in greater detail below, the final rule permits sales from vending machines and self-service merchandisers that are inaccessible to young people and permits mail-order sales. These modes of sale are either secure from access by young people (by requiring age verification upon entrance to the facility) or not used by them. The exception for paragraph (a)(2) complements another change to § 897.14 (discussed in greater detail below) to not require proof of age from persons over the age of 26.

FDA has also amended § 897.14(b) to delete the words "intending to purchase." The requirement that retailers verify the age of persons "purchasing the product" sufficiently accomplishes the provision's goal of reducing illegal sales.

(32) Several comments supported the use of identification cards to verify the purchaser's age. Some comments, responding to a question in the preamble to the 1995 proposed rule asking whether the rule should specify the types of identification that would comply with a proof-of-age requirement, advocated using identification cards, passports, or other official documents establishing the bearer's age issued by States, the Federal Government, or foreign governments. One comment recommended that States develop a uniform coding system for identification cards to permit retailers to read or to scan identification cards quickly to verify a purchaser's age. Other comments advised against the use of college or school identification cards; the comments noted that colleges and schools have little incentive to design their identification cards to be sufficiently tamper-proof.

In contrast, one comment stated that the agency should not ask for comment on the type of identification card to require, arguing that the "degree of micromanagement implied by the Agency's invitation for such comment underscores the inappropriateness of federal action in this area."

FDA recognizes the comments' concern. However, the final rule does



not require a uniform coding system or a Federal, State, or local government identification card.

(33) FDA received several comments that addressed when a retailer should inspect a purchaser's photographic identification card. One comment interpreted the provision as requiring retailers to inspect visually the photographic identification card of every purchaser, and said that this would be unreasonable. The same comment contended that retailers and their employees should be required to demand proof of age only from prospective purchasers who do not appear to be over 18; this was the standard employed in Everett, WA, which was cited in the preamble to the 1995 proposed rule.

In contrast, other comments supported age verification for all tobacco sales. Some comments from retailers indicated that some retailers check identification cards for all tobacco sales, while many comments submitted by retailers stated that they check identification cards to verify the age of purchasers who appear to be "underage." Other comments suggested that the regulation require visual inspection of photographic identification cards for purchasers who appear to be younger than 21, 25, 26, or 30 years of age. Such a requirement appeared to be independently selected to ensure that the purchaser met the age requirement in the particular jurisdiction.

Contrary to the comment that interpreted the rule as requiring proof of age in all transactions, the 1995 proposed rule would have given retailers some flexibility in deciding when to demand proof of age. The preamble to the 1995 proposed rule cited studies and reports demonstrating that few retailers request proof of age from young people attempting to purchase cigarettes or smokeless tobacco (60 FR 41314 at 41323). Consequently, proposed § 897.14(a) (now renumbered as § 897.14(b)) would have required retailers to verify that prospective purchasers are of legal age, and the preamble to the 1995 proposed rule suggested that retailers request proof of age from anyone who does not appear to be at least 26 years old (60 FR 41314 at 41323). This suggestion was similar to a recommendation made in a report by 26 State attorneys general. The agency anticipated, for example, that requiring proof of age from a senior citizen would be unnecessary, but strongly recommended requiring proof

of age from an individual who appears youthful.

However, due to concerns that, despite the language in the preamble to the 1995 proposed rule, the rule would require age verification in all cases, the agency has amended the rule to except from the age verification requirement individuals who are over 26 years old. The agency declines to amend the rule to require age verification if the purchaser appears to be 21, 25, 26, or 30 years old. Determining a person's age by his or her physical appearance alone is a subjective determination, and so requiring age verification if a person "looked" like he or she was a particular age would be difficult to administer and to enforce. By requiring age verification if a purchaser is 26 years old or younger, regardless of his or her appearance, the retailer foregoes age verification at its own risk.

The agency notes that using the higher age of 26 as the threshold for requiring proof of age should increase the likelihood that illegal sales to young people will not occur. Using a lower age, such as 18 (which is used in some States) or 21, as the threshold for requiring proof of age may enable some young people to purchase cigarettes and smokeless tobacco, and, as a result, cause a retailer to be in violation of this subpart.

(34) Many comments, particularly comments from retailers, supported the requirement for age verification but added that the requirement should be voluntary. Others said that State law or regulations requiring age verification are adequate, and that, as a result, FDA regulation is unnecessary. Other comments claimed FDA regulation would add "red tape and paperwork" that would not reduce young people's access to cigarettes and smokeless tobacco and would instead "come at great cost to taxpayers."

On the other hand, State attorneys general and other State and local enforcement authorities commented that the Federal regulations requiring age verification by inspection of photographic identification card will complement and enhance their enforcement abilities.

FDA declines to delete an age verification requirement from the rule. The preamble to the 1995 proposed rule cited studies and reports to show that young people are often able to purchase cigarettes and smokeless tobacco without showing proof of age (60 FR 41314 at 41323). In one case, the young people were able to purchase cigarettes even when they admitted that they were

under the legal age (60 FR 41314 at 41323). These studies and reports suggest that the final rule must require retailers to demand proof of age because voluntary efforts are ineffective.

As for deferring to State laws and regulations, FDA believes that State efforts to require proof of age, and retailer compliance with such efforts, should increase and become more effective due to section 1926 of the PHS Act. This provision requires States to enact and to enforce laws prohibiting manufacturers, retailers, or distributors of tobacco products from selling or distributing such products to persons under age 18 in order to receive substance abuse prevention and treatment block grants. However, State laws may differ, and so the final rule requires retailers to verify the age of purchasers. This will establish a uniform, national requirement regarding proof of age and is consistent with the assertion of Federal authority over these products under the act.

(35) Many comments pointed out that there is no penalty for parents who allow underage children to smoke.

FDA believes that the vast majority of adults and parents do not purchase tobacco products for young people. Parental actions are also beyond the scope of FDA's authority. However, it should be noted that parental consent to a young person's purchase of cigarettes and smokeless tobacco cannot override the requirements in § 897.14(a) prohibiting sales to anyone under 18 and in § 897.14(b) that each purchase is subject to age verification. Thus, under this rule, a retailer must refuse to sell cigarettes or smokeless tobacco to any young person who claims that he or she has "permission" to purchase such products for himself or herself or for an adult.

(36) One comment contended that the photographic identification card requirement is invalid because it exceeds FDA's authority under section 520(e) of the act because it does not purport to provide reasonable assurance of the safety and effectiveness of cigarettes.

FDA disagrees with the comment. Section 520(e) of the act authorizes the agency to establish, by regulation, conditions restricting the sale, distribution, or use of a device if, because of the device's potentiality for harmful effect or the collateral measures necessary to its use, the agency determines that there cannot be a reasonable assurance of the device's safety or effectiveness. A photographic identification card requirement is a

condition of sale for these products and a collateral measure that is necessary to the requirement that the products are not sold to anyone under the age of 18.

(37) One comment contended that proposed § 897.14(a) (now renumbered as § 897.14(b)) is precluded by section 1926 of the PHS Act. The comment stated that this law established Congress' intent to allow States to enact necessary programs to keep tobacco products out of the hands of young people as a condition for receiving block grant funding. According to the comment, there is no single best approach, and the FDA proposal prevents States from emulating the successful approach used in Woodridge, IL. The comment stated that FDA may not preempt State laws without making a showing of clear and manifest congressional intent to authorize its preemption of those State laws.

The agency disagrees with the comment. The preemption issues related to this rule (as well as the rule's relationship to the regulations issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) implementing section 1926 of the PHS Act regarding the sale and distribution of tobacco products to individuals under the age of 18 (the SAMHSA rule) are discussed in great detail in section X. of this document.

## 2. Minimum Age

Proposed § 897.14(a) (now renumbered as § 897.14(b)), would have required retailers to verify that persons buying cigarettes or smokeless tobacco were not younger than 18 years of age. FDA received many comments supporting a Federal minimum age to purchase cigarettes and smokeless tobacco. Some comments suggested that enforcement of this provision would be as effective as advertising limitations in controlling underage smoking. In supporting the proposal, comments noted that while most teenage smokers do not plan to be smokers 5 years after they begin smoking, less than 10 percent of teenagers are able to quit within 5 years of starting. Moreover, like their adult counterparts, 70 percent of high school seniors who smoke would like to stop smoking completely. Some comments noted that the average age at which teenage smokers first tried their first cigarette is 13 or 14 years, and by age 18, many teens are smoking daily and smoking at a rate very near the adult rate. Health-care professionals (nurses, physicians, dentists, public health officials, etc.) as a group were very

supportive of a Federal minimum age limit of at least 18.

(38) A major American medical association suggested amending § 897.14(a) (now renumbered as § 897.14(b)) to raise the minimum age of sale to 21. It noted that one State, Pennsylvania, has set 21 as the minimum age for the purchase of cigarettes, and argued that prior to enactment of the national standard of age 21 for alcohol purchase, many States had laws that allowed purchase at age 18, but subsequently changed to 21 without hardship.

Other comments advocated raising the minimum age to 19 years. Several comments explained that many high school students are 18 years old; thus, if FDA increased the minimum age to 19 years, it would be less likely that an underage high school student would be able to purchase or obtain cigarettes or smokeless tobacco, because raising the age to 19 would eliminate from the high school environment peers who are legally able to obtain nicotine-containing tobacco products. In addition, the agency received a considerable number of comments from students, teachers, and even adult smokers, urging the agency to raise the legal age to purchase cigarettes to 21, to be consistent with the legal age to purchase alcohol. Indeed, many comments assumed that the legal age was already 21 and urged the agency to retain this age limit.

In contrast, other comments supporting 18 as the minimum age for purchasing cigarettes and smokeless tobacco argued that, because most States already established 18 as the minimum age, FDA regulations did not need to establish a minimum age. A few comments, mostly from young people, asked FDA to lower the legal age for purchasing cigarettes to below 18 years of age.

In order to make its decision on the appropriate minimum age, the agency weighed a variety of factors including evidence on the onset of nicotine addiction and the history underlying the age of majority. FDA's goal is to prevent underage use of tobacco in order to preclude as many new cases of nicotine addiction as possible. The agency considered minimum ages from 18 to 21, because individuals are generally viewed as reaching adulthood in this age range. The agency faced the question: At which age in this range are most individuals able to make an informed decision to begin using a product that the overwhelming majority of individuals will not be able to stop

using, even though using the product is likely to lead to severe disability and premature death?

The agency began by reviewing key data sources on the onset and course of nicotine addiction. The National Household Surveys on Drug Abuse sought to determine the age when individuals first tried a cigarette and the age when individuals first started smoking daily—an important measure of the progression toward addiction. The survey asked questions of 30 to 39 year olds who had ever smoked daily. The average age of first trying a cigarette was 14.5 years.<sup>41</sup> Eighty-two percent had tried a cigarette before 18, 89 percent before 19, 91 percent before 20, and 98 percent before 25.<sup>42</sup> Daily smoking began slightly later. Fifty-three percent began smoking daily before 18, 71 percent before 19, 77 percent before 20, and 95 percent before 25.<sup>43</sup>

The agency reviewed the history underlying the theory of majority and the concept of adults making informed choices. Majority is defined in Black's Law Dictionary as "the age at which, by law, a person is capable of being legally responsible for all his or her acts \* \* \*, and is entitled to the management of his or her own affairs and to the enjoyment of civic rights. \* \* \*" <sup>44</sup> The 26th Amendment to the United States Constitution provides those 18 years and above with the right to vote. Prior to the adoption of the 26th Amendment in 1971, the age of majority in almost every State was 21. Each State has the power to set its own age of majority and since enactment of the 26th Amendment most States have lowered the age of majority from 21 to 18.

The agency reviewed the reasons why Congress chose 18 as the appropriate age to vote. According to a Senate report on lowering the voter age, the 21 year age was believed to be derived by historical accident. Eighteen-year olds bore many adult citizens' responsibilities such as the ability to marry and raise a family, and serve in the military. A lower voting age was seen as benefiting society by bringing into the American political system the idealism, concern, and energy of young people. (See "Lowering the Voting Age to 18," S. Rept. 92-96, 92d Cong., 1st sess., p. 5, March 8, 1971.)

While the justifications do not necessarily support establishing a minimum age of 18 for tobacco

<sup>41</sup> 1994 SGR, p. 67.

<sup>42</sup> *Id.*, p. 65.

<sup>43</sup> *Id.*

<sup>44</sup> *Black's Law Dictionary*, edited by M. A. Black, West Publishing Co., St. Paul, MN, p. 955, 1990.

products, the agency declines to raise the minimum age for several reasons. First, as stated in the preamble to the 1995 proposed rule, all States prohibit the sale of tobacco products to persons under the age of 18; currently only four States prohibit cigarette sales to persons over 18 (60 FR 41314 at 41315). Consequently, setting a national minimum age of 18 is consistent with most States. Second, selecting 18 as the minimum age is consistent with the age Congress established under section 1926 of the PHS Act, which conditions a State's receipt of substance abuse grants on State laws to prohibit any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual under the age of 18.

FDA also declines to amend the rule to eliminate a Federal minimum age and instead rely on existing State laws. Establishing 18 as the national minimum age will strengthen State and local enforcement, as discussed earlier.

FDA also declines to amend the rule to reduce the minimum age. Reducing the minimum age would undermine existing State laws and the rule's effectiveness because it would, in essence, circumvent statutory and regulatory protections by letting more young people purchase these products. Reducing the minimum age would also be contrary to the evidence cited in the preamble to the 1995 proposed rule, which shows that half of adults start smoking daily before age 18.

FDA does plan to monitor closely the incidence of new cases of nicotine addiction. If the evidence indicates that the number of new cases of nicotine addiction does not significantly decline, consistent with the agency's stated goal of a 50 percent reduction, but rather are merely delayed a year or two, FDA will consider whether increasing the minimum age for purchase of nicotine-containing tobacco products would further the goal of the rule.

### 3. Restrictions Against "Impersonal" Modes of Sale

Proposed § 897.14(b) (now renumbered as § 897.14(c)) would have required the retailer or an employee of the retailer to provide cigarettes or smokeless tobacco to a purchaser "without the assistance of any electronic or mechanical device (such as a vending machine or remote-operated machine)." The preamble to the 1995 proposed rule stated that this provision would have the practical effect of making access to cigarettes and smokeless tobacco more difficult for

young people (60 FR 41314 at 41324). In response to comments, the agency has amended § 897.14(c) to allow for the use of certain impersonal modes of sale, such as vending machines and self service displays (merchandisers only), in facilities which are inaccessible to individuals under the age of 18 at any time. Additionally, as stated in section IV.D.1. of this document, FDA has deleted the reference to "an employee of the retailer" because retailers are generally responsible for their employees' actions and has revised the text to correspond more closely with § 897.16(c).

(39) Several comments objected to proposed § 897.14(b). One comment asserted that proposed § 897.14(b) (now renumbered as § 897.14(c)) was unjustified, and arbitrary and capricious because it would apply to locations where young people are not permitted to enter and, in places where they can enter, would be unnecessary if retailers required proof of age from prospective cigarette and smokeless tobacco purchasers. The comment stated that less restrictive alternatives, such as increased supervision over self-service displays, exist. The comment further argued that FDA lacked support for this provision, stating that, regardless of how tobacco products are sold over-the-counter, the key party in the transaction is the cashier. According to the comment, requiring retail clerks to comply with applicable minimum age laws should be sufficient to prevent illegal sales to young people, thereby making the proposed provision unnecessary. The comment, therefore, stated that the evidence did not support a rule that would preclude State and local governments from relying on "less drastic controls."

In contrast, many comments agreed that this provision would reduce a young person's access to cigarettes and smokeless tobacco because it would require potential purchasers to interact with retailers or would discourage young people from purchasing these products because they would have to interact with a retailer and provide proof of age. One comment stated that the regulations establish a code of conduct for merchants, ensuring that they take practical steps to prevent illegal sales of tobacco products to young people. One comment stated that face-to-face transactions are the only way to assure that identification of under-age customers is checked.

FDA disagrees, in part, with the comments that oppose this provision. FDA declines to amend the rule to rely

on alternative measures such as increased supervision of displays or proof of age alone. The preamble to the 1995 proposed rule cited reports and studies showing that young people can easily use impersonal modes of sale despite restrictions on their placement or the installation of devices to prevent illegal sales. For example, for self-service displays, the Institute of Medicine (IOM) Report *Growing Up Tobacco Free, Preventing Nicotine Addiction in Children and Youths* (1994) referred to surveys in two communities that found over 40 percent of daily smokers in grade school shoplifted cigarettes (60 FR 41314 at 41325). For vending machines, the preamble to the 1995 proposed rule cited several studies and reports showing that young people were able to purchase cigarettes—despite laws restricting the placement of those machines, or requiring the machines to have a locking device to prevent sales to young people (60 FR 41314 at 41324 through 41325).

FDA also found that relying solely on retailers to verify the purchaser's age had limited effect on reducing young people's access to cigarettes and smokeless tobacco; retail clerks rarely asked young people to verify their age or even assisted in completing a purchase. Some retail sectors also suffered from high employee turnover rates that undermined the effectiveness of retailer programs to prevent illegal sales (60 FR 41314 at 41323). Consequently, the agency believes that the most effective approach towards reducing young people's access to cigarettes and smokeless tobacco is a sufficiently comprehensive set of access restrictions to prohibit most impersonal modes of sale, require retailers to verify the consumer's age, and make young people's access to these products more difficult.

The agency also reminds parties that these products are restricted devices because of their potentiality for harmful effect. The final rule contains restrictions that the agency believes are necessary in order to reduce the number of children and adolescents who use and become addicted to these products. Relying solely on retail clerks to verify age, increasing supervision over displays, or deferring to other less restrictive alternatives would not, in comparison to the rule's comprehensive approach, be sufficient to achieve that goal.

With respect to locations that are entirely inaccessible to young people, however, the agency has amended

§ 897.16 to permit certain modes of sale, such as vending machines and self-service displays (merchandisers only), in facilities where young people are not present, or permitted to enter, at any time. These modes of sale do not involve hand-to-hand transactions between the retailer and the purchaser. Consequently, FDA has made a corresponding amendment to § 897.14(c) to require retailers to personally provide cigarettes or smokeless tobacco to purchasers "[e]xcept as otherwise provided in § 897.16(c)(2)(ii) and revised the text to correspond more closely with the language in § 897.16(c)(1)." The amendments to § 897.16 are discussed in greater detail below.

(40) A few comments questioned the need for proposed § 897.14(b) (now renumbered as § 897.14(c)). These comments said that the rule would not prompt retailers to verify a prospective purchaser's age because retailers who sell cigarettes and smokeless tobacco to minors are already in violation of State laws.

FDA disagrees with the comments' assertion. FDA's enforcement authority and the range of sanctions under the act should give retailers additional incentives to verify proof of age. Hence, FDA believes that the weight of Federal law and these regulations will prompt retailers to pay more attention to the consumer's age. By way of analogy, the United States enjoys a very high rate of compliance with prescription drug restrictions in part because a violation of the prescription requirement is actionable under Federal law. Similarly, section 1926 of the PHS Act gives States, as a condition for receiving a block grant for the prevention and treatment of substance abuse, further incentive to ensure that illegal tobacco sales to young people do not occur and that the illegal sales rate steadily decreases from 50 percent in fiscal year 1994 (or fiscal year 1995 for some States) to 20 percent 4 years later. States must also conduct annually a reasonable number of random, unannounced inspections to ensure compliance with State law (see 61 FR 1492 at 1508, January 19, 1996). Section 1926 of the PHS Act and its implementing regulations should also prompt States to devote more attention to compliance efforts to prevent illegal sales to young people and, through the requirement for random, unannounced inspections, make retailers more aware of the need to verify the consumer's age.

#### 4. Restrictions Against the Sale of Individual Cigarettes

Proposed § 897.14(c) (now renumbered as § 897.14(d)) would have prohibited the retailer or an employee of the retailer from breaking or otherwise opening any cigarette package or smokeless tobacco product to sell or distribute individual cigarettes or any quantity of cigarette tobacco or of a smokeless tobacco that is smaller than the quantity in the unopened product. In response to comments and for other reasons discussed below, the agency has amended § 897.14(d) to prohibit retailers from breaking or otherwise opening "any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use." Additionally, as stated in section IV.D.1. of this document, FDA has deleted the reference to "an employee of the retailer" because the retailer is generally responsible for its employee's actions.

(41) Several comments opposed proposed § 897.14(c) (now renumbered as § 897.14(d)) in conjunction with proposed § 897.10 (which would establish general responsibilities for manufacturers, distributors, and retailers). The comments said it would be unreasonable to expect retailers to inspect all packages to assure compliance with minimum package requirement, as well as other requirements, and yet retailers would face significant penalties if they failed to comply. Other comments asked whether retailers would be held liable for opening shipping packages consisting of individual cigarette packages or cartons and selling the individual packages or cartons.

The comments misinterpreted the proposed provision. Section 897.14(d) does not require retailers to police minimum package requirements, but rather expressly states that the retailer shall not break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or number of cigarettes or any quantity of cigarettes or smokeless tobacco that is smaller than the quantity in the unopened package. The confusion may have stemmed from the definition of "package." Section 897.3(f) defines "package" as a "pack, box, carton, or other container \* \* \* in which

cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers." The provision, therefore, focuses on two distinct actions: (1) The retailer breaks or opens a cigarette package or smokeless tobacco product; and (2) the retailer sells or distributes a portion of the cigarette package or smokeless tobacco product to a consumer.

A literal reading of proposed §§ 897.3(f) and 897.14(d) together would prohibit a retailer from opening a carton of cigarettes to sell a single package of 20 cigarettes. The agency did not intend to prohibit retailers from opening shipped quantities or bundles of cigarette packages or cartons or smokeless tobacco in order to break that shipment down into ordinary packages, cartons, or other standard product units. The agency has amended § 897.14(d), to eliminate this unintended effect. The new language clarifies that retailers may open shipping boxes or cigarette cartons to sell a pack of cigarettes or a smokeless tobacco package. Additionally, FDA has modified the introduction to § 897.14(d), changing "the retailer shall not" break or open any cigarette or smokeless tobacco package to "no retailer may" break or open any package. This change is intended to simplify the text and does not alter a retailer's obligations under § 897.14(d).

(42) One comment from a company opposed a restriction on the sale of single cigarettes because it had made a substantial investment developing a vending machine that would sell single cigarettes that complied with applicable labeling and tax laws. The comment added that its machines are located in areas that are frequented by or limited to adults and that there is a market for adults who wish to smoke only occasionally.

The restriction against the sale of single cigarettes pertained to single cigarettes that are removed from cigarette packages or cartons and sold on an individual basis. Thus, the product described by the comment, a prepackaged single cigarette that complies with all applicable labeling and tax laws, does not appear to correspond to what is commonly known as a "loosie." As for selling a packaged single cigarette in a vending machine, the final rule permits vending machines to be used in certain locations that are entirely inaccessible to young people. This comment, and corresponding amendments to the rule, are discussed in greater detail in section IV.E.4.a. of this document.

(43) A small number of comments opposed any restriction on the sale of single cigarettes, stating that such a restriction would make purchases by adults more difficult or could actually work to the detriment of adults who are trying to reduce their cigarette consumption by purchasing single cigarettes.

Most comments, however, supported a prohibition against the sale of single cigarettes. In general, they agreed that eliminating single cigarettes would make cigarette purchases more expensive for young people and, as a result, less likely. A number of State attorneys general stated that this provision, in conjunction with others, would assist States in enforcing compliance with State laws. A few comments noted reports of single cigarette sales occurring within their State or jurisdiction; one stated that "the problem of loosies is a very old story within the inner city," while another even claimed seeing young people wait in line for free samples of single cigarettes.

The agency declines to amend the rule to exclude single cigarettes. The preamble to the 1995 proposed rule cited evidence that a significant number of retailers are willing to sell single cigarettes to young people and are sometimes more inclined to sell single cigarettes to young people than to adults (60 FR 41314 at 41324). The comments supporting the rule reinforce the notion that single cigarettes appeal to young people.

While FDA is sensitive to the fact that adults who wish to quit smoking may wish to purchase single cigarettes to reduce smoking, on balance, the agency believes that the benefits of eliminating single cigarette sales to young people outweighs any possible detriment to adults.

##### 5. Additional Comments

(44) Several comments suggested that FDA license retailers and impose fines or other sanctions on retailers who sell cigarettes and smokeless tobacco to young people.

The agency declines to amend the rule to create a licensing system. FDA notes that SAMHSA confronted similar comments when it proposed rules to implement section 1926 of the PHS Act and elected not to require a licensing system (61 FR 1492 at 1495). The preamble to the SAMHSA rule indicated that States could use a licensing system to identify retail outlets and enforce State laws, with licensure fees and civil penalties funding the States' random,

unannounced inspections and covering administrative and enforcement costs (61 FR 1492 at 1495). FDA concurs with the SAMHSA analysis and, because licensure would be a State matter, will refrain from establishing a licensing system for retailers.

As for fines and other sanctions, no amendment to the rule is necessary. The act already establishes fines and other sanctions for parties who violate the act. For example, any restricted device that is sold, distributed, or used in violation of regulations for that restricted device is misbranded under section 502(q) of the act (21 U.S.C. 352(q)), and section 301(a) of the act prohibits the introduction or delivery for introduction into interstate commerce of a misbranded device. (Section 709 of the act creates a presumption that all devices are in interstate commerce and section 304 allows seizure of adulterated or misbranded devices even in the absence of interstate commerce.) Among other things, section 301(b) of the act prohibits the misbranding of a device in interstate commerce, while section 301(c) of the act prohibits the receipt in interstate commerce of any misbranded device. Additionally, any person who violates section 301 of the act is subject to injunctions under section 302 of the act and civil penalties, fines and imprisonment under section 303 of the act, while section 304 of the act authorizes seizure actions against misbranded devices themselves without any need for proof of interstate commerce.

(45) One comment argued that retailers should be required to keep cigarette products from public view.

FDA declines to amend the rule as suggested by the comment. The agency believes that concealing these products from view would not significantly enhance the restrictions against access by young people and would instead unduly impair an adult's ability to determine what products and brands a retailer is selling as well as the retailer's ability to sell those products.

(46) One comment stated that § 897.14 can only be enforced by routine compliance checks using underage agents. The comment suggested that FDA negotiate with States to receive information on violations of State laws and to use that information against retailers who fail to comply with § 897.14.

FDA intends to cooperate with State governments to curtail illegal sales of cigarettes and smokeless tobacco to young people. Additionally, as stated earlier in this document, FDA is

authorized to commission State officials to perform certain functions on behalf of the agency. FDA may consider commissioning State officials, where appropriate, if commissioned State officials would help ensure compliance with these regulations.

(47) One comment would amend § 897.14 to refer to "purchasing" and "obtaining" cigarettes or smokeless tobacco. The comment said this would prevent young people from attempting to obtain cigarettes or smokeless tobacco from retailers by claiming to act with a parent's permission or on behalf of a parent or adult.

The agency declines to amend the rule as suggested by the comment. As written, § 897.14 prohibits retailers from selling cigarettes or smokeless tobacco to anyone under 18 and also requires retailers to verify the purchaser's age. These provisions do not make any distinction or exception as to whether the person purchasing the products claims to be purchasing the products for an adult. In other words, even if a young person claimed to have a parent's permission or to be purchasing these products for an adult, § 897.14(a) still prohibits retailers from selling cigarettes or smokeless tobacco to that young person, and § 897.14(b) requires the retailer to verify the purchaser's age.

(48) As mentioned earlier in the discussion for § 897.10, FDA has amended the final rule to create a new § 897.14(e) to require each retailer to remove or bring into compliance all self-service displays, advertising, labeling, and other items at the retailer's establishment if those items do not comply with the requirements under this part. This amendment became necessary because comments from manufacturers and retailers claimed that retailers owned the self-service displays or that, once the manufacturer's representative gives an item to a retailer, the item becomes the retailer's property. Consequently, § 897.14(e) requires retailers to remove or otherwise bring into compliance items at the retailer's establishment if those items do not comply with this subpart. This provision essentially gives retailers three options with respect to an item that violates the requirements in this rule: (1) If the item belongs to a manufacturer, the retailer could ask the manufacturer to remove the item, consistent with the manufacturer's obligations under § 897.12; (2) the retailer could convert the item to another use or alter the item to make it comply with the regulations; or (3) the retailer could remove the item.

*E. Conditions of Manufacture, Sale, and Distribution (§ 897.16)*

1. Restrictions on Nontobacco Trade Names on Tobacco Products

Proposed § 897.16 would have established several important restrictions or conditions on the sale of cigarettes and smokeless tobacco. Proposed § 897.16(a) would have prohibited the use of a trade or brand name for a nontobacco product as the trade or brand name for a tobacco product "except for tobacco products on which a trade or brand name of nontobacco product was in use on January 1, 1995." For example, Harley Davidson cigarettes would be "grandfathered" under this provision. The preamble to the 1995 proposed rule stated that the provision would be necessary to prevent the industry from circumventing the purpose behind the rule (60 FR 41314 at 41324) by benefitting from the promotion of the nontobacco items in ways that appeal to young people. FDA noted, however, that several cigarette brands already used trade names that are normally associated with nontobacco products and would exempt those brands from § 897.16. The final regulation remains essentially the same, but clarifies the agency's intent by amending the language to limit the exception to those product names "whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995."

(49) FDA received few comments on this provision. The comments asserted that the 1995 proposed rule would effect takings compensable under the Fifth Amendment.

The agency disagrees with these comments. The final rule does not violate the Fifth Amendment. This issue is discussed in greater detail in section XI. of this document.

(50) Several comments on the use of nontobacco trade names on tobacco products would delete proposed § 897.16(a), arguing that the provision will have no effect on cigarette or smokeless tobacco use by young people, and that businesses should be free to decide how to advertise or sell their products. One comment challenged the agency's authority to regulate nontobacco trade names, stating that the act only permits the agency to take action against names that are false and misleading. According to this comment, a nontobacco trade name that appeals to young people does not become subject to the act. The comment further charged

that FDA has no evidence to support a conclusion that a tobacco product bearing a nontobacco trade name would be especially appealing to young people; the comment explained that the brands mentioned by FDA in the preamble to the 1995 proposed rule—Harley-Davidson, Cartier, and Yves St. Laurent's Ritz cigarettes—either have very small market shares or are not sold in the United States.

In contrast, one comment said § 897.16(a) is "essential to avoid the same problems that occur with 'image' advertising." The comment explained that tobacco manufacturers have used nontobacco trade names on tobacco products to give the tobacco products an "instant image."

The point of this provision, like the restrictions on advertising, is to ensure that the restrictions on sale and distribution to children and adolescents are not undermined by how the product is presented to the public. As detailed in subpart D of part 897, FDA is restricting the way cigarette and smokeless tobacco are advertised in order to eliminate those elements that resonate most strongly with the needs of those under 18 to establish an appropriate image and to create a sense of acceptance and belonging. The use of nontobacco trade names has particular appeal in the former regard. If a firm could use a popular nontobacco product trade name and put it on a tobacco product, the firm could attempt to exploit the imagery or consumer identification attached to the nontobacco product to make the tobacco appeal to young people.

For example, young people might purchase a particular nontobacco product that they perceive as symbolizing the adult sophistication or sex appeal of its users; they might also be inclined to purchase cigarettes bearing the same trade name if they perceive that the cigarettes will enhance their lifestyles in the same manner. Section 897.16(a), therefore, eliminates a potential loophole in the advertising and labeling provisions.

FDA also disagrees with the comment challenging FDA's authority. Section 897.16(a) is authorized under section 502(e) of the act which permits FDA to restrict, by regulation, the sale, distribution, or use of certain devices. Prohibiting firms from adopting nontobacco product names that appeal to young people is a restriction on the product's "sale." The comment's suggestion that FDA cannot rely on section 502(a) of the act reveals a misunderstanding of FDA's position.

FDA predicated its action on section 502(e) of the act and therefore it is not necessary to address the relevance of section 502(a).

FDA is not persuaded that small market shares for cigarette products bearing nontobacco trade names undermines the need for § 897.16(a). The preamble to the 1995 proposed rule demonstrated that young people use the most heavily advertised brands and that they can purchase cigarettes and smokeless tobacco easily (60 FR 41314 at 41323 through 41326, and 41332). The brands cited in the preamble, Harley-Davidson, Cartier, and Yves St. Laurent's Ritz, are not among the most heavily advertised brands, and, according to the comment, two (Cartier and Ritz) are not sold in the United States. Thus, there is no reason to expect these brands to be especially appealing to or purchased by young people in the United States today. However, if the other provisions in this rule are effective, some manufacturers might try altering their advertising or marketing strategy in order to generate product appeal; § 897.16(a) thus eliminates this potentially significant avenue for making a product appeal to young people.

(51) A few comments noted that the provision did not elaborate on what constitutes a "trade or brand name for a nontobacco product." One comment interpreted the terms as including any nontobacco product trade name used anywhere in the world and, as a result, argued that the provision would impose an impossible burden on manufacturers to conduct trademark searches. The comment added that manufacturers would not be able to conduct trade or brand names searches with certainty (because the 1995 proposed rule did not confine itself to registered trademarks) and manufacturers would be subject to regulatory action even if they unknowingly used a trade or brand name for a nontobacco product.

In contrast, another comment noted that a brand name directory published by the Tobacco Merchants Association of the United States lists numerous brand names for both nontobacco and tobacco products. The comment suggested that there are a greater number of cigarette products whose brand names were the same as brand names for nontobacco products than the three brands that FDA identified in the preamble to the 1995 proposed rule. The comment suggested that FDA amend the rule to limit eligible brand name "tie-ins" to those relating to both tobacco products and to nontobacco products

sold in the United States as of January 1, 1995.

FDA agrees, in part, with the comments. It would be unreasonable for the regulation to encompass all possible nontobacco product trade names, regardless of their nationality or whether the trade name was a registered trademark. Neither FDA nor manufacturers would be able to ensure that a name was not used elsewhere. FDA intended that proposed § 897.16(a) would apply to trade names in use in the United States, and that the exception for nontobacco product trade names would apply only to product trade names that were in use on both tobacco and nontobacco products as of January 1, 1995. Consequently, to clarify the rule, FDA has amended § 897.16(a) to restrict manufacturers to use of those product names that were used on both nontobacco and tobacco products in the United States as of January 1, 1995.

(52) One comment would amend § 897.16(a) to state that, in addition to being on the market as of January 1, 1995, the cigarette brand had to have generated sales of at least 500 million cigarettes or 500 million grams of cigarette or smokeless tobacco in 1994. The comment explained that this amendment would eliminate a "loophole" because a product with "nominal sales volume could open up large marketing holes for all sorts of product names."

FDA declines to amend the provision as suggested by the comment. The final rule, as amended, prohibits manufacturers from using a nontobacco product trade or brand name as the trade or brand name for a cigarette or smokeless tobacco product. The sole exception is for tobacco products whose trade or brand name was on both nontobacco and tobacco products sold in the United States as of January 1, 1995. FDA will construe this exception narrowly such that the trade or brand name on the nontobacco product must be the same. For example, if the trade name for a nontobacco product was "Old Time Country Store," a cigarette product called "Old Time" would not qualify for the exception because the name is not identical to that for the nontobacco product.

(53) FDA, on its own initiative, has amended § 897.16(a) to replace the word "may" with "shall." This amendment is intended to reinforce the notion that, except as otherwise provided in § 897.16(a), manufacturers are prohibited from using a trade or brand name of a nontobacco product as the

trade or brand name for a cigarette or smokeless tobacco product.

## 2. Minimum Package Size

Proposed § 897.16(b) would have made 20 cigarettes the minimum package size for cigarettes. The preamble to the 1995 proposed rule explained that FDA selected 20 as the minimum number of cigarettes because most cigarette packs in the United States contain 20 cigarettes and that establishing a minimum package size would preclude firms from manufacturing so-called "kiddie packs." The preamble to the 1995 proposed rule explained that "kiddie packs" usually contain a small number of cigarettes, are easier to conceal, and are less expensive than full-sized packs. The preamble to the 1995 proposed rule also noted that, based on studies or reports in other countries, significant numbers of children purchase "kiddie packs" (60 FR 41314 at 41324). Thus, by establishing a minimum package size, the 1995 proposed rule would have essentially eliminated the manufacture, distribution, and sale of "kiddie packs." The final rule provides a narrow exception to the minimum package size in response to a comment on vending machines that sell certain packaged, single cigarettes.

(54) Several comments opposed creating any minimum package size. A minority disputed that the rule would be effective, stating that young people will get cigarettes anyway or will simply begin purchasing full-sized packs. One comment, submitted on behalf of specialty tobacco companies, suggested exempting specialty tobacco products from the rule. The comment explained that many specialty tobacco products are produced in package sizes smaller than 20 cigarettes, ranging from 8 to 18 cigarettes, but that young people do not purchase specialty tobacco products. Consequently, the comment sought an exemption for specialty tobacco products or for products with a very small market share. One comment asserted that small package sizes reduce smoking by adults while another comment would amend the rule to lower the minimum size to 10 cigarettes; neither comment offered any evidence to support their assertions.

In contrast, many comments supported proposed § 897.16(b). The comments indicated that eliminating "kiddie packs" is "essential to protect youth" and described "kiddie packs" as an "obvious come-on that would appeal to kids." Other comments said the provision would reduce underage

purchases because children would not be able to afford full-sized packs as easily or as quickly as they might afford "kiddie packs."

The final rule retains 20 cigarettes as the minimum package size. The agency disagrees that this provision will be ineffective. The provisions in this subpart are designed to: (1) Make young people's access to cigarettes and smokeless tobacco more difficult by restricting specific modes of access to these products that young people use, and (2) make purchases by young people more difficult (by requiring proof of age, and other methods) and more expensive (by eliminating free samples and "kiddie packs").

Additionally, while some tobacco products, specifically the specialty tobacco products, may have been sold in smaller sizes, the benefits of eliminating "kiddie packs," namely eliminating a product size that is relatively inexpensive and appealing to young people, outweigh any inconvenience to adults.

FDA also declines to create an exemption based on market share or claims that young people do not use a particular type of cigarette; such exemptions would not treat manufacturers equally, would depart from FDA's traditional approach of regulating devices as a class (see section IV.B. of this document), and would be impractical because a firm's compliance with the rule could vary depending on fluctuations in market share and use by young people. Moreover, even a small percentage of a market, such as 1 or 2 percent, could translate into a large number of Americans; for example, 2 percent of the approximately 50 million Americans who smoke would represent 1 million people. Two percent of the approximately 3 million children under age 18 who are regular smokers would represent 60,000 young people.

Furthermore, FDA declines to make 10 cigarettes the minimum package size. The comment did not offer any justification for the lower figure, and the agency believes that a smaller package size would be counterproductive because a 10-cigarette minimum size would be tantamount to making a "kiddie pack" the minimum package size for cigarettes.

(55) One comment supported the provision, but suggested that FDA amend the rule to prevent the development of "mini" cigarettes or "short smokes." The comment said such products contain less tobacco so that they can be sold at a lower price.



The agency declines to amend the rule as suggested by the comment. Section 897.3(a) define a cigarette, in part, as any product that consists of any roll of tobacco; it does not establish a minimum quantity of tobacco. Thus, while manufacturers can develop such a product, it would still be a cigarette under this rule and subject to all restrictions for cigarettes.

(56) Two comments would amend the minimum package size by increasing it to 200 cigarettes or a carton of cigarettes. The comments explained that making cartons the minimum package size would further reduce access to cigarettes by young people because cartons would be more expensive than single packs and would be harder to shoplift. The comment said that adults would not be adversely affected by such a change because adults generally buy cartons.

The agency declines to make 200 cigarettes or one carton the minimum "package" size. Eliminating cigarette packages would unduly affect those adults who prefer to purchase cigarette packs rather than cartons due to limited funds or other reasons, and would unduly affect manufacturers, distributors, and retailers because, at the very least, they would need to revise manufacturing practices or machines and/or revise or reconfigure product storage practices and units to accommodate only cartons. It is even possible that some adults might consume more cigarettes if the minimum package size were increased to 200 cigarettes.

(57) One comment challenged the agency's authority for proposed § 897.16(b). The comment argued that requiring a minimum package size exceeds FDA's authority under the act because it does not purport to provide reasonable assurance of the product's safety and effectiveness to potential users.

FDA disagrees with the comment. Section 520(e) of the act authorizes the agency to impose restrictions on the sale, distribution, and use of a device. Establishing a minimum package size is a restriction on the sale and distribution of these devices and is reasonably related to assuring the product's safety for those persons, namely young people, whom this rule protects. Cigarettes and smokeless tobacco either cause or are associated with serious adverse health effects, and the evidence suggests that "kiddie packs" appeal to young people. Hence, establishing a minimum package size that is larger than a "kiddie pack" should help reduce young people's

access to these products and, as a result, protect them from those potential adverse health effects.

(58) One comment stated that the agency lacks factual support for a minimum package size, claiming that there is no evidence that young people buy such products or that "kiddie packs" are especially popular with young people. The comment claimed that the studies cited by FDA in the preamble to the 1995 proposed rule are flawed due to small sample size. The comment disputed the results of those studies, arguing that the studies did not show whether young people favored small package sizes because they are easily concealed—a reason identified by FDA in the preamble to the 1995 proposed rule—or because they are less expensive. The comment added that FDA's rationale is further undermined by the fact that FDA has claimed both that young people are price sensitive and that they do not purchase inexpensive brands. According to the comment, it is not possible to have it both ways.

Specifically, the comment questioned the validity of the 1987 Australian study by Wilson.<sup>45</sup> The comment argued that the authors could not assure that the subject population of 14- and 15-year olds was representative and, because selection criteria for the adult subjects differed, the results from the adult population could not be compared to the results from the 14- to 15-year old subjects. The comment disputed the study's finding that young Australians favored smaller cigarette packages because the small packs were more "concealable," stating that the study did not explain whether a pack containing 15 cigarettes was significantly smaller than a pack containing 20 cigarettes. The comment also criticized the study for being unclear as to whether the researchers surveyed youth smokers alone or young smokers and other youths to determine why young people purchased the 15-cigarette package, and it criticized FDA for not mentioning that the third most popular reason for purchasing 15-cigarette packs was "reducing smoking."

FDA is not persuaded that the studies are unreliable. The comment's criticisms of the Wilson study do not acknowledge that the study's authors compensated for the lack of a

population-based probability sample by using a sample size that exceeded the required size for a simple random sample. The authors used a cross-sectional sample of 649 young people between the ages of 14 and 15. This number exceeded the 363 persons required for a simple random sample, based on an estimate that 40 percent of the 25,000 South Australian children aged 14 to 15 years old would be smokers and using 95 percent confidence intervals of 35 to 45 percent, and exceeded the 567 person sample size that would be obtained when the random sample size is multiplied by a factor of 1.3 to allow for a clustered design and increased 20 percent to allow for persons dropping out of the survey.

Additionally, while the study did say that the sample of 14- and 15-year old children was a "sample of convenience," that, alone, does not make the study unreliable. Many studies use a sample of convenience rather than a representative sample, and the application of a study's results or findings to a broader population depends on the study's methodology.

The comment's criticism of the different selection methods lacks merit because it neglects to consider the context for the selection method. The authors selected schools in order to obtain underage subjects; this selection method precluded getting a representative sample of adults (because they would not be in schools). For the adult subjects, selection was based on a probability-based method of selection instead of school affiliation. Both selection methods were scientifically valid.

Moreover, two well-conducted studies provide a reasonable basis for comparison, even between different populations. This is especially true for the Wilson study because both the adolescent and adult studies were performed under the auspices of the South Australian Health Commission and were drawn from the same geographical area within 2 weeks of each other. Thus, one can reasonably assume that the studies were well conducted and that comparisons between the adolescent and adult groups were appropriate.

Finally, the comment's criticism of Wilson's findings is also misplaced. Contrary to the comment's assertion, the issue is not whether 15-cigarette packs are smaller or more easily concealed than full-sized packs. Nor is the issue whether underage smokers, as opposed to underage smokers and other young

<sup>45</sup> Wilson, D. H., et al., "15's: They Fit in Everywhere—Especially the School Bag: A Survey of Purchases of Packets of 15 Cigarettes by 14 and 15 Year Olds in South Australia," Supplement to Community Health Studies XI (1), pp. 16s–20s, 1987.

people, prefer 15-cigarette packs. Instead, the issue is whether young people, for whatever reason, favor and purchase smaller packs. The study indicated that over 90 percent of the young people surveyed preferred 15-cigarette packs because they considered them to be less expensive, easier to conceal, or helpful to reduce smoking. This led the authors to state that, "if adolescents did not have available to them these cheaper brands, or the price was raised considerably, or packaging in a way that is more appealing to adolescent budgets was prohibited then the current popularity of 15's would be reduced considerably."<sup>46</sup>

(59) The same comment challenged a study by Hill.<sup>47</sup> The preamble to the 1995 proposed rule cited this study to show that younger children (12-year olds in the study) preferred 15-cigarette packages more than older children (17-year olds) and that older children preferred packages containing 25 cigarettes. However, the comment interpreted the Hill study in a much different manner, noting that, according to the study, the youngest age group experienced the greatest decline in smoking prevalence in the period following the introduction of the 15-cigarette package. Thus, the comment asserted that, "[t]his fact suggests that smaller packages are associated with less youth smoking, rather than more." The comment further stated that the researchers' opinion that price and "concealability" make smaller packages appealing to young people is contradicted by the findings that children in all age groups preferred 25- and 30-cigarette packages.

FDA believes that the comment misinterprets the study. While the study did indicate that the proportion of Australian students, aged 12 to 17 years, who smoked weekly declined from 1984 to 1987 (with the greatest declines in the youngest age groups), the study did not attribute the decline to the introduction of a smaller cigarette package. Instead, the study attributed the decline to "the health education and promotional campaigns that were established in Australia during the period between the surveys."<sup>48</sup>

Similarly, a closer examination of the study does not support the comment's assertion that the popularity of larger cigarette packages among Australian

schoolchildren refutes FDA's statement that the price and "concealability" of smaller packages appeal to young people. The study found that 42 percent of the children surveyed smoked cigarettes from 25-cigarette packages, with the next most popular size being 30-cigarette packages. Nearly 20 percent smoked cigarettes from 15-cigarette packages, and "preference for packets of this size showed a marked inverse relationship with age, decreasing from 30% of 12-year-old school children to 11% of 17-year-old school children."<sup>49</sup> The study did not attribute the popularity of the smaller package size to lower price or concealability but merely cited the Wilson study to say that young people "presumably" prefer the smaller packages for those reasons. Yet, regardless of the reason, the Hill study illustrates that a significant percentage of young people prefer smaller package sizes and that the percentage increases in the younger age groups.

(60) The same comment also criticized the Nova Scotia study.<sup>50</sup> FDA cited this study to show that 49 percent of tobacco users in the sixth grade purchased 15-cigarette packages. The comment criticized the Nova Scotia study for the "absurdly small size of this population sample (37 students)." The comment also criticized the Nova Scotia study's assertion that price and concealability motivate young people to purchase small cigarette packages. The Nova Scotia study indicated that only 3 percent of the sixth grade students surveyed (or one out of the 37 students) purchased single cigarettes compared to 11 percent of the twelfth grade students (or 12 students out of the 123 surveyed). The comment argued that the Nova Scotia study showed that twelfth grade students "were four times as likely as the sixth-graders to purchase *single* cigarettes" and that, "[i]f price and 'concealability' were the key factors for young people, those in the youngest age group would surely be purchasing single cigarettes, not 15's".

The comment misconstrues the importance of the study. FDA cited this study to show that 49 percent of tobacco users in the sixth grade purchased 15-cigarette packages, but the agency did not rely solely on the Nova Scotia study as evidence that young people prefer small cigarette packages. Instead, the agency cited the Nova Scotia study and the Hill study that surveyed 19,166 Australian schoolchildren to show that

the youngest children prefer smaller cigarette packages. So, even if the Nova Scotia study used a small sample size, the study's findings are consistent with the Australian study that surveyed 19,166 children.

The agency also disagrees with the comment's claim that the Nova Scotia study contradicts FDA's view that young people purchase "kiddie packs" due to their low price and small size. The study did not examine specific reasons for purchasing single cigarettes as opposed to 15-, 20-, or 25-cigarette packages, and so it would be inappropriate to draw any conclusions based on different purchase rates alone. In other words, the percentage of students who purchase a particular package size may offer little or no insight as to the reasons why a student selected a particular package size.

Other factors might also explain the low rate of single cigarette sales relative to cigarette packages. Low price and concealability might be important factors in purchasing behavior, but they may not be the controlling or sole factors behind a purchase. For example, the preamble to the 1995 proposed rule stated, among other things, that single cigarettes make children more willing to experiment with tobacco products (60 FR 41314 at 41324), and stated that young people see or use tobacco products as a badge or method of conveying or creating a certain image for themselves (60 FR 41314 at 41329). A single cigarette, sold without a package, is an ineffective "badge" compared to the more conspicuous cigarette pack. Additionally, very young children may not opt for single cigarettes because such products are typically purchased from retailers that may question the children's age. (See 60 FR 41314 at 41325 (very young children rely on vending machines more often than older children).) The Nova Scotia study, however, did not examine reasons for purchasing single cigarettes as opposed to purchasing 15-cigarette packages, and so the agency declines to draw any conclusions solely from different sales rates for single cigarettes compared to those for cigarette packages.

(61) One comment suggested amending § 897.16(b) to prohibit manufacturers, distributors, and retailers from selling or causing to be sold, distributing or causing to be distributed, "cigarettes unless contained in packages of at least 20 cigarettes." The comment said that the rule did not prevent anyone other than retailers from selling individual cigarettes.

<sup>46</sup> *Id.*, p. 19s.

<sup>47</sup> Hill, D. J., et al., "Tobacco and Alcohol Use Among Australian Secondary Schoolchildren in 1987," *Medical Journal of Australia*, vol. 152, pp. 124-130, 1990.

<sup>48</sup> *Id.*, p. 128.

<sup>49</sup> *Id.*, p. 126.

<sup>50</sup> "Students and Tobacco," The Nova Scotia Council on Smoking and Health Survey, Final Report, March 1991.

FDA believes the comment misinterpreted the rule. Section 897.3 defines a "retailer" as any person who sells cigarettes or smokeless tobacco to individuals for personal consumption. Thus, a manufacturer or distributor who attempted to sell single cigarettes to a consumer would, under the final rule, be considered a "retailer" for purposes of that transaction and would be in violation of the individual cigarette restriction in § 897.14.

(62) One comment suggested amending the rule to create a minimum package size for smokeless tobacco. The comment would make the minimum package size for smokeless tobacco equivalent to 20 doses of nicotine, but it did not state what a dose would be.

The agency agrees that a minimum package size for smokeless tobacco may be helpful, but lacks sufficient information to determine what that size should be for the various forms of smokeless tobacco on the market. Unlike cigarettes, which are generally sold in packages of 20, smokeless tobacco comes in various forms and sizes, and, with the possible exception of prepackaged forms, can be used in quantities determined by the user. One individual, for example, might place more chewing tobacco in his or her mouth than another individual. Consequently, absent more information, the agency is unable to establish a minimum package size for smokeless tobacco.

(63) The agency, on its own initiative, has amended § 897.16(b) (minimum cigarette package size) to add the introductory phrase, "Except as otherwise provided under this section." This amendment became necessary because, as discussed in greater detail in section IV.E.4.a. of this document, the agency has concluded that vending machine sales should be permitted in facilities that are inaccessible to young people, and FDA is aware of at least one type of vending machine that sells packaged, single cigarettes. The agency is aware of vending machines that dispense cartons, packages, and now packaged, single cigarettes and has made an exception for packaged, single cigarettes due to their unique nature (relatively high price compared to "loosies," packaging in compliance with labeling and tax requirements, and sale only in adult locations). Additionally, FDA, on its own initiative, has revised the rule to state that no manufacturer, distributor, or retailer "may" sell (rather than "shall" sell) cigarette packages containing less than 20 cigarettes.

### 3. Maximum Package Size

The preamble to the 1995 proposed rule also invited comment as to whether a maximum package size should be established. The preamble to the 1995 proposed rule cited one study that found that older Australian children favored cigarette packs containing 25 cigarettes (60 FR 41314 at 41324).

(64) Several comments offered suggestions regarding a maximum package size. One comment noted that packages containing 10 and 25 cigarettes have been sold in the United States and suggested that, when considering a maximum package size, FDA should consider the attractiveness of the pack and whether a larger pack would encourage increased consumption. The comment added that one option would be to limit sales to 200 units (or one carton). Another comment would make 20 cigarettes the maximum package size, but conceded that there is insufficient evidence to make a strong recommendation.

In contrast, one comment stated that the agency has no authority or evidence to justify creating a minimum package size and so it lacks authority and evidence to create a maximum package size.

Based on the comments, there is insufficient evidence to establish a maximum package size for cigarettes. There is little experience in the United States with package sizes greater than 20 cigarettes. As a result, the final rule does not establish a maximum package size for cigarettes.

### 4. Impersonal Modes of Sale

Proposed § 897.16(c) would have permitted cigarettes and smokeless tobacco to be sold only in a direct, face-to-face exchange between the retailer, or the retailer's employees, and the consumer. Thus, the proposal would have prohibited the use of vending machines, self-service displays, mail-order sales, and mail-order redemption of coupons. Implicit in this provision, and in subpart B of part 897, is the notion that transactions involving restricted devices should involve a sense of "formality" or gravity that conveys to both the seller and the buyer the seriousness of the transaction and of the products themselves. FDA has amended this provision in response to comments. As discussed in section IV.E.4.c. of this document, certain mail-order sales are now exempted from this requirement, as are vending machines and self-service merchandisers in facilities not admitting individuals under the age of 18.

a. *Vending machines.* The preamble to the 1995 proposed rule cited numerous studies and surveys showing that significant percentages of young people are able to purchase cigarettes from vending machines, even in jurisdictions that have laws restricting the placement of those machines or requiring the use of locking devices. In some cases, young people successfully bought cigarettes from vending machines 100 percent of the time (60 FR 41314 at 41324 through 41325). Consequently, the agency elected to prohibit the use of vending machines rather than restrict their placement or require locking devices.

FDA's proposal to eliminate the use of vending machines (§ 897.16(c)) generated more comments than any other provision aimed at reducing children's and adolescents' access to tobacco products; the agency received thousands of comments on this provision. While agreeing that children and adolescents should not use tobacco products, comments submitted by adult smokers, the tobacco industry, and vending machine owners and operators, strenuously objected to the provision. Nearly all of the comments in opposition stated that the provision would be unnecessary if State and local jurisdictions enforced existing laws prohibiting the sale of tobacco products to children and adolescents under the age of 18.

By contrast, concerned adults, parents, educators, State and local public health agencies, and medical professionals overwhelmingly supported the provision. In addition, tens of thousands of school children wrote letters asking that vending machines be eliminated. Nearly all comments in favor of the provision pointed to the serious health risks that a lifetime of nicotine addiction poses to children and adolescents who begin to smoke, arguing that vending machines offer children and adolescents who choose to begin to smoke easy access to cigarettes.

(65) Several comments asserted that the proposed restriction pertaining to vending machines would effect takings compensable under the Fifth Amendment.

The agency disagrees with the comments. As discussed in greater detail in the paragraph below, FDA has amended the final rule to permit vending machines in facilities that are inaccessible to young people at all times. Additionally, given the character of this regulation and the lack of reasonable investment-backed expectations in personal property, its

economic impact, while potentially significant for some persons, is not such as to effect a taking. The agency addresses Fifth Amendment issues in greater detail in section XI. of this document.

(66) Most comments submitted by adult smokers and nearly all of the comments submitted by the cigarette and vending machine industries stated that the provision would not effectively reduce children's and adolescents' access to cigarettes. The comments argued that the proposed elimination of vending machines is not supported by the evidence in the record, either because the studies cited by FDA do not measure children's and adolescents' actual purchasing habits, or because the percentage of children and adolescents who reportedly buy cigarettes from vending machines is not significant. Finally, many adult smokers and some parents argued that determined teenagers will find a way to obtain cigarettes whether or not vending machines are eliminated.

On the other hand, almost all of the children, parents, adults who do not smoke, medical professionals, and public interest groups commented that the provision would effectively reduce children's access to cigarettes. These comments generally cited personal experience in concluding that vending machines provide an easy source of cigarettes for many children who smoke. For example, the executive director of a public health education program wrote: "It is outrageous that we allow tobacco, a most addictive drug, to be sold through vending machines where anyone can purchase it!" Comments overwhelmingly concluded that the elimination of vending machines, coupled with the other proposed access and advertising restrictions and the proposed education campaign, would effectively reduce the availability of cigarettes to children.

Several comments analyzed currently available studies and concluded that "easy access to vending machines \* \* \* enable[s] young people to obtain cigarettes, and that high proportions of vending machine users are people under 18." Moreover, several comments in support of the provision cited their own studies indicating the ease with which children and adolescents obtain cigarettes from vending machines. For example, a coalition dedicated to preventing and reducing tobacco use submitted its 1994 annual report, which included an article describing an undercover buying survey, the largest of its kind, conducted in Spring, 1994. One

hundred and seven teenagers participated in the 12-county survey by entering stores under the supervision of an adult and attempting to purchase cigarettes, and:

[k]ids were more successful attempting to buy cigarettes through vending machines [than through retail outlets], without any adults trying to stop them. Teens made 21 of 24 successful attempts to purchase cigarettes through vending machines, an 88 percent success rate.

Similarly, the manager of a youth tobacco prevention program in Washington State's Department of Health commented that "[a] recent survey in one Washington county found that youth can still purchase tobacco from vending machines at a 75 percent success rate." The comment recommended that all tobacco vending machines be eliminated.

Finally, comments submitted by children, parents, and nonsmoking adults indicate that these groups believe tobacco vending machines are easily accessible to children and adolescents. One comment, typical of those submitted by children, stated: "I especially agree with getting rid of vending machines. That, I think, is probably the most common way that children get their cigarettes." The director of a public health center in California submitted the results of a poll indicating that 75 percent of Californians support banning cigarette vending machines.

Vending machines certainly represent one of the major ways that children currently obtain cigarettes. In addition to studies depicting how easily children and adolescents could purchase cigarettes from vending machines, the 1995 proposed rule cited surveys of children's actual purchasing behavior (60 FR 41314 at 41324 through 41325). Relying on both types of evidence, the agency concluded that the provision would eliminate one of the primary sources of cigarettes for at least 2 percent of 17-year-old smokers and 22 percent of 13- to 17-year-old smokers. Moreover, the agency finds that the number of children and adolescents in these two groups is substantial.

While the agency agrees that some children and adolescents who are determined to smoke may find or create new ways of obtaining cigarettes, the removal of vending machines from sites accessible to young people will eliminate what is currently a popular and easy means of access to tobacco, especially for younger children. In addition, if other access restrictions are imposed, such as requiring customers to provide proof of age, without also

eliminating vending machines, use of vending machines among children between the ages of 13 and 17 years would likely increase (60 FR 41314 at 41325). Therefore, the agency has concluded that the provision is an important part of the overall scheme to reduce children's and adolescents' access to cigarettes.

(67) The agency received many comments regarding the location of vending machines. A trade association representing the cigarette industry stated that most vending machines are currently inaccessible to children and adolescents because they are located either in areas that are off-limits to young people, such as nightclubs or casinos, or in areas that young people rarely frequent, such as industrial plants and private offices. Thus, the comment concluded, eliminating vending machines will not discourage youth smoking.

The vending machine industry and establishments that currently have vending machines unanimously opposed the provision. Some comments suggested that the agency specifically allow vending machines in locations where young people are not present. One vending machine operator commented, "[m]any cigarette machine vendors are small businessmen like myself; 95 percent of our locations are in taverns and lounges, where no one under 21 years old is allowed in." Other comments argued that, even if retail purchases become increasingly difficult, vending machines in establishments that are not open to the public should not be eliminated because children and adolescents cannot enter these places.

Both the cigarette and vending machine industries argued that FDA's conclusion, that children and adolescents can easily purchase cigarettes from vending machines even in "adult" locations, was based on flawed studies. Comments argued that the sting operations, on which these studies were based, do not demonstrate where teenagers actually or usually go. One comment, submitted by an association representing 1,700 vending machine companies, argued that: "it is highly questionable if minors might have alone and without encouragement entered taverns or bars in restaurants just to purchase cigarettes without exemption from the district attorney's office." Moreover, these comments argued, local sting operations do not establish the national cigarette purchasing habits of children and adolescents.

In contrast, a national public health organization concluded that available studies indicate that restricting the location of vending machines is an ineffective method of controlling sales of tobacco to young people. Another comment opposed to weakening the provision characterized as unreliable the number of machines currently in "adult" locations. The comment attacked as statistically unsound a vending machine industry survey that concluded that 77 percent of all vending machines are in "adult locations."

FDA has determined that cigarettes should not be dispensed to consumers from vending machines that are accessible to children and adolescents. While young people's actual current purchasing habits provide irrefutable evidence of accessibility, available evidence demonstrates that cigarette vending machines also are accessible to children and adolescents even in locations that are not often or currently frequented by young people. FDA has determined that cigarette vending machines should be eliminated from locations that are accessible to children and adolescents, whether or not children and adolescents currently use them.

While the IOM recommended that vending machines be eliminated altogether, it cautioned that, if partial bans were to be enacted, the definition of "adult" location must be narrowly drawn.

Youths do not now report "adult" locations as major sources of tobacco, but there is evidence that minors can often easily enter "adult" locations, and once inside, can easily buy tobacco products \* \* \*. If partial vending machine bans are to be effective, the statutes must define "adult" locations carefully and narrowly. For example, the bar area of a restaurant is not sufficiently inaccessible to minors to deter their purchases. \* \* \* Many bars only restrict access to alcohol; they do not restrict entrance by age. Accordingly, if vending machine are permitted at all, they should be permitted only in locations to which minors may not be admitted.<sup>51</sup>

Based on comments, FDA has determined that some "adult" locations can be made sufficiently secure to prevent young people's access and that vending machines should remain available to adults in these locations. For example, some establishments, such as nightclubs or casinos, require that patrons present proof of age before they are permitted to enter or post a guard at the door to prohibit underage access. In 1994, CDC analyzed 15 recent studies of children's access to tobacco and noted

that "[s]ome inspections of private clubs and bars were not carried out because access to the outlet was blocked by a doorman or security guard."<sup>52</sup> FDA finds that those establishments where people under the age of 18 are legally prohibited from entering and where a system exists to ensure that children are prevented from entering, can, in fact, be sufficiently inaccessible to children that the goals of the rule would not be significantly advanced by prohibiting vending machines in those limited locations.

Other "adult" establishments prohibit children and adolescents from entering, as a matter of establishment policy. For example, some private clubs do not grant membership to persons under the age of 18 and require that members provide proof of membership before entering the club. Similarly, for example, some industrial or manufacturing facilities not open to the public may, for safety reasons, prohibit the hiring of persons under the age of 18, and require that employees present proof of employment upon entering the facility. FDA finds that these establishments, like some nightclubs or casinos, can be similarly inaccessible to children and, if so, should be permitted to make cigarette vending machines available to their adult members or employees.

Futhermore, an exemption for vending machines located in areas where no person under 18 is present or permitted to enter is consistent with the "Prohibition of Cigarette Sales to Minors in Federal Buildings and Lands Act" (Pub. L. 104-52, sec. 636). This particular statute, which became law on November 19, 1995, prohibits the sale of tobacco products in vending machines located "in or around any Federal building," but the statute authorizes the Administrator of the General Services Administration (GSA) or the head of an agency to exempt areas that prohibit the "presence of minors" (whom the statute defines as individuals under age 18). See also 41 CFR 101-20.109(d) (Administrator of the GSA or agency head may designate areas where vending machine sales of tobacco products may occur "if the area prohibits minors"); 61 FR 2121, January 25, 1996.

Consequently, § 897.16(c) exempts vending machines located in establishments that are totally inaccessible to persons under 18. The

owner of the facility must ensure, by means of photographic identification or some other means, that no one under 18 enters the facility. Thus, the rule would permit a vending machine in an establishment only where persons under 18 are not present, or permitted to enter, at any time. FDA emphasizes that this narrowly drawn exemption accommodates adults only in locations where young people, in fact, have no access at any time. For example, a vending machine might be permitted in a facility that employs only adults and where guards prevent any person under 18 from entering. A vending machine would not be permitted in a facility that employs only adults but also permits employees to bring children to work. The agency further emphasizes that it is the exempt establishment's responsibility to ensure that no one under 18 is present, or permitted to enter the premises, at any time.

In addition, under § 897.16(c), a vending machine in an exempt establishment must be entirely inaccessible to children. Thus, an establishment must place the machine entirely inside the premises, beyond the point where persons are required to present proof of age, membership, or employment. Vending machines are prohibited from any public area in or around the establishment, including, for example, lobbies, parking lots, and entrances.

FDA emphasizes that the final rule exempts only establishments that are, in fact, inaccessible to young people at all times. FDA will monitor young people's access to cigarettes from vending machines in exempt establishments, and, after 2 years, will assess whether the vending machine exemption has been effective. At that time, the agency finds that vending machines continue to be accessible to young people, FDA will propose further restrictions.

(68) Several comments suggested that, rather than eliminate vending machines or restrict their location, FDA require that they be supervised. These comments would allow vending machines to be placed anywhere, even in locations frequented by children and adolescents, as long as the machines were supervised.

FDA disagrees that supervising vending machines would prevent illegal sales to children and adolescents. Comments opposed to the provision offered no evidence that supervision of vending machines would sufficiently impede a young person's access to cigarettes. In fact, studies indicate that young people are able to purchase

<sup>51</sup> IOM Report, p. 214.

<sup>52</sup> "Design of Inspection Surveys for Vendor Compliance with Restrictions on Tobacco Sales to Minors," Battelle, prepared for the CDC, OSH, p. 17, April 1994.

cigarettes even from vending machines under the immediate vicinity and control of employees.

One study conducted in a State requiring that vending machines be supervised demonstrated that youths were able to purchase from 72 percent of vending machines, in bars and taverns, within clear view of an employee.<sup>53</sup> Another report examining vending machine sales in New York City demonstrated that 11- and 12-year-olds successfully purchased cigarettes from supposedly supervised vending machines in bars and taverns 100 percent of the time. The study found that children and adolescents "had no more difficulty buying cigarettes from vending machines in bars than they had buying cigarettes from restaurants, pizza parlors, or video arcades. In all instances, the barman and/or patrons watched but did not intervene."<sup>54</sup>

In other studies, employees helped children and adolescents to illegally purchase cigarettes by providing change for the cigarette vending machine<sup>55</sup> or suggesting that the children and adolescents go next door where cigarettes were cheaper.<sup>56</sup>

Additionally, each provision in subpart B of part 897 is intended to eliminate a popular source of cigarettes and smokeless tobacco for children. The vending machine restriction is intended to complement, and be reinforced by, the other restrictions.

The preamble to the 1995 proposed rule cited studies indicating that the use of vending machines by adolescents is greater in jurisdictions that have stronger access restrictions (60 FR 41314 at 41325). Based on those studies and comments that it received, FDA concludes that decreasing the supply of tobacco products to children and adolescents by one means of access, such as restricting self-service displays, would cause an increased demand by another means of access, such as cigarette vending machines. FDA remains persuaded that, without eliminating cigarette vending machines accessible to children and adolescents,

other access restrictions would cause an increase in illegal vending machine sales.

(69) Most comments submitted by the tobacco and vending machine industries recommended that, rather than eliminate vending machines, FDA should require that they be equipped with electronic locking devices (devices that render the machine inoperable until activated by an employee) or token mechanisms (which require consumers to purchase tokens from an employee in order to use a vending machine). Either method would require a face-to-face transaction between the purchaser and the retailer.

The cigarette and vending machine industries commented that studies do not support FDA's conclusion that locking devices are ineffective. Comments asserted that the studies failed to include vending machines fitted with locking devices in traditionally adult locations or to account for the lack of enforcement in the jurisdiction in which the study was conducted. In addition, several comments pointed out that the tobacco sales ordinance in Woodridge, IL, where illegal tobacco sales were reduced from 70 percent to less than 5 percent 2 years later, included a locking device requirement rather than a ban on cigarette vending machines.

On the other hand, one comment from a public interest group strongly supported FDA's proposal to eliminate vending machines altogether and urged that FDA not permit the use of locking devices. The comment cited a survey, conducted by an association of public health officials in New Jersey, in which young people successfully purchased cigarettes from supposedly locked vending machines in 11 of 15 attempts. The comment noted that "[i]n some instances, the remote control device to operate the machine was sitting on top of the machine to save store personnel the bother of having to press the switch."

FDA acknowledges that properly installed locking devices require that vending machine purchasers engage in a face-to-face transaction, increasing the likelihood that children would be prevented from purchasing cigarettes. However, as explained in the preamble to the 1995 proposed rule, available evidence indicates that the industry is slow to install the locking devices, and that, after a short period, the locking devices are often disabled (60 FR 41314 at 41324 through 41325).

FDA agrees that the Woodridge, IL, community was able to dramatically

reduce illegal tobacco sales while permitting the use of locking devices on cigarette vending machines. However, FDA notes that when the community implemented its tobacco ordinance in May, 1989, the community had only six vending machines, and when the study was completed December, 1990, the number of vending machines had dropped to two. Moreover, despite the requirement of locking devices and persistent compliance checks by law enforcement, a child was able to purchase cigarettes from one of the two remaining vending machines in December, 1990.<sup>57</sup>

Similarly, in 1990, Minnesota enacted a law eliminating vending machines in public areas unless the machines were only operable by activation of an electronic switch or token and were under the direct supervision of a responsible employee. One year after the law was passed, a study conducted in four cities found many machines had not been fitted with the required devices and, of those fitted with the devices, there was no significant reduction in purchase success.<sup>58</sup>

IOM reviewed the available evidence and determined that locking devices do not effectively prevent youth access to cigarette vending machines. IOM noted that "although fewer cigarettes are sold to youths than where vending machines are completely unrestricted, businesses that installed locking devices on vending machines were still more likely to sell cigarettes to young people than businesses that used over-the-counter sales."<sup>59</sup>

Finally, the Inspector General reported that Utah experienced limited success with locking devices:

Reportedly, clerks would simply activate the machine without checking the age of the purchaser. Since the locking devices require employee participation, they are often not as effective in busy places, such as bars or restaurants, where employees are more likely to simply activate the machine.<sup>60</sup>

FDA has not been persuaded that vending machines equipped with locking devices sufficiently guard

<sup>53</sup> Cismoski, J., and M. Sheridan, "Availability of Cigarettes to Under-age Youth in Fond du Lac, Wisconsin," *Wisconsin Medical Journal*, vol. 92, No. 11, pp. 626-630, 1993.

<sup>54</sup> "Cigarette Vending Machines Sell Cigarettes to Children, 11-15 Years Old, 100% of the Time," Smokefree Educational Services, Inc., October 1990. "Critics Target Vending Machines," *The Christian Science Monitor*, p. 6, April 1990.

<sup>55</sup> Mead, R., "Teen Access to Cigarettes in Green Bay, Wisconsin," *Wisconsin Medical Journal*, pp. 23-24, January, 1993.

<sup>56</sup> "Springfield Teen Tobacco Purchase Survey," Stop Teenage Addiction to Tobacco (STAT), 1993.

<sup>57</sup> Jason, L. A., P. Y. Ji, M. D. Aneo, and S. H. Birkhead, "Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors," *JAMA*, vol. 266, No. 22, pp. 3159-3161, December 11, 1991.

<sup>58</sup> Kotz, K., "An Evaluation of the Minnesota Law to Restrict Youth Access to Tobacco," presented to the American Public Health Association (APHA) 121st Annual Meeting, San Francisco, CA, October 24-28, 1993.

<sup>59</sup> IOM Report, p. 213.

<sup>60</sup> "Youth Access to Cigarettes," Department of Health and Human Services (DHHS), Office of the Inspector General, Pub. No. OEI-02-90-02310, p. 9, May 1990.

against children's access to tobacco products. Comments provided no evidence, and FDA is not aware of any studies, on whether law enforcement efforts affect children's ability to access tobacco products through locked vending machines. However, one study examined the effect of law enforcement efforts on illegal vending machine sales in three comparable communities that did not require locking devices. Despite the fact that merchants in one of the three communities received a letter describing the State law and warning them of the city's intention to enforce the law, there was no significant difference in the rate of illegal vending machine sales among the communities.<sup>61</sup>

Comments also provided no evidence that restricting the location of cigarette vending machines equipped with a locking device renders the machines less accessible to children and adolescents. FDA notes that, if locking devices were effective, the location of the machine would be of no consequence. Yet, as discussed in the preceding paragraphs, FDA is persuaded that some establishments are entirely inaccessible to young people. Accordingly, the final rule allows the use of vending machines in those establishments without requiring that the machines be equipped with a locking device.

FDA declines to grant an exception for tokens in the absence of evidence that machines operated only by tokens prevent children from obtaining cigarettes. Several comments suggested, rather than eliminate vending machines, that FDA require either locking devices or tokens. These comments focused on locking devices, without offering any evidence of the number of vending machines currently operating with tokens, the extent to which tokens have been tested in the marketplace, or whether the technology prevents children and adolescents from obtaining cigarettes from vending machines. FDA is aware that three States whose laws restrict the use of vending machines permit the use of locking devices or tokens. However, FDA is not aware of any evidence indicating that the use of tokens prevents young people's access to cigarettes from vending machines that are otherwise accessible to children.

(70) The most common concern raised by adult smokers was that the elimination of vending machines would

inconvenience them. Most adult smokers stated that vending machines are closer than retail outlets to their homes or places of work. Some adult smokers stated that they would be unable to purchase cigarettes late at night if vending machines were eliminated. Others indicated that vending machines provide the only means of obtaining their brand, or of obtaining cigarettes altogether.

In contrast, while acknowledging that adult smokers would be somewhat inconvenienced, comments in support of eliminating vending machines pointed out that adult smokers would still be able to purchase their products in retail transactions. Nearly all comments in support of the provision, including comments from grade school students, parents, and health professionals, said that the significant reduction in children's access to cigarettes would outweigh any inconvenience experienced by adult smokers.

The agency is persuaded that the provision would not unduly burden adult smokers, who could continue to purchase cigarettes in retail transactions, and that the inconvenience some smokers would experience is a small burden when compared to the significant public health benefit of reducing children's and adolescents' access to tobacco.

(71) A few comments questioned the propriety of using young people in "sting" operations to determine the level of compliance with existing laws restricting the sale of tobacco products to children. One comment suggested that these operations taught children how and where to purchase cigarettes, concluding that the operations "have done more to increase smoking in our youth than any tobacco company or advertisement could have."

FDA relied on several types of evidence in proposing these regulations, including teen surveys and peer-reviewed studies. Compliance testing involves sending underage children and adolescents into tobacco outlets to attempt to purchase cigarettes or smokeless tobacco. This type of study provides reliable evidence of children's ability to illegally obtain tobacco products.

A 1994 review<sup>62</sup> of the design of recent studies indicates children who participated in these studies received specific instructions about the method

and purpose of the study and were escorted by at least one adult. Some adults waited outside the outlet for the young person while others went inside to observe the child attempt the purchase. In response to comments on the final rule on substance abuse prevention and treatment block grants (suggesting that participating in sting operations could be detrimental to children and adolescents), DHHS explained that "proper training and adult supervision can reduce any potential risk of negative consequences toward youth" (61 FR 1492 at 1494, January 19, 1996). In addition, DHHS offered States assistance in developing compliance testing procedures.

FDA is not persuaded that participating in compliance testing entices children to smoke. The agency believes that, with proper training and adult supervision, children and adolescents who participate in compliance testing will understand that their role in this testing is to help reduce teenage smoking by identifying places that illegally sell tobacco products to children, and that, after identification and publicity or enforcement action, these places will stop illegal sales.

(72) Several adult smokers commented that the provision, either alone or in conjunction with other provisions, would cause a decrease in tobacco consumption. To compensate for this loss, they argue, tobacco companies will raise their prices and governments will increase taxes. Overwhelmingly, adult smokers commented that the price of a package of cigarettes is already unfairly high.

The agency has narrowly tailored the final regulations to prevent only young people's use of cigarettes and smokeless tobacco. Because sales to children account for a small percentage of total tobacco sales, industry revenues will be significantly diminished only after many years have passed. Moreover, the long-term effect on product prices is difficult to forecast because reduced product demand could easily result in price decreases.

(73) In contrast, one comment cited a 1995 survey in which three-quarters or more of those Californians polled supported increasing the tobacco tax by 25 cents. Another comment suggested that an additional portion of excise taxes be allocated to smoking cessation programs and to prenatal care, especially antismoking messages targeted to pregnant women. Other comments noted that increased prices

<sup>61</sup> Forster, J. L., M. Hourigan, and P. McGovern, "Availability of Cigarettes to Underage Youth in Three Communities," *Preventive Medicine*, vol. 21, No. 3, pp. 320-328, May 1992.

<sup>62</sup> "Design of Inspections Surveys for Vendor Compliance with Restrictions on Tobacco Sales to Minors," Battelle, prepared for CDC, OSH, p. 14, April 1994.



could serve to deter some children and adolescents from purchasing cigarettes.

The agency cannot act on these comments as it lacks the authority to levy taxes or mandate prices.

(74) One comment submitted by cigarette manufacturers characterized as misleading FDA's claim that its proposal to eliminate vending machines is consistent with recommendations from IOM, PHS, a working group of State attorneys general, and the Inspector General of DHHS (60 FR 41314 at 41325). FDA disagrees. IOM and PHS specifically recommended that vending machines be eliminated. IOM advocated that less restrictive measures be adopted only if shown to be effective,<sup>63</sup> while PHS cautioned that alternatives be examined carefully.<sup>64</sup> Moreover, PHS specifically noted that Utah found disabling devices to be "ineffectual in practice."<sup>65</sup>

The State attorneys general determined that "very young children rely heavily on vending machines as a major source of tobacco products," and that "their use of these machines is difficult to police."<sup>66</sup> Consequently, the group recommended that retail stores "remove cigarette vending machines from their premises and sell tobacco products only from the controlled settings recommended above."<sup>67</sup> The referenced controlled settings included the use of electronic price scanners to prompt retail clerks to check a customer's identification and to display the last acceptable date of birth, using price scanner systems with tobacco "locks," and requiring tobacco products to be kept behind sales counters. The State attorneys general did acknowledge that, "at a minimum," vending machines should be modified to require tokens that could be purchased only from a store manager or be programmed to operate only if a cashier activates a remote switch, but their principal recommendation was the removal of vending machines.

While the Inspector General made no recommendation, his report noted that 42 percent of State health department

officials believe that total bans are the only way to prevent teens from using cigarettes.<sup>68</sup>

FDA believes the provision on vending machines is consistent with the positions taken by the IOM, PHS, State attorneys general, and the Inspector General of DHHS.

(75) One comment suggested that the rule define "vending machine" to avoid regulating machines that dispense cigarettes to salespersons rather than customers. The comment described a machine designed to limit theft and to control the inventory of cigarettes and other similarly packaged items in retail stores, principally supermarkets. The machine requires that a computer command be entered before it dispenses a package of cigarettes. The comment asserted that among the machine's benefits is its ability to exclude customer access to cigarettes.

FDA did not contemplate the type of inventory machine described by the comment, and the provision, as drafted, would not include this type of machine. Section 897.16(c) is intended, in part, to eliminate mechanical devices that dispense cigarettes or smokeless tobacco to purchasers in locations that are accessible to children. FDA declines at this time to define "vending machine" so as to exclude from the rule mechanical devices developed in the future, including those intended to aid in preventing theft.

(76) One comment opposed to the provision interpreted it as prohibiting a vending machine that dispenses single cigarettes, packaged separately in tubes, each bearing the Surgeon General's warning and in compliance with tax laws. The comment explained that in some adult locations, such as cocktail lounges and casinos, many adults would like to purchase a single cigarette, and that the person submitting the comment developed the machine to fill this perceived gap in the marketplace.

The proposal did not contemplate the type of machine described by the comment. Accordingly, § 897.16(c) has been amended to permit the sale of a packaged, single cigarette in locations inaccessible to persons under the age of 18. This exception is restricted to packaged, single cigarettes that comply with other applicable laws and regulations.

b. *Self-service displays.* Proposed § 897.16(c) also would have prohibited the use of self-service displays. The preamble to the 1995 proposed rule

explained that self-service displays enable young people to quickly, easily, and independently obtain cigarettes and smokeless tobacco. FDA cited one report that reviewed surveys of grade school students; the report found that over 40 percent of the students who smoked daily shoplifted cigarettes from self-service displays (60 FR 41314 at 41325). The agency also cited one study showing that tobacco sales to young people dropped 40 to 80 percent after enactment of ordinances prohibiting self-service displays and requiring vendor-assisted sales (60 FR 41314 at 41325). The proposed provision, therefore, was intended to prevent young people from helping themselves to these products and to increase the amount of interaction between the sales clerk and the underage customer.

The preamble to the 1995 proposed rule also referred to the IOM Report which stated that placing products out of reach "reinforces the message that tobacco products are not in the same class as candy or potato chips."<sup>69</sup>

In response to the comments, the agency has amended this section to except certain self-service displays (merchandisers) in facilities inaccessible to persons under the age of 18.

(77) Several comments asserted that the proposed restriction pertaining to self-service displays would effect takings compensable under the Fifth Amendment.

The agency disagrees with the comments. Given the character of the section, as modified in this final rule, and the lack of reasonable investment-backed expectations in personal property, its economic impact, while potentially significant for some parties, is not such as to effect a taking. The agency addresses Fifth Amendment issues in greater detail in section XI.A. of this document.

(78) Several comments challenged FDA's basis and authority for prohibiting self-service displays. The comments focused, in part, on the studies and reports cited by the agency. They argued that active enforcement of laws, rather than elimination of self-service displays, led to decreases in young people's access to cigarettes and smokeless tobacco. Other comments disputed whether significant shoplifting occurs from self-service displays. According to these comments, FDA did not provide any evidence to suggest that eliminating self-service displays is necessary to prevent shoplifting.

<sup>63</sup> IOM Report, p. 214.

<sup>64</sup> "Model Sale to Tobacco Products to Minors Control Act, A Model Law Recommended for Adoption by States of Localities to Prevent the Sale of Tobacco Products to Minors," DHHS, p. 2, May 24, 1990.

<sup>65</sup> *Id.*, p. 5.

<sup>66</sup> "No Sale: Youth Tobacco and Responsible Retailing Developing Responsible Retail Sales Practices and Legislation to Reduce Illegal Tobacco Sales to Minors, Findings and Recommendations of a Working Group of State Attorneys General," pp. 31-32, December 1994.

<sup>67</sup> *Id.*, p. 32.

<sup>68</sup> "Youth Access to Cigarettes," DHHS, Office of the Inspector General, Pub. No. OEI-02-90-02310, pp. 8-9, May 1990.

<sup>69</sup> IOM Report, p. 215.

One comment examined studies that FDA did not cite in the 1995 proposed rule and found one study estimating that less than 5 percent of the adolescents surveyed had shoplifted cigarettes. Also, a number of comments stated that, if shoplifting were truly a significant problem, retailers would have a financial interest in reducing their losses and would remove self-service displays themselves. The comments implied that shoplifting is not a significant problem, and several claimed FDA's rationale was inconsistent because, if young people could purchase cigarettes and smokeless tobacco easily from retailers, they would not have to steal them from self-service displays.

In contrast, several comments supported the prohibition on self-service displays, reiterating FDA's position that displays encourage shoplifting, and their absence increases the likelihood of age verification. For example, a drug addiction counselor commented that teens do not want to go to the counter and ask for cigarettes since there is a greater likelihood that they will be asked to show their identification and they might be embarrassed. One comment also asserted that retailers get products for displays at a discount, and such discounts are, in effect, a subsidy for shoplifting. Another comment alleged that, in one area of the country, low-priced brands are put in displays and that retailers are compensated for any shoplifting losses.

Comments from other areas of the country agreed that shoplifting occurs, sometimes at significant rates. One comment stated that a 1993 survey of 9th-grade students in one county revealed that 51 percent had shoplifted cigarettes. Another comment, reflecting on experiences conducting retailer compliance checks in three small towns, stated that its teenage volunteers "commented on the ease with which they could have lifted cigarettes from free-standing displays." A comment describing practices in a rural part of the country stated that theft was one method of acquiring smokeless tobacco, and that young people often began using such products at the age of 10, 11, or 12.

Other comments suggested an additional reason for eliminating self-service displays. These comments indicated that young people can easily pick up products from displays, leave their money at the cashier's desk, and leave the premises without being challenged by a retailer or before the retailer can request proof of age.

FDA believes there is ample evidence to support a restriction on self-service displays. The preamble to the 1995 proposed rule cited surveys suggesting that a significant percentage of children and adolescents (40 percent in the two areas surveyed) shoplift cigarettes (60 FR 41314 at 41325), and at least one comment reported an even higher percentage (50 percent). Although one comment from cigarette manufacturers suggested the shoplifting rate to be only 5 percent, FDA emphasizes that, even if one accepts the 5 percent figure, the numbers of young people engaging in shoplifting can be very large. For example, 5 percent of the estimated 3 million young people who smoke cigarettes daily equals 150,000 children and adolescents. Five percent of the estimated 3 million smokeless tobacco product users under the age of 21 also equals 150,000 people.

These numbers may even be artificially low because they exclude the number of young people who do not smoke or use smokeless tobacco daily, and these numbers may be extremely low if the 40 or 50 percent shoplifting rates identified by the agency or by other comments prove to be more accurate than the 5 percent rate cited by the cigarette manufacturers.

FDA also disagrees with those comments claiming that shoplifting is not a significant problem. Generally, such comments asserted that the problem is not significant because, if it were, retailers would move self-service displays, and most have not done so. Such comments, however, misconstrue the significance of the problem. The agency did not, and does not, claim that individual retailers are suffering significant shoplifting losses (although FDA did receive one comment containing information showing that shoplifting losses at two stores amounted to several thousands of dollars worth of cigarettes annually). Instead, FDA is stating that significant numbers of young people shoplift these products. The distinction is critical. To illustrate, if 1,000 retailers each lose 1 cigarette package to shoplifting, each retailer might feel that the shoplifting rate, from its perspective, is insignificant. However, if 1,000 young people acquire cigarettes by shoplifting, the shoplifting problem, from a public health perspective, then becomes much more significant.

(79) Several comments argued that the studies cited by the agency, having been conducted at only two locations in the United States (Erie County, NY, and Fond du Lac, WI), cannot be used to

justify a nationwide prohibition against self-service displays.

The agency disagrees with these comments. The comments offered no evidence to show that these communities are so distinct or unique from the remainder of the United States to require FDA to discount or to ignore their findings. To the contrary, FDA received other comments from various parts of the nation supporting the rule, and these comments often agreed that young people shoplift these products from displays.

FDA also notes that it does not require clinical investigations for product approvals to be conducted on a national scale. One important aspect of any study, whether it is submitted as part of an investigational product exemption, marketing application, or rulemaking, is whether the study is conducted and analyzed in a scientifically valid way that permits the results to be extrapolated to a broader population. In other words, the methodology and analysis are more important than where the study was conducted. If the agency could only act after nationwide studies had been conducted, it would be unable to act or to respond promptly, even in response to significant public health problems or emergencies.

(80) Several comments questioned the evidence supporting the proposed restriction on self-service displays. The comments stated that FDA had no evidence to support the assertion that removing self-service displays will increase the likelihood of retail clerks requesting proof of age. One comment stated that the one document cited by FDA (which compared smoking practices in five California counties before and after the institution of ordinances prohibiting self-service merchandising)<sup>70</sup> cannot be used to justify a rule with nationwide application because the document, which the comment correctly identified as a "position paper" rather than a study, did not: (a) Indicate whether the ordinances contained other provisions that would have led to enhanced compliance with minimum age laws; and (b) disclose whether retailers were told of the compliance testing operation before or after the fact, such that, had the retailers known, they would have been more vigilant in ensuring

<sup>70</sup> Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales," Stop Tobacco Access for Minors Project (STAMP), North Bay Health Resources Center, November 3, 1994.

compliance regardless of how their products were displayed. This comment further asserted that the act of adopting the ordinances, and the penalties they contained, may have made retailers more vigilant in ensuring compliance with minimum age laws than the restrictions in the ordinances themselves. Finally, the comment stated that the document was not a controlled study and that there was no indication that it was not biased, was subjected to peer review, or was even published in a scientific journal. The comment stated that the document would not be acceptable to FDA if it had been submitted as proof of a product's effectiveness.

Another comment echoed criticism of the document, stating that factors besides the restriction on self-service displays could have reduced tobacco use by young people and so the document does not support a prohibition against self-service displays.

FDA acknowledges that the document omitted details regarding the author's methodology and the ordinances in the 5 California counties and the 24 cities covered in the document. The agency disagrees, however, with the comments' assertion that factors other than the restriction on self-service displays or other features of the ordinances may have been principally responsible for decreasing tobacco use among young people. Such comments overlook the document's statement that the ordinances were to "prohibit self-service merchandising (display and sale) of tobacco products and point-of-sale tobacco promotional products and require only vendor-assisted sales of tobacco products and point-of-sale tobacco promotional products in retail stores."<sup>71</sup> This statement suggests that the ordinances focused on restricting self-service displays (or merchandisers) and point-of-sale promotional products rather than other activities.

Other criticisms of the document are inappropriate as well. For example, the comment claimed that other provisions in the ordinances or other factors may have contributed to the decline in tobacco use in young people so that a restriction on self-service displays, alone, may not have been a significant factor in reducing tobacco use among young people. This criticism, however, overlooks the fact that the rule's restriction on self-service displays is also complemented by other provisions (such as requiring retailers to verify age and prohibiting distribution of free

samples) that will, both individually and collectively, reduce young people's access to cigarettes and smokeless tobacco.

Similarly, FDA does not agree that the document is flawed because retailers were not informed of the compliance testing operation before it was conducted. Alerting a retailer to an upcoming compliance test would bias any results because the retailer would alter its behavior in order to "pass" the test.

Additionally, in drafting the 1995 proposed rule, FDA used the best evidence available to it. The comments did not provide any studies to contradict the cited document, and while some criticisms of the document may be valid, such criticisms do not require the agency to revoke the provision entirely. The document was not FDA's sole basis for proposing to restrict self-service displays. The preamble to the 1995 proposed rule indicated that such a restriction would also reduce shoplifting, eliminate the "message" that displays send to young people, and increase interaction between retailers and their customers. These other justifications, and the comments pertaining to them, are discussed in greater detail in this document.

(81) Other comments objected to a prohibition on self-service displays because, according to these comments, the rule did not impose any sanctions on young people or contain any provisions that would modify a young person's behavior so that he or she would not shoplift. Some comments suggested that, instead of restricting the use of self-service displays, shoplifters should be prosecuted, but these same comments also declared that State or local government authorities usually decline to prosecute young shoplifters.

As stated earlier, it would be inappropriate for FDA to amend the rule to impose penalties on young people who purchase or possess cigarettes or smokeless tobacco. The main focus of the act is on the introduction, shipment, holding and sale of goods in interstate commerce. Thus, whether young people should be prosecuted for shoplifting, and the penalty for shoplifting are appropriately matters for State or local law.

(82) Several comments challenged the statement in the preamble to the 1995 proposed rule that removing self-service displays would reinforce the message to children that tobacco products are not as acceptable as candy or potato chips. The comments said that young people

know that tobacco products are not like candy or potato chips and that there is no evidence to show that the statement is true. A small number of comments added that FDA's rationale would force retailers to remove other "unhealthy" products (such as products containing fat or cholesterol) from displays.

In contrast, a few comments agreed that self-service displays for cigarettes and smokeless tobacco convey an implied message that these products are acceptable. One comment from a local government reported that young people often see tobacco products as being socially acceptable (or less harmful to health) because they are openly displayed. The comment noted that the local jurisdiction had restricted displays to being within 20 feet of the checkout counter and in a direct line of sight, but expressed regret that it had not eliminated displays altogether. Other comments noted that many retailers display cigarettes next to candy, baseball cards, and other items that appeal to children and adolescents. These comments concluded that it is necessary to eliminate self-service displays so that young children do not associate cigarettes with other products that they find amusing or that adults give to children and adolescents as treats.

The IOM Report advanced the theory that young people see self-service displays as an implied message regarding the acceptability or safety of cigarettes and smokeless tobacco. The IOM report represents the informed decisions, opinions, and recommendations of a body of experts, and so, with respect to this issue, the agency disagrees with those comments that would have FDA dismiss the IOM's opinion.

FDA also disagrees with those comments arguing that the agency would have to eliminate self-service displays for potato chips, candy, and other supposedly "unhealthy" products. These food products do not present the same range or magnitude of adverse health effects or effects on the body to warrant tighter restrictions on their sale, distribution, or use.

(83) Several comments challenged FDA's claim that removing self-service displays would increase direct interaction between sales clerks and underage consumers. The comments asserted that removing self-service displays will not prompt sales clerks to check for proof of age and that FDA had no evidence to support this proposition. Other comments opposed any restriction on self-service displays

<sup>71</sup> *Id.*, p. 3.

because, they claimed, retail clerks, rather than self-service displays, are responsible for sales to young people. If retail clerks consistently demanded proof of age, these comments would permit self-service displays to be used.

Other comments asserted that FDA has no reasonable basis to assume that clerks will check for proof of age when clerks already ignore State laws.

In contrast, a few comments agreed that eliminating self-service displays would increase interaction between clerks and underage consumers or deter young people from attempting to purchase cigarettes or smokeless tobacco. One comment from a local board of health stated that it eliminated self-service displays because its evidence indicated that young people in the locality are less likely to purchase cigarettes if they have to request them from retail clerks. Another comment reflected on the author's own experience as a child when she would purchase cigarettes and said it is easy to grab a cigarette package, leave money on the counter, and simply leave a store before the sales clerk can react.

Section 897.14(b)(1) requires retailers to verify that persons purchasing cigarettes or smokeless tobacco are not under the age of 18. This provision, in conjunction with the prohibition against sales to anyone under 18 in § 897.14(a), the restriction on self-service displays in § 897.16(c), the sanctions that are available under the act, and the likelihood that State agencies will devote more attention to illegal sales to young people as a result of section 1926 of the PHS Act should increase the probability that retailers will verify the age of prospective purchasers.

Yet logically, removing self-service displays should increase interaction between retailers and potential consumers because the retailer, under this rule, must physically hand the product to the consumer. While this action probably will take little time (the preamble to the 1995 proposed rule and to this final rule estimate that the elimination of self-service displays would require 10 seconds of additional labor time for many retail transactions), nevertheless it increases the interaction between the retailer and potential customers. Furthermore, by restricting self-service displays, the rule eliminates a young person's ability to take a package of cigarettes or smokeless tobacco, leave money on the counter, and leave the retailer's premises without having to provide proof of age.

(84) Many comments opposed any restriction on self-service displays

because they said eliminating self-service displays would adversely affect adult consumers or would be "inconvenient" because adults would not be able to purchase products quickly; see, handle, or choose products; or obtain information about a product or a special promotion. A few comments asserted, without any supporting evidence, that self-service displays are not or cannot be used by young people, and, therefore, should not be regulated.

Conversely, one comment supporting the provision recommended that FDA clarify or modify the term "self-service displays" to distinguish self-service sales or merchandisers from advertising displays.

The comments opposing the rule misinterpreted how it would apply. The final rule prohibits self-service displays from being in facilities that are accessible to young people. Eliminating self-service displays from such facilities simply means that a consumer will not be able to take physical possession of a product without the retailer's assistance. Any inconvenience to an adult should be slight. For example, it is extremely unlikely that adults will suffer undue hardship or wait an unreasonable amount of time if they must ask a retail clerk to hand a product to them. Moreover, the provision does not prevent adults from seeing or choosing a product or from seeing or receiving information about a product; products would remain visible, but they would be behind a counter or in an area accessible only to the retailer.

Deleting self-service displays from the rule because adults wish to avoid contact with clerks would be inappropriate as well. As a practical matter, adults who use self-service displays would not be able to avoid all contact with a retailer because they presumably still interact with the retailer when they pay for the product. An important component of these regulations is to eliminate those modes of sale used by young people that do not require them to show proof of age or otherwise do not challenge a young person to show that he or she is legally entitled to purchase the product.

FDA does agree, however, that the rule should be clarified so that the reference to displays in § 897.16(c) is understood to cover self-service sales or merchandisers rather than advertising displays that contain no products and has amended the rule accordingly. However, advertising displays are restricted under the advertising provisions in this rule.

(85) The preamble to the 1995 proposed rule expressed a belief that retailers, in order to comply with a prohibition on self-service displays, could move displays behind a retail counter or create an area that would be accessed only by the retailer's employees.

Many comments rejected this notion, claiming that, due to space constraints, many retailers would be unable to move displays behind a counter and would be obliged to build areas where access would be controlled. The comments said such construction and remodeling could be expensive and could force some retailers to scale back their tobacco sales or abandon them completely; such actions would lead to decreased sales by the retailer and trigger reductions in staff and in State or local Government tax revenues.

One comment estimated that, for convenience stores, the average remodeling cost would be as high as \$7,000 per store and noted that tobacco purchases account for 28 percent of convenience store sales. So, instead of eliminating self-service displays, some comments advocated alternative approaches. The alternatives included attaching electronic article surveillance tags to products (although the comment suggesting this alternative conceded that new technology or assistance at the manufacturer's level would be needed); "source tagging," where random packages contain an electronic tag so that would-be shoplifters would not know which packages were tagged and, as a result, would be less inclined to shoplift products; and requiring displays to be within a certain distance of a cash register or the cashier's line of sight, supplemented by posting signs against underage sales and by training sales clerks. "Source tagging" would require manufacturers, rather than retailers, to insert tags into packages.

The alternatives identified by the comments appear to be less effective or less practical than removing self-service displays from places that are accessible to young people. For example, surveillance tags and, to a lesser extent, "source tagging" might deter shoplifting, but this would require all manufacturers to agree to place such tags in their products and would require retailers to install machines or gates to detect those tags. More importantly, comments from manufacturers did not address the creation or use of such tags. A "line-of-sight" or restricted-placement alternative (requiring a display to be within a certain distance of a retail employee) would require no changes by

manufacturers and few changes by retailers, yet the preamble to the 1995 proposed rule cited studies where similar requirements for vending machines failed to prevent illegal sales to young people (60 FR 41314 at 41325). Employees might also be distracted or blocked from seeing the displays, thereby reducing the effectiveness of any "line-of-sight" or restricted placement alternative. Furthermore, the alternatives would fail to eliminate the implied message that self-service displays send regarding the acceptability or safety of these products. Because FDA is unaware of any effective alternative, the agency declines to amend the rule as suggested by the comments.

FDA has, however, amended the rule to permit self-service displays (merchandisers only) in facilities that are inaccessible to people under 18 at all times. The agency made this change in response to comments stating that some facilities are inaccessible to young people and so certain requirements, such as restrictions against vending machines and self-service displays, should not apply. This exception is subject to the same restrictions as the exception on vending machine sales.

(86) Many comments, particularly from retailers, opposed eliminating self-service displays, stating that they derive a significant portion of their revenue from displays and slotting fees provided by manufacturers. Several cited figures that were in the hundreds of thousands of dollars. The comments generally stated that eliminating self-service displays would decrease or eliminate a significant portion of their revenue and, according to some, lead to layoffs or prevent them from hiring young people.

Similarly, FDA received a few comments from firms that manufacture or sell displays. These comments stated that the firms would lose significant amounts of revenue or would be forced out of business if self-service displays were eliminated.

A few comments, however, disputed whether retailers would lose slotting fees. One comment explained that manufacturers would continue to pay fees to ensure that their products would be placed in strategic locations behind the counter, while another comment noted that many retailers in a northern California region where self-service displays were eliminated did not lose slotting fees.

The agency declines to amend the rule because of the possible loss of slotting fees or other revenue from manufacturers. The theoretical loss of

fees that are, at best, tangential to the sale of these products is an inappropriate basis for determining whether this provision denies young people's access to these products effectively. Furthermore, FDA appreciates that such fees may be important to certain retailers, but, as stated earlier, the agency has no reason to conclude that all manufacturers will discontinue those fees because of this rule. The preamble to the 1995 proposed rule (see 60 FR 41314 at 41369) and one comment cited experience in California to show that retailers might not suffer significant economic losses if self-service displays are removed.

FDA reiterates that removing self-service displays from places that are accessible to young people does not mean that cigarettes and smokeless tobacco must be hidden from public view. It simply means that retailers will be required to hand these products to consumers. Presumably, if the products are moved behind the counter, manufacturers still have an incentive to ensure that their products are strategically placed in order to attract adult consumers.

(87) Several comments objected to a restriction on self-service displays, claiming that retailers have a "right" to advertise and sell products in their own establishments in any manner they select.

As mentioned in section IV.B. of this document earlier, section 520(e) of the act states, in part, that the agency may issue regulations to establish conditions on the sale, distribution, or use of a restricted device. Restrictions on cigarette and smokeless tobacco sales are appropriate given the potential adverse health effects caused by or associated with the use of these products and their accessibility and appeal to young people.

(88) A few comments said that eliminating self-service displays will make it difficult or impossible for marginal brands of cigarettes or smokeless tobacco to compete against established brands.

FDA reiterates that eliminating self-service displays from places that are accessible to young people does not mean that the products must be hidden from view; it simply means that consumers will not be able to take physical possession of the product without the retailer's assistance. Consequently, all products will face the same constraints, insofar as retailer space is concerned.

(89) Many comments would delete a prohibition against self service displays

because, according to these comments, the prohibition would be ineffective. These comments stated that self-service displays do not entice young people to smoke, do not increase consumption of tobacco products, or are only used where retailers check the consumer's age. Others stated that young people would get the products anyway, so there was no need to prohibit the use of self-service displays.

The preamble to the 1995 proposed rule stated, among other things, that young people shoplift products from displays (60 FR 41314 at 41325). Additionally, the preamble to the 1995 proposed rule indicated that young people will adjust or shift their purchasing behavior as certain avenues of obtaining these products are eliminated. (See 60 FR 41314 at 41325 (citing different vending machine use rates depending on the access restrictions used in the jurisdiction).) Given this evidence, it is reasonable to assume that, as young people are precluded from purchasing these products, they may be inclined to acquire them by theft and other means. Thus, when properly framed, the issue is not whether displays entice young people to smoke or to use smokeless tobacco (which FDA did not advance as the principal justification for the rule), but whether the agency should eliminate self-service displays as an avenue that young people use to obtain these products. The agency concludes that self service displays must be eliminated from places that are accessible to young people as part of the general restriction against impersonal modes of sale.

(90) Several comments opposed elimination of self-service displays because they claimed that retailers would be forced to hire additional staff. These comments contrasted sharply with the majority of comments from retailers who predicted that the loss of self-service displays would compel them to lay off staff. One comment explained that a self-service display frees the retailer's staff to perform other tasks. The other asserted that the rule would compel retailers to hire additional staff in order to sell these products and that this would result in an "unfunded mandate" in violation of the Unfunded Mandates Reform Act.

The preambles to the 1995 proposed rule and to this final rule estimate that eliminating self-service displays would require 10 seconds of additional labor time for many retail transactions involving cigarette cartons (60 FR 41314 at 41367). The "Analysis of Impacts"

discussion in section XV. of this document places the labor cost for this time at approximately 2.6 cents per carton. Thus, for a retailer to be compelled to hire additional staff to compensate for the loss of self-service displays, cigarette and smokeless tobacco product purchases would have to account for a substantial number of transactions. Some retailers may indeed feel that they need to hire additional staff, but the agency believes that the rule's benefits—reducing young people's access to cigarettes and smokeless tobacco nationwide—outweigh the hiring and accompanying economic burdens that might be imposed on some retailers. Moreover, because the final rule permits self-service displays (merchandisers only) in facilities that are inaccessible to under 18 people at all times, the final rule's impact on some retailers may be reduced.

FDA also disagrees with the comment claiming that the agency violated the Unfunded Mandates Reform Act. The preamble to the 1995 proposed rule contained a discussion of the Unfunded Mandates Reform Act as well as the estimated added labor costs in the "Analysis of Impacts" (60 FR 41314 at 41367 and 41359 through 41372).

(91) One comment disputed FDA's estimate that eliminating self-service would result in 10 seconds of additional labor time for most retail transactions. The comment, however, did not provide any estimate of the time that would be required.

The agency did not receive any data to suggest that the additional labor time would be greater or less than 10 seconds. While some transactions may take more than 10 seconds, the agency believes that the additional labor time will be so negligible that it will not be a significant burden on the retailer.

c. *Mail-order sales and mail-order redemption of coupons.*—i. *Mail-order sales.* Proposed § 897.16(c) would also have prohibited the use of mail-order sales and mail-order redemption of coupons. The preamble to the 1995 proposed rule stated that mail-order sales and mail-order redemption of coupons do not involve a face-to-face transaction that would enable verification of the consumer's age.

The agency received thousands of comments on the proposed restriction against the mail-order sale of cigarettes and smokeless tobacco. Comments supporting the proposed restriction noted that it would make cigarettes and smokeless tobacco more difficult for young people to obtain. Specifically,

comments stated that "mail-order sales should be prohibited since the seller has obvious difficulties verifying the age of the purchaser in selling where there is no face-to-face encounter." A comment from 26 State attorneys general stated that "ending distribution of tobacco by mail-order \* \* \* will greatly assist our efforts to enforce compliance with our state laws." As a result of some comments discussed in detail below, however, the final rule permits mail-order sales, except for redemption of coupons and free samples.

(92) The agency received hundreds of comments opposing the proposed restriction against mail-order sales. Many comments were submitted by older smokers (senior citizens, retirees on fixed incomes, etc.) who identified themselves as pipe tobacco smokers who purchased tobacco products through the mail; most individuals appeared to be clients from one tobacco product supply house in Tennessee. These comments stated that young people do not smoke pipe tobacco and added that they would like to continue to purchase their pipe tobacco through the mail.

The agency believes that the comments misinterpreted the 1995 proposed rule. The preamble to the 1995 proposed rule stated that the rule did not apply to pipe tobacco or to cigars because FDA has no evidence demonstrating that pipe tobacco and cigars are drug delivery devices under the act or that young people use such products to any significant degree (60 FR 41314 at 41322).

(93) One comment asserted that the proposed mail-order provision is unauthorized and contrary to law. According to the comment, neither section 520 of the act nor any other provision of the act gives FDA the authority to declare matter unmailable. The comment explained that, under the Prescription Drug Marketing Act (PDMA), prescription drug samples may be sent through the mail to those authorized by law to obtain them. Furthermore, the comment argued, Congress has specifically determined and legislated what products should not be sent through the mail (39 U.S.C. 3001(f) and (g) (Federal statute on "nonmailable matter")).

The agency disagrees with the comment. Section 520(e) of the act expressly authorizes the agency to issue regulations pertaining to the sale, distribution, or use of a restricted device. Restrictions on the sale or distribution of such a device through

the mail are clearly within the scope of FDA's authority under that section.

Additionally, FDA does not agree that the PDMA or 39 U.S.C. 3001 prevents the agency from acting on mail-orders. The PDMA's mail-order restrictions represented a congressional response to a specific problem, namely the diversion of adulterated prescription drug products (including drug samples) into illegal markets. Here, the products in question are devices rather than prescription drugs, and the rule does not purport to address the diversion of adulterated cigarettes or smokeless tobacco or samples of those products.

Similarly, the Postal Service provision (39 U.S.C. 3001) on "nonmailable matter" does not preclude FDA from issuing regulations pertaining to the distribution of a regulated device. The provision simply states that certain items or types of items are nonmailable and directs the United States Postal Service (USPS), in certain situations, to issue regulations (such as regulations pertaining to fragrance advertising samples). FDA interprets 39 U.S.C. 3001, therefore, as establishing certain "nonmailable" items for USPS purposes rather than precluding FDA from regulating the sale and distribution of a device pursuant to its device authority. Nevertheless, as discussed in comment 94 below, FDA has amended the rule to permit mail order sales, so the issue of the USPS restrictions on nonmailable matter is moot.

(94) The agency received many comments from individuals who contended that the proposed mail-order restriction is unwarranted because the agency cited no studies to demonstrate that young people actually use the mail to obtain cigarettes. One comment noted that IOM acknowledges that "the extent of mail-order purchase of tobacco products by minors is not known." According to the comment, the mail-order restriction must be based on actual evidence that a substantial number of young people use the mail to purchase cigarettes and not based on "theoretical purchasability."

Other comments stated that young people do not obtain cigarettes through the mail because they do not possess checks or credit cards to effectuate mail-order purchases. In addition, the comments questioned whether young people are patient enough to wait several weeks to obtain tobacco products. A few comments, including a comment from a mail-order firm, contended that mail-order purchases would be too expensive for young people, either because of the cost or the

minimum order sizes (which, according to one comment, usually consists of several pounds of tobacco). These comments opposed the proposed mail-order restriction on the basis that it would not effectively reduce young people's access to tobacco products and would instead eliminate an adult's access to entirely legal tobacco products.

Other comments from firms with a significant mail-order business stated that the elimination of mail-order sales would force the firms to terminate staff or go out of business.

The agency also received many comments from adults opposing the proposed mail-order restriction. These comments stated that because mail-order sales are highly preferable to purchases in retail stores the products sold through the mail are unavailable in stores or are less expensive than those sold in stores. Other comments (including one from a prison inmate) said that because mail-order sales serve those in rural or isolated areas, eliminating mail-order sales would eliminate the principal or sole source of tobacco for those adults.

After carefully reviewing the comments, the agency has decided to delete mail-order sales from § 897.16. The restriction was intended to preclude young people from having easy access to cigarettes and smokeless tobacco. However, there is inadequate evidence demonstrating that young people use mail-order sales to any significant degree. This lack of evidence may indicate that it is not relatively easy for young people to purchase cigarettes and smokeless tobacco through the mail.

FDA also considered the impact of the proposed mail-order restriction on adults. The agency does not intend to unreasonably interfere with an adult's ability to obtain legally his or her preferred tobacco products.

Consequently, FDA has amended § 897.16(c) to allow mail-order sales of cigarettes and smokeless tobacco. The agency emphasizes, however, that the final rule retains the restrictions against the redemption of coupons and distribution of free samples through the mail. This amendment is consistent with the IOM Report which recommended a suitably limited Federal ban on the distribution of tobacco products through the mail as part of a long-term access strategy and, at a minimum, restrictions against the mail-order redemption of coupons and the

distribution of free samples through the mail.<sup>72</sup>

FDA remains concerned, however, that young people may turn to mail-order sales as the rule's restrictions against other forms of access (such as vending machines and retail stores) become effective. Accordingly, FDA strongly advises mail-order firms to take appropriate steps to prevent sales to young people and reminds mail-order firms that § 897.14(a) prohibits the sale of cigarettes and smokeless tobacco to anyone under age 18. The agency will monitor the sales of mail-order tobacco products, and if FDA determines that young people are obtaining cigarettes or smokeless tobacco through the mail, the agency will take appropriate action to address the situation.

(95) Several comments criticized the agency for failing to consider less restrictive alternatives. The comments noted that tobacco mail-order houses require payment by check or credit card. Other comments would amend the rule to require firms to maintain records evidencing compliance with proof of age requirements. Another comment suggested a requirement for photocopies of photographic identification cards, such as an identification with a drivers license number, for mail-order transactions.

As stated previously, FDA has amended the final rule to permit mail-order sales, but will monitor such sales to ensure that young people do not obtain cigarettes or smokeless tobacco through the mail. The agency, therefore, strongly advises firms to take appropriate measures to prevent sales to young people.

(96) Several comments expressed concern about the financial well being of the USPS. These comments predicted that the USPS would lose income if tobacco products could no longer be sent by mail. The comments predicted that the USPS would be forced to raise postal rates to compensate, thus affecting product users and nonusers alike.

As stated previously, the agency has amended the rule to permit mail-order sales to continue. However, FDA notes that speculative or theoretical impacts on the USPS are not an appropriate basis for determining how or whether to regulate a restricted device under the act.

(97) One comment representing the concerns of specialty tobacco products noted that 90 percent of its manufacturer-distributor-retailer

distribution system uses the mail or other commercial carriers. This comment requested that FDA clarify that the proposed restriction on mail-order sales pertained to mail-order sales to the ultimate user rather than to inter-company transfers.

Proposed § 897.16(c) was intended to address sales and distributions to consumers. Transactions and shipments between manufacturers, distributors, and retailers, therefore, are not subject to the restrictions on mail-order sales of cigarettes and smokeless tobacco. However, because the final rule permits mail-order sales, there is no need to amend the rule to clarify this point.

(98) One comment supported the restriction against mail-order sales in part because, the comment claimed, such sales permit the purchaser to avoid taxes on these products (by purchasing the products from firms in States with lower taxes). The comment also stated that eliminating these sales would help Canadians because American mail-order firms are not subject to high Canadian taxes and can sell comparatively lower-cost cigarettes in Canada. The comment said this practice increases cigarette consumption in Canada and undermines the health benefits resulting from high Canadian taxes.

The issues raised by the comments are beyond the scope of this rule and FDA's authority.

#### ii. *Mail-order redemption of coupons.*

Proposed § 897.16(c) would have prohibited mail-order redemption of coupons. The preamble to the 1995 proposed rule addressed mail-order redemption of coupons in conjunction with mail-order sales, and the restriction against mail-order redemption of coupons was meant to apply only to coupons that a prospective purchaser would send through the mail (regardless of whether the prospective purchaser used the USPS or a private carrier) to a firm to obtain cigarettes or smokeless tobacco.

(99) Most comments on this issue mistakenly assumed that FDA was proposing to ban all direct mail coupons. These comments contended that direct mail coupons are redeemed during face-to-face transactions at larger retail establishments such as grocery stores. For the most part, these comments suggested that young people do not routinely use coupons to purchase tobacco products, noting that the smaller, convenience stores where young people frequently obtain cigarettes and smokeless tobacco often do not accept coupons.

<sup>72</sup> IOM Report, pp. 108, 225-226.



In contrast, FDA also received several comments supporting the proposal to eliminate mail-order redemption of cigarette and smokeless tobacco coupons. For example, the attorney general for a populous northeastern State commented that "[i]n another operation conducted by my office earlier this year, 30 minors mailed in coupons to obtain free samples of smokeless tobacco products from United States Tobacco Company. Virtually all of the minors were provided with such free samples."

Proposed § 897.16(c)'s reference to mail-order redemption of coupons was directed at the redemption of coupons through the mail. The provision was not intended to prevent adults from redeeming coupons at a point of sale or from receiving coupons through the mail. FDA based this provision on the IOM Report which, among other things, noted that value added promotions, including coupons, constituted the largest market expenditure by the tobacco industry in 1991, that coupons are accessible to young people through direct mail campaigns, and that price-sensitive young people are attracted to such schemes or may be increasingly attracted to such schemes as their other sources of tobacco products are restricted.<sup>73</sup>

Comments supporting this provision confirmed the need for prohibiting mail-order redemption of coupons. These comments reported incidents where one or more young people obtained several packages of cigarettes or smokeless tobacco by sending in coupons (usually for free samples). Consequently, the final rule retains the restriction against mail-order redemption of coupons. FDA adds that, for purposes of this subpart, "mail" is not confined to USPS delivery but includes items shipped through private carriers.

d. *Free samples.* Proposed § 897.16(d) would have prohibited manufacturers, distributors, and retailers from distributing or causing to be distributed any free samples of cigarettes or smokeless tobacco. The agency proposed this restriction because free samples are often distributed at "mass intercept locations," such as street corners and shopping malls, and at events such as festivals, concerts, and games. The preamble to the 1995 proposed rule stated that free samples represent a "risk-free and cost-free" way for young people to obtain and possibly use cigarettes or smokeless tobacco and that, when free samples are distributed

at cultural or social events, peer pressure may lead some young people to accept and to use the free samples (60 FR 41314 at 41326).

The preamble to the 1995 proposed rule also cited surveys and reports demonstrating that young people, including elementary school children, can obtain free samples easily. Young people were able to obtain free samples despite industry-developed, voluntary codes that supposedly restrict distribution of free samples to underage persons. The agency cited the IOM Report which suggested that distribution of free samples to young people occurs because the samplers are often placed in crowded places and operating under time constraints that may limit their ability to request proof of age. The IOM Report added that the samplers are usually young themselves and, as a result, "may lack the psychological wherewithal to request proof of age and refuse solicitations from those in their own peer group" (60 FR 41314 at 41326).

(100) FDA received a few comments that opposed any restrictions on free samples, claiming that eliminating free samples would violate the "rights" of adult consumers, reduce choices for adults, or deprive adults of the opportunity to save money.

In contrast, many comments supported proposed § 897.16(d), including several that opposed the remainder of the rule but expressly supported a prohibition on the distribution of free samples. Several comments stated that young people can easily obtain free samples; a few comments, including two from 12-year old students, mentioned that their classmates were able to receive free samples or reported that young people were able to receive free samples without being asked to show proof of age. One comment even reported that a young person was able to receive 4 cigarette packages through the mail as free samples, while another claimed to have seen 12 cans of smokeless tobacco being given to teenagers.

Another comment supported the provision, based on the author's own experience when he was 15 years old; a neighborhood grocer gave him and his friends free cigarettes "until we were hooked" and then the grocer "had steady paying customers." Other comments supported this provision for the same reason that they supported eliminating single-cigarette sales and establishing a minimum package size: Such items encourage young people to experiment with cigarettes or they

represent, as a consortium of State attorneys general said, "sales and marketing practices that provide young people with the easiest access to tobacco."

The agency agrees that § 897.16(d) will affect adults by effectively requiring them to purchase cigarettes and smokeless tobacco rather than receive them free of charge. However, the comments opposing the elimination of free samples did not offer any suggestions as to how to prevent free samples from reaching young people. In view of the evidence showing that young people obtain free samples despite any industry-imposed restrictions or (in the case of at least one comment) that they obtain free cigarettes from a retailer, the agency concludes that the benefits of eliminating free samples as a source for young people outweigh the inconvenience to adults.

FDA also disagrees with the comments asserting that eliminating free samples adversely affects an adult's ability to choose products or otherwise violates adult "rights." The final rule does not alter an adult's ability to select or purchase cigarettes and smokeless tobacco.

(101) Several comments submitted by manufacturers or their representatives opposed the prohibition against the distribution of free samples, stating that manufacturers use free samples to introduce new products, to encourage adult consumers to switch brands, or to thank their adult consumers for their patronage. Others comments added that free samples do not encourage young people to smoke or to use smokeless tobacco or that eliminating free samples would not reduce cigarette or smokeless tobacco use by young people.

The agency is eliminating free samples because they are an inexpensive and easily accessible source of these products to young people and, when distributed at cultural or social events, may increase social pressure on young people to accept and use free samples (60 FR 41314 at 41326). The preamble to the 1995 proposed rule cited studies and reports to support the agency's views; those documents contradict the comments' claim that free samples do not encourage young people to use these products or affect use by young people.

As for the rule's impact on manufacturers' practices, the public health benefits from eliminating free samples as an avenue that young people use to obtain cigarettes and smokeless tobacco outweigh any inconvenience to

<sup>73</sup> *Id.*

manufacturers who will be obliged to devise new ways to introduce new products, to get adults to switch brands, or to thank adult consumers. FDA believes that manufacturers will be able to devise new approaches to promote new brands or to attract new adult customers that comply with these regulations.

(102) One comment expressed strong opposition to proposed § 897.16(d). The comment argued that FDA lacked authority to ban free samples, especially when the agency would permit sales to adults, and that the agency had no evidence to support a ban on free samples. The comment added that the act did not extend to device samples and argued that Congress knows how to give FDA authority over samples, as evidenced by sampling provisions in the PDMA. The comment further stated that the term "sample" was over-broad because it was not limited to products distributed in public settings for promotional purposes; thus, the comment continued, any complimentary gift could be a "sample" under proposed § 897.16(d).

FDA disagrees with the comment. Section 520(e) of the act states that the agency may "require that a device be restricted to sale, distribution, or use \* \* \* upon such other conditions as the Secretary may prescribe by \* \* \* regulation." Restricting free samples is clearly a restriction on the product's distribution.

As for the PDMA, the comment's claim that the PDMA's sampling restrictions shows that Congress has not authorized FDA to regulate device samples (due to the absence of express language on device samples) fails to take into account the fact that FDA's restricted device authority is broader than its prescription drug authority. Also, the comment fails to take into account the reasons behind enactment of PDMA. PDMA was enacted not to give FDA new authority over prescription drug samples, but to curtail the illegal diversion of drugs, including samples, into the market. (See S. Rept. 100-303, 100th Cong., 2d sess. 2-3 (1988).) Before PDMA was enacted, FDA regulated prescription drug samples in the same manner as prescription drug products. Thus, PDMA is not intended to give FDA new authority over samples; instead, it reflects a congressional decision to give FDA a comprehensive and explicit set of new authority to prevent illegal diversions of prescription drug products, including the diversion of prescription drug samples to illegal markets.

FDA also declines to amend the rule to allow "gifts." Allowing "gifts" would enable parties to declare that their free samples were now "gifts" and therefore outside the rule and could lead to disputes as to whether an item was a prohibited "sample" or an allowable "gift." However, the agency will exercise discretion in interpreting and enforcing this rule. For example, a manufacturer's employee who sends cigarettes or smokeless tobacco to an adult relative to celebrate a birthday would not be subject to regulatory action under the free sample restriction in § 897.16(c).

(103) One comment stated that, notwithstanding the preamble to the 1995 proposed rule, FDA has no evidence to support a restriction on the distribution of free samples. The comment stated that the rule overestimated the prevalence of sample activities and that cigarette sampling accounted for only 0.7 percent of the total spent on cigarette advertising and promotion in 1993. The comment also said that FDA relied on an outdated version of the cigarette manufacturers' voluntary code. According to the comment, the outdated code prohibited distribution of cigarette samples within two blocks of any "center of youth activities" and "required samplers to demand proof of age in doubtful cases." The revised code adds that "[s]ampling shall not be conducted in or on public streets, sidewalks or parks, except in places that are open only to persons to whom cigarettes lawfully may be sold."

In contrast, two comments cautioned FDA against deferring to a voluntary code or relying on the industry. One comment stated that, in Maine, the industry agreed to submit reports on sampling activities to the State in place of legislation that would have curtailed sampling activities, but the industry discontinued these reports as soon as State authorities stopped sending reminders that the reports were due. Another comment stated that, in Massachusetts, a lawsuit over sampling practices by a smokeless tobacco firm ended in a settlement whereby the firm would require photocopies of identification cards for all mail-in requests for samples. The comment said that the settlement represented an improvement over requiring no proof of age at all, but noted that the firm refused to apply this practice outside the State and that the restriction did not apply to other smokeless tobacco firms. The comment also claimed that firms often agree to restrict sampling activities only after adverse publicity or agree to

restrict sampling activities without setting any measurable performance goals.

FDA disagrees with the comment asserting that the agency has no evidence to support a restriction on free samples. The preamble to the 1995 proposed rule cited several reports and surveys showing that young people, including elementary school children, obtain free samples easily (60 FR 41314 at 41326). The agency also has no assurance that the revised cigarette industry code will be any more effective than earlier versions. Moreover, as mentioned earlier in this document, FDA received comments stating that young people continue to receive free samples of cigarettes and smokeless tobacco. The comments refute the claim that voluntary industry restrictions on sampling preclude the need for FDA regulation of free samples.

Additionally, the rule offers several important advantages over voluntary codes. The rule creates enforceable obligations which, if violated, may subject the manufacturer, distributor, or retailer to sanctions under the act. These sanctions, in turn, create an incentive for regulated parties to adhere to the act and its implementing regulations. A voluntary code also applies only to the parties that accept the code or fall within the same industry; for example, a voluntary manufacturers' code might not extend to distributors or to retailers, or, as the comment recognized, a voluntary cigarette manufacturers' code might differ from a voluntary smokeless tobacco manufacturers' code.

Furthermore, a regulation creates uniform standards and policies for the same product. Those standards apply regardless of whether a firm is a member of a voluntary organization.

Finally, the agency notes that, while the comment said that "only 0.7 percent of the total spent on cigarette advertising and promotion" in 1993 went to cigarette sampling activities, this percentage still translates into a large sum. Cigarette advertising and promotion expenditures, according to the same FTC report cited by the comment, were approximately \$6 billion in 1993. Thus, the seemingly small percentage devoted to cigarette sampling activities, when translated into dollars, represents \$42 million.

(104) Several comments supported the prohibition against the distribution of free samples, but suggested that FDA amend the rule to prevent distribution of cigarettes and smokeless tobacco at prices below their fair market value. One comment would define a product's

fair market value as the average retail price in the region. Another comment would amend § 897.16(d) to prohibit sales or distribution of cigarettes and smokeless tobacco "in return for nominal consideration."

The agency declines to amend the rule as suggested by comments. While the comments have merit, FDA usually has no role in the prices charged for an FDA-regulated product. Additionally, it would be difficult for FDA to monitor fair market values for various products, and disputes would inevitably arise as to whether the "market" should cover a broader or narrower geographic area, the data used to determine the fair market value, and how compliance actions would be affected by fluctuations in the fair market value. Similar disputes would arise regarding "nominal consideration." Furthermore, regardless of the price at which the product is sold, other provisions in this subpart should deter or reduce access by young people.

*e. Restrictions on labeling and advertising.* The agency on its own initiative has added § 897.16(e) as a point of clarification to the final rule. This provision states that "no manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with the restrictions in Subparts C and D \* \* \*." The restrictions on labels, advertising, and labeling in subparts C and D of part 897 are authorized, in part, under section 520(e) of the act and are considered conditions of sale, distribution, and use. Therefore, § 897.16(e) clarifies the statutory obligations of manufacturers, distributors, or retailers under this rule.

## V. Label

In the 1995 proposed rule (60 FR 41314, August 11, 1995), subpart C of part 897 was entitled "Labels and Educational Programs," and contained two provisions. Proposed § 897.24, would have required cigarette or smokeless tobacco packages to contain the appropriate "established name" of the product; the final rule retains that provision and does not make any substantive changes to it. Proposed § 897.29 would have required manufacturers to establish and maintain a national educational program to discourage children from using cigarettes and smokeless tobacco. Based on issues raised by comments, proposed § 897.29 has been deleted from the final rule, and instead, the Food and Drug Administration (FDA) has determined

that issuing notification orders under section 518 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h) would be the most practicable and appropriate means of requiring tobacco manufacturers to inform young people of the unreasonable health risks. Discussion of the comments received regarding this education provision is included in section VII. of this document.

### A. Established Name (§ 897.24)

Proposed § 897.24 would have required that each cigarette or smokeless tobacco product package, carton, box, or container of any kind that is offered for sale, sold, or otherwise distributed bear whichever of the following established names is appropriate: "Cigarettes," "Cigarette Tobacco," "Loose Leaf Chewing Tobacco," "Plug Chewing Tobacco," "Twist Chewing Tobacco," "Moist Snuff," or "Dry Snuff."

The preamble to the 1995 proposed rule explained that this provision was intended to implement section 502(e)(2) of the act (21 U.S.C. 352(e)(2)), which states that a device shall be deemed misbranded if its label fails to display the established name for the device. Section 502(e)(4) of the act, in turn, explains that the "established name" for a device is the applicable official name of the device designated under section 508 of the act (21 U.S.C. 358), the official title in a compendium if the device is recognized in an official compendium but has no official name, or "any common or usual name of such device." In this case, no official names have been designated under section 508 of the act, and no compendium provides an established name for these products. Consequently, § 897.24 proposed designating "cigarettes," "cigarette tobacco," and the common or usual names for smokeless tobacco (such as "moist snuff" or "loose leaf chewing tobacco") as established names for these products.

(1) The agency received few comments on proposed § 897.24. One comment that opposed the provision stated that it was unnecessary and would produce anomalous results. The comment stated that, because cigarettes are already required to be labeled "cigarettes" under regulations adopted by the Bureau of Alcohol, Tobacco and Firearms (BATF) under the Internal Revenue Code (27 CFR 270.215 (1995)), "Cigarettes" is already the common and usual name and, therefore, there is no need to designate an "established name."

The agency has concluded that the BATF requirement does not conflict with the act's requirement that the label bear the established name of these products. The agency recognizes that BATF regulations currently require cigarette packages to include the word "cigarettes" on the package or on a label securely affixed to the package (27 CFR 270.215). For smokeless tobacco and chewing tobacco, BATF regulations require the packages to include the words "snuff" or "chewing tobacco," or alternatively, "Tax Class M" or "Tax Class C," respectively (27 CFR 270.216). These terms also describe the established name, as required in section 502(e) of the act.

Many of the labeling provisions of the act, including section 502(e)(2), are intended to provide important basic information to consumers and others coming in contact with a regulated product. In this case, the act requires that the established or common name be placed on the product's label in a clear way so that it is easily seen and consumers can readily identify the product. Congress provided an exception only for cases where compliance with this provision is "impracticable." If a manufacturer believes that it cannot comply with this provision of the rule, the manufacturer should consult with the agency to determine if it qualifies for an impracticability exception under section 502(e)(2) of the act.

(2) One comment that supported the provision on established name recommended that, in addition to the established names set forth in the 1995 proposed rule, little cigars and tobacco sticks should also be listed as separate products with their own specific established names, "little cigars" and "tobacco sticks" "in keeping with the manner and style of the established names to be used for smokeless tobacco products."

One comment that opposed the provision stated that since proposed § 897.3(a) would define "cigarettes" to include little cigars, the same package of little cigars that must be labeled "small cigars" or "little cigars" (under current BATF regulations, 27 CFR 270.214(c) (1995)), would also have to carry the established name of "cigarettes" under the proposed FDA regulation. The comment argued that such a conflicting labeling requirement is absurd, and would create confusion where none now exists.

The agency has modified the definition of "cigarette" found in proposed § 897.3(a) to exclude little

cigars from the final rule. The agency also advises that, to the best of its knowledge, tobacco sticks currently are not sold in the United States. If tobacco sticks were to be marketed in this country, the agency advises that such products would be subject to premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807, and could be included under the established name of "cigarette tobacco," and therefore do not need to be listed as separate products at this time.

#### B. Package Design

(3) Several comments noted that the 1995 proposed rule did not include any action to eliminate the use of the tobacco product package itself to influence children. A few comments cited a March 1995 Canadian study, which found that package designs affect the ability of teens to associate lifestyle and personality imagery to specific brands and detract from the health message.<sup>74</sup> Another study found that the "badge" value of cigarette packages for youths was decreased when the packages were stripped of their unique characteristics.<sup>75</sup> The comment suggested that the provisions of proposed § 897.30, requiring text only with black text on a white background, should be extended to cigarette packages. One comment pointed out that FDA has the authority to require plain packaging without violating the Federal Cigarette Labeling and Advertising Act (the Cigarette Act), 15 U.S.C. 1334(a), which prohibits additional statements related to smoking and health on cigarette packages.

The agency agrees with the comments that cigarette package design and imagery are powerful tools that increase the appeal of the product, especially to young people. In the preamble to the 1995 proposed rule the agency cited several studies demonstrating that "[i]magery ties the products to a positive visual image" (60 FR 41314 at 41335). Another study showed that "children and adolescents react more positively to advertising with pictures and other depictions than to advertising (or packaging) that contains only print or text" (60 FR 41314 at 41335).

The agency has considered extending the requirements of § 897.30 (text only, black on white background) to the package itself, but believes at this time these measures are not necessary considering the comprehensive nature of the regulatory scheme contained in this rule. Therefore, the agency is not extending the requirements applicable to advertising and labeling to the package itself.

#### C. Ingredient Labeling

The agency specifically requested comments on whether it should implement recommendations from the Ad Hoc Committee of the President's Cancer Panel, which recommended, among other things, that the range of tar, nicotine, and carbon monoxide delivered by each product be communicated to consumers. In addition, the Ad Hoc Committee recommended that smokers be informed of "other hazardous smoke constituents."

(4) The agency received several comments suggesting that tar and nicotine delivery or yield information should be disclosed on product packages in order to assist consumers in making more informed decisions about the use of cigarettes. Some of these comments also suggested that labels list the toxins present in, or delivered from, cigarettes and state their effect, e.g., "known carcinogen."

One comment stated that it cannot be claimed that the ingredients are trade secret information and, therefore, cannot be disclosed, because the tobacco companies voluntarily released a list of ingredients to the public in 1995. The comment noted that, under current case law, only items kept confidential qualify as trade secrets. (See *Kewanee Oil v. Bicron Corp.*, 416 U.S. 470 (1974); *Avtect Systems v. Peiffer*, 21 F.3d 568 (4th. Cir. 1994).) The comment noted further that because companies can and do perform reverse engineering on another company's products, the ingredients are not trade secret. The comment proposed that, at a minimum, FDA should designate a partial list of previously disclosed ingredients and require that the list be included on package labels. Another comment stated that only a reasonable number of ingredients should be listed on the label or in a package insert.

One comment stated that ingredient listing is not barred by the Cigarette Act or by the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Act). (See 15 U.S.C. 1331 *et seq.* and 15 U.S.C. 4401 *et seq.*) These

statutes require the current Surgeon General's warnings on tobacco products and preempt any additional statements relating to smoking or health from being required on cigarette or smokeless tobacco packages. The comment asserted that a list of ingredients is not a statement, and cannot be reasonably construed as a statement relating to smoking and health, because a statement expresses a point of view, whereas an ingredient list does not.

One comment noted that the Cigarette and Smokeless Acts require manufacturers to submit annually to the Department of Health and Human Services (DHHS) a list of ingredients added to tobacco products, and the statutes further require that the lists be treated as confidential commercial or trade secret information. (See 15 U.S.C. 1335(a) and 15 U.S.C. 4403.) The comment stated that the confidentiality provisions in both statutes bind the Secretary of DHHS with respect to trade secrets, but do not restrict FDA's authority to require ingredient listing.

FDA agrees that accurate information about the tar, nicotine, and carbon monoxide delivery from a cigarette to the user would be useful information. FDA is aware of the Federal Trade Commission's (FTC's) recent efforts to develop a system to measure, more accurately than the current test, the tar, nicotine, and carbon monoxide delivered by cigarettes. FTC has announced that it will issue a report of its findings regarding a new test method in the near future. FDA believes that it would be premature to require manufacturers to put any of this information on tobacco product labels before FTC has issued its report and made recommendations on accurately measuring the delivery of tar, nicotine, and carbon monoxide to product users.

With regard to ingredients other than tar, nicotine, and carbon monoxide, the agency agrees that it has authority under the act to require labeling or listing of other substances present or delivered by cigarettes. (See section 502(r) of the act.) The agency notes that there are hundreds of ingredients added to or delivered by cigarettes and smokeless tobacco. Even if the agency were to require listing of only a "reasonable number," current methodologies are not adequate to accurately identify and quantify the added ingredients or the constituents delivered by these products. Moreover, at this time there is not enough data to enable the agency to determine what a "reasonable" number of ingredients would be or to determine which ingredients should be listed and

<sup>74</sup> "When Packages Can Speak: Possible Impacts of Plain and Generic Packaging of Tobacco Products," Health Minister of Canada, March 1995.

<sup>75</sup> Rootman, I., B. R. Flay, and D. Flay, "A Study on Youth Smoking, Plain Packaging Health Warnings, Event Marketing and Price Reductions, Key Findings," A Joint Research Project by University of Toronto, University of Illinois, York University, Ontario Tobacco Research Unit, Addiction Research Foundation, p. 7, 1995.

which should not. Therefore, the agency is not requiring the listing of ingredients in the rule.

As discussed in the preamble to the 1995 proposed rule, cigarettes and smokeless tobacco are subject to various pre-existing requirements in the statute and the regulations. The preamble stated that such "regulations include the general labeling requirements for devices at part 801 (21 CFR part 801) (excluding § 801.62)" (60 FR 41314 at 41352). The parenthetical reference was a typographical error because the 1995 proposed rule would have exempted such products from § 801.61, not § 801.62 (60 FR 41314 at 41342). Section 801.62 states the requirements for "Declaration of net quantity of contents." This provision requires that the label of an over-the-counter device bear a declaration of the net quantity and weight of the contents, e.g., "20 cigarettes." The agency fully expects manufacturers to comply with this provision and, as discussed below, also expects manufacturers to comply with § 801.61.

#### D. Labeling for Intended Use

(5) The agency received comments suggesting that FDA require intended use information on the package label of cigarettes and smokeless tobacco. Proposed § 801.61(d) would have exempted cigarettes and smokeless tobacco from the statement of identity and labeling for intended use requirements of § 801.61. The comments stated that such information informs the public about the product's intended use. One comment supported proposed § 801.61(d).

Based on the comments received, the agency has reconsidered the matter and concluded that it is appropriate to require that this information appear on the label. Consequently, the agency has deleted § 801.61(d) from the final rule.

All over-the-counter devices are required to comply with § 801.61 and bear the "common name of the device followed by an accurate statement of the principal intended action(s) of the device" on the principal display panel of the package. (See § 801.61.) As over-the-counter devices, cigarettes and smokeless tobacco are legally required to comply with this provision.

In the 1995 proposed rule, the agency proposed to exempt these products because "section 801.61 stems, in part, from the Fair Packaging and Labeling Act (FPLA), and [t]obacco products are exempt from the statute's requirements" (60 FR 41314 at 41342). Further evaluation revealed that the

requirements in § 801.61 are also based on FDA labeling authorities including, but not limited to, section 502(a), (c), (e), (f), and (q) of the act, and not the FPLA.

Furthermore, section 1460 of the FPLA contains "Savings provisions" (15 U.S.C. 1460). The provisions state that "Nothing contained in this Act [15 U.S.C. 1451 et. seq.] shall be construed to repeal, invalidate, or supersede \* \* \* (b) the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et. seq.] \* \* \*." Thus, because FDA's assertion of jurisdiction over these products is under its statutory authority under the act, any conflict between the two statutes shall be resolved in favor of the act. (See *Jones v. Rath Packing*, 430 U.S. 519 (1977).) Consequently, section 1459 of the FPLA, which removes tobacco from the definition of "consumer commodity," and thus, removes it from jurisdiction under the FPLA, is superseded by FDA's coverage of these products under the act.

As stated in the preamble to the 1995 proposed rule, manufacturers of cigarette and smokeless tobacco are expected to comply with the general labeling requirements in part 801 (60 FR 41314 at 41352). For purposes of § 801.61, the "common name of the device" is the established name as set forth in § 897.24.

To more accurately reflect the permitted intended use of these products, the agency has modified the statement of intended use set forth in the proposal. The agency proposed that the intended use of these products be described as a "nicotine delivery device." Under this rule, these products may be intended for use only by persons 18 years of age and older. Thus, a more accurate statement of the permitted intended use of these products is "Nicotine Delivery Device For Persons 18 or Older."

Further authority for this requirement stems from section 520(e)(2) of the act (21 U.S.C. 360j(e)(2)). This provision states that: "The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe." The statement of intended use, in essence, incorporates the statement of one of the principal restrictions FDA is imposing on these products.

Accordingly, a provision has been added to § 897.25 that codifies this intended use statement and statement of restrictions for purposes of § 801.61.

#### E. Adequate Directions for Use and Warnings Against Use (Section 502(f) of the act)

(6) A few comments stated that FDA failed to discuss or provide for adequate directions for use, as required in section 502(f) of the act. The comments stated that FDA's silence on this issue is a tacit acknowledgment that the agency cannot have jurisdiction over these products because adequate directions for use cannot be prepared for them.

The agency disagrees with these comments. It does not logically follow that because the agency was silent on this issue, it does not have jurisdiction over tobacco products. In fact, in the preamble to the 1995 proposed rule, the agency cited one of the authorities for the labeling requirements for these products as section 502 of the act.

According to section 502(f) of the act, a device shall be deemed misbranded:

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

For devices, "adequate directions for use" means "directions under which the layman can use a device safely and for the purposes for which it is intended" (§ 801.5). These regulations outline the type of information which, if missing, may lead to a product being deemed to be misbranded. Such information includes conditions, purposes, and uses for which the device is intended; quantity of dose; frequency, duration, time, route or method of administration; or preparation for use (§ 801.5).

The agency acknowledges that it is very difficult to establish adequate directions for use for cigarettes and smokeless tobacco, primarily because of the inherent nature of the products, their addictiveness, the numerous hazards associated with their use, and because the behavior of each user (e.g., the depth of inhalation, the duration of puff, whether the filter holes are covered, and length of time in mouth) determines the amount of tar and nicotine delivered to the user from the device.

Section 502(f) of the act provides for an exemption for adequate directions for use if they are "not necessary for the

protection of the public health." For example, the agency has established exemptions from adequate directions for use where adequate directions for common uses of certain devices are known to the ordinary individual. (See § 801.116.) Tobacco products have a very long history of use in this country, and they are one of the most readily available consumer products on the market today. Consequently, the way in which these products are used is common knowledge. FDA believes that the public health would not be advanced by requiring adequate directions for use. Accordingly, the agency has added a provision to the final rule exempting cigarette and smokeless tobacco from the requirement of having adequate directions for use. Section 801.126, states, "Cigarette and smokeless tobacco as defined in part 897 of this chapter are exempt from section 502(f)(1) of the Federal, Food, Drug, and Cosmetic Act."

The agency has considered the requirement in section 502(f)(2) of the act that the labeling of a medical device must provide "adequate warnings against use \* \* \* by children where its use may be dangerous to health." In the agency's view, the warnings mandated by the Cigarette Act (15 U.S.C. 1333) and the Smokeless Act (15 U.S.C. 4402) satisfy this requirement. Additionally, the Surgeon General's warnings provide information warning against use in persons with certain conditions, i.e., pregnant women. Consequently, cigarettes and smokeless tobacco are not exempt from the statutory requirements under section 502(f)(2) of the act.

#### F. Package Inserts

(7) Several comments stated that FDA should require cigarette and smokeless tobacco packages to contain package inserts that contain health information and information about the chemicals added to cigarettes and smokeless tobacco. One comment stated that FDA has statutory authority to require package inserts under sections 502(a) and (q) and 520(e) of the act. Another comment stated that the agency is not preempted from requiring package inserts because sections 1334(a) and 4406 of the Cigarette Act and the Smokeless Act, respectively, preempt statements related to health "on any package," not *in* any package.

FDA agrees with the comments that it has statutory authority under the act to require package inserts for these products. Under section 502(a) of the act, a device is misbranded if its labeling is false or misleading in any

particular. Section 201 of the act (21 U.S.C. 321), the "Definitions" section of the act, describes the concept of "misleading" in the context of labeling and advertising. Section 201(n) of the act explicitly provides that, in determining whether the labeling of a device is misleading, there shall be taken into account not only representations or suggestions made in the labeling, but also the extent to which the labeling fails to reveal facts that are material in light of such representations or material with respect to the consequences that may result from use of the device under the conditions for use stated in the labeling or under customary or usual conditions of use.

These statutory provisions, combined with section 701(a) of the act (21 U.S.C. 371(a)), authorize FDA to issue a regulation designed to ensure that persons using a medical device will receive information that is material with respect to the consequences that may result from use of the device under its labeled conditions. In the prescription drug context, this interpretation of the act and the agency's authority to require patient labeling for prescription drug products have been upheld. (See *Pharmaceutical Manufacturers Assn. v. FDA*, 484 F.Supp. 1179 (D. Del. 1980) *aff'd per curiam*, 634 F.2d 106 (3rd Cir. 1980).)

Additionally, on several occasions, the agency has required patient package inserts for devices, and has specified either the express language for the patient package insert or the type of information to be included in the patient package insert. These devices include hearing aids (§ 801.420), intrauterine devices (§ 801.427), and menstrual tampons (§ 801.430).

The agency also agrees with the comment that it is not prohibited from requiring patient package inserts due to the preemption clauses in the Cigarette Act and the Smokeless Act. Each of the clauses in these statutes specifically prohibits requirements that statements relating to smoking and health be placed on the package. Package inserts, by nature, are typically found in the package.

Although the agency believes that package inserts for these products are authorized under the act and would provide useful information to users, further evaluation would be needed to determine what specific information a package insert would contain. Therefore, the agency is not requiring them as part of this rule.

## VI. Advertising

### A. Subpart D—Restrictions on Advertising and Labeling of Tobacco Products

Subpart D in part 897 contains the restrictions for advertising and labeling of cigarettes and smokeless tobacco. Subpart D of part 897 in the Food and Drug Administration's (FDA's) August 11, 1995, proposed rule (60 FR 41314) (the 1995 proposed rule) provoked some of the strongest and most passionate comments from both supporters and opponents of the proposed restrictions. Many comments from the tobacco industry, the advertising industry, public interest groups, and individuals expressed major concerns about the legality, constitutionality, and wisdom of the advertising restrictions in general and about the underlying support for individual sections of the 1995 proposed rule. Comments from the largest organization of psychologists in the world, public interest and health groups, individual advertisers, and individuals expressed strong support for the legality and constitutionality of the proposal, provided information supporting various provisions of the proposal, and emphasized the necessity for comprehensive advertising regulations.

The purpose of the advertising regulations is to decrease young people's use of tobacco products by ensuring that the restrictions on access are not undermined by the product appeal that advertising for these products creates for young people. (See *Central Hudson Gas and Electric Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 569 (1980).) Proposed subpart D of part 897 included a range of restrictions that attempted to preserve the informational components of advertising and labeling which can provide useful product information for adult smokers, while eliminating the imagery and color that make advertising appealing and compelling to children and adolescents under 18 years of age.

Briefly, the 1995 proposed rule included four provisions. Section 897.30 would have defined those media in which labeling and advertising for cigarettes or smokeless tobacco may appear. In addition, it would prohibit outdoor advertising within 1,000 feet of elementary and secondary schools and playgrounds. Proposed § 897.32 would limit all advertising to black text on a white background. Advertising in any publication that is read primarily by adults would be permitted to continue to use imagery and color. Further, all

cigarette and smokeless tobacco product advertisements would be required to include the product's established name and intended use, e.g., "Cigarettes—A Nicotine Delivery Device," and cigarette advertisements would be required to include a brief statement, such as "About one out of three kids who become smokers will die from their smoking." Proposed § 897.34 would prohibit the sale and distribution of nontobacco items, contests and games of chance, and sponsored events using any indicia of product identification (e.g., brand name, logo, recognizable pattern of color). Finally, proposed § 897.36 outlined those conditions under which the agency would find the advertising or labeling of any cigarette or smokeless tobacco product to be false or misleading.

In response to comments filed, FDA has modified the proposed regulations. Briefly, some of the more substantive changes include: The definition of adult-oriented publications remains unchanged, but the preamble makes clear that the responsibility will be assigned specifically to the manufacturer, distributor, or retailer of tobacco products that wishes to place advertisements to gather and retain competent and reliable evidence that the readership of the publication meets the criteria for an adult-oriented publication. Moreover, unrestricted advertising, i.e., with color and imagery, may be displayed at facilities described in § 897.16(c)(2)(ii) that may sell tobacco from vending machines and self-service provided that the advertising, e.g., posters and signs, must be displayed so that they are not visible from outside the facility and are affixed to a wall or fixture in the facility.

The revised intended use statement is "Nicotine Delivery Device for Persons 18 or Older," and the agency will not require a brief statement other than the Surgeon General's warnings.

As provided in the 1995 proposed rule, the final rule states that any event sponsored by a manufacturer, distributor, or retailer of tobacco products is to be sponsored only in the corporate name. Teams and entries also may be sponsored but only in the corporate name. The regulation includes a ban on all brand-identified nontobacco items, including those transactions based upon proofs-of-purchase. However, the proposed ban on contests and games has been deleted. Finally, the agency has decided to delete the definition of false or misleading advertising and labeling from this final rule because it is duplicative and

unnecessary in light of the underlying requirements in sections 201(n), 502(a), and 502(q) (21 U.S.C. 321(n), 352(a), and 352(q)) of the Federal Food, Drug, and Cosmetic Act (the act).

Section VI.B. of this document provides a general discussion of the rationale for including significant advertising restrictions in the final regulation, including a discussion in response to comments concerning the theory of advertising and the importance of color and imagery to advertising's appeal, especially for young people. This section also provides a discussion of the effects of advertising on young people, including expert opinion and research evidence provided by the American Psychological Association.

Section VI.C. of this document provides responses to questions raised about the constitutionality of the regulations. Section VI.D. of this document includes a discussion of the evidence that cigarettes and smokeless tobacco advertising plays a direct and material role in young people's decisions to purchase and use these products. This part also explains why restricting tobacco advertising will advance the Federal Government's interest in preventing the use of tobacco products by young people, and provides responses to comments about the evidence. Finally, section VI.E. of this document responds to comments concerning the factual evidence provided by FDA in support of its proposed regulation in a section-by-section format, as well as to comments claiming that each of these sections was not narrowly tailored to minimize the burden on commercial speech.<sup>76</sup>

#### B. The Need for Advertising Restrictions

In the preamble to the proposed 1995 rule, FDA tentatively asserted that a preponderance of the quantitative and qualitative studies of cigarette advertising suggested: (1) A causal

<sup>76</sup> For the purposes of section VI. of this document, the agency will refer to advertising and labeling merely as "advertising." As the agency pointed out in the preamble to the 1995 proposed rule, advertising and labeling often perform the same function: to convey information about the product; to promote consumer awareness, interest, and desire; to change or shape consumer attitudes and images about the product; and/or to promote good will for the product (60 FR 41314 at 41328). Moreover, most court cases involving advertising do not distinguish between the forms of advertising that FDA calls labeling and those referred to as advertising. When there is a need to distinguish between the two forms of promotion, for example, when labeling and advertising are subject to different statutory requirements, this document will make clear what is being discussed.

relationship between tobacco advertising and tobacco use by young people, and (2) a positive effect of stringent advertising measures on smoking rates and on youth tobacco use. In arriving at this tentative finding, FDA relied heavily on the National Academy of Sciences Institute of Medicine's (IOM's) Report entitled *Growing Up Tobacco Free, Preventing Nicotine Addiction in Children and Youths*, Washington, DC 1994 (the IOM Report) and the Department of Health and Human Services' (DHHS') Center for Disease Control and Prevention's (CDC's) Report entitled *Preventing Tobacco Use Among Young People, A Report of the Surgeon General* (1994) (1994 SGR). Both indicated that advertising was an important factor in young people's tobacco use, and that restrictions on advertising must be part of any meaningful approach to reducing smoking and smokeless tobacco use among young people. In addition, FDA was careful to note that industry statements and actions and examples of youth oriented advertising and marketing campaigns lent support to the agency's findings.

FDA's review and consideration of the comments received has led the agency to conclude that advertising plays a material role in the decision by those under 18 to use tobacco products.

#### 1. Advertising and Young People

(1) Comments from the tobacco industry argued that FDA had simply assumed that young people found cigarette and smokeless tobacco advertising to be appealing, and that there was no empirical evidence of how young people actually perceived the imagery displayed in cigarette and smokeless tobacco advertisements. The comments argued that the research cited by the agency relates primarily to the role of imagery in brand choice decisions. In addition, several comments disputed FDA's evidence that young people are particularly vulnerable to image-oriented advertisements. To respond to these comments, it is necessary to describe the function of advertising and how it affects young people.

a. *Function of advertising.* Advertisers use a mix of advertising and promotional vehicles to call attention to the product they are selling—to describe its properties, to convey its superiority over other products, and in some cases to give it an allure above and beyond the qualities of the product itself. (A red convertible can be a mode of transportation; it can also tell people a



lot about who you are, or who you think you are or want to be.)

Advertising creates a matrix of attributes for a product or product category and beliefs about the product and its possessor. It can serve to convey images that are recalled later when an event prompts the consumer to think about a purchase. Consumers, as a general rule, overestimate the effect that advertising has on the market in general, but they routinely underestimate its effect upon them and their own purchasing choices.<sup>77</sup>

As discussed in sections VI.B.1.b. and VI.B.1.c. of this document, advertising that is diverse, image-laden, and colorful can be particularly effective in attracting attention in a cluttered advertising environment. Further, advertising that is repeated frequently and in as many different media as possible is most likely to ensure that its message is received by the maximum number of consumers. This trend toward the use of many media in a coordinated effort to communicate an advertising message supports the need for a comprehensive approach to mitigating the effects of tobacco advertising.<sup>78</sup>

Every presentation can add to and build upon the imagery and appeal created for a product category or a particular brand. Print advertising, direct mail, and outdoor advertising help to create an image of the brand (and sometimes an image of the brand's user) and provide information about price, taste, relative safety, and product developments for current or prospective users. William Campbell, Chief Executive Officer of Philip Morris, explained the importance of linking the brand imagery in various media in relationship to the success in marketing its Marlboro product:

[W]e've managed to take what was originally tunnel vision advertising and positioning \* \* \* into every kind of avenue \* \* \*. For example, our auto racing activities are just another way to express the Marlboro positioning. Some would say the Marlboro Cup is different from Marlboro Country, but it is absolutely consistent.<sup>79</sup>

<sup>77</sup> Gunther, A. C., and E. Thorson, "Perceived Persuasive Effects of Product Commercials and Public Service Announcements: Third Person Effects in New Domains," *Communication Research*, vol. 19, pp. 574-575, 1992.

<sup>78</sup> Flynn, B. S., J. K. Worden, R. H. Secker-Walker, G. J. Badger, B. M. Geller, and M. C. Costanza, "Prevention of Cigarette Smoking Through Mass Media Intervention and School Programs," *American Journal of Public Health*, vol. 82, pp. 827-834, 1992.

<sup>79</sup> "Philip Morris Keeps Smoking—Campbell Sees Growth for Tobacco Unit in Declining Industry," *Advertising Age*, p. 20, Nov. 19, 1990.

The use of many different media is also important in advertising directed to children. An example of a successful multimedia approach directed to children is the cigarette smoking prevention program conducted by Flynn et al., in Vermont, New York, and Montana, and cited in the preamble to the 1995 proposed rule.<sup>80</sup> This effort combined school cigarette smoking prevention programs with a mass media intervention featuring more than 50 different television and radio spots over a 4-year period. Some communities received the school cigarette smoking prevention programs alone, and others received the school program in combination with the mass media intervention. By the final year of the program, students exposed to both school and mass media interventions were 35 percent less likely to have smoked during the past week than students exposed only to the school program. Further, this preventive effect persisted for at least 2 years following the completion of the program.<sup>81</sup> The researchers attributed the effectiveness of their program in part to the fact that their intervention used a wide variety of messages and message styles over a significant period of time.

Thus, all media collectively along with the amount of exposure time to young people, can increase the effectiveness of the advertiser's message. For example, billboards near schools or playgrounds expose children to unavoidable advertising messages for a more prolonged period of time than billboards they pass on the highway. Further, sponsored events that typically last for 2 to 3 hours ensure that those attending the event or viewing it at home on television are exposed for a sustained period of time.

b. *Color contributes.* Color is an important component of advertising. It can be used to promote a "feeling" and a message—blue is cool, red is hot, green is menthol. Studies have shown that four-color advertisements significantly increase attention and recall relative to two color or black- and white- advertisements.<sup>82</sup> Moreover, the

<sup>80</sup> Flynn, B. S., J. K. Worden, R. H. Secker-Walker, G. J. Badger, B. M. Geller, and M. C. Costanza, "Prevention of Cigarette Smoking Through Mass Media Intervention and School Programs," *American Journal of Public Health*, vol. 82, pp. 827-834, 1992.

<sup>81</sup> Flynn, B. S., J. K. Worden, R. H. Secker-Walker, P. L. Pirie, G. J. Badger, and B. M. Geller, "Mass Media Interventions for and School Interventions for Cigarette Smoking Prevention: Effects Two Years After Completion," *American Journal of Public Health*, vol. 84, pp. 1148-1150, 1994.

<sup>82</sup> Hanssens, D., and B. Weitz, "The Effectiveness of Industrial Print Advertisements Across Product

importance of color in advertising becomes more salient when it is considered that most consumer behavior occurs in conditions of "low involvement."<sup>83</sup> Low involvement conditions are those that occur when a reader skims a magazine advertisement rather than carefully searching for an advertisement for information about price, taste, relative "safety" of the product, or product improvement.

A recent article in *The European*<sup>84</sup> described the importance of color:

[S]ecuring a brand colour is more important than ever, particularly for companies chasing a youth market. The main reason is the increasing use of fast and furious graphics in advertising and marketing communications generally. "This makes owning a colour more and more important. You can keep changing the graphics, but the colour remains constant in the consumer's mind." Owning a colour also helps when sponsoring a sports event, for instance, "All Pepsi now has to do is put up lots of blue," said Brant.<sup>85</sup>

c. *The importance of imagery.* Imagery also enhances the ability of advertising to communicate more quickly in low involvement situations and in quick exposure contexts. Pictorial information is remembered much better than verbal information, as pictures perform a function of "organizing" the qualities of the product as depicted with an image. Generally, as the pictures or images in an advertisement increase (both in number and the proportion of the advertisement occupied by the image), the advertisement is more likely to be recognized, and the brand name more likely to be remembered. In most cases, pictorial or image advertising is a more robust and flexible communications medium and can be used to communicate with the functionally illiterate or the young person in a hurry.<sup>86</sup>

Categories," *Journal of Marketing Research*, vol. 17, pp. 294-306, 1980.

<sup>83</sup> MacInnis, D. J., and L. L. Price, "The Role of Imagery in Information Processing: Review and Extensions," *Journal of Consumer Research*, vol. 13, pp. 473-491, 1987.

<sup>84</sup> Short, D., "The Colour of Money," *The European*, p. 21, April 10, 1996.

<sup>85</sup> *Id.* Brant was commenting on Pepsi's decision to change its brand color to blue.

<sup>86</sup> Lutz, K. A., and R. J. Lutz, "Effects of Interactive Imagery on Learning: Applications to Advertising," *Journal of Applied Psychology*, vol. 62, pp. 493-498, 1977; Hendon, D. W., "How Mechanical Factors Affect Ad Perception," *Journal of Advertising Research*, vol. 13, pp. 39-45, 1973; See also Holbrook, M. B., and D. R. Lehmann, "Form Versus Content in Predicting Starch Scores," *Journal of Advertising Research*, vol. 20, pp. 53-62, 1980; Twedt, D. W., "A Multiple Factor Analysis of

An executive from Griffin Bacal, one of the largest advertising agencies in New York, explained how visual imagery scored with young people:

Pictures sell. Visuals count \* \* \* even those visuals that seemingly have nothing to do with the product sale. \* \* \* [including locations, sets, props, wardrobe, colors, numbers, sexes and ages of people in the ads] \* \* \* Kids want to be like each other. Group acceptance, and living the life of the gang, is critical. \* \* \* Similarly, kids define themselves by the product choices they make and share. Be sure your advertising makes the "world" accessible and "invites" the viewer to join.<sup>87</sup>

Evidence from social psychology and marketing research shows image-based advertising, such as that employed by the cigarette and smokeless tobacco industry, is particularly effective with young people, and that the information conveyed by imagery is likely to be more significant to young people than information conveyed by other means in the advertisement.

According to the "elaboration-likelihood model of persuasion," persuasive communications, such as advertisements, can persuade people either: (1) By the "central route," or (2) by the "peripheral route."<sup>88</sup> The central route refers to the process by which a person reads the messages or information contained in the advertisement and thinks carefully about it and is influenced by the strength of its arguments. The peripheral route is a process in which individuals, particularly young people, are more likely to pay attention and be persuaded by peripheral cues such as attractive models, color and scenery, which are unrelated to the primary parts of the message. Therefore, a young person, or anyone who is unmotivated or unable to carefully consider the arguments in a message, is likely to be persuaded via the peripheral route.

In markets where most brands in a product category are similar (as is the case with cigarettes and smokeless tobacco products), most advertising provides little, if any, new information. Thus, peripheral cues (such as color and imagery) take on added significance. Moreover, according to the model, for children, the motivation and ability to "elaborate" upon the arguments (pay

attention to and think about the factual information) contained in cigarette and smokeless tobacco advertising are relatively low, making young people more susceptible to influence from peripheral cues such as color and imagery.

Finally, according to the comment from the nation's largest psychological association, children generally have less information-processing ability than adults, and they are less able or less willing to pay attention to the factual information in the advertisements. This comment stated that because any possible negative health consequences associated with using tobacco products are relatively far in the future for them, children are less motivated than adults to carefully consider information such as tar and nicotine content or the Surgeon General's warnings, which are contained in cigarette and smokeless tobacco advertising. Thus, the comment concludes, color and imagery in advertisements are important components for young people.<sup>89</sup>

A communications researcher who provided comments on FDA's 1995 proposed rule for the consolidated comment of the cigarette industry asserted that the elaboration likelihood model was relevant to the way children respond to tobacco advertising, but took a somewhat different view than that expressed above. Specifically, the comment stated that children are most likely to use the central route when they are ego-involved in the subject of persuasion, and that "ego-involvement generally comes from those subjects which are salient to the groups with which one is aligned - e.g. peers." However, the comment also stated that because children would have no real experiences surrounding the initiation of cigarette smoking, they would be likely to engage in peripheral processing, and would rely on credible sources, such as peers. The comment contended,

The reason the elaboration likelihood model is relevant here is that the decision to begin smoking cigarettes does not come out of a set of fixed or habituated experiences personal to the decision maker. For that reason *this decision is likely to be one on which a person is particularly susceptible to the influence of others*, and therefore source credibility becomes key. [Emphasis added].

The agency is not convinced by the comment. This explanation does not address children's responses to tobacco

advertisements—it essentially assumes that children are influenced by advertising only insofar as it is filtered through the experience of their peers. This reasoning is both circular and illogical. However, the agency does concur with the comment's view that children typically process tobacco advertising via the peripheral route, that children are particularly susceptible to the influence of others regarding the decision to start smoking or to use smokeless tobacco, and that perceived source credibility plays an important role. FDA maintains that the "source" of the persuasive message in tobacco advertising is frequently conveyed by the imagery presented in the advertisement. The same comment expressed this sentiment, stating "[s]ince the media consumer often does not know the writer or broadcaster personally, the consumer or receiver may attribute source credibility to the media themselves." To the extent that characters featured in tobacco advertising, such as Joe Camel, the Marlboro Man or the attractive models or race car heroes typically portrayed in such advertising appear credible and appealing, they are perceived as credible sources, and could influence children regarding the decision to smoke or to use smokeless tobacco products.

## 2. Advertising and Adults

(2) Several comments from the tobacco industry and the advertising industry stated that cigarette and smokeless tobacco advertising plays an important economic role in tobacco marketing. A comment from the tobacco industry stated that FDA proposed restrictions would: (1) Substantially impair advertising of tobacco to adults; (2) deprive adults of useful information about products and services such as availability, price, and quality; (3) reduce the incentive and ability to market improved products; and (4) deprive adult smokers of the benefits of competition to provide a broad range of choices and to assure that tobacco products are provided at the lowest possible cost. Consequently, the comment said that the 1995 proposed rule would have a far greater adverse impact on advertising to adults than on advertising seen by young people.

One comment from an advertising agency argued that restrictions on the advertising of tobacco products would "significantly erode the progress made over the past 15 years in increasing the quantity and variety of information readily available to the public." This

Advertising Readership," *Journal of Applied Psychology*, vol. 36, pp. 207-215, 1952.

<sup>87</sup> Kurnit, P., "10 Tips From the Top Agency-Exec Explains How Griffin Bacal Scores with Kids," *Advertising Age Supplement*, pp. 19-20, February 10, 1992.

<sup>88</sup> Petty, R. E., and J. T. Cacioppo, *Communication and Persuasion: Central and Peripheral Routes to Attitude Change*, Springer-Verlag, New York, p. 3, 1986.

<sup>89</sup> See also, Huang, D. P., D. Burton, H. L'Howe, and D. M. Sosin, "Black-White Differences in Appeal of Cigarette Advertisements Among Adolescents," *Tobacco Control*, vol. 1, pp. 249-255, 1992.

progress, the comment reiterated, has benefited and continues to benefit the public.

Further, several comments argued that unfettered advertising is consistent with our Nation's belief in providing the broadest possible range of information to individuals, so that they can exercise informed judgment in their daily lives. For these reasons, the comment stated, further restrictions on the advertising of legal products would not be in the public interest and should be opposed.

FDA recognizes, as these comments maintained, that imagery and color make advertising appealing to adults, as well as to children, and that advertisers consistently use these elements to make advertisements compelling and attention getting. Moreover, removal of color and imagery will make advertising's role in presenting information to adults more difficult. However, as stated more fully in the preamble to the 1995 proposed rule, FDA has attempted to tailor its advertising restrictions as narrowly as possible consistent with its purpose of reducing young people's attraction to and use of tobacco. Thus, rather than banning all advertising, the proposed regulations retain the informational function of advertising by permitting text-only advertising while removing color and imagery from those advertisements to which young people are unavoidably exposed.

FDA does not believe that these restrictions should dramatically increase search costs for adult smokers and smokeless tobacco users who are actively looking for information on price and new product innovations. Text-only advertising requires a high involvement on the part of the consumer but can realistically be expected to provide sufficient information to carry the message and also provide sufficient appeal to attract current smokers and smokeless tobacco users. Some advertising for low-tar products relies on text-only or text with few pictures.

If the information about product type is important and desired by adult tobacco users, it can and will be provided by text-only advertisements if the industry desires to make the information available. As noted above, advertising for low-tar cigarettes is generally high-involvement advertising at the present and therefore can be expected to survive in a text-only environment. Nonetheless, the agency recognizes that it may be more difficult for advertising, without imagery and color, to attract the attention of current tobacco users. However, the agency has

decided that the public health benefits of reducing advertising's ability to create appeal for young people greatly outweighs the tobacco companies' interest in unrestricted advertising to adults.

The position argued by these comments is essentially that industry has the right to communicate freely with its intended audience regardless of the impact its advertising has on the illegal and vulnerable audience of children and adolescents. Other comments counter this comment asserting that it is the Government's obligation to protect children because of their special vulnerabilities, their lack of experience and knowledge, and their limited ability to make appropriate decisions regarding behavior that will have lifelong health consequences. FDA believes its obligation with respect to tobacco products is to safeguard the health and safety of young people to ensure that they do not begin a potentially lifelong addiction to products that cause so much disease and premature death.

### *C. The Regulations Under the First Amendment*

#### *1. Introduction*

Under section 520(e) of the act (21 U.S.C. 360j(e)), FDA included a number of proposed conditions in the 1995 proposed rule on how cigarettes and smokeless tobacco could be advertised as part of its proposed restrictions on the sale of these products. The agency tentatively found that these conditions are necessary to reduce the advertising's ability to create demand for these products—that is, the desire to purchase them—among children and adolescents under 18, for whom these products are not safe (60 FR 41314 at 41350). In addition, FDA tentatively found that it was necessary to include an industry-financed education program among these conditions.

In proposing these measures, FDA recognized that they would have to pass muster under the protections of communication extended by the First Amendment to the United States Constitution, in particular, under the protections extended to commercial speech (60 FR 41314 at 41353). Before addressing the commercial speech analysis, however, this section responds to several comments which registered more fundamental complaints under the First Amendment about FDA's proposed approach.

(3) Several comments, which were from the tobacco and advertising industries, found in statements made by FDA evidence of an intent not merely to

protect the health of young persons but to "delegitimize" lawful adult conduct, to engage in "viewpoint discrimination," and to run "roughshod" over the rights of cigarette and smokeless tobacco companies. One comment said that it is outside the realm of permissible exercise of governmental power to suppress speech for the purpose of instilling values that the Federal Government believes are appropriate. This comment also said that the purpose of FDA's rulemaking is to eliminate speech that conflicts with Government messages on smoking and health. The comment noted that FDA's goal is to bring about the demise of smoking as a social custom. However, a comment from a consumer group disagreed, saying instead that FDA's 1995 proposed rule was limited to covering only those activities designed to promote the sale of the product to young people and thus covered only commercial speech.

FDA has carefully considered these comments and has taken the concerns that they expressed into account as it developed this final rule. The agency recognizes that its authority is limited by the act and the Constitution. Thus, it has scrutinized each of the conditions on advertising that it proposed in light of whether the condition advances the purposes of section 520(e) of the act or some other section of the act, and whether the condition is consistent with the First Amendment.

FDA's primary concern is the public health. Because of the potentiality for harmful effects on individuals under 18 from use of cigarettes and smokeless tobacco, FDA is adopting restrictions on advertising among other restrictions on the sale, distribution, and use of these products. These restrictions will mean that it should be more difficult to sell these products to people under age 18, who currently purchase these products in significant numbers.

The agency acknowledges that insofar as these restrictions help reduce the sale of tobacco products to young people, the restrictions will have an adverse effect on the cigarette and smokeless tobacco companies. However, this fact does not mean that FDA is trying to bring about the demise of the tobacco industry. The restrictions that FDA is adopting have been tailored to help reduce tobacco advertising's ability to create an underage market for these products, while leaving open ample avenues for cigarette and smokeless tobacco companies to communicate to current users 18 years of age or older about their products. As explained in detail in

section VI.E. of this document, this is all that the First Amendment requires.

(4) Several comments argued that, in the 1995 proposed rule, FDA had understated the protection that commercial speech is afforded under the First Amendment. These comments pointed out that advertisers and consumers have powerful First Amendment rights to send and receive commercial messages. To support this point, one comment pointed out that the Supreme Court has recognized that the free flow of commercial information is "indispensable to proper allocation of resources in a free enterprise system." (See *Virginia State Bd. of Pharmacy v. Virginia Citizens' Consumer Council, Inc.*, 425 U.S. 748, 765 (1976).) The comment also pointed out that the Court went on to say that a "particular consumer's interest in the free flow of commercial information \* \* \* may be as keen, if not keener by far, than his interest in the day's most urgent political debate" (*Id.* at 763).

Another comment, however, citing *Ohralik v. Ohio State Bar Ass'n.*, 436 U.S. 447 (1978), stated that there are dangers inherent in a free-for-all marketplace, and that, at times, vigilant Government action is needed to protect the public from false, deceptive, or overbearing sales campaigns.

In addition to the comments, the agency has considered the Supreme Court's recent decision in *44 Liquormart, Inc. v. Rhode Island*, 116 S.Ct. 1495 (1996), which was handed down after the rulemaking record was closed. The Court ruled unanimously that Rhode Island's ban on all dissemination of price advertising for alcoholic beverages was violative of the First Amendment. No rationale for this judgment commanded a majority of the Court, however. Nonetheless, FDA considered each part of the principal opinion, as well as the concurring opinions, in arriving at the decisions that are set forth in this final rule.

FDA in no way underestimates the protection extended to commercial speech by the First Amendment. FDA recognizes the important societal interests served by this type of speech and has given full consideration to those interests in developing this final rule. Nonetheless, it is also true, as the agency stated in the 1995 proposed rule (60 FR 41314 at 41353 to 41354), that the measure of protection that commercial speech receives is commensurate with its subordinate position in the scale of First Amendment values, and it is subject to modes of regulation that might be

impermissible in the realm of noncommercial expression. (See *Florida Bar v. Went For It, Inc.*, 115 S.Ct. 2371, 2375 (1995).)

However, in *44 Liquormart, Inc.*, three Justices stated:

[w]hen a State entirely prohibits the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining process, there is far less reason to depart from the rigorous review that the First Amendment generally demands. (116 S.Ct. at 1507)

This statement has no application to the restrictions that FDA is imposing for two reasons. First, FDA is not entirely prohibiting the dissemination of commercial messages about cigarettes and smokeless tobacco. As explained in section VI.E. of this document, it is adopting carefully tailored restrictions on the time, place, and manner in which such messages may be conveyed so that they are not used to undermine the restrictions on access by minors. Second, the restrictions are related to the bargaining process. As explained in section II.C.3. of this document in the discussion of section 520(e) of the act, the access restrictions, and the concomitant restrictions on promotion of these products, derive from the fact that, at least as a matter of law, minors are not competent to use these products.

"The protection available for particular commercial expression turns on the nature both of the expression and of the governmental interests served by its regulation." (See *Central Hudson*, 447 U.S. at 563.) FDA has weighed these factors in deciding what restrictions on cigarette and smokeless tobacco advertising can appropriately be included in this final rule.

## 2. The *Central Hudson* Test

The comments were unanimous in agreeing that any restrictions the agency adopts on commercial speech will be assessed under the test first articulated by the Supreme Court in *Central Hudson*, 447 U.S. at 563-64. This test was originally set out as a four-step analysis in *Central Hudson*; however, in one recent case, *Florida Bar v. Went For It, Inc.*, the Supreme Court described the test as having three prongs after a preliminary determination is made, although the matters to be considered remain unchanged:

Under *Central Hudson*, the government may freely regulate commercial speech that concerns unlawful activity or is misleading\* \* \*. Commercial speech that falls into neither of these categories, \* \* \* may be regulated if the government satisfies a test consisting of three related prongs: first, the government

must assert a substantial interest in support of its regulation; second, the government must demonstrate that the restriction on commercial speech directly and materially advances that interest; and third, the regulation must be "narrowly drawn" \* \* \*. (115 S.Ct. at 2376 (citations omitted))

FDA explained in the preamble to the 1995 proposed rule why the restrictions on advertising that it was proposing met each requirement of the *Central Hudson* test (60 FR 41314 at 41354 and 41356). The agency received a number of comments on its analysis—mostly from the tobacco industry, newspaper or magazine associations, and advertisers. These comments argued that FDA's proposed restrictions failed under one or more elements of the *Central Hudson* test. The agency also received comments from a public interest group, which has the protection of commercial speech as one of its interests, and from a coalition of major national health organizations. Both of these comments argued that, in virtually all respects, FDA's proposed restrictions satisfy the *Central Hudson* test.

In the sections that follow, for each of the restrictions on advertising that the agency proposed, FDA will analyze the case law that elucidates the applicable standard, the information presented in comments, and all other available evidence and decide whether that standard is met. However, before the agency does so, it must first consider the preliminary inquiry under *Went For It* and decide whether the First Amendment provides any protection to the advertising that is restricted by this final rule.

## 3. Is Cigarette and Smokeless Tobacco Advertising Misleading, or Does It Relate to Unlawful Activity?

As stated earlier, the preliminary inquiry under the *Went for It* case is whether the commercial speech is misleading or relates to unlawful activity. FDA did not specifically address this aspect of the *Central Hudson* analysis in its proposal (60 FR 41314 at 41354). Nonetheless, several comments did.

Many of the comments asserted that the targeted speech concerns lawful conduct, and that, therefore, this aspect of the *Central Hudson* analysis is satisfied. One comment noted FDA's silence on this matter and said that there is thus no suggestion that cigarette advertisements propose an illegal transaction or urge youths to begin smoking before it is lawful for them to do so.

Some comments argued, however, that cigarette and smokeless tobacco

advertising is not entitled to First Amendment protection because it is misleading, and it concerns unlawful activity. These comments pointed out that it is unlawful in all 50 States to sell tobacco products to children under the age of 18. The comments said the evidence that FDA assembled in its 1995 proposal suggested that manufacturers of tobacco products are aware that their advertising campaigns induce minors to experiment with tobacco products (citing 60 FR 41314 at 41330–41331), and that much of the promotional efforts of the tobacco industry are geared toward an illegal end—inducing minors to try to break the law by obtaining cigarettes and smokeless tobacco that may not legally be sold or otherwise provided to them.

The comments also argued that governmental entities are entitled to broad discretion when regulating the promotion of legal products or activities that pose dangers to society (citing, e.g., *United States v. Edge Broadcasting Co.*, 509 U.S. 418 (1993)). The comments argued that cigarette advertising is designed to persuade minors that any concerns about health hazards are misplaced or overstated, and that their peers are having fun because they smoke.

Contrary positions were taken by several comments. One argued that the fact that the sale of tobacco to minors is illegal under State law does not remove the constitutional protection for advertising to adults an otherwise lawful product (citing *Dunagin v. City of Oxford*, 718 F.2d 738, 743 (5th Cir. 1983) (en banc), cert. denied, 467 U.S. 1259 (1984).) A second comment cited the conclusion of a respected researcher that: “the suggestion that advertising messages are somehow working subliminally to twist children’s minds before they are old enough to know better is a complete invention, for which there is no evidence whatever” (citing McDonald, C., “Children, Smoking and Advertising: What Does the Research Really Tell Us?,” 12 *International Journal Of Advertising* 286 (1993)). These comments also argued that given the warnings that must appear in all tobacco advertising, it could not be maintained that tobacco advertising is misleading.

FDA has carefully considered these comments. They raise the fundamental question of whether tobacco advertising is protected by the First Amendment. This question cannot be disposed of based simply on the question of whether such advertising explicitly urges young people to begin purchasing or using

tobacco products before it is lawful for them to do so.<sup>90</sup>

The Supreme Court has repeatedly said that commercial speech “related to” unlawful activity is not entitled to First Amendment protection. (See *44 Liquormart, Inc.*, 116 S.Ct. at 1505 n.7 (“By contrast, the First Amendment does not protect commercial speech about unlawful activities.”); *Florida Bar v. Went For It*, 115 S.Ct. 2376 (“Under *Central Hudson*, the government may freely regulate commercial speech that concerns unlawful activity or is misleading”); *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 69 (1983) (“The State may also prohibit commercial speech related to illegal behavior.”); *Central Hudson*, 447 U.S. at 563–564 (“The government may ban \* \* \* commercial speech related to illegal activity.” (citations omitted)).) Tobacco advertising is “related to illegal activity” in two significant respects and thus, in fact, might not be protected speech.

First, tobacco ads, at least as a legal matter, propose a commercial transaction (see *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976); *Pittsburgh Press Co. v. Human Relations Com’n*, 413 U.S. 376, 389 (1973)), that is, to sell cigarettes and smokeless tobacco. In proposing these transactions, the advertisers do not differentiate between adult and minor purchasers. Because sales to minors are unlawful in every State,<sup>91</sup> the undifferentiated offer to sell constitutes, at least in part, an unlawful offer to sell. At the very least, these advertisements are clearly perceived by minors as offers or inducements to buy and use these products. Millions of American children and adolescents act on these perceived offers. It is estimated that each year children and adolescents consume between 516 million and 947 million cigarette packages and 26 million containers of smokeless tobacco (60 FR 41314 at 41315). Thus, in a practical sense, cigarette and smokeless tobacco advertising is proposing transactions that are illegal (see *Virginia State Board of Pharmacy v. Virginia Citizens Council, Inc.*, 425 U.S. at 772), whether

or not that is the advertiser’s intent. As such, the protections of the First Amendment might not attach to such advertising because it proposes an illegal transaction. (See *Pittsburgh Press Co.*, 413 U.S. at 389; *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 638 (1985) (“The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading, \* \* \*, or that proposes an illegal transaction \* \* \*” (citations omitted)).)

Second, even if it is assumed, *arguendo*, that cigarette and smokeless tobacco ads are not, for constitutional purposes, literal offers to sell to minors, they nonetheless are “related to” an unlawful activity. Whether it is the advertiser’s intent or not, as explained in sections VI.D.3. through VI.D.6. of this preamble, cigarette and smokeless tobacco advertising has a powerful appeal to children and adolescents under the age of 18 and through this appeal, by means of the image that it projects, it has an effect on a young person’s decision to use, and thus to attempt to purchase, tobacco products. Yet, as stated above, sale of tobacco products to minors is unlawful in all 50 States, and the purchase, possession, or use of tobacco products by minors is unlawful in a majority of States.<sup>92</sup> Thus, the appeal of tobacco advertising to minors is such that this type of advertising can appropriately be viewed as encouraging, and thus being “related to”, illegal activity. As a result, it is arguable that, without more, FDA would be able to freely restrict such advertising.

Nevertheless, the advertising also relates to lawful activity—the sale of tobacco products to adults. Consequently, FDA may not have unlimited discretion to regulate tobacco advertising. (See *Dunagin v. City of Oxford*, 718 F.2d at 743.) At the very least, however, FDA should be afforded discretion to do what it has tried to do in these regulations; that is, to distinguish advertising that “relates to” commercial activity that, in substantial respects, is unlawful, the sale of tobacco products to children, from advertising that does not.

Significantly, the Supreme Court was confronted with a situation similar to this in *United States v. Edge Broadcasting*. In *Edge*, the Supreme Court upheld a Federal statute that prohibited advertising that “related to” unlawful activity (broadcast of lottery advertising by a broadcaster licensed to

<sup>90</sup> As explained more fully below, FDA finds unpersuasive the quote from McDonald because it does not address the means by which cigarette and smokeless tobacco product advertising influences minors’ decisions on whether to purchase and use these products. Therefore, the agency turns to the legal issue raised by the comments.

<sup>91</sup> “State Laws on Tobacco Control—United States, 1995,” *Morbidity and Mortality Weekly Report (MMWR)*, CDC, DHHS, vol. 44, No. ss–6, pp. 16–17, November 3, 1995.

<sup>92</sup> *Id.*

a State that does not allow lotteries), but not advertising that did not relate to unlawful activity (broadcasting of lottery advertising by a broadcaster licensed to a State that allowed a lottery.)

*Edge* was recently cited with approval by the plurality opinion in *44 Liquormart Inc.*, 116 S.Ct. at 1511. Justice Stevens (joined by Justices Thomas, Kennedy, and Ginsburg) reasoned that the statute in *Edge* “was designed to regulate advertising about an activity that had been deemed illegal in the jurisdiction in which the broadcaster was located.” He contrasted the statute in *Edge* to the statute in *44 Liquormart* which “targets information about entirely lawful behavior” (*Id.*). Thus, the Supreme Court has countenanced distinctions in how speech is regulated that are based on whether the underlying conduct to which the speech relates is *entirely lawful* or not. That is exactly the type of distinction that FDA is drawing here.

Thus, a credible argument can be made that advertising of cigarettes and smokeless tobacco, at least to the extent that it is related to sale of these products to children under 18, is not speech protected by the First Amendment, and thus that the regulations that FDA is adopting restricting such advertising are subject only to review under an arbitrary or capricious standard. (See *Florida Bar v. Went For it, Inc.*, 115 S.Ct. at 2376.) However, FDA is not relying solely on this analysis. Alternatively, FDA has assumed that a *Central Hudson* test, such as that applied in *Edge*—for products that relate to both lawful and unlawful transactions—would be appropriate here. Therefore, a full analysis of these restrictions under *Central Hudson* follows.

Before proceeding to the *Central Hudson* analysis and considering the comments that bear on it, FDA wants to emphasize that, even if the First Amendment applies to tobacco advertising, the restrictions that the agency is adopting have very limited impact on those attributes of commercial speech that are protected by the First Amendment. In *44 Liquormart, Inc.*, a plurality of the Supreme Court reemphasized that commercial speech is protected solely because of the informational value:

Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to *who is producing and selling what product, for what reason, and at what price.* So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made

through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.

116 S.Ct. at 1505 (emphasis added), quoting *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council*.

The restrictions that FDA is adopting have virtually no effect on the core informational function of commercial speech as described in *44 Liquormart, Inc.* and *Virginia Board of Pharmacy*. Except for billboards within 1,000 feet of schools and playgrounds, which, as explained below, present special circumstances, FDA is not restricting the ability of a manufacturer, distributor, or retailer to inform the public about what they are selling, why they are selling it, or the price of their products or, for that matter, about the characteristics of their products or about any other aspect of what they sell. FDA's concerns are about the ability of manufacturers to use images, color, and peripheral presentations (such as sponsorship) in their advertising and promotion of their products to create particular appeal for children and adolescents under 18. Thus, FDA has designed the restrictions that it is adopting to ensure that adults can continue to be informed by the information in tobacco advertising while restricting the noninformative aspects of advertising that appeal to children and adolescents under the age of 18. The agency will explain how it has achieved this end in the discussion that follows.

#### 4. Is the Asserted Government Interest Substantial?

Assuming that the *Central Hudson* test applies, “[t]he State must assert a substantial interest to be achieved by restrictions on commercial speech.” (See *Central Hudson*, 447 U.S. at 564.) In the 1995 proposed rule, FDA stated that this prong of the *Central Hudson* test was satisfied because the proposed regulations serve the substantial Government interest of protecting the public health. FDA stated that the advertising restrictions will help to reduce the use of cigarettes and smokeless tobacco by those who are “the most vulnerable to addiction and, perhaps, the least capable of deciding whether to use the products. Decreased use of these products will reduce the risk of tobacco-related illnesses and deaths” (60 FR 41314 at 41354).

Most of the comments that FDA received on this issue, even some from those who otherwise opposed the

agency's proposed restrictions, agreed with the agency that it has a substantial interest in protecting the health of individuals under 18 years of age.

(5) Two comments, however, said that the interest asserted by FDA is insufficient to justify the proposed restrictions on speech. One of those comments said that smoking is a legal and widespread activity, and that there is no congressional policy against smoking. One comment said that while the Government has a substantial interest in ensuring that tobacco products are used by adults only, FDA is not empowered to protect that interest.

FDA strongly disagrees with the latter comments. The Government's interest in the public health, and particularly in the well-being of minors, is well-established. (See *Action for Children's Television v. FCC*, 58 F.3d 654, 661 (D.C. Cir. 1995) and 60 FR 41314 at 41354.) In fact, the Supreme Court has found that there is a compelling, not merely a substantial, interest in protecting the physical and psychological well-being of children, *New York v. Ferber*, 458 U.S. 747, 756–57 (1982), and that the Government's interest in the well-being of youth and in parents' claim to authority in their own household can justify the regulation of otherwise protected expression, *FCC v. Pacifica Foundation*, 438 U.S. 726, 749 (1978). (See also *Denver Area Educational Telecommunications Consortium v. FCC*, 64 U.S.L.W. 4706 (in press) (June 28, 1996).)

As the agency has explained in section II.B. and in the 1996 Jurisdictional Determination annexed hereto, cigarettes and smokeless tobacco are drug delivery devices that are subject to regulation as devices under the act. Their use by children and adolescents under 18 presents serious risk to the health of this segment of the population. For example, studies show that the age one begins smoking influences the amount of smoking one will engage in as an adult and will ultimately influence the smoker's risk of tobacco related morbidity and mortality (60 FR 41314 at 41317). In addition, the risk of oral cancer increases with increased exposure to smokeless tobacco products (60 FR 41314 at 41319). Thus, the health of children and adolescents is related to their use of cigarettes and smokeless tobacco.

FDA's compelling interest in the health and well-being of minors supports restrictions on cigarette and smokeless tobacco advertising to ensure

that advertising does not undermine FDA's restrictions on the sale of these products.

One comment said that while FDA's articulated interest in protecting minors from harm clearly is substantial, this interest is not served by FDA's regulations. According to the comment, the only goal served directly by the proposed regulations is that of delegitimizing smoking. Two comments said that under the guise of protecting adolescents and children, FDA is trying to "'save' all Americans from the 'evils' of smoking." Two comments said that the agency is trying to prevent cigarette advertising from presenting smoking in a positive light. One comment, citing *Carey v. Population Services International*, 431 U.S. 678 (1977), said that the Government cannot restrict cigarette advertising because it legitimizes or favorably influences a young person's views toward tobacco products.

FDA finds no merit in these comments. Advertisements for cigarette and smokeless tobacco are not banned by the restrictions that FDA is adopting. For example, the companies are free to use advertising in almost all media that communicates to adults about the price, taste, or joys of using their product, as long as they do so using black-and-white, text-only advertisements, or using imagery and color in publications read primarily by adults. Thus, it is simply not true that manufacturers will be prevented from presenting tobacco use in a positive light or that they will be prevented from conveying truthful, nonmisleading information in almost all media.

These regulations are intended, however, as explained in section VI.E. of this document, to prevent manufacturers from advertising their tobacco products in a way that encourages underage individuals to purchase these products. They are authorized by sections 520(e) and 502(q) of the act and are in no way inconsistent with *Carey v. Population Services International*.

*Carey* involved a challenge to a law that banned all advertisement of contraceptives. The Government argued that advertising contraceptives would legitimize sexual activity of young children. The Supreme Court said that this basis was not a justification for validating suppression of expression protected by the First Amendment (431 U.S. at 701).

*Carey* is distinguishable from the present situation in several ways. The advertisements in that case stated the

availability of products and services that were not only entirely legal but were constitutionally protected because they involved the exercise of a fundamental right (*Id.*). (The Court also struck down other provisions of the law that prohibited distribution of contraceptives to anyone under the age of 16 and by anyone other than a licensed pharmacist.) Cigarettes and smokeless tobacco are neither lawful for all people nor constitutionally protected. The sale of these products to individuals under 18 is unlawful in every State (see also, 42 U.S.C. 300x-26), and possession, purchase, or use of at least some tobacco products by this segment of the population is unlawful in a majority of States.<sup>93</sup> Moreover, there was no credible suggestion in any of these comments that the restrictions on the sale of these products infringe on the exercise of a fundamental right.

The Supreme Court in *Carey* made clear the limited coverage of its holding. (See 431 U.S. at 702, n. 29 ("We do not have before us, and therefore express no views on, state regulation of the time, place, or manner of such commercial advertising based on these or other state interests.")) Thus, given the significant differences in the two situations, *Carey* does not limit FDA's ability to adopt conditions on advertising that are designed to ensure that restrictions on sale to minors are not undermined.

(6) Finally, a group of comments on this first prong of the *Central Hudson* test attacked FDA for being paternalistic. These comments said that a principal theme of commercial speech doctrine is a societal intolerance for Government-enforced ignorance designed to "help" consumers who are not trusted by bureaucrats to evaluate advertising for themselves. One comment said that how to balance short-term gratification against long-term risk is a uniquely personal analysis that is best left to individual autonomy rather than Government censorship. The comment said that people must be trusted to perceive their own best interests without Government intervention in the information flow. These comments take on a particular significance in light of the plurality's statement in *44 Liquormart, Inc. v. Rhode Island*, 116 S.Ct. at 1508, that "[t]he First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good."

<sup>93</sup> *Id.*

FDA has no disagreement with these comments with respect to individuals and, in fact, finds these regulations cannot fairly be characterized as paternalistic with respect to that population group. These regulations do not prohibit the inclusion of any information in advertising. They also do not impose the type of ban on accurate commercial information that has characterized the limitations on commercial speech that the Supreme Court has branded as paternalistic. (See, e.g., *44 Liquormart, Inc.*, 116 S.Ct. at 1510; *Virginia Bd of Pharmacy*, 425 U.S. at 769-770.)

The agency acknowledges, however, that in another respect, these regulations are paternalistic. These regulations are specifically aimed at protecting children and adolescents under the age of 18 from the appeal of tobacco advertising. The agency finds however, that for it to be paternalistic with respect to children and adolescents in no way offends the First Amendment or Supreme Court precedent. (See *Denver Area Communications Consortium, Inc. v. FCC*, No. 95-124 (U.S. June 28, 1996) *slip op.* at 25.) Nothing in *44 Liquormart, Inc.*, for example, suggests in any way that government may not be paternalistic with respect to children and adolescents under the age of 18.

In fact, the Supreme Court has stated: "\* \* \* [T]he law has generally regarded minors as having a lesser capability for making important decisions." (See *Carey v. Population Services International*, 431 U.S. at 693, n. 15.) Given these facts—that most cigarette smokers smoke their first cigarette before 18, that children and adolescents who use tobacco products quickly become addicted to them before they reach the age of 18, that among smokers aged 12 to 17 years, 70 percent regret their decision to smoke, and 66 percent state that they want to quit (60 FR 41314)—the decision to smoke is among the most important that an individual will make. Significantly, all 50 States have prohibited sales of cigarettes to people under 18 years of age. These regulations have been tailored to help ensure that individuals do not make a decision on whether to smoke before they are 18 and have a greater capacity to understand the consequences of their actions, and that they are not influenced to make this decision before that time by advertising. At the same time, FDA has sought to ensure that the restrictions do not burden any more speech than is necessary to accomplish this goal. Thus, FDA's purpose is not inconsistent with law, commercial speech doctrine, or the



country's precepts of individual autonomy.

#### *D. Evidence Supporting FDA's Advertising Restrictions*

##### 1. Introduction

Having considered the preliminary inquiry and the first prong of the *Central Hudson* analysis, the agency turns to the heart of this analysis, whether the restrictions on cigarette and smokeless tobacco advertising that FDA is imposing are in proportion to the interest that it is seeking to advance. To meet its burden on this issue, FDA first must show that tobacco advertising plays a concrete role in the decision of minors to smoke, and that each specific restriction on this advertising that it is adopting will contribute to limiting its effects and thus to protecting the health of children and adolescents under the age of 18. The extensive evidence in this proceeding fully supports these judgments.

##### 2. Do the Regulations Directly Advance the Governmental Interest Asserted?

In *Central Hudson*, the Supreme Court said that any limitation on commercial speech that the State imposes "must be designed carefully to achieve the State's goal" (447 U.S. at 564). " \* \* \* [T]he restriction must directly advance the State interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose" (*Id.*).

The Supreme Court elaborated on what this aspect of the *Central Hudson* test requires in *Edenfield v. Fane*, 507 U.S. 761, 770-771 (1993);

It is well-established that "[t]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it." \* \* \* This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree \* \* \*. Without this requirement, a state could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.

In *Edenfield*, the Court struck down a Florida ban on in-person solicitation by Certified Public Accountants (CPA's) because the State board failed to demonstrate that the harm it recited was real.

It presents no studies that suggest personal solicitation of prospective business clients by CPAs creates the dangers of fraud, overreaching, or compromised independence that the Board claims to fear. The record does

not disclose any anecdotal evidence, either from Florida or another State, that validates the Board's suppositions.

(*Id.*)

In *Rubin v. Coors*, the Court struck down a section of the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) that prohibited beer labels from displaying alcohol content because the Government failed to demonstrate that this restriction would alleviate the recited harm to a material degree. (See 115 S.Ct. at 1592.) The Court characterized the Government's regulatory scheme as "irrational" (*Id.*). See also, Justice Stevens' opinion in *44 Liquormart*, 116 S.Ct. at 1509, 1510. (In striking down Rhode Island's ban on price advertising for failure to demonstrate that the restrictions would advance the State's interest, Stevens, joined by Justices Kennedy, Ginsburg, and Souter, found that while the record "suggests that the price advertising ban may have some impact on the purchasing patterns of temperate drinkers of modest means \* \* \* no evidence [has been presented] to suggest that its speech prohibition will significantly reduce market-wide consumption." Therefore, Stevens stated that "[s]uch speculation certainly does not suffice when the State takes aim at accurate commercial information for paternalistic ends.")

Thus, under the applicable case law, to adopt the proposed restrictions on cigarette and smokeless tobacco advertising, FDA must find that it can conclude from the available evidence that: (1) Advertising plays a material role in the process by which children and adolescents decide to begin or to continue to use these products; and (2) Limitations on advertising will contribute in a direct and material way to FDA's efforts to ensure that the restrictions it is adopting on the sale and use of tobacco products to minors are not undermined.

Contrary to what some comments asserted, it is not necessary for FDA to establish by empirical evidence that advertising actually causes underage individuals to smoke, or that the restrictions on advertising will directly result in individuals that are under 18 ceasing to use cigarettes or smokeless tobacco. It is not necessary in satisfying this prong of *Central Hudson* for the agency to prove conclusively that the correlation in fact (empirically) exists, or that the steps undertaken will completely solve the problem. (See *United States v. Edge Broadcasting Co.*, 509 U.S. 418, 434-35.) Rather, the agency must show that the available

evidence, expert opinion, surveys and studies provide sufficient support for the inference that advertising does play a material role in children's tobacco use.

In the 1995 proposed rule, FDA suggested that its judgment as to whether the governmental interest involved was directly advanced by its actions was entitled to some deference. "The Supreme Court has stated that, when determining whether an action advances the governmental interest, it is willing to defer to the 'common sense judgments' of the regulatory agency as long as they are not unreasonable" (citing, *Metromedia Inc. v. City of San Diego*, 453 U.S. 490, 509 (1981) (60 FR 41314 at 41354)).

Several comments took issue with this suggestion. One comment said that FDA had mischaracterized Supreme Court jurisprudence, and two comments said that courts will defer only to common sense judgments of legislatures.

FDA disagrees with those comments. In *Florida Bar v. Went For It, Inc.*, the Supreme Court said that it had permitted "litigants," which it did not limit to State legislatures, to justify speech restrictions by "studies and anecdotes pertaining to different locales altogether, \* \* \* or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and 'simple common sense \* \* \*'" (115 S.Ct. at 2378). Thus, FDA's reliance on common sense (which, as made clear in section VI.D.3. through VI.D.6. of this document, provides only part of the basis for FDA's findings) is justified.

(7) One comment said that, rather than giving FDA deference, courts review with special care any regulations that suppress commercial speech to pursue a nonspeech-related policy.

FDA disagrees with this comment for two reasons. First, these regulations do not suppress commercial speech. While they limit such speech, they leave open significant means of communication about these products. Second, this comment derives specifically from footnote 9 of *Central Hudson*, 447 U.S. at 566 ("We review with special care regulations that entirely suppress commercial speech in order to pursue a nonspeech-related policy."). In that case, the Supreme Court found that control of demand for electricity was a speech-related policy (see 447 U.S. at 569). Similarly, the policy that FDA seeks to advance here, control of demand for cigarettes and smokeless tobacco by minors, is a speech-related policy.

(8) Finally, one comment said that FDA claimed deference for its common sense judgments to deflect attention from the lack of a factual basis for the 1995 proposed rule. Two comments, however, stated that FDA has compiled a record on the problem that is more extensive than any that existed in any of the cases in which the Supreme Court upheld restrictions on commercial speech.

In the discussion that follows, FDA reviews the evidence on whether cigarette and smokeless tobacco advertising affects the decision by minors to use these products, and whether the restrictions on advertising that it is imposing will limit the effect to a material degree. This review demonstrates that FDA's judgment on these issues is supported not only by common sense but by studies, anecdotes, history, expert consensus documents, and empirical data. All of this evidence provides support that restrictions on the advertising of these products will directly advance the Government's interest in protecting the health of children and adolescents under 18 years of age.

### 3. Is There Harm? Does Advertising Affect the Decision by Young People to Use Tobacco Products?

a. *In general.* In the preamble to the 1995 proposed rule, FDA stated that perhaps the most compelling piece of evidence supporting restrictions was that these products were among the most heavily advertised and widely promoted products in America. The agency cited the most recent Federal Trade Commission (FTC) figures of overall expenditures for 1993, that indicated that over \$6.1 billion had been spent by the cigarette and smokeless tobacco industries to promote their products in diverse media. These include magazines, newspapers, outdoor advertising, point of purchase, direct mail, in-store, dissemination of nontobacco items with brand identification, and sponsorship of cultural and sporting events.

(9) Several comments from the tobacco industry and the advertising industry criticized FDA's reliance on the immensity of advertising expenditures that show that tobacco products are heavily advertised. The comments claimed that the size of the industry advertising budget is not evidence that it is effective in causing young people to smoke. Conversely, one comment concluded that:

[h]ighly repetitious ad exposure likely leads to judgment biases in both risk and

social perceptions, such as assessments of smoking prevalence and the social acceptance experienced by smokers.

The largest psychological association, in its comments, agreed and stated that research indicates that young people are indeed exposed to substantial and unavoidable advertising and promotion,<sup>94</sup> even though they have been banned from radio and television. Referencing numerous studies, this comment stated further that:

there is considerable evidence that young people are exposed to tobacco ads, that those who smoke are especially likely to be aware of cigarette advertising, and that liking of cigarette advertising among young people is predictive of smoking behavior \* \* \*.

The comment continued that increasing one's exposure to advertising and promotions creates persuasion, and that reducing that exposure will impede that process.<sup>95</sup> One study<sup>96</sup> found that even brief exposure to tobacco advertising can cause some young people to have more favorable beliefs about smokers.<sup>97</sup>

FDA did not cite the industry's expenditures to indicate that the size of the industry's advertising budget was, in and of itself, a problem, but rather to show that the very size of the campaign, and the resultant ubiquity and unavoidability of the advertising in all media, created a climate that influences young people's decisions about tobacco use. The ubiquity creates what FDA referred to in the preamble to the proposed rule (60 FR 41314 at 41343), as "friendly familiarity" that makes smoking and smokeless tobacco use seem respectable to young people. In its comments, the advertising agency that coined this phrase in the 1960's has

<sup>94</sup> Fischer, P. M., M. P. Schwartz, J. W. Richards, A. O. Goldstein, and T. H. Rojas, "Brand Logo Recognition by Children Aged 3 to 6 years: Mickey Mouse and Old Joe Camel," *Journal of the American Medical Association (JAMA)*, vol. 266, pp. 3145-3148, 1991; Mizerski, R., K. Straughn, and J. Feldman, "The Relationship Between Cartoon Trade Character Recognition and Product Category Attitude in Young Children," presented at Marketing and Public Policy Conference, 1994.

<sup>95</sup> For example, Lavidge, R. J., and G. A. Steiner, "A Model for Predictive Measurements of Advertising Effectiveness," *Journal of Marketing*, vol. 25, pp. 59-62, 1961; McGuire, W. J., "Persistence of the Resistance to Persuasion Induced by Various Types of Prior Belief Defenses," *Journal of Abnormal and Social Psychology*, vol. 64, pp. 241-248, 1962.

<sup>96</sup> Pechmann, C., and S. Ratneshwar, "The Effects of Antismoking and Cigarette Advertising on Young Adolescents' Perceptions of Peers who Smoke," *Journal of Consumer Research*, vol. 21, pp. 236-251, 1994.

<sup>97</sup> See also, Hock, J., P. Gendall, and M. Stockdale, "Some Effects of Tobacco Sponsorship Advertisements on Young Males," *International Journal of Advertising*, vol. 12, pp. 25-35, 1993.

protested that FDA used the phrase improperly. However, regardless of the firm's protest, the agency finds that this phrase "friendly familiarity" accurately describes the effect of massive marketing that uses a variety of media and saturates potential consumers with information and imagery. Researchers have found that "the ubiquitous display of messages promoting tobacco use clearly fosters an environment in which experimentation by youth is expected, if not implicitly encouraged."<sup>98</sup>

b. *Evidence regarding young people's exposure to, recall of, approval of, and response to advertising.* Many studies have demonstrated that young people are aware of, respond favorably to, and are influenced by cigarette advertising. In the preamble to the 1995 proposed rule, FDA presented a number of studies examining young people's exposure to, recall of, approval of, and response to cigarette advertising.<sup>99</sup> Collectively, these studies showed that children who smoke are more likely to correctly identify cigarette advertisements and slogans in which the product names or parts of the slogans have been removed than are children who do not smoke, and that exposure to and approval of cigarette advertising were positively

<sup>98</sup> Bonnie, R. J., and B. S. Lynch, "Time to Up the Ante in the War on Smoking," *Issues in Science and Technology*, vol. 11, pp. 33-37, 1994.

<sup>99</sup> Chapman, S., and B. Fitzgerald, "Brand Preference and Advertising Recall in Adolescent Smokers: Some Implications for Health Promotion," *American Journal of Public Health*, vol. 72, pp. 491-494, 1982; Aitken, P. P., and D. R. Eadie, "Reinforcing Effects of Cigarette Advertising on Under-Age Smoking," *British Journal of Addiction*, vol. 85, pp. 399-412, 1990; Goldstein, A. O., P. M. Fischer, J. W. Richards, and D. Creten, "Relationship Between High School Student Smoking and Recognition of Cigarette Advertisements," *Journal of Pediatrics*, vol. 110, pp. 488-491, 1987; Botvin, G. L., C. J. Goldberg, E. M. Botvin, and L. Dusenbury, "Smoking Behavior of Adolescents Exposed to Cigarette Advertising," *Public Health Reports*, vol. 108, pp. 217-224, 1993; Klitzner, M., P. J. Gruenewald, and E. Bamberger, "Cigarette Advertising and Adolescent Experimentation With Smoking," *British Journal of Addiction*, vol. 86, pp. 287-298, 1991; Aitken, P. P., D. R. Eadie, G. B. Hastings, and A. J. Haywood, "Predisposing Effects of Cigarette Advertising on Children's Intentions to Smoke When Older," *British Journal of Addiction*, vol. 86, pp. 383-390, 1991; O'Connell, D. L., H. M. Alexander, A. J. Dobson, D. M. Lloyd, G. R. Hards, H. J. Springthorpe, and S. R. Leeder, "Cigarette Smoking and Drug Use in Schoolchildren: II. Factors Associated With Smoking," *International Journal of Epidemiology*, vol. 10, pp. 223-231, 1981; Alexander, H. M., R. Calcott, A. J. Dobson, G. R. Hards, D. M. Lloyd, D. L. O'Connell, et al., "Cigarette Smoking and Drug Use in Schoolchildren: IV. Factors Associated With Changes in Smoking Behaviour," *International Journal of Epidemiology*, vol. 12, pp. 59-66, 1983.

related to smoking behavior and intentions to smoke.

(10) Several comments from the tobacco industry and advertising groups were critical of these studies. The comments argued that none of the studies demonstrated that recognition of, exposure to, or approval of, cigarette advertising caused the initiation of cigarette smoking; that smoking in fact engendered increased exposure to, approval of and recognition of cigarette advertising; and that the samples were inappropriate and not generalizable. One comment took issue with the way in which smoking transition was defined in the Aitken study cited by the agency.<sup>100</sup> In addition, the same comment questioned the use of self-reported measures of cigarette advertising exposure in several of the studies.

FDA agrees that none of these studies individually is sufficient to: (1) Establish that advertising has an effect of directly causing minors to use tobacco products; (2) determine directionality—that is, did advertising cause the observed effect, or are smokers more observant of advertising (the Klitzner, Aitken, et al., and Alexander studies attempted to control for this effect); or (3) define terms or disprove the influence of peer pressure in smoking behavior.

However, none of these defects is sufficient to render it inappropriate for FDA to use the studies as evidence. The studies, in fact, present useful insight into how advertising affects smoking behavior and when considered with other studies provide sufficient support for the agency's conclusions. For example, one study<sup>101</sup> stated that the results show that part of the process of becoming a smoker is to adopt a preferred brand, which the advertising and tobacco industries concede is affected by advertising. Moreover, these studies clearly indicate that, at a minimum, advertising plays an important role in developing an appealing and memorable image for brands. Finally, FDA recognizes that advertising may not be the most important factor in a child's decision to smoke; however, the studies cited by the agency establish that it is a substantial,

contributing, and therefore material, factor.

c. *Evidence concerning overestimation of smoking prevalence.* In the preamble to the 1995 proposed rule, FDA cited numerous studies finding that children's misperceptions about the prevalence of smoking are related to smoking initiation and the progression to regular smoking.<sup>102</sup> Further, the evidence indicated that cigarette advertising plays a role in leading young people to overestimate the prevalence of smoking.

(11) Several comments criticized the overestimation of smoking prevalence studies presented by FDA in its 1995 proposed rule. The most common criticism was that the cited studies did not demonstrate a causal relationship between either exposure to advertising or overestimation of smoking prevalence and intentions to smoke. One comment noted that some of the cited studies did not necessarily measure "overestimation," but instead simply measured respondents' perceptions of smoking levels among their peers and adults. Another comment argued that FDA ignored other variables (such as whether or not one's friends smoked) that were predictive of smoking status or intentions to smoke.

It is true that some of the cited studies did not measure "overestimation" in the most literal sense but instead measured respondents' perceptions of smoking levels among peers and adults. However, the perceived levels were still uniformly higher among those who smoked than among those who did not. The importance of these studies is the fact that they established differences in perception between smoking and

nonsmoking young people about the prevalence, and therefore the acceptability, of smoking.

d. *The effects of selected advertising campaigns that were effective with children.* In the preamble to the 1995 proposed rule, FDA presented evidence about two campaigns that appear to have been particularly effective with children, and a historical analysis of trends in U.S. smoking initiation among 10- to 20-year-olds from 1944 to 1980.<sup>103</sup>

FDA presented several studies finding that the "Joe Camel" campaign had a significant impact on underage smoking in the United States,<sup>104</sup> and that a humorous character for Embassy Regal cigarettes named "Reg" was appealing to children in the United Kingdom.<sup>105</sup>

FDA also cited a recent study that used data from the National Health Interview Survey to study trends in smoking initiation among 10 to 20 year olds from 1944 through 1980.<sup>106</sup> The study concluded that tobacco marketing campaigns that targeted women resulted in increased smoking uptake in young women and girls, but not in adults generally.<sup>107</sup>

The Joe Camel Campaign—In the preamble to the 1995 proposed rule,

<sup>103</sup> Pierce, J. P., E. Gilpin, D. M. Burns, E. Whalen, B. Rosbrook, D. Shopland, and M. Johnson, "Does Tobacco Advertising Target Young People to Start Smoking?" *JAMA*, vol. 266, pp. 3154–3158, 1991; Fischer, P. M., M. P. Schwartz, J. W. Richards, A. O. Goldstein, and T. H. Rojas, "Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe Camel," *JAMA*, vol. 266, pp. 3145–3148, 1991; Hastings, G. B., H. Ryan, P. Teer, and A. M. MacKintosh, "Cigarette Advertising and Children's Smoking: Why Reg was Withdrawn," *British Medical Journal*, vol. 309, pp. 933–937, 1994; Pierce, J. P., L. Lee, and E. A. Gilpin, "Smoking Initiation by Adolescent Girls, 1944 through 1988: An Association with Targeted Advertising," *JAMA*, vol. 271, pp. 608–611, 1991.

<sup>104</sup> Fischer, P. M., M. P. Schwartz, J. W. Richards, A. O. Goldstein, and T. H. Rojas, "Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe Camel," *JAMA*, vol. 266, pp. 3145–3148, 1991; Pierce, J. P., E. Gilpin, D. M. Burns, E. Whalen, E. Rosbrook, D. R. Shopland, and M. Johnson, "Does Tobacco Advertising Target Young People to Start Smoking?" *JAMA*, vol. 266, pp. 3154–3158, 1991.

<sup>105</sup> Hastings, G. B., H. Ryan, P. Teer, and A. M. MacKintosh, "Cigarette Advertising and Children's Smoking: Why Reg was Withdrawn," *British Medical Journal*, vol. 309, pp. 933–937, 1994.

<sup>106</sup> Pierce, J. P., L. Lee, and E. A. Gilpin, "Smoking Initiation by Adolescent Girls, 1944 through 1988: An Association with Targeted Advertising," *JAMA*, vol. 271, pp. 608–611, 1994.

<sup>107</sup> *Id.*; See also Pierce, J. P., and E. A. Gilpin, "A Historical Analysis of Tobacco Marketing and Uptake of Smoking by Youth in the United States: 1890–1977," *Health Psychology*, vol. 14, pp. 500–508, 1995. Burns, D. M., L. Lee, J. W. Vaughn, Y. K. Chiu, and D. R. Shopland, "Rates of Smoking Initiation Among Adolescents and Young Adults, 1907–1981," *Tobacco Control*, vol. 4, suppl. 1, pp. 52–58, 1995.

<sup>100</sup> Aitken, P. P., D. R. Eadie, G. B. Hastings, and A. J. Haywood, "Predispersing Effects of Cigarette Advertising on Children's Intentions to Smoke When Older," *British Journal of Addiction*, vol. 86, pp. 383–390, 1991.

<sup>101</sup> Chapman, S., and B. Fitzgerald, "Brand Preference and Advertising Recall in Adolescent Smokers: Some Implications for Health Promotion," *American Journal of Public Health*, vol. 72, pp. 491–494, 1982.

<sup>102</sup> Chassin, L., C. C. Presson, S. J. Sherman, E. Corty, and R. W. Olshavsky, "Predicting the Onset of Cigarette Smoking in Adolescents: A Longitudinal Study," *Journal of Applied Social Psychology*, vol. 14, pp. 224–243, 1984; Collins, L. M., S. Sussman, J. Mestel Rauch, C. W. Dent, C. A. Johnson, W. B. Hansen, and B. R. Flay, "Psychosocial Predictors of Young Adolescent Cigarette Smoking: A Sixteen-Month, Three-Wave Longitudinal Study," *Journal of Applied Social Psychology*, vol. 17, pp. 554–573, 1987; Sussman, S., C. W. Dent, J. Mestel-Rauch, C. A. Johnson, W. B. Hansen, and B. R. Flay, "Adolescent Nonsmokers, Triers, and Regular Smokers' Estimates of Cigarette Smoking Prevalence: When do Overestimations Occur and by Whom?," *Journal of Applied Social Psychology*, vol. 18, pp. 537–551, 1988; 1994 SGR, p. 192–195, citing Burton, et al., The L.A./Finland Study; Sherman, S. J., C. C. Presson, L. Chassin, E. Corty, and R. Olshavsky, "The False Consensus Effect in Estimates of Smoking Prevalence: Underlying Mechanisms," *Personality and Social Psychology Bulletin*, vol. 9, pp. 197–207, 1983; Botvin, G. J., C. J. Goldberg, E. M. Botvin, and L. Dusenbury, "Smoking Behavior of Adolescents Exposed to Cigarette Advertising," *Public Health Reports*, vol. 108, pp. 217–224, 1993.

FDA described R. J. Reynolds' (RJR) use of the cartoon Joe Camel as the centerpiece of a very successful campaign that sought to revitalize Camel cigarettes. The preamble to the 1995 proposed rule described two sets of studies. One set indicated that the campaign was so pervasive and juvenile that children as young as 3 to 6 years old, recognized the Joe Camel character and knew that he sold cigarettes. The other set of studies provided evidence that the campaign had resulted in Camel's share of the adolescent youth market rising from below 4 percent of underage smokers to between 13 and 16 percent in a short period of time (60 FR 41314 at 41333).

This description of the Camel campaign produced over 200 comments from the advertising, tobacco, legal and publications industries, members of legislative bodies, State and local government officials and agencies, health providers and organizations, academics, and the general public. The latter included many anecdotal references to children's positive reactions to the campaign, including comments from parents, teachers, and children themselves. One comment, from a State attorney general, stated that "in 1993, after reviewing research documenting the extremely powerful effect R. J. Reynolds' 'Cool Joe Camel' ads have on children, I joined with 26 other State Attorneys General in calling" for a ban on that campaign.

(12) The comments differed radically in assessing the accuracy of FDA's use of Joe Camel as evidence of the effect of a youth-oriented campaign. A number of comments stated that the Joe Camel campaign was neither directed toward children nor effective at reaching them, and that FDA's evidence did not support the agency's position. The comments criticized the studies cited by FDA and referred to other studies that they believed supported their contention that the Joe Camel campaign was not directed toward children. For example, one comment argued there was no evidence to suggest that brand recognition had any influence on smoking initiation. This same comment also complained that the studies relied on by FDA were ungeneralizable and were from medical journals, not marketing journals. Another comment argued that the Pierce study cited by the agency had demonstrated only that Camel and Marlboro were thought to be

the most advertised brands across all respondent age groups.<sup>108</sup>

Several comments argued that the finding in the Fischer and Mizerski studies that children recognize Joe Camel did not necessarily indicate that they liked Joe Camel, let alone that they would be more likely to take up cigarette smoking.<sup>109</sup> For example, some comments from the tobacco industry discussed the Mizerski study funded by RJR and criticized FDA's use of it. FDA, as noted above, had cited this study in the 1995 proposed rule to show that 72 percent of 6 year olds and 52 percent of children between the ages of 3 and 6 could identify Joe Camel.<sup>110</sup> This exceeded the recognition rates for Ronald McDonald, a character frequently advertised on television. The comments, however, stated that the results of the study indicated that while recognition of the cartoon trade characters and liking of the associated product each tended to increase with age, for Joe Camel, at every age, children who recognized Joe Camel were more likely to report disliking cigarettes than did children who did not recognize Joe Camel.

Several comments also cited another study by Henke (the Henke Study),<sup>111</sup> which found results suggesting that even though recognition of brand advertising symbols increases with age, recognition does not necessarily indicate favorable attitudes about a product. Although the children in the study were generally able to recognize Joe Camel, 97 percent of the respondents reported that cigarettes were "bad for you," and all but one of the minors stated that cigarettes were for adults. Several comments also mentioned a November 1993 Roper survey of over 1,000 young people

between ages 10 and 17.<sup>112</sup> This survey found that 97 percent of those youths who recognized "Joe Camel" had negative opinions about smoking.

Finally, these comments also stated that the Joe Camel campaign did not increase the smoking rates of minors. The comments cited to data from CDC's Office of Smoking and Health's (OSH's) study "1993 Teenage Attitudes and Practices Survey, Public Use Data Tape" (TAPS II)<sup>113</sup> that show that, contrary to FDA's assertion and citation to data from Monitoring the Future,<sup>114</sup> there has not been an increase in youth smoking rates as a result of the Joe Camel campaign.

Conversely, several comments from professional associations and many from private citizens supported FDA's tentative conclusion that some tobacco advertising campaigns—particularly Joe Camel—are very effective with children. Some comments referred to the same research evidence cited by FDA in the 1995 proposed rule.

It is not the agency's position that the recognition studies provide evidence of the effect of this campaign upon the smoking habits of children. The Henke study found that children age 6 and younger do not smoke and uniformly report that they dislike smoking.<sup>115</sup> However, although young children usually dislike smoking, many of them later do smoke. FDA's point in using the recognition studies was that advertising for Camel cigarettes was so pervasive and appealing to young people that children saw the advertisements and assimilated them even though they were too young to even think about smoking. These studies provide important evidence of the pervasiveness of tobacco advertising.

The Henke study (cited by comments opposed to the 1995 proposed rule), which reported that although recognition of brand advertising symbols increases with age, recognition does not necessarily indicate favorable attitudes toward a product—is subject to

<sup>108</sup> Pierce, J., et al., "Does Tobacco Advertising Target Young People to Start Smoking? Evidence from California," *JAMA*, vol. 266, No. 22, p. 3154–3158, 1991.

<sup>109</sup> Fischer, P. M., et al., "Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel," vol. 266, pp. 3145–3148, 1991; Mizerski, R., "The Relationship Between Cartoon Trade Character Recognition and Product Category Attitude in Young Children," presented at "Marketing and Public Policy Conference," May 13–14, 1994.

<sup>110</sup> Independent research by Fischer found that 91 percent of 6 year-olds and 30 percent of 3 year-olds recognized Joe Camel. Fischer, P. M., J. W. Schwartz, A. O. Goldstein, and T. H. Rojas, "Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel," *JAMA*, vol. 266, pp. 3145–3148, 1991.

<sup>111</sup> Henke, L., "Young Children's Perceptions of Cigarette Brand Advertising Symbols: Awareness, Affect and Target Market Identification," *Journal of Advertising*, in press.

<sup>112</sup> Roper Starch, "Advertising Character and Slogan Survey," pp. 16–17, November 1993 (conducted for R. J. Reynolds Tobacco Co.).

<sup>113</sup> "1993 Teenage Attitudes and Practices Survey, Public Use Data Tape," CDC, OSH, p. 3, 1993 (unpublished data).

<sup>114</sup> Johnston, L. D., P. M. O'Malley, and J. G. Bachman, *National Survey Results on Drug Use from the Monitoring the Future Survey, 1975–1993: vol. I: Secondary School Students*, Rockville, MD, DHHS, Public Health Service (PHS), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), NIH Pub. No. 94–3809, 1994.

<sup>115</sup> Henke, L., "Young Children's Perceptions of Cigarette Brand Advertising Symbols: Awareness, Affect and Target Market Identification," *Journal of Advertising*, in press.

many of the same criticisms as those leveled by the tobacco industry at studies cited by FDA, and in fact contains more serious flaws that suggest that its results should be interpreted with a great deal of caution.

First, the sample employed in this study was both inadequate to test the author's hypotheses, and is nongeneralizable to other populations. There were only 83 participants in the study; this sample is too small to allow for adequate power to test the author's fine-grained hypotheses concerning age. In fact, the inadequate sample size led the author to collapse the participants into three age groups for many analyses, which meant that 3-year olds were placed into the same group as children who were 5-and-a-half years old. In addition, participants all were recruited from middle class neighborhoods in the same "small coastal town" in Maine. Racial breakdowns were not presented, but it is likely, given the demographics of upstate Maine, that whites were overrepresented and African-Americans underrepresented. In addition, males were overrepresented. At best, the sample represents the population of 3- to 8-year-old children in that small town in Maine, but it is not even clear that this is the case.

Second, the interview process used to collect data in the study, and even the nature of the interviewers themselves, greatly limit the conclusions that may be drawn from the study. The study used six different interviewers, five of whom were college undergraduates, and one of whom was a child care professional. Each interviewer participated in but a single training session before collecting data. Further, not all of the interviewers were blind to the hypotheses of the study. This is a great concern, considering the very subjective nature of the interview. It was not reported whether who the interviewer was had significant effects on the results of the study (and indeed the sample size is probably too small to permit such an analysis), but it is unlikely that all six interviewers conducted the interviews in precisely the same way or elicited the same types of responses from the participants.

The interview process itself appeared to be highly biased and subjective in nature. It is not surprising that the children overwhelmingly reported that cigarettes were "bad for you" and were meant for adults, given that they were being interviewed face-to-face by adult strangers. Any potential differences attributable to recognition of cigarette advertising were probably masked by

the intimidating presence of the interviewer. Further, the answers to questions such as "Do you like this product or not like this product?," and "Is this product good for you or bad for you?" can depend to a great extent on the manner in which they are asked.

Overall, the small, nonrepresentative sample, the excessive number of questionable interviewers, and the interview process itself all cast serious doubt on the value of this study. Finally, as noted in the previous paragraph, children almost uniformly report that smoking is bad, but many of them will smoke in the future in part due to the appeal created for the product by advertising.

Additional studies—Two additional studies on this issue of recognition were submitted to the docket. The first, an article by Joel S. Dubow,<sup>116</sup> merely commented on several general studies on recall of advertising. The result was that children and especially adolescents remember more about advertising than adults. (FDA agrees with the point that advertising is more memorable to children.) Further, all the advertisements tested, and those that children and adolescents remembered so well, were either on television or presented in a movie theater setting.

Children and adolescents are more visually oriented than adults; they remember what they see on television. However, as noted, commercials for cigarettes are not on television and so the high recognition rates of Joe Camel cannot be accounted for on that basis. Thus, the study begs the same question that is raised by the Mizerski study: Where did those 3 to 6 year olds see the cigarette advertisements they found so memorable?

The answer may be provided by the second recognition study submitted by RJR. One study was conducted by Roper Starch in November 1993 for RJR and tested young people's recognition of advertising characters. The results of that study show that Joe Camel was recognized by 86 percent of all 10 to 17 year olds, in both aided and unaided recall. The characters with greater recognition were all televised characters: the Energizer Bunny, Ronald McDonald, the Keebler Elves, etc. Recognition scores for those characters were in the 97 percent to 100 percent range. Of more interest, 95 percent of those who recognized Joe Camel knew that he sold cigarettes, similar to the

product familiarity rates for the other characters.<sup>117</sup>

But perhaps the most interesting answers were those provided by the children who responded that they knew that Joe Camel sold cigarettes. In response to the question, "[p]lease tell me the ways that you might have seen or heard about this character," 51 percent said the information came from a billboard advertisement, 45 percent said from an advertisement in a magazine, 32 percent said from an advertisement in the store, and 22 percent said on a tee shirt. A sizable group said they had seen him on television (42 percent). On the other hand, all the other characters were identified as having been on television (88 percent to 100 percent). Recognition based upon billboard exposure for these other characters was between 6 percent and 13 percent. Most were not recognized as having been on tee shirts.

Clearly, cigarettes are marketed differently than most consumer products; nonetheless, whatever the marketing mix used by the tobacco industry, cigarette advertisements are clearly being seen and assimilated by those too young to be interested in or to have started smoking.

A second type of study, provided evidence of the effect of this campaign on adolescent smoking rates. As noted, one comment disputed that there was a rise in young people's smoking rates that corresponded to the introduction of the Joe Camel campaign. The significance of this argument is that if smoking rates after the introduction of the Joe Camel advertising campaign did not rise, there is little reason to believe that the campaign caused young people to take up smoking. This comment referred to its own analysis of smoking trends, which it stated were derived from TAPS II<sup>118</sup> data and not from the data in Monitoring the Future used by FDA.<sup>119</sup>

FDA has provided a more detailed answer to this comment above. As explained there, the agency finds this comment to be without merit. The Monitoring the Future study is the most consistent source of data available on youth smoking rates. RJR's expert, Dr. J.

<sup>117</sup> "Advertising Character and Slogan Survey," pp. 10, 12, 22-23.

<sup>118</sup> "Current Trends: Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989-1993," *MMWR*, CDC, vol. 43, pp. 577-581, Aug 19, 1994.

<sup>119</sup> Johnston, L. D., P. M. O'Malley, and J. G. Bachman, *National Survey Results on Drug Use from the Monitoring the Future Study, 1975-1993: Vol. I; Secondary School Students*, DHHS, PHS, NIH, NIDA, NIH Pub. No. 94-3809, 1994.

<sup>116</sup> Dubow, J. S., "Advertising Recognition and Recall by Age-Including Teens," *Journal of Advertising Research*, pp. 55-60, Sept/Oct 1995.

Howard Beales, III, has referred to it as "[t]he most consistent data available" to track the incidence of teen smoking over time.<sup>120</sup> Moreover, Dr. Beales noted that other Government studies are "sporadic" and, by implication, cannot be relied upon to give an accurate picture of overall smoking trends.

The Monitoring the Future Study indicates that from 1987 to 1993, the 30-day smoking rates and daily smoking rates for male high school seniors increased steadily, although with variations in some years.<sup>121</sup> During that same period, Camel's share of the youth market rose from below 4 percent to around 13 percent (60 FR 41314 at 41330).

These data do not absolutely prove that Camel advertising "caused" a rise in youth smoking. However, they do provide further evidence that the Joe Camel campaign had an effect on youth smoking rates.

(13) Comments from the tobacco industry maintained that FTC's investigation, which failed to produce "evidence to support" FTC action against RJR for the Joe Camel campaign, should have been dispositive of the issue. Therefore, the comments argued, it is inappropriate for FDA to use the campaign as evidence that advertising causes children to start to smoke. The comments maintained that the FTC review included the same studies relied upon by FDA to condemn the Joe Camel campaign.

Comments stated further that Congress has vested jurisdiction in FTC to prosecute unfair and deceptive advertising of tobacco products, and that it has sole jurisdiction in this area. (See Federal Trade Commission Act (the FTC Act) (15 U.S.C. 41).) These comments noted further that FTC has shown its ability to fulfill its responsibilities in this area, citing two recent consent agreements secured by FTC. One was against RJR for advertising that disputed some of the health risks of smoking. (See *In the matter of R. J. Reynolds Tobacco Company*, 113 FTC 344 (1990).) The other was against American Tobacco Company for allegedly misleading statements about tar and nicotine ratings. (See *In the matter of The American Tobacco Company*, Dkt. No.

C-3547 (Consent Order, January 31, 1995).)

On the other hand, comments from two national health organizations alleged that the fact FTC concluded it was unable to take action against Joe Camel demonstrates that the FTC Act, as it is currently being interpreted by the Commission, is not sufficient to protect American youth from inappropriate tobacco advertising and that FDA, therefore, needs to take action under its authority.

The industry comments misapprehend FDA's citation to the Joe Camel campaign. As noted above, FDA cited to numerous studies that had been performed by independent researchers on children's recognition of the main character of a youth oriented advertising campaign (60 FR 41314 at 41333). The agency also cited to several documents that it had obtained that indicated that RJR may have intended for its Joe Camel campaign to appeal to and attract young people (60 FR 41314 at 41330). FDA's discussion of the marketing success of the Joe Camel campaign is not intended to suggest that FDA had found or concluded that the Joe Camel campaign violated any law, but that FDA had found in that success—tripling Camel's share of the youth market—support for restricting such activities in the future through rulemaking.

Moreover, FTC did not disagree with FDA's use of the campaign. In its comment to FDA on the 1995 proposed rule, FTC stated, "This decision [by FTC to close the RJR investigation without issuing a complaint] does not contradict FDA's conclusion." FTC continued that its failure to initiate legal action did not "mean that cigarette and smokeless tobacco advertising, in the aggregate, is not one of a number of factors that 'play[s] an important role in a youth's decision to use tobacco.'" <sup>122</sup>

(14) The other citation to the Joe Camel campaign (60 FR 41314 at 41330) utilized RJR's documents to illustrate the youth focus of one advertising campaign through use of the company's own documents. Some comments received from the tobacco industry (including one from RJR), trade associations, and some individuals disagreed with this use and stated that the Camel campaign was designed to, and did in fact, attract the attention of

young adult smokers, aged 18 to 24. These comments stated that the Joe Camel campaign was directed to adult smokers, specifically existing male Marlboro smokers aged 18 to 24. The comments stated that the illustrated character Joe Camel was developed to reposition the brand by stressing images and characteristics, such as the "Smooth Moves" image, which appeal to the young adult, particularly male, Marlboro smoker.

Industry comments further stated that the company conducted no market research on nonsmokers, and that the campaign reached adult smokers aged 18 to 24 years. One comment postulated that it is merely the cartoon form of Joe Camel that causes people to mistakenly believe that Joe Camel is child-oriented. It stated further that many adult products are advertised using illustrated characters, such as the Pink Panther for fiberglass insulation, Garfield the Cat for a hotel chain, Mr. Clean for household products, and the Peanuts characters for life insurance. Moreover, RJR stated that it made efforts to ensure that the ad copy and promotional activity for Joe Camel would not appeal to minors. It said that a skateboard promotion proposed by an advertising agency was rejected by the company because it was assumed that skateboarding is disproportionately engaged in by children and adolescents. Similarly, marketing research included 25 to 34 year olds "to serve as a safety check to make sure that the concept appeal did not skew too young."

These comments further stated that Joe Camel advertisements were directed to, and reached, the intended market. Examples of publications in which the Joe Camel advertisements were placed are *Cycle World*, *Penthouse*, *Gentleman's Quarterly*, and *Road and Track*. Joe Camel's share of 18 to 24 year olds increased by 6.9 percentage points, from 3.2 in 1986, the year before Joe Camel's inception, to 10.1 by the end of 1994. The comment stated that Camel's and Marlboro's growth came at the expense of other brands. These comments are consistent with the industry's assertion that this is the whole point of cigarette advertising: to encourage current smokers to buy the advertised brand either by switching brands or remaining loyal to their existing brands. (This comment states that because there is no evidence that smoking rates have risen among adolescents, there cannot be a reason to believe that Camel's success among adolescents came from new, as opposed to existing, smokers. See section III.B. of

<sup>120</sup> Beales, J. H., "Teenage Smoking: Fact and Fiction," *The American Enterprise*, vol. 21, March/April 1994.

<sup>121</sup> Johnston, L. D., P. M. O'Malley, and J. G. Bachman, *National Survey Results on Drug Use from the Monitoring the Future Study, 1975-1994, Vol. I: Secondary School Students*, DHHS, PHS, NIH, NIDA, NIH Pub. No. 94-3809, 1995.

<sup>122</sup> FTC analyzed the complaint recommendation before it under its unfairness jurisdiction. An action is unfair if it causes substantial consumer injury, without offsetting benefits to consumers or competition, which consumers cannot reasonably avoid. (*International Harvester*, 194 FTC 949, 1070, 1984.)

this document for a refutation of the industry assertion that smoking rates among adolescents are static.)

In contrast, comments from health organizations and concerned citizens stated that Joe Camel has been successful in attracting underage smokers. These comments further stated the belief that the campaign was intended to attract children, citing the methods of advertising and promotion employed as evidence of its intention to appeal to children. For example, one comment stated: “\* \* \* T-shirts and caps, like those marketed with ‘Joe Camel’ are found in disproportionate numbers of children.”

FDA continues to believe that RJR documents do illustrate the creation of and execution of a decidedly youth-oriented campaign.

FDA finds that previously confidential RJR documents provide convincing evidence of the company’s intention to attract young smokers and so-called presmokers to its Camel brand. These documents, identified as RJR marketing documents and submitted during the comment period, reflect a company policy that in order to grow and ensure a profitable future, the company must develop new brands that would appeal to and capture a share of the youth market. These young people were described as “presmokers” and “learners” in RJR marketing language and were identified as being 14 to 18 year olds.

While the documents concerning the Camel campaign (focus group reports, etc.) submitted by RJR to the rulemaking docket do not identify the under-18 group as the company’s target, the implication arises from the company-submitted documents that the Camel campaign was the logical outgrowth of the planning and forecasting contained in the heretofore confidential marketing documents.

In a 1972 memo entitled “Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein,” the author, Claude Teague Jr., Assistant Director of Research and Development, wrote:

[I]t may be well to consider another aspect of our business; that \* \* \* the factors which induce a presmoker or nonsmoker to become a habituated smoker. \* \* \* He does not start smoking to obtain undefined physiological gratifications or reliefs, and certainly he does not start to smoke to satisfy a nonexistent craving for nicotine. Rather, he appears to start to smoke for purely psychological reasons—to emulate a valued image, to conform, to experiment, to defy, to be daring, to have something to do with his hands, and the like. Only after experiencing smoking for

some period of time do the physiological “satisfactions” and habituation become apparent and needed. Indeed, the first smoking experiences are often unpleasant until a tolerance for nicotine has been developed. \* \* \* [I]f we are to attract the nonsmoker or presmoker, there is nothing in this type of product that he would currently understand or desire. We have deliberately played down the role of nicotine, hence the nonsmoker has little or no knowledge of what satisfactions it may offer him and no desire to try it. Instead, we somehow must convince him with wholly irrational reasons that he should try smoking, in the hope that he will for himself then discover the real “satisfactions” obtainable.<sup>123</sup>

In 1973, the same author reported in another memo, “Research Planning Memorandum on Some Thought about New Brands of Cigarettes for the Youth Market,” his thoughts on how to acquire a portion of the important youth market:

[W]e should simply recognize that many or most of the “21 and under” group will inevitably become smokers, and offer them an opportunity to use our brands. Realistically, if our Company is to survive and prosper, over the long-term we must get our share of the youth market. In my opinion this will require new brands tailored to the youth market; I believe it unrealistic to expect that existing brands identified with an over-thirty ‘establishment’ market can ever become the ‘in’ products with the youth group. Thus we need new brands designed to be particularly attractive to the young smoker, while ideally at the same time being appealing to all smokers.<sup>124</sup>

Mr. Teague then described the factors he thought must be taken into account in designing a brand that would attract young people:

Several things will go to make up any such new “youth” brands, the most important of which may be the image and quality—which are, of course, interrelated. The questions then are: What image? and What quality? Perhaps these questions may best be approached by consideration of factors influencing pre-smokers to try smoking, learn to smoke and become confirmed smokers. \* \* \* For the pre-smoker and “learner” the physical effects of smoking are largely unknown, unneeded, or actually quite unpleasant or awkward. The expected or derived psychological effects are largely responsible for influencing the pre-smoker to try smoking, and provide sufficient motivation during the “learning” period to keep the “learner” period going, despite the physical unpleasantness and awkwardness of the period. \* \* \*<sup>125</sup>

Mr. Teague continues with some reasons why young people smoke and

<sup>123</sup> Teague, C., *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein*, pp. 4–5, 1972.

<sup>124</sup> Teague, C., *Research Planning Memorandum on Some Thought About New Brands for Cigarettes for the Youth Market*, p. 1, 1973.

<sup>125</sup> *Id.*, pp. 1–2.

then gives advice on the type of advertising campaign that would appeal to the presmoker group based on these reasons:

A. *Group Identification*—Pre-smokers learn to smoke to identify with and participate in shared experiences of a group of associates. If the majority of one’s closest associates smoke cigarettes, then there is strong psychological pressure, particularly on the young person, to identify with the group, follow the crowd, and avoid being out of phase with the group’s value system even though, paradoxically the group value system may esteem individuality. This provides a large incentive to begin smoking.

\* \* \* \* \*  
[The brand’s] promotion should emphasize togetherness, belonging and group acceptance, while at the same time emphasizing individuality and “doing ones own thing.”

B. *Stress and Boredom Relief*—The teens and early twenties are periods of intense psychological stress, restlessness and boredom. Many socially awkward situations are encountered. [the documents mentions smoking gives you something to do with your hands—find an ashtray etc.]

C. *Self-Image Enhancement*—The fragile, developing self-image of the young person needs all of the support and enhancement it can get. Smoking may appear to enhance that self-image in a variety of ways. [Values mentioned in the document include adventurousness, adult image.] If one values certain characteristics in specific individuals or types and those persons or types smoke, then if one also smokes he is psychologically a little more like the valued image. This self-image enhancement effect has traditionally been a strong promotional theme for cigarette brands and should continue to be emphasized.

D. *Experimentation*—There is a strong drive in most people, particularly the young, to try new things and experiences. This drive no doubt leads many presmokers to experiment with smoking, simply because it is there and they want to know more about it. A new brand offering something novel and different is likely to attract experimenters, young and old, and if it offers an advantage it is likely to retain those users.<sup>126</sup>

In March 1976 R. J. Reynolds’ Research Department created a memo entitled, “Planning Assumptions and Forecast for the Period 19\*–1986 for R. J. Reynolds Tobacco Company.” Under a heading, The Tobacco Industry and R. J. Reynolds Tobacco Company—subheading E. Products—the memo states:

The present large number of people in the 18–35 year old age group represents the greatest opportunity for long-term cigarette sales growth. Young people will continue to become smokers at or above the present rates during the projection period. The brands which these beginning smokers accept and

<sup>126</sup> *Id.*, pp. 6–7.



use will become the dominant brands in future years. Evidence now available \* \* \* indicate[s] that the 14 to 18 year old group is an increasing segment of the smoking population. RJR must soon establish a successful new brand in this market if our position in the industry is to be maintained over the long term.  
(Emphasis omitted.)<sup>127</sup>

By the mid to late 1980's, RJR was marketing its newly revitalized Camel brand to "young adults" 18 to 20 years old. According to an internal memo cited in the *Wall Street Journal*,<sup>128</sup> the business plan for 1990 had a single-minded focus on getting young adults, especially the 18 to 20 year olds, to smoke Camels. The brand was to be refocused on young adult smokers, aged 18 to 24 with a strong emphasis on males 18 to 20.<sup>129</sup>

<sup>127</sup> An RJR spokesperson referred to these documents and did not dispute their validity. (See Levy, D., "RJR Memo Targeted Teen Market," *USA Today*, p. 1D, October 6, 1995; "Report: Teen Cigarettes Eyed," *AP Online*, October 4, 1995); *Planning Assumptions and Forecast for the Period 197\*-1986 for R.J. Reynolds Tobacco Company*, Research Department, 1976.

<sup>128</sup> Freedman, A. M., and S. L. Huang, "Reynolds Marketing Strategy Sought to Get Young Adults to Smoke Camels," *Wall Street Journal*, p. B10, col. 3, November 2, 1995.

<sup>129</sup> A 1984 strategic research document, authored by Diane Burrows of R. J. Reynolds and entitled "Younger Adult Smokers: Strategies and Opportunities," came to FDA's attention as a result of its inclusion as an exhibit attached to a brief filed by the State of Minnesota and Blue Cross in Ramsey County District Court in litigation involving the seven tobacco companies. The document was also described in numerous press accounts of the event (e.g., Phelps, D., and J. Hodges, "Suit: Kids were focus of Reynolds strategy. Documents filed in state's lawsuit against the tobacco industry show how R. J. Reynolds targeted young smokers as critical to the industry's future," *Star Tribune*, 1A, July 11, 1996; Worklan, P., "R. J. Reynolds Secret Report Targets Young Adult Market," *Chicago Tribune*, N19, July 11, 1996.) Although the agency has not relied on this memo as part of the justification for this rule, FDA is citing to it here because it is relevant to the issues discussed.

The memo indicates that by 1984, R. J. Reynolds was beginning to conduct research on the concepts detailed above that were developed during the 1970's. The memo describes the problem facing Reynolds at that time of declining market share and then proposed a solution: "RJR's consistent policy is that smoking is a matter of free, informed, adult choice which the Company does not seek to influence. However, in order to plan our business, we must consider the effects those choices may have on the future of the Industry. Furthermore, if we are to compete effectively, we must recognize the imperative to know and meet the wants of those who are 18 and have already elected to smoke, as well as those of older smokers (emphasis added)."

The memo recognizes several important facts: "The renewal of the market stems almost entirely from 18-year-old smokers. No more than 5% of smokers start after age 24." Moreover, the memo also recognizes that: "[t]he brand loyalty of 18-year-old smokers far outweighs any tendency to switch with age. Thus, the annual influx of 18-year-old smokers provides an effortless, momentum to successful 'first brands'."

Documents submitted by RJR in its comment detail its plans for developing and promoting Joe Camel as the spokesperson for the brand. In language reminiscent of the 1973 Teague memo, RJR reemphasized the importance of the young adult smokers (which RJR nicknamed the "YAS")—noting that only 5 percent of smokers start after age 24.<sup>130</sup> The paper noted that 40 percent of the "virile" segment have made a brand choice at age 18—a brand to which they will be loyal for years or throughout their smoking career. Thus, although this document describes the YAS as 18 to 24 year olds, the company's interest appears to have been with those younger than 18 who are in the process of selecting their first brand, the 14 to 18 year olds described by Teague.

In addition, the problem, the White Paper emphasized, was that Camel needed a facelift to make it relevant to this YAS group. Research, they noted, indicates that YAS see advertising as "younger adult oriented" when it is speaking directly to them. Therefore, advertising needed to be developed to speak to the target audience, to appeal to the "hot buttons" of young people such as to "escape into imagination." "Fantasy to these smokers can mean imagining a place to escape to or an image of yourself that is better than reality."

These "first brands" were identified as those which appeal to the 18-year-old smoker rather than switchers ages 19–24.

The memo identifies additional factors that had to be considered in this calculus: (1) Although 18- to 24-year-olds account for a very small part of market share, this age group represents the future of a brand. Those young, brand loyal smokers who now consume very few cigarettes, will consume more cigarettes with age and generally remain loyal to this first brand, its brand family or to the company; (2) Although young smokers are easier to switch than older smokers, a brand can not rely exclusively on switching younger smokers to produce a lasting brand equity—the major and most important share advantage available to a company is to have a cigarette brand relevant to young people and accepted by them as their "first brand."

The reports's recommendation was to research and capitalize on the factors and strategies which have been successful with youth brands of the past. This would require devoting substantial resources to identifying and tracking values, wants, and media effectiveness relevant to younger people. Because of the sensitivity of this young market, the memo continued: "brand development/management should encompass all aspects of the marketing mix and maintain a long term, single-minded focus to all elements—product, advertising, name, packaging, media, promotion and distribution. (Emphasis omitted)"

This must include, the memo stated, a careful emphasis on the "imagery and product positives" relevant to "younger adults."

<sup>130</sup> "White Paper," Camel Advertising Development, p. 1, undated.

The YAS group also relates to excitement and fun, noted the White Paper: "Younger adults center their lives on having fun in every way possible and at every time possible. Their definition of success is 'enjoying today' which differentiates them from older smokers. Advertising which incorporates an 'exciting', 'fun', 'humorous' theme provides a way for these smokers to 'feel good' about the message."

By 1988 RJR was testing its new ideas about Camel. It described the results in a *Marketing Research Report*, entitled *Camel "Big Idea" Focus Groups—Round II* dated September 21, 1988, and written by M. R. Bolger. The group was composed of male Marlboro smokers ages 18 to 34. Two groups were men 18 to 20, two groups were 21 to 24, and one group was age 25 to 34 to serve as a "safety check" to make sure the concept did not skew too young. Various themes were tested and one, "Smooth Moves," was received best by the younger portion of the target—those that had fewer responsibilities, are single, and go to parties. The focus groups also showed that premiums (nontobacco items) performed best among the younger portion of the group. Older smokers were more discerning and saw the items as being of little value to them.<sup>131</sup>

What resulted from this research was the Joe Camel campaign, an unusually successful effort, particularly with the group that RJR research documents discussed—the 14 to 18 year olds. Thus, RJR appears to have used its research on 18 to 20 year olds to its advantage with the 14 to 18 year old group—a group who shares many of the same interests and "hot" buttons of the older group. These internal documents complement those cited in the preamble to the 1995 proposed rule. In the preamble to the 1995 proposed rule, FDA described two letters from RJR sales managers about the placement of YAS [Camel] merchandise. Both letters stated that high school neighborhoods were a likely location for YAS. RJR, in its comments to the proposed rule, stated that those two letters were mistakes. However, these latest documents rebut RJR's comment. The mistake made by the two sales representatives was in speaking too clearly of the company's intention.

"Reg"—The second campaign reviewed by FDA was the "Reg" campaign used in the United Kingdom. One comment took issue with FDA's claim that the "Reg" campaign was

<sup>131</sup> Bolger, M. R., "Camel 'Big Idea' Focus Groups—Round II," *Marketing Research Report*, September 21, 1988.

particularly effective with British adolescents and argued that the study that FDA relied on was based on unreliable evidence and is not applicable to American adolescents. The comment contended that there was no evidence to show that liking the "Reg" character caused children to smoke and argued instead that children who smoked came to like "Reg." The comment also argued that the recognition task, described in the study, was too suggestive and biased, and suggested that the young people were primed and pressured to say they had seen the advertisements during "games" that they say took place before the recognition task.

First, this comment is wrong. Games were played during another portion of the study, not the one referenced. The comment confused the quantitative survey with the qualitative. Second, evidence from England about youth smoking habits is no less probative than evidence from the United States, as it provides insights into children's smoking behavior.

**Smoking Trends**—A few comments were critical of the study of trends in the smoking initiation study, which found a temporal relationship between advertising targeted at women and rising initiation rates among girls and young women.<sup>132</sup> The principal criticisms were that the authors failed to examine the actual advertising campaigns in question, that FDA failed to consider alternative explanations for the study's findings, and that the study's measures were subjective and unreliable.

In response, the agency reiterates that it did not cite to this study, or any one study, as "proof" that advertising during this period "caused" a rise in smoking initiation. The study was provided as one example of targeted marketing being "associated" with increases in cigarette consumption among young people.<sup>133</sup> A logical inference to be drawn from the cumulative effect of such studies is that advertising does play a role in young people's smoking behavior.

*e. Evidence that youth brand choices are related to advertising.* Virtually all

of the comments from the tobacco industry claimed that cigarette and smokeless tobacco manufacturers market their products solely to adults. They disputed the findings of studies, cited by FDA in the preamble to the 1995 proposed rule, examining advertising campaigns that had been particularly effective with children. In addition, while the comments acknowledged that younger smokers are the intended targets for some cigarette advertising, they argued that only younger smokers of legal age were targeted.

In the preamble to the 1995 proposed rule, FDA presented a number of studies showing that youth cigarette brand choices are related to advertising.<sup>134</sup> These studies showed that young people smoke many fewer brands than adults, and that their choices are directly related to the amount and kind of advertising. While 86 percent of youths who smoke choose the three most advertised brands,<sup>135</sup> the most commonly smoked cigarettes (39 percent) among adult smokers are brandless (i.e., private label, generics, or plain packaged products).<sup>136</sup> Another study found that children who smoke as few as one cigarette per week can identify a preferred brand.<sup>137</sup>

One comment argued that the CDC study that found that most children smoke the three most advertised brands showed only a correlation between advertising expenditures and brand preferences, and that the data did not even support this correlation consistently. The comment noted that the data on which these findings were based included 18 year olds, who are of legal age to smoke. The comment also contended that the data did not allow a determination of what came first: Changes in advertising expenditures or changes in brand preference (directionality).

<sup>134</sup> "Current Trends: Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989–1993," *MMWR*, CDC, vol. 43, pp. 577–581, August 19, 1994; Goldstein, A. O., P. M. Fischer, J. W. Richards, and D. Creten, "Relationship Between High School Student Smoking and Recognition of Cigarette Advertisements," *Journal of Pediatrics*, vol. 110, pp. 488–491, 1987.

<sup>135</sup> "Current Trends: Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989–1993," *MMWR*, CDC, vol. 43, pp. 577–581, August 19, 1994.

<sup>136</sup> Teinowitz, I., "Add RJR to List of Cig Price Cuts," *Advertising Age*, pp. 3 and 46, April 26, 1993.

<sup>137</sup> Goldstein, A. O., P. M. Fischer, J. W. Richards, and D. Creten, "Relationship Between High School Student Smoking and Recognition of Cigarette Advertisements," *Journal of Pediatrics*, vol. 110, pp. 488–491, 1987.

The same comment also criticized the study indicating that children who smoke as few as one cigarette per week can identify a preferred brand. In addition to pointing out that the study did not demonstrate a causal relationship and that the sample was not generalizable, the comment argued that:

\* \* \* other research has found that adolescents smoke a smaller number of different brands than do adults, [the researchers] tested only the correlation between adolescent smoking and advertising recognition. [The researcher] did not know which brands the adolescents in this study smoked. [emphasis in original]

Contrary to the comment, these studies are evidence that, when considered together, form a coherent pattern that establishes the role that advertising plays in young people's smoking behavior.

The CDC study<sup>138</sup> provides evidence of young people's smoking choices. Neither the fact that the data included 18-year-olds nor the question of directionality is sufficient to invalidate the study's utility. While the data available for the study contained 18-year-old use, there is little difference between 17- and 18-year-old cigarette use; certainly not enough to invalidate the general finding that underage and 18-year-old smokers choose the three most heavily advertised brands. The issue of directionality of the results is no more important. The results showed that young people chose cigarettes that are heavily advertised, not ones that are cheap or low tar, etc. The CDC study, as noted, did not prove causality—it was not intended to and it did not.

The comment's criticism of the study, which involved children who smoke as few as one cigarette a week, is not correct. The researchers did know the brands that the adolescents in the study smoked. "Fifty-two percent of all students who had used cigarettes identified a single preferred brand \* \* \*. One brand of cigarettes (Marlboro) accounted for 76% of all preferred brands." The study's finding is consistent with every other study of adolescent brand preference: Marlboro is the number one brand choice.

The effect of advertising on brand choice by young people is important. It shows that young people choose the imagery of the two or three most highly advertised brands to smoke, brands that provide specific definitions of a user.

<sup>138</sup> "Current Trends: Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989–1993," *MMWR*, CDC, vol. 43, pp. 577–581, August 19, 1994.

<sup>132</sup> Pierce, J. P., L. Lee, and E. A. Gilpin, "Smoking Initiation by Adolescent Girls, 1944 through 1988, An Association with Targeted Advertising," *JAMA*, vol. 271, pp. 608–611, 1994.

<sup>133</sup> A more sophisticated example of this type of time series analysis was published by the FTC to show that health claims in food advertising could have a beneficial effect upon people's consumption of high fiber breakfast cereals. (Ippolito, P., and A. Mathios, *Health Claims in Advertising and Labeling, A Study of the Cereal Market*, Bureau of Economics Staff Report, FTC, August 1989.)

The choice permits the user to adopt the image created by the brand.

f. *The Canada advertising case.* A series of comments raises new issues not considered in the preamble to the 1995 proposed rule.

The September 1995 decision of the Supreme Court of Canada on the Canadian Tobacco Products Control Act (TPCA),<sup>139</sup> enacted to regulate tobacco advertising and promotion in Canada, prompted several comments, primarily from the tobacco industry. The TPCA banned all tobacco advertising, restricted the promotion of tobacco products and required packaging to display prominent unattributed health messages and toxic constituent information. As soon as the TPCA was enacted in 1988, the tobacco companies challenged the act as unconstitutional. On September 21, 1995, the Supreme Court of Canada found that Parliament had the criminal law power to legislate regarding the advertising and promotion of tobacco products, but that, based on the record developed in the court below, the restrictions on advertising and promotion violated the tobacco companies' freedom of expression guaranteed to all Canadians. Several of the key sections of the TPCA were struck down by the Canadian Supreme Court. The Canadian court ruled that the government had failed to demonstrate that the restraints regarding advertising, promotion, and labeling were reasonable and justified restrictions on freedom of expression.

The Canadian court also found that the government had failed to demonstrate that less intrusive measures, falling short of a complete restriction on advertising and promotion, would be less effective in protecting young people from inducements to use tobacco products. Further, the Canadian court found that the government had failed to show that unattributed health messages were required to achieve its objective of reducing tobacco consumption. Finally, the Canadian court decided that there was no rational connection between prohibiting a tobacco product trademark on a nontobacco product and the objective of the TPCA. The decision left the advertising and promotion of tobacco products substantially unregulated in Canada.

Because of some similarities between the Canadian federal tobacco control strategy and FDA's proposed regulation, some comments suggested that the

opinions of the Canadian court are a basis for rejecting actions and laws targeting lawful tobacco advertising, particularly FDA proposed regulations. Moreover, the comments said that the Canadian court concluded that the proposed prohibition on tobacco advertising could not be sustained because it "failed the rational connection test" in that there was no causal connection "whether based on direct evidence or logic and reason" justifying the law (100 C.C.C. 3d. 449, Charter of Rights).

In contrast, one comment suggested that the ruling on this case is consistent with FDA's emphasis on reducing image advertising directed towards young people. The comment stated that FDA's focus fits the Canadian court's decision and had the Canadian government restricted image advertising rather than banning all advertising, it would have upheld the regulation.

FDA does not find the decision of the Canadian court to be contrary to its findings. The Canadian court did recognize that image or lifestyle advertising can affect overall consumption. Moreover, contrary to the comment's suggestion, the court specifically recognized that: "measures \* \* \* to prohibit advertising aimed at children and adolescents \* \* \* would be a reasonable impairment of the right to free expression, given the important objective and the legislative context" (100 C.C.C. 3d. 449).

Finally, FDA has considered a much larger quantity of evidence than that which was before the Canadian court, including the evidence concerning nontobacco item ownership by young people and the materials received during the comment period. The latter included the heretofore confidential or secret documents from RJR's marketing department and also those concerning the results of RJR's focus groups, which showed that interest in nontobacco items was highest among the young. Thus, FDA considered a much fuller record than that before the Canadian court. Moreover, the comment period provided the agency with additional evidence concerning various proposed provisions. FDA's final rule is thus based on a very complete and full record and its decisions are well justified.

g. *Roberts and Samuelson.*

Concerning the effect of advertising on consumption patterns, one study not considered by the court in Canada, but cited by FDA in the preamble to the 1995 proposed rule, was an econometric analysis employed by Roberts and

Samuelson<sup>140</sup> to show that advertising can increase the market demand for tobacco products. The study measured the effect on brand share and market size of advertising for low and high-tar cigarettes. The results indicated that advertising for low tar cigarettes did increase overall market size.

The study looked at the question of the effect of advertising not from the viewpoint of the consumer, but from the producer's perspective—how much should a firm invest in advertising in order to maximize its profits. A predicate assumption is that a manufacturer would not invest in advertising if the cost did not produce a return. This study also was conducted by independent economists and appeared in a peer reviewed journal.

Several comments criticized the study as an "ambitious failure." The industry comments criticized the study on the following grounds: The study inappropriately measures the level of advertising in messages and not in expenditures, and the study had inadequacies in some assumptions and in the data and these flaws thus call into question the study's results. Moreover, the comments alleged that misallocation of advertising expenditures may have biased the results. The results of the study show that advertising for low tar cigarettes had a beneficial effect on the overall level of consumption, but that the same effect did not occur for high tar cigarette advertising. The comments noted that young people do not consume low tar cigarettes, and therefore the results are irrelevant to a discussion of youth smoking. Moreover, the comments said that the results are not generalizable to all cigarette advertising. Finally, the comments said that population growth may have accounted for the finding of a relationship between advertising and consumption.

The agency disagrees with the criticisms of this study and finds instead that it is persuasive evidence of the effects of tobacco advertising for low-tar cigarettes on the overall market. In answer to the first criticism, the study used messages instead of expenditures as a measure of advertising in order to increase the accuracy of the analysis. It is the messages actually seen by a consumer, and not the amount spent by the company on advertising, that is more relevant in assessing the effect of advertising. If the cost of advertising

<sup>139</sup> *RJR-MacDonald, Inc. v. Canada (Attorney General)*, S.Ct. of Canada, 100 C.C.C. 3d 449, Sept. 21, 1995.

<sup>140</sup> Roberts, M. J., and L. Samuelson, "An Empirical Analysis of Dynamic, Nonprice Competition in an Oligopolistic Industry," *Rand Journal of Economics*, vol. 19, pp. 200-220, 1988.

were to go up, and thus firms would have to pay more for fewer messages, we would not expect to find a greater effect on consumers, which was the effect shown by the study.

The second issue, that there were flaws in the study, is similarly not fatal. As noted in section VI.D.4.d. of this document, each study utilizes the best data and methods available at the time. This may not be the perfect study, but its flaws are minor and do not affect its usefulness. Moreover, one major criticism was with the advertising variable and as noted more fully in section VI.D.6.a. of this document data on advertising expenditures are generally considered trade secrets by the companies. Thus, independent researchers have to use whatever data are available, even if they are not perfect. If the industry wanted to ensure more complete studies, it could release old data relevant to advertising expenditures.

Third, the comments complain that the focus of the study, low-tar advertising, limits the applicability of the results. However, the fact that this study found that advertising for low-tar cigarettes increased the market is not a limitation that restricts the results to that one example. The importance of the results is that the study shows that advertising in this oligopolistic industry can affect the market size. The purpose of dividing the market into high- and low-tar advertising was an attempt to isolate the effect of advertising for each of the product classes.

Fourth, the comments expressed concern about the possibility of population growth as an intervening factor. Population growth should not have affected the results as growth would have affected the high-tar market as well as the low-tar market, a consequence that did not occur.

FDA concludes that this study presents excellent evidence of the effect of advertising on consumption patterns and, that it would have provided quite supportive evidence before the Canada court for advertising restrictions.

h. *The African-American youth market.* Referring to the declining African American youth tobacco market, several comments argued that FDA's tentative finding in the preamble to the 1995 proposed rule on the relationship between outdoor cigarette advertising and tobacco consumption by young people is incorrect. Comments said that if cigarette advertising increases the prevalence of smoking among young people, the percentage of African-American young people who smoke

should be equivalent to that of whites, because African-American young people see as much or more cigarette advertising than do whites. However, smoking rates for young African-Americans are much lower than for white young people. One comment further indicated that African-American young people's decision to smoke may be more responsive to peer influence and parental and community advice than cigarette advertising.

It is unclear why African-American young people do not use tobacco at the same rate as white young people. It is surely not that their parents smoke less; the smoking rate among African-American adults is 26 percent, almost the same rate as for white adults.<sup>141</sup> Whatever may be the reason (and it is unknown) for the lower smoking rates among youth among that segment of the population, it does not provide sufficient evidence against advertising restrictions when other evidence shows that advertising does affect children's decisions to use tobacco products.

i. *The evidence relating to smokeless tobacco.* A couple of comments argued that FDA had presented insufficient evidence regarding the effect of advertising on the decision to use smokeless tobacco. One joint comment from the smokeless tobacco manufacturers stated:

The studies cited by the agency regarding cigarette advertisements and smoking are all either highly flawed, biased, or simply do not support the agency's hypothesis. \* \* \* Even more troubling—and from the standpoint of sustaining its legal obligation, a fatal flaw—is the agency's audacity to propose a virtual ban on advertising for smokeless tobacco products without even deigning to build a case.

The comment is correct that there is less evidence available regarding smokeless tobacco advertising practices and smokeless tobacco use. Nevertheless, the record contains sufficient evidence to provide a basis for applying the advertising restrictions in the 1995 proposed rule to smokeless products. In the preamble to the 1995 proposed rule (60 FR 41314 at 41331), reference was made to the remarkably successful regeneration of the smokeless tobacco market by U.S. Tobacco (UST), the leading smokeless tobacco company, in the 1980's. In the 1970's, the segment of the population with the highest use of these products was over age 50, and young men were among the lowest. Fifteen years later, there had been a tenfold increase in the use of smokeless

tobacco by young men, whose use became double that of men over 50. The preamble to the 1995 proposed rule attributed that increase to the concerted advertising and marketing efforts of UST.

As detailed more fully in the preamble to the 1995 proposed rule (60 FR 41313 at 41331), officials at UST held a marketing meeting in 1968 where, according to the *Wall Street Journal*, the vice-president for marketing said, "We must sell the use of tobacco in the mouth and appeal to young people \*\*\* we hope to start a fad." Another official attending the same meeting was quoted as saying, "We were looking for new users—younger people who, by reputation, wouldn't try the old products."

Later, Louis Bantle, the chairman of the board of UST, described the reason that so many young males use smokeless tobacco, "I think there are a lot of reasons, with one of them being that it is very 'macho;.'" UST's advertising utilized the themes that play well with 'macho' boys—rugged masculine images—and utilized heroes to this group—professional athletes. Bantle described the success of this program thus: "In Texas today, a kid wouldn't dare to go to school, even if he doesn't use the product, without a can in his Levis."

The UST program also utilized a promotional program that it called "graduation strategy":

UST distributes free samples of low nicotine-delivery brands of moist snuff and instructs its representatives not to distribute free samples of higher nicotine-delivery brands. The low nicotine-delivery brands also have a disproportionate share of advertising relative to their market share. For example, in 1983, Skoal Bandits, a starter brand, accounted for 47 percent of UST's advertising dollars, but accounted for only 2 percent of the market share by weight. In contrast, Copenhagen, the highest nicotine-delivery brand, had only 1 percent of the advertising expenditures, but 50 percent of the market share. This advertising focus is indicative of UST's "graduation process" of starting new smokeless tobacco product users on low nicotine-delivery brands and having them graduate to higher nicotine-delivery brands as a method of recruiting new, younger users.

(60 FR 41314 at 41331)

Therefore, the agency disagrees with the assertion that it has presented no evidence to support restricting smokeless tobacco advertising. In fact, it finds the graduation strategy to be strong evidence of the effectiveness of advertising in targeting young people to become new users and consistent with and supported by the general

<sup>141</sup> "Cigarette Smoking Among Adults—United States—, 1993," *MMWR*, CDC, vol. 43, pp. 925–930, 1994.

discussion, see sections VI.B. and VI.D. of this document.

#### 4. Why Young People Use Tobacco and the Role of Advertising in That Process

(15) Regardless of the evidence cited in section VI.D.3. of this document, many comments argued that children start to smoke and use smokeless tobacco because of influences on them other than advertising, primarily the influence of their friends and peers.

a. *Why young people use tobacco.* One comment cited studies showing that young people who were most likely to be smokers were those who were particularly rebellious or prone to deviant behavior,<sup>142</sup> and said that it was counterintuitive that young people fitting these profiles would want to conform to what advertising portrayed as desirable.

Conversely, many comments said that cigarette advertising, like all advertising portrays highly attractive images. One comment stated that when young people's peers are also smoking, this can serve to personalize the images and make them relevant for their own lives, and cause them to have favorable impressions about their friends who smoke.<sup>143</sup>

One comment argued further that children smoke because they hope to convey a positive self-image.<sup>144</sup> Hence, young people may be particularly vulnerable to being influenced by the attractive images presented in cigarette and smokeless tobacco advertising.<sup>145</sup>

Specifically, the same comment cited numerous studies that indicate that many young people smoke because they

hope to convey a positive image.<sup>146</sup> Based on these studies, the comment stated: "Image or impression management (Schlenker, 1980) has great utility for young people as they struggle for social acceptance and autonomy (citations omitted)."

Finally, the comment described the developmental aspects of adolescents that are relevant to this issue:

With respect to developmental aspects of adolescence, there are two related factors that make adolescents especially vulnerable to being influenced by tobacco advertising. First, adolescents are typically beginning to focus on peer group interactions more than on family interactions (e.g., Brown et al., 1986), which they may likewise value to a far greater extent. Second, tobacco use constitutes a "temporal trap" (Messick and McClelland, 1983) in the sense that the peer group benefits of tobacco use are immediate, while the negative consequences in terms of health outcomes are so far into the future that many adolescents, who often see themselves as invulnerable even in the present, would consider them to be irrelevant. Furthermore, the negative social consequences of tobacco use in adulthood (i.e., social stigmatization \* \*) are also unimportant to adolescents at the time they are making the decision to use tobacco products.<sup>147</sup>

Stated differently, adolescence is a time of "identity formation." Young people use the attractive imagery of advertising as a "window into the adult world." They are "susceptible to the images of romance, success, sophistication, popularity, and

adventure \* \* \*." <sup>148</sup> By adolescence, clothes, possessions, and "badge products" such as cigarettes are used to define oneself and to control relations with others.<sup>149</sup>

Support for this view of the role of tobacco advertising also comes from the tobacco industry:

FDA turns a blind eye to the fact that the personal display of products with commercial logo—through dress and other forms of expression—is a form of participation in American popular culture. It is a way to register a group identity to signal one's place in the social fabric. In addition to these comments, FDA has the words of RJR's research department in a 1973 memo, detailed in section VI.D.3.d. of this document, that chart a course for attracting the young smoker.<sup>150</sup>

On the basis of the evidence cited and reviewed in section VI.D.3. of this document, the agency finds that the suggestion that it is impossible to advertise in a way that would appeal to rebellious nonconformist teenagers is

<sup>148</sup> Nichter, M., and E. Cartwright, "Saving the Children for the Tobacco Industry," *Medical Anthropology Quarterly*, vol. 5, pp. 236–256, 1991.

<sup>149</sup> Stacey, B. G., "Economic Socialization in the Pre-Adult Years," *British Journal of Social Psychology*, vol. 21, pp. 159–173, 1982.

<sup>150</sup> A July 3, 1974 memo, authored by D. W. Tredennick, of R. J. Reynolds' Marketing Research Department was submitted to the rulemaking docket by the Attorney General of Mississippi in response to the reopening of the rulemaking record (61 FR 11349, March 20, 1996). Although the agency has not relied on the memo as part of the justification for this rule, FDA is citing to it here because it is relevant to the issues discussed. The memo was also reported in the press, see Schwartz, J., "R. J. Reynolds Marketing Memo Discusses Young Smokers' Brand Image," *Washington Post*, A03, April 23, 1996. The memo asked and answered the question: "What causes smokers to select their first brand of cigarettes?" The answers developed by Mr. Tredennick echos the concepts discussed above. The memo hypothesized that: "[t]he causes of initial brand selection relate directly to the reasons a young person smokes. The more closely a brand meets the psychological 'support' needs (advertising or otherwise communicated brand or physiological needs (product characteristics), the more likely it is that a given brand will be selected. (Emphasis added)" One important characteristic was associated with the user "image" associated with a brand. "To some extent young smokers 'wear' their cigarette and it becomes an important part of the 'I' they wish to be, along with their clothing and the way they style their hair." The memo also recognized the importance of peer influence on a young person's decisions about smoking and noted that: "It must also be true that influential young smokers (perhaps relatively few) have made brand selections based on product characteristics or advertising and promotion communication. The fact that two brands, Marlboro and Kool, have such dominant shares among youths suggests the above hypothesis \* \* \*." Tredennick noted further that both Marlboro and Kool project imagery that is psychologically important to adolescents—the need for support and strength.

<sup>142</sup> Chassin, L., C. C. Presson, S. J. Sherman, E. Corty, and R. W. Olshavsky, "Predicting the Onset of Cigarette Smoking in Adolescents: A Longitudinal Study," *Journal of Applied Social Psychology*, vol. 14, pp. 224–243, 1984; Collins, L. M., S. Sussman, J. Mestel Rauch, C. W. Dent, C. J. Johnson, W. B. Hansen, and B. R. Flay, "Psychosocial Predictors of Young Adolescent Cigarette Smoking: A Sixteen-Month, Three-Wave Longitudinal Study," *Journal of Applied Social Psychology*, vol. 17, pp. 554–573, 1987.

<sup>143</sup> Pechmann, C., and S. J. Knight, "Cigarette Ads, Antismoking Ads and Peers: Why do Underage Youth Smoke Cigarettes?" *Advances in Consumer Research*, Association for Consumer Research, edited by Corfman, K. P., and J. G. Lynch, eds., Provo, UT, vol. 23, pp. 267–268, 1996.

<sup>144</sup> Chassin, L., C. Presson, S. J. Sherman, E. Corty, and R. W. Olshavsky, "Self-Images and Cigarette Smoking in Adolescence," *Personality and Social Psychology Bulletin*, vol. 7, pp. 670–676, 1981; Barton, J., L. Chassin, C. Presson, and S. J. Sherman, "Social Image Factors as Motivators of Smoking Initiation in Early and Middle Adolescence," *Child Development*, pp. 1499–1511, 1982.

<sup>145</sup> *Id.*

<sup>146</sup> Chassin, L., C. Presson, S. J. Sherman, E. Corty, and R. W. Olshavsky, "Self-Images and Cigarette Smoking in Adolescence," *Personality and Social Psychology Bulletin*, vol. 7, pp. 670–676, 1981; Barton, J., L. Chassin, C. C. Presson, and S. J. Sherman, "Social Image Factors as Motivators of Smoking Initiation in Early and Middle Adolescence," *Child Development*, pp. 1499–1511, 1982; Belk, R. W., "Possessions and the Extended Self," *Journal of Consumer Research*, vol. 15, pp. 139–168, 1988; Belk, R. W., R. Mayer, and A. Driscoll, "Children's Recognition of Consumption Symbolism in Children's Products," *Journal of Consumer Research*, vol. 10, pp. 386–397, 1984; Brown, B. B., M. J. Lohr, and E. L. McClenahan, "Early Adolescents' Perceptions of Peer Pressure," vol. 6, pp. 139–154, 1986; Messick, P. M., and C. C. McClelland, "Social Traps and Temporal Traps," *Personality and Social Psychology Bulletin*, vol. 9, pp. 105–110, 1983; Levy, S. J., "Meanings in Advertising Stimuli," *Advertising and Consumer Psychology*, Praeger, New York, pp. 214–226, 1986; Solomon, M. R., "The Role of Products as Social Stimuli: A Symbolic Interactionism Perspective," *Journal of Consumer Research*, vol. 10, pp. 319–329, 1983.

<sup>147</sup> Brown, B. B., M. J. Lohr, and E. L. McClenahan, "Early Adolescents' Perceptions of Peer Pressure," *Journal of Early Adolescence*, vol. 6, pp. 139–154, 1986; Messick, P. M., and C. C. McClelland, "Social Traps and Temporal Traps," *Personality and Social Psychology Bulletin*, vol. 9, pp. 105–110, 1983.

without merit. Tobacco advertising plays directly to the factors that are central to adolescents as they decide whether to use tobacco products. Thus, the available evidence clearly supports a finding that advertising plays an important role in young people's tobacco use.

b. *Determinants of smoking.* Several comments from the advertising and tobacco industries claimed that the econometric studies performed for them by experts found that peers, parents, and siblings have the greatest influence on young peoples' decision to start smoking.

Citing an econometric analysis performed for RJR by Dr. J. H. Beales, on data concerning its Joe Camel advertising campaign, one comment argued that "minors balance the risks and rewards of smoking to decide whether or not to smoke, just as they would any other consumption decision. The greater an individual minor perceives the net rewards of smoking, the more likely he or she will try smoking. Minors who perceive greater net rewards of smoking are also likely to smoke more intensively."

The comment further argued that an analysis based upon this theoretical model by Dr. Beales found that neither advertising nor advertising expenditures has an appreciable effect on young people's perceptions of the benefits of smoking and thus would have no indirect effect on teenage smoking decisions.<sup>151</sup> More specifically, the comments stated that the Beales' studies show that advertising expenditures for the particular brands that most teenagers smoke, Marlboro and Camel, do not influence and are not associated with smoking decisions. Moreover, Dr. Beales reported that the results of his studies indicate further that advertising did not have an indirect effect on smoking behavior. Beales concluded that minors who had been exposed to more advertising did not identify the perceived rewards of smoking—"smoking helps when bored," "smoking helps relax," "smoking helps with stress," and "smoking helps in social situations," in a greater number than did those minors who reported less exposure. The comment concluded that the failure of the 1993 Beales study to find either direct or indirect effects from advertising on smoking behavior should be conclusive.

FDA does not agree. The 1993 Beales study presents only one analysis of

youthful smoking and that analysis is flawed.<sup>152</sup> Dr. Beales appears to have performed tests using an ordered logistic regression model to test for: (1) The effect of advertising on smoking behavior, using advertising expenditures and young people's view of "most advertised brand" as measures; and (2) smoking behavior as a function of a number of psychosocial variables and determinants.

First, a logistic model is only as good as the variables used. Thus, if a variable is misspecified or imprecise, the model's predictive capacity will be severely compromised. The variable "most advertised brand" appears to be quite imprecise as a measure to capture the effect of advertising. The most that this variable would capture would be the ability of the campaign to be seen and remembered. It would not capture the appeal of the campaign, or the effect of the campaign on consumers, nor could it measure the ability of an advertising campaign to change or create consumer action. In addition, it would not be surprising to find that almost as many nonsmoking young people as young smokers found Camel (or Marlboro) to be the most advertised brands, since those advertising campaigns were quite ubiquitous at the time the data for this study were collected and were, in fact, the most advertised brands. A variable that cannot discriminate between users and nonusers, because all had seen and remembered the advertising, cannot be expected to produce useful predictive results in a regression analysis of why people, particularly young people, smoke.

Second, Dr. Beales attempted to determine whether differences in advertising expenditures would predict smoking behavior. It appears, however, that Dr. Beales did not look at this question longitudinally—that is, he did not look at whether smoking rates varied as a function of advertising expenditures for Camel cigarettes before the Joe Camel campaign and after the campaign started. Instead, he appears to have measured smoking rates as a function of the differences in regional advertising expenditures in California during one time period. It should not be surprising therefore that little if any effect on smoking rates was found: (1) There is no reason to expect to find significant changes in smoking behavior based on small regional variations within one State in advertising expenditures, and (2) optimum

expenditures for advertising outlays in any given region would have been determined in advance by an advertising agency and therefore would more likely reflect smoking patterns already in existence. Had he wanted to measure smoking behavior as a function of Camel's advertising, he should have modeled it longitudinally over time. Since the regional advertising expenditures must have been obtained from a RJR data base, Beales clearly had access to other sources of data within the company. He therefore should have been able to acquire advertising expenditures for the Camel brand before the introduction of Joe Camel and advertising expenditures for the period after Joe Camel's appearance. This would have been a better test.

Finally, Dr. Beales performed an analysis to determine the "true" determinants of smoking. Dr. Beales' regression analysis utilized a series of psychosocial characteristics and beliefs about smoking. He found that the only factor that failed to produce an association was advertising. First, as noted, there is no reason to believe that "most advertised brand" would perform as a useful surrogate for the effects of advertising. Therefore, regardless of the value of the study, it is not good evidence concerning the role of advertising in young people's smoking decision. Second, the analysis indicates what is already known: certain beliefs and life patterns can help predict who may become a smoker. However, it does not measure what effect advertising can have on a young person's perception or beliefs.

Additional concerns about the study are similar to those that the tobacco industry comments raised about studies cited by FDA. The first concern is that several variables used in the model measure the same impact. This redundancy could create a multicollinearity problem (i.e., two or more variables vary together but it is very difficult to determine which variable influences the other). Moreover, the redundancy may have caused irrelevant variables to be included in the regression equation. Both multicollinearity and the inclusion of irrelevant variables can affect the efficiency of the model's estimates. The second concern is that the model used in the study is questionable. The correct model could well have been a double hurdle model, i.e., modeling the decision to smoke first and then modeling the choice of what brand to smoke, second.

<sup>151</sup> Dr. Beales used children's designation of a "most advertised brand" as a surrogate for the effect of advertising.

<sup>152</sup> Beales, J. H., "Advertising and the Determinants of Teenage Smoking Behavior," p. 44, 1993.

Finally, there is concern that the data for the impact of advertising expenditures and smoking behavior were incompatible and, thus, may have failed to find a relationship that did in fact exist. The teen smoking prevalence data were from a behavioral study, and the measurement of advertising expenditures was from regional advertising expenditures, undoubtedly maintained by the company. The smoking decision for a teenager may very well not have been influenced by the amount of money spent but by the number of messages he/she receives. The aggregate expenditures for advertising cannot measure the number of messages actually received by an individual teen.

Given the multitude of problems with the design of the study and the choice of variables, the study has limited capability for producing results that can adequately describe advertising effects on smoking behavior. Moreover, this study is but one of many and, whatever its value, it does not overwhelm the evidence that FDA has relied on.

c. *Laugesen and Meads*. In contrast to the Beales' study, FDA had cited a study by Laugesen and Meads, entitled "Advertising, Price, Income and Publicity Effects on Weekly Cigarette Sales in New Zealand Supermarkets,"<sup>153</sup> which provided evidence that increases in advertising expenditures had an effect on youth smoking behavior including recruiting new smokers and increasing the market base.

One comment stated that data from supermarkets were unrepresentative, both because of the percentage of sales from supermarkets in New Zealand (presumably not large), and because it is not known what percentage of sales to young people are made at supermarkets. Moreover, many conditions were not accounted for, including possible different pricing structures between retail outlets.

The comments also criticized several major assumptions they claim were made in the study, for example, that young people purchase the less expensive, down market brand. Finally, the comment criticizes the failure to control for other variables (such as rotating health warnings and new advertising restrictions).

The authors themselves responded to some of the concerns expressed. For

example, they explained that they specifically chose to collect data from supermarkets because other "authors with access to full industry data"<sup>154</sup> have recommended that the data interval [for supermarket sales] should reflect the inter-purchase time for cigarettes," which in New Zealand is a week or less. Moreover, the authors found that supermarket cigarette sales are more consistent than other points of sales. Hence there were fewer fluctuations in the demand data for cigarettes.

Moreover, in response to the second comment, the authors did not assume that young people purchase downmarket cigarettes at a higher rate than the general population, but that people with lower income, which includes young people, purchase these brands more often. But more importantly, the study found that it takes only 2 years of advertising of this downmarket brand to expand the teen market by 4 percent, and this fact was not disputed.

d. *Other comments*. Finally, several comments criticized the quality of the evidence cited by FDA in its preamble to the 1995 proposed rule. One comment stated that FDA has relied too heavily on studies conducted by physicians or others not familiar with the art and science of persuasion. Further, it asserted that most of the evidence cited in support of the regulations had been published in medical journals and not in peer reviewed marketing journals.

However, a review of the evidence presented belies that concern. First, FDA relied on the research and expert opinion of consumer psychologists, business and marketing experts, economists and social science researchers as well as medical experts. Moreover, FDA has relied on two outstanding reports issued in the past few years that specifically addressed the issue of young people's use of tobacco—the 1994 SGR and the IOM Report. Both commented extensively on the role that advertising plays in young people's smoking behavior and use of smokeless tobacco and both recommended strongly that a comprehensive plan to attack the problem of youth tobacco use include stringent advertising restrictions.

Moreover, of the 15 members of the IOM committee, 7 were expert in the fields of behavioral sciences, including psychology, psychiatry and public policy, anthropology, and economics. Similarly, the contributing authors to the 1994 SGR included experts in economics, social research, marketing, and business administration. Finally, the comments submitted include additional empirical evidence, the expert opinion of the American Psychological Association,<sup>155</sup> and the words of the tobacco industry itself, all of which are referred to in this document.

One comment criticized FDA's reliance on the IOM Report and the 1994 SGR as simply presenting "selective reviews" of much of the same "dubious literature" reviewed by FDA. Another comment stated that FDA had indiscriminately relied on studies cited in the 1994 SGR, none of which, the comment claimed, was capable of determining whether advertising influences children to initiate smoking.

Several comments appeared to place great importance on the fact that both reports acknowledge that the psychosocial and econometric research that they present do not prove that cigarette advertising causes young people to begin smoking or to use smokeless tobacco. The IOM Report stated that, because of the nature of the research, it is not known for certain whether youths already interested in smoking or smokeless tobacco become more attentive to advertisements for these products or whether these advertisements lead youths to become more interested in these products. One comment argued that the "IOM's recognition of this weakness fatally undermines its own and FDA's arguments on the impact of advertising on smoking behavior." Another comment claimed that the IOM Report acknowledges the lack of a causal relationship between advertising and smoking and acknowledges that the very econometric studies it cites are unreliable to determine whether advertising contributes to youth smoking behavior. The comment also stated that FDA misstates IOM's conclusion regarding evidence of a

<sup>153</sup> Laugesen, M., and C. Meads, "Advertising, Price, Income, and Publicity Effects on Weekly Cigarette Sales in New Zealand Supermarkets," *British Journal of Addiction*, vol. 86, pp. 83–89, 1991.

<sup>154</sup> The authors cited this study as an example of one having access to full industry data. Leeflang, P. S. H., and Reuiyl, "Advertising and Industry Sales: An Empirical Study of the West German Cigarette Market," *Journal of Marketing*, vol. 49, p. 97, 1985; Laugesen, M., and C. Meads, "Advertising, Price, Income, and Publicity Effects on Weekly Cigarette Sales in New Zealand Supermarkets," *British Journal of Addiction*, vol. 86, pp. 83–89, 1991.

<sup>155</sup> The American Psychological Association represents 132,000 members and affiliates and is the largest organization of psychologists in the world. Its comment represents the organization's "research-based recommendations" and reflects significant input from several relevant divisions including the Division of Personality and Social Psychology, the Division of Society for the Psychological Study of Social Issues, and the Division of Consumer Psychology.



causal relationship between advertising and smoking initiation. Further, several comments cited to a statement in the 1994 SGR that “no longitudinal study of the direct relationship of cigarette advertising to smoking initiation has been reported in the literature.”<sup>156</sup> However, these comments failed to include the sentence immediately preceding this quote: “Considered together, these studies offer a compelling argument for the mediated relationship of cigarette advertising and adolescent smoking.”

Another comment in support of advertising restrictions on tobacco products argued that the multidisciplinary studies cited in the 1994 SGR supported the conclusion that marketing and advertising tobacco products do play a role in tobacco use among young people. The comment suggested that this conclusion is consistent with the 1989 Surgeon General’s conclusion that “the collective empirical, experiential, and logical evidence makes it more likely than not that advertising and promotional activities do stimulate cigarette consumption.”<sup>157</sup> Additionally, the comment supported the findings of the 1994 SGR that “cigarette advertising appears to increase young people’s risk of smoking” by conveying the impression that smoking has social benefits and is far more common than it really is.<sup>158</sup> Moreover, this comment contended that the IOM’s conclusions supported FDA’s tentative view that image advertising of tobacco products is tremendously appealing to young people.

As noted more fully in section VI.B. of this document, FDA did rely heavily on the two reports, and continues to find the reports persuasive evidence. They represent mainstream scientific consensus and are appropriately entitled to a great deal of deference. The agency notes that, in a different but not entirely unrelated context, that of health claims for food, Congress has said that FDA would have to specifically justify any decision rejecting the conclusions of a report from an authoritative scientific body of the United States. (See section 403(r)(4)(C) of the act (21 U.S.C. 343(r)(4)(C)).) No justification for rejecting the IOM’s conclusions exists here.

Finally, the agency, like the 1994 SGR and IOM Report, finds that an adequate basis does exist to conclude that

advertising plays a “mediated relationship” to adolescent tobacco use.<sup>159</sup> The proper question is not, “Is advertising the most important cause of youth initiation?” but rather, “does FDA have a solid body of evidence establishing that advertising encourages young people’s tobacco use such that FDA could rationally restrict that advertising?” The answer to this question is “yes.”

#### 5. Has the Agency Met Its Burden?

(16) Several comments from the tobacco and advertising industries criticized the agency for failing to present evidence that conclusively establishes a causal link between advertising and young people’s decisions to begin using cigarettes and smokeless tobacco.

FDA disagrees that its burden is to conclusively prove by rigorous empirical studies that advertising causes initial consumption of cigarettes and smokeless tobacco. No single study is capable of doing so. As one comment stated, it would in fact be practically and ethically impossible to conduct such a study. Certainly no study presented by industry or any other party demonstrated that advertising does *not* cause the initial consumption of cigarettes and smokeless tobacco. Indeed, it should be noted that not one study cited by FDA or submitted by industry could conclusively demonstrate that *any* factor actually *caused* children to begin smoking or to use smokeless tobacco. This includes family and peer influences, which the tobacco industry repeatedly cite as the major determinants of youth smoking and smokeless tobacco use. As was suggested by a comment, however, even when a young person’s decision to smoke is strongly influenced by a friend or parent, advertising reinforces the decision and makes the young person feel good about the decision and the “identity” thereby acquired.

It should also be noted that the apparent focus on the possible causal role of cigarette and smokeless tobacco advertising in young people’s *initial* decision to smoke or to use smokeless tobacco is overly narrow. Human behavior cannot be modeled so simplistically. In point of fact, tobacco advertising has an effect on young people’s tobacco use behavior if it affects initiation, maintenance, or attempts at quitting.

The evidence that FDA has gathered in this proceeding establishes that

cigarette and smokeless tobacco advertising does have such an effect. While not all the evidence in the record supports this conclusion, there is more than adequate evidence, that when considered together, supports a conclusion that advertising, with the knowledge of the industry, does affect the smoking behavior and tobacco use of people under the age of 18. This behavior includes the decision whether to start using cigarettes or smokeless tobacco, whether to continue using or to increase ones consumption, when and where it is proper to use tobacco, and whether to quit. This evidence includes:

*Expert opinion*—The American Psychological Association provided expert opinion, with specific citation to numerous studies, to show that tobacco advertising plays directly to the factors that are central to children and adolescents and thus plays an important role in their decision to use tobacco. (See section VI.D.4.a. of this document; and 60 FR 41314 at 41329.)

*Advertising Theory*—Basic advertising and consumer psychology theory, statements from advertising experts, and general consumer testing show that advertising that is multi-media, that uses color, and that employs more pictures, characters, or cartoons as opposed to text is more robust and can be better processed, understood and remembered by children and adolescents, who have less information processing ability than adults. (See section VI.B.1. and VI.B2. of this document.)

*Studies and Surveys*—Studies show that children are exposed to substantial and unavoidable advertising, that exposure to tobacco advertising leads to favorable beliefs about tobacco use, that advertising plays a role in leading young people to overestimate the prevalence of tobacco use, and that these factors are related to young people’s tobacco initiation and use. (See sections VI.D.3.a., VI.D.3.b., and VI.D.3.c. of this document.)

*Empirical Studies*—Studies conducted on sales data have shown that advertising did increase one segment of the tobacco market (low tar cigarettes), that advertising in New Zealand had the effect of increasing tobacco sales to young people, and that a large multi-country survey showed that advertising tends to increase consumption of tobacco products. (See 60 FR 41314 at 41333 through 41334; sections VI.D.3.g., VI.D.4.c., and VI.D.6.a. of this document)

*Anecdotal Evidence, and Various Advertising Campaigns Successful with*

<sup>156</sup> 1994 SGR, p. 188.

<sup>157</sup> 1989 SGR, p. 517.

<sup>158</sup> 1994 SGR, p. 195.

<sup>159</sup> *Id.*, p. 188.

**Young People**—Studies show that the buying behavior of young people is influenced by advertising, that they smoke the most advertised brands, that children ages 3 to 6 can recognize a cartoon character associated with smoking at the same rate as they recognize Ronald McDonald, that various ad campaigns (Camel cigarettes, Reg cigarettes, products designed for women, and smokeless tobacco advertising aimed at new users) that appeared to be targeted to young people did have an effect upon young people's purchases and use of tobacco, and that young people report that they got their information about a tobacco brand from billboards, magazines, in store advertising and on teeshirts (60 FR 41314 at 41329 through 41334; and see sections VI.D.3.d., VI.D.3.e., and VI.D.3.i. of this document).

**Industry Statements**—Statements in documents created by R. J. Reynolds' researchers, by Philip Morris advertising people, by executives of US Tobacco and by people in and doing work for various Canadian tobacco companies indicate that young people are an important and often crucial segment of the tobacco market.

**Consensus Reports**—The IOM and 1994 SGR concluded on the basis of an exhaustive review of the evidence that advertising affects young people's perceptions of the pervasiveness, image, and function of smoking, that misperceptions in these areas constitute psychosocial risk factors for the initiation of tobacco use, and thus advertising appears to increase young people's risk of tobacco use.

Consequently, tobacco advertising works in a way that is roughly analogous to the way the Supreme Court described how deceptive advertising works (*FTC v. Colgate - Palmolive Co.*, 380 U.S. 374 (1965)). The Supreme Court described how sellers use deceptive practices to break down the resistance of the buying public (*Id.* at 389–90). Here, as the 1994 SGR, the IOM report, and the comment of the American Psychological Association demonstrate, cigarette and smokeless tobacco companies use image and other advertising techniques to appeal to adolescents' need to belong and to appear to be adult, and thereby to break down their resistance to tobacco use. The advertising helps the companies to overcome the fact, as documents for R. J. Reynolds show, that there is no natural craving for nicotine. While the advertising techniques used by the tobacco industry are quite different than those used by the company in the

referenced Supreme Court case, they ultimately have the same goal—to induce people, in this case young people, to purchase and use these products.

Thus, the evidence in this proceeding demonstrates that cigarette and smokeless tobacco advertising plays a material role in the decision of children and adolescents under the age of 18 to engage in tobacco use behavior. It therefore establishes that the harm from this advertising is real.

#### 6. The Efficacy of the Restrictions; Empirical Evidence Concerning Advertising Restrictions

The final aspect of the analysis under the second prong of the *Central Hudson* test requires a showing by the agency that the restrictions that it seeks to impose will alleviate the harm to a material degree. FDA finds, based upon a review of all of the evidence and the comments received, that the restrictions will, in fact, meet this test.

(17) Nearly all comments in opposition to advertising restrictions argued that the preponderance of the empirical evidence supported a finding of no effect from advertising on young people. Some comments stated that, consequently, the advertising restrictions are “unwarranted, unjustified, unnecessary, [and] will not be effective in reducing underage smoking.” Several comments, representing a variety of interest groups, claimed that the “best available evidence” found that “peer pressure,” “peer and family smoking behaviors” and “young people's perceptions of the costs and benefits of smoking” are more important than advertising and promotion in encouraging young people to experiment with cigarettes and smokeless tobacco.<sup>160</sup> Still others claimed that “being a girl,” “living with a single parent,” “having relatively less negative views about smoking,” “having no intention to stay in full-time education after age 16,” and “thinking they might be a smoker in the future,” are key influencing factors for a young person to start smoking.<sup>161</sup>

The tobacco industry and the advertising industry stated that their advertising is not directed at children and adolescents but to adults who

already use tobacco, and thus it is not a proper subject for government regulation. The advertising agency for the largest cigarette brand stated, “[T]obacco advertising has as its intended audience existing smokers \* \* \* it is not the company's desire that children start to smoke.”

However, one comment questioned this and asked how cigarette advertising that has an impact upon adults can be assumed to leave unaffected a young viewer, smoker or otherwise. The same comment also cited the words of one retired Marlboro ad man: “I don't know any way of doing this (advertising cigarettes) that doesn't tempt young people to smoke.”<sup>162</sup>

Many comments from consumer groups, public health organizations and numerous private individuals were supportive of the agency's position that the 1995 proposed rule will reduce underage smoking and use of smokeless tobacco. The comments cited evidence from numerous sources such as government officials, university researchers, and antismoking advocates to demonstrate that restrictions on advertising would be effective.

For example, a comment from a leading psychological association stated that research, common sense, and its expert opinion support that, if image-oriented advertising and promotion are replaced with text-only advertising, it would reduce the advertiser's ability to suggest that tobacco users project a desirable image, e.g., glamour, sexiness or maturity.<sup>163</sup>

FDA has concluded that restrictions on advertising and promotion are necessary to reduce the appeal of tobacco products to young people. Such restrictions will protect the access restrictions that the agency is adopting from being undermined and thereby the health of young people. To be effective,

<sup>162</sup> Daniels, D., *Giants, Pygmies and Other Advertising People*, Crain, Chicago, p. 245, 1974.

<sup>163</sup> Cohen, J. B., “Reconceptualizing Alcohol Advertising Effects: A Consumer Psychology Perspective,” *The Effects of the Mass Media on the Use and Abuse of Alcohol*, Research Monograph, No. 28, Bethesda, MD, NIH, 1995; Goldberg, M. W., J. Madill-Marshall, G. J. Gorn, J. Liefeld, and H. Vredenburg, “Two Experiments Assessing the Visual and Semantic Images Associated with Current and Plain (Generic) Cigarette Packaging,” *Advances in Consumer Research*, edited by Corfman, K. P., and J. G. Lynch, Association for Consumer Research, Provo, UT, vol. 23, 1996; Pollay, R. W., and A. M. Lavack, “The Targeting of Youths by Cigarette Marketers: Archival Evidence on Trial,” *Advances in Consumer Research*, Association for Consumer Research, Provo, UT, vol. 20, pp. 266–271, 1993; Richins, M. L., “Social Comparison and the Idealized Images of Advertising,” *Journal of Consumer Research*, vol. 18, pp. 71–83, 1991.

<sup>160</sup> Beales, J. H., “Advertising and the Determinants of Teenage Smoking Behavior,” vol. 44, 1993.

<sup>161</sup> McDonald, C., “Children, Smoking and Advertising: What Does the Research Really Tell Us?,” *International Journal of Advertising*, vol. 12, pp. 279–287, 1993; Goddard, E., “Why Children Start Smoking,” *British Journal of Addiction*, vol. 87, No. 1, pp. 17–25, 1992.

these restrictions must be comprehensive, that is, they must apply to the many types of media currently used in a coordinated way to advertise cigarettes and smokeless tobacco.

FDA finds support for the need for comprehensive regulation in the experiences of other countries which have enacted and put into place some form of restrictions on the advertising of tobacco. Some comments discussed the experience in other countries in which tobacco advertising has been banned. These comments indicated that in countries that have enacted restrictions on advertising that were not comprehensive, the industry was able to continue advertising and portraying attractive imagery in media left uncovered by regulations. For example, Canada, Finland, Great Britain, and Australia enacted regulations of tobacco advertising that did not completely ban or restrict all forms of advertising and promotion. In each of those instances, according to the comments, the tobacco industry was able to take advantage of loopholes in the system to continue to advertise to reach their target audience. Thus, in Canada the advertising ban, which did not ban nontobacco items, was accompanied by the increased use of nontobacco items that carried the tobacco brand name as a mechanism for continuing to advertise the tobacco brand and its prior image. In Great Britain, sophisticated colorful advertisements appeared when the use of human figures in tobacco advertising was banned; in Australia, loopholes in sports sponsorship provisions enabled the industry to continue sports advertising.

Another comment detailed numerous other examples of tobacco companies continuing to advertise effectively in spite of a ban or restrictions on advertising. For example, this comment noted that after France banned all cigarette advertising in magazines, Philip Morris set up a travel agency and advertised "Marlboro Country Travel" in French magazines (Thus, although there was no longer any "cigarette advertising," Philip Morris was able to continue using its western, cowboy theme in advertisements for a travel agency). The comment noted further that in Europe, advertising for cigarettes was replaced by advertisements, using the same imagery, for Camel and Marlboro sports watches and Camel boots. In Malaysia, cigarette companies set up travel agencies called Marlboro, Kent, and Peter Stuyvesant, clothing stores named Camel, jewelry stores named for Benson and Hedges, luxury

car dealerships named More, Salem record stores and Salem and More concert and movie promotions to advertise cigarettes in a country that has banned cigarette advertising. FDA finds that these comments provide strong support for the need for the advertising restrictions to be comprehensive and apply to all advertising media to be effective.

Two aspects of the evidence in this proceeding are particularly persuasive in evidencing that restrictions on advertising will directly advance the agency's goal of protecting the health of children and adolescents under 18. The experience of other countries that have adopted advertising restrictions shows that when those restrictions are enforced, they have resulted in reductions in the level of tobacco use. In addition, the courts themselves have generally found that, as a matter of common sense, reductions in advertising have produced a reduction in demand. While some comments tried to distinguish these cases, FDA finds that they are relevant.

A discussion of each of these aspects of the evidence follows:

a. *International and cross country studies.* FDA did not receive consistent comment on the international studies<sup>164</sup> that it cited in the preamble to the 1995 proposed rule on the relationship between advertising restrictions and consumption.

(18) Several comments stated that advertising restrictions have not affected tobacco product consumption, and further stated that, in fact, tobacco product consumption has increased in most countries with advertising and promotional restrictions.

In contrast, other comments supported the findings of the same studies and stated that the studies support the conclusion that advertising and promotional restrictions can be effective in curbing smoking initiation among young people.

Several comments opposing the 1995 proposed rule maintained that better surveys of the results of advertising restrictions abroad were done in conjunction with the World Health

Organization (WHO). The two WHO surveys on the health behavior of schoolchildren in four countries found that smoking among schoolchildren is related to peer smoking behaviors and to the number of smokers in the family.<sup>165</sup> More importantly, the comments said that the survey found "no systematic differences" between the smoking behavior of young people in countries where tobacco advertising is completely restricted and in countries where it is not. They asserted that the findings of the WHO survey completely repudiate FDA's assertion that advertising restrictions reduce tobacco consumption among young people. The comments further argued that a followup survey found that the prevalence of smoking among schoolchildren in countries with total tobacco advertising restrictions was actually higher than countries with fewer restrictions.<sup>166</sup>

However, the two surveys cited by these comments did not compare the percentage of young people who smoked before and after the implementation of tobacco advertising restrictions within countries. In order to realistically measure the effect of advertising restrictions, each country must be looked at individually. For example, country A, with a high rate of smoking, cuts its smoking rate in half. This would be considered a major success for country A, but country A still may have a higher smoking rate than country B. Country B may not have instituted any advertising restrictions because its smoking rate has always been low. Thus, comparing the rates of countries A and B would be like comparing apples and oranges.

Studies that have looked at before and after data from individual countries have reported downward trends in smoking rates among young people following advertising restrictions.<sup>167</sup> For example, in Norway the percentage of 15-year old boys and the percentage of 15-year old girls who were daily smokers in 1975, before a restriction on all forms of tobacco advertising and promotion was put in place, was

<sup>165</sup> Aaro, L. E., B. Wold, L. Kannas, and M. Rimpela, "Health Behavior in Schoolchildren: A WHO Cross-National Survey," *Health Promotion*, vol. 1, pp. 17-33, May 1986.

<sup>166</sup> Van Reek, J., H. Adriaanse, and L. Aaro, "Smoking by Schoolchildren in Eleven European Countries," *Proceedings of the 7th World Conference on Tobacco and Health*, Duroton, B., and K. Jamrozik, vol. 301, pp. 301-302, 1991.

<sup>167</sup> Bjartveit, K., "The Effect of an Advertising Ban—Who has the Burden of Proof," National Health Screening Service, Norway, 1994; Rimpela, M., L. E. Aaro, and A. H. Rimpela, "The Effects of Tobacco Sales Promotion on Initiation of Smoking," *Scandinavian Journal of Social Medicine*, 1994.

<sup>164</sup> Smeets, C., "Effect of Tobacco Advertising on Tobacco Consumption—A Discussion Document Reviewing the Evidence," Department of Health, Economics, and Operational Research Division, London, 1992; "Health or Tobacco—An End to Tobacco Advertising and Promotion," Toxic Substances Board (TSB), Wellington, New Zealand, May 1989; Laugesen, M., and C. Meads, "Tobacco Advertising Restriction Price, Income and Tobacco Consumption in OECD Countries, 1960-1986," *British Journal of Addiction*, vol. 86, pp. 1343-1354, 1991.

approximately 23 percent and 28 percent, respectively.<sup>168</sup> According to the WHO followup survey, the percentage of 15- to 16-year old boys and the percentage of 15- to 16-year old girls who were daily smokers in 1986-1987 was 16 percent and 17 percent, respectively.<sup>169</sup> This represents success not only with the group that was prohibited from purchasing cigarettes, those younger than 16, but also with a group that could legally purchase cigarettes. These results also appear to indicate that the restrictions did not simply move the onset of smoking to the first legal year of purchase.

Comments from the tobacco industry also relied upon research conducted by J. J. Boddewyn, which has found results contrary to those presented by FDA, to argue that tobacco advertising bans have not been a successful part of tobacco control policy.<sup>170</sup> Boddewyn's research is directly contrary to many of the studies cited by FDA in support of its 1995 proposed rule and is also inconsistent with the best available data on smoking rates from the countries studied.

Boddewyn has used selective data on the total number of cigarettes sold in a particular country as the basis for his analysis and has used it to justify a finding that, in those countries where advertising bans have been introduced, decreases in the total number of cigarettes sold have not followed. Relying solely on the number of cigarettes sold in a country to measure the effects of government restrictions fails to take into account the myriad of influences that can affect cigarette consumption and, thus, will not yield accurate results.

First, the overall number of cigarettes sold in a country may be influenced by factors other than the percentage of the population that smokes. For example, if the population of a country has risen, or if those who remained smokers were the heaviest smokers, the number of

cigarettes smoked may not fall even though the percentage of the population that smokes has decreased. Moreover, an analysis based on the number of cigarettes sold would not account for the success advertising restrictions might have had with those not yet addicted to tobacco. The preaddicted group, mostly composed of children, does not smoke as many cigarettes as do older addicted smokers. Therefore, any success in stemming initiation rates would not show up for many years if measured as fewer cigarettes consumed.

Finally, Boddewyn and others have claimed that the experience in Norway, Finland, and Sweden supports the view that advertising restrictions have been ineffective in reducing smoking rates. However, three reports<sup>171</sup> presented at the World Conference of Tobacco and Health in Paris, France in October 1994 support the conclusion that advertising restrictions, if comprehensive and enforced, are effective in helping to reduce the percentage of people who smoke, particularly young people not yet addicted to tobacco.

Bjartveit's report presented the results of the Norwegian experience after the implementation of the 1975 Norway advertising ban. In 1975, Norway banned all advertising of tobacco products and prohibited the sale of tobacco to anyone under the age of 16. Norway also required warnings on packages, an educational program, and, in 1980, a larger excise tax. The results of Norway's actions belie Boddewyn's claims. First, the prevalence of smoking for boys and girls declined between 1975 and 1990. The percentage of daily smokers aged 13 to 15 declined from 15 percent to 9 percent for boys and from 17 percent to less than 10 percent for girls. Per-capita consumption for boys and girls also declined. Between 1975 and 1994, the overall sales of cigarettes and smoking tobacco per person among 15 year olds has declined from over 2,000 grams of tobacco to less than 1,800 grams.

In 1976, Finland banned some forms of tobacco advertising and promotion and increased expenditures for health education. While relatively little data are available on the smoking trends in Finland, one comment reported data

that showed the government's actions did have an impact, although the extent has been more uneven than in Norway. Before the advertising restrictions, cigarette consumption was increasing at the rate of 2.2 percent per year. In the decade since the 1975 Finland advertising ban, the rate of increase has been cut in half to a little over 1 percent per year—a meaningful change but not a decline. However, the greatest benefits have been for teenagers. In 1973, 26 percent of 16 to 18 year olds in secondary school smoked. By 1979, 2 years after restrictions went into place, this rate dropped to 14 percent. Since that time, the decrease has continued but has leveled off. In 1973, 19 percent of 14-year old children in Finland smoked. By 1979, 2 years after the ban, only 8 percent of 14-year old children in Finland smoked, a decrease of over 50 percent.

Moreover, a report by Rimpela<sup>172</sup> provided a more complete explanation of the experience that Finland has had with its advertising restrictions. Although the 1978 Finnish Tobacco Act banned cigarette advertisements in youth magazines, it did not eliminate the advertising of product-families or the sponsorship of events. Consequently, the tobacco companies found new means of sales promotion through image advertising in these two venues. The author concluded that a promotional onslaught in these two forums undercut the so-called advertising ban, and the weak implementation of the legislation by health authorities caused the advertising restrictions to be less effective than they might have been with a total ban. The author contrasted these uneven results with the success of Norway's total ban.

The study presents strong evidence for the need for comprehensive advertising restrictions covering all forms of advertising and promotion in order to achieve the best results in reducing youth tobacco use. Finally, the restrictions imposed in Sweden have not been in effect long enough to measure accurately.

i. *The British Health Department Report.* Several comments from the tobacco industry criticized the findings of the British Health Department Report (Smee Report) that advertising increases consumption of tobacco products, and that restrictions on advertising decrease tobacco use beyond what would have occurred in the absence of

<sup>168</sup> Rimpela, M., L. E. Aaro, and A. H. Rimpela, "The Effects of Tobacco Sales Promotion on Initiation of Smoking," *Scandinavian Journal of Social Medicine*, vol. 49, pp. 1-23, 1994.

<sup>169</sup> Van Reek, J., H. Adriaanse, and L. Aaro, "Smoking by Schoolchildren in Eleven European Countries," *Proceedings of the 7th World Conference on Tobacco and Health*, Duroton, B., and K. Jamrozik, vol. 301, pp. 301-302, 1991.

<sup>170</sup> Boddewyn, J. J., "Tobacco Advertising Bans and Consumption in 16 Countries," *International Advertising Association*, 1986; Boddewyn, J. J., "Why do Juveniles Start Smoking?" *Children's Research Unit of London (CRU) Study*, 1986; Boddewyn, J. J., "Cigarette Advertising Bans and Smoking: The Flawed Policy Connection," *International Journal of Advertising*, vol. 13, No. 4: pp. 311-332, 1994.

<sup>171</sup> Bjartveit, K., "The Effect of an Advertising Ban—Who Has the Burden of Proof," *National Health Screening Service*, Oslo, Norway, October 1994; Lund, K., "Tobacco Advertising and How to Measure Its Effect on Smoking Behavior," *Tobacco and Health*, Slama, K., ed., Plenum Press, New York, pp. 199-204, 1995; Rimpela, M., L. E. Aaro, and A. H. Rimpela, "The Effects of Tobacco Sales Promotion on Initiation of Smoking," *Scandinavian Journal of Social Medicine*, vol. 49, pp. 1-23, 1994.

<sup>172</sup> Rimpela, M., L. E. Aaro, and A. H. Rimpela, "The Effects of Tobacco Sales Promotion on Initiation of Smoking," *Scandinavian Journal of Social Medicine*, vol. 49, pp. 1-23, 1994.

regulation.<sup>173</sup> The Smee Report examined: (1) The relationship between cigarette advertising, (2) the effects of partial and complete advertising bans on tobacco consumption, and (3) the results of cross-national studies. The study focused on countries for which the most complete data exists—Norway, Finland, Canada, New Zealand, and the United Kingdom. One reported result of this analysis was that in all five countries, bans or restrictions on cigarette advertising resulted in an aggregate decrease in cigarette consumption.

(19) The comments argued that the WHO study contradicts the findings of this report regarding Norway, Finland, and Canada, stating that the findings do not indicate that advertising restrictions affect consumption. Several comments stated their belief that the author's (Smee's) "sweeping and unjustified" conclusions are based on "data collected over a short time period" and on a "limited and incomplete review of the available evidence". They also argued that Smee's reliance on existing studies linking advertising and consumption is misplaced. Furthermore, the comments specifically criticized the report's use of several of the reviewed studies, which, they claim, did not apply rigorous statistical analysis. Finally, the comments stated that the author's model made no allowances for the effect of externalities, such as health shocks (the Royal College of Physicians' Report on Smoking in 1962, the Report of the Surgeon General's Panel on Smoking and Lung Cancer in 1964, etc.). All the above comments maintained that the Smee Report should not be relied upon as evidence of the causal relationship between advertising restrictions and teen smoking behavior.

FDA disagrees with the comments' assessment and finds the Smee Report to be unbiased and useful as a comprehensive survey of the literature. Upon examining the specific concerns expressed by the comments in connection with specific country analyses, FDA has found that the criticisms are without merit. For example, the comments stated that the reduction in tobacco consumption found in Norway could be attributed to externalities, such as to enforcement of other provisions of the antitobacco legislation package, e.g., health

warnings, health education, and sales restrictions. However, Smee reported that the share of reduction in tobacco consumption attributable to the advertising ban "is likely to account for the great majority of the effect." Another comment expressed concern that Smee, in reporting on the Canadian experience, failed to include income as an independent variable. The comment stated that this could seriously bias the results because real income was falling in Canada at the time the advertising ban went into effect. However, in the initial Smee model, the income variable was included, and it did not explain the variation in tobacco consumption. In the final model, Smee did not include the income variable. However, removing the income variable did not significantly change the estimated coefficient and would not have biased the estimates from the model.

Finally, all econometric studies are subject to limitations. As noted in sections VI.D.4.d. and VI.D.5. of this document, it would require controlled studies to produce better results and it is neither practical nor ethical to conduct such studies. Empirical research is always subject to the criticism that some variables were omitted, or that alternative specifications would yield different results. However, Smee collected many studies, and hence his compilation includes many different specifications of tobacco demand. Thus, although it is difficult to evaluate the causes of variations in each study, an analysis of all the existing studies should yield more generalizable and robust results than those of a single study. The question here is not whether each of the studies has limitations, but to what extent those limitations impair the findings of the overall survey. Smee's study represents the best attempt to date to compile the numerous studies on the effects of advertising restrictions on tobacco use and to provide a coherent analysis. His conclusion was that restrictions on advertising did reduce tobacco use.

A comment in support of the findings of the Smee Report stated that this study was unbiased and performed by a credible organization. The comment argued that advertising restrictions produced the decline in the percentage of young people who smoke in the countries studied. In response to the tobacco industry's claim that the total number of cigarettes consumed continued to rise in several countries, the comment said that "it takes a number of years for the impact of the

fact that fewer people are starting to smoke to show up in overall tobacco consumption data."

ii. *New Zealand Toxic Substances Board Study.* Several comments gave considerable attention to the New Zealand Government Toxic Substances Board ("TSB") Study which reviewed the effect of advertising restrictions in 33 countries.<sup>174</sup> The study concluded that there was a correlation between the degree of restrictions imposed in each country and decline in tobacco use.

(20) Comments submitted by those opposing the proposed regulations argued that the study lacked objectivity because of methodological errors, particularly in the collection, sorting and selective use of data. The comments argued that these errors removed all probative value from the study. Moreover, the comments noted that FDA's use of the study illustrates its inconclusive nature. In addition, one comment asserted that the drop-offs in consumption and the number of smokers may be related to events other than legislated restrictions.

One comment argued that several studies cited by FDA in the preamble to the 1995 proposed rule, including Chetwynd and Harrison, do not support the claimed relationship between advertising expenditures and consumption because the studies have flawed data and fundamental methodological errors. For instance, the comment argued that, in the Laugesen study on tobacco consumption in 23 Organization for Economic Cooperation and Development (OECD) countries described below,<sup>175</sup> the qualitative variables used were not relevant to the regression model and biased the results. Additionally, the comment criticized the authors of the study for ignoring contradictory findings.

One comment suggested that the findings in several smaller studies cited by FDA<sup>176</sup> do not indicate that

<sup>174</sup> "Health or Tobacco—An End to Tobacco Advertising and Promotion," TSB, Wellington, New Zealand, May 1989.

<sup>175</sup> Laugesen, M., and C. Meads, "Tobacco Advertising Restrictions, Price, Income, and Tobacco Consumption in OECD Countries, 1960–1986," *British Journal of Addiction*, vol. 86, pp. 1343–1354, 1991.

<sup>176</sup> Chetwynd, J., P. Coope, R. J. Brodie, and E. Wells, "Impact of Cigarette Advertising on Aggregate Demand for Cigarettes in New Zealand," *British Journal of Addiction*, vol. 83, p. 409–414, 1988; Harrison, R., J. Chetwynd, and R. J. Brodie, "The Influence of Advertising on Tobacco Consumption: A Reply to Jackson and Ekelund," *British Journal of Addiction*, vol. 84, pp. 1251–1254, 1989; Raferty, J., "Advertising and Smoking—A Smoldering Debate?," *British Journal of Addiction*, vol. 84, pp. 1241–1246, 1989.

<sup>173</sup> Smee, C., "Effect of Tobacco Advertising on Tobacco Consumption—A Discussion Document Reviewing Evidence," Department of Health, Economics, and Operational Research Division, London, p. 18, 1992.

advertising affects consumption. The comment argued that one of the analyses failed to account for common trends resulting from the diffusion of information about health risks. The comment further stated that Chetwynd used a model in his study that was more likely to indicate correlation than causation. The comment also asserted that the model suffers from poor data and fails to take into account changing social mores. In addition, the comment argued that a comparable study (Boddewyn) has not shown a decrease in cigarette consumption in areas that restrict advertising.<sup>177</sup>

Industry comments uniformly criticized the TSB study. This study was also criticized by the Canadian courts in the course of litigation over the validity of Canada's advertising restrictions, see section VI.D.3.f. of this document. In response, the TSB published a modification of the original study that recognized that mistakes had been made in the initial report. The reissued report was entitled "A Reply to Tobacco Industry Claims about Health or Tobacco," ISBN-0-477-04574-X (hereinafter referred to as the Reply). According to one comment from a public interest group:

The Reply re-analyzed the data of the impact of advertising in a number of countries based upon criticisms of the original report by the tobacco industry. Even after taking into account the criticisms of the tobacco industry, the New Zealand government found strong empirical evidence of the link between tobacco advertising and tobacco consumption.

In addition to the issuance of the Reply, Laugesen and Meads<sup>178</sup> retested the typology created by the TSB and applied it to 22 OECD countries for a 15-year period. In the preamble to the 1995 proposed rule, FDA referred to the Laugesen study as providing affirmation of the TSB's analysis and conclusions, that, as a group, countries prohibiting tobacco advertising in most or all media experienced more rapid percentage falls in consumption than the group of countries that permitted promotion (60 FR 41314 at 41334).

The industry comments' major criticism of the Laugesen study is that the scale developed by Laugesen is flawed. The comments criticized the amount of weight accorded to different

types of advertising restrictions (i.e., TV ban versus warning on package). However, the rating scale accurately reflects the level of restrictions in each country. The steps between the ratings in the scale may be smaller or larger than the comments believe were warranted, but the relative rankings would remain the same regardless.

Finally, several comments found fault with the smaller studies cited by FDA, including ones by Chetwynd and Harrison. Contrary to the comments' assertions, the studies do include the most relevant variables such as price, income and advertising expenditures. A major complaint of the industry regarding studies done abroad is that the advertising expenditures fail to be totally inclusive. However, the solution to that problem lies with the industry in most cases. Advertising expenditures are a closely guarded industry trade secret,<sup>179</sup> which the companies state cannot be released to the public because of their commercial sensitivity. However, the industry could release older relevant data that are no longer sensitive for the purposes of investigation and study. Moreover, researchers who have had access to industry data have not released their data sets for replication by other research groups.<sup>180</sup>

The final study criticized by the industry, performed by Harrison, was written in response to earlier criticism by the industry about the Chetwynd study, and it therefore provided some answers to the comments' concerns. For example, the comments fault Chetwynd for failing to take into account changing social mores. Harrison stated that he retested Chetwynd's model and found that the model was structurally stable through time in the long term. He also found that the long run analyses indicated that the impact of cigarette advertising on consumption may be larger than was suggested in the original work.<sup>181</sup>

After reviewing the studies provided by the comments and reevaluating the studies relied upon in the preamble to the 1995 proposed rule, FDA reaffirms

that the statement that it made in the preamble is correct:

These studies provide insight into the effects of advertising on the general appeal of and demand for cigarettes and smokeless tobacco products. They also provide evidence confirming advertising's effect on consumption and the effectiveness of advertising restrictions on reducing youth smoking. (60 FR 41314 at 41333)

Based on the foregoing, FDA finds that the international experience provides empirical evidence that restrictions on tobacco advertising, when given appropriate scope and when fully implemented, will reduce cigarette and smokeless tobacco use among children and adolescents under the age of 18. This experience provides strong evidence that the restrictions that FDA is imposing will directly advance its interest in protecting the health of these young people.

b. *Case law considering the effect of advertising and advertising restrictions upon tobacco use by young people.*

Virtually every court that has examined the issue has held that there is a direct connection between advertising and demand for the product advertised. For example, in *Central Hudson Gas and Electric*, 447 U.S. at 569, the Supreme Court stated: "[T]he State's interest in energy conservation is directly advanced by the Commission order at issue here. There is an immediate connection between advertising and demand for electricity." See also *Posadas de Puerto Rico v. Tourism Co. of Puerto Rico*, 478 U.S. at 341-342. In *United States v. Edge Broadcasting Co.*, the Supreme Court carried its position in *Central Hudson* one step further:

If there is an immediate connection between advertising and demand, and the federal regulation decreases advertising, it stands to reason that the policy of decreasing demand for gambling is correspondingly advanced.

(509 U.S. 434)

Each circuit court that has considered the issue has also concluded that the regulation of advertising is reasonably aimed at reducing demand. (See, *Anheuser-Busch, Inc. v. Schmoke*, 63 F.3d 1305, 1314-15 (4th Cir 1995), *vacated and remanded* 64 U.S.L.W. 3333 (May 20, 1996); *Dunagin v. City of Oxford, Miss.*, 718 F.2d at 750 ("[W]e hold that sufficient reason exists to believe that advertising and consumption are linked to justify the ban, whether or not 'concrete scientific evidence' exists to that effect."); and *Oklahoma Telecasters Ass'n v. Crisp*, 699 F.2d 490, 501 (10th Cir. 1983), *rev'd* on other grounds sub.nom. *Capital*

<sup>177</sup> Boddewyn, J. J., "Tobacco Advertising Bans and Consumption in 16 Countries," International Advertising Association, 1986.

<sup>178</sup> Laugesen, M., and C. Meads, "Tobacco Advertising Restriction, Price, Income, and Tobacco Consumption in OECD Countries, 1960-1986," *British Journal of Addiction*, vol. 86, pp. 1343-1354, 1991.

<sup>179</sup> Even in the United States, only FTC has access to company expenditure data and it is prevented from disclosing information concerning advertising expenditures except at the industry-agglomerated level.

<sup>180</sup> Beales, J. H., "Advertising and the Determinants of Teenage Smoking Behavior," p. 44, 1993.

<sup>181</sup> Harrison, R., J. Chetwynd, and R. J. Brodie, "The Influence of Advertising on Tobacco Consumption: A Reply to Jackson and Ekelund," *British Journal of Addiction*, vol. 84, pp. 1251-1254, 1989.

*Cities Cable, Inc. v. Crisp*, 467 U.S. 691 (1984)). In *Greater New Orleans Broadcasting Ass'n v. United States*, 69 F.3d 1296, 1301 (5th Cir. 1995), the court said:

They cannot seriously dispute that a prohibition of advertising of casino gambling directly advances the governmental interest in discouraging such gambling and fulfills the [second] *Central Hudson* prong. It is axiomatic that the purpose and effect of advertising is to increase consumer demand.

To counter the weight of this case law, comments that opposed FDA's advertising restrictions made two arguments. First, several comments from the tobacco and advertising industries argued that the agency cannot rely on the assumption of a link between advertising and demand that is embodied in these decisions and, citing the Court's more recent *Coors* decision, contended that the agency's evidentiary record will be held to a higher standard of proof.

However, as one comment correctly noted, the Court in *Coors* wrote:

It is assuredly a matter of 'common sense' that a restriction on the advertising of a product characteristic will decrease the extent to which consumers select a product on the basis of that trait. (115 S.Ct. at 1592) Moreover, in *44 Liquormart, Inc.*, Justice Stevens quoted with apparent approval *Central Hudson's* reliance on the "immediate connection" between "promotional advertising" and demand (116 S.Ct. at 1506, quoting *Central Hudson* 447 U.S. at 569). Thus, the Supreme Court continues to hold that there is a connection between advertising and demand, and FDA finds no merit to this contention in the contrary argument in the comments.

The second argument that these comments made is that because tobacco products constitute a "mature product" whose availability and qualities are widely known to consumers, the purpose and function of cigarette advertising is to build market share and to maintain brand loyalty, not to stimulate demand. FDA considers these comments in depth in the following section of this document.

c. *The function of advertising in the "mature" market.* Comments from the industry, advertisers, psychologists, and economists argued that although it may be true that advertising generally serves the function of increasing demand for a product category, that truism does not work for tobacco, which, they claim, is a mature market.

(21) The comments argued that because tobacco is a mature product, advertising serves to reinforce brand

loyalty and to induce current smokers to switch brands. They stated that because consumers are already aware of the tobacco category, advertising does not serve to inform potential consumers of the product and to entice them to become a user. One comment likened tobacco to other mature products such as soft drinks, deodorants, antiperspirants, and appliances. Moreover, this comment argued that "[b]ecause FDA lacks marketing expertise," it has been misled by the size of the industry's advertising expenditures and assumed, incorrectly, that this means that the industry is attempting to expand its overall market. Finally, several comments stated that there are no data that clearly prove that advertising and promotion increase demand in the tobacco market.

Other comments took the opposing view and agreed with FDA's assessment that tobacco advertisements make tobacco products more appealing to young people and affects tobacco use among young people. Several comments argued that the market for cigarettes and smokeless tobacco is not mature but is actually very dynamic. In addition to brand switching and brand loyalty, they argued that tobacco marketing generates market expansion. The comment noted that there is substantial movement at the margins with new customers entering the market, and many current customers trying to leave.

FDA agrees with those comments that expressed the view that labeling the tobacco market as a "mature market" is a simplistic denotation, which fails to recognize the movement into the market each day of new young smokers often motivated in part by advertising. Even "mature" markets must replenish their customer base as older consumers leave the market. In fact, approximately one million new young smokers enter the tobacco market each year. These new smokers are necessary to keep the mature market stable and to prevent decline. There is no evidence to suggest that these new smokers are predestined<sup>182</sup> to enter the market. RJR acknowledged this in one marketing memo,

"[I]f we are to attract the nonsmoker or the presmoker, there is nothing in this type of product that he would currently understand or desire. \* \* \* Instead, we somehow must convince him with wholly irrational reasons that he should try smoking."<sup>183</sup>

<sup>182</sup> Teague, C., *Research Planning Memorandum on Some Thought about New Brands of Cigarettes for the Youth Market*, 1973.

<sup>183</sup> Teague, C., *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein*, 1972.

They must be influenced by peers, parents, and advertising, either to join the market or to decline to enter.

The agency finds that regardless of whether marketers and their advertising agencies intentionally target children and adolescents, young people are still affected by advertising. Children are not isolated from tobacco advertising's attractiveness or inducements. There is no "magic curtain around children and teenagers who seek to learn how to fit into the adult world," nor is there any evidence to support a claim that young people are immune from advertising's blandishments.<sup>184</sup>

Comments asserting that tobacco advertising fails to increase consumption for the tobacco market run contrary to the views of one well-known advertising executive who stated:

I am always amused by the suggestion that advertising, a function that has been shown to increase consumption of virtually every other product, somehow miraculously fails to work for tobacco products.<sup>185</sup>

Further, the view that advertising does not affect consumption is contradicted by industry experience, logic, and evidence. It does not appear credible that the industry spends more than \$6 billion annually merely to maintain brand share and to try to switch current smokers; this argument defies common sense. The economics of this argument are strained—five manufacturers control almost 100 percent of the market, and three of these have approximately 90 percent of the market.<sup>186</sup>

The courts have also expressed skepticism about this argument. In *Dunagin v. City of Oxford, Miss.*, the advertiser's expert, a professor in sociology who specialized in alcoholism, testified that advertising merely affected brand loyalty and market share, rather than increasing overall consumption or consumption of individual consumers (718 F.2d at 748). The court rejected this argument:

It is beyond our ability to understand why huge sums of money would be devoted to the promotion of sales of liquor without expected

<sup>184</sup> Cohen, J. B., "Charting a Public Policy for Cigarettes," *Marketing and Advertising Regulation: The Federal Trade Commission in the 1990's*, edited by Murphy, P. E., and W. L. Wilkie, University of Notre Dame Press, Notre Dame, IN, pp. 234-254, 1990.

<sup>185</sup> Foote, E., "Advertising and Tobacco," *JAMA*, vol. 245, pp. 1667-1668, 1981.

<sup>186</sup> Weidner, D., "RJR Tobacco International Gets New Chief," *Winston-Salem Journal*, p. A1, Dec. 8, 1995. (Philip Morris, 45 percent, Reynolds 27 percent.); Antunes, S., "B & W Harassed Workers," *Evening Standard*, p. 47, Nov. 16, 1994. (After Brown & Williamson acquired American Tobacco, it had 18 percent of the market.)



results, or continue without realized results. No doubt competitors want to retain and expand their share of the market, but what businessperson stops short with competitive comparisons? It is total sales, profits, that pay the advertisers and dollars go into advertising only if they produce sales. Money talks: it talks to the young and the old about what counts in the marketplace of our society, and it talks here in support of Mississippi's concern.

(718 F.2d at 749)

The court concluded: "We simply do not believe that the liquor industry spends a billion dollars a year on advertising solely to acquire an added market share at the expense of competitors" (718 F.2d at 750). The same reasoning applies here.

(22) One comment discussed the results of a recent study that the comment said had been accepted for publication<sup>187</sup> which found that less than 10 percent of adult smokers switch brands each year, and that only 6.7 percent switch companies. The commentary suggests that this amount of "real" brand switching would not justify \$6.1 billion, an amount in annual advertising and promotional expenditures.

In addition to logic, there is empirical evidence that advertising can expand demand in a so-called mature market and in fact has done so in the cigarette market before. Smoking rates for teenage girls rose from 8.4 percent in 1968, when major promotional campaigns first targeted women, to 15.3 percent in 1974, by which time other tobacco companies had also begun marketing women's brands.<sup>188</sup> The same phenomenon was captured differently in a recent study<sup>189</sup> that tracked initiation rates for girls and women over a 40-year period. The study found that smoking initiation rates rose for girls under 18 during the period between 1967 and 1973 (women's targeting period), even though initiation rates did not rise for women 18 and older. Finally, as detailed more fully in the preamble to the 1995 proposed rule (60 FR 41314 at 41345), another study looked at the effect of variations in advertising expenditures for low tar

cigarettes. Although the advertising did not increase the advertiser's brand share, increased advertising for low tar cigarettes caused the entire market for cigarettes to increase.<sup>190</sup>

The ability of advertising to expand total demand for a particular class of products through market segmentation has also been demonstrated in other markets when the breakfast cereal industry first began making health claims for their products, such as those regarding the cancer-prevention benefits of dietary fiber. The creation of a new segment of the cereal market—healthy cereal—through the use of advertising resulted in an increase in the overall adult cereal market. Advertising caused an increase in aggregate demand by giving consumers a "new" product that met their needs, wants, and desires.<sup>191</sup>

Thus, advertising can serve an important role in meeting and expanding desires in the marketplace. It identifies consumers' needs and desires and then matches them with the attributes of particular product categories and brands. Advertising can perform this function through its use of explicit claims or through imagery, code words, or psychosocial cues. And, in doing so, it can both shift demand across the entire product category and create new demand.

Moreover, the industry's mature market categorization assumes that the product category has no outside competitors, i.e., that there is no other product line that competes for the consumers' attentions and dollars. For example, soft drinks are a mature market, but more healthful drinks, such as milk, juices, or even water, can attempt to draw off part of the market. In addition, soft drinks can try to expand their own market share as Coca Cola and later Pepsi did a number of years ago<sup>192</sup> when they promoted cola for breakfast.

Similarly, tobacco has competitors. New users or "presmokers," as one RJR employee refers to them,<sup>193</sup> are faced not only with tobacco imagery but also with antismoking health messages in commercial media and in schools.

Current smokers are faced with alternatives to smoking, including over-the-counter and prescription drug advertising for nicotine replacement products and stop-smoking cures. The tobacco market thus has to convince the presmoker or new smoker to switch from the nonuse category promoted by health professionals, public service announcements, and school messages, to tobacco use. Also, it must constantly convince the addicted smoker not to leave the market by use of a competing nicotine-delivery product, a nicotine replacement source, or by other voluntary means.

Finally, even the industry acknowledges that young people are a strategically important audience because brand loyalty often develops during this period of trying cigarettes and becoming a smoker. In 1973, RJR's research and development officer wrote "Realistically, if our Company is to survive and prosper over the long term, we must get our share of the youth market."<sup>194</sup> And, as noted in the preamble of the 1995 proposed rule, these words reflect those uttered by the Canadian sister company of the American tobacco company, Brown and Williamson Tobacco Corp.

If the last ten years have taught us anything, it is that the industry is dominated by the companies who respond most effectively to the needs of younger smokers.<sup>195</sup>

FDA finds that there is no merit to the industry's claim that because the tobacco market is a mature market, advertising does not stimulate demand but only reallocates the existing market between companies. Not only is the industry's argument overly simplistic, but, as shown, advertising plays an important role in creating new customers, including young people. FDA shares the incredulity expressed by the court in *Dunagin*, 718 F.2d at 750, regarding this argument: "It is beyond our ability to understand" why an industry would spend billions a year merely to acquire market share at the expense of its competitors, when it has a much harder job of convincing young people to start a habit that is neither easy to acquire nor pleasant. Consequently, FDA finds that the second prong of *Central Hudson* is satisfied, i.e., the advertising restrictions directly and materially advance the substantial state interest.

<sup>187</sup> Siegel, M., et al., "The Extent of Cigarette Brand and Company Switching: Results from the Adult Use-of-Tobacco Survey," *American Journal of Preventive Medicine*, vol. 12, No. 1, pp. 14-16, 1996.

<sup>188</sup> Botvin, G. J., C. J. Goldberg, E. M. Botvin, and L. Dusenbury, "Smoking Behavior of Adolescents Exposed to Cigarette Advertising," *Public Health Reports*, vol. 108, pp. 217, 222, 1993.

<sup>189</sup> Pierce J. P., L. Lee, and E. A. Gilpin, "Smoking Initiation by Adolescent Girls, 1944 through 1988," *Journal of the American Medical Association*, vol. 271, No. 8, pp. 608-611, 1994.

<sup>190</sup> Roberts, M. J., and L. Samuelson, "An Empirical Analysis of Dynamic, Nonprice Oligopolistic Industry," *Rand Journal of Economics*, vol. 19, pp. 200-220, 1988.

<sup>191</sup> Ippolito, P., and A. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, p. 32, 1989.

<sup>192</sup> Dourado, P., "Breakfast Cola Takes on America's Coffee Giants," *The Independent*, p. 28, April 15, 1990.

<sup>193</sup> Teague, C., *Research Planning Memorandum on Some Thoughts about New Brands of Cigarettes for the Youth Market*, p. 1, 1973.

<sup>194</sup> *Id.*

<sup>195</sup> Overall Marketing Objectives-F88, 1988 Imperial Tobacco Ltd. Marketing Plan, p. 6; 60 FR 41314 at 41331.

### E. Provisions of the Final Rule

FDA selected each of the restrictions that it included in the 1995 proposed rule based on its tentative view that the particular restriction is necessary to providing a comprehensive response to the appeal of tobacco advertising to young people. Each proposed restriction was intended to address an aspect of this advertising that contributes to its appeal. The agency tentatively concluded that, together, these restrictions will ensure that advertising is not used to undermine the access restrictions that FDA proposed and thus will help to protect the health of children and adolescents under the age of 18.

In this section of the document, FDA will respond to comments on each element of this comprehensive approach, including comments on whether the regulations are legally supportable. A key question about the agency's approach is whether there is a reasonable fit between the agency's interest and the means that it has chosen to accomplish it; that is, between the agency's interest and the specific restrictions that it proposed. This inquiry involves consideration of the restrictions under the third and final prong of *Central Hudson*.

FDA will first consider comments that raised general concerns about its approach under the third prong of *Central Hudson*. It will then consider comments that raised concerns about specific restrictions under this aspect of *Central Hudson* as part of its discussion of the comments on each restriction.

#### 1. Are FDA's Regulations Narrowly Drawn?

In the preamble to the 1995 proposed rule, FDA stated that the regulations that it was proposing met the final prong of the *Central Hudson* test (60 FR 41314 at 41355). In *Central Hudson*, the Supreme Court stated that the First Amendment mandates that speech restrictions be "narrowly drawn." The Court continued:

The regulatory technique may extend only as far as the interest it serves. The State cannot regulate speech that poses no danger to the asserted State interest, \* \* \* nor can it completely suppress information when narrower restrictions on expression would serve its interest as well.

(447 U.S. at 565, n.7) FDA pointed out, however, that: "The Supreme Court has made it clear that this prong does not require a 'least restrictive means test,' but rather that there be a 'reasonable fit' between the government's regulation and the substantial governmental

interest sought to be served" (*Board of Trustees of State University of New York v. Fox*, 492 U.S. 469, 480 (1989); (60 FR 41314 at 41355)).

(23) This statement by FDA provoked a significant amount of comment. Several comments said that FDA had mischaracterized its burden. These comments argued that *Fox* did not dilute the *Central Hudson* analysis, and that any restriction on commercial speech must be narrowly tailored. One comment pointed out that, in *Rubin v. Coors*, the Supreme Court made no mention of reasonable fit. The comment stated that in *Rubin v. Coors*, the Supreme Court said that *Central Hudson* requires that a valid restriction be no more extensive than necessary to serve the governmental interest (115 S.Ct. at 1591). Finally, one comment said that FDA was arguing that courts have applied a rational basis standard to restrictions on commercial speech, but the comment stated that FDA was wrong because courts have rejected this notion.

In response to these comments, FDA has carefully evaluated the relevant case law. The agency does not agree that it mischaracterized its burden in the 1995 proposed rule.

It is true that in *Rubin v. Coors* the Supreme Court found that the challenged statutory provision violated the First Amendment's protection of commercial speech, at least in part, because it was more extensive than necessary (115 S.Ct. at 1594). However, the Court also stated that its inquiry under the last two steps of *Central Hudson* involves "a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends" (*Id.* at 1391 (quoting *Posadas De Puerto Rico Associates v. Tourism Co. of Puerto Rico*, 478 U.S. at 341); (See also *44 Liquormart, Inc. v. Rhode Island*, 116 S.Ct. at 1510 ("As a result, even under the less than strict standard that generally applies in commercial speech cases, the state has failed to establish a reasonable fit between its abridgment of speech and its temperance goal.")).

Moreover, the Court's statement in *Rubin v. Coors* that a restriction on commercial speech must be no broader than necessary, which was cited by a comment, must be read in light of the Court's discussion of this requirement in *Board of Trustees of State University of New York v. Fox*, 492 U.S. at 476-481. In *Fox*, the Supreme Court concluded from its consideration of how this phrase has been used in its case law and in the related case law on time, place, and manner restrictions, that what is required, exactly as the agency

said in the 1995 proposed rule, is a fit between the Government's ends and the means chosen to accomplish those ends that is not necessarily perfect but reasonable (492 U.S. at 480). The Supreme Court reiterated this point in *Florida Bar v. Went For It, Inc.*, 115 S.Ct. at 2380 (citations omitted):

With respect to this prong, the differences between commercial speech and noncommercial speech are manifest. In *Fox*, we made clear that the "least restrictive means" test has no role in the commercial speech context \* \* \* "What our decisions require," instead, "is a 'fit' between the legislature's ends and the means chosen to accomplish those ends," a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is 'in proportion to the interest served' that employs not necessarily the least restrictive means but \* \* \* a means narrowly tailored to achieve the desired objective.

Thus, FDA did not mischaracterize its burden in the 1995 proposed rule. Moreover, in any event, FDA has narrowly tailored its provisions.

Before turning to the question of whether there is a reasonable fit between FDA's interest in the health of children and the restrictions that FDA proposed on tobacco advertising, the agency wishes to make clear that, contrary to the claim of one comment, it recognizes that courts have not equated the reasonable fit test with rational basis review. (See, e.g., *Florida Bar v. Went For It, Inc.*) FDA recognizes that the reasonable fit test requires that the Government goal be substantial, and that the cost of achieving that goal be carefully calculated. (See *Board of Trustees of State University of New York v. Fox*, 492 U.S. at 480.) It also recognizes that this test requires that the agency consider whether there are less burdensome alternatives to restrictions on speech.

Having already established that its goal is substantial (see section VI.C.4. of this document), FDA will consider the issues of the costs of the restrictions and alternatives to these restrictions in its analysis of the comments that follows.

(24) Several comments argued that the restrictions on cigarette and smokeless tobacco advertising that FDA proposed are not narrowly tailored. One comment said that the premise of the narrow tailoring requirement is that commercial speech is valuable, and that it may only be restricted when it is necessary to do so. Other comments argued that restrictions on speech must attack only problem speech, and that FDA had failed to prove that this is what the proposed restrictions did. These

comments stated that FDA's proposed restrictions are more extensive than necessary to achieve the agency's asserted interest, particularly because the agency had failed to show that the advertising restrictions will have any effect on underage smoking. Some comments argued that the restrictions that FDA proposed were tantamount to a ban because they will prevent the advertiser's message from reaching consumers.

Other comments disagreed. These comments said that FDA's proposed action is narrowly tailored. They argued that FDA had steered clear of imposing a categorical ban on tobacco advertising, or even broad prophylactic rules. One comment said that tailored prohibitions, instead of all-out bans, are important signposts indicating a measured response.

FDA disagrees with the comments that claimed that the restrictions were not narrowly tailored. The agency recognizes, as the Supreme Court said in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985), that it has the burden of distinguishing the harmless from the harmful. FDA has met this burden.

The restrictions that FDA is adopting are not like those in *Central Hudson*, which, even though the Public Service Commission's interest was limited to energy conservation, reached all promotional advertising, regardless of the impact of the touted service on energy use. (See 447 U.S. at 570.) Rather, FDA's restrictions are carefully crafted to focus on those media and aspects of advertising that children are routinely exposed to and that the available evidence shows has the greatest effect on youngsters, while leaving the informational aspects of advertising largely untouched. FDA is not banning outdoor advertising; it is restricting it so that it does not unavoidably confront children when they play. It is not banning print advertising. It is restricting the use of images and color, which are particularly appealing to children, in publications that have a large number of young readers under the age of 18 and in other forms of advertising to which children are routinely exposed but permitting unrestricted advertising in adult publications and adult venues. It is restricting cigarette and smokeless tobacco companies' use of brand names and product identifications in sponsored events, but again in a way that reflects the agency's concern about children and adolescents under the age of 18. That is, it is permitting companies

to sponsor in the corporate name in order to engender good will, but preventing them from using the brand specific attractive imagery that is influential with young people. Finally, it is prohibiting the use of branded promotional items because it is the young who find particular value in these items. In each of these respects, the agency has gone no further than it has found, based on the evidence, is necessary to meet its ends. (See *Dunagin v. City of Oxford, Miss.*, 718 F.2d at 751.)

Under the restrictions that FDA is adopting, firms will remain free to disseminate advertising that performs all the informational functions that are protected by the First Amendment. They will be able to disseminate information on what they are selling, for what reason, and at what price. (See *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 765 (1976); *Bates v. State Bar of Arizona*, 433 U.S. 350, 364 (1977).) Thus, the situation here is analogous to that in *Friedman v. Rogers*, 440 U.S. 1 (1979), where the Supreme Court found that a restriction on the use of optometrical trade names had only an incidental effect on the content of commercial speech. The Court said that "the factual information associated with trade names may be communicated freely and explicitly to the public" (440 U.S. at 16). So, here, any information that firms wish to communicate to adults may still be communicated by use of words. Indeed, the tobacco industry has used text-only advertising successfully in the past.<sup>196</sup>

It may be true, as some of the comments state and as the agency recognized above, that it will be more difficult for adult consumers to find cigarette and smokeless tobacco advertising without images and color, but willingness to search for information is one of the things that adults will do when they need information about price, quality, or product performance. Moreover, as discussed above, adult tobacco users are particularly interested in information on price, "safer" cigarettes, and new products, information that can be freely conveyed under FDA's regulations.

(25) The effect of the proposed restrictions on cigarette and smokeless tobacco product manufacturers' ability to communicate with adults was the subject of a number of comments. These comments argued that the proposed

restrictions would not only preclude speech that may be perceived by young people, it would preclude speech that would be received by adults. The restrictions, these comments asserted, would deprive adults, who are legally entitled to smoke, of their right to the free flow of relevant commercial information. Other comments, relying on several cases, said that the First Amendment does not countenance wholesale censorship of speech for adults under the guise of protecting children. Many comments, for example, quoted a statement from *Butler v. State of Michigan*, 352 U.S. 380, 383 (1957) ("Surely, this is to burn the house to roast the pig.") in support of this point. One comment said that FDA's purpose of reducing tobacco use by minors cannot support massive censorship between tobacco advertisers and adults.

One comment, however, argued that FDA's proposed restrictions are narrowly tailored to the specific types of advertising that are most effective with children. This comment said that these restrictions permit companies to continue marketing practices that do not appeal to children.

FDA has considered the concerns expressed in the comments. First, FDA does not agree that its interest is limited. As discussed above, the agency's interest is compelling. Nonetheless, the agency has tried very hard to tailor the restrictions on advertising in this final rule to focus them in order to limit the appeal of advertising to the young and ensure that the restrictions on access to cigarettes and smokeless tobacco will not be undermined, while at the same time, minimizing their effect on adults. Given this approach, FDA's restrictions differ significantly from those struck down in *Butler v. State of Michigan*, where the Court overturned conviction of a bookseller for selling a book to adults that contained some portions that might be objectionable to young people. In that case, the Supreme Court stated:

We have before us legislation not reasonably restricted to the evil with which it is said to deal. The incidence of this enactment is to reduce the adult population of Michigan to only what is fit for children. (352 U.S. at 383)

This statement clearly does not describe the situation under the restrictions FDA is adopting. Except for limits on images and colors, the restrictions that FDA is adopting do not limit what cigarette and smokeless tobacco manufacturers, distributors, or retailers may say. As stated above, they are free to put into words any nondeceptive message that they would have communicated by color or image.

<sup>196</sup> As discussed more fully elsewhere, advertising for low-tar products is generally more reliant on text than on imagery.

FDA's restrictions, as one comment stated, restrict only those advertising techniques that have the most appeal. Thus, contrary to the situation in *Butler v. Michigan*, these restrictions are reasonably restricted to the harms they are intended to address.

Nor are the restrictions that FDA is imposing like the one struck down in *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983), which was cited by several comments. In that case, a Federal statute prohibited the mailing of unsolicited advertisements for contraceptives. The Postal Service sought to justify this restriction as aiding parents' efforts to discuss birth control with their children. While the Court found this interest to be substantial, it found the restriction to be more extensive than the Constitution permits (463 U.S. at 73). The Supreme Court struck down the restrictions, stating: "The level of discourse reaching the mailbox simply cannot be limited to that which would be suitable for a sandbox" (*Id.* at 74). It is in this respect that FDA's restrictions differ from those in *Bolger*. While FDA may limit the type of color or imagery, or the use of noncommunicative media, i.e., hats, FDA's restrictions do not limit the types of information that can be disseminated, except within 1,000 feet of schools and playgrounds.

(26) Other comments cited *Sable Communications v. FCC*, 492 U.S. 115 (1989), in which the Supreme Court struck down an outright ban on indecent as well as obscene interstate commercial telephone messages. This case is not relevant here because FDA is not imposing an outright ban on cigarette and smokeless tobacco advertising,<sup>197</sup> and because in contrast to Congress's failure to make findings that would justify the ban in *Sable*, FDA is fully explaining the basis for each of the restrictions that it is adopting here.

Other comments cited *Erznoznik v. City of Jacksonville*, 422 U.S. 205 (1975), in which the Supreme Court struck down an ordinance that, to protect minors, made it illegal to exhibit a motion picture visible from public streets in which female buttocks and bare breasts were shown. In doing so,

the Supreme Court stated that: "Speech \* \* \* cannot be suppressed solely to protect the young from ideas or images that a legislative body thinks unsuitable for them" (422 U.S. at 213).

Again, however, FDA is imposing restrictions on the manner and, to a limited extent, places in which cigarettes and smokeless tobacco are advertised, not content restrictions. Moreover, FDA is restricting commercial speech, which, as stated in section VI.C.1. of this document, is subject to a subordinate position in the scale of First Amendment values to the noncommercial expressions involved in *Erznoznik*. Thus, this case has no application here.

(27) Finally, a few comments cited *Project 80's, Inc. v. City of Pocatello*, 942 F.2d 635 (9th Cir. 1991), a case in which the U.S. Court of Appeals for the Ninth Circuit struck down ordinances that prohibited door-to-door solicitation because they restricted both wanted and unwanted solicitations. (See 942 F.2d at 638-639.) The municipalities sought to defend these ordinances on the grounds that they did not prohibit in-home sales. However, the court said that residents who wanted to receive unwanted solicitations had to post a "Solicitors Welcome" sign, and that the Government's imposition of affirmative obligations on the residents' First Amendment rights to receive speech is not permissible (*Id.* at 639).

Presumably, the comments cited this case as evidence that FDA's restrictions on tobacco advertising sweep too broadly because they affect the rights of both minors and adults to receive speech. Again, however, the case is distinguishable. Under FDA's restrictions, adults will be able to continue to receive tobacco advertising without any obligation to take any affirmative steps. They will have to look a little harder because, to advance FDA's interest in protecting the health of minors, advertisements will generally not have images or color, and such advertising will not be around schools or playgrounds. However, the advertising should otherwise continue to be available in newspapers, magazines, and billboards and appear unrestricted in adult publications and venues. There is no indication in *Project '80, Inc. v. City of Pocatello*, that the Ninth Circuit would find in such restrictions an undue burden under the First Amendment.

This review of the case law shows that FDA's effort to tailor the restrictions that it is adopting for cigarette and smokeless tobacco advertising that

clearly distinguishes them from the governmental efforts to protect minors that have been struck down as sweeping too broadly and as impinging on the rights of adults. Under FDA's restrictions, there will still be a free flow of information to adults and not massive censorship as some comments allege. Thus, these comments do not provide a basis to conclude that FDA's restrictions fail the third prong of the *Central Hudson* test.

(28) Several comments pointed out that the Supreme Court has stated on several occasions that regulations that disregard numerous and obvious less restrictive and more precise means of achieving the government's asserted objectives are not narrowly tailored. These comments suggested that there are several less restrictive alternatives to the restrictions on advertising that FDA had proposed. One alternative pointed to by the comments was better enforcement of laws prohibiting sales to minors. The comments pointed out that Congress passed legislation as part of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act of 1992, that prohibits DHHS from providing block grants for the prevention and treatment of substance abuse unless the State prohibits the sale and distribution of tobacco products to persons under 18. The comments said that FDA should give this new law a chance to work before imposing restrictions on speech, particularly in light of the fact that DHHS itself said in its 1995 proposed rule to implement this new law that "[e]liminating virtually all sales [of tobacco products] to minors does not even present particularly difficult enforcement problems" (see 58 FR 45156 at 45165, August 26, 1993).

The other alternative, according to the comments, that exists to the restrictions is an educational campaign that is sponsored either by the Government or that is provided through voluntary counter speech by the tobacco industry.

The agency recognizes that the various opinions by the Justices in *44 Liquormart* reiterate the need to consider nonspeech restrictions. Justice Stevens, speaking for himself and Justices Kennedy, Ginsburg, and Souter stated that the legislature "cannot satisfy the requirement that its restriction on speech be no more extensive than necessary," given that alternative forms of regulation, such as taxation or limits on purchases that did not involve restrictions on speech, could achieve the goal of promoting temperance as well as, or better, than,

<sup>197</sup> The Court specifically distinguished *FCC v. Pacifica Foundation*, 438 U.S. 726 (1978), because that case did not involve a total ban on broadcasting indecent material. The Court pointed out that the FCC rule in that case sought to channel the indecent material to times of the day when children most likely would not be exposed to it (*Sable Communications v. FCC*, 492 U.S. at 127). FDA's intention here is to impose a similar type of focused and tailored restriction on tobacco advertising to limit the appeal of such advertising to children.

its ban. Moreover, Justice O'Connor in a concurrence, joined by the Chief Justice, and Justices Souter and Breyer state:

The availability of less burdensome alternatives to reach the stated goal signals that the fit between the legislature's ends and the means chosen to accomplish those ends may be too imprecise to withstand First Amendment scrutiny. (116 S.Ct. at 1521)

(29) One comment, however, argued that, for two reasons, there is no plausible claim that FDA has disregarded reasonable alternatives. First, the comment pointed out that the Federal Government has engaged in an incremental effort for 30 years to strike the appropriate balance in regulating the sale of tobacco products. This effort was successful in bringing down overall smoking rates, but youth smoking rates remained stable during the 1980's and have recently begun to rise. Because previous measures have failed, the comment said, it was now appropriate for FDA to take stricter action to reduce the use of tobacco products by minors. Second, the comment noted that a lack of narrow tailoring often manifests itself in a restraint that is either grossly underinclusive or overinclusive. The comment said that FDA had been neither here.

In *Florida Bar v. Went For It, Inc.*, 115 S.Ct. at 2380, the Supreme Court made clear that the question whether a restriction on commercial speech is reasonably well-tailored turns, at least in part, on the existence of "numerous and obvious less burdensome alternatives to restrictions on commercial speech \* \* \*." (See 115 S.Ct. at 2380 (citing *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 418 n.13 (1993)).) FDA has considered the alternatives suggested by the comments and finds that none of them is an appropriate alternative to the restrictions that FDA is adopting.

First, the Government has engaged in a 30-year effort to eliminate young people's access to and use of tobacco products. The industry, through its voluntary code and various education programs, has professed to be part of the solution. However, tobacco can be easily obtained by young people (between 516 million and 947 million packs of cigarettes sold illegally per year to children (1992-1993) (60 FR 41314 at 41315)). Moreover, although adult smoking rates have declined dramatically since the publication of the first Surgeon General's Report in 1964 (from over 42.4 percent in 1965 to 25 percent in 1993) (60 FR 41314 at 41317), young people's smoking rates failed to decline during the decade of the 1980's

and began to rise in 1991. Between 1991 and 1995, the proportion of 8th and 10th graders who reported smoking in the 30 days before the survey had risen by one-third, to about 19 percent and 28 percent, respectively. Smoking among high school seniors had increased by more than one-fifth since 1992, with 33.5 percent saying that they had smoked in the 30 days before the survey.<sup>198</sup> Thus, past efforts involving age restrictions and warning messages on packages and advertising have not been sufficient to reduce the demand for tobacco by young people. The restrictions on advertising are designed to affect the demand.

Second, the agency proposed a sufficiently comprehensive set of regulatory restrictions to address the problem of tobacco use by young people, to wit: (1) Provisions that restrict and prevent sales of tobacco products to young people; (2) provisions that reduce the appeal of tobacco products for young people that is created by advertising and promotions; and (3) a program to provide educational messages for young people to help them resist tobacco use. Thus, the agency has not relied solely on regulations that have an impact upon the speech of the tobacco industry but has included provisions to address the activity itself.

Third, while it is true that better enforcement of laws restricting sales to minors is complementary to FDA's approach, it does not eliminate the need for this action. As DHHS recognized in its final rule implementing the ADAMHA Reorganization Act of 1992, DHHS's action under that statute and FDA's regulations both address the need to reduce minors' access to tobacco products. FDA's action, however, in addition to reducing access, attempts, through the restrictions on advertising, to reduce "the powerful appeal of tobacco products to children and adolescents" (61 FR 1492, January 19, 1996).<sup>199</sup>

<sup>198</sup> "Teen Smoking, Marijuana Use Increase Sharply, Study Shows; HHS Sees Alarming 'Culturewide' Change in Progress," *The Washington Times*, p. A2, December 16, 1995; quoting from "Results from the 1995 Monitoring the Future Survey," National Institute on Drug Abuse Briefing for Donna E. Shalala, Ph.D., Secretary of Health and Human Services, December 13, 1995.

<sup>199</sup> It is true that in its August 25, 1993, proposal (58 FR 45156), DHHS stated, as the comments say, that eliminating virtually all sales to minors does not present particularly difficult enforcement problems. This statement did not imply, however, that achieving this goal would be easy, nor did it reflect consideration of what ancillary measures would be useful to help to achieve this goal. It was,

Advertising, as explained in sections VI.B. and VI.D. of this document, plays a role in the decision of children and adolescents to use cigarettes and smokeless tobacco. As long as advertising continues to play that role, young people will be motivated to obtain access to tobacco products and to attempt to circumvent any access restrictions. Thus, the restrictions on speech are necessary to prevent advertising from undermining FDA's proposed restrictions on access. First, the agency notes that the voluntary educational campaigns conducted by tobacco companies have not been effective in reducing underage tobacco use. This fact is evidenced by the increase in prevalence of tobacco use among young people. (See, e.g., 60 FR 41314 at 41315.) Second, the agency finds that any educational campaign is likely to be undermined if the young people to whom it is aimed continue to be the target of advertising that fosters the perception that experimentation with tobacco by young people is expected and accepted.

The U.S. Court of Appeals for the Fifth Circuit considered a suggestion similar to that of an educational campaign in *Dunagin v. City of Oxford, Miss.* and found it not to be an alternative to restrictions on advertising:

We do not believe that a less restrictive time, place, and manner restriction, such as a disclaimer warning of the dangers of alcohol, would be effective. The state's concern is not that the public is unaware of the dangers of alcohol \* \* \* The concern instead is that advertising will unduly promote alcohol consumption despite known dangers. (See 718 F.2d at 751; see also *Posadas de Puerto Rico Ass'n v. Tourism Co. of Puerto Rico*, 478 U.S. at 344.) This is exactly FDA's concern about the effect of advertising on underage tobacco use, and why an educational campaign, which may complement advertising restrictions, is not an alternative to them.

Thus, the agency concludes that there are no less burdensome alternatives to restrictions on advertising. In this respect, this proceeding is distinguishable from that considered in *Rubin v. Coors*, which was cited by a number of the comments. In *Rubin v. Coors*, the Supreme Court pointed to the fact that the respondent cited several options that could advance the Government's asserted interest in a manner less intrusive to respondent's First Amendment rights than the

rather, a statement of DHHS' view that this goal could be achieved.

statutory provision the Government had adopted (115 S.Ct. at 1593).<sup>200</sup> Here, as in section VI.E. of this document, there are none believed to be nearly as effective.

In *U.S. v. Edge Broadcasting Co.*, 509 U.S. 418, 430 (1993), the Supreme Court said that “the requirement of narrow tailoring is met if ‘the \* \* \* regulation promotes a substantial Government interest that would be achieved less effectively absent the regulation,’ provided that it did not burden substantially more speech than necessary to further the government’s legitimate interests.”

FDA’s restrictions on cigarette and smokeless tobacco advertising clearly meet this test. FDA’s restrictions directly and materially advance its compelling interest in the health of children and adolescents under the age of 18. The discussion of the lack of less restrictive alternatives demonstrates that the agency’s goals would be achieved less effectively in the absence of these restrictions. Finally, as the discussion on narrow tailoring and in the review of the comments on each of the regulations on advertising that follows makes clear, FDA is restricting only those aspects of advertising that have particular appeal to the young. Thus, the agency has crafted the advertising provisions with specificity to allow unrestricted advertising in those venues that are not seen by or used by children and adolescents. Accordingly, publications with adult readership and adult establishments may have unlimited print advertising. Moreover, companies are free to offer nontobacco items and events in their corporate names or unbranded. Companies, thus, can reward adult usage by providing these incentives but may not do so in a format (with brand identification and imagery) which is appealing to young people.

However, the agency has been unable to determine additional areas for unrestricted advertising. Thus, other than adult establishments, such as bars, there are no areas at other retail establishments that are not visible to young people. Billboards are ubiquitous and accessible to all ages. Nontobacco items can be restricted to dissemination to adults, but they would still serve as walking billboards. Finally, there are no adult only sponsored events—children are at the events or watching them on

television. As described more fully in section VI.E.8. of this document, in the case of auto racing, attendance by young people is on the rise.

## 2. Section 897.30(a)—Permissible Forms of Labeling and Advertising

Proposed § 897.30(a) would have established the scope of permissible forms of labeling and advertising for cigarettes and smokeless tobacco. Proposed § 897.30(a)(1) would have defined permissible forms of advertising as newspapers, magazines, periodicals, or other publications (whether periodic or limited distribution); billboards, posters, placards; and nonpoint of sale promotional material (including direct mail). Proposed § 897.30(a)(2) would have defined permissible forms of labeling as point of sale promotional material; audio and/or video formats delivered at a point of sale; and entries and teams in sponsored events.

In response to the comments, FDA has revised § 897.30(a) so that it no longer distinguishes between advertising and labeling, deletes teams and entries as permissible advertising, describes the procedure that FDA will follow when it is informed by advertisers of their intent to advertise in a medium not listed in the regulation.

In addition, the first sentence of § 897.30(a), which states that this subpart does not apply to cigarette or smokeless tobacco product package labels, has been redesignated as § 897.30(c).

(30) Several comments were received addressing the issue of permissible advertising outlets. Comments from the tobacco and advertising industries opposed the 1995 proposed rule. These comments criticized the 1995 proposed rule for not defining the term “advertising” and called the 1995 proposed rule unprecedented in the scope of its limitations on the forms of media, a violation of the First Amendment, a violation of the Administrative Procedure Act (APA), and beyond FDA’s statutory authority. Supporters of the 1995 proposed rule, including health and public interest groups, stated that it is a reasonable measure given the effect of advertising on children and that it provides manufacturers with a wide variety of means for communicating with their customers. Some supporting comments urged that the prohibition of certain media, such as the Internet, be stated explicitly.

Several comments from the tobacco industry expressed concern that FDA did not define the term “advertising”

“because § 897.30(a)(1) would limit the media in which cigarettes may be ‘advertised,’ the definition of ‘advertising’ as used by FDA is crucial; yet the term is not defined in the proposed regulations.”

Moreover, they expressed concern that the definition was so sweeping that it could literally “include reports to shareholders or potential shareholders; communications among manufacturers, wholesalers, distributors, and retailers; or even communications to the news media insofar as they might be deemed a ‘commercial use.’”

Other comments requested that the agency clarify the definition to ban product placements in movies and commercials shown in movie theaters. Several comments stated that § 897.30 should be extended to include tobacco product packages to reduce the means of a child expressing affinity with the image associated with a particular brand. One comment recommended tombstone packaging without an identifiable logo.

The agency carefully considered whether it should attempt to define the term “advertising” more explicitly than it did. “Advertising” as a term is constantly evolving, as new media and new techniques of marketing emerge. Although its boundaries are understood (and were provided in the preamble to the 1995 proposed rule), there is no one accepted definition. FTC is the Federal agency with general responsibility for regulating most consumer advertising. Yet neither FTC nor any of its rules define the general term “advertising.” The agency agrees with the approach taken by FTC and continues to believe that the term “advertising” should not be defined any more specifically. Thus, FDA finds that the description of advertising in the preamble to the 1995 proposed rule is appropriate:

Labeling and advertising are used throughout this subpart to include all commercial uses of the brand name of a product (alone or in conjunction with other words), logo, symbol, motto, selling message, or any other indicia of product identification similar or identical to that used for any brand of cigarette or smokeless tobacco product. However, labeling and advertising would exclude package labels, which would be covered under proposed subpart C. (60 FR 41314 at 41334)

The agency also agrees with comments that state that it must provide some context for the application of so open ended a definition. For example, comments contended that “commercial use” could be interpreted to include such items as trade advertising (communication between

<sup>200</sup> One alternative that the respondents in *Rubin v. Coors* advanced was prohibiting marketing efforts emphasizing high alcohol strength (115 S.Ct. at 1593.) What FDA is doing here is analogous to that alternative. It is restricting marketing efforts that have particular appeal to the young.

manufacturers, wholesalers, distributors, and retailers), shareholder reports, and possibly even communications with the news media. This was not FDA's intent. This rule is a consumer based regulation; it is not the intention of FDA to include purely business related communications. Thus, noncommercial uses would not be affected. These would include such uses as unpaid press statements, signs on factories noting locations, business cards, and stockholder reports. While many of these uses would be ordinary and necessary business expenses, they would not be commercial uses in the context of the rule's restrictions on tobacco advertising affecting minors' tobacco use.

Furthermore, the preamble to the 1995 proposed rule explained that the agency intends to permit advertising with imagery and color in publications that are read primarily by adults. For that reason, under § 897.32(a), advertisements in publications (whether periodic or limited distribution) with primarily adult readership are not restricted to a text-only format. Trade advertising in trade press publications and trade show publications, trade catalogs, price sheets, and other publications for wholesalers, distributors, and retailers that will not be seen by consumers, including minors, are unaffected by the rule.

Also, the agency does not believe that the term "advertising" needs to be defined to clarify what is *not* a permissible advertising outlet. The 1995 proposed rule clearly specifies what advertising outlets are included within the regulation's coverage. However, the agency has been persuaded to make more clear its procedures for new or uncovered media. These procedures are described in this section.

The agency does not agree with comments that the rule needs to be clarified regarding infomercials or advertorials (program length commercials). Television infomercials are not allowed under the statutory broadcast ban, and magazine advertorials would be treated like any other magazine advertising. The agency recognizes that commercial advertising messages (videos) shown in a movie theater are not addressed by the 1995 proposed rule. If this becomes a desired medium, the companies would need to notify FDA 30 days prior to using a new medium. Finally, product placements in movies, music videos, and television, if not placed at the expense of a tobacco manufacturer, distributor, or retailer, would not be affected by this rule. The

agency does not intend to regulate a film producer's artistic expression—i.e., what the producer chooses to display in movies.

The agency has decided not to include restrictions on tobacco product packaging. The agency has attempted to narrowly tailor this rule and therefore has not included packaging restrictions at this time.

(31) Several comments from the advertising industry expressed concern that the wording of § 897.30(a)(1) would ban all advertising for tobacco products that is not expressly permitted. If so, the comment states, the rule would be arbitrary and capricious because the agency did not present evidence that these unnamed advertising techniques influence young people. Another comment pointed out that the channels available to tobacco companies for communicating with adults already have been severely restricted by Congress' ban on television and radio advertising.

In contrast, comments from organizations of health professionals and a public interest group supported the scope of permissible advertising. One specific comment stated that, "The media listed in § 897.30 provide manufacturers with a wide variety of means for communicating with their customers."

The agency has determined that the scope of the permissible outlets for tobacco advertising in the 1995 proposed rule is reasonable. The permissible forms are the known current forums for tobacco labeling and advertising and account for the vast majority of advertising expenditures. While the format of much of current tobacco advertising is being restricted to a text-only format, almost all of the current media outlets being used for tobacco advertising will still be permissible. Legal users will continue to be able to receive information about cigarettes and smokeless tobacco, in a text-only format in most cases, in virtually all the same media currently used for tobacco advertising. Moreover, if an advertiser intends to use a new media outlet not included in the list of permissible advertising, its responsibility is to notify FDA and provide the agency with information about the media and the extent to which the advertising is seen by young people. FDA will review any submission and make a determination whether provisions of the final regulation provide sufficient information for the advertiser to know how to disseminate its advertising or whether the

regulations need to be amended.

Advertising in any new media will be subject to the text-only format requirement if it is a medium used by young people. Therefore, FDA has created a new § 897.30(a)(2) to reflect this new process.

The agency believes this approach is reasonable and is fully consistent with its statutory authority and with the First Amendment. In *Central Hudson Gas & Electric Co.*, 447 U.S. at 571, n.13, the Supreme Court suggested that the Public Service Commission might consider a system of previewing advertising campaigns to ensure that they will not defeat conservation policy. The Court pointed out that "commercial speech is such a sturdy brand of expression that traditional prior restraint doctrine may not apply to it" (*Id.*). Given the agency's significant interest in ensuring that the restrictions on access that it is imposing are not undermined, FDA finds that the requirement that firms consult with it before using a new advertising medium is a limited means of regulating commercial expression that is likely to vindicate FDA's public health interests. This approach will not prohibit the tobacco industry from advertising in new media but will protect young people by giving the agency an opportunity to review the problems presented by a new media and to design new regulations or adapt current ones.

(32) One comment from a public interest group concerned with electronic media urged FDA to explicitly prohibit tobacco advertising over the Internet, Worldwide Web, and other on-line services and interactive media. The comment stated that children and adolescents are increasingly using on-line services with up to 4 million Americans under age 18 using, or with access to, on-line services. The comment stated further that the interactive nature of the on-line services gives advertisements numerous advantages over traditional print advertisements. The comment emphasized that a ban on tobacco advertising over these media is necessary because the text-only format would not be as effective in reducing the appeal of tobacco advertising to minors given the interactive nature of these media.

One comment from an organization of health professionals stated that one tobacco company advertises its mail-order business through a Web site on the Internet and offers links to other tobacco-related sites. The comment wondered why this type of advertisement was not banned by FCC



since the Internet operates over telephone lines, a form of electronic media that is regulated by FCC and from which cigarette advertising is banned.

A few comments dealt with on-line advertising and recommended that the rule should limit format to black text on a plain background, require advertisers to demonstrate that significant numbers of children do not access ad sites, require use of any available blocking technology, and define "conspicuous" and "prominent" as they pertain to interactive media.

Some of these comments have suggested that advertising of tobacco products in on-line media should be banned under the Federal Cigarette Labeling and Advertising Act's (the Cigarette Act) (15 U.S.C. 1331) and the Comprehensive Smokeless Tobacco Health Education Act of 1996's (the Smokeless Act) (15 U.S.C. 4401) prohibition of advertising on any media subject to the jurisdiction of FCC. The agency leaves the issue of jurisdiction and the applicability of the broadcast ban to the Department of Justice, which has the appropriate jurisdiction over the Cigarette Act, and to FTC, which has along with the Department of Justice jurisdiction over the Smokeless Act. Were these agencies not to take action and were, tobacco advertising to continue in on-line media, then FDA is available to meet with advertisers regarding their responsibility under the final rule.

The agency recognizes the growing importance and use of on-line media and the Internet for communications of all sorts, including tobacco sales and advertising. On-line media are not included within the list of permissible outlets for tobacco advertising because the agency does not have sufficient information on the technology to include regulations in the final rule. However, advertisers interested in advertising on the Internet should notify the agency, after the rule is final, and provide the agency with sufficient information about use by young people so that the agency can make a proper determination. This notification is for discussion purposes only, and is not in any way intended to imply, or create a need for, prior approval.

The agency recognizes the concern expressed by one comment that a text-only format, without additional requirements, may not be as effective in protecting young people from on-line advertising as it would be for print advertising because of the interactive nature of on-line media. The agency would consider the unique qualities of

on-line media and the Internet in evaluating any requests to use these media. Any other statement about specific requirements for this new media or any other media would constitute speculation at this point.<sup>201</sup>

Section 897.30(a)(1) provides a comprehensive listing of the permissible forms of advertising and labeling. The evidence that FDA has gathered in this proceeding establishes the need for and importance of such a comprehensive listing. In addition to the general evidence and support provided by expert opinion, advertising theory, studies and surveys, empirical studies, anecdotal evidence, industry statements, and two consensus reports (the IOM Report and the 1994 SGR) described in section VI.D.5. of this document, FDA has found specific support for a comprehensive listing in:

*Empirical Studies*—Various economic and econometric studies of international and cross-country data show that restrictions on advertising and promotional activities can result in a decline in tobacco use (see section VI.D.6.a. of this document).

*Country Experience*—The experience of countries, such as Norway and Finland, shows that comprehensive advertising restrictions can positively affect the smoking rates of young people over time (see section VI.D.6.a. of this document).

*Advertising Theory*—Each separate advertising media plays a critical role in shaping young people's beliefs about tobacco use, and ultimately their use of tobacco products (see sections VI.D.3.a. through VI.D.3.e. of this document). Therefore, regulation of advertising must address each type of media. As will be described in the following sections of the regulation, the restrictions on each media are necessary to reduce the appeal of tobacco for young people and to prevent unrestricted tobacco advertising from undermining the regulation's access provisions. Moreover, as international experience indicates (see section VI.D.6. of this document), when regulations that are not comprehensive are implemented, tobacco money can migrate to unregulated advertising venues (e.g., if publications are prohibited, money expended on sponsorship will increase) and can undermine the force of the regulation. Thus, in order to be effective,

restrictions must be as comprehensive as possible.

Based on all of the foregoing, FDA concludes that the comprehensive listing of permissible advertising in § 897.30(a)(1) will directly and materially advance the agency's efforts to reduce consumption of tobacco products by children and adolescents under the age of 18.

### 3. Section 897.30(b)—Billboards

The agency proposed in § 897.30(b) to prohibit outdoor advertising, including but not limited to billboards, posters, or placards, placed within 1,000 feet of any public playground or playground in a public park, elementary school, or secondary school. FDA proposed this provision because these are places where children and adolescents spend a great deal of time and should therefore be free of advertising for these products. The agency tentatively concluded that this was a reasonable restriction and noted that the cigarette industry's voluntary "Cigarette Advertising and Promotion Code," (the Code) revised in 1990, contains a similar provision concerning schools and playgrounds (60 FR 41314 at 41334 through 41335).

(33) FDA received over 2,500 comments concerning this part of the 1995 proposed rule. Comments opposing this measure pointed out that the tobacco industry has established a voluntary code similar to the proposed provision with which advertisers already comply, and that therefore, there is no reason to make this measure mandatory. These comments also stated that outdoor advertising does not target children and adolescents, and that parents, siblings, and friends have a much greater influence than billboards and posters on a young person's desire to start smoking. Further, they stated that there is no evidence that this measure would reduce any teenager's desire to smoke.

Most comments supported this provision, stating that children and adolescents should not be subjected to visual images promoting tobacco use around those areas where they attend school or play. The comments argued that children and adolescents want to be like the attractive models in the advertising, and, thus, the advertisements directly influence them to start using tobacco.

In the Federal Register of March 20, 1996 (61 FR 11349), the agency reopened the comment period for the August 1995 proposed rule to place on the public record a memorandum that provided further explanation of the

<sup>201</sup> In addition to the substantive changes, the following changes in language have been made: (1) Deletion of "only" in § 897.30(a)(1); (2) substitution of (a)(2) for (b) in 897.30; and (3) deletion of "and" before "in point of sale" in § 897.30(a)(1).

agency's proposal to ban outdoor advertising within 1,000 feet of schools and playgrounds. The document provided an additional 30 days in which to comment on this new information. The memorandum stated that the agency was aware of the industry's voluntary 500-foot ban on advertising from schools and playgrounds but also that it was cognizant, based on the experience of its employees, that billboards can loom large in the sight of children and adolescents at that distance and thus would be able to capture their attention. The agency also noted that 1,000 feet is about 3 blocks and that signage kept that far away from schools and playgrounds would not loom as large, if it would be visible at all. Moreover, the 1,000 feet will protect children as they travel to and from these locations.

In response to the comments, FDA has modified the provision to clarify the coverage of the provision. Thus, the final rule states that the 1,000-foot area is to be measured from the perimeter of the playground or school. Moreover, a definition of playground is included as well as an indication that the relevant area of a playground in a larger public park is limited to the play area itself. Section 897.30(b) reads:

No outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, may be placed within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., a public park with equipment such as swings and seesaws, baseball diamonds, or basketball courts), elementary school, or secondary school.

(34) Several comments asked FDA to define what is meant by the term "playground." The comments stated that the term could be construed to include literally any place of outdoor recreation where children may play (i.e., a paved parking lot, a tennis court, or a city park), even places used primarily by persons 18 years of age or older. One of the comments noted that the industry code refers to "children's playgrounds" (i.e., playgrounds designed primarily for use by children), but that § 897.30(b) refers to "any playground."

Some comments suggested that the term "playground" should include the playgrounds of city parks, recreation facilities, theme parks (e.g., Disneyland), and national parks.

The agency agrees that it needs to clarify what is meant by the term "playground." A typical dictionary definition of "playground" states that it is: (1) An outdoor area set aside for recreation and play, especially one having equipment such as seesaws and

swings; or (2) a field or area of unrestricted activity. The intent of the proposal was not to preclude outdoor advertising within 1,000 feet of any area that would fall under this broad definition, but to preclude cigarette and smokeless tobacco advertising around those areas where children and adolescents are likely to spend a lot of time. Clearly, areas around schools with equipment such as swings and seesaws are areas where children are likely to play. Public parks for family recreational purposes with play equipment, and facilities for activities such as baseball or basketball are also areas where children and adolescents are likely to be present for hours at a time.

However, private enterprises, such as theme parks and recreational facilities, are not necessarily intended only for children and adolescents. Those that are, may require the presence of an adult for entry. There are usually entrance fees or required purchases for use of these areas. In addition, children and adolescents may not be present in these areas on any regular basis (e.g., an annual visit to a theme park). Therefore, the agency will not include these areas in the regulation. Moreover, because all outdoor advertising must be in black and white text, the agency sees no need to extend the prohibition beyond elementary and secondary schools and public playgrounds at this time.

The concern expressed that a decision by private parties to build a playground could destroy the value of a billboard sign should no longer exist. Because the agency is limiting its definition of playground to those publicly owned playgrounds, any interested party could object to the establishment of the playground.

FDA is modifying § 897.30(b) to state that outdoor advertising is prohibited within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., areas with equipment such as swings and seesaws, baseball diamonds, basketball courts), elementary school or secondary school. The agency concludes that this modification in § 897.30(b) is adequate to clarify the term "playground," and that a more specific definition for "playground" is not necessary at this time.

The agency notes that the definition makes clear that, when an area is set aside for a playground within a public park, the 1,000 feet is measured from the perimeter of the play area and not from the larger park.

(35) Several comments contended that the regulation should specify that the 1,000-foot rule should be measured from the perimeter of the property to avoid confusion. One comment asked that the provision be more clear as to what types of schools would be included within the definition.

The agency agrees with the first comment. The intent of the 1995 proposed rule was that the distance would be measured from the perimeter of the school or playground. Any other measurement could defeat the purpose of the regulation. For example, measuring from the edge of a building or from the center of a playground could allow outdoor advertising to be placed closer to the perimeter where children may be assembled or playing. In addition, for large schools or playgrounds, the outdoor advertising could feasibly be near the perimeter of the school or playground if the distance is measured from somewhere other than the perimeter. Therefore, to clarify the intent of the provision, FDA is modifying § 897.30(b) to state that no outdoor advertising may be placed within 1,000 feet of the perimeter of any playground, elementary school, or secondary school.

However, the agency does not believe that it needs to provide a definition of elementary and secondary schools, as those terms, as commonly used, include all such schools (kindergarten through 12th grade) whether public, private, or parochial.

(36) One comment stated that the tobacco industry Code of Advertising Practices (the Code) applies to outdoor advertising on billboards, and that § 897.30(b) applies to all outdoor signage, including signage on the exterior of retail establishments that sell tobacco, and conceivably even to advertising on buses, taxis, and other vehicles that might venture within the 1,000-foot zone.

Another comment stated that FDA should consider regulations that eliminate tobacco advertising via traveling vans and trailers because trailers and vans are mobile billboards and can be strategically placed to gain maximum exposure among young people.

FDA agrees that § 897.30(b) applies to more forms of advertising media than does the tobacco industry code (i.e., all outdoor advertising, not just billboards). FDA's regulation restricts all outdoor advertising of tobacco products, including, but not limited to, billboards, posters, and placards. However, the intent and purpose of § 897.30(b) is not

to prohibit signage on taxis and buses that are not located in, but may pass through, the school or play zone. Such signage is usually temporary or transient and does not present the same concern of a permanent sign.

(37) Several comments questioned the factual basis for the proposed ban on outdoor advertising of cigarettes and smokeless tobacco within 1,000 feet of schools and playgrounds and stated that "employee" experience is not a sufficient basis. One comment argued that FDA should give little weight to employee experience in light of the fact that cigarette manufacturers submitted expert testimony that children and adolescents pay relatively little attention to billboard advertising at any distance. In addition, some comments argued that FDA's analysis related solely to billboards, and that it had presented no evidence or analysis justifying a ban on store signage. Finally, several comments stated that the agency failed to take into account the "visibility" of the outdoor advertising. These comments suggested that any regulation must take into account whether obstructions exist (e.g., trees, winding roads, signage placed facing away from the prohibited area).

The agency disagrees that it has not provided an adequate basis for its proposed regulation. In addition to the analysis provided by the agency in its March 20, 1996, Federal Register document, the agency received two comments during the comment period with evidence regarding this issue. A professor of biophysics and optometry stated that he believed that there was a rational and quantitative basis for deciding on a given distance if that distance was to be based on the visibility of words on a billboard. Specifically, he stated that children and adolescents typically have 20/15 visual acuity. Therefore, it is possible, using a mathematical formula using a right-angled triangle and the definition of the tangent trigonometric function to compute the distance at which words are visible. He computed the distances from which it would be possible to see both words 1 foot high and 2 feet high. In addition, he computed the distances for a "normal" visual acuity of 20/20. If one were to average these numbers, the result would be approximately 1,200 feet, which could be rounded to 1,000 feet.

Table 1a.

	1-foot high letters	2-foot high letters
20/15 vision	917 feet	1,833 feet
20/20 vision	687.8 feet	1,376

(38) Another comment reminded the agency that two separate laws passed by Congress had provided for a 1,000-foot zone around schools as a means to protect youngsters from dangerous and unsafe behavior. The Controlled Substances Act (21 U.S.C. 860) provides additional penalties for anyone distributing or manufacturing drugs within 1,000 feet of schools, playgrounds, and universities, and 18 U.S.C. 922 prohibited possession of a firearm within 1,000 feet of schools.<sup>202</sup> Moreover, the comment contained scores of pictures of advertising billboards and signs within 500 and 1,000 feet of school and playgrounds as well as statements by children indicating that the signs are ubiquitous and attractive. The pictures and statements may only be anecdotal evidence of the proliferation of tobacco advertising near schools and playgrounds, but the number of children who provided pictures in such a short period of time indicates that the problem of advertising in proximity to schools and playgrounds is not isolated.

Moreover, the agency also disagrees that it has no basis for including other outdoor signage, including signs on stores, in the regulation. The agency provided evidence in the administrative record and comments refer to evidence,<sup>203</sup> which showed that in a test area, those stores within 1,000 feet of schools had a significantly greater percentage of windows covered with tobacco signs than those further away. Moreover, the two RJR memoranda by sales representatives, described in section VI.D.3.d. of this document, mention the importance of supplying stores near high schools with "young adult" material.

This provides sufficient support for the agency's concern with signage on stores near schools. Young people are more likely to frequent stores near schools, especially older adolescents,

and these venues should therefore be free of advertising for tobacco products.

The agency also finds that it cannot address the comments' concerns with obstructions. It would not be possible to qualify a regulation to account for the fact that trees may obstruct a sign when they are in full bloom but not in winter, or that children may be able to see signage as streets wind or that face away from the school or playground as they walk to and from school. The line that the agency has drawn is narrowly tailored (see *Board of Trustees of State University of New York v. Fox* 492 U.S. at 480) and consistent with how a standard needs to be crafted for it to be enforceable.

Finally, FDA finds that the expert testimony referred to in the industry comment that indicates that young people do not pay attention to billboards is contradicted by other evidence in the record. The Roper Starch study mentioned in section VI.D.3.d. of this document, submitted by RJR, reported that 51 percent of 10 to 17 year olds surveyed reported that they had seen or heard of Joe Camel from a billboard advertisement. For this reason, FDA is not accepting the suggestion in the comment.

(39) A number of comments from the tobacco and outdoor advertising industries stated that the tobacco industry had adopted a code in 1990, which encouraged all billboard companies to establish and manage a program to prohibit alcohol and tobacco advertisements within 500 feet of places of worship and primary and secondary schools. They noted that over 16,000 billboards nationwide have been voluntarily identified as "off limits" for these categories of advertising. As a consequence, the comments asserted that Government action is unnecessary.

One of the comments stated that the fact that members of an industry have elected to submit to a code of advertising practices does not make it reasonable for the government to impose mandatory advertising restrictions backed by criminal sanctions. It stated that private parties may voluntarily take actions that the Constitution forbids the Government to mandate. The comment argued that few industries would risk any self-regulation if their decision to do so might establish a predicate for even greater Federal regulation.

Conversely, several comments raised concerns about the voluntary code and cited numerous examples of violations that continued after the sponsors and the billboard companies had been informed of the violations. One

<sup>202</sup> Although this statute was overturned in *United States v. Lopez*, 115 S.Ct. 1624 (1995), as inappropriate under the Commerce Clause, the congressional determination that 1,000 feet was an appropriate distance was not disturbed.

<sup>203</sup> Rogers, T., E. C. Teighey, E. M. Tencoti, J. L. Butler, and L. Weiner, "Community Mobilization to Reduce Point-of-Purchase Advertising of Tobacco," *Health Education Quarterly*, 1995, in press.

comment stated that a survey found that in California tobacco advertising is more prevalent at stores within 1,000 feet of schools than at stores farther from schools. The comment asserted that statewide findings also revealed that there is more exterior store advertising in areas where at least 30 percent of the neighborhood is 18 years old or younger, and that the advertisements are placed near the candy or at a child's eye view (3 feet or below).

The agency is aware that the Code of Advertising Practices has not been uniformly observed, as several comments pointed out. Moreover, the industry code is significantly less inclusive than the proposed regulation as it covers only billboard advertising and not other forms of outdoor advertising such as posters and placards. These other forms are likely to be placed near retail establishments and in some cases, according to comments, have appeared on school fences. The agency finds that all outdoor advertising must be included in the regulation in order to provide comprehensive coverage. There is little difference between a billboard and a large poster to a child. Both are advertisements, and both are visible, so that children see them as they go to and from school and play.

In addition, the Code prohibits outdoor advertising only within 500 feet of schools, an area only a block or a block and a half from the school (there are 10 to 12 city blocks to a mile). One block will not provide sufficient protection as it would not cover the areas where many children congregate with their friends. Moreover, a child's vision does not stop at one block from school. A prohibition of 1,000 feet will ensure the absence of signs for 2 to 3 blocks from a school or playground which can be seen from these locations where children spend a significant amount of time each day. (Several comments stated that FDA had misused its math to calculate block distances in its March 20, 1996, Federal Register document (61 FR 11349).) If the misstatement caused any confusion, the agency regrets it but does not believe that the one-half block difference undermined the rationale.)

(40) One series of comments supported FDA's 1995 proposal, stating that the restriction on billboards near schools should not be compromised, nor the distance reduced.

A number of comments argued that the proposed regulation did not go far enough. One comment recommended excluding outdoor tobacco advertising

from neighborhoods where children live. Another comment stated the belief that the ban on billboards should be at least double the proposed 1,000 feet from schools, while others argued that outdoor advertising should be prohibited completely.

These comments stressed the importance of billboards and other outdoor advertising in creating cigarette brand awareness among children. For example, one comment discussed the results of a survey conducted for *Advertising Age*, which showed that 46 percent of children 8 to 13 years old said they most often saw cigarette advertising on billboards, outpacing magazines. It stated that 34 percent of children 14 to 18 years old cited billboards as the predominant advertising medium for tobacco products.<sup>204</sup> The comment stated further that all billboards, regardless of placement, are seen by significant numbers of children, therefore, it clearly makes sense that, as a means to protect children from tobacco advertising, such advertisements should be prohibited from billboards and other outdoor advertisements. The comment emphasized its point by quoting from the billboard industry's own marketing material ("Outdoor: It's not a medium, it's a large"), "You can't zap it. You can't ignore it \* \* \* It asks little time, but leaves a long impression." The comment stated that the same publication notes, "Outdoor is right up there. Day and night. Lurking. Waiting for another ambush."

One tobacco company presented evidence of the effectiveness of billboards in bringing tobacco advertising to children. RJR, in its comment on the 1995 proposed rule, as stated in section VI.D.3.d. of this document, attached a study conducted for it to test children's recognition of advertising characters and slogans (Roper Starch study). This study involved 1,117 children 10 to 17 years of age, with 86 percent of them recognizing Joe Camel using aided and unaided recall. When asked where they had seen Joe Camel, 51 percent said on billboards.<sup>205</sup> That amount of recall shows that billboards represent a very effective advertising medium and belies the industry's assertion that billboards are not an effective source of advertising information for children.

<sup>204</sup> Levin, G., "Poll Shows Camel Ads are Effective With Kids; Preteens Best Recognize Brand," *Advertising Age*, p. 12, April 27, 1992.

<sup>205</sup> "Advertising Character and Slogan Survey," pp. 10, 22.

Finally, one comment from a public interest group warned that, the more complex a rule is, the more difficult enforcement becomes. It stated that spacing limitations, such as the proposed 1,000-foot zone around schools, begs a series of questions, for example: How is that distance measured, from what point to what point. It stated that these questions would make it virtually impossible for citizens to play an active role in enforcing this rule. The comment stated that without citizen participation, billboard control is extremely difficult, and that this situation has, in fact, contributed to the industry's disregard for local and State billboard control laws.

The agency finds that the comments, as well as the evidence spelled out in the 1995 proposal, have provided ample support to establish that outdoor advertising has a significant impact on children and adolescents. While the comments have presented significant evidence in support of a ban on all outdoor advertising, the agency is not convinced that a ban or a restriction on tobacco advertising of more than 1,000 feet would be appropriate. As discussed elsewhere in this document, the agency is requiring that all permissible outdoor advertising be in a black and white, text-only, format. Therefore, some of the concerns raised by the comments requesting a complete ban on outdoor tobacco advertising or of expanding the ban are addressed by that provision. Moreover, the agency's regulations are an attempt to balance the rights of adults to receive information about a legal product with its desire to protect children from the unavoidable appeal of advertising. Thus, although the line could be drawn elsewhere, the agency finds that the 1,000 feet limitation should ensure adequate protection from visible advertising where children spend a significant amount of time but will permit adults to get information.

(41) One comment stated that FDA's action violated the APA because the agency offered no evidence in support of its claim that children spend a great deal of time in areas as far as 1,000 feet from the places specified in § 897.30(b). It added that the justification for text-only advertising undercuts FDA's justification for its 1,000-foot ban.

Another comment stated that although tobacco product advertising is disseminated through a broad spectrum of media, outdoor advertising is the only such medium that is subject to additional specific prohibitions under the 1995 proposed rule beyond the

prohibitions applicable to all tobacco product advertising. It stated that the record does not contain evidence that would establish either that these prohibited outdoor advertising signs are viewed more often by minors than other advertising media, or that outdoor advertising in general has a greater impact on minors than other media. There is nothing, the comments argued, that indicates that the mandatory content restrictions and affirmative disclosure requirements imposed by the proposal would be less effective in outdoor advertising of tobacco products than when such an advertisement is placed in a rock and roll magazine, or in an exempt publication with 1 million adolescent readers.

One of the comments stated that because the text-only requirement itself is intended to render the advertising unattractive to young people, the additional "protection" offered by the 1,000-foot rule would be wholly gratuitous.

Several comments argued that there is no proof that this additional area of ban will reduce any teenager's desire to use tobacco: a desire that has withstood the ban of TV and radio advertisements and a massive educational program. The comment stated that the 1,000-foot rule seems particularly gratuitous in view of the fact that it would ban advertising that FDA, by virtue of its proposed text-only requirement, already has stripped of the features FDA deems make it appealing to young people.

FDA disagrees with these comments. The agency's bases for the text-only requirement for billboards and for the 1,000-foot ban are reasonable and supportable, and they are not in conflict. The text-only format requirement will reduce the appeal of cigarette and smokeless tobacco product advertising to persons younger than 18 years of age without affecting the information conveyed to adults (60 FR 41314 at 41335). It is an attempt to narrowly tailor the restriction by balancing the need to restrict advertising's appeal to children with the preservation of the informational function of advertising for adults.

The prohibition on outdoor advertising within 1,000 feet of schools and playgrounds is designed to address a different problem. The concern is not the appeal of the advertising. If the problem were only appeal, the 1,000-foot restriction would not be necessary because the text-only requirement would eliminate this concern. The concern is the nature of billboards themselves. Billboards near schools and

playgrounds ensure that children are exposed to their messages for a prolonged period of time. As the Supreme Court recognized in *Packer Corp. v. Utah*, 285 U.S. 105, 110 (1934), billboards are seen without the exercise of choice or volition, and viewers have the message thrust upon them by all the arts and devices that skill can produce. This is particularly true of billboards that are readily visible (i.e., within 1,000 feet) when children play or study at a playground or school, places where by design children spend a lot of time, or when children walk to and from a school or playground. Confronted daily and unavoidably with the advertised message, even in text-only, a child gets a sense of familiarity, normalcy and acceptability of the message and the product that is advertised.

(42) Several comments stated that placing a circle with a radius of 1,000 feet drawn from the perimeter of each school and playground would establish a "forbidden zone" that would be at least 2,000 feet in diameter (i.e., over one-third of a mile). They stated that in many communities, this would be tantamount to a de facto ban, for there would be virtually no outdoor location that could escape the rule's prohibition.

Several comments pointed out that even if advertisers wanted to disseminate advertisements on billboards that complied with the FDA proposal, there would be virtually no locations where such outdoor advertising signs could be located in some cities. They submitted results of computer assisted surveys of nine cities showing the areas where outdoor advertising of tobacco products would be allowed under the 1995 proposal. The survey showed that outdoor tobacco advertising would be prohibited in 94 percent and 78 percent of the respective land mass of Manhattan and Boston under the proposal. The comment stated that this range approximates the high and low percentages that could be anticipated in other metropolitan areas in the United States. Moreover, when it correlated the data collected from the study and other data regarding the actual location of billboards, the comment found that, even under the most expansive view, not a single billboard in Manhattan (including the commercial corridor of Times Square), and no more than 24 actual billboard locations in the entire city of Boston, would be permitted to display tobacco advertisements.

The comment stated further that even if the rule permits a few locations where tobacco advertising would be allowed in

a given municipality, there is no commercial utility in a limited number of outdoor advertising signs where the location of the advertisement is dictated by the 1,000-foot rule, rather than by market demographics and vehicle circulation. According to the comments, these latter factors are what actually control billboard placement. It concluded that, as a practical matter, FDA's proposed outdoor advertising restrictions would eliminate billboards as a medium for tobacco advertising even in those jurisdictions where a small number of such signs theoretically would be available.

FDA has carefully considered the possibility that its restrictions effectively outlaw outdoor advertising in most urban areas. The agency has concluded, however, that if this situation comes to pass, it would be a consequence of the density of population in cities. FDA's intent in adopting § 897.30(b) is to restrict the accessible and intrusive communication of information about cigarettes and smokeless tobacco to children and adolescents at school and at play. It was not to provide for distances that would have the effect of banning outdoor signs from urban areas. By limiting the restriction to 1,000 feet, FDA has tried to make it no more extensive than necessary to achieve its intended end. FDA has considered the cost of its restriction but concludes that a narrower restriction would not adequately advance its purpose of protecting young people from unavoidable advertising in settings in which they are essentially a captive audience.

The 1,000-foot restriction on outdoor advertising will serve to remove what has been shown is an effective means for tobacco companies to communicate with young people in a direct and unavoidable manner. Eliminating such billboards will thus mean eliminating a means by which the industry has influenced young people to engage in tobacco use behavior. Therefore, the agency concludes that § 897.30(b) is a necessary part of its effort to reduce underage use of tobacco products.

Several comments from the tobacco industry and from retailers pointed out that § 897.30(b) would prevent retail establishments within the 1,000-foot zone from informing potential customers that tobacco (or particular brands thereof) are available for purchase therein and at what prices. These comments stated that this restriction not only would hurt the retailers but would increase, in turn, the

search costs for adult smokers. The comments stated that retailers in the small slivers of a city in which outdoor advertising would continue to be permitted would be afforded an unfair competitive advantage.

One comment added that convenience stores located within 1,000 feet of a school or playground would not even be able to put a small black on white placard on top of a gas pump that merely indicates the price of tobacco, but that a billboard across the street and located a little over 1,000 feet away from the same school or playground could carry the brand name of a tobacco product in black letters as tall as the store's front door. The comment urged FDA to recognize this distinction.

The agency acknowledges that some retailers may be prohibited from placing advertising concerning tobacco products on or around their retail establishments, while others, perhaps just across the street, can. Any minimum distance that the agency establishes will preclude some retailers from outdoor advertising at their retail establishments but not others. However, FDA has determined that it is necessary to keep outdoor advertising away from areas where children are likely to congregate daily.

FDA notes that the Supreme Court cases that have considered restrictions on speech have recognized that such restrictions may not be perfectly tailored, see, e.g., *Board of Trustees of State University of NY v. Fox*, 492 U.S. at 479. Thus, while in a few instances there may be inequities created by the line FDA has drawn, because there is a reasonable fit, as explained in section VI.E.1. of this document, between FDA's ends and the restrictions that it is adopting, these minor problems do not doom FDA's rule (*Id.* at 480).

FDA's prohibition on signage on stores within 1,000 feet of schools and playgrounds will advance the agency's interest in protecting the health of children. Several of the studies submitted with comments showed that there is more signage in and around stores near schools and playgrounds than in stores generally. The ban on outdoor advertising within 1,000 feet of schools and playgrounds will ensure that signage near schools will be removed and thus minimize any sense of familiarity that would develop.

Thus, even though the agency has carefully considered these comments, it concludes that it is appropriate to establish a minimum distance from schools and playgrounds within which all outdoor advertising is prohibited.

(43) A number of comments argued that the prohibition on tobacco billboards within 1,000 feet of schools violates the Commerce Clause as recently interpreted by the Supreme Court in *United States v. Lopez*, 115 S.Ct. 1624 (1995). In *Lopez*, the Supreme Court held that Congress lacked the power under the Commerce Clause to criminalize the possession of a gun within 1,000 feet of a school. One comment argued that the Congress's commerce power only permits it to regulate, for example, the interstate transit of advertisements, but that once the advertisement is within a state, it is private property and not subject to regulation under the Commerce Clause.

The agency disagrees. Under the Commerce Clause, Congress may "regulate those activities having a substantial relation to interstate commerce, \* \* \*, i.e., those activities that substantially affect interstate commerce." (See *Lopez*, 115 S.Ct. at 1629-30 (citation omitted).) As the Supreme Court noted in *Lopez*, "the possession of a gun in a local school zone is in no sense an economic activity that might, through repetition elsewhere, substantially affect any sort of interstate commerce" (*Id.* at 1634; see also *id.* at 1640 (Kennedy, J., concurring)). As all advertising is inherently commercial in that it proposes a sale, the placement of tobacco billboards in a local school zone is economic activity that does substantially affect interstate commerce because it affects the demand for tobacco and smokeless tobacco. That the advertisements are private property after transportation in interstate commerce does not alter this analysis. Indeed, "[a]ctivities conducted within State lines do not by this fact alone escape the sweep of the Commerce Clause. Interstate commerce may be dependent upon them." (See *United States v. Rock Royal Co-op., Inc.*, 307 U.S. 533, 569 (1939); see also *Wickard v. Filburn*, 317 U.S. 111, 127-28 (1942) (holding that, under Commerce Clause, Congress could control farmer's production of wheat for home consumption because cumulative effect of such consumption by many farmers might alter supply and demand in interstate wheat market).) As such, regulation of the placement of billboards advertising tobacco products does not violate the Commerce Clause.<sup>206</sup>

Interstate commerce may be dependent upon them." (See *United States v. Rock Royal Co-op., Inc.*, 307 U.S. 533, 569 (1939); see also *Wickard v. Filburn*, 317 U.S. 111, 127-28 (1942) (holding that, under Commerce Clause, Congress could control farmer's production of wheat for home consumption because cumulative effect of such consumption by many farmers might alter supply and demand in interstate wheat market).) As such, regulation of the placement of billboards advertising tobacco products does not violate the Commerce Clause.<sup>206</sup>

<sup>206</sup> Moreover, cigarettes and smokeless tobacco products are nicotine delivery devices. Congress plainly provided for medical devices to be federally regulated as indicated by the provision allowing seizure of devices without proof of interstate

(44) A number of comments argued that § 897.30(b) would violate the First Amendment. These comments argued that, given the requirement for black text-only on a white background, the restriction on billboards within 1,000 feet of schools and playgrounds would not directly and materially advance a substantial government interest. The comments also argued that the billboard restriction could not be considered to be narrowly tailored. One comment from a public interest group, however, argued that FDA's proposal is fully constitutional because it is much more limited than the restrictions on billboards upheld in *Penn Advertising v. Mayor and City Council of Baltimore*, 63 F.3d 1318 (4th Cir. 1995) vacated, remanded 64 U.S.L.W. 3868 (U.S. July 1, 1996), and *Metromedia, Inc. v. San Diego*, 453 U.S. 490 (1981). The comment pointed out that in *Metromedia, Inc.*, the Supreme Court held that the City's interest in traffic safety and aesthetics were sufficient to justify a ban on commercial outdoor advertising (453 U.S. at 551, n. 23). Here, the comment said, the interest that FDA has asserted is more weighty.

FDA disagrees with the comments that argued that § 897.30(b) violates the First Amendment. As explained, this restriction does advance FDA's interest beyond what is accomplished by the text-only restriction. As explained in sections VI.B. and VI.D. of this document, the regular exposure of children to tobacco advertising, even in text-only form, builds a sense of familiarity and acceptability that, reports and studies say, contributes materially to the decisions of young people to experiment with and use tobacco products. Thus restrictions that eliminate such exposure will eliminate one factor that contributes to the process by which children and adolescents decide to smoke or use smokeless tobacco and, consequently, will directly advance FDA's interest.

Moreover, the restriction that FDA is adopting is narrowly tailored to advance its interest. FDA's concern is with the advertising that can be seen from schools and playgrounds, the place at which children and adolescents spend a significant amount of time each day. Three blocks or 1,000 feet is about the distance at which signs are readily visible. Thus, FDA has restricted outdoor advertising within this distance of schools and playgrounds.

shipment (section 304 of the act) (21 U.S.C. 334)) and by a presumption that devices are in interstate commerce (section 709 of the act (21 U.S.C. 379)).

The result of FDA's restriction is that children will not be confronted with tobacco advertising as they study and play, and thus there will be a corresponding reduction in the ability of tobacco advertisers to create the impression of acceptance and familiarity that is influential with youngsters. Consequently, there is a reasonable fit between FDA's interest in protecting the health of children and the restriction on outdoor advertising that it is adopting (see *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. at 416; *Board of Trustees of State University of New York v. Fox*, 492 U.S. at 480).

Thus, FDA concludes that, in fashioning the restriction on billboards, it has fully met its obligations under the First Amendment.

In summary, FDA finds that § 897.30(b) will contribute in a direct and material way to reducing underage tobacco use. The evidence establishes that billboards are one of the most effective forms of advertising for young people, and that their elimination near schools and playgrounds will directly and materially advance FDA's goals.

**Studies**—A Roper Starch survey submitted by R. J. Reynolds found that billboards were the most mentioned source of information about Joe Camel for children (see section VI.D.3.d. of this document), and a study conducted for *Advertising Age* (April 27, 1992) discussed in this section showed that 46 percent of children 8 to 13 and 34 percent of children 14 to 18 said that billboards are a predominant form of advertising for tobacco.

**Advertising Theory**—Billboards near schools and playgrounds give the child a sense of familiarity, normalcy, and acceptability of the message on the product. Therefore, regulation of the format and even the location of some billboards and other outdoor signs within 1,000 feet of a school or playground, is essential. As discussed in this section, comments submitted in this rulemaking include photographs that evidence the intrusive effect of billboards and signage around schools and playgrounds.

**Evidence of Children's Visual Range**—Data provided by a professor of biophysics and optometry, detailed in this section, support a finding that 1,000 feet is an appropriate distance to remove signage that would be visible and readable to students.

**Congressional Finding**—As detailed in this section, Congress mandated a 1,000 foot drug free zone around schools and playgrounds (Controlled Substances Act (21 U.S.C. 860)) as an appropriate

area in which to protect young people from drug dealing near schools and playgrounds.

Finally, the agency has tailored the ban as narrowly as possible by defining playgrounds narrowly and, as noted above, by restricting the area of the ban to that consistent with children's visual range.

#### 4. Section 897.32(a)—Text-Only Format

Under proposed § 897.32(a), cigarette and smokeless tobacco product labeling and advertising, as described in § 897.30(a) and (b), would be required to use black text on a white background and nothing else. The agency tentatively concluded that this text-only requirement would reduce the appeal of cigarette and smokeless tobacco product labeling and advertising to persons younger than 18 years of age and preserve advertising's informative aspects—that is, to provide useful information to consumers legally able to purchase these products.

In response to comments, the agency has decided to permit another exception to the requirement that all permissible advertising appear in text-only. Thus, it has created an exception for advertising in adult facilities that meet the criteria of § 897.16(c)(2)(ii) provided the advertising is affixed to the wall or fixture in the facility and is not visible from outside the facility. FDA has added this provision, as paragraph (a)(1) of § 897.32 and renumbered the exception for adult publications as § 897.32(a)(2)(i) and (a)(2)(ii).

Several comments suggested that FDA should provide an appropriate definition of "text-only" for permissible audio and video advertising, specifically static black text on a white background with no music or sounds. Therefore, proposed § 897.32 has been revised in consideration of comments received. A new § 897.32(b) has been added to provide guidance for audio/video advertising. Proposed § 897.32(b) has been redesignated as (c), and proposed § 897.32(c) and (d) have been eliminated. New § 897.32(b) has been added to provide explicit format requirements for one form of permissible advertising that had been left out of the proposed regulation.<sup>207</sup>

<sup>207</sup> In addition to the substantive changes made to § 897.32, the following changes in language have been made: (1) Addition of "Except as provided." \* \* \* section," to § 897.32(a); (2) addition of "any" to § 897.32(a); (3) amended language in § 897.32(a)(2) starting with "any publication" and ending with "an adult publication" and, in the last sentence, "an adult publication,"; (4) two changes to § 897.32(a)(2)(i) "younger than 18 years of age"

Many comments were received specifically addressing the text-only proposal. That children and adolescents should not use tobacco products was the one point of agreement among them. However, many comments from adult smokers and nonsmokers, retailers, tobacco farmers, elected officials, and the tobacco, advertising, newspaper, and magazine industries strongly objected to the text-only requirement. Their major objections were that: (1) Cigarette advertising does not cause young people to start smoking; (2) the proposed advertising restrictions would violate the First Amendment; and (3) the restrictions would have the effect of a virtual ban on cigarette advertising. Some comments expressed the concern or suspicion that FDA was using this proposal, ostensibly directed at minors, as a pretext to try to ban cigarette advertising generally.

In contrast, nearly three-quarters of the comments—mostly from parents, teenagers, public health officials, teachers, doctors, public interest groups, medical organizations, and some individuals in the advertising business—supported the proposal for text-only advertisements. The major reason presented for their support was the need to eliminate the appeal for tobacco that the advertising creates among children and adolescents. Some supporters urged even stronger action such as a total ban on all tobacco advertising. Some comments expressed the opinion that even though the proposed regulations may also affect adults, any resulting reductions in smoking by adults would not necessarily be bad.

(45) A number of comments questioned the validity of the evidence cited by FDA as support for the proposal. Many of these comments came from groups representing the tobacco, advertising, and publishing industries. These comments argued that there is no evidence that advertising with color and images encourages use of tobacco by minors or that advertising converts nonsmokers or nonchewers into smokers or chewers. Moreover, these other comments argued that there is no evidence that limiting advertisements to text-only is essential to reduce youth smoking and that there is no evidence that black and white text will reduce underage smoking.

In contrast, a number of supportive comments stated that the evidence cited by FDA, as well as studies published

and "15 percent or less"; and (5) deletion of "labeling" from § 897.32(c).



since the proposal, demonstrate the special susceptibility of children and adolescents to pictures, cartoons, photographs, other graphic images and colors.

Specifically, many comments observed that the appearance of Joe Camel in traditional advertising forums (magazines, billboards) attracts children and adolescents. One child wrote that his father gave him two sports magazines. "There were eight smoking ads in them \* \* \* the last one had two pictures of Joe Camel smoking. This can attract kids to start smoking."

Studies cited in the preamble to the 1995 proposed rule and in section IV.B. of this document, demonstrate the impact that images and colors, cartoons, and pictures and other graphic material have on children and adolescents. This does not mean that the same characteristics of advertising do not appeal to or affect adults. However, the effect of these techniques on children and adolescents is magnified because of their usual level of involvement in advertising as in everything else.<sup>208</sup> As detailed more fully in section VI.B. of this document, children and adolescents respond to stimuli that interest them, and that provides them with information that is important. Young people do not have the information processing skills that adults possess, and as a result more often than not, the information that is relevant to them comes in the form of images and colors rather than with a lot of words. This fact provides an explanation why 86 percent of children and adolescents smoke the three most heavily advertised brands (all are promoted with attractive imagery), even though they are generally price sensitive.<sup>209</sup> Adults buy generic products for price reasons or low tar brands for health concerns.<sup>210</sup>

Advertising's colorful images are not as relevant to them as cost. Given these factors, FDA finds that the text-only requirement will significantly reduce the appeal of cigarette and smokeless tobacco advertising to young people and reduce its influence on them.

(46) Many comments, especially from the magazine, newspaper, advertising,

and tobacco industries, stated that the proposal will operate as a virtual ban on most types of cigarette and smokeless tobacco advertisements. These comments argued that the text-only format requirement will eliminate tobacco companies' ability to attract the attention of potential customers and to convey brand messages and will render advertising invisible to adults.

Therefore, tobacco advertisers would be far less likely to advertise in the text-only format. Also, not having a clear standard for when the text-only requirement applies (see also definition of adult publication) will cause tobacco advertisers to avoid more publications than may be necessary to ensure that they do not violate the rule. Many of these comments also argued that advertising would become ineffective. One comment said that advertising that passes unnoticed amounts to no advertising at all. This comment also asserted that, as a result of the text-only proposal, no viable alternative channels of communication would exist.

Comments from the tobacco and advertising industry suggested that the advertising industry would suffer revenue, profit, and job losses as a result of the text-only format; employees involved in graphics arts would especially be affected; and suppliers providing services and products to advertising agencies would also be adversely affected.

A number of comments supporting the proposal recommended a total ban on all tobacco advertising. Many comments stated that a ban on all tobacco advertising and marketing would be reasonable because the tobacco industry will use any available loopholes to market tobacco products and will test any partial ban.

Tobacco companies will be able to continue advertising in most of the same forums in a text-only format. Advertising with colors, pictures, and graphics will still be allowed in adult publications. Tobacco advertisers will still be able to convey information to adults about taste, price, and product development using text-only advertising. Many current advertisements for low tar cigarettes rely heavily on text formats.

The agency is not limiting fonts, font styles, or size of type because it believes that the tobacco industry and its advertising firms can use their creativity with a variety of print formats to produce text-only advertising that will effectively communicate their messages, including brand messages, to adults. However, the agency is also convinced

that print advertising, no matter how creative, will not be able to provide the attractive imagery that young people look for in advertising to explain the importance of a product to them, e.g., what to wear, whom to hang out with, how to look cool (see discussion of the importance of color and imagery in the introduction to this section).

Moreover, although the restriction to text-only advertisements may tend to solidify market position, it will not give any one company new competitive advantage over another since all companies must play by the same rules. Thus, the economic impact of the rule on the advertising business will be mitigated by a shifting of resources to create new advertising in compliance with the rule and to advertising for other businesses (see section XV. of this document entitled "Analysis of Impacts" for more information).

The agency does not support a total ban on all tobacco advertising as was suggested by a number of comments. The agency has been able to tailor the restrictions that it is adopting, by requirements such as the text-only advertisements requirement, to eliminate the appeal of tobacco advertising for children and adolescents while still allowing a means for companies to communicate with adult tobacco users. The use of text-only will mean that there can be continued advertising that is less likely to attract young people but that can convey information to adults.

(47) Several comments stated that limiting point of sale advertising to text-only would effectively ban point of sale advertising and impair retailers' ability to market tobacco products to adult customers.

Many comments noted the places one sees (and placement of) Joe Camel at point of sale, the nature of the items on which his image appears, and his ubiquitousness in and around stores, as evidence of the intent of at least one tobacco company to try to attract young people. A physician commented that he: recently was returning from an evening [of] helping to care for [a] patient who was dying of emphysema [a lung ailment caused by cigarette smoking]. I decided to stop at a convenience store \* \* \* I was confronted with no less than 14 advertisements for cigarettes. From the Camel Joe sign beckoning in the parking lot \* \* \* a customer is bombarded with ads urging them to buy cigarettes.

Another comment stated that "advertisements on convenience store doors are placed well below adult eye-level and features such popular advertising cartoons as Joe and

<sup>208</sup> One such study tested the effect of different forms of advertising on children and found that they preferred pictures to text-only. (See Huang, P. P., D. Burton, H. L'Howe, and D. M. Sosin, "Black-White Differences in Appeal of Cigarette Advertisements Among Adolescents," *Tobacco Control*, vol. 1, pp. 249-255; 1992.)

<sup>209</sup> "Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989-1993," in *MMWR*, CDC, DHHS, vol. 43, pp. 577-581, 1994.

<sup>210</sup> Teinowitz, I., "Add RJR to List of Cig Price Cuts," *Advertising Age*, pp. 3, 46, April 26, 1993.

Josephine Camel. It seems counter-intuitive to assume that such advertising is intended for adults." Another comment stated, "Tobacco companies say they do not want to entice our children to smoke, then why are Joe Camel ads above the candy counters?" One comment noted that at a major retailer near the commenter's neighborhood, Joe Camel posters are right behind an exhibit of pogs, a popular children's collectible toy.

Manufacturers and retailers are not prohibited from promoting tobacco products at the retail level. Adult consumers looking for price and product information about cigarettes and smokeless tobacco will be able to find that information by searching even without the images to attract them. Text-only point of sale advertising, like magazines or billboards, will be effective in communicating this information. Thus, FDA is not banning point of sale advertising.

While text-only point of sale advertising can be effective with adults, it will have less allure and be less appealing to children and adolescents. Children and adolescents, who are less willing to process print information in a leisurely setting (such as reading a magazine), will not find textual material appealing in the momentary time setting of a retail purchase.

(48) A comment from an advertising industry association stated that:

\* \* \* FDA's prohibition on all direct mail promotion of tobacco products except for "tombstone" messages \* \* \* is even more onerous than that imposed on publications, since at least some publications will be permitted to carry non-tombstone advertising. The disparate treatment of direct mail exposes the real purpose of the FDA to censor messages to adults, because that medium by definition can be addressed to a specific audience, i.e., adults, with little risk of inadvertent viewing by minors.

This comment also noted that this form of direct advertising is not insignificant to the industry and given the small likelihood of youth access to it, should not be severely restricted. The comment noted that total industry spending on direct mail advertising was \$33 million in 1993.

Some comments from mail-order firms noted that the text-only requirement would adversely affect catalogs for tobacco and related products, making them less appealing and less effective for marketing to adult smokers. One comment from the owner of a small (55 employees) tobacco products manufacturing business said the text-only requirement for its catalog, along with several other aspects of the

1995 proposed rule, would destroy his business:

It offends me as a good American running a clean, honest business that a cadre of bureaucrats in Washington, DC would propose a rule that could ruin my life's work. FDA has given no more thought to the impact on my business than I might give to swatting a mosquito.

A supportive comment stated that the tobacco industry has made increasing use of direct mail promotions, including contests, questionnaires, coupons, offers, and even birthday cards. It stated that no company can be certain its mailing lists do not include minors. In a 1993 survey of 12 to 17 year olds, 7.6 percent indicated they had received mail personally addressed to them from a tobacco company. This could project out to 1.6 million persons aged 12 to 17. This comment noted that a major tobacco company sent free packs of cigarettes to people on its mailing list as a holiday present "from the Camel family" and has not changed its practice despite the fact that as many as 1.6 million 12 to 17 year olds could be on tobacco company mailing lists.

Direct mail is a high involvement medium, that is, it requires the recipient to study the text in order to get the central message. In those circumstances, text-only can be effective with recipients who have an interest in the offer. There is less of a need to attract a consumer's attention with a direct mail promotion, including a catalog, than with a point of sale or magazine advertisement. A consumer opening a direct mail promotion he/she is interested in is in a high-involvement mode and is prepared to read the enclosed material and catalog. Although the material may be more easily ignored, current tobacco users who want to buy by direct mail can get the information from textual material.

Mailings in text-only to current customers and to other adult smokers are permitted under the rule. On the other hand, if a direct mail promotion or catalog is seen by a child, the text-only format would make it much less appealing and less interesting. This is especially important since there is evidence that as many as 1.6 million children aged 12 to 17 receive direct mail tobacco promotions. Thus, text-only direct mail is important to accomplish the purpose of this rulemaking. Moreover, contrary to being censorship, as some comments stated, the text-only format for direct mail will allow advertisers to send adults an encyclopedia of information about any aspect of smoking or tobacco products

while protecting children from the effects of advertising.

Although direct mail catalog advertising will be less interesting, sales should only be minimally affected. As the final rule does not include a prohibition on mail-order sales, the only restriction will be the text-only format. In addition, this should be less of an impediment than a total ban to small mail order company owners such as the commenter.

This compromise represents the agency's attempt to narrowly tailor its rule. Based on comments received from the industry, most mail-order customers purchase tobacco products for price, convenience, and uniqueness and to stockpile a long term supply. The agency believes that creative and effective advertising for adults can be designed in the text-only format for catalogs, especially for catalogs targeted to consumers purchasing tobacco products for these reasons. Therefore, FDA is not exempting direct mail promotion of tobacco products from the text-only requirement.

(49) One comment suggested that FDA create an exception for direct mail similar to that for publications. The comment said that direct marketers can target mailings so that children and adolescents are protected to, at the very least, the same degree that the regulations provide for the publishing industry.

FDA has considered this request but finds that it cannot grant it. The agency based the threshold for publications on the ground that publications with youth readership of less than 15 percent are not of interest to young people and thus would be unlikely to be read by them. The same cannot be said of direct mail advertisements that come addressed with the child's name on it. (As explained in this section, surveys show that a significant portion of tobacco direct mail advertising is sent directly to individuals under the age of 18.) The appearance of the child's name in the address will cause the child to look at the advertisement and thus will cause the message to be thrust on the child in a manner similar to messages on billboards or point of purchase (see *Packer Corp. v. Utah*, 285 U.S. 105, 110 (1934)). Thus, direct mail advertising is more similar in nature to billboards and point of purchase advertising than are publications. Consequently, as with the former types of advertising, FDA has concluded that to reduce the appeal of direct mail advertising to those youngsters who view it, it is appropriate

to require that this type of advertising be in the text-only format.

(50) A few comments said that in the same way the agency attempted to carve out an exception for publications with primarily adult readers, it should permit a similar exception for advertising in bars, clubs, etc., with customers over 21 years of age.

The agency agrees with these comments. The agency recognizes the need to precisely tailor its regulations and thus, has created an exception for advertising in adult only (18 years of age and older) facilities permitted to sell tobacco products from vending machines and self-service under § 897.16(c)(2)(ii). These facilities, which are required to ensure that no one under the age of 18 is present, or permitted to enter, the facility at any time, may display permissible advertising, i.e., with color and imagery, provided that the advertising is not visible from outside the facility and is affixed to a wall or fixture within the facility. These conditions will ensure that the advertising does not become a surrogate for outdoor advertising and is not carried from the facility.

(51) The agency received some comments from opponents and supporters of the 1995 proposed rule that stated that this provision might be counterproductive and result in increased demand for cigarettes and smokeless tobacco by minors. One comment from an association of advertising agencies stated that a reduction in spending on cigarette advertising, resulting from the proposal, could make cigarettes less expensive and increase demand for these products. In contrast, another comment from a tobacco company stated that reduced competition due to the text-only restrictions could lead to price increases for some brands which would harm the adult purchasers of those brands.

Some comments stated that the health warnings in cigarette advertising would become less effective in the proposed text-only format. This consequence could result in fewer people giving up smoking because of information in the health warnings. Some comments argued that the text-only format might actually attract more attention from minors because these advertisements would be so different from most advertising.

The agency finds that, on balance, the evidence does not support a conclusion that the text-only requirement will be counterproductive. This finding is based in part on the contradictory comments regarding the price of cigarettes. Some

comments from the advertising industry argued that tobacco companies would use the savings from doing less advertising to reduce the price of cigarettes, which would increase demand especially among young people who are price sensitive. Other comments from the tobacco industry argued that the requirement would reduce competition, which could lead to higher prices for adult consumers. This conflict points out the speculative, and therefore unconvincing, nature of the claims that the restrictions will be counterproductive.

Also, despite concerns expressed by the tobacco industry and others that the text-only format would make the Surgeon General's health warning less effective, there is evidence from the focus groups conducted by the agency that this warning is not very effective with young people now.<sup>211</sup> The text-only format will not interfere with the ability of the Surgeon General's warning to warn adults of the health hazards of smoking. This format will, however, reduce the appeal to young people that advertising creates and therefore will lessen the need for the warning for young people.

The agency has considered the concern of some comments that the text-only format will be so unlike most advertising that young people will be attracted to it. Whatever attraction the novelty has for young people, the agency has concluded that it should be less than the attraction of the current imagery in tobacco advertising.

(52) A number of comments, especially from the tobacco industry, expressed concern about the 1995 proposed rule's adverse impact on competition. Many comments stated that advertising is critical to competition, brand choice, and product innovation. Comments from the tobacco industry stated that the primary purposes of its advertising are to promote brand competition and to maintain brand loyalty. Many of these comments argued that the text-only format would stamp out competition and freeze market shares. Some comments also stated that the 1995 proposed rule would serve as a barrier to new and improved products and product innovation, especially to products like lower tar cigarettes.

Although all firms will be subject to the same rules, some firms may still gain an advantage by dominant market position or by being more creative in their text-only advertising or more

effective in their placement of advertising. Tobacco companies will still be able to advertise in virtually all the same forums they use now, but companies may gain competitive advantages by developing new marketing techniques aimed at adults that are within the rules. All industries have to adapt to changing competitive circumstances, whether caused by government regulations, demanded by the public, self-imposed as in professional sports, affected by international competition and changing technologies, or in reaction to changes in consumer preferences. Creative companies can succeed by adapting better than their competitors within the new framework.

Additionally, these advertising restrictions could make it more difficult for a new competitive tobacco company to be formed and to enter the market. But, there are much greater barriers to entry for a new firm in terms of the nature of the tobacco business, capital requirements, and the existing large firms already in the business. Nevertheless, to the extent that the regulations do produce anticompetitive effects, these are outweighed by the public health benefits of the rule.

Finally, information on new products and on product innovations need not be "stamped out." This kind of information can be conveyed in the text-only format. One example of a new product that the tobacco industry claims might not have been developed if this rule had been in effect is the low tar cigarette. Yet advertising for low tar brands tends to use much more text than regular brands because the information is factual and specific. Therefore, the agency continues to find the text-only requirement to be an appropriately tailored remedy.

(53) Comments offered differing views on the function of advertising. Some stated that imagery is necessary to attract and hold the attention of adult smokers in order to convey useful information about the product and to effectively differentiate brands, while others saw images as being too appealing to children. These latter comments argued that FDA's rule is seeking to regulate only the presentation of the advertising that attracts children (the imagery), not its content.

One small business owner said the proposed ban on imagery would make established advertising logos with pictures worthless, not just for the major tobacco companies but also for small firms in tobacco related businesses. Others stated that the 1995 proposed

<sup>211</sup> Focus group report in administrative record, December 1, 1995, 60 FR 61670.

rule is not strong enough. One comment said that FDA is mistaken in asserting that the black and white text format removes imagery and emotive content from the advertisement. It said that the regulation should also limit the type styles, font sizes, and shapes of borders and letters.

The agency continues to believe that it has created an appropriately tailored remedy. The tobacco and advertising industries argue that FDA's ban on imagery and color is overinclusive and not narrowly tailored. FDA disagrees, however. The restriction on the use of images and color preserves informational advertising because of its utility to adults while eliminating the aspects of advertising that are most attractive to young people. The agency is regulating only the manner in which advertising is presented, not the information contained in it. Also, the agency is allowing imagery in advertising in adult publications.

There is undoubtedly an impact on businesses that have established logos, pictures, and other graphics associated with their businesses or products. However, all businesses are subject to the same requirements, and thus no one business should receive any competitive advantage.

The agency does not agree with comments recommending restrictions on type styles, fonts, etc. Such a restriction on advertising is, given the currently available evidence, more restrictive than necessary. Text-only advertising should be sufficient to reduce the appeal of advertising based on imagery to children and adolescents, however creatively the text is displayed. The agency concludes that the elimination of imagery and color directly and materially advances its interest in protecting the health of young people by making tobacco advertising much less appealing to them and, therefore, it makes it less likely that they will be influenced to use tobacco products.

(54) Several comments requested that FDA provide specific regulation for audio and video formats. Specifically, the comments requested that audio be confined to a text-only format appropriate for audio (words) unaccompanied by music or sound and that video be limited to black text on a white background only. Restrictions, such as these, the comments continued, would apply the spirit of the text-only format to these media. Finally, one comment expressed the concern that without these restrictions, tobacco companies might create and disseminate

music tapes, similar to one distributed by RJR with music by "The Hard Pack." This would, the comment stated, provide aural imagery for young people.

The agency agrees that it should provide more specific guidance for permissible audio and video media and that this guidance should be a logical application of the text-only requirement. Therefore, the agency has amended § 897.32 to add a new paragraph (b), which requires text-only black and white text in video advertising, which should be static, and text-only, no music, in audio advertisements.

(55) Several comments challenged FDA's proposal to limit most advertising to the use of the text-only, black print on white background format on the grounds that this limitation would violate the First Amendment. These comments relied most heavily on three cases: *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), in which the Supreme Court struck down a restriction on the use of pictures in attorney advertising; *Shapero v. Kentucky Bar Association*, 486 U.S. 466 (1988), in which the Supreme Court held that the State may not restrict lawyer solicitations to those least likely to be read by the recipient; and *In re R. M. J.*, 455 U.S. 191 (1984), a case in which the Court struck down a requirement that lawyers use a fixed format in their advertising. One comment, however, argued that FDA's restriction is fully consistent with the First Amendment.

In *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. at 647, the Supreme Court said that "the burden is on the State to present a substantial governmental interest justifying the restriction \* \* \* and to demonstrate that the restriction vindicates that interest through [narrowly tailored] means."<sup>212</sup> FDA will apply this test here.

As explained in section VI.C.4. of this document, FDA has not merely a substantial, but a compelling, interest in the health of minors. It is this interest that led it to propose the restriction on the use of images and color in cigarette and smokeless tobacco advertising.

Several comments argued, however, that the restriction on images and color do not further FDA's interest. These comments argued that there is no evidence that the use of color and

images in advertising increases tobacco use among young people.

FDA has fully addressed this assertion. The available evidence demonstrates that pictures and colors have particular appeal to children and adolescents under 18 years of age, and that they are more important to underage individuals than other aspects of the advertisement.<sup>213</sup> Young people pay attention to peripheral cues in an advertisement, such as the models that appear in them, color, and scenery, and it is these components that tobacco advertisers use to create the images that are so important to people under the age of 18. Thus, the restriction on images and colors will have a particular effect on the appeal of advertisements to young people and make these advertisements a significantly less effective means of communicating to this group.

(56) Several comments also argued that FDA's restriction on the use of colors and images is not narrowly tailored, pointing to the fact that the agency proposed to eliminate the use of all visual images and graphic designs in cigarette and smokeless tobacco advertisements.

These comments misinterpret the rule. FDA has not restricted all use of color and images. FDA has provided that these mechanisms may continue to be used in publications with primarily adult readership and in adult-only establishments. The agency has endeavored to restrict as little speech as possible. FDA has found, however, that it could not limit the appeal of cigarette and smokeless tobacco advertising to the young if it did not restrict the use of image and color.

Each of the cases relied upon by the comments is fundamentally distinguishable from the current situation. In each of these cases, the body seeking to restrict the advertising in question failed to present any evidence that the restriction was addressing an actual harm (see *Zauderer*, 471 U.S. at 648-649; *Shapero*, 486 U.S. at 479-80; (see also *Florida Bar v. Went For It, Inc.*, 115 S.Ct. at 2378 ("Finally, the State in *Shapero* assembled no evidence attempting to demonstrate any actual harm caused by targeted direct mail."); *In re R. M. J.*, 455 U.S. at 206). Here, in contrast, the record fully establishes the reality of the harm, and that FDA's interest will be directly and materially advanced by the

<sup>212</sup> *Zauderer* actually states " \* \* \* through the least restrictive available means." However, in *Board of Trustees of State University of N.Y. v. Fox*, 492 U.S. at 479-481, the Court clarified this phrase as requiring narrowly tailored means.

<sup>213</sup> See, e.g., Petty, R. E., and J. T. Cacioppo, *Communication and Persuasion: Central and Peripheral Routes to Attitude Change*, Springer-Verlag, New York, 1986.

restriction on colors and images. For these reasons, FDA finds no merit to these comments.

In summary, FDA finds that the evidence amassed during this investigation and provided by comments provides ample support for its requirement that all forms of advertising that children see and are exposed to can have an effect upon their attitudes about tobacco use.

The empirical studies and surveys, expert opinion, anecdotal evidence, industry statements, and consensus report described in section VI.D.5. of this document implicate advertising as an important source of information for young people's attitudes about, and use of, tobacco products. This evidence shows that any regulation that hopes to be successful must be comprehensive and include some type of restriction upon all forms of advertising and promotions. FDA's regulation provides restrictions that will contribute directly and materially to that end but that are tailored as narrowly as possible. Except in the limited case of outdoor advertising within 1,000 feet of schools, no informational advertising will be disturbed. However, those aspects of advertising that have particular appeal to young people will be banned.

**Color and Imagery**—Color and imagery are necessary ingredients for advertising in conditions of "low involvement," such as occurs when skimming a magazine or seeing a billboard (see sections VI.B.1.b. and VI.B.1 c. of this document).

FDA's restriction will eliminate the color and imagery but will permit information to be communicated. This requirement is as important for in-store advertising, billboards, and direct mail, as it is for traditional publications. As discussed in this section, young people get their information and product imagery from all these sources: (1) Point of sale advertising confronts young people when they go to make a purchase. The imagery is as large as life and presents the child with an enticement at the time when purchase is immediately available. It can as effectively impart information to adults with words. (2) Direct mail can frequently wind up in the hands of a young person or be addressed personally to the child or adolescent. One study found that 7.6 percent of children 12 to 17 years questioned had received mail personally addressed to them from a tobacco company (1.6 million teens).

**Billboards**—Billboards provide a major source of information about

tobacco for young people. One study published in *Advertising Age* (April 27, 1992), found that 46 percent of children 8 to 13 years old and 34 percent of children 14 to 18 cited billboards as the predominant advertising medium for tobacco products (see section VI.E.3. of this document). The Starch Survey conducted for R.J. Reynolds found that 51 percent of children 10 to 17 who recognized Joe Camel as a tobacco mascot, reported seeing him on billboards (see section VI.D.3.d. of this document).

**Cross-Country and International Studies**—Studies described evidence that regulations that are stringent and comprehensive will have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones (see section VI.D.6.a. of this document). The text-only requirement, while not as stringent as a ban, will accomplish its purpose while preserving the informational function of advertising.

Finally, the regulation is narrowly tailored. It permits adult publications and adult locations to display advertising with images and colors. The agency has attempted to define these venues with as much precision as possible but recognizes that there may be some difficulties in application. It, therefore, has made it clear that it will work with the industry to try to establish as clear rules as possible. In-store, outdoor, and direct mail advertising do not lend themselves to such tailoring. Nonetheless, the agency is confident that adults seeking information about products can be adequately informed at time of purchase or by mail order catalogue using text-only.

#### 5. Section 897.32(a)—Definition of "Adult Publication"

The preamble to the 1995 proposed rule explained that the agency was interested in permitting advertising in publications that are read primarily by adults to continue to use imagery and color. For that reason, under proposed § 897.32(a), advertisements in publications with primarily adult readership would not be restricted to a text-only format. The agency proposed to define such publications as those: (1) Whose readers age 18 or older constitute 85 percent or more of the publication's total readership,<sup>214</sup> or (2) that are read

by fewer than 2 million people under the age of 18, whichever method ensures the fewest young readers. The agency defined the readership of a publication as the total number of people that read any given copy of that publication and stated in the preamble that it should be measured according to industry standards and, at a minimum, by asking a nationally projectable survey of people what publications they read or looked at during any given time. The preamble to the 1995 proposed rule noted that a reader is one who said that he or she read the last issue of a publication. The 1995 proposed rule provided that before disseminating advertising containing images and colors, it would be the company's obligation to establish that the publication meets the criteria for a primarily adult readership.

Numerous comments were received by the agency regarding the exception from the text-only requirement for adult publications and the definition of an adult publication. Comments from the newspaper, magazine, and advertising industries were particularly critical of the readership thresholds chosen for the definition of an adult publication and were especially concerned about whether there would be any reliable and practical way to determine readership levels for most publications. Many comments from individuals who supported the text-only requirement saw this exception as a possible loophole for the tobacco industry to escape the text-only restrictions.

In a notice published in the Federal Register of March 20, 1996 (61 FR 11349), the agency reopened the comment period to place on the public record a memorandum that provided further explanation of the agency's proposal to exempt publications with primarily adult readership from the text-only requirement. The document provided an additional 30 days to comment on this new information. The memorandum stated that the agency had selected the 85 percent per 2-million threshold based on the public perception that certain magazines are likely to be of interest to young people under the age of 18. The agency extrapolated from the readership percentages for those publications to the proposed threshold levels. Data supporting this line had been placed in the administrative record for the proposed rule (vol. 105, document 1550) and additional readership data was

<sup>214</sup> This portion of the definition was edited in the final rule to make the two provisions parallel. Thus, § 897.32(a)(2)(i) now reads, "whose readers younger than 18 years of age constitute 15 percent

or less of the total readership as measured by competent and reliable survey evidence."

provided during the comment period. The agency noted additionally that at some point the number of underage readers is so great that the publication can no longer be considered to be of no interest to those under 18, regardless of the percentage of the readership. The agency selected 2,000,000 as that level.<sup>215</sup>

(57) Some comments objected to the proposed readership thresholds, calling them arbitrary and stating that FDA provided no basis, no rational justification, and no evidence for them. One tobacco industry comment stated that it used an FTC methodology based on readership and the number of pages of advertising to conclude that magazines with greater readership by minors tend to have less cigarette advertising than other publications.

Some comments also objected to the 2 million minor readers threshold because it would subject some adult-oriented magazines to the tombstone format even though their percentage of minor readers is very low. One comment cited the following examples and readership figures: *People Magazine* (3,020,000 minors: 7.8 percent of all readers) and *Better Homes and Gardens* (2,042,000 minors: 5.5 percent of all readers); *Time* (1,972,000 minors; 7.66 percent of all readers) and *Newsweek* (1,911,000 minors; 8.01 percent of all readers) are also close to the threshold. In addition, some comments suggested that FDA's explanation that 2,000,000 is a large number is not adequate basis for regulation.

Some comments stated that the proposed thresholds were unfair to the up to 85 percent, or more in some cases, of a publication's readers who were adults. "Such a regulation is inconsistent with the principle that the government may not 'reduce the adult population \* \* \* to reading only what is fit for children.'"

In contrast, comments supporting the proposal stated that just because the line (i.e., thresholds) could be drawn differently was not important as long as FDA can rationally explain why it drew the line where it did. One comment suggested that FDA should require the text-only format in the 10 most read magazines by young people in addition to the present proposal. Some comments recommended requiring the text-only format for advertisements in all publications.

One comment stated that no tobacco advertising, even text-only, should be

allowed whatsoever in publications with youth readership, and adult publications should have text-only tobacco advertisements. This comment also said that the agency should monitor this exception to ensure that tobacco companies don't increase advertising in national adult publications that are widely read by the entire family including children and adolescents and to be wary of tobacco companies creating their own adult publications saturated with tobacco advertising.

Other comments supporting the proposal stated that some degree of overinclusiveness is acceptable and expected because of the difficulties in fine-tuning any regulation. Other comments saw any exception for any publications as a potential loophole that could be used by tobacco companies to continue using imagery in advertising. They said that experience in other countries with tobacco advertising restrictions showed that "the tobacco industry used all of its creativity to manipulate the system to take advantage of whatever opportunities were still available to reach their target audience, particularly young, impressionable individuals."

The comments received, especially from the magazine and newspaper industries, made clear that both defining an adult publication and determining whether a particular publication meets the definition are difficult issues. However, while these comments were helpful in pointing out the difficulty of defining an adult publication, they did not offer any realistic alternative definition in terms of a readership-by-minors threshold. Because of the concern about tobacco use by children and adolescents, which was voiced by virtually all comments pro or con, the agency believes it has sufficient evidence to justify a text-only requirement. However, the agency's concern is with advertising that affects minors and with tailoring the restrictions in this final rule to burden as little speech as possible. Therefore, FDA concludes that an exception from the text-only requirement for publications that are read primarily by adults is still reasonable and feasible.

The agency has decided to retain the exception for adult publications and to retain the readership thresholds in this final rule. The 15 percent young readers threshold is reasonable based on readership data submitted with comments. The 15 percent threshold would require text-only advertising in the following sports and racing magazines: *Sports Illustrated* (18

percent), *Car and Driver* (18.3 percent), *Motor Trend* (22.1), and *Road & Track* (20.6 percent) and in the following general circulation magazines: *Rolling Stone* (18.5 percent), *Vogue* (18 percent), *Mademoiselle* (19.7 percent), and *Glamour* (17.1 percent).<sup>216</sup> The agency's judgment is based on common public perception that these are the types of magazines that young people under the age of 18 will find of interest and read. Thus, based on public perceptions and inductively given the nature of the magazines involved, FDA finds a 15 percent cut-off to be appropriate.

The 2 million number is justified based upon the agency's concern for young people. The agency finds that at some point, the number of underage readers is so great that the magazine can no longer be considered to not be of interest to children and adolescents under 18 years of age. This threshold would require text-only advertising in a publication like *People*, where the percentage of readers who are minors is only 7.8 percent, but where the number of readers under 18 years of age is 3,020,000. Publications like *Time*, *Newsweek*, *Family Circle*, and *Popular Mechanics*, however, would not be subject to the text-only format under either threshold; based on how these publications are affected, FDA concludes that, on balance, the thresholds are reasonable.<sup>217</sup> The agency's concern is not with the "intended" audience of the publication because there is no magic curtain between the interests of young adults and adolescents. The agency's concern is to protect children from the appeal of advertising that they cannot avoid. Fifteen percent youth readership or 2 million young readers narrowly addresses this concern.

The agency does not agree with comments that the rule should be made more restrictive by, for example, allowing only text-only advertising in adult publications and no advertising at all in other publications. The text-only format will reduce the appeal of tobacco advertising to young people while allowing communication of important information to adults. The agency will continue to monitor the effect on young people of text-only advertising as well as the exception created for adult publications and will consider taking any additional action that is appropriate.

<sup>215</sup> See section XV. of this document, Analysis of Impacts, for a discussion of publications that would be affected.

<sup>216</sup> Barents Group, LLC, citing Publishers Information Bureau and Mediamark Research, Inc., pp. 53-54.

<sup>217</sup> *Id.*

Finally, the agency finds no basis to the comments' concern that the regulations will reduce the reading level of adults to those of children. The agency has crafted the exception for adult publications specifically to minimize the effect of the regulations on adults. Moreover, text-only, or the absence of color and imagery, will have significantly less impact on adults than on young people. As discussed more fully in the introduction to this section, adults generally have more capacity to engage in high involvement search than do young people. Furthermore, full information will be available to them in the text format. The First Amendment demands no more.

(58) Several comments recognized that FDA made the March 20, 1996, Federal Register document and the associated data in the record publicly available to meet its obligation under the APA to provide interested parties with an opportunity to comment meaningfully on the proposed rule. These comments stated, however, that one of the memoranda, dated March 11, 1996, placed on the public record by the Federal Register document makes clear that FDA had readership numbers in mind when it developed the proposal, but that the agency had failed to disclose those numbers to the public. The comments said that these numbers are neither reflected in the memorandum added to the record in the March 20, 1996, Federal Register document nor the administrative record that FDA has made publicly available. The comments said that the memorandum in question refers to readership numbers that were in comments submitted by the tobacco industry, and thus these numbers could not have been the numbers that FDA considered in developing its proposal. The comments said that FDA's failure to disclose this information rendered the proceeding arbitrary and capricious.

These comments are in error. FDA placed the information that it relied upon in developing the tentative 15-percent threshold on public display at approximately the time that it published the proposed rule. The data appear at pages 95T030074-75 of the administrative record (vol. 105, number 1550). (The numbers are similar but not identical to those supplied by the industry.) As one comment pointed out, in *Connecticut Light and Power Co. v. Nuclear Reg. Com'n.*, 673 F.2d 525, 530 (D.C. Cir.), cert. denied 459 U.S. 835 (1982), the United States Court of Appeals for the District of Columbia Circuit stated, "In order to allow for

useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules." The agency fully complied with this expectation by including the data that it had reviewed in the material that it made publicly available. Thus, the agency finds the claims in the comments summarized here to be without any basis in fact.

(59) Several comments asserted that the memorandum added to the record in the March 20, 1996, Federal Register document did not provide a reasoned explanation for the threshold that FDA had proposed. Several comments argued that there is no principle in, or discernible from, the memorandum that leads to the choice of 15 percent, as opposed to 49 percent, as the ceiling for the percentage of underage readers a publication could have and still be considered primarily adult. One comment said that FDA's reasoning was circular. Other comments said that FDA had pointed to no facts in the March 20, 1996, Federal Register document or the attendant memorandum that supports its judgment. These comments stated that FDA merely applied an arbitrarily chosen 15 percent figure to readership data and concluded that it had hit the right number. Some comments questioned why a publication with 84 percent adult readership was problematic, while a publication with 86 percent adult readership was not. Of all the comments that criticized FDA's proposed threshold, only one provided any alternative. This comment cited the tobacco industry's voluntary Cigarette Advertising and Promotion Code, Advertising 1(a), which prohibits advertising in publications directed primarily to those under 21 years of age.

In contrast to the foregoing comments, which were from the tobacco and advertising industries, a comment from a coalition of groups concerned about smoking and health stated that the agency's tentative judgment was unbiased, reasonable, and narrowly tailored to meet FDA's stated goal of limiting the specific forms of advertising that have the greatest impact on children to those publications that do not have a regular heavy readership of children.

FDA has carefully reviewed these comments. Based on this review, FDA first considered whether its March 20, 1996, Federal Register document and the memorandum added to the record under that notice had adequately

explained the basis for the proposed threshold.

The legislative history of the APA states that agency notice must be sufficient to fairly apprise interested parties of the issues involved, so that they may present responsive data or arguments thereto (S. Doc. 248, 79th Cong., 2d sess. 200 (1946)). The notice must disclose in detail the thinking that has animated the form of the proposed rule and the data on which that rule is based. (See *Home Box Office, Inc. v. FCC*, 567 F.2d 9 (D.C. Cir. 1977).) In *Connecticut Light & Power v. Nuclear Reg. Com'n.*, 673 F.2d at 530, the court held that a notice of proposed rulemaking should provide an accurate picture of the agency's reasoning, so that interested persons may comment meaningfully on the proposed rule.

The March 20, 1996, Federal Register document and the associated data in the record clearly meet this standard. As stated in this section, FDA made clear that its tentative judgment was based on a review of available data (from Simons Market Research) on the readership profiles of various publications. By dividing the publications based on whether, in the FDA employees' experience, the publications were publicly perceived as being of interest to minors or not and then examining readership information on each publication, FDA employees found that the publications that were viewed as being of interest to young people had readerships that included individuals under the age of 18 at a level of 15 percent or higher. FDA also found that the information on additional publications that it received during the comment period produced results that were consistent with the pattern that emerged from its initial review.<sup>218</sup>

Thus, FDA's reasoning is not circular. FDA based the threshold on its tentative finding, from the work that its employees had done, that the publications viewed as of interest to young people had readerships that were more than 15 percent under 18. Significantly, while the comments of the tobacco and advertising industry disagreed with the basis for the proposed threshold in various ways, none presented any data showing that publications with a youth readership of 15 percent or more are not viewed by consumers as of interest to young people.

It is important to keep in mind that the purpose of the threshold is to ensure

<sup>218</sup> See memorandum of March 11, 1996, added to the administrative record in the March 20, 1996, Federal Register.



that no more speech than necessary is burdened by FDA's restriction on advertising. Given that FDA wants to ensure that its restriction is as narrowly tailored as possible, in response to the criticisms in the comments, FDA considered whether there was a more appropriate basis on which to craft the restriction. Unfortunately, the comments criticizing the proposal were not helpful. The only suggested alternative to the proposed threshold that they put forward was the provision in the Code. This provision is inadequate on its face, however, because it is based on a minimum age of 21, rather than 18, which is the minimum provided in the laws of all the States and section 1926 of the PHS Act. Moreover, the comment that suggested this alternative gave no indication of how the age group to which a publication is primarily directed would be determined.

As a matter of common sense, FDA focused on the percentage of readers under the age of 18 in the general population and on comparing that percentage to the percentage of readers under 18 years of age for a particular publication. Certain conclusions can logically be drawn on the basis of such a comparison. If the percentage of young readers of a publication is greater than the percentage of young people in the general population, the publication can be viewed as having particular appeal to young readers. A publication with a youth readership percentage that is approximately equal to the percentage of young people in the general population can be viewed as one of general appeal, including appeal to young readers. A publication with a lower percentage of young readers than in the general population, however, would obviously be one of limited appeal to young people, and thus one that could appropriately be considered of interest primarily to adults.

Given the logic of this approach, FDA turned to the U.S. census. What the agency found is that young people between the ages of 5 and 17 constitute approximately 15 percent of the U.S. population.<sup>219</sup> Since this percentage is the same as the one that FDA used in developing the proposal, this approach fully supports the approach that FDA proposed. (Although 5 and 6 year olds may not be reading magazines, utilizing this age group builds in a margin for error.) It ratifies the judgments that FDA

employees made in arriving at the proposed threshold.

Some may assert that it is mere coincidence that the two approaches produce the same result. FDA disagrees. The congruence of the two approaches, the FDA employee anecdotal search and the use of the census data, is attributable to the basic validity of the premise underlying FDA's initial approach. Magazines have reputations as to the audiences to which they appeal, and those reputations are generally earned based on the nature of their contents. Thus, contrary to the assertions in some of the comments, the 15 percent threshold is well-supported and appropriate.

As for the question as to why a publication with 84 percent adult readership would be problematic, while a publication with 86 percent adult readership would not, the agency turns to the case law on narrow tailoring, which is, as stated in section VI.E. of this document, what this exercise is about. In *Board of Trustees of State University of N.Y. v. Fox*, the Supreme Court stated:

In sum, while we have insisted that "the free flow of commercial information is valuable enough to justify would-be regulators the costs of distinguishing \* \* \* the harmless from the harmful," \* \* \* we have not gone so far as to impose upon them the burden of demonstrating that the distinguishment is 100% complete, or that the manner of restriction is absolutely the least severe that will achieve the desired end. What our decisions require is a "fit between the legislature's ends and the means to accomplish those ends," \* \* \* —a fit that is not necessarily perfect but reasonable \* \* \*. (492 U.S. at 480 (citations omitted))

FDA has done its best to distinguish publications that are likely to be read by children and adolescents from those that are not. FDA finds that, if its restriction on advertising is to be meaningful, it must be based on a line that is enforceable. While only 2 percentage points separate a publication with 84 percent adult readership from one with 86 percent (although those 2 percentage points can mean a difference of tens of thousands of youngsters), the underrepresentation of underage readers in the readership of the latter publication establishes its limited appeal to young readers, and thus that it is less likely to be read by them.

For the foregoing reasons, FDA is adopting the 15-percent threshold.

(60) Comments from an association of magazine publishers and others expressed a number of concerns about the adequacy of current data for determining whether a publication met

the definition of an adult publication. Some comments said that current data and methodology to determine youth readership, while adequate for marketing purposes, are totally inadequate to justify their use as measuring devices for the imposition of criminal or civil liability on the exercise of First Amendment rights. These comments noted that the vast majority of magazines do not subscribe to either adult or youth surveys. Two comments stated that only about 2 percent of all magazines participate in the two major adult audience surveys. One comment stated that participation in the youth readership surveys, Simmons's STARS and MediaMark Research Inc.'s (MRI's) TEENMARK, is even more limited, just over one-half of one percent of all magazines.

One comment noted that to comply with the 1995 proposed rule, publications must identify readers of all ages but that current audience measurement systems do not provide this comprehensive coverage especially for readers younger than 12 years of age. Another comment noted that since the survey organizations do not survey individuals on college campuses, in the armed services, or in institutional settings, adult readership would be underestimated. Several comments noted the difficulty in determining readership data for any one issue of a magazine. Another comment noted that multi-issue advertisements would be a problem for publications right around the threshold if the publication crosses back and forth.

Several comments noted that the survey organizations would have to make substantial methodological changes to the surveys to meet the 1995 proposed rule's standard. One comment said that some problems would include adding magazines to the surveys, and dealing with unreliable results. Another comment asked who would decide the research design for the surveys since different research methodologies could be competent and reliable yet result in different conclusions. Another comment said that it could be prohibitively expensive to increase audience samples to create a legally enforceable standard, and that changes to audience measurement procedures could undermine the usefulness of the surveys for their designed marketing information purpose.

One supporting comment from an association of addiction specialists stated that "the agency should require the industry to monitor with surveys of ad recall (correlated with tobacco use

<sup>219</sup> U.S. Bureau of the Census, Population Paper Listing 21, 1994.

and intention to use patterns) among the population under age 18 years to help the agency understand the extent to which image-based messages continue to reach the young."

One comment pointed out that it would be virtually impossible to determine a legally enforceable standard for the 15 percent youth readership threshold since there is substantial variation in audience estimates between survey organizations and over time. Several comments noted that FDA's definition of a reader is not consistent with the definition used by Simmons and MRI.

Some comments suggested that a more realistic measure of who reads a publication would be who subscribes to it. Other comments opposed this alternative stating that the key criteria should be regular readership, not paid subscribers. One comment said that "[t]his alteration of the proposed exemption would destroy the intent and purpose of the advertising limitation."

Several comments said that the proposal would violate due process by punishing publishers or advertisers who are unable to determine whether their conduct violates the law because the survey data are not sufficiently comprehensive and reliable. Several comments, including one from an association of newspaper publishers, expressed concern about who would determine readership. One comment asked whether a newspaper would be subject to criminal liability based on readership data it supplies, and whether the responsibility for ascertaining whether a publication qualifies as an adult publication would be on those running the advertisements.

The agency recognizes the limitations of current readership data and the difficulties of using current readership surveys to meet the requirements of this rule. However, the agency concludes that the exception from the text-only format for adult publications is feasible as well as reasonable. First of all, the burden of proof for determining youth readership is placed by the rule on the tobacco company doing the advertising, not on the publication or the advertising agency. Under § 897.32(a)(2), the tobacco company will need to be able to demonstrate that a publication in which it is running an advertisement with images and colors meets the definition of an adult publication. Therefore, only the tobacco company will be subject to any penalties for improperly placing advertisements, even if it used data provided by the publication as part of its determination.

Second, either of the two methodologies can be used to measure readership. In addition, the agency has modified § 897.32(a)(1) and (a)(2) to make clear that any other competent and reliable private sector survey evidence may be used. A tobacco company may use one of the two major customary and reasonable readership surveys (such as MRI and Simmons). The agency does not believe that there is only one acceptable methodology. The agency is willing to accept the standard methodology currently used by MRI and Simmons as evidence. Moreover, the agency is willing to use the age range of 12 to 17, which appears to be the current standard for defining youth, in determining youth readership.

If a particular publication is not currently covered by one of the major surveys, it is the tobacco company's responsibility to develop the readership data necessary to justify a decision to advertise in that publication. The company could request a survey by one of the major survey firms, or it could develop an acceptable alternative. In either case, the agency will be available to work with the company. The company will always have the alternative to advertise in any publication in the text-only format.

The agency also acknowledges the difficulty in determining the youth readership for any particular issue of a publication. Thus, data from a survey for the most recent issues of a publication can serve as proof of readership for comparable upcoming issues unless a particular upcoming issue is being targeted at younger readers. The survey schedule used by the major survey organizations would be acceptable to the agency. A tobacco company could utilize a more frequent survey schedule if it believed the readership had changed in its favor. A rolling average of a certain number of issues could be used, for example, to determine youth readership. The problem of multi-issue contracts for advertising could be solved by a survey for a comparable period of time (e.g., winter months) preceding the contract.

The agency is willing to accept the definitions of a reader that are customarily used by the major survey organizations. The agency does not agree that using subscribers to a publication in lieu of readers is a better measure. Many children who read a publication will not be listed as subscribers (for example, *Sports Illustrated* has a youth readership of 18 to 20 percent but a youth subscriber rate

of only 6.5 or 7 percent).<sup>220</sup> Also, adults are more likely to subscribe for their families, thereby creating an underestimation of youth exposure.

(61) Several comments assumed that the purpose of the March 20, 1996, Federal Register document was to justify the restriction on advertising format that the agency had proposed for other than adult-oriented publications. These comments argued that explaining how the agency arrived at the 15 percent and 2 million readership thresholds does not approach the factual justification necessary to restrict First Amendment freedoms.

Other comments asserted that FDA's assumption that certain magazines were of interest to those under 18, as the starting point in arriving at the 15 percent threshold, shows that the limits were content based. These comments argued that basing restrictions on content violated the First Amendment.

The comments misunderstood FDA's purpose in proposing, and in adopting, the 15 percent and 2 million under 18 readership thresholds and of the memoranda added to the public record in the March 20, 1996, Federal Register document that indicated how the agency tentatively arrived at those thresholds. As discussed in section VI.D. of this document, the evidence in this proceeding establishes the effect of cigarette and smokeless tobacco advertising on those under 18 years of age. This evidence fully justifies FDA's decision to restrict the advertising for these products.

However, in imposing such a restriction on commercial speech, FDA has an obligation to ensure that the restriction is no more broad than necessary to serve the agency's substantial interests (*Board of Trustees of State University of N.Y. v. Fox*, 492 U.S. at 476). The purpose of the memorandum was to document FDA's efforts to tailor the restriction to ensure that it did not restrict advertising in those publications that were not likely to be read by children or adolescents and thus were not likely to have an effect on the group that FDA is trying to protect. Consequently, contrary to the claims of the first group of comments, the agency's goal in the memorandum was not to justify a restriction on First Amendment freedoms but to explain how it sought to ensure, and why its tentative decision was that, the limits it proposed to place on the coverage of the

<sup>220</sup> Interview on "The News Hour With Jim Lehrer," Public Broadcasting Systems, May 16, 1996.

restriction are reasonable (see *Id.* at 480).

On the other hand, other comments that opposed FDA's proposed restriction on format said that the threshold would have different impacts on similar publications. One comment provided the following examples of publications that would be considered "youth oriented" or primarily adult under the 15 percent threshold (the comment argued that the effects of the 2 million readership threshold were not relevant to the rationality of the 15 percent threshold):

Table 1b.—Examples of Publications

Youth Oriented Publications	Primarily Adult Oriented Publications
Popular Science .....	Popular Mechanics
Soap Opera Weekly .....	Soap Opera Digest
Outdoor Life .....	Field and Stream
Cable Guide .....	TV Guide
Mademoiselle .....	Cosmopolitan

The positions taken by these comments makes clear that the thresholds were not content based. If the thresholds were content based, then publications that have similar content would be subject to the same restriction. They are not. The reason they are not is that FDA's goal in arriving at the thresholds was to ensure that cigarette and smokeless tobacco advertisements that are likely to be seen by children and adolescents are the kinds of advertisements that are likely to appeal to them. The agency's only way of judging the likelihood that an advertisement that appears in a publication will be seen by those under the age of 18 is by considering the readership profile of that publication. Thus, the agency has tailored the threshold to either reflect the percentage of readership that are under 18 years of age or to ensure that publications with an extensive youth readership are covered.

The comments that complained about the differing impact of FDA's threshold on similar publications, given the purpose of the threshold, serve to underline its significance. The information submitted by the comments shows that there are significant differences in the readership of similar publications and thus in the likelihood that the material contained in these publications will be seen by young people. The treatment of publications under the agency's restriction reflects the latter fact, not the former.

*Popular Science* magazine has a readership that is 6 percent more

youthful than *Popular Mechanics*; *Soap Opera Weekly* has a 3 percent more youthful readership than *Soap Opera Digest*; and there is a 9 percent bigger youth audience for *Outdoor Life* than for *Field and Stream*. These differences are not minor or meaningless and demonstrate that, although the 15 percent threshold is not perfect, it will serve, as it was designed to, protect those under 18. *TV Guide* and *Cosmopolitan* are not excluded although, as mass distribution magazines the percentage of young readers is less than 15 percent, because they attract over 2 million young readers—a number of young people too large to ignore.<sup>221</sup>

(62) Many comments, especially from the magazine and newspaper industries, expressed concerns about the impact of this proposal on their way of doing business. One comment stated that the proposed text-only format would provide financial disincentives for magazines and newspapers to attract young readers, especially if the publication were near the borderline of being required to use the text-only format. This comment suggested that the provision would affect editorial and content decisions regarding young readers.

Some comments noted that newspapers have been struggling to attract young readers raised on television, but that success in doing this might cause the loss of significant tobacco advertising revenue. One newspaper industry association comment stated that the rule would discourage newspaper programs promoting youth reading and literacy. Some comments stated that the loss of advertising revenue could cause publications to decrease content and increase prices. Some comments thought the result of these effects of the rule would be losses in jobs in the newspaper and magazine industries.

The agency is not sure what impact the exception for adult publications will have on incentives for magazines and newspapers to attract young readers, on editorial content, and on youth literacy programs. The comments that raised these issues mostly speculated about these effects and did not provide any data as to how many of the thousands of newspapers and magazines in the United States carry tobacco advertising, or on what portion of their total advertising revenue comes from tobacco companies. Many business factors affect

a publication's decisions regarding its target audience and editorial content, and these are likely to change for a variety of reasons. Those publications affected by this regulation will have to adjust just as they would if a major advertiser reduced its advertising. Under the rule, all publications could still accept text-only advertising. The cigarette and smokeless tobacco industries are capable of designing their advertising to be attractive to adult readers (see section VI.E.4. of this document). Thus, it seems as likely that the effects of the rule in these areas will be minimal and will be far outweighed by the overall benefits of reducing youth smoking. The effect of the rule on prices and jobs in the magazine and newspaper industries is addressed in the section on the economic impact of the rule.

(63) Several comments argued that FDA's restrictions on the format of advertising, and the standard that it proposed for deciding whether a publication has a predominantly adult readership, interfere with the rights of newspapers and magazines to decide what to print. One comment said that some publications will not want to give up revenue from tobacco advertising. Therefore, the comment continued, these publications will base decisions about editorial content on how appealing a particular story would be to readers under the age of 18. Because of the impact of the restrictions on editorial content, the comment concluded, they should be subject to strict scrutiny rather than the more limited scrutiny given to commercial speech.

FDA finds no merit to this argument. A similar argument was made in *Pittsburgh Press Co. v. Pittsburgh Com'n on Human Relations*, 413 U.S. 376 (1973). The newspaper company in that case, which involved a First Amendment challenge to a municipal ordinance that prohibited a newspaper from carrying gender-designated advertising for nonexempt job opportunities, argued that the focus of the case must be on the exercise of editorial judgment by the newspaper rather than on the commercial nature of the ads in question.

The Supreme Court rejected this argument. The Court said that under some circumstances, at least, a newspaper's editorial judgments in connection with an advertisement take on the character of the advertisement. In those cases, "[t]he scope of the newspaper's First Amendment protection may be affected by the content of the advertisement"

<sup>221</sup> Barents Group, LLC, citing Publishing Information Bureau and Mediamark Research, Inc., pp. 53–54.

(*Pittsburgh Press Co.*, 413 U.S. at 386). The Court said that, at least under some circumstances, a commercial advertisement remains commercial in the hands of the media (*Id.* at 387). The Court found that nothing about the decision to accept a commercial advertisement for placement in a gender-designated column lifts the newspaper's actions from the category of commercial speech. The Court said that the ad was in practical effect a commercial statement (*Id.* at 387–88; see also *United States v. Hunter*, 459 F.2d 205, 212 (4th Cir. 1972) (“But it has been held that a newspaper will not be insulated from the otherwise valid regulation of economic activity merely because it also engages in constitutionally protected dissemination of ideas”)).

Here, the question that is raised is whether or not a publication will decide to put itself in a position of being able to accept an advertisement that is particularly appealing to individuals under 18 years of age or not. Nothing about this judgment distinguishes it from the commercial speech itself. Because nothing about FDA's restrictions would prevent the publication from carrying a cigarette or smokeless tobacco advertisement no matter what judgment the publication makes, essentially the editorial judgment comes down to the question of what will be the format of the advertisement that it will carry. This judgment clearly comes within the category of commercial speech, and FDA has fully justified its regulation of commercial speech under the *Central Hudson* test.

#### 6. Advertising—§ 897.32 Requirements for Disclosure of Important Information

a. *Established name and intended use*—§ 897.32(c). Proposed § 897.32(b) (now renumbered as § 897.32(c)) provided that each manufacturer, distributor, and retailer (of tobacco and smokeless tobacco) advertising or causing to be advertised, disseminating or causing to be disseminated, advertising, but not labeling, permitted under § 897.30(a), shall include, as provided in section 502(r) of the act, the product's established name and a statement of its intended use as follows: “Tobacco—A Nicotine Delivery Device,” “Cigarette Tobacco—A Nicotine-Delivery Device,” or “Loose Leaf Chewing Tobacco,” “Plug Chewing Tobacco,” “Twist Chewing Tobacco,” “Moist Snuff” or “Dry Snuff,” whichever is appropriate for the

product, followed by the words “A Nicotine-Delivery Device.”

The preamble to the 1995 proposed rule explained that section 502(r)(1) of the act requires, for any restricted device, that all advertising or other descriptive printed material contain a true statement of the device's established name. Under section 502(r)(2) of the act, a restricted device is misbranded unless all advertising contains “a brief statement of the intended uses of the device.” The agency explained in the preamble to the 1995 proposed rule that it is necessary to require that the product's established name and intended uses be placed on all advertising, under section 520(e) of the act, as a measure that affirmatively identifies the products to persons reading the advertising (the other brief statement requirements under section 502(r)(2) of the act are discussed in section IV.E.6.b. of this document).

The agency did not receive any comments on the “established name” provision and has thus codified the provision in the final rule as § 897.32(c). The agency has modified the “intended use” provision in this final rule to require that cigarette and smokeless tobacco advertising contain the statement “A Nicotine-Delivery Device for Persons 18 or Older.” For clarity, the agency has referenced subpart D generally rather than § 897.30(a) specifically. As stated in the 1995 proposed rule, the established name requirement applies to both tobacco and smokeless tobacco.

(64) Several comments opposed the proposed “intended use” provision. One tobacco industry comment stated that FDA's proposal is not authorized under section 502(r) of the act because: (1) The “intended use” of tobacco products is for smoking taste and pleasure, not a “nicotine delivery device;” (2) the “intended use” provision of the act does not require that manufacturers list all information related to all purposes for which a drug is intended; and (3) FDA is not free to prescribe an “intended use” of its own invention. The comment also argued that FDA's statement, which communicates only that a cigarette yields nicotine, is not a statement of “intended use” and is of no value to consumers who obtain more complete nicotine information that cigarette manufacturers already provide in advertising.

The agency disagrees with the comments stating that it is not free to prescribe an intended use. As discussed in this section, the agency is required by

section 502(r)(2) of the act to require a brief statement of intended use for all restricted devices.

Additionally, it is within FDA's primary jurisdiction and expertise to determine a device's intended use. FDA has decades of experience evaluating the intended uses of FDA-regulated products, including restricted devices, prescription and over-the-counter drugs, biological products, and dietary supplements through its review and approval process for those products.

As described in the 1996 Jurisdictional Determination annexed hereto, the available evidence demonstrates that manufacturers intend to affect the structure and function of the body by delivering pharmacologically active doses of nicotine to the consumer. Although the agency proposed that the intended use include the language “Nicotine Delivery Device,” the agency has determined, based on the comments received, that a more accurate statement of the intended use would provide more value to consumers. Because cigarettes and smokeless tobacco products can legally be sold only to those persons 18 years of age and older, the agency believes the intended use statement should reflect the target population for which the product is intended. Often, the intended use statement for a drug or device includes the patient population by whom the product may be used. Accordingly, the intended use statement has been revised to require the following language on all advertisements for cigarette and smokeless tobacco: “A Nicotine-Delivery Device For Persons 18 or Older.”

b. *Section 897.32(d) Brief statement.* Proposed § 897.32(c) and (d) would have required that each manufacturer, distributor, and retailer of cigarettes include in all advertising, but not labeling, a brief statement, printed in black text on a white background that was readable, clear, conspicuous, prominent, and contiguous to the Surgeon General's warning. Because the Smokeless Act preempts other statements about tobacco use and health in advertising, the 1995 proposed rule stated that the provision only applied to cigarettes (and not smokeless tobacco). The 1995 proposed rule provided one brief statement as an example (“ABOUT 1 OUT OF 3 KIDS WHO BECOME SMOKERS WILL DIE FROM THEIR SMOKING”) (60 FR 41314 at 41338). The agency requested comment on what other information should be included in the brief statements concerning relevant

warnings, precautions, side effects, and contraindications and on how best to ensure that the statement will be clear, conspicuous, and prominently displayed. The agency also requested comment on whether it should require a listing of the component parts or ingredients of these restricted devices.

The preamble to the 1995 proposed rule explained that the agency was proposing to require this brief statement under section 502(r)(2) of the act. The preamble stated that the act specifically excludes labeling from the requirements in section 502(r) of the act. The 1995 proposed rule stated that the agency would specify the design, content, and format of the brief statements, in part based on focus groups with young people, to ensure that the information would be communicated effectively to young people.

The agency received numerous comments on this brief statement, and about half of the comments supported the provision and half opposed it. Most of the comments that supported the brief statement requirement recommended other information to be included in the brief statement, and offered suggestions on how best to ensure that the statement will be clear, conspicuous, and prominently displayed.

During the comment period, FDA performed extensive focus group testing on the brief statement to evaluate the content and various formats for the brief statement to determine if the information would be communicated effectively to young people. Those results were placed on the public record and made available for comment, 1 month prior to the close of the comment period. FDA received a few comments on the focus group results from the tobacco industry and concerned individuals.

The final rule does not specify a particular statement to be placed in all cigarette advertisements, as proposed in § 897.32(c), nor does it require the brief statement to be targeted to young people. Rather, the agency has concluded that the current Surgeon General's warnings contain important health information, concerning the risks related to the use of cigarettes, of the sort required under section 502(r) of the act and, consequently, has decided not to require a specific, different statement. Specifically, the Surgeon General's warnings currently required to be included in cigarette advertisements and on cigarette packages contain the following information: Cigarettes cause lung cancer, heart disease and

emphysema, may complicate pregnancies, and contain carbon monoxide; smoking by pregnant women may result in fetal injury, premature birth and low birth weight; and quitting reduces serious risks.

The agency has also considered the fact that there is a heightened public awareness by adults of the addictiveness of cigarettes, as well as the serious health effects that can result from their use. Much of this awareness stems from: (1) The publicity of the numerous Surgeon General's reports that have issued in the last few decades, (2) the campaigns supported by health groups and State and local governments, as well as (3) the attention generated by the agency's investigation of these products.

Under the current circumstances, the agency has determined that the current Surgeon General's warnings, which must be in virtually all advertisements, contain the type of important health information required under section 502(r) of the act. Accordingly, the agency has determined that advertisements that contain the current Surgeon General's warnings meet section 502(r) of the act.

Finally, because the agency has determined that the Surgeon General's warnings are adequate, and those warnings must be displayed in a format prescribed by law, there is no longer any need for proposed § 897.32(d), which required that the brief statement be readable, clear, conspicuous, prominent, and contiguous to the Surgeon General's warning.

(65) One comment argued that the proposed warning requirement for tobacco is not a warning, nor is it part of a brief statement, as those terms are used in section 502(r) of the act. The comment stated that because FDA proposes to allow tobacco to be marketed as devices subject only to general controls, one of which is the brief statement provision, then the "brief statement" must be capable of providing, with other general controls, "reasonable assurance of the safety and effectiveness" of tobacco under the act. The comment argued that because FDA regards tobacco as having "dangerous health consequences" (60 FR 41314 at 41349), and does not believe that tobacco can be "safe and effective" for anyone, then FDA's proposed "brief statement" provision is not within the scope of the act. The comment stated that the only warning that is consistent with FDA's view would be one that warned against anyone using the device at all.

The comment miscomprehends the purpose of the brief statement, which is to provide information about the risks and benefits regarding the product. This provision is not intended to serve, on its own, as a mechanism to provide reasonable assurance of safety for these products.

(66) One comment argued that even if FDA could validly require a brief statement for tobacco as an exercise of its statutory authority, the imposition of a warning requirement as part of the brief statement is invalid because advertisements for tobacco are already required to bear the Surgeon General's warning under 15 U.S.C. 1333(a)(2) and (a)(3). In addition, the comment stated that FDA is not authorized to require that the information be presented "in a lurid fashion to achieve an ulterior purpose" or as "a threat intended to scare people," and that the warning information is meant only for the purposes of enabling the physician or patient to make a rational risk/benefit judgment.

Another comment argued that the contention that the Surgeon General's warning is "ineffective" is without merit. The agency agrees that the current Surgeon General's warnings contain the type of important health information that advertisements must contain under section 502(r)(2) of the act. Accordingly, the agency has determined that advertisements that contain the current Surgeon General's warnings sufficiently meet the brief statement requirement of the act.

(67) One comment stated that the brief statement provision would "cause so much visual clutter in tobacco advertising as to render effective communication nearly impossible."

Another comment stated that FDA will be unable to justify the economic burdens on communication with adults that are created by the brief statement requirement because, in order to include all the mandated statements, advertisers would be required to purchase additional space and thus would have to reduce, because of budgetary pressures, the number of advertisements they could place.

Because the agency has determined that the current Surgeon General's warnings will be sufficient as a brief statement, the issue raised by these comments is no longer pertinent.

(68) Several comments which supported the 1995 proposed rule suggested alternative statements and submitted recommended language for the brief statement. Many comments suggested specific types of information

for inclusion in the brief statement. Several comments provided recommendations on how the statement could be "clear and conspicuous." One comment stated that messages must be carefully pretested on members of the target audience to ensure that labels: (1) Attract attention; (2) are personally relevant; and (3) do not elicit psychological reactance, i.e., behaviors directly counter to those desired due to irritation, rebellion, or misinterpretation. The comment recommended that messages be varied periodically to ensure that they remain attention-getting and pertinent.

Several comments recommended that the rule be more specific in what is meant by "readable, clear, conspicuous, prominent" by giving either a detailed set of format specifications of the lettering and background or by giving a set of performance criteria. One comment enclosed an unpublished review on warnings, which recommended that warnings should attract attention of the target audience by using high contrast and color; separating warnings from other information; considering size (relative to other information in the display) and location (since people tend to scan left to right and top to bottom warnings should be located near the top or to the left, depending on the overall design of the display); and by using signal words to capture attention, such as "CAUTION," OR "WARNING," pictorials, rotational warnings to avoid habituation, and auditory warnings. In addition, the review stated that warnings should describe the hazard, without "overwarning," and describe the nature of the injury, illness or property damage that could result from the hazard. The review recommended that written warnings should be organized with an attention getting icon and signal word at the top, then hazard information, then instructions. Finally, the review recommended that warnings should instruct about appropriate and inappropriate behaviors, motivate people to comply, be as brief as possible, and should last and be available as long as needed.

One comment recommended that the relevant warnings, precautions, side effects, and contraindications be in a language understandable and appealing to even the youngest potential tobacco user. Several comments recommended that a minimum size should be required, expressed as a percentage of the advertisement (e.g., 25 percent of the advertisement). Several comments recommended that a border be placed

around the brief statement and suggested other graphic enhancements to make the information in the brief statement more noticeable.

The agency recognizes that there are several ways to communicate the requirement for "relevant warnings, precautions, side effects, and contraindications" set forth in section 502(r) of the act. In this case, however, the agency has determined that the current Surgeon General's warnings are sufficient as at least one way of complying with section 502(r) of the act. In addition, the agency appreciates the numerous suggestions on how to make the brief statement readable, clear, conspicuous, and prominent. However, since no additional information will be required at this time, and the format for the Surgeon General's warnings is determined by law, the agency has deleted proposed § 897.32(d).

(69) One comment stated that FDA's attempt to gather information through the focus group studies about adolescents' perceptions of the adequacy of the Surgeon General's warnings for use in designing its own additional warning underscores the direct conflict between the Cigarette Act and the proposed regulation.

This comment has misinterpreted the purpose and the results of the focus group testing. FDA's focus groups were intended to explore how adolescents perceive various messages. The Surgeon General's warnings, as well as other warnings, were tested with the focus groups merely to serve as a basis for reactions to messages that currently exist in the public domain.

(70) FDA received few comments concerning the focus group results. In general, these comments questioned the validity and usefulness of focus groups. Further, some comments asserted that the warnings preferred by the young people in the focus groups may have unintended consequences.

As discussed in this section, the focus groups tested a variety of specific brief statements that were intended to be directed towards young people. However, the agency has decided that the final rule will not specify a particular brief statement, but will accept the current Surgeon General's warnings as sufficient. Moreover, section 502(r) of the act does not require that the brief statement be directed to young people, but rather that it provide "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications." This function is adequately filled by the intended use

statements required by § 897.32(c) and the Surgeon General's warnings. Thus, because the final rule is not based on the focus group results, the agency need not address the previous comments concerning the focus group results.

#### 7. Section 897.34(a) and (b)—Promotions, Nontobacco Items, and Contests and Games of Chance

The agency proposed in § 897.34(a) to prohibit the sale or distribution of all nontobacco items that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristic. FDA stated in the 1995 proposal that this requirement is intended to reach such items as tee shirts, caps, and sporting goods and other items bearing tobacco brand names or other indicia of product identification (60 FR 41314 at 41336).

As discussed in the preamble to the 1995 proposed rule (60 FR 41314 at 41336), a Gallup survey found that about one-half of adolescent smokers, and one-quarter of all nonsmokers, own at least one promotional item. The IOM found that this form of advertising is particularly effective with young people. Young people have relatively little disposable income, so promotions are appealing because they represent a means of "getting something for nothing." In many cases, the items—tee shirts, caps, and sporting goods—are particularly attractive to young people. Some items, when used or worn by young people, also create a new advertising medium—the "walking billboard"—which can come into schools or other locations where advertising is usually prohibited (60 FR 41314 at 41336). Moreover, this form of advertising has grown in importance over the last 20 years. The portion of annual expenditures of the cigarette industry devoted to these promotions rose from 2.1 percent in 1975 to 8.5 percent in 1980.<sup>222</sup>

On the basis of the evidence before it, the agency tentatively concluded that the ban on nontobacco items was necessary to eliminate the something-for-nothing appeal of these items, as well as to prevent wearers or users of these items from becoming image-laden walking advertisements.

FDA proposed in § 897.34(b) to prohibit all proof of purchase transactions of nontobacco items as well as all lotteries, contests, and games of chance associated with a tobacco purchase. The agency stated that, because contests and lotteries are

<sup>222</sup> IOM Report, p. 109.

usually conducted through the mail, it was not able to devise regulations that would reduce a young person's access to contests or lotteries.

(71) FDA received a substantial number of comments concerning the 1995 proposed rule to prohibit these promotional activities. Comments opposing these provisions argued that tobacco companies should be allowed to advertise in a fair manner however they wish. Many comments from individuals stated that they like the "freebies." They contended that the agency does not have authority to regulate the clothes people wear or to ban contests and promotional activities that are only available to adults. A number of comments from individuals stated that what they did with their lives was their business.

Comments also objected to the agency's proposed ban on contests and games of chance. These comments stated that existing laws and regulations already provide a sufficient regulatory framework.

The majority of comments, however, supported these provisions and stated that children and adolescents should not be "walking billboards." Moreover, these comments argued that even though young people cannot participate in the contests, they can easily get caught up in the excitement of promotional activities. Comments declared that prohibiting tobacco product-related gifts, items, contests, and games of chance will break the enticing connection between sports and tobacco use.

The agency agrees with the comments that said that existing laws and regulations of lotteries, contests, and games of chance are sufficient. First, there appears to be little evidence about these practices and young people's participation in them. Secondly, current laws prohibit all games of chance and the like that are advertised on a product label or that are conditioned on the sale of the product. Therefore, participation, if any, by minors is not necessarily related to a purchase. Third, any promotional material associated with the advertising of the games, which is of primary concern, will be required to appear in text-only format. Therefore, the agency has modified this section to delete the ban on these practices. In addition, the agency has modified § 897.34(a) to clarify that responsibility for complying with this provision rests with the manufacturer and the distributor of imported tobacco, but not other distributors or retailers.

(72) Comments differed on whether proposed § 897.34(a) is beyond FDA's

authority under the act. The comments addressed a number and variety of legal issues. One comment stated that FDA has no authority to ban the items and services covered by § 897.34(a). It stated that items and services (e.g., travel agencies) bearing indicia of tobacco product identification are not foods, drugs, cosmetics, or devices as defined in the act and, therefore, are outside the agency's jurisdiction.

Another comment stated that nontobacco items cannot be regulated as advertising in the way FDA proposes because: (a) The 1995 proposed rule extends to goods and services provided to product users in connection with cigarette purchases, most of which are not displayed or disseminated to the general public, and thus do not constitute advertising (see *Marcy v. Nissen Corp.*, 578 F. Supp. 485, 507 (N.D. Ind. 1982), *aff'd sub nom. Marcy v. Marcy Gymnasium Equip. Co.*, 725 F.2d 687 (7th Cir. 1983)); and (b) many of the types of items covered by § 897.34(a) are promotional items but not advertising (e.g., a logo-bearing mug given away or sold by a manufacturer is not an advertisement).

One comment, which favored the provision, provided support for the classification of promotional items as advertising. The comment referenced *Public Citizen v. FTC*, 869 F.2d 1541 at 1556 (D.C. Cir. 1989), in which the U.S. Court of Appeals for the D.C. Circuit held that the Smokeless Act requirement that "advertisements" carry health warnings "plainly covers utilitarian items [nontobacco items] that are distributed for promotional purposes." FTC defined utilitarian objects as items that are sold or given or caused to be sold or given by any manufacturer, packager, or importer to consumers for their personal use and that display the brand name, logo, or selling message of any tobacco product (16 CFR 307.3n). FDA's interpretation of what is covered by § 897.34(a) and (b) is consistent with this definition. The comment also stated that as a result of that court case, FTC's smokeless tobacco rules now require that utilitarian items promoting smokeless tobacco bear specific health warnings required of all smokeless tobacco advertising (16 CFR 307.9).<sup>223</sup>

<sup>223</sup> The FTC comment also indicated that although nontobacco items are "advertising" under the Smokeless Act, a different legislative history exempts these items from the Cigarette Act. The comment stated that the definition of advertising under the Cigarette Act is understood to exempt utilitarian items because of legislative history expressly stating Congress's intent to preserve the arrangement under consent agreements entered into

Another comment pointed out that the *Public Citizen* case provides ample legal precedent not only for the conclusion that promotional materials are advertising, but also that they have a direct impact on a minor's tobacco use. The court, relying on evidence compiled by the FTC, found that "in the case of adolescents, utilitarian items might be among the most effective forms of promotion" (869 F.2d at 1549 n. 15). In addition, the lower court provided an additional rationale for restriction based upon the items' longevity and durability.

[P]rinted advertising is customarily quickly read (if at all) and discarded (as, of course, are product packages) by typical consumers. "Utilitarian objects," on the other hand \* \* \* are retained, precisely because they continue to have utility. They are also likely to be made of durable substances: fabric, plastic, glass, or metal. They may be around for years. And each use of them brings a new reminder of the sponsor and his product \* \* \*

(688 F. Supp. 667, 680 (D.D.C. 1988), *aff'd*, 869 F.2d 1541 (D.C. Cir. 1989))

The agency finds that the reasoning in the *Public Citizen* case is persuasive and compels the conclusion that branded nontobacco items are advertising. It also finds that young people acquire and use these products.

Moreover, the agency finds nothing in the *Marcy v. Nissan Corp.* case is to the contrary. In relevant parts, that case involved an endorsement that appeared in the front of a users' manual. The court held that this endorsement did not constitute "advertising" because it is not "distributed to the general public for the purpose of promoting plaintiffs' products: it is a user's manual and is provided to a purchaser of the defendants' equipment together with the equipment in order to describe its proper use" (578 F.2d at 507). Promotional items are distributed or sold to the general public. They are festooned with the product's brand name or identification, and they are intended to remind the user and others who see the item about the product. As the court in *Public Citizen* found, "each use of them brings a new reminder of the sponsor and his product" (688 F. Supp. at 670). Therefore, the comments' suggestion that these advertising items are beyond FDA's jurisdiction is plainly wrong.

(73) One comment, which had argued that promotional items were not drugs or devices nor were they advertising, objected as well to FDA's alternative

by the tobacco industry in 1972 and 1981 (*Public Citizen*, 869 F.2d at 1555).



categorization of these items as labeling. The comment stated that nontobacco items could constitute "labeling" only if there were a "textual relationship" between them and the product (*Kordel v. United States*, 335 U.S. 345, 350 (1948)). The comment argued further that items that provide no more substantive information than a brand name, logo, or recognizable color or pattern of colors simply do not explain the use of the product, and therefore do not constitute labeling. The comment concluded that if the items are not advertising or labeling, FDA would not have authority to take the actions required by this provision.

The agency agrees that these promotional items are neither devices nor drugs; however, this fact is not relevant to the agency's authority to proscribe their use. As explained earlier in this document, FDA has authority to impose restrictions on the access to and promotion of devices under section 520(e) of the act, and this authority provides the basis for restrictions on advertising, including those that FDA is imposing on promotional items. FDA also derives authority for these restrictions from section 502 of the act. Likewise, it is not relevant in this instance whether the items are described as advertising or labeling. The agency has the authority to restrict them because they promote the use of restricted devices, cigarettes and smokeless tobacco, by young people and thus undercut the restrictions on access to these products that FDA has imposed. Therefore, FDA has authority to regulate how these promotional items are used by manufacturers, distributors, and retailers of the restricted devices.

(74) Many comments challenged FDA's evidentiary basis for this provision. Those opposing the provision made the point that promotional items do not cause young people to use tobacco, and that banning them will not reduce tobacco use. These comments fall into two categories: Those that rely on theoretical or policy arguments and those that provide or criticize studies or other evidence.

*a. Theoretical or policy considerations.* Several comments argued generally that it is well-documented that the significant factors associated with regular underage tobacco use are peer pressure and smoking by friends, older siblings and parents. They noted that FDA cited no evidence that the use of a tobacco trademark on a nontobacco product, such as a lighter or jacket, has any impact on underage tobacco

consumption, or that its removal will reduce youth tobacco use. Consequently, they argue, banning the use of tobacco brand names on nontobacco products will fail to achieve FDA's goal of curbing teen smoking.

One comment maintained that people, including those under age 18, do not wear these items in order to advertise anything or to be "walking billboards." Rather, according to this comment, they wear them to make a public statement, because they find the items aesthetically pleasing, or for other reasons. Moreover, the comment argued, FDA has no authority to regulate the attire of adults, school students, or anyone else.

In addition, the comment argued, the goal of these programs is to reinforce brand loyalty among existing customers. Their purpose is to expand market share among existing smokers, not to induce nonsmokers to start smoking. These programs are, by their very nature, aimed at people who already are smokers, that is, the merchandise is provided only to consumers who have accumulated and submitted significant numbers of proofs of purchase. No one would be persuaded to start smoking by a cents-off coupon or by the offer of a free cigarette lighter, but a smoker might be tempted by the offer. The comment argued that in the hard fought battles for market share among cigarette companies, discounts and premiums represent a way to promote and retain brand loyalty and to weaken loyalty to competitors' brands.

Some comments bolstered their arguments with a citation to the decision of the Supreme Court of Canada, which, they claimed, invalidated a similar ban. The Canadian court concluded that there was no direct or indirect evidence of any causal connection between the objective of decreasing tobacco consumption and the absolute prohibition on the use of a tobacco trademark on articles other than tobacco products. These comments argued that FDA should follow the Canadian judgment (see section VI.D.3.f. of this document for a complete discussion of this case).

On the other hand, one comment stated that U.S. and international experience provide substantial support for a ban. It stated that in the United States, nontobacco items were heavily used by RJR to market its Camel tobacco to young people.

In addition, one comment that supported FDA's action stated that young people participate to a marked extent in tobacco company promotions. It noted that these promotions all use

attractive imagery and prizes that are intrinsically interesting to adolescents. Other comments stated that these promotions are particularly effective with young people, who have less disposable income. The items are a way for young people to get something for nothing and provide added incentive for young people to purchase tobacco products. One comment that supported this provision stated that these items can become "walking billboards," that can come into schools and other places where tobacco advertising is generally prohibited.

Another comment stated that the ban serves as an important corollary to the advertising restrictions, specifically, it argued that the impact of removing tobacco product advertisements from minors' magazines would surely be reduced if minors themselves continued wearing the advertisements on their heads and bodies. The comment asserted that there is a correlation between participation in a promotion and susceptibility to tobacco use.

*b. Studies and evidence.* One comment referenced a new study<sup>224</sup> that found that participation in tobacco company promotions by 12 to 17 year olds is more predictive of susceptibility to use tobacco products than smoking by those close to the individual. The measure of "participation" was the possession of a catalog, the ownership of any promotional item, or the saving of coupons that could be redeemed for promotional items. The study found that catalog ownership was the most common form of participation in tobacco company promotions.

A comment that opposed this provision argued that FDA had cited no credible studies that demonstrate either that these items are especially appealing to young people, or that possessing these items causes young people to start smoking or to smoke more. It stated that although FDA relied on a study by Dr. John Slade<sup>225</sup> that reported that there is an association between participating in promotions and a person's susceptibility to tobacco use, FDA did not describe the study thoroughly. The comment stated that the notion of susceptibility is itself problematic. It stated that even if this study is taken at face value, it does not support FDA's conclusions. While the study reported that 83.5 percent of

<sup>224</sup> Evans, N., et al., "Influence of Tobacco Marketing and Exposure to Smokers on Adolescent Susceptibility to Smoking," *Journal of the National Cancer Institute*, vol. 87, pp. 1538-1545, 1995.

<sup>225</sup> Slade, J., et al., "Teenagers Participate in Tobacco Promotions," presented at the 9th World Conference on Tobacco and Health, October 10-14, 1994.

respondents age 12 to 17 were aware of at least one tobacco company promotion, it also reported that only 10.6 percent of respondents owned a nontobacco promotional item. These numbers, the comment asserted, do not support the theory that nontobacco items are appealing to youth or have a discernible impact on youth smoking rates.

Moreover, the comment took exception with Dr. Slade's finding that 25.6 percent of 12 to 13 year olds and 42.7 percent of 16 to 17 year olds participate in promotional programs such as Camel Cash or Marlboro miles. The comment stated:

the reason for these apparently high percentages is clear from the most cursory analysis of the data \* \* \* [I]n this supposedly random survey, fully 45.7 percent of the households of 12-13 year olds interviewed had someone at home who smoked (37.9 percent in households of 16-17 year olds), and yet, in reality only 25 percent of the American public—half the rate of the population relied upon by Dr. Slade—smoke. [Thus], the unrepresentative sample population Dr. Slade employed created a significant bias, which distorts the results of this survey and renders them entirely unreliable.

Finally, one comment stated that the primary basis for the provision appeared to be data<sup>226</sup> that allegedly show that 44 percent of teenage smokers and 27 percent of teenage nonsmokers have received nontobacco promotional items. The comment stated that the study is irrelevant because it drew no conclusion as to the significance of the number, nor did it indicate how the teenagers received the items.

In response, the agency concludes that the evidence presents a compelling case to prohibit the sale and distribution of all nontobacco items that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristic. The evidence establishes that these nontobacco items are readily available to young people and are attractive and appealing to them with as many as 40 to 50 percent of young smokers having at least one item (60 FR 41314 at 41336). The imagery and the item itself create a badge product for the young person and permit him/her the means to portray identification.

FDA has shown that tobacco advertising plays out over many media, and that any media can effectively carry the advertising message. Moreover, the

agency recognizes that the tobacco industry has exploited loopholes in partial bans of advertising to move its imagery to different media. When advertising has been banned or severely restricted, the attractive imagery can be and has been replicated on nontobacco items that go anywhere, are seen everywhere, and are permanent, durable, and unavoidable. By transferring the imagery to nontobacco items, the companies have "thwarted" the attempts to reduce the appeal of tobacco products to children.

In addition, items, unlike advertisements in publications and on billboards, have little informational value. They exist solely to entertain, and to provide a badge that, as the Tobacco Institute asserted, allows the wearer to make a statement about his "social group" for all to see. But because tobacco is not a normal consumer product, it should not be treated like a frivolity. Advertising that seeks to increase a person's identification with and enjoyment of an addictive deadly habit has the ability, particularly among young people, to undermine the restriction on access that FDA is imposing. For these reasons, the agency continues to find sufficient evidence to support a ban on these items.

Finally, regarding the unpublished paper by Dr. Slade, the comment has confused the household smoking rate with the overall population smoking rate. The smoking rate per household can be as high as twice the overall adult smoking rate. For example, if the smoking rate for adults were 25 percent and assuming two adults per household and only one of the pair smokes, then the household smoking rate could be as high as double that of the individual rate. Therefore the range of possible household smoking rates would be 25 percent to 50 percent, with 44 percent being quite plausible.

Lastly, the comments that state that peer pressure and smoking by friends and family are significant factors in influencing a young person's tobacco use, rather than promotional items, fail to recognize that if a young person is influenced by what a peer says about tobacco use, he or she will also likely be influenced by that same peer wearing a tobacco promotional item.

(75) One comment from a small smokeless tobacco company expressed concern because much of the packaging used for its products also bears its corporate logo. Moreover, several of its brand names include words in its corporate logo. Thus, the comment argues that FDA might find that its

corporate logo is an "inducement of product identification" covered by the restrictions in § 897.34. The comment stated that promotional items are a small but important part of its advertising and promotional activity, and these items allow its customers to feel like a part of an extended family. It would be unfair, the comment argued, as well as harmful to the company, if FDA were to determine that a corporate logo may not be used on promotional items.

One comment stated that the total merchandising and ban in § 897.34(a) is unreasonably broad in scope. It stated that it virtually limits all merchandising, because all colors or patterns of colors are associated with some brand or another of tobacco product. The comment stated that the proposed regulation is so confusingly vague that one could argue that a "distributor" would be prohibited from using the color red in any event for any product category, brand, or corporation because Marlboro brand tobacco products utilize the color red.

Another comment stated that because the definitions of "cigarette" and "smokeless tobacco product" are limited to tobacco products with nicotine, the agency should consider the possibility that a tobacco company could market a nicotine-free brand extension of a cigarette or a smokeless tobacco product and advertise this product free of restrictions. The comment stated that the advertising for such a product could have carryover value for the nicotine containing versions of the product thereby undermining the intent of the regulations.

The agency agrees that it needs to clarify the scope of § 897.34(a). The regulation covers any item with indicia of the brand identity. If the corporate logo is not an indicium of a brand identity, its use would not be prohibited in nontobacco labeling or advertising. On the other hand, if a corporate logo includes an identifiable brand name or image, it must comply with the restrictions. Any other position would permit a company to evade the intent of this regulation by using a corporate logo to continue to display brand imagery. For example, RJR may continue to sell or distribute hats and tee shirts with the name "R. J. Reynolds" on them, but not the name "Camel." Nor can it put the Camel inside the Reynolds logo. The agency, therefore, has amended § 897.34(a) to state that the indicia of product identification cannot be identical or similar to, or identifiable

<sup>226</sup> "Teenage Attitudes and Behavior Concerning Tobacco—Report of the Findings," the George H. Gallup International Institute, Princeton, NJ, p. 59, September 1992.

with those used "for any brand of cigarettes or smokeless tobacco".

In addition, it is not the agency's intention to ban the use of registered or recognizable colors for all advertising. Only the owner or user of the brand identification is prohibited from using that color or pattern of colors in a manner so as to advertise tobacco or smokeless tobacco. For example, Philip Morris would be prohibited from using the distinctive red, black, and white pattern of colors which identify Marlboro, but neither RJR nor Joe's Garage would be prohibited by the regulations from using those colors.

Finally, in response to the last comment, the agency has restricted the coverage of this regulation to promotions of cigarettes and smokeless tobacco products containing nicotine. It has no evidence justifying a broader coverage of the regulation to nicotine-free products at this time. However, a company could not give a nontobacco product (a nicotine free product) a tobacco brand name. This is exactly what this section of the final rule forbids.

(76) Several comments argued that § 897.34(a) constituted a restriction on symbolic expression that cannot be characterized as commercial speech. The comments argued that these items do not propose a commercial transaction. One comment argued that in *Cohen v. California*, 403 U.S. 15 (1971), the Supreme Court recognized that otherwise objectionable words worn on a jacket are fully protected speech.

FDA finds no merit to these comments. Section 897.34(a) on its face is limited only to manufacturers and to distributors of imported cigarettes or smokeless tobacco. It does not limit the rights of individuals to express themselves by wearing an article of clothing that bears a picture of a cigarette or a logo.<sup>227</sup> What it does limit is the ability of manufacturers and some distributors of tobacco and smokeless tobacco to do what is the essence of commercial speech—to take actions to call public attention to the products whose logo the items bear, so as to arouse a desire to buy those products. (See *Public Citizen v. FTC*, 869 F.2d at 1554.) Because this is what the nontobacco items that are the subject of

§ 897.34(a) are designed to do, they share all the characteristics of the pamphlets that the Supreme Court in *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66–67 (1983), found to be commercial speech. Consequently, FDA may regulate the nontobacco items as commercial speech, as long as its regulation passes muster under the *Central Hudson* test (see 463 U.S. at 68).

(77) Some comments challenged the constitutionality of the prohibition on the use of a cigarette or smokeless tobacco brand logo on nontobacco products under the *Central Hudson* test. The comments argued that the prohibition does not directly advance FDA's interest because the prohibition is unrelated to the goal of protecting children. The comments also argued that the prohibition is not narrowly tailored because it is not limited to children and not limited to products that are particularly attractive to children.

Several comments disagreed and argued that the prohibition is a constitutionally permissible restriction on speech. One of these comments pointed to the finding in the IOM's Report *Growing Up Tobacco Free* of the effectiveness of this type of advertising with young people. The comment said that FDA would therefore be justified in prohibiting its use.

FDA has carefully considered these comments. The agency concludes that the prohibition on the use of a cigarette or smokeless tobacco brand logo on nontobacco items is a permissible restriction under the First Amendment.

First, this restriction will directly advance FDA's interest in protecting the health of people under 18 years of age. In *Public Citizen v. FTC*, 869 F.2d at 1549 n. 15, the Court of Appeals for the D.C. Circuit recognized that the nontobacco "utilitarian items might be among the most effective forms of promotion with respect to adolescents." This judgment is consistent with much of the other evidence in the administrative record. A 1992 Gallup survey found that 44 percent of all adolescent smokers and 27 percent of adolescent nonsmokers owned at least one promotional item from a tobacco company.<sup>228</sup> Testing by RJR in 1988 found that nontobacco items performed best among young adults.<sup>229</sup>

The IOM Report pointed out that the ubiquity of nontobacco items conveys the impression that tobacco use is the norm.<sup>230</sup> As stated in section VI.D.3.c. of this document, this impression, that tobacco use is widespread and accepted, fosters experimentation with tobacco and smokeless tobacco by young people. This fact led the IOM to recommend that the use of tobacco product logos on nontobacco items be prohibited.<sup>231</sup> The IOM said that this and several other related steps (including requiring the use of the text-only format) were necessary to eliminate those features of advertising that tend to encourage tobacco use by children and youths.

Thus, the prohibition on the use of these logos will directly advance FDA's interest. The IOM's recommendation provides significant evidence of this fact.

Second, even though FDA is prohibiting the use of brand logos on nontobacco items, this restriction meets the requirement of narrow tailoring. The Supreme Court has held that a ban may satisfy this requirement if the agency's judgment is that it is "perhaps the only effective approach" (*Board of Trustees of the State of N.Y. v. Fox*, 492 U.S. at 479). In this case, FDA has determined that a ban of these items is necessary for several reasons. The appeal of something for nothing items for youngsters is great, and the extent of the appeal makes it virtually impossible to distinguish among items, as suggested by one comment. As the IOM pointed out, these items, when worn or used by children, are capable of penetrating areas of a child's world that might be off-limits to other forms of advertising.<sup>232</sup> Because they penetrate the young persons' world, they are very effective in creating the sense that tobacco use is widely accepted, which, as stated in section VI.D.3.c. of this document, is extremely important to children and adolescents. These items act like a badge that marks an individual as a member of a group, another attribute that makes them particularly attractive for young people. There is no way to limit the distribution of these items to adults only. The industry claims that it already is taking sufficient action to ensure that only adults get these items<sup>233</sup> but as the evidence

<sup>227</sup> The fact that individuals would be free to make their own articles of clothing with brand names of tobacco products on them does not make the regulations fatally underinclusive. (See *U.S. v. Edge Broadcasting Co.*, 509 U.S. 434 ("Accordingly, the Government may be said to advance its purpose by substantially reducing lottery advertising, even where it is not wholly eradicated."))

<sup>228</sup> "Teenage Attitudes and Behavior Concerning Tobacco—Report of the Findings," The George H. Gallup International Institute, Princeton, NJ, pp. 17, 59, September 1992.

<sup>229</sup> Bolger, M. R., *Marketing Research Report, entitled Camel "Big Idea" Focus Groups-Round II*, September 21, 1988.

<sup>230</sup> IOM Report, p. 110.

<sup>231</sup> *Id.*, p. 133.

<sup>232</sup> *Id.*, p. 110.

<sup>233</sup> The Cigarette Advertising and Promotion Code, subscribed to by the major cigarette manufacturers, contains three provisions that

indicates, a substantial number of young people have them. As noted in this section, almost one-half of young smokers and one-quarter of nonsmokers have one or more items. Moreover, even were items to be distributed to adults only, this would not prevent the wearers from becoming walking advertisements that would continue to display the attractive imagery.

For all these reasons, FDA finds that all nontobacco items that bear cigarette or smokeless tobacco brand logos are capable of playing a significant role in a young person's decision to engage in tobacco use. Because no distinction among these products is apparent, and no way of limiting their availability to adults is possible, FDA finds that the most direct and effective means of controlling their appeal to adolescents and children under the age of 18 is to prohibit manufacturers, distributors, and retailers of tobacco products from distributing or selling them.

(78) One comment opposed § 897.34(a) because the comment argued that the provision would impose restrictions on an otherwise lawful use of trademarks. It stated that § 897.34(a) would prohibit the right of any trademark owner to use a trademark for the sole reason that the trademark is used by another party on tobacco products. The comment stated that § 897.34(a) also would prevent large distributors and retailers, who handle a wide variety of both tobacco and nontobacco products, from distributing or selling any product which happened to bear the same or similar mark as that used on a tobacco product. The comment stated that, for example, grocery markets could not stock or sell Beechnut baby food or chewing gum because Beechnut also is used as a trademark for chewing tobacco even though the manufacturers are two different companies with the same name. It stated that the Lanham Act (15 U.S.C. 1051 (1996)) would, and in fact does, permit such identically branded products to coexist in the marketplace because of the absence of any likelihood that these products would be associated or confused with each other.

FDA recognizes that § 897.34(a) as proposed created unintended confusion and therefore will amend the provision to clarify the agency's meaning. Changes have been made that are intended to clarify § 897.34(a) so that retailers and distributors of domestic tobacco products are not included, thus

avoiding the problem identified with the comment and making it possible for grocers to sell Beechnut baby food and Beechnut tobacco products.

(79) Several comments stated that § 897.34(a) would unlawfully constrain the separate and distinct activity of trademark diversification in connection with products that are unrelated to the marketing of tobacco products by cigarette manufacturers. One comment contended that general bans on the licensing of brand logos pertaining to tobacco products are incompatible with long-established principles of international trademark law. The comment asserted that the use of such trademarks in a nontobacco context is not an indirect means of advertising or promoting tobacco products. The comment stated further that it is an increasingly common practice in many industries to "spin off" new products by marketing them under a trademark that has acquired some cachet or represents quality. It stated that such licensed products are not marketed in an effort to sell the "root" product, rather, the trademark has some "detachable" qualities that help build demand for the licensed goods. It stated that the same is true of marketing a nontobacco product under the trademark of a tobacco product.

FDA cannot agree with the comments' claims. While the agency recognizes that the use of these trademarks on hats and tee shirts promotes the underlying tobacco product by continuing the extensive imaging in these venues. Moreover, as the court in *Public Citizen*, 869 F.2d at 1549, n. 15, recognized, branded nontobacco items might be the most effective type of promotion to young people. Therefore, failure to include this form of advertising and promotion in the regulation, would weaken considerably FDA's efforts to reduce the appeal of these products to young people under 18, and would undermine the agency's access restrictions.

The agency also disagrees with the comment's suggestion that § 897.34(a) effects a taking (or deprivation of a property right) by prohibiting the use of tobacco trademarks to market nontobacco products. Section 897.34(a) clearly relates to commercial speech and the comment is merely attempting to cloak commercial messages with the issues of registrability and value of well-known trademarks. As discussed in section XI. of this document, the agency has determined that this regulation does not effect a taking compensable under the Fifth Amendment.

One comment that supported FDA's proposal stated that smokeless tobacco makers circumvent the FTC regulation that covers the use of brand names of smokeless tobacco products on promotional items such as caps and tee-shirts. For instance, rather than stop making such items, U.S. Tobacco has registered Skoal Bandit Racing, Skoal—Copenhagen Pro Rodeo, and Skoal Music as service marks and places these names on many of the items it offers the public, thereby evading FTC's regulation. The comment stated that this experience demonstrates the need for regulations of this sort to be comprehensive.

The comment stated further that there may be other relatively easy ways around § 897.34(a). It stated that if the rights to a brand name were transferred to an entity that was not a manufacturer, distributor, or retailer that this separate entity could then license back the use of the brand name to the tobacco company and proceed to market, license, distribute, or sell other goods and services using that same brand name. The comment stated that one way to close this loophole would be to require manufacturers to own the trademarks and the rights to all associated symbols for each brand they produce.

FDA disagrees with these comments and believes that the concerns expressed are misplaced. Section 897.34(a) prohibits all use of the Skoal brand name on nontobacco items, whether used alone, i.e., "SKOAL," or with other words, such as "Skoal Racing Bandit." In addition, the provision forbids not just the use of the brand name, logo, etc. by the manufacturer but also the marketing, licensing, distributing, selling of them, or the causing of any of those activities; thus, effectively preventing the type of license-transfer arrangement described in the comment.

(80) Several comments stated that FDA cannot ban contests and lotteries under section 520(e) of the act, because they are not devices. Moreover, the comments stated that existing laws and regulations provide adequate protection and to the extent that the participation of minors in these activities is a problem the States already have ample power to regulate them.

In addition, a comment stated that FDA offered no evidence, or citation to studies, that contests, lotteries, or games involving tobacco products have particular appeal to adolescents. Moreover, the comment stated, that any inability to quantify participation by youth does not mean that the agency

address the necessity of preventing anyone under the age of 21 from getting promotional items.

can ban an entire form of promotion to adults.

One comment pointed out that, by law, customers wishing to participate in games of chance or similar promotional activities must be adults. The comment stated that banning such activity bears no relationship to achieving FDA's stated purpose. The sole effect of FDA's ban would be to unjustly impair the relationship between tobacco manufacturers, retailers, and their adult customers.

One comment stated that the agency should not prohibit all use of contests or games of chance by the tobacco industry because regulations already exist and are enforced by the Bureau of Alcohol, Tobacco, and Firearms (BATF).

Another comment stated that the proposed rule misunderstands the nature of such activities, misrepresents the appeal of promotions, and assumes without proof that promotions induce young people to smoke. It stated that promotional activities are not undertaken to encourage people, young or old, to smoke, but rather to introduce existing smokers to the brand being promoted and to provide them with incentives to choose that brand over others. Moreover, participation in such games is expressly limited to smokers who are 21 years of age or older.

Conversely, one comment provided support for the 1995 proposed rule. It stated that, while it is unlikely that anyone under 18 years of age actually has ever received any of the major prizes or offers from the give-aways, the award of prizes is not the point of these marketing tools. It stated that the consumer's participation in the fantasy of the prize in association with the brand being promoted is the reason these contests are used.

FDA has been persuaded by the comments to modify § 897.34(b) regarding lotteries and games of chance in connection with nontobacco items. Federal law already prohibits "any certificate, coupon, or other device purporting to be or to represent a ticket, chance, share, or an interest in, or dependent on, the event of a lottery to be contained in, attached to, or stamped, marked, written, or printed on any package of tobacco products" (26 U.S.C. 5723(C)). BATF has issued regulations enforcing this provision (27 CFR 270.311).

In addition, although no Federal agency has issued specific restrictions on games of chance and lotteries in connection with advertising of tobacco products, Federal and State law prohibit games, contests, and lotteries if based on

product purchase (18 U.S.C. 1302–1307, 1341 (1995)). Given these existing Federal requirements, the agency has concluded that there is no need to add FDA regulations. Therefore, § 897.34(b) has been modified to delete the provision concerning lotteries and games of chance but to continue to the prohibition of gifts and proof of purchase acquisitions.

It must be understood, however, that advertising for games, lotteries, or contests may not contain any indicia of product identification other than black text on a white background, since the advertisement for a contest in the name of a tobacco brand, or identifiable as a tobacco brand, is restricted to text-only format as required in § 897.32(a). The agency points out that, as part of the review of the regulation that it plans to undertake in 2 years, FDA intends to consider the effect of games of chance and lotteries on young people and determine whether additional regulations are necessary.

Based on the evidence amassed during its investigation, and the surveys described in the preamble to the 1995 proposed rule (60 FR 41314 at 41336) and submitted during the comment period, FDA has concluded that nontobacco items (identified with a tobacco brand), either sold, given away, or provided for proof of purchase are an instrumental form of advertising in affecting young people's attitudes towards and use of tobacco. Moreover, banning this form of advertising is essential to reduce tobacco consumption by young people. This form of advertising has grown in importance over the last 20 years. As discussed in this section, expenditures rose from 2.1 percent in 1975 to 8.5 percent in 1980 (60 FR 41314).

*Studies*—A Gallup survey found that about one-half of young smokers and one quarter of all non-smokers, own at least one promotional item (60 FR 41314 at 41336). Another study, detailed more fully in this section, found that participation in tobacco company promotions (owning an item, collecting coupons for gifts, or having a catalogue) by 12 to 17 year olds is more predictive of susceptibility to use of tobacco products than smoking by those close to the individual. Another study, by Slade, found that 25.6 percent of 12 to 13 year olds and 42.7 percent of 16 to 17 year olds participate in promotional programs such as Camel Cash and Marlboro miles (60 FR 41314 at 41336).

*Evidence Provided by Industry Members*—Two separate studies done for R.J. Reynolds, and described in this

section, found that tee shirts were a significant source of information about tobacco for some young people and that these items performed best among young people.

A ban on this type of advertising will prevent the "something for nothing appeal" of give aways and proofs of purchase and will eliminate the walking billboard, who can enter schools and other locations where advertising is inappropriate. Thus, FDA concludes that the restriction it is adopting on this type of promotional material will directly advance FDA's efforts to substantially reduce consumption of tobacco products by children and adolescents under 18.

#### 8. Section 897.34(c)—Sponsorship of Events

Proposed § 897.34(c) provided that "no manufacturer, distributor, or retailer shall sponsor or cause to be sponsored any athletic, musical, artistic or other social or cultural event, in the brand name, logo, motto, selling message, recognizable color or pattern of colors, or any other indicia of a product identification similar or identical to those used for tobacco or smokeless tobacco products." Proposed § 897.34(c) would have permitted a manufacturer, distributor, or retailer to sponsor or cause to be sponsored any athletic, musical, artistic or other social or cultural event in the name of the corporation that manufactures the tobacco product, provided that both the registered corporate name and the corporation were in existence before January 1, 1995.

The preamble to the 1995 proposed rule explained that sponsorship by cigarette and smokeless tobacco companies associates tobacco use with exciting, glamorous, or fun events such as car racing and rodeos, and provides an opportunity for "embedded advertising" that actively creates a "friendly familiarity" between tobacco and sports enthusiasts, many of whom are children and adolescents. The preamble to the 1995 proposed rule cited several studies that demonstrate the impact of sponsorship on consumer attitudes (60 FR 41314 at 41337 through 41338). The proposed restriction was intended to break the link between tobacco company-sponsored events and use of tobacco and reduce the "friendly familiarity" that sponsorship generates for a brand.

(81) FDA received a substantial number of comments concerning the agency's 1995 proposal on sponsorship, including comments submitted by the

tobacco industry, motorsport industry, advertising agencies, adult smokers, medical professionals, public interest groups, and racecar drivers. Approximately 300,000 individuals submitted a form letter that was produced by 1 tobacco manufacturer. The form letter inaccurately referred to the 1995 proposal as a "ban on tobacco sponsorship of events including concerts, State fairs and consumer promotions" whereas the agency proposed to permit tobacco company sponsorship of all events to continue as long as they are in the corporate name. Other comments submitted by the tobacco industry, adult smokers, and motorsport industry strongly objected to the provision. In contrast, those comments submitted by public interest groups, medical professionals, and some racecar drivers strongly supported the provision.

In response to comments, the agency has modified this provision to prohibit all sponsored entries and teams using the brand name in addition to the prohibitions that were proposed. Moreover, the final rule clarifies that the corporate entity that can sponsor events, teams and entries must not only be registered but that the registration must be in active use in the United States, and the corporate name cannot include any indicia of product identification "that are identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco."

(82) Several comments addressed the issue of whether young people attend, or even see, sponsorship events. Some comments opposed the provision, arguing that sponsored events (such as motorsport events and seniors golf tournaments) are created for and attended by adult smokers, and that there is no credible evidence that these events are targeted at, created for, attended by, or even seen by significant numbers of children and adolescents. One comment stated that "contrary to FDA's assertions," the industry takes special steps to ensure that material distributed at events is not attractive to minors. One comment stated that "[r]ecent industry studies demonstrate that the overwhelming majority of fans at motorsports events are adults," and that "for example, 97 percent of NASCAR Winston Cup Series race attendees are 18 years of age and older [and] [m]ore than 90 percent of NHRA Winston Drag Racing Series attendees are 21 years old and older." The underlying studies were not, however, cited or attached to the comment.

One comment added that motorsport events are not seen by "significant" numbers of children under the print media standard proposed by FDA (i.e., the "15 percent/2 million benchmark"). The comment argued that:

[o]n the one hand, the agency concedes that image advertising is permissible in publications with a primarily adult readership because "the effect of such advertising on young people would be nominal," but on the other hand, it attempts to measure the impact of cigarette brand sponsorships \* \* \* by using statistics on the viewing audience of sponsored motorsport events without recognizing that these figures demonstrate the fact that the vast majority of viewers of such events are adults.

The comment stated that:

[I]n fact, the 64.05 million underage viewers of the 354 motorsport broadcasts studied represents only 7 percent of the total viewing audience of these broadcasts. This averages out to 180,806 underage viewers per event. These figures are far below the 15 percent and two million readership benchmarks that are permitted for image advertising in print media.

\* \* \*

The comment also stated that FDA made no attempt to measure the percentage of adolescents in the live gate of sponsored events, and that industry estimates indicate that the overwhelming percentage of fans attending motorsport events are adults.

One comment stated that the price of a typical ticket to a stock car race event is expensive enough to preclude adults from taking their children to events and to preclude children themselves from attending these events.

Other comments supported the provision, stating that tennis tournaments, sports car, motorcycle and powerboat racing, and rodeos all are aimed at sports enthusiasts, many of whom are children or teenagers, and that rock concerts and country music festivals are "magnets" for adolescents.

One comment stated that:

[it] is also no coincidence that when the tobacco industry sponsors events where the audience is almost entirely educated adults, the sponsorship is in the name of the corporation (i.e., art exhibits, modern dance companies), but when the event fits the psychological image the tobacco industry needs to attract adolescents, the sponsorship is in the name of the brand most likely to appeal to those children (Virginia Slims, Marlboro, Winston, Skoal Bandit).

The agency, which acknowledges the comments' reports on the number of young people at events, did not receive any data to support or refute these numbers. However, recent reports in the press indicate that the number of young people attending these events may be growing.

In NASCAR we found a great kids' business. I was astounded by their information, statistics and demographics regarding kids. [Fred Siebert, president of Hanna-Barbera, Inc., explaining why the company is sponsoring a cartoon race car to appear in NASCAR races emblazoned with Fred Flintstone and other cartoons on the hood.] After reviewing the 1995 NASCAR season, we concluded that a sizable number of attendees at NASCAR events were families with kids ages 6-11. Yet we felt NASCAR was not specifically serving that audience. [Gary Bechtel, owner Diamond Ridge Motorsports, who will field a NASCAR car and team named Cartoon Network Wacky Racing.]<sup>234</sup>

\* \* \* \* \*

We looked at NASCAR and saw how quickly it was growing nationally and the fact that so many families go to the races it seemed like a natural fit.<sup>235</sup> Moreover, the agency finds that 64.05 million underage viewers (or 180,806 underage viewers per event) is clearly not "insignificant." As discussed in the preamble to the 1995 proposed rule, the "Sponsor's Report," which estimated the value of all product exposure for most U.S. automobile races, found that 354 motorsport broadcasts "had a total viewing audience of 915 million people, of whom 64 million were children and adolescents." The preamble to the 1995 proposed rule stated: "the impact of sponsoring televised events such as these automobile races is perhaps most apparent when one realizes that over 10 million people attended these events, while 90 times that number viewed them on television" (60 FR 41314 at 41337). In addition, recent news accounts indicate that televising of races has increased both in volume and diversity. For example, television can often support three major races in 1 day. The two cable ESPN channels had 150 hours of auto racing programming in May, 1996, including 95 hours of live races, time trials, qualifying and practice laps.<sup>236</sup>

The effect of sponsored events on the young people who attend or see these events is enormous. Advertising affects young people's opinion of tobacco products, first, by creating attractive and exciting images that can serve as a "badge" or identification, second, by utilizing multiple and prolonged exposure in a variety of media, thereby

<sup>234</sup> "Diamond Ridge Motorsports and Hanna-Barbera, Inc., to form Wacky Racing Team Changing Face of NASCAR; Deal Launches Cartoon Network Consumer Branding Initiative," *Business Wire*, November 10, 1995.

<sup>235</sup> "Automobile Racing's Widening Appeal Gets the Flintstones in Sponsor Table," *The Times Union*, p. B11, March 30, 1996.

<sup>236</sup> Moore, S., "Ladies and Gentlemen, Start Your Televisions," *Washington Post*, May 26, 1996.

creating an impression of prevalence and normalcy about tobacco use, and finally, by associating the product with varied positive events and images. The sponsorship of events by tobacco companies uniquely achieves all three objectives. Sponsorship creates an association between the exciting, glamorous or fun event with the sponsoring entity. Whether at the live gate, or on television, young people will repeatedly see and begin to associate the event, which they are enjoying, with the imagery and appeal of the product. All of the attendant concerns of hero worship of the sports figures and glamorization of the product by identification with the event are present, whether there are thousands or hundreds of thousands of young people in attendance. Race car drivers are extremely popular with young people and often are looked up to as heroes. According to one promoter of NASCAR properties, "We've found that boys look to NASCAR drivers the same way they do to heroes, such as firemen, policemen, professional fighters, or astronauts."<sup>237</sup>

Furthermore, sponsorship events present a prolonged period of time in which to expose the audience, including young people, to the imagery. Sponsorship events do not provide people with a momentary glimpse at the imagery, but from 1 to 2 or 3 hours of constant attractive imagery. The audience has more than enough time to associate the images of the sporting event or the concert with the product.

The agency agrees that there may be some events (such as seniors golf tournaments) that are primarily attended by adult audiences. The agency also does not claim that *all* sponsorship events are *attended* primarily by young people, but that the *exposure* (which includes television broadcasts) of young people to sponsored events is substantial. Even if a small percentage of young people attend certain sponsorship events, the amount of television exposure that young people receive is substantial.

In addition, the agency recognizes that numbers or percentages of the audience less than 18 may be lower than the threshold established for "adult" publications. However, the type of exposure in these two media are dramatically different. Young people reading or flipping through a magazine

may momentarily glance at advertisements if they are interesting or eye-catching, and as a result, the exposure, if any, to one particular advertisement may be brief (the average time spent viewing an advertisement is about 9 seconds<sup>238</sup>). However, young people who attend sponsorship events or view them on television are unavoidably bombarded with posters, signs, hats, t-shirts, cars, and the like, linked with a fun, exciting, or glamorous event that they enjoy for a prolonged period of time. Often, celebrities participating in these events are wearing clothes and hats bearing the brand name and attractive imagery, and young people come to associate athletes who they admire with tobacco products. The amount of time viewed and the positive association with the event are incalculable as persuasive messages. Thus, the agency rejects the idea of setting a minimum attendance threshold for brand name advertising.

(83) FDA received many comments addressing its use of the concept of "friendly familiarity" in connection with tobacco sponsorship of events. Several comments stated that FDA misunderstood the theory,<sup>239</sup> arguing that sponsorships and promotions do not cause young people to smoke, and that FDA has failed to meet its burden of demonstrating that a ban of such activities will result in any decrease in underage smoking. In fact, according to this comment, the studies demonstrate that young people are most familiar with the brands of tobacco that are most heavily advertised.

One comment asserted that since motorsport advertising and promotion comprises a small percentage of overall tobacco advertising (on the order of 4 or 5 percent of total tobacco advertising), there is little support for the conclusion that tobacco sponsorship of motorsports has any significant effect on the rate of youth smoking.

One comment from a 26-year old ex-smoker (who began smoking at age 10, and smoked for 13 years) and NASCAR racing fan stated:

[M]y favorite driver is sponsored by a beer company. I don't drink and I'm not going to start because my favorite driver has that

<sup>238</sup> Fischer, P., J. Richards, and E. Berman, "Recall and Eye Tracking Study of Adolescents Viewing Tobacco Advertisements," *JAMA*, vol. 261, pp. 84-89, 1989.

<sup>239</sup> The comment stated that "[t]he need to establish a 'friendly familiarity' with a brand name is not about deciding to smoke \* \* \* nor about deciding to use a commodity at all—the decision to make a category purchase within a mature product category is ALREADY made before advertising affects the brand choice within the category."

sponsor. However- if I DID drink already, I may switch brands to support my driver. All the advertising in the world will not sway me (or most-intelligent people) to do something I wouldn't do anyway.

In contrast, several comments labeled the 1995 proposed rule a "reasonable measure" and stated that "the evidence cited by FDA in support of this proposal is substantial and entirely consistent with the best available evidence." One comment supported FDA's sponsorship restrictions because sponsorship heightens product visibility, molds consumer attitudes, links the product with a particular lifestyle, and thus increases sales.

One comment commended FDA for drawing a "reasonable line—one that allows tobacco companies to continue to sponsor events and therefore to reap the corporate good will that flows from sponsorship, but compels the companies to jettison the hard-sell message that now typifies these events."

Several comments stated that the events sponsored by tobacco companies have a direct and powerful impact on young people because they are fun, exciting, and glamorous, and events such as tennis tournaments (Virginia Slims), sports car (NASCAR), motorcycles and powerboat racing, rodeos, rock concerts, and country music festivals are aimed at sports and music enthusiasts, including children or teenagers. The comment stated that when minors view these events, either in-person or on the television, they are: "inundated with images of the brandname or product logo (which are pasted on uniforms, vehicles, signs and virtually every surface imaginable), creating a direct and compelling association between the product and an enjoyable event."

The comment stated that children and young adults are particularly vulnerable to this sort of product advertising, because adolescence is the time of life during which identities are shaped. The comment further stated that there is ample evidence that demonstrates that the sponsorship of events leads to strong associations between the event and the brandname, that in turn influences the purchasing decisions of minors.

One comment stated that Virginia Slims' sponsorship of tennis was vital to the image advertising Philip Morris used to sell Virginia Slims tobacco to adolescent girls, and that Marlboro sponsorship of racing events is no less effective with adolescent boys. The comment stated that sports sponsorship has a secondary impact because "[t]he athletes who participate in the sponsored event, whether they be race

<sup>237</sup> Williams, S., "NASCAR Races into Kid's Licensing, National Association for Stockcar Auto Racing Seeking Promotional Appeal and Other Products," *Children's Business*, vol. 9, No. 7, p. 28, July 1, 1994.



car drivers or tennis players, become walking advertisements and role models." The comment stated that "[a]s reflected by the Industry's own Code, everyone agrees that athletes should not endorse tobacco products because of her potential impact on children, but being a spokesperson for the Virginia Slims Tennis Tournament, NASCAR racing, etcetera is no less effective."

The agency finds that the evidence regarding the effect of advertising and sponsorship on children's smoking behavior is persuasive and more than sufficient to justify this regulation. The preamble to the 1995 proposed rule described the available evidence and explained why the agency is regulating sponsored events. The evidence demonstrates that sponsorship of sporting events by tobacco companies can lead young people to associate brand names with certain life styles or activities and can affect their purchasing decisions (60 FR 41314 at 41336 through 41338). The industry, in its comments, has questioned the relevance of the evidence but has failed to demonstrate that FDA's tentative views were wrong (the industry's criticisms of the individual studies are described below).

Sponsorship events actively create an association between tobacco and event enthusiasts. People under the age of 18 are still forming attitudes and beliefs about tobacco use, see smoking and smokeless tobacco use as a coping mechanism, a gauge of maturity, a way to enter a new peer group, or as a means to display independence (60 FR 41314 at 41329). This final rule is intended to break the link between tobacco brand-sponsored events and images and use of tobacco by young people. In addition, the tobacco industry itself has recognized the vulnerability of young people to advertising featuring sports heroes and other celebrities. In its 1994 Code, the cigarette industry promised that "No sports or celebrity testimonials shall be used or those of others who would have special appeal to persons under 21 years of age."<sup>240</sup> The impact of tobacco's association with the race driver, the car, or the event is no less powerful and no less persuasive.

Finally, although motorsport advertising comprises only a small percent of overall tobacco advertising, its effect, like that of magazines, or hats and tee shirts, is cumulative. Each separate advertising venue, in and of itself, does not produce the entire effect.

However, taken together, the effect of each advertising exposure is magnified beyond each discrete exposure, to create the impression that cigarette and smokeless tobacco use is widespread and widely accepted. These impressions, as stated in section IV.D.3.c. of this document, are very influential to children and adolescents.

(84) Several comments criticized in detail the studies relied on by FDA to show the effect that sponsorship has on young people.

One comment stated that the studies relied on by FDA (40 FR 41331 and 41332) do not provide scientifically valid support for the conclusion that there is a causal relationship between the promotional and sponsorship activities banned under § 897.34(c) and the problem of underage smoking.

The agency proposed to regulate sponsored events based upon its tentative finding that the best evidence supported such regulation. Although the comments argued that the studies are inadequate, the comments offered no new evidence to suggest that the conclusions are invalid.

(85) One comment argued that although the conclusion reached by an unpublished paper by John Slade<sup>241</sup> is that 7 percent of the viewing audiences for NASCAR races are youths, the NASCAR Demographics brochure states that "NASCAR records of the age of persons who attend motorsport events show that only 3 percent are youths." The comment stated that this does not constitute a principled basis for outlawing tobacco company sponsorship of these races even if every other assumption FDA makes about the impact of event sponsorship were true.

The agency disagrees with the comments on the paper by Dr. Slade. Slade's paper established that these events are attended by and seen by a large number of young people. The study measured its stated objective, it establishes the important fact that children are being unavoidably exposed over and over again to attractive and appealing images associated with tobacco products at NASCAR events. The study establishes that young people are present at events where a popular sport is associated with tobacco on signs, cars, people, etc.

The agency also disagrees with the comment that suggested that the price of tickets to motorsport events was

sufficiently high to preclude adults from taking their children to see them. In fact, some motorsport events allow children to attend free of charge or offer discount tickets for children.<sup>242</sup>

(86) One comment stated that the study performed by Aitken, et al.<sup>243</sup> (the Aitken study) did not attempt to gauge whether exposure to tobacco-sponsored events or teams engendered favorable feelings for tobacco products in the surveyed young people and stated that the study only addressed the effect of factors such as sex, age, and socioeconomic status on awareness of cigarette sponsorships. The comment also stated that the Aitken study did not test the effect of sponsorship activities in this country, and that FDA ignores the fact that tobacco companies sponsor a wider variety of more popular sports in the United Kingdom, such as "snooker, cricket and darts." Finally, the comment accused FDA of "selective reading," citing FDA's omission of a statement made by the authors when discussing past studies that even though minors may be aware of the sponsorships, "[t]his of course does not mean that cigarette advertising plays a part in inducing children to start smoking." The comment also criticized the author of the study for stating that even though very few of the primary schoolchildren named John Player Special or Marlboro as being associated with racing, "[t]his suggests that linkages or associations between brand names (or their visual cues) and exciting sports are often unconscious, or at the very least, not readily retrieved by consciousness (Aitken et al., p. 209)." The comment claims "[t]hat astonishingly biased hypothesis was not tested by any questions that attempted to probe the 'unconscious' or the 'consciousness' of the interviewees."

The agency disagrees with the comment's criticism of the Aitken study. This study conducted in the United Kingdom demonstrated that primary schoolchildren who said that they intended to smoke when they were older tended to be more favorably disposed to cigarette advertising. Moreover, Aitken's comment that this

<sup>242</sup> See, e.g., Rosewater, A., "Retirement is no Drag for Prudhomme," *Plain Dealer*, p. 7D, June 4, 1996; "Fun Book 96/ This Spectator Sport: Easy Over," *Newsday*, p. 80, May 19, 1996; Schmiedel, M., "Motor Sports World Motorcycle Trials in Exeter Next Weekend," *The Providence Journal-Bulletin*, p. 13D, May 19, 1996.

<sup>243</sup> 60 FR 41314 at 41337, n. 226; citing Aitken, P. P., D. S. Leather, and S. I. Squair, "Children's Awareness of Cigarette Brand Sponsorship of Sports and Games in the UK," *Health Education Research, Theory and Practice*, vol. 1, pp. 203-211, 1986.

<sup>240</sup> Cigarette Advertising and Promotion Code, 1990.

<sup>241</sup> 60 FR 41314 at 41337, n. 225; citing Slade, J., "Tobacco Product Advertising During Motorsports Broadcasts: A Quantitative Assessment," presentation at the 9th World Conference on Tobacco and Health, October 10-14, 1994.

study did not mean that advertising plays a part in inducing children to start smoking" is an accurate statement of the study. The purpose of the study was to examine the effect of sponsorship on children's awareness of tobacco sponsorship and brand name identification with that sport, not on their smoking behavior. This fact is not a flaw but a description of the study design and the study's limitations. The study, however, is quite useful in showing the effect of sponsored events on young people's awareness of brands.

In addition, the comment selectively quoted a portion of the Aitken study (regarding linkages), while ignoring the reason the statement was made. The author of the study made this statement in the context of the finding that whereas only 9 percent of the primary schoolchildren named John Player Special or Marlboro as sponsoring or being associated with racing cars, 47 percent of primary schoolchildren chose John Player Special or Marlboro as being liked by "someone who likes excitement and fast racing cars." The authors also found that linkages or associations between cigarette brand names (or their visual cues) and exciting sponsored sports can be elicited by simple advertisements, even among children who do not have a critical awareness of the purpose of commercial sponsorship. This type of linkage is the primary issue, rather than whether such information is "conscious" or "unconscious" in nature.

(87) One comment stated that the study performed by Ledworth<sup>244</sup> (the Ledworth study), which found that even a fairly brief exposure to tobacco sponsored sporting events on television may increase children's brand awareness, failed to control for other sources of information that could result in brand awareness (i.e., if a family member smokes), and that even the author of the study stated that further investigation needed to be done to determine whether tobacco sports sponsorship persuades children to smoke. The comment also stated that FDA cannot extrapolate the study results to the United States because the study was based on foreign sponsorship and viewership practices, which differ significantly from those in this country. The comment stated that the differences are highlighted by the fact that 74 percent of the surveyed children watched at least part of the snooker

match, and that the child viewership of NASCAR is "\* \* \* significantly more limited, at most, even by Slade's number, to 7 percent."

The agency disagrees with the comment's criticism of the Ledworth study. The Ledworth study demonstrates the power of association between an event and brand awareness among young people. The study is evidence of the important link formed by that association.

(88) One comment stated that the study performed by Hock et al.<sup>245</sup> (the Hock study), which showed that nonsmoking boys who saw a tobacco sponsorship advertisement had a diminished concern that tobacco hurt sports performance, "has no real relevance to the issue of event sponsorship and suffers from obvious, significant methodological flaws." The comment explained that the video viewed by one of the groups contained an advertisement promoting a cigarette company's sponsorship of a sporting event and thus reports the effect of a particular advertisement, not the effects of the types of sponsorships at issue here. The comment also stated that American tobacco companies are not permitted to advertise sponsorships in this fashion under 15 U.S.C. 1335 (the television advertising ban). The comment argued that the portion of the conclusion quoted by FDA overstates the results of the flawed research because the authors themselves emphasized that "nonsmokers'" general attitudes to smoking were not significantly affected by exposure to sponsorship events. Finally, the comment argued that, among the group of smokers, the authors reported that exposure to the sponsorship advertisement did not affect the smokers' brand choices, and that the authors cautioned that "these findings do not, in themselves, constitute a case for legislation."

The agency disagrees with the comment's criticism of the Hock study. Although the advertisement used in the Hock study may have been different than advertisements that appear in the United States, and only a single advertisement was tested, these factors alone do not render the author's conclusions invalid. Again, most importantly, the study provides evidence that brand sponsorship produces awareness of the product and the brand in young viewers. The agency

also disagrees with the comment's assertion that FDA overstated the findings of the study. The agency specifically acknowledged in the preamble to the 1995 proposed rule that exposure to the particular advertisement did not affect overall attitudes toward smoking (60 FR 41314 at 41338).

Moreover, the agency disagrees with the comment regarding brand preferences of smokers. As the study authors noted, the study primarily focused on nonsmokers. Thus, the fact that there were few smokers in the study makes it more difficult to find significant effects on smokers. In addition, the authors note more than once that the effects of sponsorship appear to be primarily on nonsmokers.

The important point of this study and the others cited by the agency is that sponsorship of events helps create a positive association between the event and the tobacco company. The child relates the event to the product and this contributes to the perception that tobacco use is acceptable and not dangerous. This attitude helps an environment that fosters experimentation with tobacco products.

Finally, the comment asserted that FDA's reliance on the two-page memorandum from Nigel Gray<sup>246</sup> is "not only disingenuous, but demonstrates that FDA has not evaluated the data on which it purports to rely." The comment stated that "the statistics cited in this study lack any explanation or support." The comment also states that "[t]he conclusions stated in the memorandum are at odds with those in the studies by Aitken and Hock cited by FDA." The comment stated that the author cited a "Western Australian survey" that found that 65 percent of 10 to 11 year olds surveyed believed that tobacco sponsorship of sports is advertising for tobacco, whereas the Aitken study "found that only 4 percent of 10 to 11 year olds identified advertising as a component of sports sponsorships by tobacco companies." The comment also argued that the study by Hock found no effect of the sponsorship advertisement on brand choice, whereas the memorandum by Gray revealed that sponsorship did effect brand choice.

The agency recognizes that there are problems with the two-page memorandum from Nigel Gray because the data on which it was based have not been made available. Therefore, the

<sup>244</sup> 60 FR 41314 at 41338, n. 227; citing Ledworth, F., "Does Tobacco Sports Sponsorship on Television Act as Advertising to Children," *Health Education Journal*, vol. 43, no. 4, 1984.

<sup>245</sup> Hock, J., P. Gendall, and M. Stockdale, "Some Effects of Tobacco Sponsorship Advertisements on Young Males," *International Journal of Advertising*, vol. 12, pp. 25-35, January 1993.

<sup>246</sup> 60 FR 41314 at 41338, n. 228; citing memorandum from Gray, N., (Anti-Cancer Council of Victoria), to all members of the Federal Parliament, December 15, 1989.

agency has placed no weight on its findings and does not rely on it in the final rule.

On the other hand, the memorandum cannot be used to diminish the usefulness of the other studies that have been cited. A careful reading of the data presented by the Aitken study reveals that indeed 17 percent of 10 to 11 year olds identified advertising as a component of sports sponsorship by tobacco companies. While it is true, as the comment indicated, that 4 percent mentioned only the advertising component, the comment has overlooked the fact that an additional 13 percent of 10 to 11 year olds mentioned both advertising and economic components.

In summary, these studies provide ample support that brand name sports sponsorship produces, for young people, memorable associations between the sport and the tobacco product and brand name. As shown in section VI.B.1. of this document, young people pay attention to and rely on peripheral cues such as the color and the imagery of advertising for some of their information about products. Tobacco sponsorship creates powerful images of fun and excitement to add to that "information" mix.

(89) FDA had proposed that entries, such as racing cars, or events or teams that participate in events be permitted to display a brand name in a black and white text only format. Thus, although the Skoal 500 would be prohibited, the Skoal Bandit racing car could participate in a race event.

Several comments supported the provision's requirement for teams and entries but recommended that the agency go further to restrict labeling on entries and teams in sponsored events. One comment, which was submitted by a "participant in motorsport events," stated that "even when the Marlboro name, for example, is removed from a racing car body, the distinctive color scheme still sends the Marlboro message, loud and clear."

One comment stated that "under the rationale applied to the regulation on event sponsorship, \* \* \* FDA would be justified in restricting tobacco companies from entry and team sponsorship." The comment recommended that FDA "limit the scope of the terms 'entries' and 'sponsored events,' for the breadth of possible entries and possible events is enormous." The comment stated that for instance, professional sporting events such as football, basketball, baseball, and hockey games, should be excluded

from 'sponsored events,' so that tobacco product brand names cannot be used as the name of a professional sports team." The comment stated that the term "entries" is ambiguous because, for example, a race car competing in a sponsored race would qualify as an "entry" under the proposed rule, "but would the Company X Choir be considered an 'entry' when it appears in a sponsored concert?"

The agency has carefully considered the comments and has decided to delete "entries and teams in sponsored events" from the list of permissible advertising media in § 897.30(a) and to specifically include teams and entries within the scope of the ban on sponsored events. The agency is persuaded that sponsored teams and entries, such as cars: (1) Create the same associations with sports figures and other "heroes," (2) create a linkage between a tobacco product and an enjoyable and exciting event when they appear as part of an event, (3) are displayed for a significant period of time. They have the same potential to create images and influence children and adolescents as does sponsorship of events, and (4) are able to leave the event and be seen at fairs and malls and other places frequented by young people.

The agency appreciates the comment's suggestions that color and imagery are as problematic as the brand name but advises that the comment has misinterpreted the 1995 proposed rule. Proposed § 897.34(c) stated that sponsorship would be prohibited in "the brand name, logo, motto, selling message, recognizable color or pattern of colors, or any other indicia of a product identification similar or identical to those used for tobacco or smokeless tobacco products." Thus, a car sponsored by Philip Morris may not be named after the Marlboro brand nor be painted in the distinctive tri-color pattern.

(90) Some comments addressed the issue of whether sponsorship is advertising. One comment argued that the International Events Group's (IEG) "IEG Complete Guide to Sponsorship" states that sponsorship is not advertising, and that the guide explains that advertising involves the delivery of messages about specific product attributes, while sponsorship merely shapes the consumer's image of the brand. Moreover, to the extent the IEG is identifying sponsorship as advertising, the comment asserted that the IEG guide is a publication by an organization that depends on sponsored events for its existence, and is not in the

business of conducting objective, statistically sound studies on the effects of sponsorship. Thus, the comment asserted, FDA has not cited any scientific study supporting the theory that sponsorship is advertising.

The comment argued that the position that sponsorship and advertising are one and the same is inconsistent with pronouncements from Congress and from the FTC. The comment argued that both Congress and the FTC have recognized that advertising includes messages about product attributes or appealing visual imagery, and the use of a brand name to identify an event includes neither. The comment asserted that "nothing in the [FTC]'s findings suggests a rationale that would apply to the mere display of a logo, trademark, or other product identifier when divorced from a selling message." The comment asserted that Congress has never classified sponsorship of events using brand names as advertising, and that the few times it has addressed this issue, Congress has issued laws that distinguish advertising from other forms of promotion that do not have the same impact as advertising.

The comment referred to an FTC order *In the Matter of Lorillard Tobacco*, 80 FTC 455, 457 (1972), which the comment argues defines "advertising" to include only those practices that typically contain a selling message; and *United States v. R.J. Reynolds Tobacco Company*, No. 76-Civ-814 (JMC) (SDNY 1981), which the comment argued confirms the Government's view that the selling message in advertising, not the mere display of a logo, was the focus of its concern.

In addition, the comment argued that another Federal agency agrees with this interpretation. The comment stated that the FCC, expressly permits "logos or logograms" as long as such announcements do not contain "comparative or qualitative descriptions, price information, calls to action, or inducements to buy, sell, rent or lease."

In contrast, some comments supported the assertion that sponsorship is very effective advertising. One comment included in its appendices the transcript of an ABC News Day One story broadcast August 10, 1995, that reported on the commercial value of sponsorship. The comment also included a recent story in *Winston Cup Scene* (October 19, 1995) which describes the advertising value that sponsors expect to receive from their sponsorships.

Contrary to the comments cited, the FTC asserted, in its comment, that sponsorship is advertising, citing its 1992 consent order involving the Pinkerton Tobacco Co., (Consent Order C-3364 (1992)).

The comment also stated that in 1995, the Department of Justice announced consent decrees resolving allegations that Philip Morris, Inc., and the owners of Madison Square Garden in New York City violated the Cigarette Act's ban prohibiting advertising for tobacco on television and other media regulated by FCC through the display of cigarette brand names and logos at live sporting events that were broadcast on television (*United States v. Madison Square Garden, L. P.*, No. 95-2228 (S.D.N.Y., April 7, 1995); *United States v. Philip Morris, Inc.*, No. 95-1077 (D.D.C. June 6, 1995)). The consent decrees prohibit Philip Morris and Madison Square Garden from placing cigarette advertising in places regularly in the camera's focus where they might be seen on television.

The agency finds that sponsorship is advertising within the scope of this regulation. The claim by the comments that the *Lorillard* and *Reynolds Tobacco* consent orders demonstrate that the FTC does not find sponsorship to be advertising is incorrect. The two cited cases are consent orders that did not provide a definition of advertising but limited the coverage of the consent order to the specific types of advertising mentioned in the order. The two orders clearly excluded categories of obvious advertising from the coverage of the order (see, e.g., point of sale advertisements less than 36 square inches).

Although the agency acknowledges that the "IEG Complete Guide to Sponsorship" (IEG guide) states that sponsorship is not advertising, IEG is creating a semantical distinction between one form of advertising (traditional media advertising) from other types of advertising (e.g., promotional items, sponsorship). The IEG guide states that "[w]hat sponsorship generally accomplishes *better* [emphasis added] than advertising is establishing qualitative attributes, such as shaping consumers' image of a brand, increasing favorability ratings, and generating awareness." In addition, the IEG guide states that sponsorship is more effective than advertising in increasing "propensity to purchase." This latter description of sponsorship falls within the courts definition of advertising in *Public Citizen v. FTC*, 869 F.2d at 1554, as

"any action to call attention to a product so as to arouse a desire to buy."

The agency finds for all these reasons that sponsorship can be regulated as advertising under the act.

(91) Several comments argued that FDA does not have the authority to restrict sponsorship events. One comment stated that FDA has no authority to regulate cigarette advertising to "break the link" between sponsored events and use of tobacco, and reduce the "friendly familiarity" that sponsorships generate among young people. The comment stated that FDA can prohibit only false or misleading restricted device advertising and cannot prohibit advertising that simply links a name to a product. One comment stated that it is difficult to understand how the sponsorship of the IndyCar Marlboro 500 or the National Hot Rod Association Winston Drag Racing Series, promotional activities that would be prohibited under the 1995 proposed rule, involve the "misbranding" of tobacco products.

Several comments addressed the issue of whether FDA's proposed ban on brand name sponsorship violates the First Amendment. Several comments argued that the proposed restrictions on advertising and promotional activities are overly broad and violate the First Amendment because the 1995 proposed rule would prohibit virtually all forms of tobacco sponsorship and advertising at motorsport events, and FDA made no attempt to limit the restrictions to advertisements directed at minors. One comment argued that the provision would not directly and materially advance the government's interest, because there is no reasonable basis for asserting that sponsorship causes youth tobacco use. The comment stated that FDA did not attempt to differentiate between those events that attract children and adolescents and those that attract adults. Thus, according to the comment, a ban on tobacco sponsorship of an event that few or no children or adolescents attend will not directly and materially advance a reduction in underage tobacco use.

In contrast, one comment which supported the provision stated that sponsored events have a direct and powerful impact on young people, and thus there is a "reasonable fit" under the final two prongs of the *Central Hudson* test. The comment argued that the 1995 proposed rule is narrowly tailored because "FDA has selected the approach that best effectuates its goal of reducing tobacco consumption by minors, without needlessly restricting

the industry's ability to sponsor events and garner the good will that flows from such sponsorship."

FDA concludes that sponsorship of events and sponsored teams and events is an advertising medium that is effective in influencing young people's decision to engage in smoking behavior and tobacco use.

As explained in this section, the agency has authority to restrict advertising of restricted devices like tobacco and smokeless tobacco under sections 520(e) and 502(q) of the act. As the studies described in this section<sup>247</sup> demonstrate, sponsorship associates the advertised brand with the event and thus shapes the image of the brand and the individual's image of tobacco use. Sponsorship of rodeos and car racing, for example, associates the product with events where risks are high but socially approved and are taken by individuals who brave the odds.<sup>248</sup> This type of situation fits in very well with the image concerns of adolescent males described in section VI.D.4.a. of this document.

Youths who attend the sponsored event are directly and unavoidably confronted with messages for the sponsoring product. This exposure creates a sense of familiarity and acceptance similar to that created by billboards near schools and playgrounds.

In addition, the sponsored events are televised. As a result of this fact, through mention of the sponsor and camera shots that pan the place where the event is held, awareness of the brand is created, along with the associations described above.

Given these factors, a restriction on sponsorship will be effective in limiting the influences on children and adolescents to use tobacco products and thus in protecting their health. Moreover, there is a reasonable fit between the restriction and FDA's interest. The restriction focuses on the use of the brand because of the association between the brand and tobacco use.<sup>249</sup> By building associations with the brand, sponsorship and the advertising displayed at the event creates a desirable image for young people that contributes to a positive feeling about the product that sponsors

<sup>247</sup> See e.g., Aitken, P. P., D. S. Leathar, and S. I. Squair, "Children's Awareness of Cigarette Brand Sponsorship of Sports and Games in the U.K.," *Health Education Research*, vol. 1, pp. 203-211, 1986.

<sup>248</sup> IOM Report, p. 112.

<sup>249</sup> Hock, J., P. Gendall, and M. Stockdale, "Some Effects of Tobacco Sponsorship Advertisements on Young Males," *International Journal of Advertising*, vol. 12, No. 1, January 1993.

the event. This positive image not only provides a brand that the young person might select but also adds to the young person's positive feelings about using the product. It is the creation of this association that FDA will prevent by restricting sponsorship.

FDA is not aware of any way to limit the restriction to events that are attended by young people. However, FDA has no desire to restrict manufacturers' abilities to contribute to the community by sponsoring athletic, cultural, or other events. Thus, the agency has narrowly tailored the restriction on sponsorship to use of brand identification because it presents the harm that FDA is trying to eliminate. For these reasons, FDA concludes that its restrictions on sponsorship are consistent with its legal authority and with the First Amendment.

(92) Several comments (including one from a participant in motorsport events) argued that allowing tobacco companies to place brand names and logos at highly visible locations during broadcast sporting events has afforded tobacco companies the opportunity to circumvent the Cigarette Act, which prohibited broadcast advertising of cigarettes. One comment stated that tobacco companies receive millions of dollars of free brand name television and radio exposure during these events and use messages in these advertisements that are particularly effective with children. One comment stated that "the degree to which sponsoring events gives tobacco companies television time is staggering," and "[j]ust in the televising of the Indiana 500 [sic], Marlboro received almost 3½ hours of television exposure and 146 mentions of its brand name." The comment cited cases where Congress and the courts have already recognized and upheld the importance and the constitutionality of keeping tobacco advertising off the airwaves (*Capital Broadcasting Co. v. Mitchell*, 333 F. Supp. 582 (D.D.C. 1971), *aff'd sub nom. Capital Broadcasting Co. v. Acting Attorney General*, 405 U.S. 1000 (1972)), and concluded that a reviewing court would likely sustain the provision regarding event sponsorship simply because it has become a pervasive tool used by the tobacco industry to evade the restriction on television advertising.

The agency finds that there is adequate support for its ban on brand name sponsorship of events. As stated in the preamble to the 1995 proposed rule and in response to an earlier comment, "[t]he amount and financial value of television exposure gained by

a firm can be substantial." The preamble to the 1995 proposed rule cited two studies which discussed the impact of sponsoring televised events and concluded that:

[t]he impact of sponsoring televised events such as these automobile races is perhaps most apparent when one realizes that over 10 million people attended these events, while 90 times that number viewed them on television.

(60 FR 41314 at 41337)

By restricting brand name sponsorship of events, the final rule will eliminate those brand name sponsored events that continue to permit tobacco product brand names to appear on television.

(93) Several comments expressed concern that the 1995 proposed rule was not sufficiently inclusive; specifically, it did not prohibit the incorporation of an event in a brand name by someone other than the tobacco company and did not explicitly ban the use of the name of a foreign tobacco company in U.S. sport events. Some comments stated that restricting sponsorship of entertainment and sporting events to corporate name only for corporate sponsors that had been in existence prior to January 1, 1995, "leaves open many shadow entities incorporated under tobacco brand names because tobacco transnationals have been creating these front groups for years to escape promotion restrictions in other countries."

One comment stated that Canada, after it had banned brand name sponsorship, found that industry used new "corporations" such as Camel Racing PLC to continue sponsoring in a brand name. Thus, the comments recommended that the regulation ensure that corporate sponsorship of events be allowed only if the corporate name is the name of the manufacturing entity and that the name has no similarity to a brand name of any of that manufacturer's tobacco products.

Several comments expressed concern about a recent trend among U.S. manufacturers to develop brands that are made by a corporate entity. For example, one comment stated that RJR has developed a series of brands with an art deco style of pack design and is selling them through a wholly owned subsidiary named Moonlight Tobacco.

Another comment stated that Philip Morris has been test marketing a brand called "Dave's," which it produces through a boutique company named "Dave's Tobacco Company." These comments stated that the agency should amend the 1995 proposed rule to prohibit any corporate name or logo that

had a brand name or product identification within it.

Finally, a comment stated that there are many other existing brand names that are also corporate names, such as "Rothmans" and "Sampoerna" (a brand of clove cigarette (Kretek) imported from Indonesia) that are manufactured overseas. This comment argued that non-U.S. corporate names must also be included in the final rules proscription.

The agency recognizes the concern expressed by the comments. As stated in the preamble to the 1995 proposed rule, the requirement that the corporation be in existence on January 1, 1995, is intended to prevent manufacturers from circumventing this restriction by incorporating separately each brand that they manufacture for use in sponsorship (60 FR 41314 at 41336). The comments have suggested that manufacturers may circumvent this restriction by the use of shadow entities, many of which have already been incorporated under tobacco brand names in other countries (or have been incorporated as events). The agency agrees that the proposed restrictions do not prevent this type of circumvention.

Thus, in response to the comments' suggestions, the agency has modified the proposed regulations to reflect that the registered corporate name and corporation must have been in existence and registered in the United States and have been in active use in this country before January 1, 1995. Thus, FDA has modified § 897.34(c) to state: "Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered, and in use in the United States prior to January 1, 1995, \* \* \*." This provision makes clear that manufacturers are free to sponsor events in their corporate name but contains language that will prevent the type of circumvention of the restriction that was posited by the comments.

The agency also agrees with the comments that suggest that manufacturers may also attempt to circumvent this restriction by placing within the corporate name or logo elements of brand identification such as names (Smokin' Joe), colors (the tricolor decoration), etc. Tobacco products can be promoted using more than just the brand name. In fact, the name may be less important than the attractive

imagery, recognizable colors and patterns of colors (Marlboro), characters and heroes (Joe Camel racecar drivers) all of which provide the user with a desired image. A yellow motorcross bike with a head of a Camel conveys the image of Joe Camel without the name of the product. Therefore, it is necessary in order to break the link between the event and the product to restrict the images in addition to the name. Thus, FDA has modified § 897.34(c) so that it concludes with the following statement:

“\* \* \* and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco products.”

The agency also recognizes that at some time in the future, corporate entities may be formed to sell tobacco products, which are new to the tobacco business and in no way associated with current manufacturers. Should those entities desire to sponsor events, they would be precluded by the language of § 897.34(c) from doing so. The agency envisions that such entities could petition the agency, under 21 CFR part 10, for an exemption from this provision.

(94) One comment stated that FDA's proposed ban on brand-name sponsorship is an unjustified limitation on the right of private individuals to select their own sponsors.

This comment has misinterpreted the 1995 proposed rule. The rule does not limit the “right” of private individuals to select sponsors. Individuals are free to select any sponsor they choose. The rule, however, prohibits the event from including any brand name, logo, symbols, motto, selling message, or any other indicia of product identification similar or identical to those used for any brand of cigarette or smokeless tobacco. However, the final rule does not prevent corporate sponsors that were in existence and registered in the United States before January 1, 1995, from advertising in their registered corporate names.

(95) Several comments stated that sponsorship restrictions would have a negative impact on sports events. Approximately 300,000 copies of one form letter were submitted as comments. All included the statement: “I am 21 years of age or older and oppose the new regulations proposed by the Food and Drug Administration (Docket No. 95N-0253) that would prohibit tobacco company sponsorship

of entertainment and sporting events.” The form letter also stated that “If FDA gets control of tobacco and bans tobacco sponsorships, ticket prices could rise as well. And there might be fewer events. All this adds up to consumers being the big losers.”

One comment stated “I oppose any attempt by President or FDA to deny RJR the right to sponsor the Winston Cup Racing Series!” One comment stated “[b]y banning the sponsorship of NASCAR, the races won't get any money, and if they have to stop racing, that will make me mad, and I am too old to be getting mad—75 years [old].”

One comment stated that because of the potential loss of economic support, many events will not be viable if cigarette company sponsorship is no longer available. Several comments argued that FDA's proposed ban on sponsorship, promotional programs, and contests would eliminate events enjoyed primarily by adults. One comment stated that “[w]e believe that we and millions of other middle class fans like us, will no longer be able to afford the NASCAR we love.” One comment stated that the provision “will adversely affect the economy of the tobacco industry and that affects many people in many States, not just the racing industry and communities.”

One comment stated that the loss of sponsorship revenue to race track owners, operators, and promoters would negatively affect the motorsports industry because racing fans will suffer in the form of increased ticket prices or decreased services at motorsports events, and increased ticket prices will decrease attendance at race events, forcing racetrack operators to cut jobs and other employee benefits, further depressing the economies of hundreds of communities around the nation. The comment also stated that since motorsports injects hundreds of millions of dollars into local and regional economies, particularly in rural and suburban communities that have been the hardest hit by recession and job losses, FDA's proposed regulation would have a substantial impact on local and regional economies across the country and hurt the future of motorsports.

In contrast, one comment that supported the proposal was from a “dedicated car racer,” and stated that “the truth is that car racing will do just fine without tying its wonderful image to the interest of the cancer promoters.” The comment stated that:

in Europe where racing cars run without any cigarette advertising whatsoever, people

camp out for days trying to get into the events, and that the recent Formula One European Grand Prix was run in cold miserable, weather with packed stands and not a single cigarette logo in sight.

The comment stated that “I hope [FDA] will look out for the rest of us and stand firm in favor of a ban on tobacco advertising at all sporting events.”

One comment stated that “many of the millions of dollars spent on these promotions are available to the cigarette industry only because 3,000 children start smoking each day,” and “[t]his situation can be viewed as an industry demanding a bounty of 3,000 lives per day in exchange for its financial support of the sports, music, and other entertainment appealing to children and youth.”

One comment stated that:

the abundance of other sponsors indicates that auto racing would not fail if tobacco products are not allowed to be event sponsors and if teams sponsored by tobacco products are restricted to black and white uniform and car designs. Similar fears were expressed when cigarette commercials were banned from electronic media, but they proved groundless.

The comment stated that sponsors do not make a sport such as auto racing or rodeo popular because auto racing and rodeo are “compelling, popular spectator sports in their own right.” The comment stated that “popular sports attract sponsors who want to advertise.” The comment stated that “[t]he Olympics would remain a premier sporting event without Coca-Cola or Kodak” and “NASCAR stock car racing is among the most popular spectator sports to thrive.” The comment stated that “the audience is not there because of tobacco: tobacco is there because of the audience.”

The agency advises that the concerns expressed by some of these comments have misinterpreted the rule. The rule does not “prohibit tobacco company sponsorship of entertainment and sporting events” or “ban tobacco sponsorships, promotional programs, and contests.” The rule prohibits a sponsored event from being identified with a cigarette or smokeless tobacco product brand name or any other cigarette or smokeless tobacco brand identifying characteristic. All athletic, musical, artistic, or other social or cultural events would be permitted to be sponsored in the name of the tobacco company as long as the other conditions in § 897.34(c) are met.

In addition, the tobacco industry accounts for only 4 percent of all sponsored events. This rule does not prohibit the other 96 percent of

nontobacco forms of sponsorship (60 FR 41314 at 41337). Thus, even if the restriction on sponsorship of tobacco products resulted in a decrease of tobacco company sponsored events, the events will still exist through the support of the nontobacco forms of sponsorship. The agency agrees with the comment that "auto racing would not fail if tobacco products are not allowed to be event sponsors." Thus, restricting tobacco product brand name sponsorship clearly will not "ban all sponsorship events."

Finally, recent news stories quote persons knowledgeable about car racing saying racing would survive without tobacco sponsorship, for example, one quote: "If this happened 10 years ago, it would have been crushing to the racing industry. Now people are lining up to take Winston's place."<sup>250</sup>

In conclusion, FDA finds that sponsorship of events (such as car races, tennis matches, and rodeos) and entries in those events (race cars and drivers, tennis players) can have a profound effect on young people's attitude about and use of tobacco by providing multiple and prolonged exposure to the brand name and logo in a variety of media, thereby creating an impression of prevalence and normalcy about tobacco use (see section VI.D.3.c. of this document), by associating the product with varied positive events, images, and heroes, and by creating attractive and exciting images that can serve as a "badge" or an identification (see section VI.D.4.a. of this document). The industry itself recognizes the concern that sports figures as endorsers can create problems of hero worship and emulation; its Code promises not to employ sports or celebrity testimonials or those of others "who would have special appeal to persons under 21 years of age." Sponsorship creates no less of an association than an endorsement. Moreover, FDA finds that restrictions on sponsorship identified with a tobacco brand are necessary to reduce tobacco use by young people. These findings are based on studies and recent reports that the number of young people who attend these events or see them on television is significant and growing.

**Studies**—Four different studies, one each by Slade, Aitken, Ledworth, and Hock (60 FR 41314 at 41337 and 41338) and described further in this section,

provide evidence that sponsored events of all types are attended, and seen on television, by a substantial number of young people, and that the effect of the exposure is to increase brand awareness and association between the brand and the event. This attitude contributes to a sense of friendly familiarity about tobacco use and a perception that tobacco use is acceptable and common place.

Surveys on attendance and TV audience, described further in this section, establish that attendance by children at events and viewership by children and adolescents on television are significant. The preamble to the proposed rule used the number 64 million as an annual approximation of underage viewers of motorsport events in addition to those at the event (60 FR 41314 at 41337). In addition, newspaper articles detailed in this section describe the increasing importance of young people to sponsored events as a growing part of the live audience. Moreover, although less data is available on other types of sponsored events, comments received by the agency in response to the proposed rule, and described further in this section, state that many children and teenagers watch tennis, motorcycle and powerboat racing, and rodeos on television and attend and watch on television rock concerts and country music festivals.

Finally, the agency has tailored the restriction narrowly. The agency recognizes the importance of corporate sponsorship in engendering goodwill for a company with its customers and in providing support to sports, the arts, and music. Therefore, the agency has crafted the regulation to not interfere with this aspect of sponsorship but has merely denied the companies the right to use brand and product identification, which are most appealing to young people.

#### 9. Proposed § 897.36—False or Misleading Statements

The agency proposed in § 897.36 that labeling or advertising of any cigarette or smokeless tobacco product:

is false or misleading if the labeling or advertising contains any express or implied false, deceptive, or misleading statement, omits important information, lacks fair balance, or lacks substantial evidence to support any claims made of the product. This provision would have explicitly implemented sections 201(n), 501(a) (21 U.S.C. 351), and 502(q)(1) of the act. Section 897.36 was meant to be illustrative rather than exhaustive.

The agency stated in the 1995 proposed rule that its regulations

concerning prescription drug advertising provide great specificity as to what constitutes violative advertising (part 202 (21 CFR part 202)) but that this same degree of specificity is not practical in the case of a widely used consumer product like tobacco because the advertising for it contains an unlimited variety of claims that make categorization difficult. Therefore, the agency tentatively concluded that it would provide general guidance for the types of advertising claims that will be considered violative, rather than to attempt to identify every possible type of false and misleading claim (60 FR 41314 at 41339 and 41340).

(96) Several comments objected to various portions of the definition, for example the phrases "omits important information" and "lacks fair balance." They asserted that the phrases expand the definition of what constitutes "misleading" advertising, are subjective, and make compliance burdensome because the phrases are not defined. Moreover, the comment complained that neither "fair balance" nor "substantial evidence" were appropriately included in the definition of false and misleading.

Additionally, the comments argued that laws regarding false and misleading advertising are well established, and that false and misleading advertising is subject to the jurisdiction of the FTC. The comment stated that it was, therefore, inappropriate for FDA to establish vague and overreaching parameters of "unfair and deceptive" advertising.

One comment stated that what "information" is important is undefined. It stated that there is always information that someone may consider "important" (e.g., price, availability, freshness, taste research), and that it would be unreasonable to allow FDA, or any regulatory organization or entity, to review tobacco advertising in the capacity of determining information that should have been included. This comment argued that the legal precedent defining deceptive advertising is already established and should not be changed by FDA.

One comment stated that by introducing the word "important" into the proposed standard for misbranding of tobacco, FDA has impermissibly gone beyond the "materiality" test for misbranding set forth by Congress in section 201(n) of the act, acted arbitrarily and capriciously, and proposed a new standard that is unconstitutionally vague.

<sup>250</sup> Quoting Ardy Arani, a director of the Atlanta-based Championship Group, a sports marketing agency in Jacobsen, G., "Mass Merchandisers Jostle With Tobacco Companies to Cash in on the Auto Racing Craze," *The New York Times*, p. D71, February 21, 1996.



One comment stated that FDA also proposes that labeling or advertising would be false or misleading if it "lacks fair balance." It stated that FDA has obviously borrowed this concept from the prescription drug regulations (§ 202.1(e)(5)(ii)), but it is inapplicable to tobacco. The comment stated that, first, the "fair balance" requirement for drugs is based not on the section 502 "false or misleading" prohibition but rather on section 502(n)(3), which requires that prescription drug advertising contain a "true statement" relating to "side effects, contraindications, and effectiveness."

The comment stated that, second, as the drug regulation makes clear, the "fair balance" required is between information about a product's therapeutic benefits and information about its adverse effects when used. It stated that because no therapeutic claims are made for tobacco, the "fair balance" concept is simply inapplicable.

One comment, however, stated that, under this regulation, advertising for cigarettes and smokeless tobacco will be considered false or misleading if it "omits important information." It stated that this is a reasonable rule, and that it should be part of the final rule, but it is one that may be difficult for manufacturers to comply with absent guidance from FDA.

FDA has been persuaded that the proposed general guidance in proposed § 897.36 on what might constitute false and misleading advertising has created unintended confusion. Under section 502(a) and (q)(1) of the act, any restricted device is misbranded if its advertising or labeling is false or misleading in any particular. Section 201(n) of the act states that:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

After review of the applicable provisions of the act concerning labeling and advertising, the agency has determined that those provisions are adequate and that the definition in proposed § 897.36 is unnecessary.

Because cigarette and smokeless tobacco advertising remains subject to regulatory action if it is false or misleading in any particular, FDA has decided to delete § 897.36 from the final rule.

(97) Some comments supporting proposed § 897.36 recommended that specific restrictions be placed on advertising that emphasizes tar and nicotine levels and implies a weight benefit to tobacco products.

Other comments suggested requiring the disclosure of ingredients. These comments argued that consumers do not know the ingredients of these products or the functions that these ingredients serve. It added that consumers do not know the doses of nicotine and other critical materials that they ingest with these products. The comment stated that terms such as "light" and "low tar" have little meaning in view of the tendency of consumers to smoke cigarettes differently depending upon the way nicotine delivery has been engineered. A comment from a tobacco company opposed disclosure of ingredients fearing loss of valuable trade secret information.

The agency has decided that these comments fall outside the scope of this rulemaking. The agency did not propose labeling or advertising restrictions concerning the levels of tar, nicotine, or other components of cigarettes or smokeless tobacco, or perceived benefits of tobacco products, only that labeling or advertising not be false or misleading. It did not receive comments sufficient to warrant restrictions addressing these issues. Consequently, advertising and labeling claims will be evaluated on a case by case basis for compliance with sections 201(n), 502(a), (q), and (r), 510(j) (21 U.S.C. 360(j)), and 520(e) of the act. Therefore, FDA is not modifying part 897 to address these concerns at this time.

#### F. Additional First Amendment Issues

Finally, several general issues were raised by commenters concerning the nature of the protection afforded commercial speech by the First Amendment.

(98) One comment argued that the original understanding of the First Amendment was that truthful commercial messages are fully protected.

In response to this comment, FDA points out that the Supreme Court took the position that the First Amendment does not protect commercial speech (see *Valentine v. Chrestensen*, 316 U.S. 52 (1942)), until it repudiated that position in *Virginia State Bd. of Pharmacy v.*

*Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). Since 1976, the Court has decided numerous cases, most recently *Rubin v. Coors, Florida Bar v. Went For It, Inc.*, and 44 *Liquormart Inc. v. Rhode Island*, that address the level of protection afforded commercial speech by the First Amendment. FDA has followed that case law in its development of this final rule. Therefore, FDA has developed this final rule in accordance with the applicable law.

(99) A comment filed by an association of advertising agencies warned that the proposed regulations "establish a dangerous precedent that could open the floodgates to dramatic government intrusion into the process of communication \* \* \* and [are] a dangerous blueprint for government censorship of other kinds of advertising." The comment expressed concern that regulations of advertising for tobacco products will permit, in fact will encourage, the future regulation of other "controversial products."

Tobacco products are not "controversial" products as these comments contend. They represent the single most preventable cause of death in the United States (1989 Report to the Surgeon General at p. i). Not only is the harm caused by tobacco use real (the comment refers to "imagined harm"), but the product that produces the disease and death is addictive. Moreover, tobacco use begins among young people, who may be able to describe the risks of tobacco use, but who do not personalize that risk to themselves. These young people begin to use tobacco before they can adequately weigh the consequences of use and thus, become addicted and subject to the real long term harms caused by tobacco use. That is why all 50 States and the District of Columbia outlaw the sale of tobacco products to those under 18 years of age. Finally, as discussed in section VI.D. of this document, advertising does affect young people's decision to use tobacco products in a significant and material way. This is not an "assertion" made out of whole cloth but a reality. Thus, regulation of tobacco advertising may set a precedent for future government action, but it sets a high threshold for such regulation.

The Supreme Court has granted ample protection to commercial speech, but the Court has also stressed, nothing in the First Amendment prevents the Government from ensuring "that the stream of commercial information flows cleanly as well as freely." (See *Edenfield*

v. *Fane*, 506 U.S. 761, 768.) One comment noted: "This concern takes on special force where, as here, crucial public health concerns are implicated, and where a particularly powerful seller \* \* \* has used its virtually limitless resources to saturate the marketplace with its promotional messages."

The Government's interest in protecting the health of children and teenagers through measures designed to prevent them from beginning a lifetime of addiction and disease is of the highest order and is sufficient justification for the restrictions finalized here.

## VII. Education Campaign

In the Federal Register of August 11, 1995 (60 FR 41314), the Food and Drug Administration (FDA) proposed to require that tobacco companies establish a national education program, using television as its predominant medium, to discourage children and adolescents from using cigarettes and smokeless tobacco (the 1995 proposed rule). The agency received more than 1,500 comments concerning the program, nearly three-quarters of which favored going forward with it. The comments raised many issues concerning the program as proposed, including whether the proposed funding would be either equitable or sufficient, whether industry's level of involvement would jeopardize its effectiveness, whether current industry educational programs are sufficient, about the design of the educational programs, the manufacturer's obligations to carry them out, the agency's statutory authority to require an education campaign under section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(e)), and the constitutionality of the campaign as proposed.

The agency has reexamined its statutory authority for requiring an education campaign and believes that section 518(a) of the act (21 U.S.C. 360h(a)) is more appropriate and practicable than the restricted device authority in section 520(e) of the act under which FDA had proposed the education campaign. Under section 518(a) of the act, if the agency finds that a device presents an unreasonable risk of substantial harm to the public health, that notification is necessary to eliminate this risk, and that no more practicable means is available under the act, then, after consultation with device manufacturers, the agency may issue a notification order that requires them to notify the appropriate persons in a form appropriate to eliminate the risk. The

agency has used section 518(a)'s separate, affirmative grant of statutory authority on a number of occasions to compel medical device manufacturers to provide notice to users or potential users of their products about risks presented by their use or misuse.

The agency believes that, with respect to cigarettes and smokeless tobacco, it could make the findings required by section 518(a) of the act and so could order tobacco manufacturers to notify young people about the substantial health risks that tobacco products present in a form appropriate to eliminate the risk. That is, the agency believes that it could find that cigarettes and smokeless tobacco present an unreasonable risk of substantial harm to the public health, that notification is necessary to eliminate this risk, and that no more practicable means is available under the act.

The agency has concluded, therefore, that it will not require an education campaign as part of this tobacco rule. The agency intends, however, to send letters that indicate that the agency believes that it could make the statutory findings necessary to issue notification orders under section 518(a) of the act to cigarette and smokeless tobacco manufacturers. As section 518(a) of the act requires, these consultation letters will offer tobacco companies an opportunity to consult with the agency about the necessity for, and specific requirements of, any notification orders before the agency issues any orders to the companies.

Because the education campaign will not be a requirement of this final rule, the agency need not respond to the many comments that it received concerning the proposed campaign. Nevertheless, because the agency intends to pursue implementation of an education campaign using the notification provision of section 518(a) of the act, the agency will respond briefly to comments that questioned the effectiveness and design of the proposed education campaign.

(1) The agency received comments questioning the effectiveness of other educational campaigns and the agency's use of these campaigns to support the position that a national educational campaign would be effective in helping reduce tobacco use among young people. Comments from the tobacco industry argued that studies cited by FDA are scientifically flawed and therefore that the agency overstated the likely effects of the provision. One industry comment argued that FDA

misinterpreted a study by Simonich<sup>251</sup> (the Simonich study), cited in the preamble to the 1995 proposed rule to demonstrate that the media campaign conducted under the Fairness Doctrine (FD) reduced cigarette consumption by 6.2 percent (60 FR 41314 at 41327). The comment concluded that the data from the Simonich study indicated that the overall effect of the Fairness Doctrine was merely a 0.4 percent decline in per capita consumption.

FDA disagrees with the industry's interpretation of the Simonich study. The agency believes that the Simonich study results, correctly interpreted, indicate that the FD education campaign reduced per capita cigarette consumption an average of 4.5 percent,<sup>252</sup> that is, a 4.5 percent reduction in consumption over the period of time over which the FD was in effect for entire quarters. Thus, the FD education campaign did play an important role in reducing per capita cigarette consumption.

(2) Comments also questioned the effectiveness of education programs cited by the agency. The tobacco industry's comment argued that California's \$26 million multi-year media campaign actually confirmed that televised education campaigns do not influence youth smoking. Further, the comment stated that it was not possible to say what impact, if any, a national media campaign's introduction or termination had on consumption in Greece because Greece's educational television and radio advertising campaign was only one element of an overall education campaign.

With regard to the California media campaign, FDA notes that this campaign was directed to adults, not young people. Moreover, the media campaign was countered by increased per capita spending by the tobacco industry in the types of imagery-based advertising that influences children and adolescents. Therefore, the agency would have expected the media campaign to have had a greater negative impact on tobacco use by adults than by children and

<sup>251</sup> Simonich, W. L., "Government Antismoking Policies," Peter Lang Publishing, Inc., 1991.

<sup>252</sup> Simonich modeled the effect of the FD as: %  $\Delta$  Consumption =  $-0.063(X_t + .46416X_{t-1} + .46416^2X_{t-2} + .46416^3X_{t-3})$  where  $X_t$  represents antismoking advertising expenditures in quarter  $t$  and  $-0.063$  is the coefficient for the FD stock variable obtained from the analysis (*Id.*, p. 153). FDA used Simonich's model and his "Estimated Fairness Doctrine Real Advertising Expenditure per Capita 14+" data series (*Id.*, pp. 250, and 259-260) to calculate the quarterly percent reduction in per capita cigarette consumption from March 1967 through April 1970. The average percent reduction in consumption for this period was 4.5 percent.

adolescents. FDA continues to believe that California's efforts indicate that education campaigns, over time, can counter and reduce the impact of prosmoking efforts.

Further, while the comment correctly notes that Greece's national effort to reduce smoking included posters, booklets, and similar educational materials distributed through schools, health centers, and other channels, the primary and most significant element of its program consisted of antismoking messages broadcast on television and radio. FDA continues to believe the Greek experience indicates, as stated in the preamble to the 1995 proposed rule, that intensive education and media messages about the health risks associated with tobacco use can be effective.

(3) Many comments from the tobacco and media industries and from adult smokers argued that an education campaign is unnecessary because cigarette manufacturers, individually and through the Tobacco Institute, have undertaken voluntarily a variety of educational programs aimed at discouraging underage smoking, and because antismoking lessons are taught in schools.

By contrast, other comments questioned industry's commitment to reduce underage use of tobacco products. For example, several comments emphasized that a voluntary program run by industry in the mid 1980's failed to acknowledge that tobacco is addictive or causes disease.

FDA agrees with comments that the tobacco industry has failed to include in its voluntary youth educational programs important information, such as the addictive nature of tobacco and the association between tobacco use and disease. FDA further agrees that this lack of complete information about tobacco products makes it necessary to require that messages about the risks of tobacco use be directed to children and adolescents. The recently observed decline in the proportion of youth who see smoking as dangerous, despite the widespread dissemination through schools of information about the health hazards associated with tobacco use, supports the need for an immediate response to this problem. Moreover, recent evidence suggests that school-based education programs most effectively reduce underage smoking when used in conjunction with media messages.

#### VIII. Additional Regulatory Requirements

Subpart E of part 897 in the Food and Drug Administration's (FDA's) August 11, 1995, proposed rule (60 FR 41314) would have consisted of three provisions: § 897.40 would have required manufacturers to submit certain reports and would have required manufacturers, distributors, and retailers to make records available to FDA upon inspection; § 897.42 would have instructed manufacturers, distributors, and retailers to comply with any more stringent State or local requirements relating to the sale, distribution, labeling, advertising, or use of cigarettes and smokeless tobacco and would have notified State and local governments how to request an advisory opinion concerning the preemptive effect of part 897 on any particular State or local requirement; and § 897.44 would have required the agency to take additional regulatory measures if, 7 years after the date of publication of the final rule, the percentage of people under age 18 who smoke cigarettes had not decreased by 50 percent since 1994 and/or the percentage of males under 18 who use smokeless tobacco had not decreased by 50 percent since 1994.

Proposed § 897.40 Records and Reports, would have implemented sections 510(j) and 704(a) of the act (21 U.S.C. 360(j) and 374(a)) with respect to cigarettes and smokeless tobacco. Section 510(j) of the act requires the submission of labels, labeling, and a representative sampling of advertising to FDA, and section 704(a) of the act gives the agency inspection authority, which also includes the authority to examine records, files, papers, processes, controls, and facilities: bearing on whether \* \* \* restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act.

Proposed § 897.42 Preemption of State and Local Requirements and Requests for Advisory Opinions, was intended to reflect the preemption provision in section 521(a) of the act (21 U.S.C. 360k(a)); that section states, in relevant part, that:

no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which

relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

Proposed § 897.42 was also intended to recognize that many States and local governments have enacted innovative and effective laws and regulations pertaining to cigarettes and smokeless tobacco and to encourage further activity in these areas (60 FR 41314 at 41340).

In proposed § 897.44 Additional Regulatory Measures, FDA recognized that many different factors influence a young person's decision to start smoking or to use smokeless tobacco and that the affected industries have historically shown their ability to find new ways of promoting their products whenever restrictions were imposed (60 FR 41314 at 41341). Consequently, to guard against the possibility that its comprehensive regulations might be circumvented and to give firms an incentive to take appropriate actions to discourage cigarette and smokeless tobacco sales to people under 18, the agency proposed to require additional regulatory measures if the outcome-based objectives specified in proposed § 897.44 were not met.

In response to comments and upon further examination of existing statutory and regulatory requirements, the agency has deleted §§ 897.40, 897.42, and 897.44 from the final rule.

#### § 897.40—Records and Reports

Proposed § 897.40(a) would have required each manufacturer to submit, on an annual basis, copies of all labels (or a representative sample of labels if the labels would be similar for multiple products), copies of all labeling, and a representative sample of advertising. Proposed § 897.40(b) would have provided an address for such materials.

(1) The agency received a number of comments from distributors, wholesalers, and retailers stating that it would be too costly and time-consuming, and thus too burdensome for small businesses to submit the information required by proposed § 897.40(a) and further, that the information collected would not be useful in prohibiting young people from using tobacco products.

These comments misread proposed § 897.40(a) by interpreting the section to apply to distributors of tobacco products. By its terms, this provision only applied to manufacturers of cigarettes and smokeless tobacco. FDA agrees with the comments that it is unnecessary for the agency to receive labels, labeling, and a representative

sampling of advertising for cigarettes and smokeless tobacco handled by distributors. In order to clarify this point further, FDA has deleted proposed § 897.40(a) and (b), and is explicitly exempting distributors of cigarettes and smokeless tobacco from the registration requirement in section 510 of the act. Exempting distributors from the registration requirement results in their exemption from the record submission requirements in section 510(j) of the act. The agency has amended the existing device registration and listing regulations in part 807 by adding a new provision, at § 807.65(j), to reflect this exemption.

FDA is authorized, under section 510(g)(4) of the act, to exempt persons from the requirement of registering under section 510 of the act. The agency agrees with the comments discussed above that stated that reporting by distributors would be too burdensome and would not result in any useful information. FDA believes that it will receive all the information it needs from manufacturers, who are required to list information with FDA under section 510 of the act. Further, there was virtually no public comment supporting a registration and listing requirement for distributors. Based on these considerations, FDA finds that it is appropriate to exempt distributors of cigarettes and smokeless tobacco, as defined in § 897.3(c), from the registration requirement in section 510 of the act as originally proposed because compliance with section 510 of the act by distributors "is not necessary for the protection of the public health."

A comment from the cigarette industry argued that § 897.40(a) was inconsistent with the recordkeeping requirements in part 807 (21 CFR part 807) (the device registration and listing regulations) by requiring annual submissions. A comment from a public health organization supported proposed § 897.40, and stated that the reporting requirements were the same as those faced by other manufacturers of drug delivery devices.

Cigarette and smokeless tobacco manufacturers are required to register and list under section 510 of the act. Upon consideration of the industry comment, the agency believes it is more appropriate for manufacturers to comply with the existing device registration and listing requirements in part 807 than to create new requirements in this regulation. Therefore, as stated earlier, FDA has deleted proposed § 897.40(a) and (b) from the rule.

(2) A comment from the country's largest association of health professionals supported proposed § 897.40, but suggested that FDA expand the reporting requirements to have each manufacturer monitor brand-specific uptake by children and adolescents. The comment suggested that these data could be used to supplement information from the Monitoring the Future project and other surveys that do not currently contain brand-specific data. The comment also stated that cigar and loose-leaf tobacco manufacturers should be required to monitor and report on use of their products by people under 18.

The agency declines to accept the comment's suggestions. FDA believes it is not necessary to obtain such data at this time. Rather, it is more appropriate to allow the provisions of the final rule to become effective and to monitor the effectiveness of the program before considering the addition of new requirements. FDA also notes that it is not asserting jurisdiction over cigars; cigar manufacturers are not subject to the requirements of this rule.

Proposed § 897.40(c) would have required manufacturers, distributors, and retailers to make records and other information available to FDA inspectors for purposes of inspection, review, copying, or any other use related to the enforcement of the act.

(3) An industry comment argued that proposed § 897.40(c)—which required manufacturers, distributors, and retailers to "make all records and other information collected under this part and all records and other information related to the events and persons identified in such records" available to FDA officials—so exceeds FDA's authority that it fails the test set out in *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950), and, therefore, violates the Fourth and Fifth Amendments to the Constitution. The comment argued that § 897.40(c) may require the release, for example, of marketing strategies, sales figures, profits, personnel data, and proprietary information.

FDA disagrees with this comment, but nevertheless, the agency has deleted § 897.40(c). Part 897 does not add records requirements beyond those applicable to devices generally under existing regulations, e.g., part 803 (21 CFR part 803) (medical device reporting), part 804 (21 CFR part 804) (medical device distributor reporting), part 807 (registration and listing), and part 820 (21 CFR part 820) (good manufacturing practice). Section

897.40(c), as proposed, is therefore unnecessary, since FDA retains the records, reports, and inspection authority with respect to cigarettes and smokeless tobacco that it has with respect to other restricted devices. This authority is found, for example, in sections 510, 519, 702, 703, and 704 of the act (21 U.S.C. 360, 360i, 372, 373, and 374). In particular, section 704 of the act explicitly authorizes the agency to inspect records regarding restricted devices, including records and reports (and the related research) required under section 519 of the act, shipment data, and data as to the qualifications of technical and professional personnel performing functions subject to the act, except that such inspections may not extend to financial, sales, pricing, or other personnel and research data.

Warrantless inspections of drug and device manufacturers authorized by section 704 of the act are "reasonable" and therefore consistent with the Fourth Amendment, in part because section 704 delineates the scope of inspections with respect to prescription drugs and restricted devices. (See *United States v. Jamieson-McKames Pharmaceuticals*, 651 F.2d 532, 538 and n.9 (8th Cir.), *cert. denied*, 455 U.S. 1016 (1981).)

In particular, section 704 of the act meets the test established by the Supreme Court, and cited in the comment, that is applied to scrutinize administrative subpoenas under the Fourth Amendment's proscription of unreasonable searches and seizures and the Fifth Amendment's Due Process Clause: "the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant" (*Morton Salt*, 338 U.S. at 652 (regarding order requiring report about compliance with earlier agency order); see also *EEOC v. Shell Oil Co.*, 466 U.S. 54, 72 n.26 (1984) (citing *Morton Salt* regarding administrative subpoena); *Reich v. Montana Sulphur and Chem. Co.*, 32 F.3d 440, 448 (9th Cir. 1994) (same), *cert. denied*, 115 S.Ct. 1355 (1995); *Resolution Trust Corp. v. Walde*, 18 F.3d 943, 946 (D.C. Cir. 1994) (same)).

The comment stressed that § 897.40(c) as proposed failed to satisfy the first part of the *Morton Salt* test because the act does not grant FDA authority to regulate tobacco products and because Congress has repeatedly refused to give FDA such authority. As discussed in detail in the 1996 Jurisdictional Determination annexed hereto, FDA is extending jurisdiction over tobacco products by a lawful application of the act. Moreover, the records, reports, and

inspection provisions in sections 510, 519, 702, 703, and, in particular, section 704 of the act, clearly specify the agency's authority to inspect regarding restricted devices, including records and reports required pursuant to section 519 of the act. An inspection of records from manufacturers, distributors, or retailers regarding tobacco products—which are restricted devices and which pursuant to this rule are subject to the reporting requirements of parts 803 and 804—is therefore “within the authority of the agency” as required by the Supreme Court in *Morton Salt* (338 U.S. at 652). Moreover, because sections 704 and 519 of the act define the scope of such requests, by their terms, such requests would meet the second and third parts of the *Morton Salt* test, since they would not be “too indefinite and the information sought [would be] reasonably relevant” to enforcement of the provisions of part 897 (*Id.*).

Even in the absence of proposed § 897.40(c), manufacturers, distributors, and retailers of cigarettes and smokeless tobacco are subject to the same records access and inspection requirements as are any manufacturers, distributors, and retailers of restricted medical devices. As discussed in this section, these requirements are fully consistent with the Fourth and Fifth Amendments.

(4) Several comments from distributors and retailers asserted that the recordkeeping requirements in proposed § 897.40(c) would be expensive and especially hard on small businesses. A few comments also claimed that proposed § 897.40(c) would not affect sales to children and adolescents, but would instead result in lost business as distributors or retailers would have to take the time to prepare and to maintain records. A small number of comments simply opposed proposed § 897.40(c) without providing any reason or said it was “offensive,” “intrusive,” or would not produce any useful information during an inspection.

As stated previously in this section, FDA has revised the rule to delete § 897.40(c) entirely. The agency believes that the existing reporting requirements in other regulations (such as part 803 for medical device reporting (as amended by this rule), part 804 for medical device distributor reporting (as amended by this rule), part 807 for registration and listing (as amended, to exclude distributors of cigarettes and smokeless tobacco), and part 820 for good manufacturing practices) make proposed § 897.40(c) unnecessary. The agency has also amended the rule to exempt distributors of cigarettes and

smokeless tobacco from part 807. Thus, distributors are only expected to comply with the medical device distributor reporting requirements in part 804.

Retailers have no recordkeeping or reporting requirements under part 897.

Notwithstanding these changes to the rule, FDA believes that the comments misunderstand the purpose of recordkeeping and reporting. The records and reports that were described in the 1995 proposed rule were never intended to have a direct role in reducing illegal sales to children and adolescents. Neither were they intended to divert distributor or retailer staff to ministerial functions or to intrude into business activities. To the contrary, records and reports can help firms and FDA ensure compliance with the regulations. For manufacturers, distributors, and retailers, records and reports demonstrate whether they have complied with a particular requirement. Records are especially valuable in this respect because FDA's enforcement strategy relies heavily on site inspections to determine whether a party has complied with a statutory or regulatory requirement, and records can show or help an agency inspector determine whether a firm has a good compliance history. Firms that have good compliance histories usually are inspected less frequently than others, whereas firms with poor compliance histories may be inspected more frequently or more rigorously.

Inspections have other important benefits for firms. Inspections can reveal areas where firms can improve their operations. Inspections also apply to firms equally, regardless of their size, so firms that manufacture, distribute, or sell the same or similar products meet the same conditions or requirements. Furthermore, inspections, and FDA enforcement generally, give consumers greater assurance in the products they purchase because those products are held to the same standards or requirements.

For FDA, records and reports can provide information on current industry practices and trends, help identify potential problems in a regulatory program or in a firm's or industry's practice, and even conserve agency resources by letting the agency concentrate its inspection efforts on firms with poor compliance histories.

Thus, for these reasons, FDA disagrees with those comments suggesting that recordkeeping and reporting requirements or FDA inspections will have no useful purpose.

#### § 897.42—Preemption of State and Local Requirements and Requests for Advisory Opinions

(5) FDA received several comments that opposed proposed § 897.42, claiming that it was inconsistent with the process for requesting exemptions from the preemption requirement in section 521 of the act. The agency also received some comments supporting proposed § 897.42 precisely because it would have recognized and would have preserved more stringent State and local requirements.

After careful consideration and closer review of the act, the agency has deleted proposed § 897.42 from the rule. This issue is addressed in greater detail in section X. of this document.

Under § 897.44 of the 1995 proposed rule, FDA would have established goals of a 50-percent reduction in cigarette use by individuals under the age of 18 years; a 50-percent reduction in smokeless tobacco use by males under the age of 18 years; and no increase in smokeless tobacco use by females under the age of 18 years. The agency stated it would take additional regulatory measures if these goals were not met 7 years after the publication date of the final rule.

FDA derived its outcome-based goals from the “Healthy People 2000” objectives. “Healthy People 2000” sets national health promotion and disease prevention objectives for Americans. The report was a joint effort by the U.S. Public Health Service (PHS), the Institute of Medicine (IOM) at the National Academy of Sciences (NAS), almost 300 national membership organizations such as the American Medical Association (AMA), the American Academy of Pediatrics (AAP), and the Blue Cross and Blue Shield Association, and all State health departments. “Healthy People 2000” established a basic goal to reduce by half the initiation of cigarette smoking by children and youth by the year 2000.

The agency proposed measuring progress toward the stated goals by use of an objective, scientifically valid, and generally accepted survey, such as the Monitoring the Future Project (MTFP). MTFP, funded by the National Institute on Drug Abuse (NIDA) and administered by the Institute for Social Research at the University of Michigan, has collected data on daily smoking by 12th graders every year since 1976 and on smokeless tobacco use by 12th graders for the years 1986 to 1989 and 1992 to 1995.

The agency did not include any specific additional requirements in the

1995 proposed rule, but stated that FDA would propose specific additional measures when it publishes a final rule and invited public comment on what additional requirements should be considered.

The agency received a number of comments arguing that the agency should wait until it knows specifically what progress has been made toward the goals before proposing additional regulatory measures. This approach would allow the agency to identify specific barriers to achieving the goals and to tailor any additional requirements to these barriers. Other comments argued that FDA must provide the public an opportunity to comment on specific additional regulatory measures before they would take effect. FDA has decided that there is merit to these comments. At this time, therefore, the agency is not proposing additional regulatory measures beyond the restrictions in this regulation and the requirements under section 518 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h). The agency instead plans to monitor industry compliance with the agency's requirements as well as the progress made toward meeting the stated goals of reducing the use of tobacco products by individuals under the age of 18 within 7 years. In the event that additional measures are necessary to achieve the goals, the agency retains the authority to propose and issue additional regulatory requirements in a future rulemaking proceeding.

FDA received approximately 60 individual comments related to this provision, about evenly divided in support and opposition. Opposition came primarily from the tobacco manufacturing and advertising industries and from tobacco retailers. Comments from several State legislators also opposed additional measures, as did one from a State department of agriculture. Some comments maintained the provision was invalid and unconstitutional; others objected that "when regulations fail, the answer is not more regulations."

Support for the measure came from national health organizations, State health departments, and individuals who identified themselves as parents, public health professionals, educators, and former smokers. Supporters stressed the importance of effective measures to improve the health of current and future generations.

(6) One comment opposing the proposed provision contended that imposing additional regulatory

measures at the time that the final rule is published would be unreasonable because it would not permit a flexible response to future circumstances. It argued, for example, that the same additional regulatory measures "apparently would be triggered at the specified date regardless of whether the reduction in the next 7 years is 49.8 percent or 2 percent."

Several comments in support of the provision also advocated greater flexibility, but for different reasons. Because of the serious adverse health effects linked to the use of tobacco products, these comments urged the agency not to wait 7 years to evaluate progress and institute corrective measures. Instead, they recommended interim or ongoing review of compliance with the regulations and progress toward achieving the goals.

FDA agrees it is useful to put in place a system that will allow flexibility in responding to future circumstances. Therefore, the agency has decided to review on an ongoing basis the effectiveness of specific provisions. It will rely on data from the MTFP and other surveys recognized as using sound methodology to help measure compliance with the provisions, detect loopholes, and evaluate progress in achieving the goals. This will permit FDA to identify problem areas in a timely manner and seek public comment on whether additional measures should be considered.

(7) Some comments objected to any further restrictions. Others argued specifically against further advertising restrictions, saying it is illogical to impose such additional measures without first considering and attacking other causes for continued smoking among youth. A few comments were concerned that the proposed provision would inevitably result in a complete ban of all tobacco products, with a few of those charging that this was FDA's true intent.

One comment objected to the agency announcing as part of a final rule specific measures it will impose, rather than simply propose, some time in the future, maintaining that " \* \* \* the agency will have failed to provide meaningful notice and opportunity to comment."

Many comments supported additional regulatory measures, if needed, to achieve the desired reductions in tobacco use by young people. Some advocated further restrictions on advertising, including: (1) Eliminating all tobacco product advertising except for point-of-purchase announcements of

product availability limited to black and white text only; (2) prohibiting all point of purchase advertising; (3) eliminating direct mail marketing for cigarettes and smokeless tobacco; (4) prohibiting all outdoor advertising; (5) prohibiting advertising in publications marketed to youths, and possibly revising the definition of "adult publications"; and (6) outlawing all marketing of cigarettes and smokeless tobacco. One comment recommended plain packaging of cigarettes, and one suggested broadening the proposed education program.

Comments also proposed additional sales restrictions on tobacco products, including stringent licensing requirements, increasing the age of sale to 19, and selling cigarettes in cartons only.

FDA rejects the comments suggesting that the agency intends to eventually ban all tobacco products, as the agency has repeatedly stated that such an outcome is not the appropriate public health response under the act. FDA is not proposing the additional restrictions on advertising or access suggested in the comments because FDA does not anticipate at this time that these additional measures will be required.

## IX. Implementation Dates

The Food and Drug Administration (FDA) has concluded that the provisions of this rule should become effective 1 year after its date of publication in the Federal Register, with three exceptions. A 6-month effective date is established for the requirements in § 897.14(a) and (b) prohibiting retailers from selling cigarettes or smokeless tobacco to persons under age 18 and requiring retailers to check photographic identification of young purchasers for proof of age. The requirement in § 897.34(c) prohibiting sponsorships using cigarette or smokeless tobacco brand names or other indicia of product identification will be effective 2 years from the date of publication of this final rule. Finally, manufacturers will be required to comply with the registration and listing requirements in part 807, and the good manufacturing practice requirements in part 820, 2 years from the date of publication of this final rule.

Although the agency specifically requested comment on when the various provisions in the proposed rule should become effective, FDA received relatively few comments on this subject.

(1) One comment that opposed the rule argued that FDA should give industry an opportunity in a hearing to challenge the "factual underpinnings"

of the rule before proceeding to implementation. In contrast, a supporting comment strongly favored immediate action to implement the rule, and a second comment stated that postponing implementation by even a year "means that another 500,000 young people will become regular users of tobacco products." Another supporting comment recommended that the effective date for provisions that prohibit sales to persons under 18 be no more than 90 days from the date the final regulations are issued, and that the effective date for provisions affecting advertising and labeling be 6 months from the date the final regulations are issued.

FDA is not persuaded that a hearing is needed on the "factual underpinnings" of the rule. In the preamble to the 1995 proposed rule, the agency provided its rationale and evidentiary basis for each provision of the regulation; interested persons have had a full opportunity to submit their comments and any factual supporting data for the agency to consider. Informal notice and comment rulemaking does not require more. Moreover, the agency believes that there would be little to gain from holding such a hearing, and that this step would needlessly delay implementation of the final rule. Full responses to the challenges made by this and other comments on the factual bases for the rule are provided in this document.

Because FDA has found that thousands of children purchase cigarettes every day, the agency agrees with the supporting comments that restrictions on such sales should be put into effect as soon as possible. FDA recognizes, however, that the States also have laws restricting youth access to tobacco products, some of which may be preempted under section 521 of the act by this final regulation. The agency intends to allow sufficient time for applications for exemption from preemption to be requested, considered by the agency, and acted upon. Therefore, FDA has determined that § 897.14(a) and (b), which prohibit the sale of tobacco products to individuals under the age of 18 and require retailers to examine a photographic identification to ensure that the purchaser is at least 18 years of age, and is basic to the goals of this final rule, will become effective 6 months from the date of publication of this final rule in the Federal Register. This should allow adequate time for the agency to process the applications for exemption from preemption while not unduly delaying

the implementation of a very important part of the regulation.

(2) As for the recommendation by one comment that the advertising and labeling provisions of the rule become effective 6 months after the final rule is issued, FDA believes that this period of time is not consistent with the agency's policy of allowing sufficient time for affected entities to learn about and comply with new regulatory requirements. Instead, based on its own experience and that of other Government agencies in regulating product advertising and labeling, FDA has arrived at a period of 1 year from the date of publication of this final rule in the Federal Register for manufacturers, distributors, and retailers to meet most of the requirements of the rule. In reaching this conclusion, FDA has taken into consideration the time needed to comply with all the requirements of the rule, including time for designing new labeling and advertising, for printing or filming these new materials, for affixing new product labels and disseminating new advertising materials, and for using up existing inventories of products, supplies of promotional materials, and coupons that do not comply with the new requirements.

Examples of activities that will become violative and must cease 1 year from the date of publication of this rule in the Federal Register include vending machine sales of cigarettes and smokeless tobacco and sales from self-service displays (except in the narrowly-defined locations that are exempted), sales of single cigarettes from opened packages ("loosies"), sales of packages with fewer than 20 cigarettes, mail-order redemption of coupons for tobacco products, distribution of free tobacco samples, and the sale or distribution of nontobacco items showing the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern or colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Examples of additional requirements that must be met 1 year from the date of publication include all advertising requirements (except as noted below), and the requirement that manufacturers not use a trade or brand name of a nontobacco product on a cigarette or smokeless tobacco product except as specified in § 897.16(a).

The agency is excepting from the 1-year implementation period the requirement that manufacturers comply with the existing registration and listing

requirements, found in part 807. The agency recognizes that manufacturers are not accustomed to complying with these recordkeeping and reporting requirements and will require additional time in which to develop appropriate compliance procedures. Therefore, FDA is granting manufacturers 2 years from the date of publication of this final rule to begin complying with the requirements under part 807. The same reasoning has led the agency to allow manufacturers the same 2-year-period to prepare before they are required to comply with the good manufacturing practice requirements in part 820.

Finally, the agency is also excepting from the 1-year implementation period the prohibitions in § 897.34 (c) of sponsorship using cigarette or smokeless tobacco brand names or other indicia of product identification. The agency recognizes that sponsorship of events is often arranged well in advance and that some event promoters may be disadvantaged if they are not allowed adequate time to replace tobacco sponsors who elect to cease sponsoring the event, rather than switch to their corporate name. Accordingly, this final rule provides that § 897.34(c) will become effective 2 years from the date of publication of this final rule.

#### X. Relationship Between the Rule and Other Federal and State Laws

This section of the document discusses issues concerning the relationship between this rule and other Federal and State laws. More specifically, sections X.A. and X.B. of this document analyze comments that addressed the potential effect upon this rule of other Federal statutes that contain express provisions that restrict some areas of Federal regulation of tobacco products. Section X.C. of this document analyzes comments that raised the issue of whether this rule conflicts with the congressional purpose behind the current regulatory scheme for tobacco products. Section X.D. of this document analyzes comments that addressed the issue of whether Congress intended for the current regulatory scheme for tobacco products to be exclusive, such that this rule might be foreclosed. Finally, sections X.E. and X.F. of this document analyze comments that addressed the preemptive effect under the Federal Food, Drug, and Cosmetic Act (the act) that the Food and Drug Administration's (FDA's) regulation of tobacco products as drug delivery devices will have upon



State and local requirements and upon State product liability claims.

*A. The Federal Cigarette Labeling and Advertising Act*

(1) A number of comments argued that FDA's August 11, 1995, proposed rule (60 FR 41314) (the 1995 proposed rule) is precluded by section 5 of the Federal Cigarette Labeling and Advertising Act (the Cigarette Act (15 U.S.C. 1334)). Other comments expressed the opposite view, stating that 15 U.S.C. 1334 did not preclude the 1995 proposed rule. Some of the comments that found no preclusion noted that the scope of 15 U.S.C. 1334 is narrow, and applies only to cigarette packages, thereby allowing for regulation of cigarette advertising and promotion as contemplated by the 1995 proposed rule. After considering all of the comments, FDA has concluded that none of the rule's provisions, as embodied in the final rule, is expressly precluded by the Cigarette Act. The following analysis explains this conclusion.

The Cigarette Act contains the following provisions pertaining to regulation of cigarettes:

(a) No statement relating to smoking and health, other than the statement required by [15 U.S.C. 1333], shall be required on any cigarette package.

(b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

(15 U.S.C. 1334 (emphasis added))

15 U.S.C. 1334(b) is expressly limited to requirements or prohibitions imposed under State law, that relate to advertising or promotion of cigarettes. Thus, 15 U.S.C. 1334(b) is inapplicable to FDA's regulation under part 897 and does not foreclose FDA from regulating cigarette advertising or promotion.

15 U.S.C. 1334(a), which applies to statements on the cigarette package, extends to both Federal and State regulation. However, the scope of 15 U.S.C. 1334(a) is narrow, precluding Federal and State regulation of cigarettes only to the extent that such regulation would require any statement (other than the statement required by 15 U.S.C. 1333) "relating to smoking and health" to appear on the cigarette package.

There are two types of information that the final rule requires on cigarette packages. The first is the "established name," such as "Cigarettes," which is required by section 502(e)(2) of the act (21 U.S.C. 352(e)(2)), and which the

agency is implementing under § 897.24. The established name requirement is applicable to all devices regulated under the act, and it serves merely to aid consumers in the identification of the product.

The second type of information that the final rule requires on cigarette packages is the statement of intended use and age restriction required under § 897.25. This statement informs consumers about the products' intended uses and that the products may not be sold to persons under the age of 18.

Neither the established name nor the statement of intended use and age restriction is "relat[ed] to smoking and health." Any indirect relationship these requirements might have to smoking and health is incidental and would be too "tenuous, remote, or peripheral" to trigger preclusion under 15 U.S.C. 1334(a). (See *District of Columbia v. Greater Washington Bd. of Trade*, 113 S. Ct. 580, 583 n.1 (1992) ("Pre-emption does not occur \* \* \* if the [law at issue] has only a 'tenuous, remote, or peripheral' connection with [the subject to which preemption is applicable], as is the case with many laws of general applicability") (citations omitted).) To find otherwise could render the limiting language of 15 U.S.C. 1334(a) meaningless. (See *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. 1671, 1677 (1995) (finding that overly broad construction of the phrase "relate to" "would \* \* \* read Congress's words of limitation as mere sham, and [would] read the presumption against pre-emption out of the law whenever Congress speaks to the matter with generality").)

The agency notes that the established name requirement under § 897.24 is analogous to requirements imposed by the Bureau of Alcohol, Tobacco and Firearms (BATF) on cigarette packages. Under 26 U.S.C. 5723(b), "[e]very package of tobacco products \* \* \* shall \* \* \* bear the marks, labels, and notices, if any, that the Secretary by regulation prescribes." Under this statutory provision, BATF has issued regulations requiring, for instance, that "[e]very package of cigarettes shall \* \* \* have adequately imprinted thereon, or on a label securely affixed thereto, the designation 'cigarettes', the quantity of such product contained therein, and the classification for tax purposes, i.e., for small cigarettes, either 'small' or 'Class A', and for large cigarettes, either 'large' or 'Class B'." (See 27 CFR 270.215.) In the same way that the requirement under 27 CFR

270.215 does not run afoul of 15 U.S.C. 1334 because it does not relate to smoking and health, the established name requirement under § 897.24 is also not precluded.

Further guidance on the scope of preclusion under the Cigarette Act can be found in the legislative history and purpose behind the Cigarette Act. The history and purpose make clear that Congress intended 15 U.S.C. 1334 to preclude only those "statements" that constituted warning or cautionary statements on cigarette packages. (See *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2618-19 (1992) (finding that "no statement relating to smoking and health" language in 1965 version of the Cigarette Act referred to the sort of warning provided for in section 4 of that statute).)<sup>253</sup> (See also H. Rept. 449, 89th Cong., 1st sess. (1965), reprinted in 1965 U.S. Code Cong. & Admin. News 2350, 2350 (the Cigarette Act prohibits "the requirement of any other caution statement on the labeling of cigarettes under laws administered by any Federal, State, or local authority").)

Clearly, neither § 897.24 nor § 897.25 is a warning or cautionary statement of the type Congress intended to preclude under 15 U.S.C. 1334. Accordingly, the requirements under these sections of the final rule are not foreclosed by the Cigarette Act.

*B. The Comprehensive Smokeless Tobacco Health Education Act*

(2) Several comments noted that the 1995 proposed rule would prohibit advertisements for smokeless tobacco from appearing in certain locations and media. One comment stated that any prohibition on advertising under the 1995 proposed rule amounts to a "compelled absence of advertising," and is as much a "statement relating to the use of smokeless tobacco and health" as is an explicit message requirement. Thus, the comment asserted that such restrictions are expressly precluded by the Comprehensive Smokeless Tobacco Health Education Act (the Smokeless Act).

<sup>253</sup> Some of the comments take issue with FDA's application of Federal-State preemption law, pointing out that the Supremacy Clause and Tenth Amendment upon which this law is based have no application in determining the relationship between different Federal statutes. FDA is fully aware that Federal-State preemption law, as well as those cases such as *Cipollone* that apply it, do not directly govern the present situation concerning preclusion of Federal regulations by Federal law. However, the principles contained in Federal-State preemption law provide some general guidance for determining the scope of preclusion intended by Congress, regardless of whether that preclusion is directed at State or Federal law.

Another comment stated that FDA's proposed restrictions on the advertising of smokeless tobacco are foreclosed because they directly affect such advertising in a manner that is "so nearly identical" "in purpose and effect" to the advertising requirements mandated by the Smokeless Act that they fall within that statute's express prohibition of any other Federal "statement" related to smoking and health. In contrast, some comments stated the position that the 1995 proposed rule is not expressly precluded by the Smokeless Act.

After considering all comments, FDA has concluded that none of the 1995 proposed rule's provisions, with one exception, is expressly precluded by the Smokeless Act. The following analysis explains this conclusion.

The Smokeless Act contains the following provision pertaining to regulation of smokeless tobacco:

*No statement relating to the use of smokeless tobacco and health, other than the statements required by [15 U.S.C. 4402], shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.*

(15 U.S.C. 4406(a) (emphasis added))

15 U.S.C. 4406(a) precludes only "statement[s]." Most requirements under the final rule, such as those that limit the locations or media in which smokeless tobacco may be advertised, do not constitute "statements" within the meaning of 15 U.S.C. 4406(a). (See *Banzhaf v. Federal Communications Commission*, 405 F.2d 1082 (D.C. Cir. 1968) (holding that the FCC ruling was not precluded by the Cigarette Act because the ruling did not require inclusion of any "statement \* \* \* in the advertising of any cigarettes"), *cert. denied*, 396 U.S. 842 (1969).) Thus, those sections of the final rule that limit the location or media in which smokeless tobacco may be advertised, as well as other requirements in the final rule that do not actually mandate an affirmative statement, are not expressly precluded by the Smokeless Act.

Only three sections of the final rule actually require inclusion of a "statement" on the packaging or in the advertising of smokeless tobacco. These sections are §§ 897.24, 897.25, and 897.32(c). In addition, proposed § 897.36, which is being omitted from the final rule for reasons discussed later in this section, would have required such a statement.

As with cigarettes, § 897.24 requires that packages of smokeless tobacco bear the products' established names.

Section 897.25 mandates, in part, that packages of smokeless tobacco bear a statement of the products' intended uses and age restriction. Section 897.32(c) requires that advertising for smokeless tobacco include the products' established names and statements of their intended uses. (See section 502(r)(1) and (r)(2) of the act.)

For reasons similar to those discussed with regard to the Cigarette Act, none of the statements required under §§ 897.24, 897.25, and 897.32(c) are precluded under 15 U.S.C. 4406(a). (See section X.A. of this document.) First, the required statements do not directly "relat[e] to the use of smokeless tobacco and health." Second, the required statements are not "statements" of the sort precluded by 15 U.S.C. 4406(a) because they do not convey any type of cautionary message or warning of the sort Congress intended to foreclose. Accordingly, the statements are not precluded by 15 U.S.C. 4406(a).

Proposed § 897.36 would have declared the labeling or advertising of cigarettes and smokeless tobacco to be false or misleading if it contained "any express or implied false, deceptive, or misleading statement, omit[ed] fair balance, or lack[ed] substantial evidence to support any claims made for the product." Upon review of the comments and reconsideration of this provision, FDA believes that, in some instances, manufacturers of smokeless tobacco might have been required under FDA's proposed rule to incorporate a statement relating to the use of smokeless tobacco and health on the package or in the advertising of a smokeless tobacco product in order to correct an omission of important information or a lack of fair balance. Similarly, cigarette manufacturers might have been required to include a statement relating to smoking and health on the cigarette package. Such requirements would be precluded under the Smokeless Act or the Cigarette Act. Thus, FDA has omitted § 897.36 from the final rule.

The agency notes, however, that tobacco products, like other products regulated under the act, are still subject to section 502(a) of the act, which provides, in part, that a device shall be deemed to be misbranded "[i]f its labeling is false or misleading in any particular." Any requirement imposed under section 502(a) of the act upon tobacco products is limited, however, to the extent that it is precluded by the Smokeless Act or the Cigarette Act.

### *C. Conflict With Congressional Purpose Behind Current Regulatory Scheme For Tobacco Products*

A number of comments asserted that the 1995 proposed rule conflicts with other Federal statutes that regulate tobacco products. These comments focused on three specific statutes: The Cigarette Act, the Smokeless Act, and the Public Health Service Act (the PHS Act)

#### *1. The Cigarette Act and The Smokeless Act*

(3) A number of comments argued that the 1995 proposed rule would conflict with, and would nullify, some of the congressional objectives behind the Cigarette Act and the Smokeless Act. Based on the alleged conflict, some of the comments asserted that the general provisions of the act must give way to the specific provisions of the Cigarette Act and the Smokeless Act.

FDA disagrees. As explained in sections X.A. and X.B. of this document, FDA regulation of tobacco products under the authority of the act does not conflict with the Cigarette Act or the Smokeless Act, and thus such regulation is clearly capable of coexisting with these statutes. (See *Connecticut National Bank v. Germain*, 112 S. Ct. 1146, 1149 (1992) ("so long as there is no 'positive repugnancy' between two laws, a court must give effect to both") (citation omitted); *Morton v. Mancari*, 417 U.S. 535, 551 (1974) ("The courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective").)

The comments asserted a number of areas in which the 1995 proposed rule would allegedly conflict with Federal law and congressional intent:

(4) Numerous comments argued that the 1995 proposed rule is precluded because Congress, through enactment of the Cigarette Act and the Smokeless Act, intended to foreclose all Federal agencies other than the Federal Trade Commission (FTC) and the Federal Communications Commission (FCC) from regulating the labeling and advertising of tobacco products. Some of the comments criticized the 1995 proposed rule, asserting that it would cause tobacco product manufacturers to be held to separate and conflicting standards of conduct by different agencies, thus conflicting with congressional intent to prevent "diverse, nonuniform, and confusing cigarette

labeling and advertising regulations." As a specific example of potential separate and conflicting Federal standards, some of the comments noted that proposed § 897.34 would completely prohibit the use of some promotional items that are exempted by FTC from the congressionally mandated warning under the Cigarette Act.

FDA disagrees with these comments. When Congress enacted the Cigarette Act and the Smokeless Act, it very carefully considered the proper scope of preclusion applicable to Federal agencies in the regulation of tobacco products. The express terms of 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a) clearly reflect the full scope of preclusion of Federal agencies intended by Congress.

Had Congress believed more preclusion to be necessary, it could have easily expanded the express scope of 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a). (See *Banzhaf*, 405 F.2d at 1089 (Had Congress intended to foreclose other types of Federal regulation, "it might reasonably be expected to have said so directly—especially where it was careful to include a section entitled 'Preemption' specifically forbidding designated types of regulatory action"); *Central Bank of Denver v. First Interstate Bank*, 114 S. Ct. 1439, 1448 (1994) (Congress knows how to enact legislation expressly).) Indeed, Congress took this very approach with respect to the scope of preemption applicable to States under the Cigarette Act when it drafted 15 U.S.C. 1334(b) in a broad manner to encompass "requirement[s]" and "prohibition[s]."

The discrepancy in Congress' choice of words with regard to the scope of 15 U.S.C. 1334(a) and (b) is significant in its implications. By not including "requirement or prohibition" in 15 U.S.C. 1334(a) and expressly foreclosing only "statements" relating to smoking and health, Congress clearly intended to narrowly limit the scope of foreclosure of regulation applicable to Federal agencies. (See *Brown v. Gardner*, 115 S. Ct. 552, 556 (1994) ("[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion")) (citation omitted). In a similar fashion, Congress demonstrated an intent to restrict the scope of Federal preclusion under 15 U.S.C. 4406(a) by narrowly tailoring the language of that subsection.

Thus, given the narrow scope of 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a), the Cigarette Act and the Smokeless Act

do not foreclose "separate" Federal requirements, other than cautionary health-based statements as discussed in sections X.A. and X.B. of this document. Although the final rule imposes requirements on tobacco product manufacturers, these requirements do not conflict with the Cigarette Act or the Smokeless Act and, consequently, are not precluded by those statutes. Moreover, that FTC might allow certain actions under its statutory mandate does not preclude FDA from prohibiting such actions under a different statutory mandate. (See *New York Shipping Ass'n v. Federal Maritime Comm'n*, 854 F.2d 1338, 1367 (D.C. Cir. 1988) ("there is no anomaly if conduct privileged under one statute is nonetheless condemned by another"), *cert. denied*, 488 U.S. 1041 (1989).)

(5) Some of the comments asserted that Congress intended that the sole health-based restraints that were to be imposed on the commerce of tobacco products were to be those provided in the Cigarette Act and the Smokeless Act.

FDA disagrees with this assertion. First, FDA clearly may exercise legal authority to regulate tobacco products when the evidence establishes that the products have intended uses that fall within the act's definition of a "drug." Indeed, the agency has done so in several instances. (See, e.g., *United States v. 354 Bulk Cartons \* \* \* Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (cigarettes claimed to reduce weight were drugs because they were intended to affect the structure or function of the body); *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336, 338–39 (D.N.J. 1953) (cigarettes claimed to prevent respiratory diseases were drugs because they were intended to treat or prevent disease).) Moreover, the comments' assertion that health-based constraints can be imposed upon tobacco products only under the Cigarette Act and the Smokeless Act necessarily leads to the erroneous conclusion that much Federal and State regulation, such as health-based workplace smoking restrictions and health-based age limits on access, is foreclosed. As other comments recognized, Congress obviously did not intend for such broad preclusion to be the case. (See *Banzhaf*, 405 F.2d at 1089 (finding that "[n]othing in the [Cigarette Act] indicates that Congress had any intent at all with respect to other types of regulation by other agencies—much less that it specifically meant to foreclose all such regulation").)

(6) Some comments asserted that FDA's proposed restrictions on certain advertising for tobacco products are at odds with congressional intent to allow the continued use of advertising for these products in conjunction with the statutorily required warnings.

FDA disagrees. As discussed in sections X.A. and X.B. of this document, preclusion of Federal regulation of advertising for tobacco products is very narrow in scope and does not encompass FDA's final rule. Moreover, as one court has noted:

[T]here is no anomaly if conduct privileged under one statute is nonetheless condemned by another; we expect persons in a complex regulatory state to conform their behavior to the dictates of many laws, each serving its own special purpose. (*New York Shipping Ass'n*, 854 F.2d at 1367)

Thus, the mere fact that certain advertising for tobacco products is permitted under the current regulatory scheme for those products does not preclude FDA from placing restrictions on such advertising.

(7) Some comments alleged that the 1995 proposed rule would conflict with Federal law and congressional intent because it would have an impact on the commerce of tobacco products.

FDA disagrees. Any proscriptive regulation of tobacco products inevitably imposes economic burdens upon commerce of those products. Thus, following the comments' line of argument, all proscriptive regulation of cigarettes is foreclosed by the Cigarette Act and the Smokeless Act. As explained in this section, however, by enacting 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a), Congress chose the proper level of limitation on Federal regulations that it concluded was necessary to protect the commerce of tobacco products from being unduly economically burdened. Because requirements contained in the final rule are not precluded under those provisions, the fact that the requirements will have economic consequences upon the commerce of tobacco does not mean those requirements are foreclosed.

(8) One comment argued that the 1995 proposed rule is precluded because Congress could not have intended for any agency to have the authority to prohibit the sale of cigarettes. The comment derived this "intent" from pieces of legislation enacted by Congress that provide for the regulation of specific aspects of cigarettes but do not prohibit their sale.

FDA disagrees. Enactment of legislation giving other agencies authority over particular aspects of

cigarettes means only that Congress has decided to take those particular actions; it does not imply that Congress has determined that other Federal regulation is prohibited. Congress can implement policy in only one way: passage of a bill by the House and the Senate that is either signed by the President or approved by an overridden veto. (*INS v. Chadha*, 462 U.S. 919, 954–58 (1983); *Central Bank*, 114 S. Ct. at 1453.) Because Congress has not adopted any legislation that specifically prohibits FDA from regulating tobacco products, the final rule is not precluded.

In summary, FDA's final rule has been narrowly tailored so that it does not conflict with the existing statutory scheme governing tobacco products, and the final rule is not precluded.

## 2. The PHS Act

Section 1926 of the PHS Act conditions a State's receipt of the full amount of Federal block grants (to be used for prevention and treatment of substance abuse) upon the recipient State having in effect a law that makes it "unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18" (42 U.S.C. 300x-26(a)(1)).

(9) Some of the comments argued that section 1926 of the PHS Act demonstrates an intent on the part of Congress to preserve, and encourage enforcement of, State youth access restrictions. The comments asserted that because FDA regulation of youth access to tobacco products would have a preemptive effect upon some State regulation in this area, the 1995 proposed rule conflicts with this congressional intent. Accordingly, argued the comments, section 1926 of the PHS Act precludes FDA from regulating youth access.

While FDA agrees that section 1926 of the PHS Act indicates a congressional intent to encourage States to establish age limits on the purchase of tobacco products, neither the statute's language nor its legislative history prohibits Federal regulation of youth access. The restrictions in the final rule regarding the sale and distribution of tobacco products do not conflict with section 1926 of the PHS Act, and, in fact, facilitate the end result that Congress sought—reducing youth smoking—by "reducing the appeal of cigarettes and smokeless tobacco to, and limiting access by, persons under 18 years of age." (See 60 FR 41314 at 41321.) Accordingly, FDA's regulation of youth access is not precluded by the existence

of section 1926 of the PHS Act. (See 61 FR 1492, January 19, 1996.)

(10) One comment asserted that the 1995 proposed rule is precluded by section 1926 of the PHS Act because, "in the legislative process that led to enactment of [section 1926], Congress considered and rejected a variety of specific requirements of the very type that FDA now proposes." The Supreme Court, however, has made clear that courts are "'reluctant to draw inferences from Congress' failure to act.'" (*Brecht v. Abrahamson*, 113 S. Ct. 1710, 1719 (1993) (citations omitted).) The mere fact that Congress, in enacting section 1926 of the PHS Act, did not incorporate requirements of the type FDA is now imposing in no way precludes FDA's final rule which was issued under the agency's regulatory authority under the act.

## D. Occupation of the Field

(11) Numerous comments asserted that the 1995 proposed rule is impliedly precluded by the comprehensiveness of existing legislation relating to regulation of tobacco products. Several comments argued that Congress has specifically reserved the power to regulate tobacco for itself, and thereby has occupied the field. A number of comments asserted that the present system of congressional control over tobacco products precludes FDA regulation absent a new mandate from Congress.

FDA disagrees with these comments. The statutes enacted by Congress for regulation of tobacco products do not amount to a comprehensive scheme. Rather, they address only a few specific aspects relating to regulation of tobacco products. Moreover, even if Congress' actions in this area were "comprehensive," Congress clearly did not intend for regulation under the Cigarette Act and the Smokeless Act to be exclusive. (See *Banzhaf*, 405 F.2d at 1089 (finding that Congress did not intend to foreclose Federal regulation of cigarettes outside the narrow scope of preclusion contemplated by the Cigarette Act).) As explained in greater detail in sections X.A., X.B., and X.C. of this document, the statutes that the comments cite, whether viewed individually or collectively, do not preclude FDA from regulating tobacco products.

First, as some comments noted, Congress has not taken action to exclude from FDA's jurisdiction tobacco products that fall within the act's definitions of "drug" and "device." The face of the statute is the first place that a court must look to determine whether

Congress has spoken to a particular issue and whether congressional intent in regard to that issue is clear. (*Kofa v. INS*, 60 F.3d 1084, 1088 (4th Cir. 1995); *Metropolitan Stevedore Co. v. Rambo*, 115 S. Ct. 2144, 2147 (1995).) Under the act, FDA has jurisdiction over products that are intended to address disease or to affect the structure or any function of the body. (See section 201(g) and (h) of the act, 21 U.S.C. 321(g) and (h); 60 FR 41314 at 41463.) Thus, the relevant language of the act—"intended to affect the structure or any function of the body"—does not on its face exclude tobacco products.

Congress is able to exclude and has excluded specific products, including tobacco products, from a statute's reach when it wishes to do so. For example, Congress has expressly excluded other products from FDA's jurisdiction under the act. (See, e.g., section 201(i) of the act (21 U.S.C. 321(i)) (excluding "soap" from definition of "cosmetic"); section 201(s) of the act (excluding "color additive" from definition of "food additive").) Moreover, Congress has expressly excluded tobacco products from the reach of other regulatory statutes. (See, e.g., 15 U.S.C. 2052(a)(1)(B) (Consumer Product Safety Act); 15 U.S.C. 1261(f)(2) (Federal Hazardous Substances Act); 15 U.S.C. 2602(2)(B)(iii) (Toxic Substances Control Act); 21 U.S.C. 802(6) (Controlled Substances Act); 15 U.S.C. 1459(a)(1) (Fair Packaging and Labeling Act).) Indeed, tobacco is excluded from the definition of "dietary supplement" under the act, but no similar exclusion appears in the definition of "drug" or "device." See section 201(g), (h), and (ff) of the act (21 U.S.C. 321(g), (h), and (ff)). The absence of an express exclusion for tobacco products from the act's definitions of "drug" and "device" eviscerates the contention that Congress clearly intended to preclude FDA from regulating tobacco products.

Second, as recognized by some comments, the fact that statutes such as the Cigarette Act and the Smokeless Act delegate some regulatory authority over tobacco products to other Federal agencies does not preclude FDA's rule. Numerous Federal agencies have overlapping and complementary jurisdiction that arises from their differing missions and expertise. (See, e.g., *Rueth v. EPA*, 13 F.3d 227, 228 (7th Cir. 1993) (EPA and Army Corps of Engineers have concurrent jurisdiction under the Clean Water Act); *Public Utility Dist. No. 1 v. Bonneville Power Admin.*, 947 F.2d 386, 395 (9th Cir. 1991) (FERC has concurrent jurisdiction

with other Federal agencies as well as States over hydroelectric projects), *cert. denied*, 112 S. Ct. 1759 (1992); *United Packinghouse, Food and Allied Workers Int'l Union v. NLRB*, 416 F.2d 1126, 1133–34 n.11 (D.C. Cir.) (NLRB and EEOC have concurrent jurisdiction over racial discrimination claims), *cert. denied*, 396 U.S. 903 (1969).) As discussed in section X.C. of this document, the fact that several agencies are already charged with regulating certain aspects of tobacco does not preclude FDA from asserting jurisdiction for different purposes. (See *Banzhaf*, 405 F.2d at 1089 (“Nothing in the [Cigarette Act] indicates that Congress had any intent at all with respect to other types of regulation by other agencies—much less that it specifically meant to foreclose all such regulation”).)

In conclusion, FDA's final rule is not precluded by the existing regulatory scheme for tobacco products.

#### *E. Preemption of State and Local Requirements Under Section 521(a) of the Act*

Under proposed § 897.42, State or local requirements that are more stringent than, and do not conflict with, requirements imposed under FDA's final rule would not have been preempted under section 521 of the act (21 U.S.C. 360k).

(12) Several comments supported the intended exclusion from preemption under proposed § 897.42, noting that it is essential that State and local officials retain the ability to enact and enforce laws which they believe are most effective when actively enforced at the local level.

In contrast, several comments took issue with the proposed exclusion and asserted that regulation of tobacco products by FDA as drug delivery devices would result in the preemption of State and local laws. The comments characterized the “blanket” exclusion from preemption under proposed § 897.42 as being at odds with the statutory preemption established by section 521(a) of the act and with the exemption procedures established by section 521(b) and by FDA's regulations.

Several comments argued that proposed § 897.42 would conflict with congressional intent behind the act. One comment noted that preemption under section 521(a) of the act was intended to establish national uniformity in medical device regulation, protecting such products from onerous burdens on interstate commerce created by a patchwork of State and local

requirements. The comment argued that the proposed exclusion from preemption would cause uniform Federal standards to become displaced by diverse State and local requirements. Another comment asserted that, by allowing more stringent State and local requirements, proposed § 897.42 was at odds with the act because Congress did not intend for FDA's device regulations to be minimum standards; rather, it intended for those regulations to be the governing standards unless local circumstances justified an exception.

Finally, one comment pointed out that the 1995 proposed rule would permit only those State and local requirements that are at least as “stringent” as the requirements imposed under FDA's rule. The comment asserted that FDA may not preempt any State laws, however, without first showing a “clear and manifest congressional intent” to authorize preemption of those State laws.

As a preliminary matter, two points of clarification are necessary. First, proposed § 897.42 would not have caused State and local laws to become Federal requirements, as one of the comments anticipated. Rather, the 1995 proposed rule would have allowed State and local laws to remain in force subject solely to State or local enforcement.

Second, proposed § 897.42 would not have “resuscitated” State and local laws that would otherwise be preempted by the Cigarette Act or the Smokeless Act, as some of the comments anticipated. Instead, the exclusion from preemption in proposed § 897.42 would have applied only to preemption under section 521 of the act.

Upon consideration of all of the comments relating to proposed § 897.42, the agency recognizes that significant concerns have been raised with regard to the validity of FDA's proposed preemption exclusion for all more stringent State and local legislative enactments. Most notably, the agency concurs that the notice and comment process of the current rulemaking does not provide the type of opportunity for an oral hearing contemplated under section 521(b) of the act. In light of this concern, FDA has deleted proposed § 897.42.

The agency's 1995 proposed rule to exclude all more stringent State and local requirements from any preemptive effect under this rule was based on a recognition of the pioneering and continuing role in the area of regulation of youth access to tobacco products that States have played, particularly certain active tobacco-control States. Federal

cooperation with, and continued reliance upon, innovative and aggressive State and local enforcement efforts is essential.

FDA believes the requirements it is establishing in this final rule set an appropriate floor for regulation of youth access to tobacco products but do not, as a policy matter, reflect a judgment that more stringent State or local requirements are inappropriate. For example, FDA chose 18 as the age below which cigarettes and smokeless tobacco may not be marketed to children and adolescents. This choice reflected a finding that all but four States have a comparable restriction which addresses the most vulnerable population. However, many comments argued that a higher age would be more effective. While FDA has decided not to establish an age above 18 in the final rule, the agency may, under the exemption process established under section 521(b) of the act, defer to those States that conclude that a higher age is more effective and that apply for an exemption.

In implementing section 521 of the act, FDA has historically interpreted that provision narrowly and found it to have preemptive effect only for those State and local requirements that in fact clearly impose specific requirements with respect to specific devices that are manifestly in addition to analogous Federal requirements. (See § 808.1(d) (21 CFR 808.1(d)).) Moreover, section 521 of the act “does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act” (§ 808.1(d)(2)).

The agency's assertion of jurisdiction over tobacco products does not preclude any State or local requirements other than those expressly preempted by section 521(a) of the act. Moreover, consistent with FDA's interpretation of section 521(a) of the act, only a limited number of State and local requirements are preempted and even those may qualify for exemption from preemption under section 521(b) of the act.

Examples of State and local laws FDA believes are preempted, consistent with its longstanding approach to implementing section 521 of the act, are the following:

- *More stringent age restrictions*—Three States restrict cigarette sales to anyone under 19 years of age, and one State has 21 years as the minimum age. These restrictions are preempted because they are more stringent than the final rule, which prohibits sales only to individuals under age 18.

• *Restrictions on the distribution of free samples of tobacco products*—

Approximately 40 States, the District of Columbia, and many local governments restrict the distribution of free samples of tobacco products. For example, Nebraska bans samples, coupons, and rebate offers for smokeless tobacco. Oklahoma and several other States prohibit the free distribution of tobacco to individuals under 18 and within 500 feet of schools, playgrounds, or other locations used primarily by individuals under 18. Approximately 12 States restrict where free samples may be distributed. These restrictions are preempted to the extent that they are different from, or in addition to, the final rule, which prohibits any distribution of free samples.

• *Restrictions on placement of vending machines*—Most States, the District of Columbia, and several local governments impose restrictions on the placement of vending machines. These restrictions are preempted to the extent that they are different from, or in addition to, the final rule, which prohibits the use of vending machines except in certain locations and under certain conditions.

• *Restrictions on outdoor advertising*—Restrictions on outdoor advertising are preempted to the extent that they are different from, or in addition to, the final rule, which restricts the location, format, and content of such advertising. For example, Ordinance 307, which was enacted by the Mayor and City Council of Baltimore, MD, prohibits the placement of any sign that “advertises cigarettes in a publicly visible location,” i.e., on “outdoor billboards, sides of building[s], and free standing signboards.” This ordinance was upheld by the Fourth Circuit in the face of a challenge based on preemption under the Cigarette Act and on First Amendment grounds. (See *Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore*, 63 F.3d 1318 (4th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2574 (1996).) Subsequently, the Supreme Court vacated judgment in *Penn Advertising* and remanded the case to the United States Court of Appeals for the Fourth Circuit for further consideration in light of *44 Liquormart, Inc. v. Rhode Island*, 116 S. Ct. 1697 (1996). If Ordinance 307 is ultimately upheld in its present form, it will be preempted under section 521 of the act to the extent that it is different from, or in addition to, the final rule.

• *Prohibitions and restrictions relating to free-standing displays*—Prohibitions and restrictions relating to free-standing

displays are preempted to the extent that they are different from, or in addition to, the final rule, which allows free-standing displays but restricts the location, format, and content of such displays.

• *Requirements relating to identification checks for purposes of age verification*—Requirements relating to identification checks for purposes of age verification are preempted to the extent that they are different from, or in addition to, the final rule, which requires identification checks for anyone under the age of 26.

Examples of State or local laws or regulations that are not preempted include:

• *Equivalent age restrictions*—Most States establish 18 years as the minimum age for purchasing cigarettes or smokeless tobacco. These restrictions are not preempted because they are equal to, or substantially identical to, requirements imposed under the final rule. (See § 808.1(d)(2).)

• *Restrictions on the sale or distribution of tobacco products*—Several local governments restrict the locations (such as public parks, public buildings, etc.) at which tobacco products may be sold or distributed. These restrictions are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to the locations at which tobacco products may be sold or distributed.

• *Restrictions on smoking in public places*—Approximately 48 states, the District of Columbia, and many local governments have some restrictions on smoking in public places. These restrictions are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to restrictions on smoking in public places.

• *Penalties on underage persons who purchase tobacco products*—These penalties are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to penalties on underage persons who purchase tobacco products.

• *Prohibition on use or possession of tobacco products by underage persons*—These prohibitions are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to prohibitions on the use or possession of tobacco products by underage persons.

• *Age restrictions on persons who sell tobacco products*—Some local governments have statutes or regulations that establish a minimum

age for persons selling tobacco products. These restrictions are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to age restrictions on persons who sell tobacco products.

• *Tobacco excise taxes*—All 50 States and the District of Columbia have excise taxes on cigarettes, and 42 States have excise taxes on smokeless tobacco. These excise taxes are not preempted because they are not “requirements applicable to a device” within the meaning of section 521(a) of the act. (See § 808.1(d)(8).)

• *Access-control mechanism requirements for vending machines*—Approximately six States and some local governments require access-control mechanisms on vending machines, such as locking devices or token acceptors. These requirements are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to access-control mechanisms for vending machines.

• *Posting of signs*—Approximately 24 States have statutes requiring certain parties to post signs at vending machines stating that sales to underage persons are prohibited. One State requires owners or operators of vending machines to post signs warning of the dangers of cigarette use during pregnancy. In addition, many local governments require that signs be posted in areas in which smoking is prohibited by law. These requirements are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to the posting of signs.

• *License requirements*—Some local governments impose license requirements upon retailers of tobacco products. These requirements are not preempted because they are not “requirements applicable to a device” within the meaning of section 521(a) of the act. (Cf. § 808.1(d)(3).)

The examples set forth above reflect the types of State or local requirements of which the agency is currently aware.<sup>254</sup> There may be other State or local requirements pertaining to cigarettes and smokeless tobacco. With regard to particular State or local requirements that are not described above, any State, political subdivision, or other interested party may, in accordance with § 808.5 (21 CFR 808.5),

<sup>254</sup> State Legislated Actions on Tobacco Issues, Coalition on Smoking OR Health, Bartelt, J., ed., December 31, 1995.

request an advisory opinion from the agency as to whether such State or local requirements are preempted.

State and local requirements that are preempted by the requirements of FDA's final rule may be exempted from preemption in accordance with section 521(b) of the act and its implementing regulation, part 808 (21 CFR part 808). Section 521(b) of the act and part 808 provide that FDA may, by regulation issued after notice and an opportunity for an oral hearing, exempt a State or local device requirement from preemption under such conditions as the Commissioner of Food and Drugs (the Commissioner), may prescribe if the requirement is: (1) More stringent than Federal requirements applicable to the device under the act; or (2) required by compelling local conditions, and compliance with the State or local requirement would not cause the device to be in violation of any requirement applicable under the act.

By a separate document to be published in the Federal Register, FDA will be informing all State and local governments that they may submit applications to exempt from preemption under section 521(b) of the act those State and local requirements pertaining to cigarettes and smokeless tobacco that are preempted by the final rule. A State or local requirement will be exempted from preemption under section 521(b) of the act if the State or local requirement: meets the exemption requirements established under that section and is consistent with the goals in the final rule. Exemptions from preemption that FDA grants apply only to preemption under section 521 of the act.

Because the issues raised by these applications for exemption will be similar or related, the Commissioner has determined that it would be advantageous for all concerned to propose a single regulation granting or denying exemptions for each particular State or local requirement, and, if necessary, to hold a single hearing covering all applications for exemption from preemption for requirements pertaining to cigarettes and smokeless tobacco. Although each application will be considered as part of a single proceeding, each individual application will be evaluated on its merits and the circumstances applicable to the particular submitting jurisdiction.

#### *F. Preemption of State Product Liability Claims Under Section 521(a) of the Act*

(13) Several comments asserted that, under section 521(a) of the act, State product liability claims would be

preempted if FDA asserts jurisdiction over tobacco products as drug delivery devices.

Based on FDA's understanding of the theories of recovery advanced in tobacco product liability cases, and the nature of the Federal requirements being established in the final rule, FDA does not expect any of these Federal requirements to preempt any tort claims relating to tobacco products. The following analysis explains this conclusion.

The Supreme Court recently held that the scope of preemption under section 521(a) with regard to State product liability claims is very narrow. Indeed, a plurality of the Court noted that "few, if any, common-law duties have been pre-empted by [section 521(a)]." *Medtronic, Inc. v. Lohr*, 64 U.S.L.W. 4625, 4634 (U.S. June 26, 1996) (Nos. 95-754 and 95-886) (plurality opinion).

Preemption occurs "only where a particular state requirement threatens to interfere with a specific federal interest." *Medtronic*, 64 U.S.L.W. at 4634. Thus, State requirements of "general applicability" such as State product liability claims are not preempted, except where they have "the effect of establishing a substantive requirement for a specific device" that is "different from, or in addition to," a specific requirement imposed under the act (§ 808.1(d); *Medtronic*, 64 U.S.L.W. at 4633-34). Moreover, Federal requirements must be "applicable to the device" in question, and they preempt State product liability claims only if the Federal requirements are "specific counterpart regulations" or "specific" to a "particular device" (§ 808.1(d); *Medtronic*, 64 U.S.L.W. at 4634).

In summary, FDA is aware of no tort claims against tobacco products that will be preempted by the Federal requirements being established in the final rule.

#### **XI. Miscellaneous Constitutional Issues**

##### *A. Takings Under the Fifth Amendment*

(1) Several industry, retail, and individual comments argued that parts of the regulations effect takings compensable under the Fifth Amendment's Takings Clause (the Takings Clause), which provides that "private property [shall not] be taken for public use, without just compensation." For example, comments argued that proposed § 897.34 will restrict or even prohibit tobacco manufacturers' use of their trademarks and copyrighted property, or that it will deprive industry members both of the goodwill generated by their sponsorship of sports and

cultural events and of valuable tobacco trademarks. Comments argued that § 897.16(a) effects a taking of intellectual property because it prohibits the use of nontobacco trademarks (with grandfathered exceptions) to market tobacco products. Several comments argued that § 897.16(c) effects a taking of vending machines and self-service displays, as well as contractual rights to place tobacco vending machines on other people's property. Comments argued that the requirement that advertising use only black text on white background in § 897.32(a) effects a taking because nonconforming signs—for buses and on billboards, for example—will have to be destroyed, as would tobacco advertisements on billboards and signs within 1,000 feet of schools and public playgrounds under § 897.30(b).

Comments also argued that the proposed ban on mail-order sales of tobacco products would effect a taking of mail-order businesses. Mail-order sales, however, are not prohibited under the final rule. Many retailers argued that the prohibition of self-service displays and the corresponding requirement that tobacco products be shelved behind sales counters violate the Fifth Amendment.

The Food and Drug Administration (FDA) disagrees that any of these provisions effects a taking in violation of the Fifth Amendment.

In its final form, § 897.16(a) prohibits manufacturers from using the trade or brand name of a nontobacco product as the trade or brand name of a cigarette or smokeless tobacco product, with the exception of those names on both tobacco and nontobacco products that were sold in the United States on January 1, 1995. In its final form, § 897.16(c) prohibits the use of vending machines and self-service displays to sell cigarettes and smokeless tobacco, except that vending machines (including those that sell packaged, single cigarettes) and self-service displays may be used to sell these tobacco products in adult-only establishments. (As proposed in the 1995 proposed rule, § 897.16(c) would have prohibited their use entirely.)

In its final form, § 897.30(b) prohibits tobacco product advertisements within 1,000 feet of a public playground or a secondary or elementary school. In its final form, § 897.32(a) permits only advertising that uses black text on a white background (except in adult publications and in facilities where persons under 18 are not present or permitted). In its final form, § 897.34(a)



prohibits the sale of nontobacco items or services that bear the brand names or other indicia of identification for cigarettes or smokeless tobacco. In its final form, § 897.34(c) prohibits the sponsorship of athletic, musical, cultural, or other social or cultural events in the brand names or other indicia of identification for cigarettes or smokeless tobacco.

A takings analysis begins with a determination of what interest a person has in the thing that is allegedly taken—in this case, in vending machines and self-service displays, copyrighted material, and trademarks and goodwill—and whether that interest “can be considered property for the purposes of the Taking Clause of the Fifth Amendment.” (See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1001 (1984).) If a cognizable property interest is identified, the Supreme Court has developed three factors for courts to consider in assessing whether a regulatory taking has occurred: (1) The character of the governmental action; (2) its economic impact; and (3) its interference with reasonable investment-backed expectations (*Id.* at 1005).

#### 1. The Interests at Issue

Some of the interests affected by the final rule—vending machines, self-service displays, and existing nonconforming advertising on signs and billboards, for example—is tangible property, whereas contract rights, trademarks and goodwill, and copyrighted material (e.g., the nonconforming copyrighted material on signs and billboards) affected by these provisions are intangible property interests.

Tangible personal property—such as vending machines, self-service displays, and signs and billboards advertising tobacco products—is property for purposes of the Takings Clause (see *United States v. General Motors Corp.*, 323 U.S. 373, 383–84 (1945)), although personal commercial property is afforded less protection than real property under the Takings Clause (see, e.g., *Lucas v. South Carolina Coastal Council*, 112 S. Ct. 2886, 2899 (1992)).

Intangible interests may be compensable under the Takings Clause as well. For example, in *Ruckelshaus*, the Supreme Court determined that trade secret information—which is intangible—was property compensable under the Takings Clause. The Court noted that the extent of the property right in trade secret information “is defined by the extent to which the

owner of the secret protects his interest from disclosure to others,” (that is, it is property only insofar as others are excluded from its use) and that it has “many of the characteristics of more tangible forms of property”—for example, trade secret information is assignable, it can form the res of a trust, and it passes to a trustee in bankruptcy (*Ruckelshaus*, 467 U.S. at 1002).

Vending machine owners may have contracts that give them exclusive rights to sell tobacco products at a particular location. These contract rights would typically be assignable, they may form the res of a trust (see, e.g., *Wadsworth v. Bank of California*, 777 P.2d 975, 978 (Or. Ct. App. 1989)), and rights of action based upon them can become part of a bankruptcy estate (e.g., *In re Ryerson*, 739 F.2d 1423, 1425 (9th Cir. 1984)). (See also U.C.C. 9–106.) Such vending machine owners’ contracts may therefore create contract rights that would be compensable property under the Takings Clause.

Material can be copyrighted if it is an original work of authorship—such as written, musical, pictorial, or graphic work—that is fixed in a tangible medium of expression from which the work can be reproduced (17 U.S.C. 102(a)). By Federal statute a copyright is assignable (17 U.S.C. 201), and there are rights to exclusive use (17 U.S.C. 106), subject to certain limitations (17 U.S.C. 107–20) and enforceable through infringement actions (e.g., 17 U.S.C. 501). A copyright can form the res of a trust (*Bartok v. Boosey & Hawkes, Inc.*, 523 F.2d 941, 948 (2d Cir. 1975)) and it can become property of an estate in bankruptcy (*United States v. Inslaw, Inc.*, 932 F.2d 1467, 1471 (D.C. Cir. 1991), *cert. denied*, 502 U.S. 1048 (1992)). Sharing many of the characteristics of more tangible property, a copyright is also compensable property under the Takings Clause.

Trademarks are words, names, symbols, devices, or combinations thereof that a person uses, or intends to use and has applied to register, to identify or distinguish his or her goods from others on the market and to identify their source (15 U.S.C. 1127). The primary purpose of trademarks is to protect consumers by preventing deceitful marketing of one product or service as another. As the Supreme Court has stated,

[t]he law of unfair competition has its roots in the common-law tort of deceit: its general concern is with protecting consumers from confusion as to source. While that concern may result in the creation of “quasi-property rights” in communicative symbols, the focus

is on the protection of consumers, not the protection of producers as an incentive to product innovation.

(*Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 157 (1989))

When associated with goodwill, trademarks also share—with trade secret information and copyrights—the features of more tangible property. For example, the Lanham Act (15 U.S.C. 1053 *et seq.*) allows assignment of a trademark only “with the goodwill of the business in which the mark is used or with that part of the goodwill of the business connected with the use of and symbolized by the mark” (15 U.S.C. 1060). Indeed, when Congress amended the Lanham Act in 1988 to allow intent-to-use applications for registration of trademarks, it prohibited assignment of such applications to be “consistent with the principle that a mark may be validly assigned only with the business or goodwill attached to the use of the mark” (S. Rept. 515, 100th Cong., 2d sess. 31 (1988), reprinted in 1988 U.S.C.C.A.N. 5577, 5593–5594).

Owners of trademarks also have rights of exclusive use of marks—that is, against infringement—because “[b]y applying a trademark to goods produced by one other than the trademark’s owner, the infringer deprives the owner of the goodwill which he spent energy, time, and money to obtain” (*Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 854 n.14 (1982)). “Registration bestows upon the owner of the mark the limited right to protect his goodwill from possible harm by those uses of another as may engender a belief in the mind of the public that the product identified by the infringing mark is made or sponsored by the owner of the mark” (*Societe Comptoir de L’Industrie Cotonniere Etablissements Boussac v. Alexander’s Dep’t Stores, Inc.*, 299 F.2d 33, 36 (2d Cir. 1962)). Like trade secret information, a trademark can be the res of a trust (see *Coca-Cola Bottling Co. v. Coca-Cola Co.*, 988 F.2d 414, 430–432 (3d Cir. 1993)) and it can pass to the trustee in bankruptcy (*Inslaw*, 932 F.2d at 1471).

The agency notes that a trademark itself, unaccompanied by goodwill, lacks these characteristics of property. The agency therefore believes that a trademark itself is not property cognizable under the Takings Clause. Based on the foregoing analysis, however, the agency believes that a trademark and the accompanying goodwill together are property cognizable under the Takings Clause. These conclusions are consonant with the recognition that a trademark has

value as property for the owner "only in the sense that a man's right to the continued enjoyment of his trade reputation and the good will that flows from it, free from unwarranted interference by others, is a property right, for the protection of which a trademark is an instrumentality" (*Hanover Star Milling Co. v. Metcalf*, 240 U.S. 403, 413 (1916); see also S. Rept. 1333, 79th Cong., 2d sess. (1946), reprinted in 1946 U.S. Code Cong. & Admin. News 1274, 1277 ("the protection of trade-marks is merely protection to goodwill")).

Nevertheless, this conclusion must be reconciled with Supreme Court precedent on takings of goodwill. In particular, the comments cited *Kimball Laundry Co. v. United States*, 338 U.S. 1 (1949), for the proposition that the Takings Clause requires compensation for a regulatory taking of goodwill. The general rule is that the Takings Clause does not require compensation for goodwill when the Government takes a place of business because the business's goodwill may be transferred to a new place of business (338 U.S. at 11–12 and 15; see also *General Motors*, 323 U.S. at 379 (when Government permanently takes land, "compensation for that interest does not include \* \* \* [even] the loss of goodwill which inheres in the location of the land")). In *Kimball*, however, the Court allowed compensation for loss of a laundry business's goodwill, or going-concern value, incident to the physical taking of the laundry. It did so because the Government intended to operate the laundry temporarily during wartime, after which the laundry would revert to the business; the business could not invest in a new laundry because it would someday be the owner of two laundries, neither of which it could then operate profitably (338 U.S. at 14–15). The Court therefore likened the situation to those in which the Government takes a utility with the intention of operating it itself; the going-concern value of the utility is taken in those cases and is therefore compensable (*Id.* at 12–13).

*Kimball* and *General Motors* therefore indicate that goodwill is compensable under the Takings Clause only when no business remains after a taking to whose benefit the goodwill may inure. (See also *District of Columbia v. 13 Parcels of Land*, 534 F.2d 337, 349 & n.7 (D.C. Cir. 1976).) With respect to goodwill associated with a trademark, use of which is limited by a regulation, these cases indicate that the property interest may be compensable only if the

regulation allows no goodwill to inure to the benefit of the owner.

For purposes of the following analysis of whether the regulations effect a taking, the agency assumes that copyrighted material, the interests in trademarks and associated goodwill, contracts, self-service displays, vending machines, and tobacco advertising on signs and billboards are property interests that may be compensable under the Takings Clause if taken.

## 2. The Takings Analysis

[W]hat constitutes a "taking" for purposes of the Fifth Amendment has proved to be a problem of considerable difficulty. While this Court has recognized that the "Fifth Amendment's guarantee \* \* \* [is] designed to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole," this Court, quite simply, has been unable to develop any "set formula" for determining when "justice and fairness" require that economic injuries caused by public action be compensated by the government, rather than remain disproportionately concentrated on a few persons.

(*Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 123–24 (1978) (citation omitted) (alterations and deletions in original); Ruckelshaus, 467 U.S. at 1005) Still, the Supreme Court has identified three factors for courts to consider in assessing whether a regulatory taking has occurred: (1) The character of the governmental action; (2) its economic impact; and (3) its interference with reasonable investment-backed expectations (*Ruckelshaus*, 467 U.S. at 1005; *Penn Central*, 438 U.S. at 124).

The force of any one of these factors may be "so overwhelming \* \* \* that it disposes of the taking question" (*Ruckelshaus*, 467 U.S. at 1005 (finding interference with reasonable investment-backed expectations by use of trade secret information in pesticide approval process to be decisive)). So, for example, if the economic impact is to rob real property of "all economically beneficial uses," the regulation effects a taking (*Lucas*, 505 U.S. at 1019 (emphasis in original); see also *id.* at 1027–1028 (limiting holding to real property)). When examined in light of these three factors, FDA's proposed regulations do not effect a compensable taking under the Fifth Amendment of the Constitution.

## 3. The Character of the Governmental Action

With respect to the first factor, courts are more likely to find a taking when the interference with property can be

characterized as a physical invasion by the Government (e.g., *United States v. Causby*, 328 U.S. 256, 261–62 (1946) (characterizing Government's use of flight path just over property as physical invasion)) than when the interference is caused by a regulatory program that "adjust[s] the benefits and burdens of economic life to promote the common good" (*Penn Central*, 438 U.S. at 124). Courts have accorded particular deference to governmental action taken to protect the public interest in health, safety, and welfare. (See *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 488 (1987); *Penn Central*, 438 U.S. at 125–26; *Atlas Corp. v. United States*, 895 F.2d 745, 757–58 (Fed. Cir.), cert. denied, 498 U.S. 811 (1990).) In addition, the Supreme Court has repeatedly rejected compensation claims when the Government has regulated in order to prevent harmful activity:

The power which the States have of prohibiting such use by individuals of their property as will be prejudicial to the health, the morals, or the safety of the public, is not—and, consistently with the existence and safety of organized society, cannot be—burdened with the condition that the State must compensate such individual owners for pecuniary losses they may sustain, by reason of their not being permitted, by noxious use of their property, to inflict injury upon the community.

(*Mugler v. Kansas*, 123 U.S. 623, 669 (1887) (holding that State law prohibiting manufacture or sale of alcohol effected no taking of brewery even though law entirely destroyed brewery's beneficial use); see also *Keystone*, 480 U.S. 470 (1987) (no taking by law prohibiting mining of coal); *Goldblatt v. Town of Hempstead*, 369 U.S. 590 (1962) (no taking effected by regulation that closed gravel pit); *Miller v. Schoene*, 276 U.S. 272 (1928) (no taking effected by State-ordered felling of cedar trees); *Hadacheck v. Sebastian*, 239 U.S. 394 (1915) (no taking effected by ordinance prohibiting operation of brickyard in residential area); *Reinman v. City of Little Rock*, 237 U.S. 171 (1915) (no taking effected by ordinance prohibiting stable in residential area); *Powell v. Pennsylvania*, 127 U.S. 678 (1888) (no taking effected by law preventing manufacture of margarine)).

First, the final rule's interference with property interests cannot be characterized as a physical invasion of property. The final rule prohibits some uses of some types of property, but the Government is neither using nor acquiring property under the regulations (*Penn Central*, 438 U.S. at 128). For example, certain uses of vending

machines, self-service displays, and signs and billboards are prohibited, but the Government is itself neither using nor acquiring them. The same is true of the intangible property at issue, contracts, copyrights, and trademarks and the associated goodwill: The agency is prohibiting certain uses—indeed, all uses of tobacco trademarks on nontobacco items, including when tobacco companies have also registered the tobacco mark as a mark for nontobacco products or services—but the Government is not itself using these contract rights, copyrights, or trademarks (and thereby tobacco companies' goodwill). It "has taken nothing for its own use" (*Connolly v. Pension Benefit Guar. Corp.*, 475 U.S. 211, 224 (1986)).

Second, these final regulations seek to promote the public health by limiting access to tobacco products by consumers in the age group most likely to become addicted to them: Those under the age of 18. The regulations are intended to help reduce significantly the harms that use of tobacco products among this age group causes. They do so by prohibiting the sale of tobacco products to persons under the age of 18; that is, the regulations require modes of sale through which the retailer can verify the age of the purchaser or to which only those 18 or over will have access. In particular, the final rule permits vending machines and self-service displays and accompanying advertising only in places to which young people do not have access.

The final regulations also limit promotion of tobacco products to persons under the age of 18. They do so by prohibiting certain venues for tobacco advertising, namely, within 1,000 feet of schools and public playgrounds. They also require black text/white background advertisements in remaining venues with the exception of adult newspapers, magazines, periodicals, and other publications, and in adult-only establishments. They also prohibit use of tobacco trademarks on nontobacco products and in the sponsorship of events. As a consequence, use of tobacco industry trademarks, copyrights, and advertising techniques is limited, although not ended. Nonconforming signs and billboards will be prohibited, thereby reducing the remaining useful life of those currently in use when the regulations become effective. Use of nontobacco trademarks is limited only by prohibiting their use on tobacco products (except for nontobacco

trademarks used on tobacco products in the United States on January 1, 1995).

These regulations substantially advance, and are rationally related to, FDA's legitimate interest in promoting the public health and reducing harm by limiting both youth access to tobacco products and, as discussed in the context of the First Amendment, their promotion to youth. (See *Keystone*, 480 U.S. at 485; see also *Pace Resources, Inc. v. Shrewsbury Township*, 808 F.2d 1023, 1030 (3d Cir.) ("[T]he governmental action is entitled to a presumption that it does advance the public interest."), *cert. denied*, 482 U.S. 906 (1987).) Moreover, they are directed at stopping activity that is illegal in every State: Sales of tobacco products to those under the age of 18 (*Keystone*, 480 U.S. at 492 n.22). This factor of the takings analysis indicates that these regulations effect no takings.

#### 4. The Economic Impact of the Governmental Action

The second factor to consider is the economic impact of the governmental action. "There is no fixed formula to determine how much diminution in market value is allowable without the fifth amendment coming into play" (*Florida Rock Indus., Inc. v. United States*, 791 F.2d 893, 901 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1053 (1987)). It is clear, however, that a regulation's economic impact may be great without rising to the level of a taking. (See *Pace Resources*, 808 F.2d at 1031 (citing *Hadacheck v. Sebastian*, 239 U.S. 394 (1915)) (no taking even given reduction in value from \$800,000 to \$60,000); *Village of Euclid v. Ambler Realty Co.*, 272 U.S. 365 (1926) (no taking despite 75 percent diminution in value).) Mere denial of the most profitable or beneficial use of property does not require a finding that a taking has occurred. (See *Florida Rock*, 791 F.2d at 901; see also *Andrus v. Allard*, 444 U.S. 51, 66 (1979).) Rather, courts look for drastic interference with a property's possible uses. (See *Pace Resources*, 808 F.2d at 1031.)

In assessing whether a regulation effects a taking, the Supreme Court has considered whether the regulation denies an owner the "economically viable use" of his property. (See, e.g., *Keystone*, 480 U.S. at 499.) Courts focus on the remaining uses permitted and the residual value of the property. (See *Pace Resources*, 808 F.2d at 1031.)

Although certain uses of copyrights and copyrighted material developed by tobacco companies and of tobacco and nontobacco trademarks will be

prohibited or curtailed, other uses will remain once the final rule takes effect. That is, under § 897.16(a), nontobacco trademarks may not be used to market tobacco products (with the exception of trademarks that had such uses before January 1, 1995) and so they may lose the (speculative) value of such licensing arrangements, but they retain the vast bulk of their value as trademarks for the product or brand for which they were originally developed, and they retain the value of their potential use to market all legal, nontobacco products. Under §§ 897.30(b) and 897.32(a), some copyrighted advertising material that appears on billboards or signs within 1,000 feet of a school or playground or that is not black text/white background may be rendered useless when the rule becomes effective (the copyrighted design itself may be used in other venues, such as adult publications or in adult-only establishments). Under § 897.34(a), tobacco product brand names and logos may be used only to market tobacco products; they therefore lose the value of any use on nontobacco products and, under § 897.34(c), they lose the value of any use to sponsor events when the rule becomes effective. By and large, however, tobacco copyrights and trademarks will retain significant, economically viable uses when the rule becomes effective.

Tobacco companies have, however, registered some of their tobacco trademarks (e.g., Skoal Bandit on a race car as an entertainment service mark, Marlboro on tennis caps), or marks that incorporate a tobacco trademark (e.g., The Marlboro Country Store on, for example, hats and boots; Skoal Pro Rodeo promoting and sponsoring rodeos; Winston West promoting and sponsoring auto racing events), as marks for nontobacco products, services, or events. Under § 897.34, all use of these registered nontobacco marks will be prohibited when the rule becomes effective. With respect to these registered nontobacco trademarks, and indeed with respect to all tobacco company trademarks, their associated goodwill will remain with the tobacco companies and will inure to their benefit in the sale of tobacco products. Accordingly, this factor of the takings analysis indicates that the final rule effects no taking of these interests.

Section 897.16(c) prohibits the use of tobacco product vending machines and self-service displays except in adult-only establishments (where graphic advertisements will also be permitted). This restricted use may limit the number of venues in which these

vending machines and self-service displays may be used and may exclude venues where their use is most profitable. The value of vending machines and self-service displays may therefore drop. But diminutions in property value do not establish a taking. (See *Penn Central*, 438 U.S. at 131.) Indeed, "[g]overnment hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law" (*Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 413 (1922)). Vending machines and self-service displays may have to be moved from currently legal venues to adult-only establishments or to warehouses, or they may need to be retrofitted for use with other products if retrofitting is possible. Although compliance may require vending machine and self-service display owners to spend money, "[r]equiring money to be spent is not a taking of property" (*Atlas Corp.*, 895 F.2d at 756 (discussing regulatory requirement that mining corporations reclaim uranium and thorium tailings and decommission mills)). Finally, if there are not sufficient numbers of adult-only establishments, some vending machines and self-service displays may have no economically viable use because of the final regulation, but a regulation that makes personal commercial property "economically worthless" does not effect a per se taking, as it would with real property. (See *Lucas*, 505 U.S. at 1027-1028.) Contracts to offer exclusively tobacco products in vending machines at nonadult-only establishments may also become "economically worthless" once the regulation becomes effective. Likewise, although §§ 897.32(a) and 897.30(b) may shorten the useful life of advertising materials on placards and billboards that are not black text/white background or that are near schools and playgrounds (albeit with a grace period of at least the delayed effective date) and such materials may be "economically worthless" as a result, this does not effect a taking per se.

In summary, examination of the economic impact factor of the takings analysis suggests that the regulations, when they finally become effective, will effect no takings of trademarks and goodwill, copyrights, and many vending machines and self-service displays. It leaves open the possibility, however, that the rule may effect a taking of some vending machines and contracts, and of some self-service displays and of nonconforming signs and billboards.

#### 5. Interference with Reasonable Investment-backed Expectations

The final factor to consider is whether a company has a reasonable investment-backed expectation in continuing to use the property at issue, whether it be vending machines, self-service displays, nonconforming signs and billboards, copyrighted material, or trademarks and goodwill. To be reasonable, expectations must take into account the power of the State to regulate in the public interest. (See *Pace Resources*, 808 F.2d at 1033.) Reasonable expectations must also take into account the regulatory environment, including the foreseeability of changes in the regulatory scheme. "In an industry that long has been the focus of great public concern and significant government regulation," *Monsanto*, 467 U.S. at 1008, the possibility is substantial that there will be additional regulatory requirements. "Those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end" (Connolly, 475 U.S. at 227 (citation omitted)). Given a long history of Government regulation of an industry, its members are "on notice that [they] might be subjected to different regulatory burdens over time" (*California Hous. Sec., Inc. v. United States*, 959 F.2d 955, 959 (Fed. Cir.), cert. denied, 506 U.S. 916 (1992)).

Commerce in tobacco products has been regulated for years on the Federal, State, and local levels. For example, States first began restricting tobacco sales to minors, distribution of free samples, and vending machine sales in the 1970's. By 1994 all 50 States prohibited tobacco sales to young people, 38 States restricted the distribution of free tobacco products, and 28 States imposed restrictions on vending machine sales ("State Legislated Actions on Tobacco Issues," Coalition on Smoking OR Health (Washington, DC 1994)). Tobacco manufacturers as well as distributors and retailers who have chosen to distribute or sell tobacco products have therefore had reasonable notice that the regulatory scheme to limit use of tobacco products by minors might change.

Moreover, the particular restrictions on access and on promotion adopted in these regulations, or variations thereof, have been proposed or considered for several years by Government bodies, including Congress, the States, and public health agencies. (See, e.g., H. Rept. 5041, 101st Cong., 2d sess. (1990); H. Rept. 1250, 101st Cong., 1st sess.

(1989).) For example, on at least two occasions a tobacco industry representative testified before Congress that pending legislation would, like several previous legislative proposals, effectively ban advertisements for tobacco products ("Tobacco Control and Marketing: Hearings on H. Rept. 5041 Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce," 101st Cong., 2d sess. 491-494 (1990) (statement of Charles O. Whitley on behalf of The Tobacco Institute); "Tobacco Issues: Hearings on H. Rept. 1250 Before the Subcomm. on Transp. and Hazardous Materials of the House Comm. on Energy and Commerce," 101st Cong., 1st sess. 302 (1989) (statement of Charles O. Whitley on behalf of The Tobacco Institute)), making for far more restrictive limits on advertisements and promotion than those imposed by this rule. Given these facts, a reasonable person should have expected the possibility of regulations such as these. In addition, when sales to young people are illegal, investments in promotions designed to appeal to young people cannot be considered reasonable (see discussion of R. J. Reynolds' use of promotional materials in the Joe Camel Campaign in section VI. of this document). In any case, once the agency gave notice of its proposed rulemaking with respect to tobacco, tobacco manufacturers, distributors, and retailers had notice that certain investments were risky, and they will enjoy the economic benefit of those investments and of investments that they had previously made until the rule is finally effective.

As discussed in section IV. of this document, the number of tobacco product vending machines fell by half between 1988 and 1993 and, since 1990, virtually no new tobacco product vending machines have been manufactured (60 FR 41314 at 41325); because the market in tobacco product vending machines is declining, investment-backed expectations in both vending machines and vending machine contracts are not reasonable. Moreover, many self-service displays were given to retailers by tobacco manufacturers (see 60 FR 41314 at 41323); to that extent, the retailers have no investment-backed expectation in them.

Finally, the Supreme Court has stated that it is unreasonable to have high investment-backed expectations in personal property:

[I]n the case of personal property, by reason of the State's traditionally high degree of control over commercial dealings, [the

property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless (at least if the property's only economically productive use is sale or manufacture for sale).

(*Lucas*, 505 U.S. at 1027–1028)

Since all of the property at issue here—vending machines, self-service displays, the advertising material on signs and billboards, contract rights, copyrights, and trademarks and associated goodwill—is personal property, there can be no reasonable investment-backed expectation that regulation will not render them economically worthless. Consideration of this factor of the takings analysis indicates that the final rule effects no takings of any property.

#### 6. Summary

With respect to trademarks and goodwill and copyrights, the three factors in a takings analysis indicate that these regulations will effect no takings. Only the economic impact of the rule on advertising materials on signs and billboards and on some vending machines and related contract rights and some self-service displays leaves open the possibility that a taking may occur, but the impossibility of reasonable investment-backed expectations with respect to personal property used for sale strongly counters this factor, as stated by the Supreme Court in *Lucas*, as does the harm-prevention character of this regulation. Analysis of the three factors considered together shows that these final regulations do not effect a taking of vending machines, self-service displays, signs and billboards advertising tobacco products, contract rights, or copyrights and trademarks and goodwill. The agency concludes that the comments that argued that the regulation effects takings are, for the above-stated reasons, unpersuasive.

#### *B. Substantive Due Process, Equal Protection, and Restrictions on Use of Trade Names*

(2) Comments argued that § 897.16(a) (which restricts the use of nontobacco trade or brand names as the trade or brand name of cigarettes or smokeless tobacco) and § 897.34(a) (which prohibits the marketing of nontobacco items and services that bear tobacco brand names and other symbols of cigarettes and smokeless tobacco) violate the Due Process Clause of the Fifth Amendment to the Constitution and the Equal Protection Clause of the Fourteenth Amendment. One comment asserted that each of these provisions

prevents companies from entering a completely legal business using their own trade names but provided no further explanation of its reasoning; FDA therefore understands it to suggest that these provisions classify companies as either tobacco or nontobacco companies, that this classification violates equal protection, and that these provisions violate due process in that they infringe on property interests in trade names by prohibiting companies from entering legal businesses using their own trade names. Another comment echoed this latter point and argued that the agency was denying tobacco companies due process because it has no authority to prohibit the lawful use of tobacco trademarks on other products.

The agency disagrees with these comments. The Fifth Amendment Due Process Clause states that “[n]o person shall \* \* \* be deprived of life, liberty, or property, without due process of law.” Under due process as applied to economic regulation, “[i]t is enough that there is an evil at hand for correction, and that it might be thought that the particular legislative measure was a rational way to correct it” (*Williamson v. Lee Optical of Oklahoma, Inc.*, 348 U.S. 483, 488 (1955)). (The agency has addressed why it has the statutory authority to issue this rule in section II. of this document.)

The Fourteenth Amendment's Equal Protection Clause states that “[n]o State shall \* \* \* deny to any person the equal protection of the laws.” By its terms, the Fourteenth Amendment does not apply to action by the Federal Government, as it is directed at the States. But the Supreme Court has held that the Fifth Amendment's Due Process Clause includes an equal protection component equivalent to the Fourteenth Amendment's Equal Protection Clause. (See *Bolling v. Sharpe*, 347 U.S. 497 (1954); see also *Buckley v. Valeo*, 424 U.S. 1, 93 (1976) (per curiam) (“Equal protection analysis in the Fifth Amendment area is the same as that under the Fourteenth Amendment”).) Under equal protection review, an economic regulation is valid as long as the classification that it makes is “rationally related to a legitimate state interest” (*City of New Orleans v. Dukes*, 427 U.S. 297, 303 (1976)).

Sections 897.16(a) and 897.34(a) easily pass muster under the requirements of both due process and equal protection. FDA's interest in the health and well-being of children and adolescents is certainly legitimate (indeed, it is a compelling interest). (See

*New York v. Ferber*, 458 U.S. 747, 757–58 and n.9 (1982).) Moreover, because they limit trade and brand name uses that enhance the appeal and promote the use of cigarettes and smokeless tobacco to young people, the provisions are rationally related to this interest and are a rational way to reduce addiction to tobacco products and the health consequences that follow.

#### *C. Procedural Due Process Under the Fifth Amendment*

(3) An industry comment asserted that the regulation of tobacco manufacturers' use of their copyrights and trademarks affects a property interest so as to require an adjudication; put another way, the comment argued that use of rulemaking to adopt a regulation effecting these property interests violates the Fifth Amendment Due Process Clause, which states that “[n]o person shall \* \* \* be deprived of life, liberty, or property, without due process of law.”

The agency disagrees. The agency has issued this final rule under its “authority to promulgate regulations for the efficient enforcement of the Act” under section 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)) and its authority under section 520(e) of the act (21 U.S.C. 360j(e)) to issue regulations to restrict the sale, distribution, or use of a device. The agency issues such regulations under the rulemaking procedures established by the Administrative Procedure Act (APA) in 5 U.S.C. 553 and its own regulations in part 10 (21 CFR part 10), in particular § 10.40. Neither the act, the APA, nor the agency's regulations require a hearing for a rulemaking under sections 701(a) and 520(e) of the act.

The comment nevertheless contended that due process requires that tobacco manufacturers be provided the opportunity for a formal hearing (i.e., more than just an opportunity to provide written comments). A formal hearing is required, according to the comment, because FDA is asserting jurisdiction over cigarettes and smokeless tobacco based upon a determination of the intent of all tobacco manufacturers, but it is relying on evidence of intent with regard to only a subset of tobacco manufacturers.

As discussed in the 1996 Jurisdictional Determination annexed hereto, the evidence shows that cigarettes and smokeless tobacco are highly addictive, cause other psychoactive effects (such as relaxation and stimulation), and affect weight

regulation, and that these effects are widely accepted in the scientific community. Based on this evidence, it is foreseeable to any reasonable manufacturer that consumers will use such products for their addictive, psychoactive, and other pharmacological effects. The evidence also shows that actual consumer use of these products for their pharmacological effects is predominant and, in fact, nearly exclusive. Based on this evidence of the foreseeable and actual consumer use of these products for their pharmacological effects, the agency has concluded that all cigarette and smokeless tobacco manufacturers "intend" their products to affect the structure or function of the body, and that these products are, therefore, nicotine delivery devices under the act. In addition, the agency collected evidence of the tobacco industry's statements, actions, and research demonstrating awareness of the addictive and other pharmacological effects of these products, the industry's knowledge that consumers use these products for these effects, and the industry's deliberate manipulation of levels of nicotine in these products to ensure that adequate amounts of nicotine are delivered to consumers. These internal documents are further evidence in support of the conclusion that cigarette and smokeless tobacco manufacturers intend their products to be drug delivery devices, but they are not necessary for that conclusion. The agency, therefore, has not inferred the intent of one company based exclusively on the internal documents of another. Moreover, assuming that copyrights and trademarks are property protected by the Fifth Amendment's Due Process Clause, due process does not require that FDA provide tobacco manufacturers with a hearing beyond the opportunity for notice and comment that it has already provided. The Supreme Court has stated that the APA established "the maximum procedural requirements" that the courts can impose upon agencies in conducting rulemaking procedures and that the circumstances in which courts may require additional procedures, "if they exist, are extremely rare" (*Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519, 524 (1978)). The Court further stated that due process may "in some circumstances" require "additional procedures" beyond those required by the APA "when an agency is making a 'quasi-judicial' determination by which a very small number of persons are

'exceptionally affected, in each case upon individual grounds'" (*Id.* at 542 (quoting *United States v. Florida East Coast Ry.*, 410 U.S. 224, 242-245 (1973))).

By this test, due process does not require that the agency provide tobacco manufacturers with a hearing. Simply put, the agency is not making "a quasi-judicial determination by which a very small number of persons are exceptionally affected, in each case upon individual grounds" (*Vermont Yankee*, 435 U.S. at 542 (quotations omitted)). The final rule at issue here prospectively limits the sale and promotion of cigarettes and smokeless tobacco to individuals under the age of 18; it imposes conditions on all manufacturers, distributors, and retailers of tobacco products and will affect the access to tobacco products of millions of individuals under the age of 18. The final rule is therefore "an agency statement of general \* \* \* applicability and future effect designed to implement, interpret, or prescribe law or policy" (5 U.S.C. 551(4)); in other words, it is a rule under the APA, and the agency followed APA rulemaking in formulating it (5 U.S.C. 551(5)). Like the nuclear fuel cycle rulemaking in *Vermont Yankee*, 435 U.S. at 528-530, and the rulemaking about ambient air quality standards for lead in *Lead Indus. Ass'n v. Environmental Protection Agency*, 647 F.2d 1130, 1136-1144 (D.C. Cir.), cert. denied, 449 U.S. 1042 (1980), this process is "a rulemaking proceeding in its purest form," and not a "quasi-judicial determination" to which due process requirements beyond the requirements of the APA might apply. (See *Vermont Yankee*, 435 U.S. at 542 n.16; *Lead Indus. Ass'n*, 647 F.2d at 1171 n.119.)

In any case, manufacturers have had ample opportunity during the comment period for this rulemaking to submit evidence—including other internal tobacco industry documents or affidavits from their employees—that contradicts any evidence, including internal tobacco industry documents, that the agency has placed in the administrative record. And they have submitted voluminous comments with supporting documentation to the agency. The manufacturers have therefore been "afforded a meaningful opportunity to be heard and to controvert the evidence. Fairness demands no more" (*Lead Indus. Ass'n*, 647 F.2d at 1170 (quotations omitted)).

In summary, due process does not require that FDA provide manufacturers with an adjudicative hearing. The notice

and opportunity for comment provided in this rulemaking are all that fairness and due process require here. And, as discussed in greater detail in section XII. of this document, this rulemaking meets all the requirements of the APA for informal rulemaking.

## XII. Procedural Issues

### A. Introduction

The Food and Drug Administration (FDA) went to great lengths to involve the public in this proceeding. On February 25, 1994, David A. Kessler, Commissioner of Food and Drugs (the Commissioner) wrote to Scott Ballin, chairman of the Coalition on Smoking OR Health, regarding the possibility of FDA regulation of cigarettes in response to certain petitions that had been filed with the agency. The Commissioner explained:

[T]he agency has examined the current data and information on the effects of nicotine in cigarettes \* \* \*. Evidence brought to our attention is accumulating that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers \* \* \*. This evidence \* \* \* suggests that cigarette vendors intend the obvious—that many people buy cigarettes to satisfy their nicotine addiction. Should the agency make this finding based on an appropriate record or be able to prove these facts in court, it would have a legal basis on which to regulate these products \* \* \*.

In the months that followed, the Commissioner testified twice before Congress regarding the accumulating evidence relating to the intended use of cigarettes.<sup>255</sup> That testimony was extensive and detailed.

In July and August of that year, FDA Associate Commissioner for Regulatory Affairs, Ronald G. Chesemore wrote to the major cigarette and smokeless tobacco companies requesting all documents relating to "all research on nicotine \* \* \*, including their pharmacological effects, and all documents relevant to the nicotine" in their products. On August 1, 1994, FDA held a Drug Abuse Advisory Committee meeting that was fully open to the public on the subject of the abuse potential of nicotine.

On August 11, 1995, FDA provided the public with an extensive Federal Register document setting forth its

<sup>255</sup> Statement by the Commissioner on Nicotine-Containing Cigarettes, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives (Mar. 25, 1994); Statement by the Commissioner on the Control and Manipulation of Nicotine in Cigarettes, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives (June 21, 1994).

rationale for proposing to restrict the sale of cigarettes and smokeless tobacco in a 60 page discussion supported by 442 endnotes (the 1995 proposed rule) (60 FR 41314 to 41375). The agency carefully documented each of the essential propositions offered in support of its reasoning. Indeed, most of the 442 endnotes in the 1995 proposed rule contain multiple authorities for the agency's position and, in all cases, the agency provided the reader with specific page references to the numerous studies, reports, and industry documents on which it relied.

In the same issue of the Federal Register in a document entitled "Analysis Regarding The Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products," FDA also provided an analysis of the agency's authority to assert jurisdiction over cigarettes and smokeless tobacco based on the evidence before the agency at that time (the 1995 Jurisdictional Analysis) (60 FR 41453 to 41787). In the text of the 1995 Jurisdictional Analysis, the agency supported its reasoning with appropriate citations to case law, statutes, and regulations. In addition, the 1995 Jurisdictional Analysis was supported by over 600 footnotes, each of which provided the factual context for the agency's legal position.

On August 16, 1995, the agency placed on public display some 20,000 pages of materials that it cited in the 1995 proposed rule and in the 1995 Jurisdictional Analysis. With the exception of three documents, which the agency referenced only in the 1995 Jurisdictional Analysis, the agency made available to the public all of the materials on which it was relying on as of that time for support.

On September 29, 1995, the agency supplemented the administrative record by putting on public display approximately 13,000 documents comprising some 190,000 pages of factual and analytical materials the agency considered in the course of issuing the 1995 proposed rule and the 1995 Jurisdictional Analysis. Although it was under no legal obligation to do so, the agency made these additional materials available because of the importance of this proceeding.

The agency also made two other significant additions to the public record. On December 1, 1995, the agency announced the findings of focus group studies concerning possible brief statements to be included on all cigarette advertising (60 FR 61670), and added to the record for the rulemaking

proceeding a report of these findings and approximately 1,500 pages of supporting documentation. Second, in the Federal Register of March 20, 1996 (61 FR 11349), the agency published notice of an additional 30 day comment period limited to specific documents the agency added to the proposed rulemaking docket, and to the docket in support of the agency's analysis of its jurisdiction (61 FR 11419). These materials consisted of two declarations and a report from three former tobacco industry employees, as well as FDA memoranda to the record regarding adult publications and billboards.

In addition, the agency has added to the final record of this proceeding a comparatively small number of documents that expand upon or confirm information made available in the 1995 proposed rule or the 1995 Jurisdictional Analysis, or that address alleged deficiencies in the agency's initial record.

The administrative record now also includes the comments received from the public. The agency received over 700,000 comments, some directed to the 1995 Jurisdictional Analysis, some directed to the 1995 proposed rule, and many with overlapping discussions. Though many comments consisted of form letters, the agency received over 95,000 distinct or unique sets of comments. Five major cigarette manufacturers jointly submitted 2,000 pages of comments and 45,000 pages of exhibits. The major smokeless tobacco manufacturers jointly submitted 474 pages of comments and 3,372 pages of exhibits. The initial comment period remained open for 144 days.

(1) Despite the agency's extraordinary efforts to involve the public in this proceeding, FDA received several comments regarding the procedures the agency followed in providing notice of the 1995 proposed rule and in publishing the 1995 Jurisdictional Analysis. Some of these comments complained that the agency designated certain documents in the administrative record as "confidential," and that the shielding of these documents denied the public a meaningful opportunity to participate in the rulemaking process. One of these comments also contended that FDA refused to disclose certain nonconfidential information on which the agency had relied. Some comments also argued that FDA failed to set forth a balanced view of the issues presented by the 1995 proposed rule, thereby rendering the notice inadequate and "misleading" under the Administrative Procedure Act (the APA). In their view,

FDA concealed certain issues in order to deny the public the right to participate in the rulemaking process. Finally, at least one interested person maintained that the comment period for the 1995 proposed rule was so short as to be arbitrary and capricious.

As the discussion that follows in this section of the document demonstrates, the agency's notice, the public availability of the information the agency relied upon at the notice stage of this proceeding, and the opportunity for comment, went well beyond the requirements of the APA, well beyond what is required by case law construing the APA, and well beyond the agency's own procedural requirements for informal rulemaking.

## B. Adequacy of the Record

(2) Several industry comments complained about the adequacy of the record in support of the 1995 proposed rule. They contended that the agency violated the APA, 5 U.S.C. 553(b) and (c), and the Due Process Clause of the Fifth Amendment to the Constitution, by failing to disclose all of the information the agency "considered or relied upon in the proceeding."<sup>256</sup> In particular, these comments complained that the public was deprived of the opportunity to comment meaningfully because, according to these comments, the agency relied on confidential documents and on substantial amounts of undisclosed data. One comment went so far as to claim that "a substantial portion" of the material FDA relied upon was not made available for public scrutiny.

The record in support of the 1995 proposed rule provided the public not only with a "reasonable opportunity" for comment, but with an extraordinary opportunity to examine the agency's position. The claim that the agency withheld "a substantial portion" of the materials on which it relied is simply unfounded.

### 1. The Administrative Record

In an informal rulemaking proceeding, the APA itself requires only that the "notice of proposed rule making" include a statement of the time, place, and nature of the proceeding, "reference to the legal

<sup>256</sup> Because the APA in this context provides the public at least as much protection as the Due Process Clause of the Constitution, the agency will address these procedural objections solely under the APA. See *Forester v. Consumer Prod. Safety Comm'n*, 559 F.2d 774, 787 (D.C. Cir. 1977); *Ass'n of Nat'l Advertisers, Inc., v. Federal Trade Comm'n*, 627 F.2d 1151, 1166 (D.C. Cir. 1979), cert. denied, 447 U.S. 921 (1980).



authority under which the rule is proposed," and "either the terms or substance of the proposed rule or a description of the subjects and issues involved" (5 U.S.C. 553(b)). The APA, thus, does not expressly require disclosure of the information on which the agency relies in proposing a regulation.

Nevertheless, courts have implied under the APA a requirement that an agency give notice of the information on which it actually relies to support a proposed rule, and make that information available to the extent it is not readily accessible to the public. (See Davis, K. and R. Pierce, Jr., *Administrative Law Treatise*, vol. 3, section 7.3 at 305-09 (3d ed. 1994) (discussing one of the seminal cases on disclosure of data relied on to support a rulemaking proceeding, *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973), cert. denied, 417 U.S. 921 (1974).) No court, however, has required the degree of public disclosure at the notice stage of a rulemaking proceeding that FDA undertook here.

Indeed, the primary cases cited by the comments, namely, *Portland Cement Ass'n, supra*, *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977), and *United States Lines, Inc. v. Federal Maritime Comm'n*, 584 F.2d 519 (D.C. Cir. 1978), address agency conduct that bears little resemblance to FDA's efforts in this proceeding. While FDA has provided a remarkable degree of factual support and procedural openness, these cases involved instances in which agencies provided the public with no information whatsoever or otherwise excluded a study that was critical to the administrative proceeding. In *Portland Cement*, the Environmental Protection Agency altogether failed to provide the public an opportunity to comment on the test results and procedures on which the agency relied as the critical basis for the emission control level adopted by the agency. That is, the agency set very specific pollution control limits, but failed to make public until after the close of the comment period the details of crucial tests relied upon to determine these limits (486 F.2d at 392).

In *Nova Scotia Food Prods.*, "all the scientific research was collected by the agency, and none of it was disclosed to interested parties as the material upon which the proposed rule would be fashioned" (568 F.2d at 251) (emphasis added). And in *United States Lines*, where a common carrier challenged an order of the Federal Maritime

Commission amending a contract between two competitors, the court found that the Commission had made "critical findings" on the basis of data which was neither identified in its decision nor included in the administrative record. Rather, the Commission based its decision on "reliable data reposing in the files of the Commission" (584 F.2d at 533). The reviewing court simply had no idea of the factors or data on which the Commission had relied (*Id.*).

Thus, at best, the case law requires agencies to disclose studies and data actually relied upon by the agency. Even then, the cases that have struck down agency rulemaking are generally confined to instances in which the agency provided woefully inadequate information to the public or failed to disclose a critical piece of information. (See, e.g., *Kennecott Corp. v. Environmental Protection Agency*, 684 F.2d 1007, 1018-19 (D.C. Cir. 1982) (agency acted arbitrarily and capriciously when it failed to include in the public docket during the comment period any documents supporting a particular proposed regulation); compare *Personal Watercraft Indus. Ass'n v. Department of Commerce*, 48 F.3d 540, 544-45 (D.C. Cir. 1995) (while agency must disclose information critical to its decision to regulate a particular activity, absent prejudice an agency may rely on studies developed after close of comment period that are not critical to the underlying proposal).)

Finally, FDA's own procedural regulations require that the agency include with the notice of proposed rulemaking, among other things, "references to all information on which the Commissioner relies for the proposal \* \* \*" (§ 10.40(b)(vii) (21 CFR 10.40(b)(vii)) (emphasis added); see 21 CFR 10.3 (defining the term "administrative record" to mean the materials on which the agency "relies to support the action"). Thus, even under the agency's own procedural regulations, FDA is required—when it initiates informal rulemaking—to supply the public only with the materials the agency is relying upon to support the proposed action.

Here, the materials the agency relied on are the materials the agency cited in the 1995 proposed rule and the 1995 Jurisdictional Analysis. Not only did the agency provide these materials to the public, but it also provided the roughly 190,000 pages of factual and analytical materials the agency considered but did not rely upon in either the 1995 proposed rule or the 1995 Jurisdictional

Analysis. Moreover, the agency provided over 1,000 endnotes and footnotes directing readers to each and every document, including every study, Government report, journal article, industry document, and agency record on which FDA relied to support the 1995 proposed rule and the 1995 Jurisdictional Analysis.

Out of all this material, the only nonpublic materials on which the agency relied were two confidential documents<sup>257</sup> and two lines of text the agency redacted from a document the agency placed on the public record.<sup>258</sup> The agency relied on this material only in the context of the agency's 1995 Jurisdictional Analysis. None of these documents is pivotal to the analysis of jurisdiction in that none provides the sole or principal basis for the agency's conclusion that cigarettes and smokeless tobacco are drug delivery devices under the Federal Food, Drug, and Cosmetic Act (the act). Further, as discussed in the 1996 Jurisdictional Determination annexed hereto, the decision to keep these materials confidential did not in any way undermine the quality of the public participation in this proceeding. In sum, the procedures the agency followed in assembling a public record in this proceeding simply are not in line with the facts described in cases like *Portland Cement*, *Nova Scotia Food Products*, and *United States Lines*.

<sup>257</sup> The two confidential documents the agency directly referenced are the 1991 Handbook on Leaf Blending and Product Development (Confidential Document 75) and the unredacted summary of notes of FDA trip visits (Confidential Document 74). The summary was compiled from notes and handouts that are also designated as confidential (Confidential Documents 69, 70, 71, 72, and 73). The agency views the summary as a stand-alone document to the extent it distills a large volume of disparate handwritten notes and handouts. Also, the agency cited only to the summary itself. Nevertheless, even if the summary were counted as five documents rather than one, the agency at most relied on six confidential documents. The agency's basis for relying on these documents in the 1995 Jurisdictional Analysis is discussed in detail in the 1996 Jurisdictional Determination, annexed hereto.

<sup>258</sup> On page 255 of the 1995 Jurisdictional Analysis (60 FR 41453, 41716), the agency redacted several lines of text along with a footnote that identified the sources for the redacted text. The footnote consisted of references to two sources, both of which appeared on the agency's public docket for the 1995 Jurisdictional Analysis: J. E. Kiefer, "Cigarette Filters for Altering the Nicotine Content of Smoke" (Report No. 71 5003 7), Tennessee Eastman Co., pp. 1-2; August 18, 1971, and J. G. Curran, Jr., and E. G. Miller, "Factors Influencing the Elution of High Boiling Components of Cigarette Smoke from Filters," *Beitr. Tabakforsch.*, pp. 5 and 67, 1969. The Kiefer document appeared on the public docket with certain trade secret information redacted from the document. The Curran document was made available to the public in full.

## 2. The Agency's Use of Confidential Documents

a. *Confidential documents on which the agency did not rely.* The agency placed in a confidential docket 75 documents from the approximately 210,000 pages of materials the agency made available at the opening of this proceeding. The agency identified each of these 75 documents for the public in an index filed on September 29, 1995, on the public docket. (See 60 FR 66981 at 66982, December 27, 1995.) Of these 75 documents, 73 were not even relied upon by the agency to support either the 1995 proposed rule or the 1995 Jurisdictional Analysis.

Sixty-one of these 73 confidential documents consisted either of commercial information and trade secrets that the industry urged FDA to keep confidential (Confidential Documents 1–12, 16–21, and 62–73), or unpublished manuscripts for which the agency lacked the authors' permission, as of September 29, 1995, to make them available for widespread dissemination (Confidential Documents 22–52). The remaining 12 documents were either proprietary reports and other copyrighted information—such as financial reports generated by Dun and Bradstreet—which the agency lacked permission to reprint (Confidential Documents 13–15, and 53–58), or confidential documents that supported a pending new drug application (Confidential Documents 59–61).

Again, the agency did not rely on any of these 73 documents as support for the 1995 proposed rule. Therefore, the agency was not even required to include these documents in the administrative record of the notice of proposed rulemaking. (See 21 CFR 10.40(b)(vii).) It likewise follows that because the agency did not rely upon these documents, the decision to protect them cannot be said to have unfairly interfered with the public's ability to question the agency's rationale for the rule. (See *Mid-Tex Electric Coop., Inc. v. Federal Energy Regulatory Comm'n*, 773 F.2d 327, 344 (D.C. Cir. 1985) (agency's failure to disclose two studies was "manifestly harmless" because the agency did not rely on the studies to support any finding or conclusion); *Conference of State Bank Supervisors v. Office of Thrift Supervision*, 792 F. Supp. 837, 843 (D.D.C. 1992) (there is no violation of the APA's notice requirements where the agency has declined to disclose materials on which it did not rely in proposing the rule); *B.F. Goodrich Co. v. Department of Transp.*, 541 F.2d 1178, 1184 (6th Cir.

1976) (only the basic data "upon which the agency relied in formulating the regulation" must be published for public comment), *cert. denied*, 430 U.S. 930 (1977); K. Davis, *Administrative Law Treatise*, section 7.3 at 307 (3d ed. 1994) ("If an agency does not attempt to support its final rule by reference to an undisclosed study, it seems apparent that the agency was not required to make the study available to potential commentators.") The agency went well beyond existing requirements to make publicly available thousands of additional documents for public review—in recognition of the uniqueness and public importance of this proceeding. This effort by the agency should not be used now as a basis for suggesting that the agency was required to publish all information that it had on hand.

Finally, at the close of this rulemaking proceeding and with the publication of the annexed 1996 Jurisdictional Determination, the agency will supplement the public docket with copies of those confidential items for which the agency previously lacked permission to publish, but for which permission has now been granted. Most of the unpublished manuscripts in the confidential docket—none of which were relied upon by the agency to support the rule—will be available through this addition to the public record.

b. *Confidential documents on which the agency relied.* In support of the 1995 Jurisdictional Analysis, FDA relied on only 2 of the 75 documents designated as confidential: A summary of notes taken by FDA investigators during site visits to manufacturing plants run by Brown and Williamson, Philip Morris, and R. J. Reynolds (Confidential Document 74); and a 1991 Brown and Williamson handbook on leaf blending and product development (Confidential Document 75).<sup>259</sup> In addition, the agency relied in its 1995 Jurisdictional Analysis on two lines of text that were redacted from a document that appeared on the public docket.<sup>260</sup> The 1995 proposed rule itself did not rely on any

of these documents.<sup>261</sup> A thorough discussion of these three documents, and the agency's basis for relying on them to support its analysis of jurisdiction, is provided in section VI. of the 1996 Jurisdictional Determination, annexed hereto.

## 3. The Claim that FDA Relied on "Unknown" Undisclosed Data

(3) An association representing the tobacco industry also claimed that the agency withheld certain data and calculations used to construct a series of charts showing that nicotine and tar levels in smoke have risen steadily from 1982 to 1991. (See 60 FR 41453 at 41728 to 41731.) These charts appeared only in the context of the agency's 1995 Jurisdictional Analysis. A thorough discussion of how the agency constructed these charts, and on what data the agency relied, is provided in sections II. and VI. of the 1996 Jurisdictional Determination, annexed hereto.

<sup>261</sup> One comment noted that the agency relied in the 1995 proposed rule on undisclosed information gathered from former industry sales representatives and managers. (See 60 FR 41314 at 41323.) The reference in the rule to interviews with former sales representatives and managers appears in the discussion of proposed § 897.12 *Additional Responsibilities of Manufacturers*. The agency used the information gathered from these individuals to support the proposition that manufacturers direct their sales representatives to police retailers' cigarette and smokeless tobacco displays. Accordingly, the agency proposed to require sales representatives to be responsible for removing violative visual displays and advertising used in retail outlets. In light of comments received, the agency has decided to revise § 897.12 to eliminate this requirement. Because manufacturer sales representatives will no longer be held responsible for maintaining retailers' fixtures, the agency's reliance on the interviews in the 1995 proposed rule, and the issue of whether the agency should have made more information on this matter available to the public, is moot. Davis, K. C., and R. J. Pierce, Jr., *Administrative Law Treatise*, vol. 1, section 7.3 at p. 307 (3d ed. 1994) ("If an agency does not attempt to support its final rule by reference to an undisclosed study, it seems apparent that the agency was not required to make the study available to potential commentators"). Finally, as the agency explained in its December 27, 1995, Federal Register notice, the agency has not made such information available to the public because of the need to protect the identity of individuals who came forward during the agency's investigation and who might not otherwise have come forward (see 60 FR 66981, 66982). As discussed in section VI. of the 1996 Jurisdictional Determination, FDA believes there are circumstances in which an agency may rely on confidential information in a rulemaking proceeding, and that there are ways in which an agency may present such information in order to preserve the public's right to a reasonable opportunity to participate in the proceeding (60 FR 66981). The agency, however, has not relied on any such material in this final rulemaking.

<sup>259</sup> The agency did not acknowledge ownership of the handbook in the 1995 Jurisdictional Analysis, or in the September 29, 1995, index to the administrative record. However, in a set of comments filed by Brown & Williamson, the company itself acknowledged publicly its ownership of the handbook. (See Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), pp. 37–38).

<sup>260</sup> Kiefer, J. E., "Cigarette Filters for Altering the Nicotine Content of Smoke," Tennessee Eastman Co., Report No. 71 5003 7, pp. 1–2, August 18, 1971.

#### 4. The Claim that FDA Failed to Include in the Record New Drug Application (NDA) Data on Which it Relied

(4) One comment claimed that the agency relied on studies in seven NDA's for the proposition that a high proportion of smokers are addicted to nicotine, but failed to make adequate disclosure of these NDA's. In particular, this comment stated that the agency failed to include any information in the public docket for NDA 18-612 (Nicorette gum, 2 milligrams (mg)) and NDA 20-385 (Nicotine nasal spray), and included only summaries for five other NDA's the agency cited. To the extent the agency relied on any of these NDA's, it did so only in the context of the 1995 Jurisdictional Analysis. A comprehensive discussion of the agency's reliance on this material is provided in section VI. of the 1996 Jurisdictional Determination, annexed hereto.

#### 5. The Agency's Reliance in the Final Rulemaking on New Materials

In an FDA informal rulemaking proceeding, the final administrative record must contain the proposed rule, including all information that the Commissioner identifies or files with the proposal, all comments received on the proposal, including all information submitted as part of the comments, and the notice issuing the final regulation, including all information that the Commissioner identifies or files with the final regulation (§ 10.40(g)). An agency may rely on information and data that were not included at the proposal stage that expands on or confirms information in the proposal or addresses alleged deficiencies in the preexisting data, provided that no prejudice is shown.<sup>262</sup> Otherwise, "[r]ulemaking proceedings would never end if an agency's response to comments must always be made the

subject of additional comments" (*Community Nutrition Inst. v. Block*, 749 F.2d 50, at 58). Accordingly, the agency has cited in this preamble and in the 1996 Jurisdictional Determination annexed hereto, a small amount of information that is needed to respond fully to the comments or that otherwise supplements the information contained in or filed with the 1995 proposed rule. These documents include published scientific articles, reference texts, letters to tobacco industry counsel, an abstract that the tobacco industry asked to include in the record, three publicly released tobacco company documents, Congressional hearing transcripts, and newspaper articles. The agency has placed this cited information in the administrative record.

#### C. Adequacy of the Notice

(5) Two industry comments argued that the public's participation in the rulemaking process has been frustrated because the agency presented a "one-sided" view in its 1995 notice of proposed rulemaking. They claimed that FDA failed to satisfy the APA's notice requirement for informal rulemaking because the agency neither disclosed nor discussed the supposedly "large body" of information that is "inconsistent with, or otherwise not supportive of, the proposed rule." Further, the agency did not, in their view, provide a "reasoned explanation" for departing from past precedent on the issue of whether FDA should regulate all cigarettes and smokeless tobacco.

These comments provided no legal authority to support the proposition that, at the notice stage of a proceeding, the agency is required to anticipate all challenges to its reasoning, and must attempt to answer those challenges. Rather, at the notice stage of a rulemaking proceeding, the agency's obligation is to include sufficient detail on the content of the rule, and on the basis in law and fact for the rule, to allow for meaningful and informed comment. (See *American Medical Ass'n v. Reno*, 57 F.3d 1129, 1132 (D.C. Cir. 1995); *Home Box Office, Inc. v. Federal Communications Comm'n*, 567 F.2d 9, 35-36 (D.C. Cir.), cert. denied, 434 U.S. 829 (1977).)

More specifically, in an informal rulemaking proceeding, the APA requires public notice of an agency's intention to issue a regulation (5 U.S.C. 553(b)). The notice must include "reference to the legal authority under which the rule is proposed," and "either the terms or substance of the proposed rule or a description of the subjects and

issues involved" (5 U.S.C. 553(b)(2) and (b)(3)). FDA's own regulations require that a notice of proposed rulemaking include "a preamble that summarizes the proposal and the facts and policy underlying it, \* \* \* all information on which the Commissioner relies for the proposal, \* \* \* and cites the authority under which the regulation is proposed" (21 CFR 10.40(b)(vii)).

Under case law construing section 553 of the APA, notice of informal rulemaking must be "sufficiently descriptive of the 'subjects and issues involved' so that interested parties may offer informed criticism and comments" (*Ethyl Corp. v. Environmental Protection Agency*, 541 F.2d 1, 48 (D.C. Cir.) (en banc), cert. denied 426 U.S. 941 (1976)). Notice is sufficient under the APA "if it affords interested parties a reasonable opportunity to participate in the rulemaking process" (*Forester*, 559 F.2d at 787; *accord State of South Carolina ex rel. Tindal v. Block*, 717 F.2d 874, 885 (4th Cir. 1983), cert. denied, 465 U.S. 1080 (1984)). And, insofar as the 1995 proposed rule relied on a technical study or specific data essential to an understanding of the rule, the notice should have disclosed this information to the extent needed to allow for "meaningful commentary" (*Connecticut Light and Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530-31 (D.C. Cir.), cert. denied, 459 U.S. 835 (1982)).

In this instance, the 1995 proposed rule met both the APA's notice requirements (as interpreted by prevailing case law), as well as FDA's own procedural requirements. The agency by any standard "fulfilled its obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible" (*Air Transport Ass'n of America v. Civil Aeronautics Board*, 732 F.2d 219, 225 (D.C. Cir. 1984) (quoting *Home Box Office, Inc.*, 567 F.2d at 36)).

#### 1. The Agency Provided Adequate Notice of the Key Legal and Factual Issues

Although the APA's notice requirements could have been met by a far briefer presentation, the agency chose to supply the public with a notice that explored in full the wide range of factual and legal issues presented. In doing so, the agency discussed the most significant issues that the two industry comments claimed were missing from the notice.

(6) The comments contended that the agency failed to discuss past instances

<sup>262</sup> See, e.g., *Personal Watercraft v. Department of Commerce*, 48 F.3d 540, 544 (D.C. Cir. 1995) ("Agencies may develop additional information in response to public comments and rely on that information without starting anew unless prejudice is shown."); *Solite Corp. v. Environmental Protection Agency*, 952 F.2d 473, 484 (D.C. Cir. 1991) ("[C]onsistent with the APA, an agency may use 'supplementary' data, unavailable during the notice and comment period, that expands on and confirms information contained in the proposed rulemaking and addresses alleged deficiencies in the preexisting data, so long as no prejudice is shown."); *Community Nutrition Inst. v. Block*, 749 F.2d 50, 57-58 (D.C. Cir. 1984) (agency may rely on information that "expanded on and confirmed" information in the 1995 proposed rule and addressed alleged deficiencies in the record); see also Davis, K. C. and R. J. Pierce, Jr., *Administrative Law Treatise*, section 7.3 (3d ed. 1994).

in which it declined to exercise jurisdiction over cigarettes and smokeless tobacco, including FDA's response to a 1977 citizen petition. One comment in particular insisted that such a discussion would have alerted the public to the idea that Congress enacted preemptive legislation in reliance on FDA's past pronouncements, legislation which the comments argue bars FDA from regulating these products.

The agency acknowledged in the 1995 Jurisdictional Analysis, published in conjunction with the 1995 proposed rule, that it has in the past refrained from exercising jurisdiction generally over all cigarettes and smokeless tobacco (unless claims were made for the product) (60 FR 41453 at 41482 n. 5). Among other things, the agency referred readers to the published decision in *Action on Smoking and Health [ASH] v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). That decision discussed, and indeed arose from, the 1977 citizen petition which, as one comment claimed, the agency "conscientiously avoid[ed]" in order to "mislead[]" the public. Not only does the *ASH* opinion discuss the petition and the agency's position at that time with respect to exercising jurisdiction generally over cigarettes, it also recounts for the reader the agency's historical position on the issue (*Id.* at 237-241). Moreover, the agency placed in the administrative record copies of documents in which FDA declined to exercise jurisdiction, including FDA's response to ASH's 1977 citizen petition.<sup>263</sup>

In addition, the agency attached as part of an appendix to its 1995 Jurisdictional Analysis copies of the Commissioner's testimony before the House Subcommittee on Health and the Environment of the Committee on Energy and Commerce on March 25, 1994 (Appendix 7). At the outset, the Commissioner stated:

Although FDA has long recognized that the nicotine in tobacco products produces drug-like effects, we never stepped in to regulate most tobacco products as drugs. One of the obstacles has been a legal one. A product is subject to regulation as a drug based primarily on its intended use. \* \* \* With certain exceptions, we have not had sufficient evidence of such intent with regard to nicotine in tobacco products. \* \* \*

<sup>263</sup> Letter from D. Kennedy (FDA) to J. Banzhaf (ASH) of Dec. 5, 1977, (denial of 1977 petition); Letter from J. E. Goyan (FDA) to J. Banzhaf (ASH) of Nov. 25, 1980; Public Health Cigarette Amendments of 1971, Hearings Before the Consumer Subcommittee of the Committee on Commerce, U.S. Senate, 92d Cong., 2d sess., pp. 239-246.

Mr. Chairman, we now have cause to reconsider this historical view. \* \* \* This question arises today because of an accumulation of information in recent months and years. In my testimony today, I will describe some of that information. (Appendix 7 at 1-2 (footnote omitted)) This testimony, like the reference to the *ASH* decision, adequately put the public on notice of FDA's past position.<sup>264</sup>

Nor does FDA agree with the comment's argument that Congress, in reliance on past FDA pronouncements, enacted legislation precluding FDA from regulating tobacco products under the act. As discussed in detail in sections IV. and V. of the annexed 1996 Jurisdictional Determination, the agency has never categorically disclaimed jurisdiction over tobacco products and Congress has never expressly forbidden FDA from asserting jurisdiction over these products. The agency has no affirmative obligation to posit in its notice of proposed rulemaking arguments it believes are legally infirm. (Cf. *Florida Power and Light Co. v. United States*, 846 F.2d 765, 771 (D.C. Cir. 1988), *cert. denied*, 490 U.S. 1045 (1989).)

Two tobacco industry comments also claimed that the agency unfairly underplayed the complexity of issues such as "intended use," product categorization, regulatory authority over combination products, and the applicability of the medical device provisions of the act to cigarettes and smokeless tobacco. Instead, one of these comments asserted that all the agency had done was publish "a tendentious anti-tobacco, pro-FDA-regulation manifesto" and, as such, the agency's notice was "fraudulent." The agency disagrees with this characterization. More to the point, the agency disagrees with the argument that the agency

<sup>264</sup> As discussed in section IV. of the 1996 Jurisdictional Determination, the agency's decision not to include a prolonged discussion of past agency decisions is based on the fact that the agency is now operating under a different set of facts. The agency did not commit a procedural error by failing to chronicle exhaustively decisions it made in a factually distinguishable context. Moreover, one of the comments faulted the agency for failing to give notice of the "several" citizen petitions filed since 1977 that requested that the agency regulate cigarettes. In fact, the agency incorporated by reference into the opening docket for the 1995 Jurisdictional Analysis all significant dockets opened since the conclusion of the *ASH* litigation that relate to the agency's jurisdiction over cigarettes and other nicotine delivery systems. The index the agency provided to the public on September 29, 1995, in conjunction with the public display of the administrative record (as of that date), included a description of nine dockets the agency incorporated by reference into the record supporting the 1995 Jurisdictional Analysis.

somehow deprived the public of fair notice.

Again, to satisfy the APA's notice requirement, the agency must specify with particularity the legal authority on which its proposal is based (K. C. Davis & R. J. Pierce, Jr., *Administrative Law Treatise* (vol. 1, 3d ed. 1994) section 7.3 at 299). Notice must be "informative" and must "fairly apprise" interested persons (*Id.* at 299 and 300). The agency need not, however, unravel for the public each and every theoretical step in the analysis. (See *Chemical Waste Management, Inc. v. Environmental Protection Agency*, 869 F.2d 1526, 1535 (D.C. Cir. 1989) (even where agency statement in notice of rulemaking assumes rather than invites comments on an issue, notice is sufficient if it provides interested parties "with a clear indication of the agency's intended course of action \* \* \*"); *Center for Auto Safety v. Peck*, 751 F.2d 1336, 1361 (D.C. Cir. 1985) ("It is simply not the case, however, that all of the essential postulates for an agency rule must be contained in the record.")).

Nevertheless, the agency provided the public a detailed explanation of why it regards cigarettes and smokeless tobacco as drug/device combination products, and why it believes the device provisions of the act may, and should, be used to regulate these products. The agency set forth its rationale for regulating these products as devices in both the August 11, 1995, proposed rule (see 60 FR 41314 at 41348 to 41350) and again in the August 11, 1995 Jurisdictional Analysis (see 60 FR 41453 at 41521 to 41525). Further, the agency identified the precise statutory provisions under which it proposed to regulate these products (see 60 FR 41314 at 41346 to 41352, and 41372).

The agency also put the public on notice, by referencing the Intercenter Agreement between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health, that preloaded drug delivery systems are often regulated using the drug authorities under the act. The agency adequately explained—for notice purposes—why in this instance it proposed a different approach (60 FR 41314 at 41348 to 41350).

With respect to the application of the concept of "intended use," the lengthy discussion in Part II of the 1995 Jurisdictional Analysis provided the public with full disclosure of the agency's rationale for regulating cigarettes and smokeless tobacco based on the "intended use" of these products. The core facts and precedents on which

the agency relied were displayed in a manner the agency believes invited maximum public scrutiny. The agency even provided the public with 11 different examples (9 from the 1980's and 1990's) of the application of the intended use concept to the determination of whether a product, absent express claims, may be regulated as a drug or a device (60 FR 41453 at 41527 to 41531). This level of explanation more than satisfied the notice requirements of the APA as interpreted by the relevant case law.

Finally, the quantity and quality of comments the agency received on the 1995 proposed rule and the 1995 Jurisdictional Analysis suggest that, in fact, the public was adequately notified of the relevant issues. The agency received more comments in this proceeding than it has ever received on any other subject, with over 700,000 comments (including form letters) and over 95,000 distinct or unique sets of comments. More important, the agency received hundreds of pages of comments on the very issues the agency is said to have hidden from the public. Indeed, the two industry comments who complained most vigorously about the supposed deficiencies in the agency's notice of proposed rulemaking themselves filed volumes of comments on the issues they claim the agency concealed.<sup>265</sup> Even the comments of interested nonindustry persons evidenced fair notice of the agency's reasoning for applying the device provisions of the act to cigarettes and smokeless tobacco.<sup>266</sup>

In *Chemical Waste Management*, the plaintiff complained that the Environmental Protection Agency's (EPA) notice of proposed rulemaking treated a certain controversial issue "as an accomplished fact" (869 F.2d at 1535). Like two of the comments here, the plaintiff in *Chemical Waste Management* argued that the APA required the agency to highlight the fact

that its position was subject to debate and to solicit comments on the issue. The United States Court of Appeals for the District of Columbia rejected this argument because EPA had provided notice of its intended course and because the agency in fact received numerous comments on the issue (869 F.2d at 1535). (See also *Shell Oil Co. v. EPA*, 950 F.2d 741, 757 (D.C. Cir. 1991) (recognition of a certain issue in comments may be used to infer that adequate notice of the issue was given); *Haralson v. Federal Home Loan Bank Board*, 678 F. Supp. 925, 926 (D.D.C. 1987) (same).)

As in cases such as *Chemical Waste Management*, the comments FDA received demonstrate that there is no serious claim to be made that the agency has concealed issues from the public. Interested persons representing both sides in this controversial proceeding commented on the very issues the agency supposedly underplayed in its notice of proposed rulemaking.<sup>267</sup>

The comments that challenge the adequacy of the agency's notice confuse the merits of the issue with procedure. The supposed deficiencies in FDA's legal reasoning, and the supposed failure to discuss contrary authorities, raise substantive issues to be resolved during the comment and response-to-comment phase of the proceeding. The possibility that some of the agency's legal conclusions may be subject to debate does not render the notice inadequate. (See *Chemical Waste Management, Inc.*, 869 F.2d at 1535; *Natural Resources Defense Council, Inc. v. Hodel*, 618 F. Supp. 848, 864-65 (E.D. Cal. 1985).)

## 2. The Agency Provided a "Reasoned Explanation" for its Current Position

Several tobacco industry comments also claimed that the agency violated the APA's notice provisions by failing to include a "reasoned explanation" for departing from past precedent on the issue of whether to regulate all cigarettes and smokeless tobacco. In their view, the 1995 proposed rule and the 1995 Jurisdictional Analysis were procedurally infirm because the agency did not adequately explain its basis for past decisions not to regulate these

products, and did not distinguish those decisions from its present position. One of these comments likewise asserted that the agency was required to include in the administrative record each and every document "that formed the basis for, or was an expression or reflection of, FDA's consistent position over more than 80 years that it does *not* have jurisdiction to regulate cigarettes." The absence of this material, according to the comment, demonstrates that the agency failed to consider "obviously relevant" contrary information in proposing to regulate these products.

The authorities cited in the comments at best require that, by the close of an administrative proceeding, the agency must provide a "reasoned explanation" to the extent the agency has departed from a prior formal position. (See, e.g., *RKO Gen., Inc. v. FCC*, 670 F.2d 215 (D.C. Cir. 1980) *cert. denied*, 456 U.S. 927 (1982) (challenge to final order of Federal Communications Commission denying renewal of television license); *Baltimore and Annapolis R. R. v. Washington Metro. Area Transit Comm'n*, 642 F.2d 1365 (D.C. Cir. 1980) (challenge to final order of transit commission); *Greyhound Corp. v. ICC*, 551 F.2d 414 (D.C. Cir. 1977) (challenge to final decision of the labor board); *International Union, United Auto Workers v. NLRB*, 459 F.2d 1329 (D.C. Cir. 1972) (challenge to final decision of labor board); see also *Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto Ins.*, 463 U.S. 29, 43 (1983) (challenge to final rule rescinding passive restraint seatbelt requirement contained in a Department of Transportation standard).) None of these cases, which involved challenges to final agency orders and final rules, holds that at the notice stage of a proceeding, when an agency is proposing to depart from a prior position, the agency must provide a comprehensive "reasoned explanation."

The agency nevertheless agrees that the rulemaking proceeding, taken as a whole, should clearly and rationally justify changes in existing policies. Thus, FDA included in its notice of proposed rulemaking and 1995 Jurisdictional Analysis ample reference to its prior policy and a more than ample discussion of the agency's rationale for changing its policy. Indeed, the very intent of the 1995 Jurisdictional Analysis, and the 622 footnotes supporting the analysis, was to provide the public with a full view of the evidence that supports the need for the agency to take a different approach to the regulation of these products.

<sup>265</sup> See, e.g., Joint Comments of the Smokeless Tobacco Manufacturers, Comment (January 2, 1996), at 43 to 73 (discussing the agency's historical position on agency jurisdiction over tobacco products), at 99-258 (discussing the agency's application of the concept of intended use to tobacco products), and at 259-307 (analyzing the agency's position that cigarettes and smokeless tobacco are combination products that may be regulated as restricted devices); Joint Comments of Cigarette Manufacturers at, among other places, Vol. I (discussing FDA's historical position on jurisdiction), Vol. II (discussing the concept of intended use), and Vol. V (discussing the regulation of cigarettes as medical devices).

<sup>266</sup> See, e.g., Public Citizen Litigation Group, comment (January 2, 1996); American Heart Association, comment (December 26, 1995).

<sup>267</sup> The agency also received a comment criticizing the agency for failing to discuss the June 1994 Federal Trade Commission's (FTC) decision regarding the "Joe Camel" advertising campaign. In section VI. of this document, the agency discusses the FTC's decision, showing that the FTC's decision in 1994 with respect to the "Joe Camel" campaign was neither relevant to, nor contradicted, FDA's discussion of the campaign in the 1995 proposed rule.

As FDA made clear at the outset of its 1995 Jurisdictional Analysis, its decision to propose to regulate these products, when in the past it chose not to (except where claims were made), is based on the fact that "[t]he quality, quantity, and scope of the evidence available to FDA today is far greater than any other time when FDA has considered regulation of cigarettes and smokeless products." (60 FR 41453 at 41464, n. 1.) Footnote 5 of the 1995 Jurisdictional Analysis, in particular, made clear that: (1) The agency in the past had declined to exercise jurisdiction generally over these products; and (2) the reason for taking a different position today is that the evidence before the agency regarding the intended use of these products "has changed dramatically." (60 FR 41453 at 41482, n. 5). In addition, the agency repeatedly stated that its analysis was based on "evidence now available to the agency" (60 FR 41453 at 41464), "current evidence" (60 FR 41466), evidence accumulated since 1980 (60 FR 41482, n. 5), and evidence that has emerged since 1980 or was not widely known until recently (60 FR 41453 at 41483 to 41484, and 41539).

Neither the APA nor the case law cited in the comments requires an agency to provide a thorough "reasoned explanation" for departing from precedent at the notice stage of a proceeding. Rather, the APA at best requires that the agency give notice of its proposal to take a different position or view, and give enough information to allow the public a reasonable opportunity to comment. Not until the close of the proceeding, after public comment has been received, must the agency ensure that it has provided a "reasoned explanation." The agency believes in this instance that its discussion at the notice stage met the standard that courts ordinarily do not impose until the close of an administrative proceeding. Nonetheless, the agency has provided a detailed discussion of the legal and factual bases for taking its current position in section IV. of the 1996 Jurisdictional Determination, annexed hereto.

Finally, the agency does not agree that it was required to include in the record, at the notice stage of the proceeding, each and every prior agency "decision, statement, and finding." Rather, the agency appropriately included in the record enough documentation to give the public notice of the agency's prior position, and notice of the agency's prior reasoning for declining to exercise jurisdiction generally over these

products (absent express claims). For example, the agency incorporated by reference into the administrative record supporting the 1995 Jurisdictional Analysis all significant dockets opened since the conclusion of the 1977 ASH litigation that relate to the agency's jurisdiction over these products. In addition, the agency included in the record in support of its 1995 Jurisdictional Analysis its response to the original ASH citizen petition. The response to the ASH petition outlines in detail the "contrary" view the agency allegedly concealed, including full discussions of the agency's enforcement history with respect to tobacco products and the agency's significant past pronouncements on the subject. In any case, the tobacco industry itself, through its comments, has introduced many of the agency's earlier statements into the administrative record for this proceeding. Thus, unlike the facts presented in cases such as *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986) or *Walter O. Boswell Memorial Hospital v. Heckler*, 749 F.2d 788 (D.C. Cir. 1984), as referenced in the comment, the administrative record for this proceeding already contains the "adverse" information claimed to be lacking, by virtue of the agency's inclusion of documents in the record and the comments received by the agency.

#### D. Adequacy of the Comment Period

FDA received at least one comment urging that the comment period was unreasonably short in light of the complexity of the proposed rule, the number of materials the agency put on public display, and the possible impact of the rule on the tobacco industry. This comment argued that the agency acted arbitrarily and capriciously in deciding to "limit" the comment period to 144 days from the publication of the August 11, 1995, proposal and 95 days from the public release of the documents FDA considered but did not rely upon.

Far from having "limited" the comment period, FDA provided more than twice as much time for comment as the agency's regulations require. (See 60 FR 53560, October 16, 1995 (extending comment period for the proposed rule); 60 FR 53620, October 16, 1995 (extending comment period on Jurisdictional Analysis).)

The APA requires only that an agency "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments \* \* \*." (5 U.S.C. 553(c).) This is all the APA requires;

there is no statutory requirement concerning how many days an agency must allow, nor is there a requirement that an agency must extend the period at the request of an interested person. (See *Phillips Petroleum Co. v. EPA*, 803 F.2d 545, 559 (10th Cir. 1986).)

FDA's own regulations generally afford the public 60 days to comment on a proposed rule, unless the Commissioner shortens or lengthens the period for good cause (21 CFR 10.40(b)(2)). Executive Order 12889 implementing the North American Free Trade Agreement prescribes a minimum comment period of 75 days on certain proposed rules, except when good cause is shown for a shorter comment period. (See 58 FR 69681, December 30, 1993.)

Here, the agency provided the public with 144 days from the publication of the notice, 139 days from the release of the documents the agency cited in support of the rule and the 1995 Jurisdictional Analysis (on August 16, 1995), and 95 days from the release of the materials the agency considered but did not directly rely upon (on September 29, 1995). Thus, even when counting from the date the agency released additional documents of no direct relevance to the 1995 proposed rule, the agency provided much more time for comment on the notice of proposed rulemaking than its regulations, or the Executive Order, require.

Further, on March 20, 1996, the Federal Register published a notice providing an additional 30-day comment period limited to specific documents the agency added to the proposed rulemaking docket (see 61 FR 11349, March 20, 1996) and to the docket in support of the agency's analysis of its jurisdiction (see 61 FR 11419, March 20, 1996). Although the agency expressly limited the scope of the matters on which interested persons could comment, the March 20, 1996, action did provide the public with yet another 30 days on which to comment on issues related to such core subjects as the manipulation of the nicotine content of cigarettes and smokeless tobacco. The March 20, 1996, action also reopened the comment period with respect to the record in support of the agency's proposal to regulate the advertising of these products in "adult publications" and billboard advertising.

The agency is not persuaded that any interested person has been unfairly prejudiced by the length of the comment period. First, FDA considers requests to extend the comment period on a case-by-case basis. Here, on the one hand, the

authors of the comment (the Tobacco Institute together with five major tobacco companies) presented in their request for additional time no compelling reasons to extend the period (such as a new, material study). On the other hand, FDA is faced with a matter raising serious public health concerns. For those reasons, the agency denied the request to extend the period for as long as had been requested (see 60 FR 53560).

Second, each of the five tobacco companies who submitted this joint comment complaining about the length of the comment period also filed suit against FDA 1 day before the Federal Register published FDA's notice of proposed rulemaking. The timing appears to indicate that these firms had been preparing to respond to an FDA proposal to regulate cigarettes and smokeless tobacco for some time. In any case, they were able, jointly, to submit 2,000 pages of comments and 45,000 pages of exhibits within the time allotted for commenting on the Jurisdictional Analysis and the proposed rule. Their submissions far outweigh any others. The agency, therefore, is not persuaded that these interested persons suffered prejudice as a result of FDA's allowing twice as much time as the agency's regulations require. (See *Conference of State Bank Supervisors v. Office of Thrift Supervision*, 792 F. Supp. 837, 844 (D.D.C. 1992) (in light of the comments received, court declined to find that 30-day comment period was insufficient to allow opportunity for meaningful public participation); *Phillips Petroleum Co.*, 803 F.2d at 559 (citing cases in which courts have upheld notice periods of 45 days or less).)

In sum, the agency believes it provided ample additional time for comments—nearly 90 days more than is provided for in the agency's own procedural regulation. Given that it received over 95,000 distinct sets of comments, the agency is not persuaded that the length of the comment period unfairly hampered the quality of the public debate on this matter.

#### E. Conclusion

Because of the importance of the issues involved in this proceeding, the agency compiled the most extensive administrative record in support of a proposed rulemaking in its history. FDA employed procedures that exceeded all legal requirements in giving the public a reasonable opportunity to participate in this matter.

### XIII. Executive Orders

#### A. Executive Order 12606: The Family

Executive Order 12606 (E.O. 12606) directs Federal agencies to determine whether policies and regulations may have a significant impact on family formation, maintenance, and general well-being. The preamble to the 1995 proposed rule stated that the rule would have "no potential negative impact on family formation, maintenance, and general well-being." Specifically, the Food and Drug Administration (FDA) said that the rule would not affect family stability or marital commitments, would not have a significant impact on family earnings, and would not impede parental authority and rights in the education, nurture, or supervision of children. To the contrary, the preamble to the 1995 proposed rule said that the rule would "help the significant majority of American families that seek to discourage their children from using cigarettes and smokeless tobacco" because "[t]he pervasive promotion and easy availability of these products \* \* \* severely hinder the individual family from carrying out this function by itself" (60 FR 41314 at 41356).

In the Federal Register of August 11, 1995, the preamble to the proposed rule (60 FR 41314) (the 1995 proposed rule) also stated that, under section 1(g) of the Executive Order (which instructs agencies to ask about a rule's "message" to young people concerning their behavior, their personal responsibility, and societal norms), the rule would "help reduce the conflict between the anti-smoking messages issued by Federal and State authorities and the pro-tobacco messages seen in advertising" that are attractive to children. This would enable young people "to understand how prevalent tobacco use is in society and also appreciate how their decisions regarding cigarette and smokeless tobacco use can affect their health" (60 FR 41314 at 41356).

In the 1995 proposed rule, FDA invited comments and suggestions on the rule's effect on the family.

FDA received several comments that disagreed with FDA's analysis.

(1) One comment said that the rule would have a significant economic effect on family earnings through increased costs (in order to comply with the rule) or the possible loss of jobs. Another comment said that the rule would destroy some family businesses, especially those dependent on vending machines selling cigarettes or on

sponsorships by cigarette or smokeless tobacco manufacturers.

The agency disagrees with the comments. FDA reiterates that the rule does not affect sales to adults. It is narrowly drawn to reduce young people's access to cigarettes and smokeless tobacco and to reduce the appeal of those products to young people. In short, the rule is intended to prevent illegal sales to young people, and the agency has no evidence to suggest that a significant number of families depend on such sales.

FDA also notes that the final rule, as amended, permits vending machines in facilities that are inaccessible to young people and also permits sponsorships under certain restrictions. These changes to the rule should reduce the potential economic impact on families dependent on vending machine earnings or sponsorships or enable them to adjust their affairs to maintain family earnings.

(2) Several comments said that the rule interferes with parents' ability to raise their children, but did not elaborate on how the rule supposedly interfered in child-rearing.

The agency disagrees with the comments. The rule does not direct parents to educate or raise their children in any particular manner and, insofar as adults are concerned, does not regulate the use of cigarettes or smokeless tobacco by adults. It does reduce both their access and appeal to young people and, as a result, should help those parents who are trying to prevent their children from becoming regular users of these products. Thus, the rule does not interfere with parental authority or the manner in which parents educate, nurture, or supervise their children.

FDA, therefore, reiterates that the rule does not have a negative impact on family formation, maintenance, and general well-being and is consistent with Executive Order 12606.

#### B. Executive Order 12612: Federalism

Executive Order 12612 (E.O. 12612) requires Federal agencies to carefully examine regulatory actions to determine if they have a significant impact on the States, on the relationship between the States and the Federal government, and on the distribution of power and responsibilities among the various levels of government. E.O. 12612 directs Federal agencies that are formulating and implementing policies to be guided by certain federalism principles, such as encouraging a "healthy diversity in the public policies adopted by the people of the several States according to their own



conditions, needs, and desires" (section 2 of E.O. 12612).

Although § 897.42 of the 1995 proposed rule would have excluded from preemption under section 521 of the act more stringent State and local requirements that do not conflict with requirements imposed under FDA's final rule, FDA has deleted § 897.42 from the final rule because of significant concerns with regard to the validity of that section's proposed preemption exclusion. See discussion in section X. of this document. Thus, under the express provisions of section 521(a) of the act, FDA regulation of cigarettes and smokeless tobacco as nicotine-delivery devices will result in preemption of State and local requirements governing the sale and distribution of cigarettes and smokeless tobacco when such requirements are different from, or in addition to, the requirements under FDA's final rule.

FDA received many comments on the 1995 proposed rule regarding its possible impact on State and local governments. Most comments came from individual State legislators in over 15 States (often using the same text or paragraphs). FDA also received comments from United States Senators and Representatives, four State governors, three lieutenant governors, as well as a number of State and local health departments, substance abuse programs, and law enforcement agencies. In addition, FDA received comments from industry trade associations and individual retailers. After careful consideration of these comments, FDA has assessed the rule's impact on the States, on the relationship between the States and the Federal government, and on the distribution of power and responsibilities among the various levels of government. As discussed below in this section, the agency concludes that the preemptive effects of the final rule are consistent with E.O. 12612.

(3) Many comments, including several from legislators, expressed opposition to the 1995 proposed rule on the grounds that the rule adversely affected State sovereignty by infringing on States' rights to regulate tobacco products, to protect their citizens, and to regulate businesses within the State. Some comments from State legislators criticized the rule, interpreting it as a statement that the State are "unable to care for [their] own children," while other comments said that legislators, not FDA, should address issues affecting private citizens because legislators are elected officials who can be held

politically accountable by their constituents.

Some comments asserted that the 1995 proposed rule would prevent States from experimenting with or trying different local approaches to reduce the accessibility and appeal of cigarettes and smokeless tobacco products. Some of these comments argued that their State laws were either adequate or superior to the 1995 proposed rule, citing, for example, State vending machine restrictions, State laws prohibiting distribution of tobacco products to minors, and State proof-of-age requirements. Moreover, some comments argued that FDA has failed to show that youth access to, and use of, tobacco products is a national (rather than State) concern warranting Federal action.

In contrast, several comments from State departments of health and State attorneys general noted that tobacco regulation is not solely a State issue. Moreover, some of the comments supported the rule for its potential impact on public health and on illegal sales of tobacco products to young people.

FDA recognizes the pioneering and continuing role in the area of regulation of youth access to tobacco products that States have played, particularly certain active tobacco-control States. Federal cooperation with, and continued reliance upon, innovative and aggressive State and local enforcement efforts is essential.

As explicitly recognized in E.O. 12612, however, Federal action limiting the discretion of State and local governments is appropriate "where constitutional authority for the action is clear and certain and the national activity is necessitated by the presence of a problem of national scope" (section 3(b) of E.O. 12612). The final rule meets both of these conditions. First, the constitutional authority for the final rule is clearly rooted in the act which was enacted by Congress under the authority of the Commerce Clause of the Constitution, art. I, section 8, cl. 3. Second, youth access to cigarettes and smokeless tobacco is a problem of national scope that necessitates the provisions established by the final rule.

As discussed in the preamble to the 1995 proposed rule, approximately 3 million children under the age of 18 are daily smokers (60 FR 41314 at 41317). Moreover, every day, approximately another 3,000 young people become regular smokers (*Id.*). Children annually consume hundreds of millions of cigarettes, with the estimates ranging

from 516 million to 947 million packages (*Id.*). Although most segments of the American adult population have decreased their use of cigarettes, smoking among young people has recently begun to rise (60 FR 41314 at 41315). With regard to smokeless tobacco, similar statistics demonstrate the extent of the problem in this area—an estimated 1 million adolescent males use smokeless tobacco (60 FR 41314). These figures clearly demonstrate a serious problem which exists at a national level. The health effects associated with cigarettes and smokeless tobacco are well established and have national social and health implications that warrant Federal attention.

As discussed in section X. of this document, FDA believes the requirements it is establishing in this final rule set an appropriate floor for regulation of youth access to tobacco products but do not, as a policy matter, reflect a judgement that more stringent State or local requirements are inappropriate. Indeed, State and local governments may apply for exemption from preemption under section 521(b) of the act with regard to State and local requirements governing the sale and distribution of cigarettes and smokeless tobacco. A State or local requirement will be exempted from preemption under section 521(b) of the act if the State or local requirement: meets the exemption requirements established under that section, and is consistent with the goals in the final rule. The availability of exemptions from preemption established under section 521(b) of the act enables State and local governments to preserve or enact more stringent requirements governing the sale and distribution of cigarettes and smokeless tobacco.

(4) Several comments asserted that States should be free to decide how to allocate their resources, including decisions as to whether any resources should be spent on tobacco control. Other comments expressed concern as to the rule's possible impact on State resources, explaining that States lacked resources to enforce the rule or predicting that FDA would lack sufficient resources to enforce the rule and, as a result, would have States handle enforcement matters.

FDA believes that these concerns are unfounded. First, because FDA is responsible for enforcing this rule, the rule should not require the expenditure of State resources for its enforcement. Second, with regard to State tobacco control, State and local governments will retain flexibility to choose the

appropriate allocation of their resources in this area through the availability of exemptions from preemption under section 521(b) of the act.

(5) Several comments also expressed strong concern regarding the rule's possible impact on the State economies, particularly with respect to farmers, manufacturers, distributors, and retailers. A detailed analysis of the rule's economic impact can be found in section XV. of this document.

Section 3(d)(3) of E.O. 12612 directs Federal departments and agencies to consult with appropriate officials and organizations representing the States in developing those standards. Similarly, section 4(d) of E.O. 12612 instructs Federal departments and agencies to consult, to the extent practicable, with State officials and organizations when the Federal department or agency "foresees the possibility of a conflict between State law and federally protected interests within its area of regulatory responsibility." Moreover, section 4(e) of E.O. 12612 requires Federal departments and agencies to "provide all affected States notice and an opportunity for appropriate participation in the proceedings" when the Federal department or agency proposes to act through rulemaking to preempt State law.

The proposed rule published in the Federal Register of August 11, 1995, notified States and local governments of the Federal interest in regulating the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents. FDA, through the comment period on the proposed rule, gave State and local governments notice and an opportunity to participate in the rulemaking process, as required by E.O. 12612. This final rule, as well as the exemption document, which appears elsewhere in this issue of the Federal Register, provide additional notice to State and local governments. Further opportunity for participation is provided by the availability of exemptions from preemption set forth in section 521(b) of the act.

In conclusion, FDA has determined that the preemptive effects of the final rule are consistent with E.O. 12612.

*C. Executive Order 12630:  
Governmental Actions and Interference  
with Constitutionally Protected Property  
Rights*

Executive Order 12630 (E. O. 12630) directs Federal agencies to "be sensitive to, anticipate, and account for, the obligations imposed by the Just Compensation Clause of the Fifth

Amendment in planning and carrying out governmental actions so they do not result in the imposition of unanticipated or undue additional burdens on the public fisc" (Section 3(a)). Section 3(c) of the order states that actions taken to protect the public health and safety "should be undertaken only in response to real and substantial threats to public health and safety, be designed to advance significantly the health and safety purpose, and be no greater than is necessary to achieve the health and safety purpose." Additionally, section 4(d) of E.O. 12630 requires, as a prerequisite to any proposed action regulating private property use for the protection of public health and safety, each agency to: (1) Clearly identify the public health or safety risk created by the private property use that is the subject of the proposed action; (2) establish that the proposed action substantially advances the purpose of protecting the public health and safety against the identified risk; (3) establish, to the extent possible, that the restrictions imposed on private property are not disproportionate to the extent to which the use contributes to the overall risk; and (4) estimate, to the extent possible, the potential cost to the Government should a court later determine that the action constitutes a taking.

The agency, in the preamble to the 1995 proposed rule, considered whether the rule would result in a "taking" of private property and concluded that, while some requirements might affect private property, the rule did not result in a "taking" of that property. (See 60 FR 41314 at 41357 through 41359.) In brief, the preamble to the 1995 proposed rule noted that the proposal would prohibit the use of a nontobacco product trade name on a tobacco product, eliminate vending machines and self-service displays, restrict outdoor advertising from being placed within 1,000 feet of any elementary or secondary school or playground, prohibit all brand identifiable nontobacco items (such as hats and tee-shirts), and require established names and a brief statement on labels, labeling, and/or advertising. Sponsorship, under the 1995 proposed rule, would be limited to the corporate name. The preamble to the 1995 proposed rule explained that the rule did not result in a "taking" because the rule would not require the Government to physically invade or occupy private property and would not deny all economically viable uses of property. For example, the preamble to the 1995 proposed rule also

stated that some items, such as vending machines, self-service displays, and nontobacco items, could be adapted to other uses. The preamble to the 1995 proposed rule also found that the rule substantially advanced the purpose of protecting the public health and that the restrictions were not disproportionate to the extent to which the use of the private property contributed to the public health risk (60 FR 41314 at 41357 through 41359). FDA also invited interested persons to submit information to enable the agency to determine the potential cost to the Government if a court found that the actions described in the 1995 proposed rule constituted a taking.

The final rule, as amended, prohibits the use of a trade name of a nontobacco item for any tobacco product, restricts the placement of vending machines and self-service displays, restricts outdoor advertising from being placed within 1,000 feet of any elementary or secondary school or playground, prohibits all brand identifiable nontobacco items, such as hats and tee-shirts and requires established names on labels, labeling, and/or advertising, and places certain restrictions on sponsorship. Thus, the final rule, in many respects, is more lenient than the 1995 proposed rule. For example, the 1995 proposed rule would have eliminated the use of vending machines; the final rule permits vending machine sales to occur in locations that are inaccessible to young people. The 1995 proposed rule would have eliminated mail-order sales; the final rule permits such sales to continue. So, given that the 1995 proposed rule did not result in a "taking," the final rule, being more lenient than the 1995 proposed rule, also should not result in a "taking."

Nevertheless, FDA received several comments asserting that the rule would effect a "taking" of private property. Most comments did not assign a specific monetary value to the private property which they felt would be "taken" or, instead, gave values or figures applicable to the entire industry rather than values or figures that would apply to the market (which, in this case, would be sales to people under age 18) affected by the rule.

(6) Several comments, particularly from retailers, claimed that the 1995 proposed rule's restrictions on self-service displays constituted a "taking." A few comments explained that, for self-service displays, requiring the displays to be moved behind the counter would be analogous to a Government requiring an easement on real property and, as a

result, would violate the Fifth Amendment. FDA also received a small number of comments from firms that manufacture displays; these firms argued that the rule would essentially force them out of business and represent a "taking" of the business.

FDA disagrees with the comments. The final rule, as amended, permits self-service displays (merchandisers only) in facilities that are totally inaccessible to young people. Thus, in those facilities where merchandisers will be permitted, the rule will not require the merchandisers to be removed, and firms that manufacture merchandisers will continue to have a market for their merchandisers.

Retailers might be able to avoid or reduce the rule's impact on some merchandisers if those merchandisers could be adapted to other uses. For example, a merchandiser that consisted of bare shelves could be used to display products other than cigarettes and smokeless tobacco. Other merchandisers could be moved and, as a result, would retain their utility; for example, a counter display that stands near a cash register could be moved behind the counter and still be used for cigarettes and smokeless tobacco.

Additionally, as explained in greater detail in section XI. of this document, reductions in personal property's value, even prohibitions on all economically viable uses, and financial expenditures to comply with a regulatory requirement do not necessarily establish a taking.

(7) Several comments asserted that the rule would eliminate the use of vending machines. In the preamble to the 1995 proposed rule, FDA cited an article from a vending machine publication to suggest that vending machines could be converted to sell other products and so, while the 1995 proposed rule would prohibit the use of vending machines for cigarettes and smokeless tobacco, the ability to convert a vending machine to other uses reduced the likelihood of a "taking" (60 FR 41314 at 41358). However, FDA received several comments explaining that some cigarette vending machines, particularly older models, cannot be adapted to other uses so that the 1995 proposed rule would destroy the value of those older vending machines.

As discussed earlier in this document, the final rule permits vending machines in facilities that are totally inaccessible to young people. While this may limit the number of places where vending machines may be used, may exclude vending machines from places where they were used most profitably, or, for

those vending machines that cannot be moved, may compel the vending machine owner to convert the machine to other uses, if possible, the final rule's restrictions do not constitute a taking. Reductions in personal property's value, even prohibitions on all economically viable uses, and financial expenditures to comply with a regulatory requirement do not necessarily establish a taking.

(8) Several comments asserted that the rule would reduce sales or tax revenues, prompt companies to terminate employees, or suspend sponsorship of events, thereby depriving States of revenues associated with those sponsored events or eliminating the event itself. For example, one State legislator claimed that the rule would adversely affect automobile racing events in the State, leading to a loss of 8 million dollars in revenue and adversely affecting the State's tourism department. Another State legislator asserted that the rule's sponsorship restrictions would end rodeo events in the State.

FDA disagrees with the comments. While the rule's economic impacts may be significant, those impacts do not necessarily result in a taking. For example, the final rule does not require firms to terminate employees or to stop sponsoring events. In fact, the final rule expressly permits sponsorships in the corporate name. The concerns expressed by the comments are also speculative and, to the extent that they do occur, would result from decisions made by third parties rather than by FDA. The Fifth Amendment requires just compensation for a governmental taking of private property; it does not require compensation for the consequential damages resulting from the exercise of a lawful Government regulation on that property.

Indeed, as noted in the preamble to the 1995 proposed rule, courts have generally required either a physical invasion of the property or a denial of all economically beneficial or productive use of the property and examined the degree to which the governmental action serves the public good, the economic impact of that action, and whether the action has interfered with "reasonable investment-backed expectations" (60 FR 41314 at 41357 through 41358). The preamble to the 1995 proposed rule noted that deprivation of the most beneficial use of property does not constitute a taking and that Government regulation often involves adjustment of rights for the public good. If every Government regulation resulted in a taking, then the

Government would be effectively required to "regulate by purchase" (60 FR 41314 at 41358 (citing *Andrus v. Allard*, 444 U.S. 51, 65 (1979))). Here, the agency is not directing retailers to terminate staff, taking revenue belonging to retailers, or ending sponsored events. It is only issuing regulations to reduce illegal cigarette and smokeless tobacco to young people and the appeal of such products to young people. Retailers would still receive revenues from legal sales to adults; sponsorships in the corporate name could occur.

Other cases support the notion that lawful regulatory action does not constitute a taking merely because the Government action diminishes the value of private property, reduces profits, or prevents the most beneficial use of property (see *Carlin Communications, Inc. v. Federal Communications Comm'n*, 837 F.2d 546, 557-558 n. 5 (2d Cir.), *cert. denied*, 488 U.S. 924 (1988) (FCC regulation of "dial-a-porn" services to protect minors did not constitute a taking); *Galloway Farms, Inc. v. United States*, 834 F.2d 998 (Fed. Cir. 1987) (trade embargo, while closing off certain markets, did not eliminate all economic value so no taking occurred); *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Public Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), *cert. denied*, 469 U.S. 1215 (1985) (nursing home's decision to participate in Medicaid program was voluntary and so a statute pertaining to Medicaid rates did not constitute a taking); *Carruth v. United States*, 627 F.2d 1068, 1081 (Ct. Cl. 1980) (regulation affecting contaminated peanuts, while reducing their value, did not constitute a taking); *Warner-Lambert Co. v. Federal Trade Comm'n*, 562 F.2d 749, 759 n. 45 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978) (FTC order requiring corrective advertising did not constitute a taking)).

Furthermore, courts have generally declined to require compensation for the loss of contracts that could not be completed following the enactment of a new statute or regulation or action by the Government and have not required compensation for the loss of future or anticipated profits. In *Omnia Commercial Co. v. United States*, 261 U.S. 502 (1923), the Supreme Court had to decide whether the Government's acquisition of a steel company's entire production of steel plate constituted a taking of a firm's contract for a large quantity of steel plate from the same steel company. The Court wrote that, "There are many laws and governmental

operations which injuriously affect the value of or destroy property—for example, restrictions upon the height or character of buildings, destruction of diseased cattle, trees, etc., to prevent contagion—but for which no remedy is afforded. Contracts in this respect do not differ from other kinds of property” (*Id.* at pp. 508 through 509). The Court reviewed earlier decisions and stated that:

The conclusion to be drawn \* \* \* is, that for consequential loss or injury resulting from lawful governmental action, the law affords no remedy. The character of the power exercised is not material. \* \* \* If, under any power, a contract or other property is taken for public use, the Government is liable; but, if injured or destroyed by lawful action, without a taking, the Government is not liable.

(*Id.* at p. 510)

The Court held that while the Government took the steel, it did not take the contract itself and that “[f]rustration and appropriation are essentially different things” (*Id.* at p. 513). (See also *Louisville & Nashville R.R. Co. v. Mottley*, 219 U.S. 467, 484 (1911); *NL Industries, Inc. v. United States*, 839 F.2d 1578, 1579 (Fed. Cir.), *cert. denied*, 488 U.S. 820 (1988) (“frustration of a business by loss of a customer was not a taking”); *Carruth*, 627 F.2d at 1081 (“[I]n cases where there has been no direct appropriation of property by governmental agencies, consequential damages resulting from the exercise of lawful regulations are not compensable takings within the purview of the Fifth Amendment”).)

Thus, FDA disagrees with the comments suggesting that the rule will result in a taking of jobs or future revenues associated with sponsored events.

(9) Several comments said that the 1995 proposed rule’s restrictions on the use of trade names constitute a taking of trade names or the goodwill associated with a tradename or asserted that one has a “right” to use a brand name in any manner.

As discussed in section XI. of this document, the agency disagrees that any provision in this rule effects a taking of trademarks and goodwill.

#### XIV. Environmental Impact

In the Federal Register of August 11, 1995 (60 FR 41314), the preamble to the proposed rule stated that FDA had determined under § 25.24(a)(8), (a)(11), and (e)(6) that the proposed action was of a type that does not individually or cumulatively have a significant impact on the human environment. No new information or comments have been

received that would affect the agency’s previous determination that this action has no significant impact on the human environment, and that neither an environmental assessment nor an environmental impact statement is required.

#### XV. Analysis of Impacts

##### A. Introduction and Summary

The Food and Drug Administration (FDA) has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts and equity). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of such rule on small entities. Section 202 of the Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 (adjusted annually for inflation) in any year. Section 205 of the Unfunded Mandates Reform Act also requires that the agency identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule. The following analysis, in conjunction with the remainder of this preamble, demonstrates that this rule is consistent with the principles set forth in the Executive Order and in these two statutes.

FDA published its preliminary economic analysis in the preamble to its 1995 proposed regulation. In response, the agency received thousands of comments raising economic issues or concerns. Representatives of affected industry sectors emphasized burdens in excess of those estimated in the preliminary economic analysis. Other comments stressed the considerable economic value of the expected public health benefits. Although few comments provided quantifiable data on projected

economic impacts, whether benefits or burdens, a report prepared by the Barents Group and presented as Volume 11 of the Tobacco Institute submission provided a comprehensive critique of the methodology, assumptions, and cost estimates presented in FDA’s preliminary economic analysis and developed alternative estimates of regulatory costs. Other comments addressed selected economic issues. FDA carefully examined and evaluated the reasoning and data presented in these comments, accepted those that were persuasive, and presents this revised analysis of the final rule.

In its preliminary analysis, FDA based the benefits of the 1995 proposed rule on a finding that compliance could help to achieve the Department’s “Healthy People 2000” goal of reducing underage tobacco use by one-half. Comments received in response to the proposal have reinforced the agency’s conviction that this goal can be realized, although it will require the active support and participation of State and local governments and civic and community organizations, as well as manufacturers and retail dispensers of tobacco products. In the Federal Register of January 19, 1996 (61 FR 1492), the Substance Abuse and Mental Health Services Administration (SAMHSA) issued a regulation governing a program of State-operated enforcement activities to restrict the sale or distribution of tobacco products to individuals under the age of 18. SAMHSA predicted that its rule would cut the rate of underage tobacco consumption by between one-tenth and one-third. FDA can not separately quantify the incremental benefits of the respective agency programs, due to the substantial interdependencies and uncertainties regarding future compliance with these rules; but finds that its final rule and the SAMHSA regulation are fully complementary and, working together, will produce results that would more than equal the sum of their independent efforts.

Each year, an estimated 1 million adolescents under the age of 18 begin to smoke cigarettes. The Centers for Disease Control and Prevention (CDC) estimate that approximately one in three of these adolescents will die of smoking-related diseases, and FDA has concluded that this projection provides the best estimate of the excess fatality rate. FDA finds that even overly conservative projections indicate that achieving the “Healthy People 2000” goal of reducing underage tobacco use by one-half would prevent well over

60,000 early deaths, gaining over 900,000 future life-years for each year's cohort of teenagers who would otherwise begin to smoke. The monetary value of these health benefits (at a 3 percent discount rate) is estimated to total \$28 to \$43 billion per year and includes \$2.6 billion in medical cost savings, \$900 million in productivity gains from reduced morbidity, and \$24.6 to \$39.7 billion per year in

willingness-to-pay values for averting premature fatalities. (Because of the long periods involved, a 7 percent discount rate reduces the total benefits to about \$9.2 to \$10.4 billion per year). If the agency's goal were exceeded, these benefits would be even larger. Moreover, if even a fraction of the goal were achieved, the benefits would substantially outweigh the costs of the rule. As shown in Table 1c, halting the

onset of smoking for only 1/20 of the 1 million adolescents who become new smokers each year would provide annual benefits valued at from \$2.8 to \$4.3 billion a year. In addition, although FDA has not quantified the benefits of reducing the number of serious illnesses attributable to the use of smokeless tobacco by youngsters under the age of 18, the agency is convinced that these benefits also will be substantial.

TABLE 1c.—ANNUAL ILLNESS-RELATED BENEFITS OF ALTERNATIVE EFFECTIVENESS RATES (UNDISCOUNTED LIVES AND LIFE-YEARS; 3% DISCOUNT RATE FOR MONETARY VALUES)<sup>1</sup>

Fraction of Teenage Cohort Deterred	Fewer Teen-agers who will Smoke as Adults <sup>3</sup> (No.)	Smoking Related Deaths Averted (No.)	Life-Years Saved (No.)	Medical Savings (\$bils.)	Morbidity-Related Productivity Savings (\$bils.)	Mortality-Related Will- ingness-to-Pay		Total Benefits	
						Life-Yrs. Saved (\$bils.)	Deaths Averted (\$bils.)	Low (\$bils.)	High (\$bils.)
1/2 <sup>2</sup>	250,000	60,200	905,300	2.6	0.9	24.6	39.7	28.1	43.2
1/3	167,000	40,100	603,600	1.8	0.6	16.4	26.4	18.7	28.8
1/5	100,000	24,100	362,100	1.1	0.4	9.8	15.9	11.2	17.3
1/10	50,000	12,000	181,100	0.5	0.2	4.9	7.9	5.6	8.6
1/20	25,000	6,000	90,500	0.3	0.1	2.5	4.0	2.8	4.3

<sup>1</sup> Totals may not add due to rounding.

<sup>2</sup> Estimate used in analysis.

<sup>3</sup> Assumes 50% of adolescents who are deterred from smoking continue to refrain as adults.

In its evaluation of the economic impact on industry, FDA also includes those costs that might be attributable to the SAMHSA program, as the rules of both agencies work collectively to reduce youth access to tobacco products. As a result, the overall estimated compliance costs of the rules range from \$174 million to \$187 million in one-time costs and from \$149 million to \$185 million in annual operating

costs (see Table 2). Manufacturers of tobacco products will incur one-time costs ranging from \$78 million to \$91 million, primarily for removing prohibited point-of-sale promotional items and self-service displays, and for changing package labels. As the responsibility for removing the prohibited point-of-sale promotional and display items resides with the owner, manufacturers and retailers may

ultimately share the costs of removal and replacement. FDA's cost estimates assume that manufacturers will pay for most removal and installation activities and retailers will pay for most replacement items. (If, in fact, retailers assume most removal responsibilities, the estimated manufacturer costs fall by about \$47 million).

TABLE 2.—COSTS OF FDA AND SAMHSA REGULATIONS (\$ mils.)<sup>1</sup>

Requirements By Sector	One-Time Costs	Annual Operating Costs
<b>Tobacco Manufacturers</b>	<b>78–91</b>	<b>2</b>
Point-of-Sale Advertising	30	
Self-Service Ban	40	
Label Changes	4–17	
Paperwork Requirements		1.2
Training	1.5	0.2
Readership Surveys	2	1
<b>Retail Establishments</b>	<b>96</b>	<b>78</b>
Training	34	20
I.D. Checks		43
Self-Service Ban	57	11
Point-of-Sale Advertising	5	
Vending Machines		3.5
<b>Consumers</b>		<b>41–50</b>
I.D. Checks		41–50
<b>Government</b>		<b>28–55</b>
States (SAMHSA)		25–50
FDA		3–5
<b>TOTAL</b>	<b>174–187</b>	<b>149–185</b>

<sup>1</sup> Assumes manufacturers remove prohibited retail display. If retailers bear full burden, manufacturer one-time costs fall by about \$47 million and retailer one-time costs rise by about \$17 million. Advertising restrictions are considered under distributional effects. Excludes costs of short-term resource dislocation and educational programs.

Retail establishments will incur an estimated \$96 million in one-time costs. About \$57 million of these costs are due to the self-service restriction, primarily for replacing display cases and other functional promotional items. (If retailers rather than manufacturers remove the prohibited point-of-sale advertising and display items, the estimated retailer costs rise by about \$17 million). The retail sector will also incur about \$78 million in annual costs. In addition to new labor costs attributable to the self-service restrictions, both the FDA and SAMHSA rules impose costs for training employees to verify customer ages, for routinely checking I.D.'s of young purchasers, and for foregoing profits due to reduced vending machine sales. Consumers will bear costs of up to \$50 million annually for incurring some delay in checkout lines. Finally, enforcement of these rules may cost the FDA from \$3 million to \$5 million per year and State governments from \$25 million to \$50 million per year for administering various SAMHSA enforcement programs.

FDA could not, however, quantify every regulatory cost. For example, the agency may require certain tobacco manufacturers to broadcast educational messages under the agency's notification process. Cost estimates for these activities will be developed in parallel with the program elements. In

addition, a number of commercial sectors will experience costs for short-term dislocations of current business activities. Neither FDA nor any of the industry comments on the agency's proposal projected the magnitude of these costs, but they would be mitigated for those businesses that anticipate the adjustments in long-term business plans.

In addition to the costs described previously, the rule will create significant distributional and transitional effects. Some industry comments asserted that FDA had neglected the cost of lost sales revenues in its preliminary economic analysis and one industry study estimated these "Illustrative Costs" at from \$1.3 billion to \$3.3 billion per year. In fact, FDA had considered these sector-specific revenue reductions, but described the impacts as distributional effects, rather than as net societal costs. For example, any lost sales experienced by suppliers of advertising were considered distributional impacts, because dollars not spent on advertising will not be lost to the U.S. economy, but will be spent on other goods and services. As acknowledged by the authors of one of the economic impact analyses commissioned by the tobacco manufacturing industry:

\* \* \* when tobacco product manufacturers decrease their advertising expenditures, the money not spent translates into increased profits for the industry. The

increased profits ultimately end up in the hands of the companies' owners (shareholders) either as direct payouts or as investments on their behalf in other lines of business. In general, these profits are ultimately recycled into increased consumption and investment by the owners of the companies.

Similarly, the anticipated slow but persistent decline in tobacco product sales revenues are not societal costs, because the dollars not spent on tobacco-related items will be spent on other goods or services.

Nevertheless, FDA is aware that many tobacco-related industry sectors will be adversely affected by this rule. Tobacco manufacturers and suppliers will face increasingly smaller sales, because reduced tobacco consumption by youth will lead, over time, to reduced tobacco consumption by adults. The impact of this trend on industry revenues, however, will be extremely gradual, requiring over a decade to reach an annual decrease of even 4 percent. Also, if State and Federal excise tax rates on tobacco products remain at current levels, tax revenues would decrease slowly over time, falling by about \$231 million and \$196 million, respectively, by the 10th year following compliance with the regulation.

Tobacco manufacturers spent \$6.2 billion on advertising, promotional, and marketing programs in 1993, and about 30 percent may be substantially altered to reflect the various "text only"

restrictions or other prohibitions. If tobacco companies choose to reduce advertising and promotional activities due to the FDA restrictions, the sectors affected would include advertising agencies and communications media, owners of retail and outdoor advertising space, and recipients of corporate brand-name sponsorships (especially auto racing). These businesses would need to attract new revenues to maintain current levels of profitability. Similarly, vending machine operators will need to find substitute products to replace up to 3 percent of their sales revenues.

In summary, FDA finds that compliance with this rule will bring significant health benefits to the U.S. population. The rule will also exact long-term revenue losses on the tobacco industry and short-term costs on various affiliated industry sectors. With regard to small businesses, many near-term impacts will be small or transitory, but some business will be adversely affected. For a small retail convenience store not currently complying with this rule, the additional first year costs could average \$400. For those convenience stores that already check customer identification, these costs average \$137, largely to relocate tobacco product displays. Moreover, the rule will not produce significant economic problems at the national level, as the long-term displacement within tobacco-related sectors will be offset by increased output in other areas. Thus, under the Unfunded Mandates Act, FDA concludes that the substantial benefits of this regulation will greatly exceed the compliance costs that it imposes on the U.S. economy. In addition, the agency has considered other alternatives and determined that the current rule is the least burdensome and most cost-effective alternative that would meet the objectives of this rule.

#### B. Statement of Need for Action

The need for action stems from the agency's determination to ameliorate the enormous toll on the public health that is directly attributable to the consumption by adolescents of cigarettes and smokeless tobacco. According to the nation's most knowledgeable health experts, tobacco use is the most important preventable cause of morbidity and premature mortality in the United States, accounting each year for over 400,000 deaths (approximately 20 percent of all deaths). Moreover, these morbidity and mortality burdens do not spare middle aged adults—with the average smoking-

related death responsible for the loss of up to 15 life-years.<sup>268</sup>

In its guidelines for the preparation of Economic Impact Analyses, OMB asks that Federal regulatory agencies determine whether a market failure exists and if so, whether that market failure could be resolved by measures other than Federal regulation. The basis for this request derives from standard economic welfare theory, which by assuming that each individual is the best judge of his/her own welfare, concludes that perfectly competitive private markets provide the most efficient use of societal resources. Accordingly, the lack of perfectly competitive private markets (market failure) is frequently used to justify the need for Government intervention. Common causes of such market failures include monopoly power, inadequate information, and market externalities or spillover effects.

While FDA agrees that various elements of market failure are relevant to the problem of teenage use and tobacco addiction, the agency also believes that this regulatory action would be justified even in the absence of a traditional market failure. As noted previously, the implications of the market failure logic are rooted in a basic premise of the standard economic welfare model—that each individual is the best judge of his/her own welfare. FDA, however, is convinced that this principle does not apply to children and adolescents. Even steadfast defenders of individual choice acknowledge the difficulty of applying the "market failure" criterion to non adults. Littlechild, for example, adds a footnote to the title of his chapter on "Smoking and Market Failure"<sup>269</sup> to note that "[t]he economic analysis of market failure deals with choice by adults." Although both Beales<sup>270</sup> and Viscusi find that young persons balance risks and rewards in making decisions on whether or not to smoke, Viscusi explains that:

[n]evertheless, there are some classes of choices that have major consequences, and for that reason society may wish to reserve the privilege of making these choices until a

particular age is reached. These limits should, however, be set according to the age at which individuals are believed to be capable of making reasonable long-term decisions regarding their welfare, rather than some arbitrary date independent of the choice context. The emerging consensus of smoking restriction policies has focused age 18 as the minimum age for the purchase of cigarettes.<sup>271</sup>

FDA concludes, therefore, that even if some children do make rational choices, the agency's regulatory determinations must reflect the societal conviction that children under the age of legal consent cannot be assumed to act in their own best interest.<sup>272</sup>

In particular, FDA finds that the pervasiveness and imagery used in industry advertising and promotional programs often obscure adolescent perceptions of the significance of the associated health risks and the strength of the addictive power of tobacco products. Section VI. of this document describes numerous studies on the shortcomings of the risk perceptions held by children. Health economist Victor R. Fuchs describes the typical sequence:

There is considerable evidence that the [time discount] rate falls as children mature. Infants and young children tend to live very much for the present; the prospect of something only a week in the future usually has little influence over their behavior. As children get older their time horizons lengthen, but once adult status is reached there seems to be little correlation between time discount and age.<sup>273</sup>

Thus, although most youngsters acknowledge the existence of tobacco-related health risks, the agency finds that the abridged time horizons of youth make them exceptionally vulnerable to the powerful imagery advanced through targeted industry advertising and promotional campaigns. In effect, these conditions constitute an implicit market failure not adequately remedied by existing government action.

Moreover, the agency does not view these results as inconsistent with the growing economic literature based on the Becker and Murphy models of "rational addiction."<sup>274</sup> Although several empirical studies have

<sup>268</sup> Statement of Clyde Behney and Maria Hewitt on Smoking-Related Deaths and Financial Costs: Office of Technology Assessment Estimates for 1990 Before the Senate Finance Committee, pp. 1-2, April 28, 1994.

<sup>269</sup> Littlechild, S. C., "Smoking and Market Failure," in "Smoking and Society: Toward a More Balanced Assessment," edited by R. D. Tollison, Lexington Books, p. 271, 1986.

<sup>270</sup> Beales III, J. Howard, "Advertising and the Determinants of Teenage Smoking Behavior," p. 44, 1993.

<sup>271</sup> Viscusi, W. K., "Smoking: Making the Risky Decision," Oxford University Press, New York, p. 149, 1992.

<sup>272</sup> Goodin, R. E., "No Smoking: The Ethical Issues," University of Chicago Press, pp. 30-32, 1989.

<sup>273</sup> Fuchs, V. R., "How We Live," Harvard University Press, Cambridge, MA, pp. 228-229, 1983.

<sup>274</sup> Becker, G. S., and K. M. Murphy, "A Theory of Rational Addiction," Journal of Political Economy, vol. 96, No. 4, pp. 675-700, 1988.



demonstrated that, for the general population, cigarette consumption is "rationally addictive" in the sense that current consumption is affected by both past and future consumption.<sup>275</sup> Chaloupka notes that this "rationality" does not hold for younger or less educated persons, for whom past but not future consumption maintains a significant effect on current consumption. He concludes, "[t]he strong effects of past consumption and weak effects of future consumption among younger or less educated individuals support the a priori expectation that these groups behave myopically."<sup>276</sup>

FDA's justification of this regulation relies on the total costs associated with childhood addiction to tobacco, rather than on the external or spillover costs to nonusers. Nevertheless, a further market failure would exist if the use of tobacco imposed such costs on nonusers. Many studies have attempted to calculate the societal costs of smoking, but few have addressed these externalities. The most detailed research on the issue of whether smokers pay their own way is the 1991 study by Manning, et al.,<sup>277</sup> which develops estimates of the present value of the lifetime external costs attributable to smoking. This study examines differences in costs of collectively financed programs for smokers and nonsmokers, while simultaneously controlling for other personal characteristics that could affect these costs (e.g., age, sex, income, education, and other health habits, etc.). The authors found that nonsmokers subsidize smokers' medical care, but smokers (who die at earlier ages) subsidize nonsmokers' pensions. On balance, they calculated that, before accounting for excise taxes, smoking creates net external costs of about \$0.15 per pack of cigarettes in 1986 dollars (\$0.33 per pack adjusted to 1995 dollars by the medical services price index). While acknowledging that these

estimates ignored external costs associated with lives lost due to passive smoking, perinatal deaths due to smoking during pregnancy, and deaths and injuries caused by smoking-related fires, the authors concluded that there is no net externality, because the sum of all smoking-related externalities is probably less than the added payments imposed on smokers through current Federal and State cigarette excise taxes. A Congressional Research Service Report to Congress concurred with the study's conclusion.<sup>278</sup> although many uncertainties remain regarding the potential magnitude of the omitted cost elements.

### C. Regulatory Benefits

#### 1. Prevalence-Based Studies

The benefits of the regulation include the costs that would be avoided by reducing the adverse health effects associated with the consumption of tobacco products. Most research on the costs of smoking-related illness has concentrated on the medical costs and productivity losses associated with the prevalence of death and illness in a given year. These prevalence-based studies typically measure three components: (1) The contribution of smoking to annual levels of illness and death, (2) the direct costs of providing extra medical care, and (3) the indirect costs, or earnings foregone due to smoking-related illness or death.<sup>279</sup>

In a recent statement, the former U.S. Office of Technology Assessment (OTA) declared that "the greatest 'costs' of smoking are immeasurable insofar as they are related to dying prematurely and living with debilitating smoking-related chronic illness with attendant poor quality of life." Nonetheless, OTA calculated that in 1990 the national cost of smoking-related illness and death amounted to \$68 billion and included \$20.8 billion in direct health care costs, \$6.9 billion in indirect morbidity costs, and \$40.3 billion in lost future earnings from premature death.<sup>280</sup> More recently,

the CDC estimated the 1993 smoking-attributable costs for medical care, alone, at \$50 billion.<sup>281</sup> Unfortunately, these prevalence-based studies do not answer many of the most important questions related to changes in regulatory policy, because they present the aggregate cost of smoking-related illness in a single year, rather than the lifetime cost of illness for an individual smoker. As noted in the 1992 Report of the Surgeon General, most prevalence-based studies fail to consider issues concerning "the economic impact of decreased prevalence of cigarette smoking, the length of time before economic effects are realized, the economic benefits of not smoking, and a comparison of the lifetime illness costs of smokers with those of nonsmokers."<sup>282</sup> In effect, although these studies are designed to measure the smoking-related draw on societal resources, they are not well-suited for analyzing the consequences of regulation-induced changes in smoking behavior.

#### 2. FDA's Methodology

An alternative methodology, termed incidence-based research, compares the lifetime survival probabilities and expenditure patterns for smokers and nonsmokers. As this approach models the individual life-cycle consequences of tobacco consumption, FDA relied on these incidence-based studies for its original analysis of the proposed rule to value the beneficial effects of the rule over the lifetime of each new cohort of potential smokers. The methodology incorporates the following steps:

- A projection of the extent to which the rule will reduce the incidence, or the annual number, of new adolescent users of tobacco products;
- A projection of the extent to which the reduced rates of adolescent tobacco consumption will translate to reduced rates of lifetime tobacco consumption;
- A projection of the extent to which the reduced rates of lifetime tobacco consumption will decrease the number of premature deaths and lost life-years; and
- An exploration of various means of estimating the monetary value of the expected health improvements.

Office of Technology Assessment Estimates for 1990 Before the Senate Finance Committee, p. 2, April 28, 1994.

<sup>281</sup> "Medical-Care Expenditures Attributable to Cigarette Smoking—United States, 1993," in *Morbidity and Mortality Weekly Reports (MMWR)*, CDC, DHHS, vol. 43, No. 26, pp. 469–472, July 8, 1994.

<sup>282</sup> 1992 SGR, p. 111.

<sup>275</sup> Becker, G. S., M. Grossman, and K. M. Murphy, "An Empirical Analysis of Cigarette Addiction," *The American Economic Review*, vol. 84, No. 3, pp. 396–418, June 1994; Chaloupka, F., "Rational Addictive Behavior and Cigarette Smoking," *Journal of Political Economy*, vol. 99, No. 4, pp. 722–742, 1991; Keeler, T. E., T. W. Hu, P. G. Barnett, and W. G. Manning, "Taxation, Regulation, and Addiction: A Demand Function for Cigarettes Based on Time-Series Evidence," *Journal of Health Economics*, vol. 12, pp. 1–18, 1993.

<sup>276</sup> Chaloupka, F., "Rational Addictive Behavior and Cigarette Smoking," *Journal of Political Economy*, vol. 99, No. 4, p. 740, 1991.

<sup>277</sup> Manning, W. G., E. B. Keeler, J. P. Newhouse, E. M. Sloss, and J. Wasserman, "The Costs of Poor Health Habits, A RAND Study," Harvard University Press, Cambridge, MA, 1991.

<sup>278</sup> Gravelle, J. G., and D. Zimmerman, "CRS Report for Congress: Cigarette Taxes to Fund Health Care Reform: An Economic Analysis," Congressional Research Service, p. 1, March 8, 1994.

<sup>279</sup> See "Smoking and Health in the Americas: A 1992 Report of the Surgeon General in collaboration with the Pan American Health Organization," Department of Health and Human Services (DHHS), Public Health Service (PHS), CDC, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Office on Smoking and Health (OSH), pp. 105–112, 1992, (hereinafter referred to as "1992 SGR") for a full summary of these methodologies and findings.

<sup>280</sup> Statement of Clyde Behney and Maria Hewitt on Smoking-Related Deaths and Financial Costs:

The annual benefits of the 1995 proposed rule were measured as the present value of the lifetime benefits gained by those youngsters, who in the absence of the proposed regulation, would have become new smokers. Upon review of the public comments, FDA found none that would persuade the agency to revise its projections. In general, the relevant comments expressed no objection to the basic methodology or model, but some disputed the accuracy of the specific data estimates. The following paragraphs describe the FDA assumptions that underlie these benefit estimates and present the agency's response to the applicable public comments.

### 3. Reduced Incidence of New Young Smokers

FDA's preliminary analysis assumed that 1 million youngsters become new smokers each year. One trade association comment questioned this figure, asserting that the relevant studies included individuals over the age of 18. However, the 1985 National Health Interview Survey reported 1.08 million 20-year old smokers, and the Combined National Health Interview Surveys for 1987-1988 found that 92 percent of 20-year old smokers had started smoking by age 18. Taking 92 percent of 1.08 million yields 993,600 new underage smokers per year. This figure is supported by parallel estimates of the SAMHSA. Based on data from the 1994 National Household Survey on Drug Abuse, SAMHSA estimated that 1.29 million persons under age 20 became daily smokers in 1993, and that 1.1 million of these persons were under the age of 18. As a result, FDA retains confidence in its original estimate of 1 million new smokers per year.

The regulation targets youngsters by restricting youth access to tobacco products and by limiting advertising activities that affect adolescents. Several communities have demonstrated that access restrictions are extremely effective when vigorously applied at the local level. Woodridge, IL, for example, achieved a compliance rate of over 95 percent. Moreover, 2 years after that law was enacted, a survey of 12- to 14-year-old students indicated that overall smoking rates were down by over 50 percent (over 2/3 for regular smokers).<sup>283</sup>

<sup>283</sup> Jason, L. A., P. Y. Ji, M. D. Anes, and S. H. Birkhead, "Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors," *The Journal of the American Medical*

Advertising and promotional restrictions will augment these efforts to limit the attractiveness of tobacco products to underage consumers. As discussed in detail in section VI. of this document, no one study has definitively quantified the precise impact of advertising or of advertising restrictions. Nevertheless, much of the relevant research indicates that advertising restrictions will reduce consumer demand. For example, according to the 1989 report of the Surgeon General, "The most comprehensive review of both the direct and indirect mechanisms concluded that the collective empirical, experiential, and logical evidence makes it more likely than not that advertising and promotional activities do stimulate cigarette consumption."<sup>284</sup> Similarly, after a careful examination of available studies, Clive Smee, Chief Economic Adviser to the United Kingdom Department of Health determined that, "the balance of evidence thus supports the conclusion that advertising does have a positive effect on consumption."<sup>285</sup> A detailed evaluation of the effects of advertising on youth consumption of tobacco products is provided in section VI. of this document.

In Northern California, 24 cities and unincorporated areas in 5 counties adopted local youth tobacco access ordinances that prohibit self-service merchandising and point-of-sale tobacco promotional products in retail stores. Survey measures of the impact of these ordinances by the Stop Tobacco Access for Minor Project (STAMP) found that, on average, tobacco sales to minors dropped by 40 to 80 percent.<sup>286</sup>

In its analysis of the 1995 proposed rule, FDA argued that, while quantitative estimates of the effectiveness of its regulation cannot be made with certainty, comprehensive

*Association (JAMA)*, vol. 266, No. 22, p. 3159, December 11, 1991.

<sup>284</sup> DHHS, "Reducing the Health Consequences of Smoking: 25 Years of Progress," A Report of the Surgeon General, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, DHHS publication No. (CDC) 89-8411, p. 517, 1989 (the 1989 SGR).

<sup>285</sup> Leaney, K., "Effect of Tobacco Advertising on Tobacco Consumption: A Discussion Document Reviewing the Evidence," Economics and Operational Research Division, Department of Health, London, p. 22, October 1992.

<sup>286</sup> Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring only Vendor-Assisted Tobacco Sales," North Bay Health Resources Center, Stop Tobacco Access to Minors Program (STAMP), Petaluma, CA, p. 4, November 3, 1994.

programs designed to discourage youthful tobacco consumption could reasonably achieve the "Healthy People 2000" goal of halting the onset of smoking for at least half, or 500,000, of the 1,000,000 youngsters who presently start to smoke each year. In the Federal Register of January 19, 1996 (61 FR 1492) SAMHSA published a regulation governing a program of State-operated enforcement activities that would restrict the sale or distribution of tobacco products to individuals under 18 years of age. SAMHSA had originally estimated that its program would reduce tobacco consumption by youth and children by from one-third to two-thirds, but subsequently determined that reductions of between one-tenth and one-third would be "more realistic given the uncertainties implicit in varying levels of State enforcement and the absence of meaningful controls on tobacco advertising and promotion."<sup>287</sup> While strongly supporting the objectives of the SAMHSA program, FDA finds that achieving the "Healthy People 2000" goal will demand a full arsenal of controls to complement and fortify the new State inspectional programs, including restrictions on industry advertising and promotions and quite possibly educational messages to counter the influence of ongoing marketing activities.

Numerous public comments to the 1995 proposal addressed the issue of the effectiveness of the regulation. Many argued that tobacco advertising does not increase tobacco use, or that the enforcement of existing or forthcoming State laws, alone, could accomplish reasonable goals. In contrast, many others supported a comprehensive regulation, contending that only vigorous enforcement of new restrictions would bring significant results. As outlined earlier in the preamble in this document, FDA has determined, based on a full examination of the evidence, that the combined effect of the regulations (restricting advertising and promotion, prohibiting self-service sales, providing new labeling information, and imposing age verification obligations) and educational programs will significantly diminish the allure as well as the access to tobacco products by youth. The agency acknowledges the imposing size of the required effort, but is confident that its goals are reasonable and presents regulatory benefits based on the presumption that the "Healthy People 2000" goals will be met.

<sup>287</sup> 61 FR 1502, January 19, 1996.

FDA agrees, however, that these projections are uncertain and therefore also presents estimates of benefits at effectiveness levels that are considerably smaller. The agency conducted this exercise not because its estimates are excessively speculative or arbitrary, as suggested by one comment, but because sensitivity analyses are part of generally accepted "best practice" for the conduct of cost-benefit analysis and are recommended by OMB guidance. These results demonstrate that even if the rule were only modestly effective in reducing tobacco use, it yields justifiable benefits.

One comment urged the agency to demonstrate the effectiveness of tobacco marketing restrictions over and above those for access restrictions or public information campaigns. FDA is unable to forecast the independent results of each regulatory provision, due to the high degree of interdependence among the various requirements, but notes that SAMHSA concluded that its access restrictions, alone, would reduce underage tobacco consumption by one-tenth to one-third. If so, accomplishing the "Healthy People 2000" goal implies that the FDA rule would generate incremental tobacco use reductions of

between 17 and 40 percent for youngsters under 18 years of age.

#### 4. Reduced Number of Adult Smokers

The major beneficiaries of the rule are those individuals who would otherwise begin using tobacco early in life and who, accordingly, are unlikely to start using tobacco products as an adult. Evidence suggests that this percentage will be high, as over half of adult smokers had become daily cigarette smokers before the age of 18. Moreover, the 1994 Surgeon General's Report indicates that 82 percent of persons (aged 30 to 39) who ever smoked daily began to smoke before the age of 18. That report concludes that "if adolescents can be kept tobacco-free, most will never start using tobacco."<sup>288</sup> Although some comments disagreed with that conclusion, FDA believes that the Surgeon General's Report is correct. Nonetheless, to account for the possibility that some would-be smokers who are prevented from smoking until they are age 18 may eventually start smoking as adults, FDA uses the more conservative assumption that these rules will lead to a tobacco free adult life for only one-half of the estimated 500,000 youngsters who will be deterred from starting to smoke each year.

Accordingly, FDA calculates the annual benefits from the lifetime health gains associated with preventing 250,000 adolescents from ever smoking as an adult. Further, in response to comments that challenge this estimate, FDA presents sensitivity analysis showing results using a wide range of alternative rates.

#### 5. Lives Saved

Based largely on data from Peto, et al., who found that about half of all adolescents who continue to smoke regularly throughout their lives will eventually die from a smoking-related disease,<sup>289</sup> CDC estimates that about one in three adolescent smokers will die prematurely.<sup>290</sup> Although the CDC projection provides the best estimate of this excess fatality rate, it does not provide a distribution of the smoking-related fatalities over time. Consequently, FDA derived this distribution by comparing age-specific differences in the probability of survival for smokers and nonsmokers. The probability of survival data for the agency's estimate are derived from the American Cancer Society's Cancer Prevention Study II, as shown in Table 3.

TABLE 3.—PROBABILITY OF SURVIVAL BY AGE, SEX, AND SMOKING STATUS  
(Probabilities of a 17-year-old surviving to age shown)

Age (Years)	Male Neversmokers	Male All Smokers	Female Neversmokers	Female All Smokers
35	1	1	1	1
45	0.986	0.966	0.988	0.984
55	0.951	0.893	0.962	0.939
65	0.867	0.733	0.901	0.831
75	0.689	0.466	0.760	0.630
85	0.336	0.159	0.453	0.289

Source: Thomas Hodgson, "Cigarette Smoking and Lifetime Medical Expenditures," *The Milbank Quarterly*, vol. 70, No. 1, 1992, p. 91. Based on data from the American Cancer Society's Cancer Prevention Study II.

FDA initially multiplied differences in the probabilities of death for smokers versus nonsmokers within each 10-year period by the number of smokers remaining at the start of each 10-year period. Assuming an equal number of males and females, the excess deaths among smokers in all age groups totaled almost 28 percent of the 250,000 cohort. FDA recognizes that this methodology probably understates the current risk of

smoking, because it arbitrarily assumes that the smoking-related risks for females will continue to be smaller than for males, even though female smoking patterns are presently comparable to those of males. Nevertheless, FDA used this model to support its proposed regulation and maintains the calculation to demonstrate the robustness of the results. Moreover, because some comments suggested that these data may

not account for all potentially confounding variables, such as alcohol consumption or other lifestyle differences, FDA further adjusted the mortality estimate to 24 percent to reflect findings by Manning et al., that such nontobacco versus tobacco lifestyle factors may account for 13 percent of excess medical care expenditures. Thus, the benefits projections presented below conservatively rely on the probabilities

<sup>288</sup> 1994 SGR, pp. 5 and 65.

<sup>289</sup> Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, Jr., "Mortality from Smoking in Developing Countries, 1950–2000," Oxford University Press, p. A10, 1994. Indirect estimates from national vital statistics.

<sup>290</sup> Memorandum from Michael P. Eriksen (CDC) to Catherine Lorraine (FDA) August 7, 1995 and CDC Fact Sheet; citing Pierce, J. P., M. C. Fiore, T. E. Novotny, E. J. Hatzianandreu, and R. M. Davis, "Trends in Cigarette Smoking in the United States: Projections to the Year 2000," *JAMA*, vol. 261, pp. 61–65, 1989; Unpublished data from the 1986

National Mortality Followback Survey, CDC, OSH; Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, "Mortality from Smoking in Developed Countries, 1950–2000: Indirect Estimates from national Vital Statistics," Oxford University Press, Oxford, 1994.

shown in Table 3, corrected by the 13 percent lifestyle influence adjustment. In sum, they indicate that achieving the "Healthy People 2000" performance goal will prevent about 60,200 smoking-related fatalities among each year's cohort of potential new smokers.

The economic assessment of health-related variables requires discounting the value of future events to make them commensurate with the value of present events. For this analysis, a 3 percent discount rate is used to calculate the present value of the projections. (This rate was recommended by the Panel on Cost-Effectiveness in Health and Medicine, a nonfederal multidisciplinary group of experts in cost-effectiveness analysis, convened by the Office of the Assistant Secretary for Health in 1993.<sup>291</sup> Since the Office of Management and Budget (OMB) Circular A-94 recommends the use of 7 percent as a base case, FDA presents summary estimates below for discount rates of both 3 percent and 7 percent.) On the assumption that it would be roughly 20 years for each year's cohort of new adults to reach the midpoint of the 35 to 45 age bracket and 60 years to reach the 75 to 85 age bracket, these calculations indicate that the present value of these benefits equate to 15,863 lives per year.

#### 6. Life-Years Saved

The number of life-years that will be saved by preventing each year's cohort of 250,000 adolescents from acquiring a smoking addiction was calculated from the same age-specific survival differences between smokers and nonsmokers. In each 10-year life span, the number of years lived for each cohort of persons who would have been smokers but who were deterred was compared to the number of years that would have been lived by that same cohort if they had been smokers. The difference between these two measures is the life-years saved for that 10-year period.<sup>292</sup> Deducting the 13-percent lifestyle adjustment indicates that, over the full lifetime of each cohort, the regulations will gain an estimated 905,000 life-years, which translates to almost 4 years per smoker and 15 years

per life saved.<sup>293</sup> The present value of these additional life-years equates to 211,391 life-years annually.

#### 7. Monetized Benefits of Reduced Tobacco Use

There is no fully appropriate means of assigning a dollar figure to represent the attendant benefits of averting thousands of tobacco-induced illnesses and fatalities. However, to quantify important components of the expected economic gains, FDA developed estimates of the value of the reduced medical costs and the increased worker productivity that will result from fewer tobacco-related illnesses. In addition, since productivity measures do not adequately address the avoidance of premature death, FDA adopted a willingness-to-pay approach to value the benefits of reduced tobacco-related fatalities.

#### 8. Reduced Medical Costs

On average, at any given age, smokers incur higher medical costs than nonsmokers. However, nonsmokers live longer and therefore continue to incur medical costs over more years. Several analysts have reported conflicting estimates of the net outcome of these factors, but the most recent research is the incidence-based study by Hodgson,<sup>294</sup> who found that lifetime medical costs for male smokers were 32 percent higher than for male never-smokers and lifetime medical costs for female smokers were 24 percent higher than for female never-smokers. Hodgson determined that the present value of the lifetime excess costs were about \$9,400 in 1990 dollars (future costs discounted at 3 percent).<sup>295</sup> As noted earlier, the incidence-based study by Manning, et al., implies that about 13 percent of the excess medical costs were attributable to factors other than smoking. Accounting for this reduction and adjusting by the consumer price index for medical care raises the present value of Hodgson's excess medical cost

per new smoker to \$10,590 in 1994 dollars. Thus, those 1,000,000 young people under the age of 18, who currently become new smokers each year, are responsible for excess lifetime medical costs measured at a present value of \$10.6 billion (1,000,000 x \$10,590). Because FDA projects that achieving the "Healthy People 2000" goals will prevent 250,000 of these individuals from smoking as adults, the medical cost savings are estimated at \$2.6 billion per year.

#### 9. Reduced Morbidity Costs

An important cost of tobacco-related illness is the value of the economic output that is lost while individuals are unable to work. Thus, any future reduction in such lost work days contributes to the economic benefits of the regulation. Several studies have calculated prevalence-based estimates of U.S. productivity losses due to smoking-related morbidity, but FDA knows of no incidence-based estimates. Hodgson, however, has shown that, in certain situations, incidence measures can be derived from available prevalence measures. For example, he demonstrates that in a steady-state model the only difference between prevalence and incidence-based costs is due to discounting.<sup>296</sup> Accordingly, FDA has adopted Hodgson's method to develop a rough approximation of incidence-based costs from an available prevalence-based estimate of morbidity costs.

Rice, et al.,<sup>297</sup> found that lost wages due to tobacco-related work absences in the United States amounted to \$9.3 billion in 1984. This equates to \$12.3 billion in 1994 dollars when adjusted by the percentage change in average employee earnings since 1984. Although FDA does not have a precise estimate of the life-cycle timing of these morbidity effects, the relevant latency periods would certainly be shorter than for mortality effects. Thus, to account for the deferred manifestation of smoking-related morbidity effects, FDA assumed that they would occur over a time horizon equal to 80 percent of that previously measured for mortality effects. Although one comment mistakenly assumed that FDA had made no adjustment for lifestyle differentials between smokers and nonsmokers, in fact, these estimates were further

<sup>291</sup> Gold, M. R., J. E. Siegel, L. B. Russell, and M. C. Weinstein, "Cost-effectiveness in Health and Medicine," Oxford University Press, p. 232, 1996.

<sup>292</sup> For each 10-year age interval, the number of life-years is calculated as the number of people in each cohort (250,000) times the probability of surviving until the end of that age interval times 10 years of life, plus the number expected to die in that interval times an assumed 5 years of life.

<sup>293</sup> The calculation procedure probably understates total life-years saved, because it misses smoking related-fatalities that occur within the same 10-year age interval. However, because more of these misses involve fatalities that, if avoided, would add few life-years, the resulting 15-year average life-years saved may be high. FDA's benefit estimates, however, remain understated because they are based on total life-years saved, not average life-years saved.

<sup>294</sup> Hodgson, T. A., "Cigarette Smoking and Lifetime Medical Expenditures," *The Milbank Quarterly*, vol. 70, No. 1, p. 97, 1992. (Based on data from the American Cancer Society's Cancer Prevention Study II).

<sup>295</sup> *Id.* (Using the average of the male and female totals).

<sup>296</sup> Hodgson, T. A., "Annual Costs of Illness Versus Lifetime Costs of Illness and Implications of Structural Change," *Drug Information Journal*, vol. 22, No. 3, p. 329, 1988.

<sup>297</sup> Rice, D. P., et al., "The Economic Costs of the Health Effects of Smoking, 1984," *The Milbank Quarterly*, vol. 64, No. 4, p. 526, 1986.

reduced by 13 percent to reflect the Manning, et al., findings. Finally, because the long-term decline in smoking prevalence has exceeded the growth in population, FDA reduced the incidence-based costs by another 20 percent. At a 3 percent discount rate, this methodology implies that the incidence-based cost of smoking-related morbidity, or the present value of the future costs to 1 year's cohort of 1,000,000 new smokers, is about \$3.5 billion. Thus, the estimated annual morbidity-related savings associated with preventing 250,000 new youths per year from smoking as adults is estimated at about \$879 million.

#### 10. Benefits of Reduced Mortality Rates

From a societal welfare perspective, OMB guidance advises that the best means of valuing benefits of reduced fatalities is to measure the affected group's willingness-to-pay to avoid fatal risks. Unfortunately, the specific willingness-to-pay of smokers is unknown, because institutional arrangements in the markets for medical care obscure direct measurement techniques.<sup>298</sup> Nevertheless, many studies have examined the public's willingness-to-pay to avoid other kinds of life-threatening risks, especially workplace and transportation hazards. An EPA-supported study<sup>299</sup> found that most empirical results support a range of \$1.6 to \$8.5 million (in 1986 dollars) per statistical life saved, which translates to \$2.2 to \$11.6 million in 1994 dollars. However, the uncertainty surrounding such estimates is substantial. Moreover, Viscusi has shown that smokers, on average, may be willing to accept greater risks than nonsmokers. For example, smokers may accept about one-half the average compensation paid to face on-the-job-injury risks.<sup>300</sup> FDA therefore has conservatively used \$2.5 million per statistical life, which is towards the low end of the research findings, to estimate society's willingness-to-pay to avert a fatal smoking-related illness. Thus, the annual benefits of avoiding the discounted number of 15,863 premature fatalities would be \$39.7 billion.

An alternative method of measuring willingness-to-pay is to calculate a value for each life-year saved. This approach

is intuitively appealing because it places a greater value on the avoidance of death at a younger than at an older age and is the traditional means of assessing the cost-effectiveness of medical interventions. Nevertheless, there have been few attempts to determine the appropriate value of a life-year saved. OMB suggests several methodologies, including annualizing with an appropriate discount rate the estimated value of a statistical life over the average expected life-years remaining. For example, at a 3-percent discount rate, a \$2.5 million value per statistical life for an individual with 35 years of remaining life-expectancy converts to about \$116,500 per life year. Since achieving the agency's goals were estimated to save 211,391 discounted life-years annually, this calculation yields annual benefits of \$24.6 billion.

FDA notes that even these values understate the full value of the health impact, because they fail to quantify any reduction in either the adverse effects attributable to passive smoking or the infant and child fatalities caused by mothers' smoking. Moreover, these totals may not capture the heavy toll of psychic loss to surviving family members, or the corresponding economic losses among family members for the mental health care of grief-related depression and other conditions that often follow the premature death of middle aged adults.<sup>301</sup>

#### 11. Reduced Fire Costs

Every year lighted tobacco products are responsible for starting fires which cause millions of dollars in property damage and thousands of casualties. In 1992, fires started by lighted tobacco products caused 1,075 deaths and \$318 million in direct property damage.<sup>302</sup> A reduction in the number of smokers, and the corresponding number of cigarettes smoked, will result in a drop in the number of future fires. In the 1995 proposal, FDA estimated that if the number of fires falls by the same percentage as the expected reduction in cigarette sales, this implies present value savings of \$203 million for the value of lives saved and \$24 million for the value of averted property damage, totaling \$227 million annually over a 40-year period.

One comment denied the existence of any association between fires and cigarette consumption. FDA acknowledges that the relationship may be nonlinear, but finds the asserted lack of a positive correlation implausible. This comment further stated that residential fires caused by smoking and deaths from residential fires caused by smoking decreased from 1983 to 1992 by 39 percent and 40 percent, respectively, or about 5.5 percent annually. Accounting for this trend would lower FDA's fire cost estimate to a present value savings of \$145 million for the value of lives saved and \$17 million for the value of averted property damage, totaling \$162 million annually over a 40-year period. Even these estimated savings significantly underestimate the potential benefits, however, because they exclude both nonfatal injuries and the need for temporary housing.

#### 12. Smokeless Tobacco

The Smokeless Tobacco Council, Inc., remarked that FDA had not attempted to measure the benefits that would result from the decreased use of smokeless tobacco products by underage youths. The introduction to the 1995 proposed regulation, however, explained that the use of smokeless tobacco causes severe health effects. While data are not available on age-specific differences in the probability of survival for smokeless tobacco users as compared to nonusers, the 1994 Surgeon General Report indicates that the "primary health consequences during adolescence include leukoplakia, gum recession, nicotine addiction, and increased risk of becoming a cigarette smoker. Leukoplakia and/or gum recession occur in 40 to 60 percent of smokeless tobacco users."<sup>303</sup> Oral leukoplakias have a 5-percent chance of becoming malignancies in 5 years.<sup>304</sup> Cancers of the nasal cavity, pharynx, larynx, esophagus, stomach, urinary tract and pancreas have also been linked to smokeless tobacco use.<sup>305</sup> Other effects include discoloration of teeth, periodontal disease and excessive tooth wear and decay.<sup>306</sup> One study of female snuff users showed that it increased one's risk of developing oral and

<sup>298</sup> Schelling, T. C., "Economics and Cigarettes," *Preventive Medicine*, vol. 15, pp. 549-560, 1986.

<sup>299</sup> Fisher, A., L. G. Chestnut, and D. M. Violette, "The Value of Reducing Risks of Death: A Note on New Evidence," *Journal of Policy Analysis and Management*, vol. 8, No. 1, pp. 88-100, 1989.

<sup>300</sup> Viscusi, W. K., "Fatal Tradeoffs: Public and Private Responsibilities for Risk," Oxford University Press, p. 24, 1992.

<sup>301</sup> Harris, M., "The Loss That is Forever The Lifelong Impact of the Early Death of a Mother or Father," Penguin Books, 1995.

<sup>302</sup> Miller, A. L., "The U.S. Smoking-Material Fire Problem Through 1992: The Role of Lighted Tobacco Products in Fire," National Fire Protection Association, p. 2, 1994.

<sup>303</sup> 1994 SGR, p.39.

<sup>304</sup> *Id.*

<sup>305</sup> Goolsby, M. J., "Smokeless Tobacco: The Health Consequences of Snuff and Chewing Tobacco", *Nurse Practitioner*, vol. 17, No. 1, p. 31, January 1992.

<sup>306</sup> *Id.*

pharyngeal cancer between 1.5 to 4.2 times.<sup>307</sup>

If the provisions pertaining to smokeless tobacco are as effective as those pertaining to cigarettes, the rule will prevent about 36,500 youths from becoming adult users of smokeless tobacco. This projection assumes that the number of underage users will decrease by 50 percent and one-half of those youths will remain nonusers after reaching 18 years of age. The estimate also assumes that the ratio of new underage users to total underage users parallels that of cigarette users (i.e., approximately one-third) and that about 440,000 youths under the age of 18 are current users of smokeless tobacco products.<sup>308</sup>

Leukoplakia and/or gum recession are estimated to occur in 40 to 60 percent of smokeless users.<sup>309</sup> If even 50 percent of these cases were caused by smokeless tobacco use, the previous assumptions imply that these regulations will prevent from 7,300 to 11,000 cases of leukoplakia and/or gum recessions per year. Although FDA can not estimate the number of oral or other cancers prevented, the realized number will be substantial.

### 13. Summary of Benefits

The discussion above demonstrates the formidable magnitude of the economic benefits available from smoking reduction efforts. As described, FDA forecasts annual net medical cost savings of \$2.6 billion and annual morbidity-related productivity savings of \$900 million. From a willingness-to-pay perspective, the annual benefits of reduced smoking-related disease mortality range from \$24.6 to \$39.7 billion. As a result, the value of the annual disease-related benefits of achieving the "Healthy People 2000" goal is projected to range from \$28.1 to \$43.2 billion. (Following Hodgson, this analysis uses a 3-percent discount rate. A 7-percent rate reduces these benefits to a range of \$9.2 to \$10.4 billion). These totals do not include the benefits expected from fewer fires (over \$160 million annually), reduced passive smoking, or infant death and morbidity

associated with mothers' smoking. Moreover, while FDA believes these effectiveness projections are plausible, much lower rates still yield impressive results. Table 1c of this section summarizes the disease-related health benefits and illustrates that youth deterrence rates as small as 1/20, which would prevent the adult addiction of at least 25,000 of each year's cohort of 1,000,000 new adolescent smokers, would provide annual benefit values measured in the billions of dollars. Moreover, the higher risk estimates suggested by Peto, et al., could significantly increase these values. In addition, while FDA could not quantify the benefits that will result from the projected decline in the use of smokeless tobacco, they would be considerable.

### D. Regulatory Costs

A recently issued guideline for conducting economic analysis of Federal regulations, prepared under the auspices of OMB, states that:

[T]he preferred measure of cost is the "opportunity cost" of the resources used or the benefits foregone as a result of the regulatory action. Opportunity costs include, but are not limited to, private-sector compliance costs and government administrative costs. Opportunity costs also include losses in consumers' or producers' surpluses, discomfort or inconvenience, and loss of time \* \* \*. An important, but sometimes difficult, problem in cost estimation is to distinguish between real costs and transfer payments. Transfer payments are not social costs but rather are payments that reflect a redistribution of wealth. While transfers should not be included in the [Economic Analyses'] estimates of the benefits and costs of a regulation, they may be important for describing the distributional effects of a regulation.<sup>310</sup>

Accordingly, FDA finds that the final rule will impose new cost burdens on manufacturers, retailers, consumers, and Government regulators of tobacco products. In addition, certain industry sectors will experience lost sales and employment, but these revenue losses will be at least partly offset by gains to other sectors, as discussed in the "Distributional Effects" section of this document.<sup>311</sup> While a number of industry comments argued that the agency's preliminary analysis was

deficient for not including these lost revenues in its cost-benefit assessment, FDA finds that the revenue losses suggested by these comments do not meet the previous definition of "opportunity cost;" because they fail to provide the changes in net costs that are necessary to estimate producer surplus, conventionally defined as sales minus variable costs. This rule will affect producer surplus in several industries and only net changes in these surplus' are social costs. Calculating such changes would require a multi-market model of economic changes over many years. Such general equilibrium models have not been used by Federal agencies for regulatory analyses, are not specifically recommended by the OMB guidance, and would be impractical to use, especially where major markets are dominated by few firms.

The most comprehensive critique of FDA's preliminary economic analysis was prepared by the Barents Group, economic consultants to the Tobacco Institute. While the Barents Group developed independent estimates of economic costs, in many instances its methodology was consistent with FDA's analysis of its 1995 proposal. Often, however, the Barents Group had access to more recent data, or to additional data provided by the affected industries. FDA's revised cost estimates rely extensively on these new data, but as described below, the agency's final cost estimates are far smaller than those presented by the Barents Group.

### 1. Number of Affected Retail Establishments

A critical variable underlying the agency's cost estimates is the number of retail outlets currently selling over-the-counter (OTC) tobacco products. A major confounding factor is that the U.S. Census publishes product line data only for establishments with payroll. For its original estimate of the number of retail establishments selling tobacco products, FDA relied on 1987 Census data to count the number of affected payroll establishments and very conservatively included every nonpayroll establishment in those categories that traditionally sell tobacco products (general merchandise stores, grocery stores, service stations, eating and drinking places, drug stores, and liquor stores). FDA estimated that the number of establishments selling tobacco products OTC included 275,000 payroll establishments and 215,000 nonpayroll establishments, for a total of 490,000 retail establishments. To account for all other business categories that might sell

<sup>307</sup> Winn, D. M., W. J. Blot, C. M. Shy, L. W. Pickle, A. Toledo, and J. F. Fraumeni, "Snuff Dipping and Oral Cancer Among Women in the Southern United States," *The New England Journal of Medicine*, vol. 304, No. 13, pp. 745-749, Table 2, March 26, 1981.

<sup>308</sup> Estimates of youth smokeless usage vary. This projection relies on a conservative estimate of total youth (ages 12-17) usage calculated from data in the Statistical Abstract of the U.S. 1995, 115th edition, Tables 16 and 218.

<sup>309</sup> 1994 SGR, p.39.

<sup>310</sup> Economic Analysis of Federal Regulations Under Executive Order 12866, January 11, 1996. Prepared by interagency group convened by OMB and co-chaired by a Member of the Council of Economic Advisers.

<sup>311</sup> This analysis evaluates the regulation following the Kaldor-Hicks criteria for societal welfare maximization.

OTC tobacco products, FDA estimated a total upper bound range of 600,000 establishments. FDA did not know how many locations currently served by cigarette vending machines would convert to OTC operations following implementation of the regulation, but estimated the number at 100,000, raising the upper bound total to 700,000 future establishments.

FDA still has no definitive estimate of the number of retail outlets selling tobacco products. For their economic analysis, the Barents Group used 1992 U.S. Census estimates for the number of affected retail establishments with payroll, but adopted an alternative methodology to estimate the number of affected establishments without payroll. The Barents Group subdivided retail businesses into 10 categories: General merchandise stores, supermarket/grocery stores, convenience stores without gas, convenience stores with gas, gasoline service stations, eating places, drinking places, drug and proprietary stores, specialty tobacco stores, and miscellaneous retail stores. Within each category, the Barents Group assumed that the percentage of nonpayroll establishments selling tobacco products would be the same as the percentage of payroll establishments selling tobacco products. As a result, they concluded that the number of retail payroll establishments selling tobacco products OTC is approximately 283,000, and the number of retail nonpayroll establishments selling tobacco products OTC is about 107,000, for a total of 390,000 retail outlets. The Barents Group's subsequent calculations are less

clear and not documented in their appendix on methodology. Noting that FDA had estimated an upper bound of 600,000 establishments selling OTC tobacco products, they assumed the existence of an additional 100,000 to 200,000 nonretail establishments, such as operations within manufacturing or service businesses, that sell OTC tobacco products. Finally, the Barents Group accepted FDA's estimate that about 100,000 current vending machine locations would convert to OTC sales for tobacco products and proposed total lower and upper bound estimates of from 500,000 to 700,000 establishments.

For this final economic analysis, FDA adopts the apparent mid-point of the Barents Group's forecast of the number of establishments that will sell tobacco products, or about 500,000 current establishments and a total of 600,000 future establishments. FDA estimates by business category are displayed in Table 4 and follow closely the methodology presented by the Barents Group, except for slight adjustments to eliminate nonstore outlets. Because Census data on the number of establishments without payroll were not reported separately for convenience stores, convenience stores with gas, or specialty tobacco stores, these outlets are counted with the higher level outlet categories.

## 2. Removing Self-Service and Other Prohibited Retail Displays

The 1995 proposed regulation restricted all point of purchase advertising to "text only" and banned the use of all self-service displays by requiring vendors to physically provide

the regulated tobacco product to purchasers. In its original analysis, FDA explained that the proposed ban on self-service displays would affect many retail stores selling tobacco products, although shoplifting concerns had already caused a large number of these stores to place tobacco products in areas not directly accessible to customers. Those retailers that discontinued self-service displays typically modified their stores by either: (1) Placing tobacco products behind or above store cashiers or in locked cases located within close reach of store cashiers, (2) placing tobacco products behind only one or two checkout lines, similar to the "cash only" or "less than 10 items" lines commonly found in supermarkets, (3) dispensing tobacco products from a controlled area of the store, where store employees also conduct other administrative or customer-service tasks, or (4) installing a signaling system, whereby assigned store clerks bring requested tobacco products to individual checkout stations. Each store's physical configuration dictates the most cost-effective approach, but at least one regional survey found that retail outlets readily complied with comparable local ordinances without architectural remodeling or substantial refitting of checkout counters or store aisles.<sup>312</sup>

<sup>312</sup> Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring only Vendor-Assisted Tobacco Sales," North Bay Health Resources Center, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.



TABLE 4.—ESTIMATED NUMBER OF ESTABLISHMENTS CURRENTLY SELLING TOBACCO PRODUCTS OVER-THE-COUNTER

Kind of Business	Number of Retail Establishments with Payroll	Percentage of Retail Establishments with Payroll Selling Tobacco Products	Number of Retail Establishments with Payroll Selling Tobacco Products	Total Number of Retail Establishments without Payroll	Estimated Number of Retail Establishments without Payroll Selling Tobacco Products <sup>(i)</sup>	Estimated Total of Establishments Selling Tobacco Products Over-the-Counter <sup>(k)</sup>
	(1)	(2)	(3)	(4)	(5)	(6)
Retail Establishments:						
General Merchandise	34,606	35.01%	12,117	28,010 <sup>(f)</sup>	9,807	21,924
Supermarket/Grocery	126,785 <sup>(a)</sup>	56.19%	71,240	97,061 <sup>(g)</sup>	54,538	125,778
Convenience Stores	30,748	95.62%	29,400	— <sup>(h)</sup>	—	29,400
Convenience Stores with Gas	57,033 <sup>(b)</sup>	91.02%	51,913	— <sup>(h)</sup>	—	51,913
Service Stations	71,336 <sup>(c)</sup>	53.21%	37,958	14,248	7,581	45,539
Eating Places	377,760 <sup>(d)</sup>	3.17%	11,992	96,538	3,065	15,057
Drinking Places	55,848	19.24%	10,745	27,733	5,336	16,081
Drug Stores	48,142	60.33%	29,046	3,031	1,829	30,875
Tobacco Stores	1,477	100.00%	1,477	— <sup>(h)</sup>	—	1,477
Miscellaneous Retail Stores	273,256 <sup>(e)</sup>	9.15%	24,995	490,633 <sup>(i)</sup>	44,879	69,874
Other Establishments	—	—	—	—	—	100,000
Total	1,076,991		280,883	757,254	127,035	507,918

(a) Category contains food stores (SIC 54) with payroll, excluding convenience food stores (SIC 541 pt) and convenience food/gasoline stores (SIC 541 pt).

(b) Category contains convenience food/gasoline stores (SIC 541 pt) and gasoline/convenience food stores (SIC 554 pt).

(c) Category excludes gasoline/convenience food stores (SIC 554 pt).

(d) Category contains eating and drinking places (SIC 58), excluding drinking places (SIC 5813).

(e) Category contains miscellaneous retail stores (SIC 59 ex. 591), excluding nonstore retailers (SIC 596) and tobacco stores and stands (SIC 5993).

(f) 1992 Nonemployer Statistics Series only provides data on variety and miscellaneous general merchandise establishments without payroll.

(g) 1992 Nonemployer Statistics Series only provides data on grocery stores, retail bakeries, and other food stores without payroll.

(h) 1992 Nonemployer Statistics Series does not provide data on establishments without payroll for these categories.

(i) Category contains miscellaneous retail stores (SIC 59 ex. 591), excluding nonstore retailers (SIC 596).

(j) Column (2) times Column (4).

(k) Column (3) plus Column (5).

Source: Columns (1)–(4) from U.S. Census of Retail Trade Merchandise Line Sales and Nonemployer Statistics Series; Columns (5) and (6) projections according to Barents Group LLC Appendix I methodology.

Because prevailing business practice is for tobacco manufacturers to assist and even pay for most product display equipment,<sup>313</sup> FDA had assumed that manufacturers would share with retailers any expense of relocating displays and that the majority of the costs would be to relocate self-service displays for cartons. FDA estimated one-time costs of \$22 million to be shared by manufacturers and retailers and additional annual operating costs of \$14 million to be incurred by retailers (all in 1994 dollars). In stark contrast, the Barents Group projected one-time costs of from \$558 to \$780 million in 1996 dollars (\$520 to \$728 million in current dollars), with 62 percent attributed to the replacement of display items by retailers and the remaining 38 percent to manufacturers due to "time costs involved in removing banned display and promotional items, whether the work would be performed directly by a manufacturer's employee or subcontracted out to a display distributor." As explained below, FDA finds that many aspects of the Barents Group's estimates are seriously flawed. Nevertheless, the agency has adopted the basic framework of that analysis and its revised estimates reflect the Barents Group's methodology and data, unless specifically modified as discussed below.

a. *The Barents Group's methodology.* The Barents Group's cost projections were based on estimates of an average outlet cost for each of seven outlet categories. Each average outlet cost was multiplied by the total number of outlets of that category in the United States to produce national cost estimates. The actual outlet cost data were collected by A. T. Kearney, Inc., still another business consulting firm. The Barents Group explained that:

[O]ur estimates are based on a compliance audit study conducted especially for this purpose by A. T. Kearney, Inc. A. T. Kearney performed an in-depth study of the actions and efforts that would be required of tobacco manufacturers' representatives, of point-of-sale display item distributors, and of tobacco retailers in order to bring stores into compliance with the proposed regulations. Detailed surveys were conducted of seven categories of retail outlets in five U.S. metropolitan areas, for a total of 88 retail outlets. Surveyors performed a detailed inventory of the many types of tobacco product displays and promotional materials which are currently found in stores. The surveyors noted which items would need to be modified or replaced.

A. T. Kearney reportedly completed a comprehensive on site compliance

protocol checklist at 88 establishments randomly selected in 5 general regions of the United States. The individual display items were grouped into 41 discrete item categories and a lengthy discussion of the methodology and results are presented as a Technical Appendix to the Barents Group's comments.

b. *The Barents Group's miscalculations.* To evaluate these results, FDA carefully reviewed the A. T. Kearney survey data and the Barents Group's extrapolation procedures and attempted to replicate the aggregate estimates. In doing so, numerous computational discrepancies were identified. For example, in calculating retailer time costs, the Barents Group intended to use an estimated retail employee wage of \$9.51, but in fact used the estimated wage for a manufacturer's sales representative of \$25.70. (See Appendix Table "Initial Compliance Effort Costs per Retail Store.") Also, the Barents Group's calculations relied on incorrectly transposed data for the average number of disposable displays per store and miscalculated compliance effort costs for five of the seven types of business. Further, A. T. Kearney reported that only one-third of the lighted signs and clocks would need to be replaced by retailers, but the Barents Group's calculations assumed that all would be replaced. Finally, A. T. Kearney reported that retailers would not replace most promotional posters, signs and displays, but the Barents Group's calculations assigned each \$85 in replacement costs. Correcting these errors reduces the Barents Group's low and high cost estimates by \$77 and \$108 million, respectively.

Even more important, in aggregating the unit costs for "Compliance Activity No. 19—Remove and replace interior newsstands and shopping basket racks and baskets and shopping carts," A. T. Kearney committed a major error that dominates the aggregated cost totals. In discussing the costs for this item, A. T. Kearney focused on the need to replace shopping basket racks, which " \* \* \* are free-standing units and contain about 20 shopping baskets, that also contain the name or logo of the cigarette manufacturer." Although it seems probable that the logos or brand names affixed to these items could be either removed or obscured, the survey data indicate that six supermarket/grocery stores, three convenience stores, two tobacco stores and one convenience store with gas would replace shopping basket racks. The detailed survey data for supermarket/grocery stores,

however, reveal that one store supposedly possessed 71 racks, two stores 50 racks, and the remaining three stores 41, 32, and 10 racks, respectively. Even a casual review of these data suggests that individual hand-held shopping baskets rather than basket racks were counted. Indeed, an FDA contractor visited the five Washington, DC area outlets in which A. T. Kearney observed the largest number of racks and found scores of plastic hand-held baskets adorned with simple advertising stickers, but only a few basket racks.<sup>314</sup>

Although the advertising on these plastic baskets could easily be removed or covered, or new plastic baskets purchased quite inexpensively, the Barents Group's calculations inadvertently assumed that a distribution services contractor would be hired to remove each plastic hand-held shopping basket at a fee of \$45 apiece and that a retailer would spend 30 minutes plus an additional \$89 replacement fee for each plastic hand-held shopping basket in its possession. Thus, the estimated cost attributed to each hand-held basket was \$138 and the cost for just the one outlet reporting 71 shopping baskets totaled \$9,850. Extrapolating to each outlet category, the A. T. Kearney results implied that removing and replacing plastic hand-held baskets would cost, on average, over \$1,300 for each supermarket/grocery store and \$300 for each convenience store in the United States. Its projected costs for removing and replacing the hand-held shopping baskets in all supermarket/grocery stores in the United States ranged from \$163 million to \$229 million. For all outlet types, costs for these hand-held baskets were estimated at \$194 to \$271 million, or 43 percent of the national point-of-sale costs estimated by the Barents Group.

Based on site visits, FDA modified Kearney's field data for the correct number of shopping basket racks in the Washington, DC area establishments. Furthermore, FDA contractors determined that the hand-held shopping baskets could easily be modified by a marketing representative, who would take, at most, 5 minutes to affix new stickers on each basket or rack. For a rack of 20 baskets, this task was estimated to take a total of 105 minutes, plus about \$42 for stickers. These adjustments reduce the Barents Group's estimated one-time costs by \$180 to \$252 million.

<sup>313</sup> *Id.*

<sup>314</sup> Buck, E., "Site Visit Report," April 24, 1996.

*c. The Barents Group's extrapolation procedure.* The Barents Group contributed still another bias by their method of extrapolating these survey results to the assumed range of 500,000 to 700,000 retail establishments. A. T. Kearney surveyed stores in only seven business categories: General Merchandise, Supermarket/Grocery, Tobacco Specialty, Convenience Store without Gas, Convenience Store with Gas, Service Station, and Drug Store. To represent all affected outlets, the Barents Group apportioned the full upper and lower bounds for their estimated number of establishments (500,000 and 700,000) among 10 business categories "based on the fractions they represent in the Census sample of with-payroll retail stores selling tobacco products." (Eating Places, Drinking Places, and Miscellaneous Retailers were added for this outlet allocation, but were assigned no costs because they are not " \* \* \* the types of retail outlets where the vast majority (more than 90 percent) of tobacco product sales occur and where promotional items are most prevalent." That is, the Barents Group used a proportional adjustment to raise each establishment category count so that the lower and upper bound totals sum to 500,000 and 700,000, respectively. The estimated number of establishments in each category was then multiplied by the average cost for each business category using data from the A. T. Kearney site visits.

The implications of these inappropriate establishment number extrapolations are considerable. For example, A. T. Kearney surveyed a sample of 10 outlets from its first business category—General

Merchandise Stores. These 10 outlets, which include three K-Mart and two Wal-Mart stores, averaged over 84,000 square feet of space, with the smallest store measuring 40,000 square feet. The U.S. Census reports only 12,117 such establishments with payroll. The Barents Group's proportional adjustment automatically expanded this outlet type count to between 21,299 and 29,818. (See Barents Group's Appendix Table.) Thus, to generate a national estimate of costs, the Barents Group applied the cost per establishment for its sample of very large general merchandise stores to roughly double the number reported in the U.S. Census for such establishments with payroll. This methodology inappropriately bases the per outlet cost for thousands of small nonpayroll and nonretail outlets on the per outlet cost reported for very large general merchandise stores.

The identical problem holds for the Barents Group's projection of the A. T. Kearney survey sample of 27 Supermarket/Grocery stores. Although this sample includes a few moderately sized establishments (1 less than 1,000 square feet and 4 less than 5,000 square feet), 21 of the establishments exceed 10,000 square feet and the average sized facility is almost 35,000 square feet. Nevertheless, the Barents Group's apportionment procedure inflates the number of establishments in this category from the U.S. Census estimate of 71,240 with payroll to 125,222 and 175,311, on the dubious assumption that thousands of small nonpayroll or other nonretail establishments are best represented by the A. T. Kearney sample of mostly large supermarkets/grocery stores.

FDA's fundamental concern is not with the Barents Group's estimate of 500,000 to 700,000 affected establishments (although the upper bound of this estimate should be 600,000, because there would be no display relocation costs for the additional 100,000 outlets assumed to be established at existing vending machine locations), but with the allocation of the small establishments among the largest business categories surveyed by A. T. Kearney. To offset this bias, FDA reallocated the number of establishments in the business categories used to extrapolate the outlet cost estimates. As shown, in Table 5, FDA takes the number of establishments in the first two business categories—General Merchandise and Supermarket/Grocery stores—directly from the U.S. Census number of establishments with payroll, because there would be very few nonpayroll or nonretail establishments equivalent to those surveyed. For outlet extrapolation purposes, FDA assigns its estimated number of nonpayroll establishments in these two business categories to the Convenience Store category, on the assumption that this category is most representative of the small establishments excluded from the Census product line data. Although the Barents Group omitted all costs for Eating Places, Drinking Places, and Miscellaneous Retail Stores, FDA groups these outlets under Other Establishments and assumes certain minimal costs, as explained below. This redistribution of the establishment category groupings reduces the Barents Group's low cost estimate by \$65 million and its high cost estimate by \$170 million.

TABLE 5.—ESTIMATED NUMBER OF ESTABLISHMENTS REMOVING SELF-SERVICE AND OTHER PROHIBITED RETAIL DISPLAYS

Kind of Business	Number of Retail Establishments with Payroll Selling Tobacco Products Over-the-Counter	Estimated Number of Retail Establishments without Payroll Selling Tobacco Products Over-the-Counter	Estimated Total Number of Establishments Selling Tobacco Products Over-the-Counter
A. T. Kearney Categories:			
General Merchandise	12,117	— (A)	12,117
Supermarket/Grocery	71,240	— (B)	71,240
Convenience Stores	29,400	64,345 (C)	93,745
Convenience Stores with Gas	51,913	— (D)	51,913
Service Stations	37,958	7,581	45,539
Drug Stores	29,046	1,829	30,875
Tobacco Stores	1,477	— (E)	1,477
Other Establishments	—	—	201,012 (F)
Total	233,151	73,755	507,918

(A) Variety and miscellaneous general merchandise stores are tallied as convenience stores.

(B) Food stores are tallied as convenience stores.

(C) This category includes food, variety, and miscellaneous general merchandise stores. The 1992 Nonemployer Statistics Series does not provide information about convenience stores without payroll.

(D) The 1992 Nonemployer Statistics Series does not provide information about establishments without payroll for this category.

(E) The 1992 Nonemployer Statistics Series does not provide information about establishments without payroll for this category.

(F) Includes retail establishments excluded from the Kearney field audit and other establishments selling tobacco products over-the-counter.

d. *Further modifications.* The Barents Group faulted FDA for not including costs for the removal of banned display items or for the replacement of banned point-of-sale promotional materials. Their estimates assumed that manufacturers alone would bear these costs, since the proposed regulation required that manufacturers remove all prohibited advertising displays. The final regulation, however, places this responsibility on the owners of the displays, which may frequently be the retail establishments. FDA cannot forecast the ultimate distribution of display ownership, but in view of current business practices, assumes that the manufacturer representatives will at least participate in the removal process. Nevertheless, this change in regulatory responsibility is likely to shift a greater share of the cost burden to retailers.

On the other hand, the Barents Group assumed that retailers alone would replace those promotional items having a utilitarian function, including display cases, signs, shopping carts or baskets, newspaper racks, ash trays, and clocks. FDA believes that this assumption is unfounded, because many retailers will modify rather than replace these items and many manufacturers will share the replacement burden with retailers. For example, one report describing the results of a local self-service ban indicated that, "tobacco distributors and tobacco company sales representatives furnished behind-the-counter shelving and locking cases for tobacco products to retailers at no charge in order to assist retailers comply with self-service/vendor-assisted regulations."<sup>315</sup> Again, however, the future allocation of these costs among manufacturers and retailers is unknown. For its initial estimates, except as explained below, FDA maintains the Barents Group's assumptions that removal costs are primarily borne by the manufacturer and replacement costs by the retailer. In fact, both cost categories will be shared and the implications of these assumptions are illustrated below through sensitivity analysis.

In February 1996, economic consultants to FDA attempted to replicate the A. T. Kearney field audit in Boston (the Eastern Research Group, Inc. (ERG).)<sup>316</sup> and in Washington, DC (an independent contractor). While most observations of the number of affected display cases were reasonably consistent with the A. T. Kearney findings, the observed number of exterior and interior promotional materials deviated significantly from the A. T. Kearney audit data. One explanation may be that the seasonal items available at the end of November had been removed by the following February. As a result, FDA has not adjusted its calculations to account for these discrepancies (except for the cost of basket racks in the Washington, DC stores), but used certain insights from these visits to revise the Barents Group's unit cost assumptions, as follows:

(i) The agency rejects the Barents Group's assumption that retailers rather than manufacturers will bear the costs of replacing promotional unattached counter displays. Because many of these items will be moved to visible locations behind counters, it is far more likely that manufacturers, not retailers, would pay for replacements. For its revised estimate, therefore, FDA assumes that manufacturers will pay replacement costs for unattached counter displays. Although total costs are unchanged, this assumption increases the costs for manufacturers by \$17 million and decreases the costs for retailers by an equal amount.

(ii) A. T. Kearney and the Barents Group contradict themselves on the cost of removing disposable display cases. A. T. Kearney describes these units as temporary displays "frequently found in association with promotional offerings, sales, or seasonal themes," but assumes that retailers will replace them with permanent self-standing retail pack cases at \$250 each. In contrast, the Barents Group calculations imply that a distribution services company will remove each display for a fee of \$150 and retailers will replace each item for \$50. FDA agrees with the Barents Group that retailers will not replace temporary units with permanent retail pack cases.

Moreover, if a marketing representative can throw away free-standing ash trays filled with sand, as noted by A. T. Kearney, then a marketing representative can also dismantle and throw away disposable displays made of cardboard and plastic. FDA estimates, therefore, that instead of hiring a distribution services company, the manufacturer's representative will take no more than 15 minutes to remove each disposable unit, install a new unattached counter display and restock any excess inventory in a nonself-service area. This assumption decreases the estimated one-time costs by \$7 million.

(iii) The A. T. Kearney cost-estimating methodology for the self-service ban implies that store modifications take place in a sequential pattern, with no allowances for economies of scale. For example, the outlet cost for hiring a distribution services contractor to relocate or replace display cases was calculated as a fixed multiple of the number of cases to be removed, even though many establishments must remove several display cases. This approach overstates costs by ignoring the significant scale economies achievable by performing all compliance activities at one time. Thus, FDA modified A. T. Kearney's distribution services costs for the removal, relocation and installation of small attached, retail pack, and carton self-service display cases by assuming that the first display unit in an outlet would be removed at a unit charge of \$90, \$150, or \$185, respectively, but that each additional unit would be removed at one-half of these costs. For those stores with different sizes of display cases, the first unit was assumed to be the most expensive to remove (e.g., a carton display would be considered the first item when there is also a retail pack display or a small attached display). Adjusting for these scale economies reduces the estimated total costs by \$15 million.

(iv) A. T. Kearney assumed that many promotional items, such as signs and clocks, would be removed by a distribution services company hired by the manufacturer. FDA's consultants, however, found that almost all of the promotional material observed could be easily removed or modified by retail personnel or marketing representatives.

<sup>315</sup> Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring only Vendor-Assisted Tobacco Sales," North Bay Health Resources Center, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

<sup>316</sup> "ERG's Review of Docket Materials Concerning FDA's Proposed Regulations Covering Tobacco Products: Final Site Visit Report," Eastern Research Group, April 22, 1996.

For example, rather than needing a contractor to remove the lighted sign in one of the sampled outlets, ERG found that the front panel was easily removable and could be quickly replaced by an acceptable panel. Although a few signs may require substantial time to dismantle, most of these items will take just a few minutes to remove. To account for this range, FDA assumes that a manufacturer's representative will take 15 minutes to remove and dispose of the various exterior signs, banners, clocks and news stand displays, as well as the interior lighted signs and clocks, lowering total costs by \$27 million.

(v) A. T. Kearney assumed that many display cases located in nonself-service areas would be removed and replaced, because of improper advertising. They assumed that the manufacturer would pay for the removal of the old case and the installation of the new case, but that the retailer would purchase the new display case. Contrary to this finding, FDA consultants found no sites in the Boston or Washington, DC regions where it was necessary to replace nonself-service displays. Because in each instance, all visible advertising could be altered or obscured, retailers would almost always opt to cover impermissible advertising rather than to purchase new display cases costing up to \$300. Accordingly, FDA estimated that it would take 15 minutes and \$5 worth of stickers to cover each small attached display; 25 minutes and \$10 worth of stickers to cover each retail pack display; and 35 minutes and \$15 worth of stickers to cover each carton display. This modification decreases total costs by \$20 million.

(vi) Even though the A. T. Kearney audit identified a number of self-service display cases that did not fit in the nonself-service area but could be

retrofitted with locks, the Barents Group did not include cost estimates for these items. FDA estimates that it would take 30 minutes of retailer time and cost about \$10 for materials to add a lock to these display cases, increasing the total one-time costs by \$1.5 million.

(vii) In its analysis of the 1995 proposed regulation, FDA acknowledged that the required reconfiguration of tobacco displays may also impose added labor costs for some purchase transactions, especially for those stores that move inventory to areas located away from employee work stations. On the assumption that the ban on self-service tobacco displays would require 10 seconds of additional labor time for 75 percent of all retail transactions involving cartons, FDA had estimated costs of about \$14 million per year. Although a few comments indicated that the self-service ban would increase labor costs, the Barents Group did not include such costs in its assessment. Nevertheless, FDA believes that some establishments, particularly those selling a substantial number of cigarette cartons that could not be stored within easy reach of a checkout station, could experience increased annual labor costs. Thus, FDA recalculated its estimate based on the updated retail employee compensation rate of \$9.51 suggested by the Barents Group and the new site visit data from the A. T. Kearney study, which imply that only about 40 percent of cigarette cartons are purchased at establishments that sell cigarette cartons from self-service areas. These adjustments project additional annual labor costs of about \$10.9 million per year.<sup>317</sup>

<sup>317</sup> Derived from assumption that 10 percent of carton transactions are for multiple (2) cartons, and that cartons constitute 85 percent of tobacco sales at supermarket/grocery stores, general merchandise stores, drug stores, and tobacco stores, and 10

Except for those adjustments, FDA used the information found in the A. T. Kearney field audit to develop its revised estimate. For comparison, the original Barents Group estimates of the number of establishments and one-time point-of-sale costs (corrected for miscalculations as described above) are shown in Table 6 and FDA estimates of one-time costs in Table 7. Detailed summaries of the FDA one-time cost estimates are presented in Table 8 and Table 9 and indicate that costs related to self-service display cases comprise 73 percent of the total, followed by 18 percent for promotional materials and 9 percent for nonself-service display cases. As explained above, these estimates assume that manufacturers will bear the cost of removing all promotional items and retailers will bear the cost of replacing most functional items. Because the regulation places the removal responsibility on owners of the materials, FDA does not know how these obligations will be divided. However, if retail outlets, rather than manufacturers, must remove these items, the overall cost to manufacturers falls by about \$47 million and the cost to retailers increases by about \$17 million. (Retail compensation rates are about one-third of manufacturer rates, according to the Barents Group data). The following discussion describes specific compliance costs for each outlet category.

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percent of tobacco sales at other outlets. Tobacco sales data from 1992 Census of Retail Trade, pp. 3-31. Kearney site visits found that 80 percent of general merchandise stores, 33 percent of supermarket/grocery stores, 25 percent of convenience stores, 17 percent of service stations, 30 percent of drug stores, 42 percent of tobacco stores had self-service carton display cases.

TABLE 6.—BARENTS GROUP LLC ESTIMATE OF ONE-TIME POINT-OF-SALE REGULATORY COSTS <sup>1</sup>

Kind of Business	Estimated Number of Establishments		Average Cost per Facility (\$)	Estimated Point-of-Sale Costs (Lower)			Estimated Point-of-Sale Costs (Upper)		
	Lower	Upper		Retail Costs (\$)	Manufacturer Costs (\$)	Total Costs (\$)	Retail Costs (\$)	Manufacturer Costs (\$)	Total Costs (\$)
General Merchandise	21,299	29,818	1,067	13,268,172	9,449,404	22,717,576	18,575,066	13,228,900	31,803,966
Supermarket/Grocery	125,222	175,311	2,356	182,028,407	112,960,223	294,988,630	254,840,061	158,144,493	412,984,554
Convenience Stores	51,678	72,349	925	24,408,368	23,382,610	47,790,978	34,171,621	32,735,564	66,907,185
Convenience Stores with Gas	91,250	127,750	515	21,656,668	25,294,382	46,951,050	30,319,336	35,412,134	65,731,470
Service Stations	66,721	93,409	217	4,894,902	9,616,053	14,510,955	6,852,833	13,462,416	20,315,250
Drug Stores	51,056	71,478	167	4,472,540	4,054,323	8,526,863	6,261,520	5,676,020	11,937,541
Tobacco Stores	2,596	3,635	2,940	4,486,055	3,147,456	7,633,511	6,281,514	4,407,166	10,688,680
Total	409,822	573,750		255,215,112	187,904,451	443,119,563	357,301,952	263,066,694	620,368,645

<sup>1</sup> Totals may not add due to rounding.

TABLE 7.—FDA ESTIMATE OF ONE-TIME POINT-OF-SALE REGULATORY COSTS

Kind of Business	Estimated Number of Establishments <sup>1</sup>	Average Cost Per Facility (\$)	Estimated Point-of-Sale Costs <sup>2</sup>		
			Retail Costs (\$)	Manufacturer Costs (\$)	Total Costs (\$)
General Merchandise	12,117	919	7,874,058	3,263,894	11,137,952
Supermarket/Grocery	71,240	810	32,655,560	25,067,316	57,722,876
Convenience Stores	93,745	364	12,271,061	21,879,370	34,150,431
Convenience Stores with Gas	51,913	213	1,397,066	9,644,359	11,041,425
Service Stations	45,539	122	2,560,164	2,974,000	5,534,164
Drug Stores	30,875	160	2,978,007	1,966,563	4,944,570
Tobacco Stores	1,477	2,175	2,165,591	1,046,163	3,211,753
Other Establishments	210,012	19	522,765	3,384,741	3,907,506
Total	507,918		62,424,273	69,226,404	131,650,677

<sup>1</sup> Number of establishments from Table 5.<sup>2</sup> Totals may not add due to rounding.

TABLE 8.--SUMMARY OF AVERAGE COMPLIANCE COSTS BY KIND OF BUSINESS<sup>1</sup>

Compliance Activities	General Merchandise	Supermarket/ Grocery	Convenience Stores	Convenience Stores with Gas	Service Stations	Drug Stores	Specialty Tobacco Stores	Other Establishments
	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)
<b>Promotional Materials:</b>								
No. 3 Ext. Attached Signs	*	1.19	*	*	1.07	*	*	*
No. 4 Ext. Movable Sign Board	*	0.95	0	2	3.75	*	8.57	0
No. 5 Ext. Decal/Stickers	*	0.85	0	2	2.82	*	4.02	*
No. 6 Ext. Lighted Signs/Clocks	*	0.61	0	2	0.85	*	16.34	1
No. 7 Ext. Signs, Posters & Displays	*	0.38	0	1	1.36	*	1.43	*
No. 8 Ext. Movable Window Signs	*	0.95	0	1	1.33	*	1.54	*
No. 9 Ext. Open/Closed Signs	*	0.43	0	3	2.14	*	0.98	0
No. 10 Ext. Signs on Gas Pumps	*	0.43	0	1	0.14	0	0.59	3
No. 11 Ext. News Stand Displays	*	7.42	1	*	*	*	*	*
No. 12 Ext. Novelty Item Displays	*	*	*	*	*	*	*	*
No. 13 Ext. Banners	*	*	*	*	*	*	*	*
No. 14 Signs, Posters & Banners	0.34	*	0.80	2	1.07	*	0.54	0
No. 15 Lighted Signs, Clocks/Mach. Dev.	19.61	1.14	0	1	1.71	0	2.14	0
No. 16 Decals/Stickers	0.26	10.29	1	5	8.17	7	28.60	1
No. 17 Shelf Marker w/Adv.	0.60	0.79	0	1	0.67	0	0.93	0
No. 18 Shopper Aids	0.04	0.44	0	1	1.49	1	0.96	0
No. 19 News Racks, Shop. Bask., Carts	*	0.42	0	0	0.31	0	0.21	0
No. 20 Fl. St. Ash Trays, Waste Basket	*	83.75	10	12	9.66	5	14.50	1
No. 21 Merch. w/ Ref. to Tobacco Prod.	*	3.30	0	*	9.89	5	24.71	1
Promotional Materials Subtotal:	20.85	112.92	14	100.67	23.47	19	106.39	5
<b>Self-Service Display Cases:</b>								
Small, Unattached								
No. 22 Space Available, Ads Removed	*	0.32	0	1	0.71	1	3.21	0
No. 23 Unit Must Be Replaced	10.60	25.52	3	53.00	8.83	7	141.33	6
Small, Attached								
Removal and Installation/Relocation								
No. 24 Unit Must Be Replaced	13.50	65.00	8	*	*	*	*	*
No. 25 Space Available, Ads Removable	10.00	55.56	7	*	*	*	*	*
Packs								
Removal and Installation								
No. 26 Space Available, No Ads	67.50	86.11	11	*	6.25	5	193.75	9
No. 27 Space Available, Ads Removable	0.79	*	0	*	*	*	*	*
No. 28 Unit Must Be Replaced	200.00	0.29	0	*	*	*	0.66	0
No. 29 Unit Modified w/Locking Doors	1.48	222.22	27	*	20.83	17	625.00	29
		3.28	0	*	*	16	*	*



TABLE 8.--SUMMARY OF AVERAGE COMPLIANCE COSTS BY KIND OF BUSINESS--(CONTINUED)

Compliance Activities	General Merchandise	Supermarket/ Grocery	Convenience Stores	Convenience Stores with Gas	Service Stations	Drug Stores	Specialty Tobacco Stores	Other Establishments
	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)
<b>Cartons</b>								
No. 10 Space Available, No Ads	166.50	65.09	46.25	13	15.42	37.00	262.08	12
No. 41 Unit Must Be Replaced	390.00	155.56	112.50	31	25.00	60.00	775.00	36
No. 14 Disposable, Replaced	35.41	3.83	1.19	0	3.69	8.85	11.07	1
Self-Service Subtotal:	895.78	685.12	214.28	59	47.00	148.42	37.62	2
<b>Non-Self-Service Display Cases:</b>								
<b>Small, Unattached</b>								
No. 15 Advertising Removable	*	0.16	2.41	1	3.75	2.14	0.89	0
No. 16 Unit Must Be Replaced	*	*	26.50	7	*	*	13.25	1
<b>Small, Attached</b>								
No. 37 Advertising Removable	*	1.27	3.75	1	2.86	1.50	2.14	0
No. 38 Unit Must Be Replaced	*	*	8.57	2	0.95	*	*	*
<b>Packs</b>								
No. 39 Advertising Removable	*	0.40	1.07	0	0.36	1.71	0.18	0
No. 40 Unit Must Be Replaced	*	2.30	*	*	*	*	*	*
<b>Cartons</b>								
No. 41 Advertising Removable	2.57	1.43	*	*	*	0.64	0.36	0
No. 42 Unit Must Be Replaced	*	6.66	7.05	2	4.70	*	*	*
No. 43 Disposable, Replaced	*	*	*	12	4	*	*	*
Non-Self-Service Subtotal:	2.57	12.22	49.35	14	12.61	6.00	16.82	1
<b>TOTAL:</b>	919.20	810.26	364.29	100	121.53	160.15	2,174.51	100
				100	100	100	100	100

Totals may not add due to rounding.

TABLE 9.--SUMMARY OF TOTAL COSTS FOR COMPLIANCE ACTIVITIES BY KIND OF BUSINESS<sup>1</sup>

Compliance Activities	General Merchandise (\$000)	Supermarket/Grocery (\$000)	Convenience Stores (\$000)	Convenience Stores with Gas (\$000)	Service Stations (\$000)	Drug Stores (\$000)	Specialty Tobacco Stores (\$000)	Others (\$000)	ALL ESTABLISHMENTS (\$000)
<b>Promotional Materials:</b>									
No. 1 Ext. Attached Signs	*	85	*	*	49	*	*	*	134
No. 4 Ext. Movable Sign Board	*	68	602	148	171	*	13	*	1,002
No. 5 Ext. Decal/Stickers	*	60	565	146	39	*	6	*	816
No. 6 Ext. Lighted Signs/Clocks	*	43	383	471	62	*	24	*	984
No. 7 Ext. Signs, Posters & Displays	*	27	181	69	*	*	2	*	279
No. 8 Ext. Movable Window Signs	*	68	979	111	73	*	1	*	1,232
No. 9 Ext. Open/Closed Signs	*	31	206	*	*	18	1	118	375
No. 10 Ext. Signs on Gas Pumps	*	*	*	12	7	*	*	*	19
No. 11 Ext. News Stand Displays	*	529	*	*	*	*	*	*	529
No. 12 Ext. Novelty Item Displays	*	*	*	*	*	*	*	*	*
No. 13 Ext. Banners	*	*	75	185	49	*	1	*	310
No. 14 Signs, Posters & Banners	4	81	161	89	78	5	3	34	456
No. 15 Lighted Signs, Clocks/Mach. Dev.	238	733	1,724	848	372	101	42	657	4,715
No. 16 Decals/Stickers	3	57	221	35	33	40	1	258	647
No. 17 Shelf Marker w/Adv.	7	31	201	77	83	12	1	75	488
No. 18 Shopper Aids	1	30	18	16	1	1	0	9	75
No. 19 News Racks, Shop. Bask., Carts	*	5,967	502	502	*	*	21	*	10,566
No. 20 Pl. St. Ash Trays, Waste Basket	*	235	4,077	513	*	*	37	*	784
No. 21 Merch. w/ Ref. to Tobacco Prod.	*	*	45	37	54	*	3	*	139
<b>Promotional Materials Subtotal:</b>	253	8,044	9,437	3,261	1,069	177	157	1,151	23,549
<b>Self Service Display Cases:</b>									
No. 22 Space Available, Ads Removed	*	23	125	124	33	33	5	215	557
No. 23 Unit Must Be Replaced	128	1,818	4,968	2,751	402	*	209	*	10,277
<b>Small, Attached</b>									
No. 24 Unit Must Be Replaced	164	4,631	*	519	*	278	*	1,809	7,400
No. 25 Space Available, Ads Removable	121	3,958	*	*	*	*	*	*	4,079
<b>Packs</b>									
No. 26 Space Available, No Ads	818	6,135	*	*	285	232	286	*	7,755
No. 27 Space Available, Ads Removable	*	*	*	*	*	*	*	*	*
No. 28 Unit Must Be Replaced	10	21	*	46	*	*	1	*	77
No. 29 Unit Modified w/Locking Doors	2,423	15,831	*	*	949	772	923	*	20,898
<b>Cartons</b>	18	234	*	*	*	*	*	*	251
<b>Removal and Installation</b>									
No. 30 Space Available, No Ads	2,017	4,637	4,336	*	702	1,142	387	*	13,222
No. 31 Space Available, Ads Removable	*	19	111	*	*	*	*	*	19
No. 32 Unit Must Be Replaced	*	*	10,546	*	1,138	1,853	1,145	*	114
No. 33 Unit Modified w/Locking Doors	4,726	11,082	*	*	168	273	16	*	30,489
No. 34 Disposable, Replaced	429	273	*	*	214	*	56	*	1,159
	*	149	*	*	*	*	*	*	419

TABLE 9. -- SUMMARY OF TOTAL COSTS FOR COMPLIANCE ACTIVITIES BY KIND OF BUSINESS -- (CONTINUED)

Compliance Activities	General Merchandise (\$000)	Supermarket/Grocery (\$000)	Convenience Stores (\$000)	Convenience Stores with Gas (\$000)	Service Stations (\$000)	Drug Stores (\$000)	Specialty Tobacco Stores (\$000)	Others (\$000)	ALL ESTABLISHMENTS (\$000)	%
Self-Service Subtotal:	10,854	48,808	20,087	3,440	3,891	4,583	3,030	2,024	96,717	73.5
Non-Self-Service Display Cases:										
No. 15 Advertising Removable Small, Unattached	*	11	226	334	171	66	1	431	1,239	0.9
No. 16 Unit Must be Replaced Small, Attached	*	*	2,484	2,446	*	*	20	*	4,949	3.8
No. 17 Advertising Removable	*	90	351	235	130	46	3	301	1,157	0.9
No. 18 Unit Must be Replaced Packs	*	*	803	*	43	*	*	*	1,847	0.6
No. 19 Advertising Removable	*	28	100	25	16	53	0	*	223	0.2
No. 40 Unit Must be Replaced Cartons	*	164	*	*	*	*	*	*	164	0.1
No. 41 Advertising Removable	31	102	*	*	*	20	1	*	153	0.1
No. 42 Unit Must be Replaced	*	475	*	*	*	*	*	*	475	0.4
No. 43 Disposable, Replaced	*	*	661	1,302	214	*	*	*	2,177	1.7
Non-Self-Service Subtotal:	31	870	4,626	4,340	574	185	25	732	11,385	8.6
TOTAL:	11,138	57,723	34,150	11,041	5,534	4,945	3,212	3,908	131,651	100

\* Totals may not add due to rounding.

e. *General merchandise stores.* None of the general merchandise stores in the A. T. Kearney sample had exterior promotional materials and only a few had interior promotional materials. Eighty percent of the stores had only self-service displays, with carton displays more numerous than pack displays at these locations. The average per facility one-time costs estimated by FDA were \$919. Overall, 97 percent of the outlet costs related to the replacement of self-service display cases, although in some general merchandise stores, tobacco products were stocked on shelves rather than in special display cases, which suggests that the costs for this business category may be overstated.

f. *Supermarket/grocery.* Unlike general merchandise stores, supermarkets had significant promotional materials. While both packs and cartons were sold at most locations, over 75 percent of the stores already had nonself-service display areas. FDA estimates per facility costs at \$810. Self-service display case removal and replacement amount to 85 percent of the total cost, whereas promotional materials account for 14 percent. Commenting on the feasibility of the proposed FDA self-service ban, the Food Marketing Institute argued that most retail food stores do not have adequate space at checkout lines for tobacco products and rejected the practicability of alternative procedures. They suggested that the only option available to many food retailers would be to remodel and set-up a controlled area for the sale of tobacco products, costing up to \$50,000 per store. The A. T. Kearney audit, however, found that a majority of supermarket/grocery stores have already installed nonself-service areas for tobacco products and would not need to reconfigure their stores. While some establishments will incur costs above the average, the A. T. Kearney site visit data suggest that most stores could comply by either moving inventory to nonself-service areas or by purchasing new displays that are compatible with existing store configurations.

g. *Convenience stores.* Stores in this category exhibited numerous interior and exterior promotional items. All of the convenience stores surveyed had nonself-service display cases and 50 percent had carton displays. FDA estimates per facility costs of \$364. Costs for removing and replacing self-service display cases made up 59 percent of the total, while costs for promotional materials and nonself-

service display cases were 28 percent and 14 percent, respectively.

The National Association of Convenience Stores (NACS) faulted FDA on its assumption that the main cost of the self-service ban would be to relocate tobacco product inventory, contending that their members would incur thousands of dollars in reconfiguration costs. According to NACS:

[i]t is largely irrelevant that retailers already keep packs behind the counter. Many NACS members keep large quantities of packs and cartons in self-service displays and would have to reconfigure their stores to comply with the ban on self-service sales. Based on an estimate from one member with a high volume of self-service cigarette sales, NACS suggested it could cost \$4,320 and \$10,120, respectively, to reconfigure a newer and older convenience store.

Based on other evidence, however, FDA does not believe that a large number of stores will be forced to undergo extensive modifications and finds that most convenience stores can adequately adapt space either behind or above checkout counters. As noted earlier, one regional survey reported that retail outlets readily complied with local self-service restrictions without architectural remodeling or substantial refitting of checkout counters or store aisles.<sup>318</sup> Space above counters is typically available for display cases either by suspending a case from the ceiling or by supporting a case on beams from the counter. In its survey, A. T. Kearney found at least some tobacco products sold from nonself-service space in every convenience store. Although it is possible that stores might incur added inventory handling costs if this space were smaller than optimal, FDA concludes that major reconfiguration would rarely be required and relies on the A. T. Kearney survey data, as adjusted, to project average costs for this sector.

h. *Convenience stores with gas.* Like convenience stores without gas, these establishments had numerous interior and exterior promotional materials. About 89 percent of the stores surveyed had nonself-service display cases. FDA estimates per facility costs of \$213. Consistent with the findings of the Barents Group, the average outlet cost

for this sector is about one-half that of convenience stores without gas.

In comments to the 1995 proposed rule, the Society of Independent Gasoline Marketers of America (SIGMA) did not present specific data on the cost to their members, but indicated that many members would be required to reconfigure their stores. They stated that:

[m]any SIGMA members keep large quantities of packs and cartons in self-service displays and would have to reconfigure their stores to comply with the ban on self-service sales. At a minimum, these members would have to install new cabinets to accommodate tobacco products behind the counter. Many members would have to enlarge the counter area to make room for the new cabinets. In contrast, the A. T. Kearney field audit found few convenience stores with gas that have self-service displays, other than unattached promotional counter displays. Costs to remove or replace promotional counter displays will be borne primarily by manufacturers, not retailers. In sum, the costs for self-service display cases amount to about 31 percent of the total, promotional material 30 percent, and nonself-service display cases 39 percent.

i. *Service stations.* These establishments had both interior and exterior promotional material. Seventy-five percent of the locations surveyed had only nonself-service display cases and one-fourth had carton displays. FDA estimates the per facility cost at \$122.

j. *Drug stores.* Drug store outlets had few exterior and interior promotional materials. As in general merchandise stores, tobacco products were stocked on shelves in some locations. Ninety percent of the stores surveyed by A. T. Kearney already had nonself-service displays and approximately 70 percent had carton displays. FDA estimated \$160 cost per facility for this category of business. About 93 percent of the total one-time costs are for replacement of self-service display cases.

k. *Tobacco stores.* These stores had substantial promotional materials and multiple display cases. FDA estimates per facility costs of \$2,175. About 94 percent of the costs are for self-service display cases, with promotional materials and nonself-service display cases dividing the remaining 6 percent. While not reflected in the cost totals, these establishments may choose to operate as "adult only" restricted areas to avoid replacing self-service display cases.

l. *Other establishments.* This category includes eating/drinking establishments and miscellaneous retail stores, which

<sup>318</sup> Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales," North Bay Health Resources Center, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

were excluded from the A. T. Kearney audit, plus the estimated 100,000 nonretail establishments that sell tobacco products OTC, such as hotels, factories and sporting facilities. Due to the low volume of tobacco product sales at these establishments, FDA assumed that only a small quantity of packs and no cartons would be sold. Lacking detailed data, FDA assigned costs of \$19 per outlet, based on the costs of removing promotional materials and relocating and replacing small attached display cases, as reported for drug stores.

### 3. Label Changes

The final regulation requires that the tobacco product package contain the established name of the tobacco product in a specified size. FDA estimated the compliance costs for printing new labels in its earlier analysis of the proposed regulation and has received no comments that improve those original estimates.

Approximately 933 varieties of cigarettes are currently produced in the United States.<sup>319</sup> FDA does not have information on the number of smokeless tobacco varieties, but assumes that the total number of cigarette and smokeless tobacco varieties is roughly 1,000. Because most varieties of cigarettes are packaged in both single packs and cartons, the total number of labels is assumed to number about 2,000.

FDA used two approaches to estimate the cost to industry of changing these labels. The first approach relied on information compiled by The Research Triangle Institute (RTI) for its report to FDA on the cost of changing food labels.<sup>320</sup> RTI reported a cost of about \$700 for a 1-color change in a lithographic printing process. FDA multiplied this figure by 4 to account for a 2-color change on the actual warning labels and an additional 2 colors for modifications to the existing label to make room for the warning label. This calculation yielded incremental printing costs of about \$2,800 per label, or \$5.6 million for all 2,000 varieties of affected tobacco products. Adjusting this figure downward by RTI's methodology to account for the current frequency of label redesign predicts that the total one-time cost of completing these label changes within a 1-year compliance

period would be approximately \$4 million.

The second approach was to use cost information provided in the regulatory impact analysis of a roughly comparable Canadian regulation.<sup>321</sup> The Canadian Government estimated a cost of \$30 million to change labels for about 300 cigarette varieties. Most Canadian cigarettes are likewise sold in two sizes, but about 20 percent are also sold in flip top packages.<sup>322</sup> Canadian labels, however, are typically printed using a gravure method; which, according to RTI, is about 3.5 times as expensive as the lithography process used in the United States. Adjusting the Canadian estimate upward, to account for the larger number of cigarette and smokeless tobacco varieties in the United States; and downward, for the smaller number of packages per variety and the smaller cost of the lithography printing process, provides a \$17 million estimate for the total cost of these label changes.

### 4. Educational Program

FDA may issue notification orders under section 518(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C.360h(a)) to require manufacturers of cigarettes and smokeless tobacco products to fund consumer educational programs. While the precise details of these orders are still under development, these orders may involve the achievement of specific performance objectives by directing manufacturers to initiate informational programs designed to transmit messages that will reach the majority of young people. The 1995 proposed regulation directed manufacturers to spend at least \$150 million annually on this program. While industry comments were critical, many other comments suggested that this figure was too low. One comment noted that \$150 million is equivalent to about one week of pro-tobacco expenditures and another that the industry gained \$221 million in profits from underage sales. Still another pointed out that the current dollar value of the informational advertising that was conducted under the Fairness Doctrine would amount to about \$300 million per year. One study appears to indicate that 75 percent of adolescents aged 12 to 17 could have been reached in 1985 to

1986 with multiple messages at a cost of about \$17 million a year.<sup>323</sup> FDA is still evaluating various types of informational programs, with respect to both effectiveness and practicality. Before a final decision is reached, the agency will determine the costs of selected alternatives.

### 5. Restricted Advertising and Promotional Activities

a. *Tobacco industry.* The determination of the societal costs attributable to the restrictions on tobacco product advertising and promotion is complex. While there is no doubt that individual manufacturers realize enhanced goodwill asset values from advertising programs, the industry has long held that advertising prompts brand-switching, but does not increase aggregate sales. Of course, if this were true, advertising would be unprofitable from the standpoint of the industry as a whole and reduced levels would increase rather than decrease aggregate industry profits. In addition, if the primary motivation for tobacco advertising is to promote brand-switching, then, as long as all firms are equally restricted from advertising, the above mentioned loss in goodwill value will be substantially reduced.

In its comments, the tobacco industry claimed that tobacco advertising and promotion have virtually no effect on youth consumption. Although FDA does not accept this claim, the agency does not consider the expected voluntary reduction in the consumption of tobacco products to be a societal cost. Although industry sales will fall, they will reflect new consumer preferences and consumer dollars no longer used on tobacco products will be redirected to other more highly valued areas. Thus, for the most part, the resulting reduction in industry sales are not net costs and the potential magnitude of this revenue transfer is discussed below under the heading of Distributional Effects. Moreover, as shown in that discussion, any short-term frictional or relocation impacts will be significantly moderated by the gradual phase-in of the economic effects.

b. *Advertising industries.* In its original analysis, FDA argued that advertising and promotional restrictions will impose no long term net costs on society. The Barents Group's study found that the various suppliers of

<sup>319</sup> "Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes," Federal Trade Commission, 1994.

<sup>320</sup> French, M. T., D. M. Neighbors, L. K. Carswell, K. B. Heller, and G. L. McDougal, "Compliance Costs of Food Labeling Regulations," Final Report, RTI Project Number 233U-3972-02 DFR, January 1991.

<sup>321</sup> Department of National Health and Welfare, "Tobacco Products Control Regulations, amendment," *Canada Gazette*, Part II, vol. 127, No. 16, pp. 3277-3294, August 11, 1993.

<sup>322</sup> Kaiserman, M., Department of National Health and Welfare, Canadian Government, personal communication, February 1, 1995.

<sup>323</sup> Bauman, K. E., J. D. Brown, E. S. Bryan, L. A. Fisher, C. A. Padgett, and J. M. Sweeney, "Three Mass Media Campaigns to Prevent Adolescent Cigarette Smoking," *Preventive Medicine*, vol. 17, pp. 510-530, 1988.

industry advertising will incur substantial regulatory costs. It estimated that illustrative annual costs for this sector could reach \$722 million to \$2.17 billion, or up to one-half of its estimate of the total costs of the FDA proposal.

Upon review, FDA remains firmly convinced that its original position was correct. That is, from the standpoint of assessing societal costs and benefits, reduced revenues from tobacco advertising and promotional activities are not net costs and are appropriately considered a distributional impact. Indeed, FDA believes that a strong argument can be made that, even irrespective of health benefits, these advertising restrictions will decrease net societal costs by freeing productive resources for alternative uses. This does not imply that no individual business entities will be negatively impacted. Many of the companies that currently benefit from tobacco promotions (e.g., advertising agencies, publishers, sporting event promoters) will suffer lost revenues and those firms that specialize in those activities may lose a substantial part of their business. Nevertheless, from a societal perspective, these losses will be counterbalanced by an increase in demand for other consumption and investment goods, so that nontobacco-related entities will gain sales. Although overlooked in most industry comments, this result is acknowledged within the comments submitted for the Tobacco Institute by the Barents Group:

A key assumption in the simulations is that, when tobacco product manufacturers decrease their advertising expenditures, the money not spent translates into increased profits for the industry. The increased profits ultimately end up in the hands of the companies' owners (shareholders) either as direct payouts or as investments on their behalf in other lines of business. In general, these profits are ultimately recycled into increased consumption and investment by the owners of the companies. That report also reveals the underlying distributional nature of the impacts by explaining that its modeling incorporates the assumption that:

\* \* \* in the long run economic losses in one sector of the economy will be redistributed to other sectors of the economy, i.e., winners and losers will generally balance out for the economy as a whole. Further discussion of the impact of these revenue transfers is included below under the section on "Distributional Effects."

c. *Retail sector.* In addition to the previously estimated direct costs associated with the removal of prohibited point-of-purchase advertising, promotional restrictions

will impact the retail sector because they will lead to a long-term decline in tobacco products sales and a potential fall in promotional allowances (slotting fees) from manufacturers. Once again, these impacts are not net societal costs, since reduced tobacco product sales will be counterbalanced by increased sales for other products or services; and smaller promotional allowances, if they occur, are gains to tobacco manufacturers that would be used for other purchases. Consequently, these impacts also are examined below under "Distributional Effects."

d. *Consumers.* Advertising restrictions may impose costs on society if they disrupt the dissemination of relevant information to consumers. Firms engage in advertising to inform potential customers about their product (informative advertising) or to persuade customers that a product is desirable (persuasive advertising). According to the FTC's Bureau of Economics, the benefits of advertising derive from:

\* \* \* its role in increasing the flow and reducing the cost of information to consumers \* \* \* First, advertising provides information about product characteristics that enables consumers to make better choices among available goods \* \* \* Second, theoretical arguments and empirical studies indicate that advertising increases new entry and price competition and hence reduces market power and prices in at least some industries \* \* \*. Third, advertising facilitates the development of brand reputations. A reputation, in turn, gives a firm an incentive to provide products that are of consistently high quality, that live up to claims that are made for them, and that satisfy consumers.<sup>324</sup>

FDA has considered each of these issues. First, while agreeing that many forms of advertising offer substantial benefits to consumers, the agency nevertheless believes that consumers will lose little utility from these particular advertising restrictions. The regulation does not prohibit factual, written advertising. Thus, the rule will not impede the dissemination of important information to most consumers. In its preliminary analysis, the agency concluded that, "[w]hile imagery and promotional activities may be important determinants of consumer perceptions and sales, they typically provide little meaningful information on essential distinctions among competing tobacco products" (60 FR 41314 at 41368).

<sup>324</sup> Recommendations of the Staff of the Federal Trade Commission, "Omnibus Petition for Regulation of Unfair and Deceptive Alcoholic Beverage Advertising and Marketing Practices," Appendix A, pp. 3-4, March 1985.

One industry comment strongly opposed this position, arguing that advertising is important for product improvement and that past restrictions on the advertising of "low tar" products retarded product innovation. The crux of the argument is that color and/or imagery are prerequisites for disseminating relevant quality information and that, in its absence, consumers could not be adequately informed about the merits of new products. FDA, however, is not persuaded that manufacturers will be unable to convey vital information. The agency finds that true product improvements in this industry are rare, but where they exist, manufacturers could rely on traditional ads in adult-oriented publications and on "text only" advertising elsewhere. Moreover, FDA and other public health agencies would likely coordinate with companies in disseminating truly important consumer safety information.

The implications of FTC's second point, which addresses the effect of advertising restrictions on market power and prices, are less certain, as various empirical studies have reached conflicting conclusions. One industry comment insisted that FDA's regulation will deprive consumers of the benefits of competition, stating that, "[u]ndoubtedly the clearest measure of consumer benefit is the effect of advertising on price." To support this view, the comment references several studies that demonstrate the ability of advertising to reduce product prices. The comment also contended that the "[e]limination of advertising will predictably consolidate the market as marginal brands are abandoned and fewer brands are introduced" and that, "[o]ver time this can also reduce the number of players, as companies with dominant brands drive out others."

FDA agrees that advertising can often lead to decreased product prices, but notes that the other industries referenced (e.g., eyeglasses and pharmaceuticals) are much more competitive than tobacco products. Moreover, economists have found that advertising can also serve as a barrier to entry in oligopolistic industries. One author, for example, determined that ready-to-eat breakfast foods companies used advertising programs to support brand proliferation strategies in order to dominate retail shelf space.<sup>325</sup> These programs helped to keep new firms out and prices high without necessarily

<sup>325</sup> Sutton, J., "Sunk Costs and Market Structure," The MIT Press, Cambridge, Massachusetts, pp. 229-247, 1991.

embodying improved quality. Thus, in certain circumstances, oligopolistic firms can use extensive advertising to create barriers for suppressing innovation and competition. FDA cannot determine whether tobacco advertising restrictions would ultimately increase or decrease product prices.

Finally, FTC's third point, which emphasizes the positive aspects of advertising in supporting brand reputations, is more relevant for long-lived items, such as consumer durables, where purchases are infrequent or personal experience is inadequate. Advertising is less likely to play a key role in assuring high quality levels for tobacco products, where consumer search costs are low and a brand's reputation for quality is tested by consumers every day. For these products, high quality will remain a prerequisite of commercial success irrespective of advertising strategies.

Other analysts suggest still other potential attributes of product advertising. For example, according to F. M. Scherer, author of a widely read text on industrial organization:

Advertising is art, and some of it is good art, with cultural or entertainment value in its own right. In addition, it can be argued that consumers derive pleasure from the image advertising imparts to products, above and beyond the satisfaction flowing in some organic sense from the physical attributes of the products. There is no simple case in logic for distinguishing between the utility people obtain from what they think they are getting and what they actually receive. As Galbraith observed, "The New York housewife who was forced to do without Macy's advertising would have a sense of loss second only to that from doing without Macy's."<sup>326</sup>

Similarly, Becker and Murphy have argued that advertisements should be considered "goods" if people are willing to pay for them and as "bads" if people must be paid to accept them.<sup>327</sup> They explain that, in general, the more easily the advertisements can be ignored, the more likely it is that the ads themselves provide utility to consumers. Newspaper and magazine advertisements, for example, must provide positive consumer utility or they would be ignored by readers. This final rule allows such advertisements to continue, some in their current form, others in a text-only format. (In fact, industry outlays for newspaper and magazine advertisements have dropped

sharply in recent years and currently constitute less than 5 percent of the industry's total advertising and promotion budget).<sup>328</sup> Conversely, the extraordinary growth in industry advertising and promotion has occurred in areas that are typically bundled with other products, or placed in prominent public settings that are difficult to ignore. Thus, there is considerable question about the contribution of these programs to consumer utility.

#### 6. Training

a. *Retailers.* The final regulation does not explicitly require retail employees who sell tobacco products to be trained in checking customer I.D.'s. FDA understands, however, that some training is essential to effective performance. In its analysis of the proposed regulation, FDA estimated total annual costs of \$10 million for employee training at retail outlets. This estimate assumed that an average of 12 employees per store at 467,000 retail stores (assuming 1/3 of 700,000 stores already conducted training) would receive 15 minutes of training at a compensation rate of \$7.41/hour. The Barents Group commented that FDA's analysis did not account for many individual cost elements, resulting in a significant underestimate of total training costs. It estimated one-time training costs of \$184 to \$257 million and recurring annual training costs of \$48 to \$67 million.

Specifically, the Barents Group stated that FDA relied on outdated compensation data. FDA had obtained these data from a 1992 report prepared by Price Waterhouse for the Tobacco Institute, but agrees that more recent data are available and employs the suggested compensation rate of \$9.51 for its revised estimate. The Barents Group also claimed that FDA failed to consider recurring training costs due to annual employee turnover and annual updating, focusing instead on one-time training costs only. This criticism is not valid. Table 2 of the original analysis (60 FR 41314 at 41360) clearly lists training costs for retail establishments as an annual operating cost and the text (60 FR 41314 at 41367) refers to a "per year" cost. Because employees would be trained when first hired, this estimate implied a 100 percent employee turnover rate.

To refine its analysis, however, FDA has disaggregated the cost elements. Although the Barents Group accepted FDA's preliminary estimate of 12 employees per retail store, FDA now believes that this figure is accurate only for retail stores with payroll. Stores without payroll constitute a significant percentage of the stores selling tobacco products and, on average, are much smaller. As explained above, FDA estimates that about 600,000 establishments will sell over-the-counter tobacco products, including the 100,000 that replace those vending machines that are removed. Table 10 presents the data that underlie FDA's revised estimates of the number of employees who will be trained. For existing retail establishments with payroll, FDA assumes that training will be needed for all employees in the affected outlets, except in General Merchandise and Supermarket/Grocery stores, where one-third of the employees will be trained. For establishments without payroll, nonretail establishments, and new establishments replacing vending machines, Census data on the number of employees is not available, but FDA assumes that an average of six employees will be trained. As shown in Table 10, these calculations indicate that training will be required for a total of 4.2 million workers.

The Barents Group further faulted FDA for underestimating the training time that would be required to educate retail sales clerks about recognizing proper forms of identification and handling related customer service problems. It assumed that 2 hours of training would be necessary. FDA, however, reviewed the time needed to present the training materials from several corporate entities and finds that they need not exceed one hour. For example, one large convenience store corporation uses a 45 minute training videotape that covers the sale of tobacco products, but also covers the sale of alcohol and possible inhalants, including means for recognizing inebriated or drugged individuals. Moreover, many establishments, especially small stores, will provide no formal training, but will provide instruction during the work day with minimal lost time. Thus, FDA believes that average costs are reasonably based on a 1-hour training program.

<sup>326</sup> Scherer, F. M., *Industrial Market Structure and Economic Performance*, 2nd edition, Rand McNally College Publishing Co., Chicago, IL, p. 380, 1980.

<sup>327</sup> Becker, G. S., and K. M. Murphy, "A Simple Theory of Advertising as a Good or Bad," *Quarterly Journal of Economics*, vol. 108, p. 941, November 1993.

<sup>328</sup> Federal Trade Commission Report to Congress for 1993: Pursuant to the Federal Cigarette Labeling and Advertising Act, issued 1995.



TABLE 10.—NUMBER OF EMPLOYEES TO BE TRAINED

Kind of Business	Payroll Establishments				Nonpayroll Establishments		Total Employees Trained
	Establishments Selling Tobacco Products	Employees Per Store	Percent Trained	No. of Employees Trained	Establishments Selling Tobacco Products	No. of Employees Trained <sup>1</sup>	
General Merchandise	12,117	60.1	33%	242,593	9,807	58,842	301,435
Supermarket/Grocery	71,240	20.9	33%	497,253	54,538	327,228	824,481
Convenience Store/no gas	29,400	5.6	100%	164,718	---	---	164,718
Convenience Store/gas	51,913	6.8	100%	353,868	---	---	353,868
Gas Station	37,958	6.0	100%	228,002	7,581	45,486	273,488
Eating Place	11,992	16.5	100%	198,212	3,065	18,390	216,602
Drinking Place	10,745	5.4	100%	58,498	5,336	32,016	90,514
Drug/Proprietary Store	29,046	12.2	100%	354,730	1,829	10,974	365,704
Specialty Tobacco	1,477	3.7	100%	5,530	---	---	5,530
Miscellaneous	24,995	5.2	100%	130,253	44,879	269,274	399,527
<b>Retail Subtotal</b>	<b>280,883</b>			<b>2,233,656</b>	<b>127,035</b>	<b>762,210</b>	<b>2,995,867</b>
Nonretail <sup>2</sup>							<b>600,000</b>
Converted Vending Machines <sup>2</sup>							<b>600,000</b>
<b>Total</b>							<b>4,195,867</b>

<sup>1</sup>Assumes 6 employees per establishment.

<sup>2</sup>Assumes 100,000 outlets with 6 employees to be trained.

Sources: Table 4 for description of establishment data; 1992 Census of Retail Trade, Subject Series: Establishment and Firm Size (Table 1) for employment data; FDA estimates for percent trained.

Adopting FDA's original estimate that about one-third of all affected establishments already provide employee training (also assumed by the Barents Group), implies one-time employee training costs of \$26.6 million (4.2 million employees x 2/3 x \$9.51). The Barents Group suggested, however, that even employees who currently receive training would need 5 extra minutes on the new regulations, which adds about \$1.0 million to the cost estimate. Next, the Barents Group included costs for time spent by trainers, assuming that the training would be provided by an outside source. FDA believes that a more typical approach would have a store supervisor provide the training. Using \$13.64 as the compensation rate for a retail manager, as suggested by the Barents Group, and adjusting for the assumed one-third current compliance rate in existing establishments, yields a one-time cost for trainer time of \$6 million. Thus, FDA projects total one-time training costs of about \$33.5 million.

In addition, FDA estimates that employee turnover, using the Barents Group suggested rate of 42 percent, will add annually recurring training costs of about \$11.2 million. Also, new employees will receive I.D. check training as part of their initial orientation activities. Since stores may provide this to several new employees at once, using either written or video training materials, FDA estimates that retail managers, on average, would

spend about 1 additional hour per year providing this training. This adds \$6.0 million to the annual training costs. The Barents Group also recommended annual reinforcement training. An annual 10-minute reinforcement training period for employees of those establishments that do not already have a training program will cost about \$2.9 million. In sum, these annual recurring training costs total about \$20 million.

The Barents Group also assumed that retail managers would need extensive training to understand the new regulations. FDA estimated in its 1995 proposal that manufacturers' representatives would need about 8 hours of training on their new responsibilities and the Barents Group assumed that retail managers would need a similar duration of training. FDA rejects this estimate, however, as the final provisions affecting retailers are straight-forward and will be routinely communicated through traditional industry channels.

b. *Manufacturers representatives.* In its preliminary economic analysis, FDA estimated that 7,300 manufacturer representatives would be trained for 8 hours at a cost of \$25.00 per hour. After noting FDA's "undocumented" cost estimate, the Barents Group proceeded to apply the identical number of training hours to their "documented" cost estimate of \$25.70 per hour. They also suggested a 15 percent labor turnover premium, giving a total cost of \$1.5 million. As the final rule eliminates

the monitoring burden for these employees, this training cost should be correspondingly smaller. Nevertheless, these manufacturer employees will still need to determine the types of displays that remain permissible. FDA therefore accepts the \$1.5 million cost estimate.

#### 7. Access Restrictions

a. *Manufacturers.* Although voluntary decreases in the sale of consumer products do not impose long-term net societal costs, mandatory restraints on the access of consumers to desired products may imply economic costs. Economists typically measure producer-related inefficiencies attributable to product bans by calculating lost "producers' surplus," which is a technical term for describing the difference between the amount a producer is paid for each unit of a good and the minimum amount the producer would accept to supply each unit, or the area between the price and supply curve. Data derived from Cummings, et al., indicate that youngsters under the age of 18 consume 316 million packs of cigarettes per year, leading to industry profits of \$118 million.<sup>329</sup> On the assumption that the regulation would reduce teenage smoking by one-half, these profits would fall by about \$59

<sup>329</sup> Cummings, K. M., T. Pechacek, and D. Shopland, "The Illegal Sale of Cigarettes to U.S. Minors: Estimates by State," *American Journal of Public Health*, vol. 84, No. 2, p. 301, February 1994, (derived by subtracting sales to 18-years-olds from the reported 516 million packs consumed).

million. However, because most of this profit stems from illegal sales to youths, FDA has not counted this figure as a societal cost.

b. *Consumers.* Consumer surplus is a concept that represents the amount by which the utility or enjoyment associated with a product exceeds the price charged for the product. Because it reflects the difference between the price the consumer is willing to pay and the actual market price, it is used by economists to measure consumer welfare losses imposed by product bans. However, FDA's rule imposes no access restrictions on adults, who will be free to consume tobacco products if they so desire. Thus, FDA has not included any value for lost consumer surplus in its estimate of the societal costs of these access restrictions.

#### 8. I.D. Checks

a. *Retailers.* For the 1995 proposed regulation, FDA estimated that retail establishments would bear annual compliance costs of \$28 million for consumer identification checks. This figure was derived by multiplying the estimated retail employee compensation rate by the extra time that might be needed to complete purchase transactions. The estimate measured the cost to retailers for either increasing the number of working hours of existing staff or for hiring new staff to handle the added workload. The Barents Group commented on numerous aspects of this compliance cost estimation, accepting several key FDA assumptions, but rejecting others in deriving its estimate of \$142 million per year.

In its preliminary analysis, FDA estimated the number of tobacco product transactions for the 18 to 26 year-old age group based on data that reflected the tobacco consumption of cigarette smokers 5 to 6 years after high school<sup>330</sup> and the annual per capita consumption of smokeless tobacco.<sup>331</sup> The Barents Group faulted FDA for limiting these transactions to 18 to 26 year-olds, asserting that the standard practice for alcohol sales is to request identification for anyone who appears to be 30 years old or younger. The Barents Group calculations actually estimated compliance costs on the assumption that customers up to age 34 would be asked for identification, because some

older consumers would appear to be only 30 years old.

FDA has not accepted this Barents Group assumption for several reasons. First, the legal age of purchase for alcohol in all 50 States is 21 years, whereas the rule for cigarettes and smokeless tobacco sets 18 as the legal age of purchase. This 3-year difference implies that comparable cigarette and smokeless identification checks would be expected only up through age 27. Also, the current policy and practice of many retail stores is to request identification from tobacco consumers only up to age 26. Requiring proof of age for anyone who appears younger than 26 years of age was also recommended by a working group of 26 State Attorneys General.<sup>332</sup> Finally, the Barents Group's use of age 34 to provide a margin of safety for identifying those under the age of 30 is illogical, since the FDA rule requires retail stores to identify consumers who are under the age of 26, not 30.

The Barents Group accepted the FDA assumption that an I.D. check would take an average of 10 seconds, but referenced a study by A. T. Kearney that found that the actual time needed to verify a photo I.D. for a tobacco product sale averaged 8.3 seconds. Because FDA has no better data, the agency adopts 8.3 seconds as the average time needed to conduct an I.D. check. The Barents Group further commented that FDA used outdated employee compensation data in its calculations. FDA's revised totals use the Barents Group's employee compensation estimate of \$9.51/hour (1994 dollars) as the time value for retail sales employees.

FDA originally assumed that only 75 percent of all retail transactions for the 18 to 26 year-old age group would be extended due to I.D. checks. The Barents Group argued that the correct percentage should be 100 percent, as the rule would apply to all sales to the relevant age group. FDA continues to believe that this assumption leads to an over-estimate of the probable costs. First, not every moment of a clerk's time is effectively utilized and a few seconds more per transaction will not always result in lost labor productivity. Second, many smokers patronize the same retail store almost daily and are well-known to clerks. I.D. checks for these customers will take little extra time. Finally, many customers will take less time to produce an I.D., once they realize that

identification checks have become routine. Nevertheless, FDA adopts the Barents Group's 100-percent assumption to assure a full accounting of the relevant costs.

One comment claimed that FDA failed to include the cost of hiring additional sales clerks. As noted above, the FDA calculation does reflect the cost of the additional labor time that might be needed. The Barents Group also inexplicably asserts that FDA failed to consider I.D. checking costs as annual costs, instead listing them as a one-time cost. Table 2 of the original analysis (60 FR 41314 at 41360), clearly lists the \$28 million identification check cost as an annual operating cost and the accompanying text (60 FR 41314 at 41367) refers to the figure as a "per year" cost. The Barents Group further faulted FDA for not taking into account the cost of checking I.D.'s for those youths under age 18, who will still attempt to buy cigarettes. While a small percentage of underage smokers may opt for this course of action, few would return to complying outlets. Thus, FDA believes that any plausible estimate of the associated costs would be less than \$1 million annually.

FDA originally estimated the number of tobacco product transactions for the 18 to 26 year-old age group at 2.2 billion, but has updated its estimate to 2.5 billion.<sup>333</sup> Also, the 80-percent current noncompliance rate that had been assumed for the 1995 proposal may be too high, as the Surgeon General estimated that minors are unable to make an OTC purchase of tobacco products about one-third of the time.<sup>334</sup> Nevertheless, FDA retains this assumption to calculate a cost to

<sup>333</sup> 1994 Population data for 18 to 26 year-olds from 1995 Statistical Abstract, Table 16. Cigarettes: Number of smokers for age group calculated from Table 217 (1993 data). Average packs/yr. and total packs/yr. for smokers aged 18 to 26 calculated from data in Table 20, 1994 SGR, p. 85. (Those smoking 1 to 5 cigarettes/day assumed to smoke 3, those smoking 20+ cigarettes/day assumed to smoke 25). The resulting number of packs smoked by 18 to 26 yr.-olds totals about 2.5 billion. If even 1 percent of these transactions were for cartons, this number falls to about 2.3 billion. Smokeless: Total units of smokeless products sold calculated from data in *Spit Tobacco and Youth: Additional Analysis*, Dept. of Health and Human Services, June 1993, Excise Tax calculations, Option 4; Units consumed by youths from the Institute of Medicine Report (the IOM Report) "Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths", p. 8. 1994, Usage data and total units (cans or pouches) consumed for age group for those aged 18 to 26 from "Use of Smokeless Tobacco Among Adults-U.S., 1991" in "MMWR", CDC, DHHS, volume 42, No. 14, p. 264, 1993. The number of containers sold for 18 to 26 yr. old age group totals about 0.2 billion.

<sup>334</sup> IOM Report, p. 202.

<sup>330</sup> 1994 SGR, p. 85.

<sup>331</sup> U.S. Department of Commerce, *Statistical Abstract of the United States 1993*, 113th edition, p. 137, 1993; DHHS, Office of Inspector General, *Spit Tobacco and Youth: Additional Analysis*, June 1993.

<sup>332</sup> "No Sale: Youth Tobacco and Responsible Retailing," Findings and Recommendations of Working Group of State Attorneys General, p. 28, December 1994.

retailers for I.D. checks of \$43 million per year (2.5 billion transactions x 8.3 seconds/transaction x \$9.51/hour ÷ 3600 seconds/hour x 80 percent noncompliance rate). This revised estimate exceeds FDA's original \$28 million figure, but remains far below the \$142 million estimate of the Barents Group.

b. *Consumers.* The Barents Group also criticized FDA for not quantifying the costs to consumers for the extra time needed to undergo I.D. verifications. They estimated this cost at \$282 million a year. FDA agrees that consumers would incur time costs and, for its revised estimates, adopts the analytical framework suggested by the Barents Group, which counts only the time lost by young customers. (The Barents Group suggests that older consumers also would experience delays, but FDA's estimates already account for the cost of additional clerk time that would offset longer checkout lines. Younger customers, however, must wait while their age is verified, even when additional checkout clerks are available.) To estimate the time cost, FDA applies the same methodology that was used to estimate the time cost for retail employees. That is, 2.5 billion transactions taking an extra 8.3 seconds each for the 18 to 26 year-old age group, adjusted for a 20 percent current compliance rate. The Barents Group used an average hourly private sector compensation rate (\$15.13/hour) as the basis of its consumer time cost estimate, but FDA finds this average rate too high for young consumers and estimates a range of \$9 to \$11 per hour.<sup>335</sup> As a result, FDA's estimate of the cost to consumers for lost time cost amounts to between \$41 and \$50 million per year.

## 9. Vending Machines

In its comments on the costs of FDA's proposed vending machine ban, the Barents Group reports that automatic vending machine operators will lose \$403 million in annual revenues. They then subtract an estimated \$281 million offset for future over-the-counter sales (calculated by assuming an equal number of future packs sold and an \$.80

price premium for vending machine packs) to project a net \$122 million of regulatory costs to the retail sector. Although not acknowledged, this methodology implicitly assumes that a redistribution of revenues (from vending machine owners to over-the-counter sellers) does not generate added societal costs. Elsewhere, the Barents Group includes distributional impacts in cost totals. Nevertheless, even this \$122 million estimate is far too high.

The fundamental problem is that changes in revenue, as discussed above, do not measure economic costs. The relevant economic measure of regulatory costs to an industry is the change in producer surplus that a firm makes from selling a good or service. Because producer surplus is difficult to measure, accounting profits are sometimes used as a proxy. By examining only lost revenues, the Barents Group ignores the difference in the operating costs of the alternative sales channel, despite its recognition that "[i]n general terms, the extra margin at vending machines reflects the costs to vending machine owners of operating these machines, in addition to a return on their labor effort and capital investments." In other words, the reason that cigarettes purchased from a vending machine are more expensive is that it costs more to sell a pack of cigarettes by vending machine. Consequently, if cigarette sales shift from more expensive-to-operate vending machines to OTC, the loss of industry profits is much smaller than the loss of industry revenues.

An approximate assessment of the net impact on retail profits requires a comparison of the pretax profit margins for vending machine operations as compared to OTC sales. The Barents Group cited survey results from the National Automatic Merchandising Association (NAMA) showing an average pretax profit margin of 3.8 percent in 1993 and 2.0 percent in 1992, for an average 2.9 percent for vending machine operations. Because cigarette vending machine sales have decreased in recent years, current profit margins might be even smaller. Coincidentally,

the Barents Group reports that the estimated average industry profit margin for convenience stores is also 2.9 percent. If this rate applies to cigarette sales at convenience stores and if all lost vending machine cigarette sales were transferred to convenience stores, the net pretax cost to the industry would be \$3.5 million, not \$122 million (\$403 million to \$281 million) x 2.9 percent). Moreover, NAMA reports that over 50 percent of all vending machines are located in bars and taverns and many others in business establishments frequented only by adults. The final rule permits vending machines in those places where the owner can ensure that no young people under age 18 are present at any time. FDA does not know how many vending machines will be moved to restricted areas in compliance with this rule, but the number will further reduce this annual cost.

## 10. Readership Surveys

The Barents Group reported that 101 leading national magazines had advertisements for tobacco products in 1994. In addition, Barents obtained youth and adult readership data for 1994 from MediaMark Research, Inc. (MediaMark), for 41 of these 101 magazines. Applying the regulatory threshold of 2 million readers or 15 percent of total readership below the age of 18, Barents projected that advertisements in 32 of the 41 magazines (78 percent) would be restricted to "text only" by the proposed regulation. In comparison, FDA examined copyrighted youth and adult readership data from the Simmons Marketing Bureau, Inc. (Simmons), another major marketing research firm, and found that only 13 of the 27 magazines with tobacco ads (48 percent) had youth readership over the threshold. A comparison of youth readership levels from MediaMark and Simmons for magazines that had tobacco advertisements in 1992 is shown in Table 11.<sup>336</sup>

advertising share data from Barents and advertising revenues from *Advertising Age*. Advertising revenue was unavailable for five small publications that accounted for less than one percent of tobacco magazine advertising spending in 1994. To estimate tobacco advertising expenditures in these five publications, FDA assumed total advertising revenues for each publication equal to \$14,388, which is the lowest total revenue reported in *Advertising Age* for 1994.

<sup>335</sup> Data from the 1995 *Statistical Abstract of the United States*, Table 677 lists weekly earnings for full time wage and salary workers for the group "16 to 24 year-olds" in 1994. Table 682 lists median hourly earnings for workers paid hourly rates for the same group in 1994. Assuming a 40 percent increase for benefits, the compensation rates for these two tables for 16 to 24 year-olds are \$9.98/hour and \$7.87/hour, respectively.

Using these figures will result in a low estimate for the 18 to 26 year-old group because 25 and 26 year-olds earn more than 16 and 17 year-olds.

Conversely, using a benefits/wage ratio of 40 percent for 18 to 26 year-olds will overstate the costs because lower paid workers (hourly and part-time workers, college students) are more likely to have less generous benefits packages (little or none of the following: paid vacation, sick leave, employer-paid health insurance). FDA increased the estimated compensation rates to \$9 to \$11/hour to assure it does not underestimate the true compensation rate.

<sup>336</sup> Tobacco industry spending on magazine advertising was calculated using tobacco

TABLE 11.—AVAILABLE YOUTH READERSHIP DATA FOR PUBLICATIONS  
WITH TOBACCO ADVERTISEMENTS IN 1994

Publications with Youth and Adult Readership Data	Estimated Percentage of 1994 Tobacco Industry Spending on Magazine Advertisements	MediaMark Research Inc. (1994 readership data)		Simmons Market Research Bureau, Inc. (1994 readership data)	
		Number of Readers Under 18 (000)	Percent of Readers Under 18 (%)	Number of Readers Under 18 (000)	Percent of Readers Under 18 (%)
Sports Illustrated <sup>1,2</sup>	10.0	5,201	18.0	4,614	17.1
People <sup>1,2</sup>	9.8	3,020	7.8	2,465	8.0
TV Guide <sup>1,2</sup>	6.5	6,739	13.2	7,102	15.6
Time	4.1	1,972	7.7	n/a	n/a
Parade <sup>2</sup>	3.7	n/a	n/a	6,059	6.9
Cosmopolitan <sup>1</sup>	3.1	2,279	12.8	1,410	11.4
Woman's Day	3.0	1,202	4.8	n/a	n/a
Entertainment Weekly <sup>2</sup>	2.9	n/a	n/a	674	15.3
Better Homes & Gardens <sup>1</sup>	2.4	2,042	5.5	785	3.4
Newsweek	2.4	1,911	8.0	n/a	n/a
Family Circle	2.1	1,210	4.2	646	3.5
Field & Stream	2.1	1,760	11.1	815	7.9
Glamour <sup>1,2</sup>	2.0	2,216	17.1	1,540	17.4
Rolling Stone <sup>1,2</sup>	2.0	1,869	18.5	1,506	20.1
Ladies' Home Journal	1.7	838	4.4	n/a	n/a
McCall's	1.7	1,274	6.7	506	3.7
Redbook	1.7	1,153	7.8	565	5.4
Car & Driver <sup>1</sup>	1.6	1,465	18.3	n/a	n/a
Life <sup>1</sup>	1.6	2,665	12.9	n/a	n/a
Popular Mechanics	1.5	1,617	14.5	744	10.3
Outdoor Life <sup>1</sup>	1.3	1,579	18.0	569	8.8
Us	1.2	814	13.8	n/a	n/a
New Woman	1.1	685	14.0	n/a	n/a
Road & Track <sup>1</sup>	1.1	1,234	20.6	n/a	n/a
Soap Opera Digest	1.1	1,299	14.4	853	12.6
Mademoiselle <sup>1,2</sup>	1.0	1,369	19.7	959	18.5
Vogue <sup>1,2</sup>	1.0	2,237	18.0	1,300	17.4
Hot Rod <sup>1</sup>	0.8	2,295	28.0	n/a	n/a
Ebony <sup>1</sup>	0.7	2,111	15.8	1,046	9.4
Gentlemen's Quarterly <sup>1</sup>	0.7	1,037	15.1	n/a	n/a
Motor Trend <sup>1</sup>	0.7	1,393	22.1	n/a	n/a
Premiere <sup>1</sup>	0.7	617	25.8	n/a	n/a
Sport <sup>1,2</sup>	0.7	2,274	33.8	1,132	24.0
Elle <sup>1</sup>	0.6	819	17.8	409	14.4
Essence <sup>1</sup>	0.6	1,251	16.9	537	9.4
Sports Afield	0.6	n/a	n/a	0	0.0
True Story	0.5	740	14.8	n/a	n/a
Jet <sup>1</sup>	0.4	1,724	16.7	1,169	12.2
Popular Science <sup>1,2</sup>	0.4	1,906	20.8	874	16.1
Self <sup>1</sup>	0.4	786	16.2	n/a	n/a
Harper's Bazaar <sup>1</sup>	0.3	718	18.2	n/a	n/a
The Sporting News <sup>1,2</sup>	0.3	1,394	27.8	666	15.7
Cable Guide <sup>1</sup>	0.2	3,358	22.6	n/a	n/a
SKI <sup>1,2</sup>	0.0	827	26.4	584	24.9

<sup>1</sup>MediaMark youth readership exceeds regulatory threshold.<sup>2</sup>Simmons youth readership exceeds regulatory threshold.Source: Barents Group LLC Tables IV-1 and A-2; Simmons Market Research Bureau, Inc.; R. Craig Endicott, "The Ad Age 300," *Advertising Age*, June 19, 1995.

The final regulation requires that specific youth and adult readership data be available for any magazine that displays a tobacco advertisement with color or imagery. Simmons currently conducts interviews with adults in approximately 20,000 households annually and subsequently returns to about 3,000 of these households to interview their youth members. In general, however, marketing research

firms collect data on youth readership only for those magazines commonly read by this age group. Thus, although 78 percent and 48 percent of the magazines in the two youth readership samples described above exceeded the regulatory readership threshold, these sample results likely overestimate the percentage of magazines with current tobacco ads that exceed the threshold.

Simmons now collects adult readership data for about 230 magazines and youth readership for about 65 magazines. Because tobacco manufacturers currently advertise in about 100 magazines, the industry could often add magazines that are currently part of an ongoing adult readership survey to a youth survey, saving approximately 60 percent of the cost of collecting both adult and youth data.

Because FDA does not know how tobacco manufacturers will adapt their marketing strategies to the new regulatory thresholds, it is difficult to predict the number of new readership surveys that may be initiated. It seems likely, however, that tobacco companies will both increase the frequency of advertising in "adult" magazines that already carry tobacco advertisements and find suitable "adult" magazines to replace many of the other magazines.

One plausible scenario is that approximately one-half, or 50, of the magazines with current tobacco ads would not qualify as "adult" publications, because they exceed the youth readership threshold; and that the tobacco industry would choose to advertise in 50 other "adult" publications that do not currently carry tobacco ads. To identify these 50 additional "adult" magazines, the industry might need to collect new youth readership data for up to 100 magazines. In addition, as noted above, of the original 100 magazines with current tobacco advertising, youth readership data is now available for at least 40. Thus, the tobacco industry may initially need to obtain new youth readership data for the remaining 60 magazines. In total, therefore, the tobacco industry might opt to obtain youth readership data for an additional 160 publications in the first year that the rule becomes effective. In subsequent years, this number might fall to about 100 surveys, as the industry would concentrate its survey efforts on publications very likely to qualify.

If a marketing research firm collects youth readership data, the cost may depend on the particular characteristics of the magazines being surveyed. The tobacco industry could choose, however, to hire a survey firm to develop and administer a questionnaire solely to gather readership data for magazines with tobacco advertising. While FDA is uncertain about which approach the industry would take, the agency estimates that such new surveys might cost approximately \$2 million in one-time costs and \$1 million in annual costs, based on an average cost of about \$650 and \$350 per sample household.

#### 11. Records and Reports

Manufacturers will need to comply with device regulations governing submissions of representative labels and advertising, medical device reporting (MDR's), establishment registration and product listing, and current good manufacturing practices (CGMP's).

a. *Labels and advertising.* The rule requires that each manufacturer annually submit to FDA copies of representative samples of labels and advertising. While the agency expects about 1,000 product labels, FDA has no direct evidence on the number of advertisements that will be submitted. An approximate estimate, however, can be derived from the number of advertising samples submitted by the pharmaceutical industry. First, FDA calculated that of the \$6.1 billion in advertising and promotional outlays reported to the FTC by the tobacco industry, only about \$1.2 billion is spent on printed advertisements. (Derived by subtracting categories for "Coupons/Value Added," "Promotional Allowances," "Specialties Items," and "Free Samples" from the total \$6.1 billion).

The pharmaceutical industry spends an estimated 22.5 percent of sales on marketing, of which about one-quarter may be allocated to advertising ethical pharmaceuticals.<sup>337</sup> The approximately \$50 million in annual sales of pharmaceutical manufacturers, therefore, implies a \$2.5 billion annual advertising budget. FDA estimates that it currently receives about 25,000 pieces of pharmaceutical advertising per year. As the pharmaceutical budget is roughly twice the size of the \$1.2 billion tobacco industry figure derived above, the agency might receive half as many documents. Alternatively, reduced promotional activities may prompt an increase in the number of printed advertisements prepared by tobacco companies, although the Barents Group assumed this number would decline. Therefore, FDA projects that it will receive the same number of advertisements for tobacco products as it currently receives for pharmaceutical products, or about 25,000 per year, plus about 1,000 labels.

Estimates of the time burden of these paperwork submissions ranged from 20 minutes (The Barents Group) to 1 hour and estimates of the hourly cost ranged from \$25.00 (Tobacco Institute) to \$45.26 (the Barents Group). Using the high end of both ranges provides an upper bound cost estimate of \$1.2 million. This figure is significantly lower than either the original FDA estimate, or the Barents Group estimate of \$55 to \$57 million, largely because the final rule imposes no specific

paperwork requirements on retail establishments.

b. *MDR's.* The final rule will require MDR's for serious unexpected incidents. FDA assumes that 31 manufacturing companies<sup>338</sup> and 1,365 distributors<sup>339</sup> will bear total one-time costs of \$21,000 and \$231,000, respectively, for establishing and documenting procedures for MDR reporting. These costs include 32 hours of effort per manufacturing firm and 8 hours per distributor. Based on estimates previously developed for the Medical Device User Facility and Manufacturer Reporting Final Rule, these activities were distributed over wage rates averaging \$21.17. Annual costs for MDR reporting requirements are more difficult to predict, because they depend on the number of adverse event reports that will be submitted. FDA projects, however, that followup investigation and reporting of a single event takes about 8 hours of labor and costs about \$218. Thus, if 50 adverse event reports were filed annually, the annual cost would be about \$11,000. In addition, if each manufacturing company submits a single baseline report and annual updates, these costs would be about \$2,100 annually, based on unit costs of \$54 and \$14 per report, respectively. Annual certification is necessary, but is typically a formality in terms of data collection and reporting and is estimated to cost about \$800 for all manufacturers and \$35,000 for all distributors assuming 1 hour of professional and clerical time at \$25.80 per hour.

c. *Registration and listing.* Registration and listing duties are estimated to take 41 manufacturing establishments 2 hours each to prepare at a unit cost of \$42, totaling about \$1,700 per year for the industry.

d. *CGMP's.* The Tobacco Institute asserted that cigarette manufacturers would need substantial time to comply with CGMP's as the industry "would need to adopt major new systems \* \* \* [and] make major changes to their procedures just to accommodate the recordkeeping required." Conversely, the economics study prepared by the Barents Group for the Tobacco Institute showed no additional costs for this requirement. FDA agrees that these costs

<sup>338</sup> 1992 U.S. Census of Manufactures, Industry Series, Tobacco Products, Table 1a. A few U.S. agents designated to represent foreign manufacturers would also need to file forms, but these costs should be minimal.

<sup>339</sup> Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States (unpublished data).

<sup>337</sup> U.S. Congress, Office of Technology Assessment, "Pharmaceutical R&D: Costs, Risks and Rewards," OTA-H-522 Washington, DC: U.S. Government Printing Office, pp. 303–304, February 1993.

should be minimal for facilities with good quality assurance programs. Its CGMP's do not specify a specific format, but encompass a wide variety of broad requirements for documenting operating procedures. Contrary to the Tobacco Institute's claim that "even a well-run cigarette manufacturing facility would need to adopt major new systems," CGMP's are, in fact, based on the activities of well-run operations. Moreover, device CGMP's are currently under revision to bring them even closer to ISO 9001, the generally recognized international standard for quality assurance systems. Thus, while FDA has little experience with day-to-day tobacco manufacturing procedures, the agency does not anticipate the need for substantial quality system redesign. Wholesalers and distributors also submitted comments contending that the CGMP's would create added paperwork burdens, but the agency has exempted these sectors from the CGMP requirements.

## 12. Government Enforcement

FDA estimates of internal costs for administering and enforcing this regulation are extremely uncertain, as they will depend on the working relationships to be established with State tobacco control programs. As a best estimate, however, FDA projects that between 30 to 50 full-time employees (FTE's) will be needed to implement the rule. Fully loaded employee costs vary with the type of employee (e.g., field inspectors versus administrative), but an average of \$100,000 per FTE places the dollar cost at between \$3 and \$5 million per year. SAMHSA has estimated that State

programs will need between \$25 and \$50 million annually to administer and enforce appropriate State operations.

## 13. Comparison of Benefits to Costs

FDA expects the net societal benefits of the rule to far exceed the regulatory costs. Based on the analysis presented above, the estimated one-time costs of the combined FDA and SAMHSA rules are \$174 to \$187 million and the estimated annual costs are \$149 to \$185 million. Taking the midpoint of the ranges and annualizing the one-time costs at 3 and 7 percent, respectively, yields total annualized costs of \$172 million and \$180 million. In contrast, the agency's best estimate of the monetized regulatory benefits that would follow a 50 percent reduction in underage tobacco use ranges from \$28.1 to \$43.2 billion at a 3 percent discount rate and from \$9.2 to \$10.4 billion at a 7 percent discount rate. Thus, as shown in Table 12, the *net* benefits (benefits minus costs) of a total effectiveness rate of 25 percent range from \$27.9 to \$43 billion at a 3 percent discount rate and from \$9.0 to \$10.2 billion at a 7 percent rate. Table 13 indicates that those figures imply a cost per life-year saved of from \$800 to \$4,700 and a cost per death avoided of from \$11,000 to \$52,000. As noted earlier, these benefits are exclusive of the substantial health improvements expected to result from the reduced consumption of smokeless tobacco.

The substantial differential between these estimated costs and benefits withstands rigorous sensitivity analysis (see Table 12). For example, SAMHSA estimated that its rule would reduce underage tobacco use by from one-third

to one-tenth. The approximate midpoint of that estimate (20 percent) constitutes about 40 percent of the regulatory benefit of reducing underage tobacco use by one-half. If, for illustrative purposes, these results, as well as a proportional fraction of the relevant costs,<sup>340</sup> are attributed to SAMHSA, the *incremental* net benefits of the FDA rule still range from \$16.8 to \$25.8 billion at a 3 percent discount rate, and from \$5.4 to \$6.2 billion at a 7 percent discount rate.

Moreover, FDA assumed that reaching the "Healthy People 2000" goal would deter about one-quarter of the 1 million youth under age 18 who currently begin to smoke each year from ever smoking as an adult. Thus, this goal implies a 25 percent overall effectiveness rate. If, however, these rules prevent smoking as an adult for even 5 percent of the teenagers who would otherwise become adult smokers, they would produce estimated annual net benefits of from \$5.4 billion to \$8.5 billion at a 3 percent discount rate and from \$1.7 billion to \$1.9 billion at a 7 percent discount rate. Even if this latter scenario attributed 40 percent of the benefits and relevant costs to SAMHSA, the annual *net* benefits of the FDA rule would still range from \$3.3 billion to \$5.1 billion at a 3 percent discount rate and from \$1.0 billion to \$1.2 billion at a 7-percent discount rate. This last example implies a cost per life-year saved of \$3,500 to \$21,100 and a cost per death avoided of \$47,000 to \$234,246. These figures are well within the range of values for health interventions typically considered cost-effective.

TABLE 12.—NET BENEFITS

(\$ Billions)

Discount Rate	Effectiveness Rates									
	25%		15%		10%		5%		2.5%	
	Low	High	Low	High	Low	High	Low	High	Low	High
3%	27.9	43.0	16.7	25.7	11.1	17.1	5.4	8.5	2.6	4.1
7%	9.0	10.2	5.3	6.1	3.5	4.0	1.7	1.9	0.74	0.86
Illustrative Incremental Net Benefits <sup>1</sup>										
3%	16.8	25.8	10.0	15.5	6.7	10.3	3.3	5.1	1.6	2.5
7%	5.4	6.2	3.2	3.7	2.1	2.4	1.0	1.2	0.45	0.53

<sup>1</sup> Attributes 40% of benefits and associated costs to SAMHSA

<sup>340</sup> Costs include 100 percent of SAMHSA's state enforcement costs, plus 40 percent of retail training

costs, vending machine costs, and retail and consumer I.D. check costs.

TABLE 13.—COST EFFECTIVENESS

Discount Rate	Effectiveness Rates									
	25%		15%		10%		5%		2.5%	
	Cost/Life-Year Saved (\$)	Cost/Death Avoided (\$)	Cost/Life-Year Saved (\$)	Cost/Death Avoided (\$)	Cost/Life-Year Saved (\$)	Cost/Death Avoided (\$)	Cost/Life-Year Saved (\$)	Cost/Death Avoided (\$)	Cost/Life-Year Saved (\$)	Cost/Death Avoided (\$)
3%	815	10,862	1,358	18,103	2,038	27,155	4,075	54,310	8,151	108,621
7%	4,722	52,423	7,870	87,372	11,804	131,059	23,609	262,117	47,218	524,235
Illustrative Incremental Cost-effectiveness <sup>1</sup>										
3%	706	9,413	1,177	15,689	1,766	23,533	3,532	47,067	7,064	94,134
7%	4,220	46,849	7,033	78,082	10,549	117,123	21,098	234,246	42,197	468,492

<sup>1</sup> Attributes 40% of benefits and associated costs to SAMHSA

#### E. Distributional Effects

These regulations will impose a variety of sector-specific distributional effects. Those sectors affiliated with tobacco and tobacco products will lose sales revenues and these losses will grow over time. Businesses engaged in the provision of tobacco product advertising may also face reduced revenues. Simultaneously, nontobacco-related industries will gain sales, because dollars not spent for tobacco products will be spent on other commodities.

##### 1. Tobacco Manufacturers and Distributors

For its calculation of regulatory benefits, FDA estimates that implementation of the regulations may reduce the cigarette consumption of underage smokers by one-half within 7 years. As discussed earlier in this section, based on data presented in Cummings, et al., FDA finds that teenage smokers under the age of 18 consumed about 316 million packs of cigarettes in 1994. A 50-percent cut in sales would drop the number of packs sold by 158 million. Moreover, FDA has assumed that at least one-half of those 500,000 teenagers who would be deterred from starting to smoke each year would refrain from smoking as adults, decreasing the number of adult smokers by 250,000 per year. Because each adult smoker consumes about 500 packs per year, about 124 million fewer packs would be sold per year.

Thus, achieving the agency's goal would reduce cigarette consumption by 158 million packs in the first year (while only teenagers are affected), 158 million plus 124 million packs in the second year, 158 million plus 2 times 124 million packs in the third year, and so on. Since 1994 cigarette shipments

totaled 36.3 billion packs,<sup>341</sup> cigarette consumption would fall by about 0.4 percent in the first year, 1.8 percent in the fifth year, and 3.5 percent in the tenth year following implementation. (In fact, these reductions may take even longer, because it may be several years before the 50-percent effectiveness level is achieved, and because young adults smoke fewer packs than older adults).

Hence, annual tobacco revenues will decline slowly over time. The U.S. Bureau of the Census estimates 1994 revenues for cigarette and smokeless tobacco manufacturers at about \$25.9 billion.<sup>342</sup> Assuming comparable reductions in smokeless tobacco, these calculations imply that tobacco manufacturer revenues will fall by \$128 million in the first year (0.5 percent), \$501 million in the fifth year (1.9 percent), and \$966 million in the tenth year (3.7 percent). While these reductions are significant, the gradual phasing of the impacts will significantly dissipate any associated economic disruption.

In a 1992 report prepared for the Tobacco Institute, Price Waterhouse estimated that the tobacco manufacturing, warehousing and wholesale trade sectors employed about 107,000 full-time workers.<sup>343</sup> Thus, a constant production-to-employment ratio projects that a 3.7-percent reduction in sales over a 10-year period

would result in the displacement of about 4,000 jobs, or 400 jobs annually among manufacturers, warehousemen, and wholesalers. Alternatively, a University of Virginia study concluded that "the Price Waterhouse study for the Tobacco Institute provides estimates of tobacco's impact that are high compared to other measures."<sup>344</sup> That study referenced a recent U.S. Department of Agriculture analysis by Gale that found that manufacturing and wholesale trade activities employ only 83,000 full-time equivalent workers.<sup>345</sup> If true, this finding reduces these job loss estimates to about 3,000 jobs, or 300 annually.

The smaller job loss estimate is generally confirmed by a recent study by Warner, et al., who applied a computer simulation model to forecast the regional impact of reductions in tobacco use.<sup>346</sup> The authors used "a state-of-the-art macroeconomic model to simulate what would happen if consumers reduced their tobacco expenditures, with the same level of spending redistributed to other goods and services \* \* \*." One scenario assumed that tobacco control activities would reduce the expected rate of tobacco purchases by 2.06 percent per year, or roughly 5 times the estimated effect of the FDA rule. While this scenario does not present direct impacts to the tobacco industry alone, it forecasts job losses after 8 years of 6,401 for all U.S. wholesalers and 5,957 for Southeast Tobacco Region

<sup>341</sup> "Tobacco Situation and Outlook Report," U.S.D.A., Economic Research Service, p. 4, April 1995.

<sup>342</sup> "1994 Annual Survey of Manufactures: Value of Product Shipments," U.S. Department of Commerce, Bureau of the Census, Table 1, p. 210. ASM does not report data below the 5-digit SIC Code Level. FDA assumed chewing tobacco represented the same percentage of SIC Code 2131 (Chewing and Smoking Tobacco) in 1994 as it did in 1992 when it was classified at a 6-digit SIC code in the Census of Manufacturers.

<sup>343</sup> "The Economic Impact of the Tobacco Industry on the United States in 1990," Price Waterhouse, p. ES-3, October 1992.

<sup>344</sup> Knapp, J. L., "Tobacco in Virginia," Weldon Cooper Center for Public Service, University of Virginia, p. 5, December 1995.

<sup>345</sup> Gale, F., "What Tobacco Farming Means to Local Economies," U.S. Department of Agriculture, Economic Research Service, Agriculture Economic Report Number 694, p. 5, September 1994.

<sup>346</sup> Warner, K. E., G. A. Fulton, P. Nicolas, and D. R. Grimes, "Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States," JAMA, pp. 1241-1246, April 24, 1996.



manufacturers. Accounting for the multiple of 5, comparable job losses attributable to the FDA rule would total about 2,600 after 8 years, or about 325 annually.

The Barents Group did not address the long-term gradual decline in tobacco use projected by FDA. Nevertheless, it claimed that the agency underestimated the economic impact on industry by failing to account for the lost sales to adults that would result from the proposed ban on vending machines and self-service displays and the required checking of customer I.D.'s. The Barents Group argued that the added consumer inconvenience imposed by these provisions was tantamount to an increase in the effective price of tobacco products, which would rapidly decrease the consumption of tobacco by adults. Relying on "hypothetical scenarios" that assume demand declines of 5 and 10 percent, the Barents Group forecast that the tobacco manufacturing industry would lose from 1,800 to 3,700 jobs due to this increased consumer inconvenience.

FDA believes these Barents projections are substantially overstated. Impacts associated with cigarette consumption declines of 5 to 10 percent cannot possibly be attributed to the loss of vending machines, because vending machine purchases make up less than 1 percent of all cigarette purchases. Further, according to NAMA, there are only 141,000 cigarette vending machines currently in use (and that number is falling rapidly), and the cost analysis prepared by the Barents Group predicted that 100,000 of these machines would be replaced by new OTC establishments. Thus, the Barents Group's own analysis eliminates any added consumer inconvenience from three-quarters of the existing inventory of machines. Moreover, the near-term impact on adult tobacco consumption will be further moderated both because the final rule allows vending machines in "adult" facilities, and because the added inconvenience cost will be partially offset by the lower price of the OTC product. These factors together make it extremely unlikely that fewer vending machines will lead to a substantial near-term fall in tobacco industry sales revenues.

The likelihood that tobacco sales will decline significantly due to inconvenience imposed on adult customers by the self-service restriction is similarly remote. While some purchasers would need more time to complete a transaction, other purchasers would save time by no longer having to

search and retrieve a desired product. In the absence of empirical evidence, the result is indeterminate; but FDA has seen no convincing evidence or arguments to demonstrate that any delays caused by the self-service restriction will significantly curtail adult tobacco use.

Finally, although FDA calculated above that increased delays due to I.D. checking could cost young adult consumers under the age of 26 up to \$50 million per year, even this cost would not lead to significant consumption declines. As described, the increased checkout waiting time for young purchasers was estimated to average about 8.3 seconds, which translates to a cost of about 2.3 cents per transaction, or 1.35 percent of the cost of a pack of cigarettes. According to the Barents Group, representative estimates of demand elasticities for cigarettes range from -0.6 to -1.0. Young adults under the age of 26, however, purchase only about 10 percent of all tobacco products. Thus, the fall in total tobacco sales would be, at most, 0.1 percent, not the 5 to 10 percent assumed by the Barents Group. Moreover, even the 0.1 percent figure is an overestimate, because those consumers irritated by the delay will increase the volume of tobacco products purchased per transaction. As a result, the number of cartons sold will rise, but the decline in tobacco product sales revenues attributable to the inconvenience effects of I.D. checks will be negligible.

## 2. Tobacco Growers

As explained above, total cigarette and chewing tobacco consumption is expected to decrease by 0.5 percent in the first year, 1.9 percent by the fifth year, and 3.7 percent by the tenth year, following compliance with the regulation. Price Waterhouse estimated that, on a full-time equivalent basis, about 153,000 farmers grew tobacco in 1990. Based on these figures, constant production-to-employment ratios imply employment losses among tobacco growers of about 5,700 after 10 years, or about 570 annually. Alternatively, the Gale study for the U.S. Department of Agriculture (USDA) <sup>347</sup> estimated the number of full-time equivalent tobacco farmers to be only 65,400, which would reduce the job loss estimate to about 2,500 by the tenth year, or 250 annually.

This latter figure also closely fits the findings of Warner, et al., who, as

<sup>347</sup> Gale, F., "What Tobacco Farming Means to Local Economies," USDA, Economic Research Service, Agriculture Economic Report Number 64, p. 5, September 1994.

described above, used a "state-of-the-art" macroeconomic simulation model to project the employment effects of declining tobacco consumption. <sup>348</sup> Assuming domestic tobacco consumption decreases of 2.06 percent per year, Warner, et al. predicted about 7,500 job losses within an 8-year period for "Southeast Tobacco Region" farmers. As this fall in tobacco use is roughly five times that projected by FDA, the analogous job loss estimate would be about 1,500 over the 8-year period, or about 190 per year.

According to the USDA study by Gale, "[f]or most farms, tobacco growing is a part-time, seasonal enterprise, and production per farm is usually small. About two-thirds of tobacco farmers work off-farm." <sup>349</sup> Citing 1987 Census of Agriculture data, Gale notes that only 65 percent of the farms growing tobacco in the United States reported earning more than half of their receipts from tobacco, and of those farms, approximately 80 percent had total farm sales under \$20,000. He explains that the availability of alternative land uses will dictate the economic results:

The key factor in adjustment to a smaller tobacco industry is the alternative uses available for land, labor, and capital used in tobacco production \* \* \* For the most part, concern is focused on rural areas where tobacco is grown because this stage of production has the most specialized resources with fewer attractive alternative uses. In many areas, small farms that are unviable without tobacco profits would cease production and their land would be absorbed into larger neighboring farms or converted to other uses \* \* \* In marginal farming areas \* \* \* much of the land devoted to tobacco would be converted to residential, commercial, industrial, or forestry uses, in which case it would still generate income for the local economy \* \* \* This land is already being converted to nonfarm uses in rapidly growing areas like southern Maryland and Raleigh-Durham, North Carolina. <sup>350</sup> FDA notes that the economic consequences of these trends will be substantially mitigated by the very moderate pace of the projected changes.

## 3. Vending Machine Operators

The final regulation prohibits all vending machine sales of regulated tobacco products except for those machines located in a facility where

<sup>348</sup> Warner, K. E., G. A. Fulton, and D. R. Grimes, "Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States," JAMA, pp. 1241-1246, April 24, 1996.

<sup>349</sup> Gale, F., "What Tobacco Farming Means to Local Economies," USDA, Economic Research Service, Agriculture Economic Report Number 64, p. 1, September 1994.

<sup>350</sup> *Id.*, p. iii.

persons under the age of 18 are not present at any time. In recent years, cigarette vending sales have dropped precipitously, due to numerous restrictive State and local ordinances. According to the NAMA:

[t]he 1986 cigarette location survey mirrored an industry with about 700,000 cigarette vending machines on location. In 1994, the vending industry was estimated to have between 141,000 and 400,000 cigarette machines. This represents a decline in the number of cigarette vending machines on location of between 43 percent and 80 percent.

The U.S. Department of Commerce<sup>351</sup> reports that 1992 sales of tobacco products by automatic merchandising machine operators were about \$452 million, or 7.1 percent of that sector's total sales, but a NAMA fact sheet shows this rate continuing to fall, dropping from 8.5 percent in 1990 to 2.7 percent in 1994. One trade magazine explains that, "[c]igarette vending, once an industry mainstay, is now a niche

business increasingly conducted by specialized enterprises."<sup>352</sup>

Referring to 1992 Census data, NAMA declared that over 3,000 vending machine operators supply cigarettes, not including the bars, restaurants, hotels, and bowling alleys that own their own machines. On average, these mostly small firms receive 10 percent of their revenues from cigarette sales, although some firms are even more dependent. While some vending machines can be converted to sell other products, one large cigarette machine manufacturer maintained that more than 85 percent of the existing machines can be converted only for new products with packaging similar in dimension and form to cigarette packages.

While vending operators will need to develop new markets to replace the already dwindling sales revenues from cigarette vending machines, the overall economic impact will be mitigated somewhat by FDA's decision to exempt "adult only" locations from the ban. According to a 1995 NAMA survey, 58

percent of cigarette vending machines are located in bars and cocktail lounges, 11 percent in factory/plant locations, and 3 percent in business offices.<sup>353</sup> Those locations that do not permit the entry of youngsters under the age of 18 will be exempted from the cigarette vending machine restriction.

#### 4. Advertising Sector

In annual reports to FTC, manufacturers of cigarettes and smokeless tobacco reported 1993 advertising and promotional/marketing expenditures of \$6.0 billion and \$119 million, respectively (see Table 14). About \$2.6 billion (43 percent) of these outlays went to consumers as financial incentives to induce further sales (e.g., coupons, cents-off, buy-one-get one free, free samples), and \$1.6 billion (26 percent) to retailers to enhance the sale of their product. The remaining \$1.9 billion (31 percent) were related to consumer advertising activities that will be significantly modified by the "text only" restrictions.

TABLE 14.—TOBACCO ADVERTISING/PROMOTIONAL EXPENDITURES  
1993 (Millions of Dollars)<sup>1</sup>

Promotion Type	Cigarettes	Smokeless	Total
Coupons/Value Added	2,559	32	2,591
Promotional Allowances	1,558	13	1,571
Point of Sale	401	13	414
Specialties Items	756	4	760
Outdoor	231	1	232
Magazines	235	7	242
Public Entertainment	84	23	107
Free Samples	40	16	56
Transit	39	0	39
Newspapers	36	1	37
Direct Mail	31	1	32
Endorsements	0	0	0
All Others	64	7	71
<b>Total</b>	<b>6,035</b>	<b>119</b>	<b>6,154</b>

<sup>1</sup> Totals may not add due to rounding.  
Source: U.S. Federal Trade Commission

FDA cannot project the ultimate industry response to these advertising restrictions. On the one hand, the effectiveness of many advertisements will fall. On the other hand, many alternative marketing promotional activities will be prohibited or constrained even more stringently, raising the relative desirability of the remaining advertising options. Moreover, as described above, FDA may

require new informational programs that would generate a substantial increase in advertising industry revenues. Nevertheless, if tobacco outlays fall, there will be short-term dislocations as industry resources are redirected to other uses. One firm that depends heavily on tobacco advertising warned of severe economic burdens, pointing to income and job losses for many of its employees and suppliers. Most

advertising suppliers, however, are not overly specialized with respect to particular consumer products and would redirect resources to other advertising purchasers, albeit at some revenue loss. While FDA is aware that such demand shifts cause short-term disruption, the U.S. economy creates and discards thousands of products each day. For most advertising media, the ability to respond rapidly to

<sup>351</sup> U.S. Department of Commerce, "Merchandise Line Sales," 1992 Census of Retail Trade, RC92-S-3RV, pp. 3-27, 3-31.

<sup>352</sup> *Vending Times*, Census of the Industry Issue, p. 36-D, 1995.

<sup>353</sup> National Automatic Merchandising Association, Cigarette Vending Machine Location Study, conducted August 31, 1995.

changing markets is a mainstay of economic survival.

a. *Print media.* The final regulation requires that advertising of cigarettes or smokeless tobacco be restricted to black text on a white background in those publications where youthful readers constitute more than 15 percent of total readership or number more than 2 million. FDA cannot reasonably forecast the future marketing strategies of tobacco manufacturers, but foresees a possible fall in the \$242 million worth of magazine advertising and the \$37 million worth of newspaper advertising that tobacco manufacturers reported to the FTC in 1993. These advertising revenues comprised about 1.1 percent and 0.1 percent of the 1992 value of shipments for periodicals and newspapers, respectively.<sup>354</sup> The Barents Group identified 32 leading magazines with tobacco advertising in 1994 that have youth readership levels exceeding the regulatory threshold and found that these publications received, on average, 7.3 percent of their total advertising revenues from tobacco in 1994. They also predicted, based on the sharp downward trend of these advertising outlays, a 21-percent drop in magazine advertising and a 45-percent drop in newspaper advertising for tobacco products by 1996, irrespective of the FDA regulation.

The impact of these restrictions on the various advertising media and agencies is difficult to determine. The Barents Group contended that FDA had argued in its original analysis that "regulations for print media will have little or no adverse impact." In fact, FDA made no such projection, although the agency did present several historical examples of advertising bans (e.g., the broadcast ban on tobacco products) where advertising revenues rebounded in spite of new legal restrictions. The Barents Group also faulted FDA for not comparing actual revenues after the broadcast ban to revenues "that *would have been expected* in the absence of the ban." FDA, however, does not believe that this "counterfactual" logic for estimating costs precludes the agency from suggesting that income and employment would not necessarily fall in the wake of new advertising restrictions.

Several comments declared that advertising outlays would fall sharply and subscription prices rise. According to the Barents Group, imagery is a prerequisite for effective promotion and,

in its absence, magazine and newspaper advertising revenues would fall by 25 to 75 percent. It also predicted that the reduced revenues would, in turn, force publication subscription prices to rise.

FDA agrees that there will be adverse impacts on certain publications, but notes that the tobacco industry is currently shifting its advertising budget away from print media and that only 6 of the 32 affected magazines identified by the Barents Group received over 10 percent of their revenues from tobacco products. Moreover, as noted earlier, while FDA cannot project the tobacco industry's marketing strategies, the agency suggests that restricted promotion alternatives could reestablish print advertising as a relatively attractive option for conveying product information to adult readers; thereby slowing or even reversing the recent slide in this type of tobacco advertising.

The Barents Group also asserted that the commercial printing industry, as well as other industry sectors, would be harmed by restrictions on coupons and "retail value added" promotions. These expenditures, which account for \$2.6 billion, or 42 percent of the total tobacco advertising and promotional outlays reported to FTC in 1993, include outlays associated with cents-off coupons and multiple pack promotions, such as "buy one, get one free" or "buy two, get one free;" as well as other give-away promotions, such as "buy cigarettes and get a free promotional item." The former activity will be permitted but the latter prohibited under the final regulation. Although a comment submitted by the Tobacco Institute noted that, "[a]nalytically, such spending is more akin to a price cut than to advertising,"<sup>355</sup> the Barents Group, nonetheless, concluded that, "[a] considerable part of this spending would likely be eliminated by the proposed regulations." FDA, however, does not agree that the printing industry will be significantly affected by changes in "coupons and value added" outlays. Cents-off coupons and multiple pack promotions are the principal components of these promotions and will continue to be available under the final rule.

b. *Advertising agencies and other suppliers.* Advertising agency revenues are directly tied to the level of advertising expenditures by product manufacturers. If tobacco manufacturers reduce advertising outlays, these agencies will lose income. The Barents

Group found that, in 1993, tobacco companies routed almost \$1 billion through ad agencies (less than 1 percent of the reported \$131.3 billion spent on U.S. media advertising in 1992).<sup>356</sup> Assuming agency fees of 10 percent (while overlooking the proposed \$150 million educational campaign), it suggested that advertising declines of 25 to 75 percent would decrease agency annual revenues by \$25 million to \$77 million. Assuming a 50 percent drop (\$140 million) in magazine and newspaper advertising, the Barents Group next applied a simulation model to predict that supplier firms among advertising agencies, government, business and professional services, and commercial printers businesses would lose revenues of from \$12 to \$23 million. While acknowledging that, "\* \* \* there will be eventual offsetting revenue gains in other industries not shown \* \* \*," these other sectors were not identified and the offsetting revenues not explicitly quantified. The Barents Group correctly noted that the adjustments will involve short-term costs to the affected sectors, but did not estimate the expected magnitude of these adjustment costs.

c. *Outdoor advertising industry and public transit authorities.* The final rule restricts tobacco billboards and public transit advertising to black text on a white background and bans all stationary outdoor tobacco ads within a 1,000-foot radius of any school or public playground. The Barents Group predicted that almost all urban areas would be covered by the ban and expected almost no new outdoor tobacco advertising "even in permitted areas due to the relative ineffectiveness of black-and-white text as an advertising medium." Further, explaining that the \$232 million spent on outdoor advertising in 1993 accounts for about 14 percent of all outdoor advertising in the United States, the Barents Group found it unlikely that the industry could find new means of maintaining its current revenues.

In fact, the billboard industry and public transit districts will have to find replacements irrespective of this regulation. According to the Barents Group projections, spending on outdoor advertising by tobacco companies will fall by almost 40 percent between 1988 and 1996 (Appendix Table). One billboard trade source notes that, "almost 60 percent of the industry's 1979 revenues were derived from

<sup>354</sup> Statistical Abstract of the United States, p. 750, 1995.

<sup>355</sup> Beales, J. H., "Advertising and the Determinants of Teenage Smoking Behavior," vol. 44, p. 13, 1993.

<sup>356</sup> Endicott, R. C., "Top Advertisers Rebound, Spending to \$36 Billion," *Advertising Age*, vol. 64, No. 41, p. 1, September 29, 1993.

tobacco and alcohol advertisers. Today that number is down to 13 percent, replaced by retail, business and consumer services, entertainment, and travel advertisers.”<sup>357</sup> Similarly, FDA’s preliminary economic analysis had recognized that Canada’s billboard industry had rapidly adjusted to a recently imposed advertising ban and “quickly replaced \$20 million in lost cigarette revenues with ads for food, soap, toothpaste and beer.”<sup>358</sup>

In 1993, tobacco industry spending on public transit ads (\$39.1 million) contributed less than 1 percent to total public transit revenues, having declined by 35 percent from 1990 to 1993. Acknowledging that these expenditures would continue to fall, irrespective of this rule, the Barents Group argued that since relatively few transit authorities accept tobacco ads, the impact of the regulation would be significant for those few.

d. *Specialty item suppliers.* The prohibition of nontobacco specialty items bearing the name or logo of tobacco products will affect a substantial number of specialty manufacturers. In earlier comments to FTC,<sup>359</sup> the Specialty Advertising Association International noted that it “represents 4,400 firms that manufacture or sell utilitarian objects imprinted with advertising \* \* \* predominantly small businesses.” It is likely that some of these firms would, at least initially, lose part of this \$760 million market and would experience short-term costs while exploring other business options.

The Barents Group projected that manufacturer outlays for these promotional items, in the absence of the FDA rule, would triple between 1993 and 1996, rising from \$760 million to \$2.2 billion, assumed that the rule would cause revenue decreases of 25 to 75 percent, and modeled the impacts among other affected industry sectors (e.g., miscellaneous manufacturers producing matches and matchbooks, cigarette lighters, pens and pencils, sporting goods, etc.). The revenue and employment losses, therefore, were measured from a baseline that assumed a tripling of future industry revenues. While these growth projections may be optimistic, they demonstrate the rapid swings that typify the market for many

of these industries. Indeed, the Barents Group’s forecasts imply that even if the FDA rule were to reduce the 1996 level of tobacco industry advertising on specialty items by 50 percent, these outlays would still exceed the 1995 level.

In any case, FDA believes that the Barents Group’s forecasted impacts may be overestimated, as they primarily reflect static outcomes, whereas firms supplying such products are constantly adjusting production in response to rapidly shifting patterns of demand. While these regulatory changes will impose short-term dislocation costs, these costs will be significantly mitigated in view of the extensive lead time provided. Again, the Barents Group noted that FDA had not quantified these transitory costs, but it also provided no estimate.

e. *Sponsorship recipients.* According to reports submitted to FTC, U.S. tobacco companies spent \$107 million on public entertainment, primarily sporting events, in 1993.<sup>360</sup> In comparison, total spending on corporate sponsorships for sports, arts, and other entertainment by all North American companies is estimated to reach \$5.4 billion in 1996.<sup>361</sup> FDA received numerous public comments asserting that the loss of sponsorship revenues for sporting events would increase ticket prices and, in turn, reduce spectator attendance. In particular, comments pointed to the potential loss of jobs, employee benefits, and business revenues associated with race track events.

The Barents Group contended that a substantial part of the payments made by tobacco manufacturers would be eliminated by a ban on tobacco brand sponsorships, because few sponsors would agree to continue sponsorships under corporate names. Acknowledging the lack of reliable information on economic impacts; it, nonetheless, referenced several studies showing that lost sponsorship dollars decrease revenues and temporary jobs for local economies. The Barents Group predicted that, as tobacco companies eliminate payments, other advertisers would replace the major sponsorships, but leave reduced or no funding for the less popular events. On this basis, it

projected a 25 to 75 percent reduction in sponsorship dollars, calculated to result in revenue losses of \$27 to \$80 million.

Among the affected U.S. sporting events, the auto racing industry receives the greatest amount of tobacco sponsorship revenues. The Barents Group relied on various editions of the *IEG Intelligence Reports* (IEG) to list these sponsorships. In reviewing the IEG data and other sources, FDA found that about \$29 million worth of 1995 tobacco sponsorship revenues were designated for the National Association for Stock Car Auto Racing (NASCAR);<sup>362</sup> which amounted to about 8.3 percent of estimated NASCAR sponsorship revenues<sup>363</sup> and about 1.4 percent of estimated NASCAR total revenues.<sup>364</sup> The IEG data listed Indy Car tobacco sponsorships totaling only about \$13 million, although these data did not cover all events.

As the majority of the NASCAR tobacco sponsorship revenues were directed to the Winston Cup or other lead series, FDA agrees that a major effect of the ban will be to decrease the price of sponsorships, permitting smaller sponsors to “trade up” to the more prestigious sponsorships left vacant by tobacco companies. Although new company sponsors will be attracted by the lower overall sponsorship costs, this “ripple effect” will impose shortfalls for some smaller or lower profile events. This economic impact will be somewhat mitigated, however, by the rapid growth in nontobacco sponsorships. According to IEG estimates, over the past year, motorsport sponsorship spending rose by about 17 percent<sup>365</sup> and total North American corporate sponsorship spending by about 15 percent.<sup>366</sup>

<sup>362</sup> 1995 IEG Intelligence Report lists \$26.7 million in tobacco sponsorships of NASCAR. Two tobacco-sponsored events did not list the sponsorship fees, which FDA estimates at about \$1 million apiece.

<sup>363</sup> Koenig, B., “NASCAR takes Lead in Race for Sponsors: Stock-car Racing Gains Corporate Funds as CART and IRL Lag in Money and Ratings”, *The Indianapolis Star*, March 8, 1996, *Business* p. F01.; MacCrae, M., “Ricky Craven Collectibles Boost Intensive Fan Interest in Driver”, *Bangor Daily News*, May 2, 1996.

<sup>364</sup> Oliver, S., “A Fan-Friendly Sport,” *Forbes*, p. 70, July 3, 1995; Horovitz, B., “Fine-Tuning an Image-New Sponsors Race to NASCAR,” *USA Today*, Final Edition, p. 1B, April 5, 1996.

<sup>365</sup> MacCrae, M., “Ricky Craven Collectibles Boost Intensive Fan Interest in Driver,” *Bangor Daily News*, May 2, 1996.

<sup>366</sup> *IEG’s Complete Guide to Sponsorship*, p. 3, 1995.

<sup>357</sup> Burns, K., “Driving Into the Future with New Technology,” *Outdoor Advertising Magazine*, p. 5, January/February 1995.

<sup>358</sup> Wolfson, A., “Canada’s Ad Ban Puts Cigarettes Out of Sight,” *The Courier-Journal*, pp. A1, A4, August 1, 1994.

<sup>359</sup> 56 FR 11661 (March 20, 1991).

<sup>360</sup> Federal Trade Commission Report to Congress for 1993: Pursuant to the Federal Cigarette Labeling and Advertising Act, p. 18, 1995; Federal Trade Commission Report to Congress: Pursuant to the Comprehensive Smokeless Tobacco Health Education Act of 1986, p. 24, 1995.

<sup>361</sup> EPM Communications, Inc. “Entertainment Marketing Letter,” February 1, 1996. Based on IEG Sponsorship Report.

## 5. Retail Sector

In addition to incurring the economic costs described earlier, certain segments of the retail industry will experience adverse distributional impacts to the extent that they receive smaller promotional allowances (slotting fees) from manufacturers. In 1993, industry promotional allowances totaled \$1.6 billion dollars. According to FTC:

Promotional allowances are designed to encourage wholesalers and retailers to stock and promote a company's products, including such things as trade allowances and slotting allowances. Trade allowances provide deals to cigarette wholesalers, dealers and merchants in the form of free goods or price reductions in return for the purchase of specific quantities of goods. Slotting allowances include fees that the cigarette manufacturers pay retailers to encourage them to carry a new product or to allocate premium shelf space to a product. Trade contests and incentives, training programs, and trade shows may also be counted as promotional allowances. One major convenience store association, estimating that its members currently receive about \$5,000 per store, remarked that convenience stores would "bear a disproportionate burden should such allowances be eliminated as a result of the ban on self-service displays." Other retailers expressed similar concerns over the prohibition of self-service displays and promotional advertising, fearing it would lead to the elimination of these revenues.

The Barents Group argued that there were strong reasons to believe that promotional allowances would fall sharply as "tobacco products are withdrawn to inaccessible areas of the store, [and] the products taking their place will offer lower allowances." While acknowledging that, "[t]he possibility of promotional payments continuing may depend on whether the proposed regulations would allow the tobacco packages and cartons to be displayed from behind the check-out counter or from some other secured location in the stores," they nonetheless presented "illustrative" revenue reductions of from 25 to 50 percent and projected total revenue losses to the retail sector of \$556 to \$1,112 million. Using the higher percentage, their analysis implies that pretax profit margins would fall 12.4 percent for the average sized convenience store and even more for smaller stores. Moreover, they predicted that about 2 percent of currently profitable convenience stores would thereafter incur losses.

FDA suspects that many of these concerns are unwarranted as tobacco manufacturers will continue to place

significant value on having their products situated in highly visible locations. Although desirable locations behind counters or in locked display cases will be more limited, there is little reason to believe that manufacturers would stop competing for the best display space available. One comment indicated that following a self-service ban in a local area of Northern California, some retailers:

\* \* \* reported losses of tobacco industry-paid slotting fees \* \* \* because of the removal of self-service promotional tobacco displays, racks and kiosks; \* \* \* other retailers reported they did not lose [sic] tobacco industry-paid slotting fees if tobacco displays, racks or kiosks are relocated behind the counter or if they are replaced by locking cases \* \* \* [There were] no reported losses of other tobacco industry-paid advertising fees, promotional allowances or other financial incentives paid to retailers for advertising, promoting and marketing tobacco products in their stores.<sup>367</sup> Because of the regional aspects of this ban, it was a "worst case" situation for retail stores. If self-service displays were a prerequisite for promotional allowances, tobacco manufacturers would have quickly transferred them to other near-by localities, where self-service was permitted. The fact that this did not generally occur demonstrates that factors other than self-service displays can support manufacturer promotional payments to retailers.

Another comment noted that, "[i]n at least some areas, cigarette companies have continued payments to retailers for favored display space. For instance, Philip Morris has provided clear, plastic cases for the display of cigarette packs and cartons in some stores. These cases are placed on a checkout counter but only accessed from the clerk's side. This arrangement permits prominent display of cigarette packs to customers who are thereby offered cigarettes at close range while being unable to pick up packs or cartons themselves." In discussing the effects of the Canadian advertising ban, a Canadian study<sup>368</sup> suggested that, "[i]n the absence of advertising and promotion outlets \* \* \* the cigarette industry may be expected to provide greater incentives to retailers to provide

more and better shelf space for their brands in order to provide availability to the buyer in the store." Moreover, because FDA has not banned all point-of-purchase tobacco advertising, "text only" advertising at retail stores will be extremely important to tobacco product marketers.

In addition, alternative opportunities for point of purchase (POP) advertising have climbed briskly, as POP experts "cite in-store advertising as the fastest growing segment of the media industry."<sup>369</sup> That same Northern California study expressly noted the "[r]eplacement of self-service tobacco displays, racks and kiosks with \* \* \* non-tobacco products such as candy, gum and soft drinks for which the retailer receives slotting fees from the manufacturers of these products."<sup>370</sup>

In sum, FDA cannot predict with certainty the direction of future payments by product manufacturers to retailers. The agency points out, however, that this rule would affect neither the trade allowances that are commonly paid to both wholesalers and retailers, nor the slotting allowances paid to retailers to encourage them to carry a new product or to assure the availability of a particular brand in a retail outlet. Further, while many current promotional activities will be prohibited, a substantial number will remain available. As the competitive pressures that drive promotional allowances are unlikely to abate, manufacturers will continue to compete vigorously through programs involving both "text only" promotions and select product placements.

## 6. Other Private Sectors

FDA is aware of several recent studies that address the contribution of tobacco to the U.S. economy; or alternatively, the losses to the U.S. economy that would follow a decline in tobacco-related expenditures. The Tobacco Institute's Price Waterhouse report<sup>371</sup> purports to measure the induced effect on the national economy of spending by the tobacco core and supplier sector employees and their families. That

<sup>369</sup> "P-O-P Scores with Marketers," *Advertising Age*, p. 2, September 26, 1994.

<sup>370</sup> Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales," North Bay Health Resources Center, Stop Tobacco Access for Minors Program (STAMP), Petaluma, CA, pp. 2-3, November 3, 1994.

<sup>371</sup> "The Economic Impact of the Tobacco Industry on the United States in 1990," Price Waterhouse, October 1992.

<sup>367</sup> Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales," North Bay Health Resources Center, Stop Tobacco Access for Minors Program (STAMP), Petaluma, CA, pp. 2-3, November 3, 1994.

<sup>368</sup> "When Packages Can't Speak: Possible impacts of plain and generic packaging of tobacco products," Expert Panel Report, Prepared at the request of Health Canada, p. 140, March 1995.

report concluded that the induced or multiplier effects support 2.4 jobs for every 1 job in the core and supplier sectors combined, and over \$3 in compensation for every \$1 in the other two sectors. However, a review of that report, by Arthur Andersen Economic Consulting, explained that such multipliers lead to "massive and unrealistic estimates."<sup>372</sup> That review further emphasized that "money now being spent on tobacco would not disappear if demand for tobacco were to fall," though the Price Waterhouse report implicitly made that assumption. The Arthur Andersen review concluded that these multipliers "provide no basis by themselves for predicting how many jobs would be lost by a reduction in tobacco spending." FDA strongly supports this latter view.

The American Economics Group (AEG), in a new study submitted by the Tobacco Institute, employed a national input-output model to project broad sectoral and regional estimates of "the induced impact of the FDA proposed regulations nationwide." Applying the low and high illustrative costs estimated by the Barents Group, AEG predicted job losses of between 32,000 and 92,500. In addition to the printing and publishing industries, significant employment cutbacks were found for food, apparel and textiles, paper, metals, motor vehicles, and other miscellaneous manufacturers.

FDA is skeptical of the results of this AEG study. First, the input-output methodology employs an inherently static approach for estimating economic impacts. Indeed, the Barents Group, in its second report for the Tobacco Institute, explained that input-output models will not capture changing economic conditions, because they fail to account for changing market prices. Thus, "the input-output approach fails to measure the effects of reallocating displaced workers and resources to other parts of the economy." Furthermore, the AEG study suffers from the same fundamental problem as the earlier Price Waterhouse analysis: It assumes that all reduced industry revenues are lost to the economy. This methodology is simply inappropriate. Finally, the AEG study is based upon the illustrative cost estimates of the Barents Group. As described in detail above, these cost estimates are unreasonably high. Although some

tobacco advertising may decrease, a significant portion will be redirected towards the remaining permissible promotional activities.

In a second report, the Barents Group presented the results of using its own cost estimates in a general equilibrium model to simulate the impacts of the estimated reductions in advertising and promotional spending on revenue and employment for 56 sectors of the U.S. economy. This model predicted 21,000 to 44,000 U.S. job losses, largely among wholesale and retail businesses, but also within advertising, printing, apparel and miscellaneous manufacturing industries. FDA finds, however, that this study also is subject to several serious deficiencies. In particular, the Barents Group relies on its own illustrative cost estimates as model inputs. As noted above, FDA believes these estimates are far too high. Next, the study focuses solely on those industry sectors predicted to lose jobs, while ignoring those sectors expected to gain jobs. In fact, the study explicitly acknowledges that the underlying model assumes that:

the aggregate level of employment is not changed in the long run as a result of implementing the new regulations. In other words, though particular jobs in particular industries are expected to disappear permanently, the number of man-hours worked per year in the economy as a whole is assumed not to change in the long run  
\* \* \*

The Barents Group selectively shows changes in revenue and employment for the losers only.

Other analysts concluded that such models should not be used to assess longer term national economic impacts, because resources diverted from one use would be reallocated to the production of other goods and services. As one economist explained "[i]f the focus is longer term, involving a period of, say, more than 2 years, then the induced effect should not be included in the measure because money not spent in one industry would find another outlet with equal (undistinguishable) induced effects."<sup>373</sup>

Some comments addressed regional issues, pointing to the importance of tobacco products to the economies of several states. Comments noted, for example, that about 177,000 North Carolinians were employed by tobacco and that Price Waterhouse estimated that the economic activity of these

workers supported total State employment of 260,000. FDA is aware that tobacco growing states will experience some adverse economic effects. Nevertheless, as discussed above, the agency finds that the income and employment impacts associated with reduced tobacco consumption will be extremely gradual. Moreover, reduced tobacco consumption will minimally affect or even boost the economies of nontobacco states. For example, a recent economic simulation of the regional impacts of spending on tobacco products by Warner, et al., found that after 8 years, a 2 percent per year fall in tobacco consumption (which substantially exceeds the FDA forecast for this regulation) would cause the loss of 36,600 jobs for the Southeast Tobacco region of the United States (0.2 percent of regional employment); whereas the nontobacco regions of the United States would gain 56,300 jobs.<sup>374</sup> That study concluded that "[t]he primary concern about tobacco should be the enormity of its toll on health and not its impact on employment."

#### 7. Excise Tax Revenues

The rule will decrease State and Federal tobacco tax revenues as fewer youths will become addicted to tobacco products. These excise tax losses will increase as more youths become nonsmoking adults. According to the Tobacco Institute, State cigarette excise taxes totaled \$6.2 billion for the year ending June 30, 1993.<sup>375</sup> As State excise taxes on other tobacco products (including smokeless tobacco) are reported at \$226 million, FDA assumes that the value of all State excise taxes affected by this regulation is about \$6.4 billion annually. Federal excise taxes on cigarettes totaled \$5.5 billion for the year ending June 30, 1993. Federal excise taxes on smokeless tobacco are expected to be about \$27 million, according to the Smokeless Tobacco Council. As described above, FDA estimates that compliance will reduce tobacco product sales by a gradually increasing rate over time; tobacco sales will fall by 0.5 percent in the 1st year, 1.9 percent in the 5th year, and 3.7 percent in the 10th year. Thus, the rule will decrease State excise taxes on affected tobacco products by from \$30 million in the 1st year to \$231 million in the 10th year and Federal tobacco

<sup>372</sup> "A Review of the Price Waterhouse Economic Impact Report and Tobacco Institute Estimates of 'Economic Losses from Increasing the Federal Excise Tax,'" Arthur Andersen Economic Consulting, p. 93, October 6, 1993.

<sup>373</sup> Gray, H. P., and I. Walter, "The Economic Contribution of the Tobacco Industry," in *Smoking and Society: Toward a More Balanced Assessment*, edited by R. D. Tollison, Lexington Books, p. 248, 1986.

<sup>374</sup> Warner, K. E., G. A. Fulton, P. Nicolas, and D. R. Grimes, "Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States," *JAMA*, April 24, 1996.

<sup>375</sup> The Tobacco Institute, "The Tax Burden on Tobacco," vol. 28, p. 4, 1993.

taxes by from \$25 million in the 1st year to \$196 million in the 10th year.

Since tobacco taxes represented less than 1 percent of total revenues on both the State and Federal level in 1992,<sup>376</sup> even the estimated tenth year impact measures only 0.03 percent of all State tax revenues and less than 0.02 percent of all Federal revenues. Nonetheless, if necessary, governments could raise tobacco product excise rates to offset these revenue losses. A full evaluation of the fiscal consequences, however, would involve a variety of public health ramifications. For example, State Medicaid programs will benefit from reduced tobacco-related medical care expenditures, but will need to finance additional nursing home expenditures associated with increased life expectancy.

#### F. Small Business Impacts

The Regulatory Flexibility Act requires agencies to prepare a final regulatory flexibility analysis if a rule will have a significant economic impact on a substantial number of small entities. Analyses in this section, as well as in other sections of this preamble, constitute the agency's compliance with this requirement. According to the Regulatory Flexibility Act, the final regulatory flexibility analysis must contain "a succinct statement of the need for, and objectives of, the rule." Section XV.B. of this document explains that the need for action stems from the enormous toll on the public health that is directly attributable to the consumption of tobacco by children and adolescents under the age of 18. As described, the primary objective of the regulation is to achieve the "Healthy People 2000" goal of reducing by one-half the number of youngsters who use tobacco.

The final regulatory flexibility analysis must also provide "a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a

summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments." The analyses presented previously in this section addressed the first two of these elements.

With respect to the changes made in the proposed rule as a result of public comments, the agency has reconsidered several of its earlier decisions, at least partly due to their projected effect on small businesses. The preamble above describes these changes and presents the agency's rationale for each modification. For example, the proposed regulation banned all vending machine sales of tobacco products. In response to public comment, the final regulation exempts from the ban those vending machines in "adult only" locations. FDA does not know how many small businesses will be able to take advantage of this exemption, but it will maintain at least one line of sales for small vending machine operators without jeopardizing the protection of young people.

In addition, the proposed regulation prohibited direct mail-order sales of tobacco products. The public comments, however, indicated that many adults, especially those who are elderly or who have limited mobility, would be substantially inconvenienced and several small businesses would be adversely affected by this ban. Even more importantly, studies suggest that teenagers purchase cigarettes from vending machines or retail merchants rather than from nonretail channels. FDA took these considerations into account and the final regulation does not prohibit mail-order sales of cigarettes.

The final regulatory flexibility analysis must also include "a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available." U.S. Census data for 1993 indicate that most

cigarette manufacturers are large businesses, with only 4 employing fewer than 500 employees.<sup>377</sup> The small business size standard established by the U.S. Small Business Administration (SBA) for this industry is 1,000 employees.<sup>378</sup> The Federal Trade Commission (FTC) provided a list of 52 cigarette importers and small cigarette manufacturers filing plans with that agency, but could not distinguish manufacturers from importers.<sup>379</sup> The 1993 Census data show that 14 of the 20 firms manufacturing chewing and smoking tobacco employ fewer than 500 employees, the SBA size standard for this sector.<sup>380</sup> Also, most of the nation's 124,000 tobacco farms are small; almost 99 percent of the farms growing tobacco in 1992 had total farm sales under the SBA small business size standard of \$500,000, and almost 91 percent had total farm sales under \$50,000.<sup>381</sup> Further, 1993 Census data show that 1,332 of 1,365 tobacco wholesale trade firms (98 percent) employ fewer than the 100-employee threshold that constitutes a small business according to the SBA.<sup>382</sup> As noted above, the effect of the regulation on tobacco manufacturing, growing, and wholesale trade operations will be very gradual, taking over 10 years to reach a 4 percent reduction.

The regulation will affect numerous retail establishments, including food stores, small general merchandise stores, small tobacco stores and small gasoline stations. Table 15 displays the relative share of the tobacco market for the major types of tobacco-dispensing outlets with payroll in 1992. As shown, food stores and service stations received about 75 percent of all tobacco sales revenue and tobacco products comprised 5 to 7 percent of the total sales of many of these establishments. Table 16 indicates that the great majority of all retail outlets in these sectors are small businesses.

<sup>376</sup> U.S. Department of Commerce, *Statistical Abstract of the United States 1994*, 114th edition, No. 464, p. 298, 1994.

<sup>377</sup> Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States p. 68.

<sup>378</sup> U.S. Small Business Administration, "Table of Size Standards," March 1, 1996.

<sup>379</sup> Federal Trade Commission, "Cigarette Importers and Small Manufacturers Plans Filed, May 26, 1993–October 14, 1994."

<sup>380</sup> Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States p. 69.

<sup>381</sup> 1992 Census of Agriculture, U.S., vol. 1, excerpts from pp. 109–110, 125–126.

<sup>382</sup> Special Census Tabulation prepared by U. S. Bureau of Census for U.S. Small Business Administration, Table 3—United States.



TABLE 15.—SALES OF TOBACCO PRODUCTS AS A PERCENTAGE OF TOTAL SALES—1992  
(Establishments with Payroll Only)

Establishment Type	Tobacco Sales		% of Total Sales	
	(\$ Mils)	(%)	Establishments Handling Tobacco	All Establishments
<b>All</b>	<b>30,559</b>	<b>100</b>	4.5	2.9
Food Stores	16,132	52	4.5	4.4
Service Stations	7,136	23	7.1	5.3
Drug and Proprietary	2,235	7	3.7	2.9
General Merchandise	3,182	10	2.4	1.3
Liquor Stores	1,045	3	8.0	5.1
Eating and Drinking	219	1	3.0	0.1
Tobacco Stores & Stands	610	2	78.1	78.1

Source: 1992 Census of Retail Trade, Merchandise Line Sales

TABLE 16.—NUMBER OF SMALL RETAIL BUSINESSES

Establishment Type	Firms With Payroll		Establishments Without Payroll
	Total	Small <sup>1</sup>	
All		473,668	275,432
Food Stores	588,505	104,541 <sup>2</sup>	97,061
Service Stations	127,575	53,288 <sup>3</sup>	14,248
Drug and Proprietary	62,585	25,396	3,031
General Merchandise	28,606	8,176	28,010
Liquor Stores	10,264	22,859	8,811
Eating and Drinking	26,565	258,381	124,271
Tobacco Stores & Stands	331,703	1,027	n.a.

<sup>1</sup> Assumes Small Business Administration size standard of \$20 million in annual sales for food stores, \$6.5 million for service stations and \$5 million for all others.

<sup>2</sup> Due to data limitations, includes firms with annual sales up to \$25 million.

<sup>3</sup> Due to data limitations, includes firms with annual sales up to \$10 million.

Source: 1992 Census of Retail Trade, Establishment and Firm Size, 1992 Census of Retail Trade, Summary.

To illustrate the effects of this proposal on a typical small retail store, FDA separately utilized Census data to estimate that the average-sized convenience store sells 177 packages of tobacco products daily, of which about 25 might be purchased by young adults aged 18 to 26.<sup>383</sup> Based on the cost assumptions described previously, the outlet's first year costs would total about \$400, with the largest single cost, \$199, the labor cost for checking identification. For those stores that already verify the age of young customers of tobacco products, the additional costs fall to \$137.

This estimate does not account for the possible reduction in promotional allowances, as FDA believes that competitive pressures will continue to lead manufacturers to rely on promotional allowances to compete for the best shelf space available for their products. Because FDA rejected the idea of prohibiting any visible display of tobacco products, retailers can retain slotting fees by choosing to display tobacco products either behind counters or in transparent locked display cases. Nevertheless, some small establishments might experience reduced promotional payments following a ban on self-service marketing.

Census data for 1992 indicate that almost 4,000 of 4,800 merchandising machine operator businesses (83 percent) reported annual receipts below the SBA size standard of \$5 million.<sup>384</sup> One trade association noted that almost three quarters of all vending machine operators had annual sales of less than \$1 million.<sup>385</sup> As explained earlier, prohibiting all cigarette vending machines would initially reduce the revenues of vending machine operators by an average of 2.8 percent. Because only about one-half of the merchandising machine establishments

sell cigarettes, some businesses specializing in cigarette sales would experience greater revenue declines; although this effect will be moderated to the extent that cigarette vending machines are placed in areas restricted to adults, which would not be prohibited by the final rule.

The rule would also affect the distribution of specialty items showing a tobacco product logo or name. Industry comments do not provide precise data on the size distribution of these firms, but as noted above, the Specialty Advertising Association International indicates that 80 percent of the manufacturers and 95 percent of the distributors in this industry have annual sales below \$2 million. While the marketplace in which these firms traditionally compete demands a quick response to shifting consumer trends, this rule would have at least short-term impact on some small firms.

FDA has received no data that would allow it to estimate the number of small firms that are currently involved with some aspect of tobacco advertising or the fraction of these firms that will be affected. In 1992, 861 of 904 year-round outdoor advertising firms (95 percent) reported sales revenues of less than the SBA size standard of \$5 million.<sup>386</sup> The impact of this rule, however, is difficult to assess without knowing how the tobacco industry will alter its advertising strategies. Indeed, one of the largest outdoor advertising firms recently decided to reject all tobacco business, potentially increasing sales to the smaller firms.<sup>387</sup>

The regulation restricts tobacco advertising to "text only" in magazines with youth readership above the regulatory threshold. Of the identified 101 magazines with tobacco ads in 1994, 79 were published by large firms (over 500 employees). Less than 3 percent of the total revenue of the remaining 22 publications (which include, Inc., Rolling Stone and Penthouse) was derived from tobacco ads.<sup>388</sup> It is likely, moreover, that many of these magazines could avoid the "text only" restriction for tobacco advertising by demonstrating a low youth readership.

The regulation will also affect a substantial number of small race tracks,

although FDA does not know how many small tracks currently receive significant revenues from tobacco sponsors. As discussed previously, some small operations will likely lose promotional revenues from tobacco companies, but the sport is growing rapidly and other product manufacturers should make up a substantial part of the shortfall.

The final regulatory flexibility analysis must include "a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record." A full description of the requirements and classes of affected small entities has been provided earlier in this section and a quantitative review of the paperwork burdens imposed by the rule is provided in section XVI. of this document. No special professional skills will be required to prepare the reports or records required by the regulation.

The final regulatory flexibility analysis must also include "a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected."

The earlier sections of this document provide a full explanation of the agency's basis for selecting each provision of the final rule. In each instance, FDA evaluated the implications of each reasonable regulatory alternative and selected only those requirements that were absolutely necessary to satisfy the agency's statutory goals. As described, FDA found that its objectives for reducing the use of tobacco by young people could not be achieved with a partial or one-dimensional approach, but required a comprehensive set of regulatory restrictions. Thus, the final set of selected provisions reflect a careful examination of the relevant facts presented to the rulemaking record, the agency's objective of curtailing the use of tobacco by youngsters without creating unnecessary economic burdens, and a full assessment of the agency's legal authorities. Because the rejected alternatives would either provide less protection of public health, or achieve

<sup>383</sup> Based on data from the 1994 SGR, p. 85, and the "Tobacco Situation and Outlook Report" April, 1995, p. 4, FDA estimates that smokers aged 18 to 26 account for about 10 percent of all cigarettes smoked. Alternatively, data from the Statistical Abstract, tables 16 and 218, show that smokers aged 18 to 26 comprise 18 percent of all smokers. FDA used the midpoint of the 10 to 18 percent range to avoid underestimating the cost to small retailers. In addition, data from the 1996 Census of Retail Trade, Subject Series-Merchandise Line Sales, pp. 3-9 on the number of convenience stores with payroll and their total tobacco sales, and the average price per pack, were used to estimate the average number of packs sold daily at convenience stores to smokers aged 18 to 26.

<sup>384</sup> 1992 Census of Retail Trade, "Establishment and Firm Size," Table 4 p. 1-99.

<sup>385</sup> "1993: Industry Posts Best Growth in Four Years," *Automatic Merchandiser*, p. A2, August 1994.

<sup>386</sup> 1992 Census of Service Industries, pp. 1-145 and 1-195.

<sup>387</sup> Collins, G., "Major Advertising Company to Bar Billboard Ads for Tobacco," *New York Times*, A15, May 3, 1996.

<sup>388</sup> 1996 *Directory of Corporate Affiliations U.S. Private Companies*, New Providence, NJ; Reed Elsevier, Inc.; "Company Profiles" database, Information Access Co., Foster City, CA.

only minimal improvements at unwarranted cost, the agency found that the approach selected for the final rule best fit its statutory mandate.

As noted, earlier sections of the preamble fully describe the agency's rationale for selecting each provision of the final rule and for rejecting each alternative approach. Although many alternatives were considered, specific exemptions based solely on business size were not adopted, because FDA believes that children would too frequently exploit such opportunities. Unlike certain other regulations where restrictions on large firms alone might be acceptable, tobacco products are purchased easily from small, as well as large firms. An exemption for small retailers, for instance, would shift underage sales to those locations, lessening or eliminating the benefits of the remaining access restrictions. The following discussion summarizes the agency's consideration of several other regulatory alternatives.

#### *G. Other Alternatives*

One regulatory alternative would have banned all tobacco advertising; or alternatively, all tobacco advertising in selected media, such as all written publications, or all outdoor billboards. FDA rejected this approach in order to focus on those media and aspects of advertising that children are routinely exposed to and that have the greatest effect on youngsters. For example, the final rule permits black and white "text only" tobacco advertising in all written publications and color and imagery in magazines with fewer than 2 million youthful readers if youth constitute less than 15 percent of the publication's readership. Billboards are permitted to show black and white "text only" ads if located at least 1,000 feet from schools or public playgrounds. Thus, the rule leaves the informational aspects of advertising largely untouched.

Another suggested alternative was to combat underage tobacco use by relying on either voluntary compliance or on better enforcement of laws prohibiting sales to minors. As discussed earlier in this document, the tobacco industry's voluntary advertising code has failed to stop illegal sales to underage buyers. FDA agrees that these approaches can be partially effective, but finds that they inadequately counter the appeal of tobacco products for young people that is created by advertising and promotions. Thus, the agency concludes that there is no less burdensome alternative for achieving its goals that

would exclude appropriately tailored restrictions on tobacco advertising.

One alternative considered by the agency was a far more prescriptive monitoring requirement for tobacco manufacturers. Under this rule, each manufacturer of tobacco products would have been required to adopt a system for monitoring the sales and distributions of retail establishments. These monitoring systems were to: (1) Include signed written agreements with each retailer, (2) contain adequate organizational structure and personnel to monitor the labeling, advertising, and sale of tobacco products at each retail distribution point, and (3) establish, implement, and maintain procedures for receiving and investigating reports regarding any improper labeling, advertising, or distribution. The additional costs for this monitoring were estimated at about \$85 million per year. FDA rejected this alternative, because it decided that the industry might employ its resources more efficiently if permitted to choose among alternative compliance modes.

Another suggested alternative would have required package inserts containing educational information in cigarette and smokeless tobacco. FDA had incomplete data to estimate the additional cost of this requirement, but based on comments submitted by industry in response to a Canadian proposal, tentatively projected one-time costs of about \$490 million and annual operating costs of about \$54 million. This alternative was not selected because the agency was not certain that the benefits of this provision would justify the compliance costs.

FDA also considered setting the permissible age for purchase at 19 rather than 18, because many 18-year-old adolescents are still in high school and can easily purchase tobacco products for younger classmates. This alternative would have added costs of about \$34 million annually, mostly due to lost producer profits. The final regulation restricts access to regulated tobacco products for persons under the age of 18, because most adult smokers have already become smokers by the age of 18, and because that age limit is already consistent with most State and local laws.

#### *H. Unfunded Mandates Reform Act of 1995*

On the basis of the preceding discussion, under the Unfunded Mandates Act, FDA concludes that the substantial benefits of this regulation will greatly exceed the compliance costs that it imposes on the U.S. economy. In

addition, the agency has considered other alternatives as discussed in section XV.G. of this document and determined that the current rule is the least burdensome and the most cost effective alternative that would meet the objectives of this rule.

#### *XVI. Paperwork Reduction Act of 1995*

The 1995 proposed rule would have collected information from manufacturers, distributors, and retailers of cigarettes and smokeless tobacco. Proposed § 897.24 would have required such persons to use established names for cigarettes and smokeless tobacco. Proposed § 897.29 would have required manufacturers to establish and maintain educational programs. Proposed § 897.32 would have required manufacturers, distributors, and retailers to observe certain format and content requirements for labeling and advertising. Proposed § 897.40 would have required manufacturers to submit labels, labeling, and advertising to FDA.

The preamble to the 1995 proposed rule, in discussing the Paperwork Reduction Act, also invited comments on four questions: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden (60 FR 41314 at 41356).

#### *A. Comments on the Paperwork Reduction Act Statement*

A small number of comments, primarily from a trade association representing cigarette manufacturers and from distributors, addressed FDA's Paperwork Reduction Act statement. In general, these comments asserted that FDA's figures were incorrect or that the rule would duplicate existing reporting requirements. Few comments provided any figures or evidence to justify using different estimates.

(1) One comment, submitted by a trade association representing major cigarette manufacturers, said FDA's Paperwork Reduction Act statement underestimated the paperwork burden due to the exclusion of burden on retailers. The comment asserted that FDA did not explain how it calculated the number of respondents and burden hours for these sections and that the absence of an explanation made it difficult to assess the agency's estimate.

The comment explained that the agency's Paperwork Reduction Act estimate said there would be 200,000 respondents for proposed § 897.40, but that the agency's analysis of impacts estimated that 700,000 retail stores sell tobacco products. The comment also asserted that the average burden per response, under proposed §§ 897.32 and 897.40, should be 1 hour instead of 20 minutes. Thus, the comment concluded that if all 700,000 outlets spend only 60 minutes annually to comply with all recordkeeping requirements, at a cost of \$10 per hour, retailers, alone, would spend 700,000 hours and \$7 million to comply with the recordkeeping requirements in §§ 897.32 and 897.40.

The agency believes that the comment misinterprets the figures in the proposed rule's Paperwork Reduction Act statement. To begin with, the comment mistakenly equates the Paperwork Reduction Act statement's reference to "annual number of responses" with the annual numbers of people or firms that might be affected. The annual number of responses simply refers to the annual number of things, whether those things are pieces of labeling, labels, advertisements, or other items, that the agency might receive under that particular regulatory requirement. So, for example, if the agency expected to receive only 500 labels, the "annual number of responses" would be 500, regardless of whether the number of firms who might be affected by the rule was greater or less than 500.

Focusing on §§ 897.32 and 897.40 (the provisions cited by the comment), proposed § 897.32 would have established specific format and content requirements for labeling and advertising. For example, proposed § 897.32(a) would have required labeling and advertising to use only black text on a white background; the only exception would be advertising appearing in "adult" periodicals. Proposed § 897.32(b) would have required advertising to carry the product's established name and a statement of intended use, and specified those names and the statement of intended use. Proposed § 897.32(c) would have required advertising to carry a specific brief statement. The agency believed that these proposed requirements and specific statements were so precise that manufacturers, distributors, or retailers could determine their regulatory obligations quickly. For example, it should be quite simple to determine whether an advertisement uses black text on a white background.

Proposed § 897.40(a) would have required manufacturers to provide copies of labels, labeling, and a representative sampling of advertising to FDA. This, too, would not appear to be an extremely time-consuming task, particularly when the rule permits manufacturers to provide a representative sampling of advertising.

To estimate the time required to comply with proposed §§ 897.32 and 897.40, the agency tried to examine other large-scale labeling and reporting programs. FDA found that one Federal department conducts a large-scale labeling program that receives approximately 200,000 labels annually and that each label requires a maximum of 20 minutes to review. Consequently, the 1995 proposed rule adopted the 200,000 figure as the estimated number of responses. In the absence of better data, the proposed rule assigned the maximum review time (20 minutes) to its estimates for average burden per response.

FDA, however, has revised the 200,000 figure and now estimates that approximately 25,000 pieces of labeling or advertising will be affected by § 897.32. (The agency has deleted § 897.40 from the rule in favor of other, preexisting regulations.) As described in greater detail elsewhere in this document, the agency derived these figures by using advertising expenditures by the cigarette and smokeless tobacco industries and by the pharmaceutical industry, applying the ratio of such expenditures against the 25,000 pieces of advertising that the agency receives from the pharmaceutical industry, and projecting that printed advertisements may increase due to the rule's effect on promotional activities. Consequently, FDA now estimates that 25,000 pieces of labeling and advertising will be affected.

Thus, the agency does not agree that the estimated number of responses should be 700,000 or more because the response rate is not determined by the number of retailers. However, because the comment estimated that firms would require 1 hour to comply, the agency will use the 1 hour figure and has adjusted its paperwork estimates accordingly.

(2) The same comment also asserted that FDA's recordkeeping estimate was incorrect for manufacturers. The comment stated that FDA did not explain how it calculated the burden hour response for manufacturers under proposed § 897.40 and asserted that manufacturers would need 40 hours to document compliance with the

educational program requirements in proposed § 897.29 alone. The comment estimated that the recordkeeping costs for the manufacturers' educational programs would be \$25 per hour, for a total cost between \$55 and 57 million annually. The comment explained that the costs may be even higher because highly skilled persons would be needed to comply with the rule.

The comment misinterprets the agency's Paperwork Reduction Act burden estimate. For § 897.29, FDA estimated that 1,000 hours would be needed to comply with the educational program requirements; this estimate included all functions related to the development of an educational program, including recordkeeping. Section 897.40(b), would have required manufacturers, distributors, and retailers to make records (including records on a manufacturer's educational program efforts) available to FDA on inspection. Because the estimate for proposed § 897.29 included time spent on recordkeeping associated with the educational program, the agency's estimates for proposed § 897.40 properly excluded time spent on maintaining educational program records. Otherwise, this time would have been counted twice. In any event, the comment is moot because FDA has deleted § 897.29 and § 897.40 from the final rule.

(3) FDA received several comments from distributors, claiming that the 1995 proposed rule would result in substantial paperwork and provide duplicative information. The comments stated that the device listing provisions of part 807 require each medical device wholesaler to prepare and file reports of all regulated products. If each brand and package style of cigarettes and smokeless tobacco are considered a separate device, this would substantially increase paperwork and duplicative reporting.

The comment correctly notes that part 807, as currently written, requires distributors to register and list devices (21 CFR 807.20). However, FDA has amended part 807 to exempt distributors of cigarettes and smokeless tobacco. Thus, distributors do not have to comply with part 807, nor do they have to comply with § 897.40 because FDA has deleted § 897.40 from the final rule.

(4) Several comments, primarily from small businesses and convenience stores, said that the 1995 proposed rule would have no impact and that adding paperwork would not curb underage smoking.

The agency disagrees with the comments. The final rule restricts young people's access to cigarettes and smokeless tobacco and reduces their appeal to young people. FDA believes that the final rule, in conjunction with State and local government efforts, will prevent large numbers of young people from using or experimenting with these products. Yet, insofar as any information collection burden is concerned, FDA points out that the rule's paperwork requirements are a function of the act and are being imposed to further the purposes of the act and of this final rule, not in any attempt to curb underage smoking by simply adding paperwork for paperwork's sake.

(5) One comment said that FDA could reduce the information collection burden in proposed § 897.29 (the educational program) by requiring manufacturers to contribute to an educational fund that an independent agency, such as FDA, CDC, or NIH, could use. The comment said that this would create a positive incentive for companies to change their marketing practices and would reduce the need for extensive recordkeeping and regulatory oversight of manufacturers.

The agency has deleted the educational program provision from the final rule. Consequently, the information collection burden associated with proposed § 897.29 no longer exists.

(6) In response to comments, FDA has amended the final rule to include a medical device reporting requirement for manufacturers and distributors at

§§ 803.19 and 804.25. For manufacturers, these reports are limited to adverse events (resulting from product contamination, a change in ingredient or in any manufacturing process, or serious adverse events that are not well-known or well-documented by the scientific community. For distributors, these reports are limited to adverse events related to contamination. FDA estimates that it will receive 50 reports and each report will require 8 hours to prepare. The agency has amended the information collection burden to reflect these changes to the rule.

(7) FDA has also revised the information collection figures for § 897.24 which requires an established name on labels. The revision changes the number of respondents from 1,000 to 2,000 to reflect the agency's position that there are 1,000 varieties of cigarettes and smokeless tobacco products and that each variety has 2 labels, thus resulting in 2,000 affected labels.

(8) FDA has also revised the information collection figures for § 897.32 to account for the survey evidence that is needed to establish that a magazine, newspaper, or other periodical is an "adult" publication that is exempt from the requirement of black text on a white background. The agency estimates that such surveys will result in a capital cost of \$2 million, with annual costs of \$1 million. FDA estimates that 31 recordkeepers would be affected at a total burden hour figure of 100,000 hours.

#### *B. Information Collection Provisions in the Final Rule*

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirements are shown below with the estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

*Title:* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents.

*Description:* The final rule requires the collection of information regarding cigarettes and smokeless tobacco. The final rule requires manufacturers, importers, and distributors to report certain adverse events to FDA and requires manufacturers to use established names for cigarettes and smokeless tobacco. The final rule also requires manufacturers, distributors, and retailers to observe certain format and content requirements for labeling and advertising, and requires manufacturers, distributors, and retailers to notify FDA if they intend to use an advertising medium that is not listed in the regulations.

*Description of Respondents:* Businesses.

Table 17.—Estimated Annual Reporting and Disclosure Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
803.19	49	1	49	8	392	21,000	13,680
804.25	1	1	1	8	8	231,000	35,220
897.24	2,000	1	2,000	40	80,000	17,000,000	0
897.30	1	1	1	1	1	0	0
897.32	25,000	1	25,000	1	25,000	0	0
Total Burden					105,401	17,250,000	48,900



TABLE 18.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record- keeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
897.32	31	1	31	3,226	100,000	2,000,000	1,000,000
Total Burden					100,000	2,000,000	1,000,000

The 1995 proposed rule provided a 90-day comment period (extended to 144 days in the Federal Register of October 16, 1995, 60 FR 53560). As discussed previously, the revised burden hour estimates in the final rule are based partially on comments received.

The information collection provisions in the proposed rule were approved under OMB no. 0910-0312. Because of changes made since the proposed rule, FDA has submitted the information collection provisions of the final rule to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register of OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule.

#### XVII. Congressional Review

This final rule has been determined to be a major rule for purposes of 5 U.S.C. 801 *et seq.*, Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121). FDA is submitting the information and reports as required by that statute.

#### List of Subjects

##### 21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

##### 21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

##### 21 CFR Part 804

Imports, Medical devices, Reporting and recordkeeping requirements.

##### 21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

##### 21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

##### 21 CFR Part 897

Advertising, Cigarettes, Labeling, Sale and distribution, Smokeless tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 801, 803, 804, 807, and 820 are amended and a new part 897 is added as follows:

#### PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

2. Section 801.126 is added to subpart D to read as follows:

##### § 801.126 Exemptions for cigarettes and smokeless tobacco.

Cigarettes and smokeless tobacco as defined in part 897 of this chapter are exempt from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act.

#### PART 803—MEDICAL DEVICE REPORTING

3. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

4. Section 803.19 is amended by adding new paragraphs (f) and (g) to read as follows:

##### § 803.19 Exemptions, variances, and alternative reporting requirements.

\* \* \* \* \*

(f) Manufacturers as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for serious adverse events that are not well-known or well-documented by the scientific community, including events related to contamination, or a change in any ingredient or any manufacturing process.

(g) User facilities are exempt from submitting medical device reports concerning cigarettes and smokeless tobacco under this part.

#### PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

5. The authority citation for 21 CFR part 804 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

6. Section 804.25 is amended by adding a new paragraph (c) to read as follows:

##### § 804.25 Reports by distributors.

\* \* \* \* \*

(c) Distributors as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for adverse events related to contamination.

#### PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

7. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: Secs. 301, 501, 502, 510, 513, 515, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374).

8. Section 807.65 is amended by adding a new paragraph (j) to read as follows:

##### § 807.65 Exemptions for device establishments.

\* \* \* \* \*

(j) Distributors of cigarettes or smokeless tobacco as defined in part 897 of this chapter.

#### PART 820—GOOD MANUFACTURING PRACTICE FOR MEDICAL DEVICES: GENERAL

9. The authority citation for 21 CFR part 820 continues to read as follows:

Authority: Secs. 501, 502, 515, 518, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360e, 360h, 360i, 360j, 371, 374).

10. Section 820.1 is amended by adding and reserving new paragraph (e) and adding new paragraph (f) to read as follows:

##### § 820.1 Scope.

\* \* \* \* \*

(e) [Reserved]

(f) This part does not apply to distributors of cigarettes or smokeless tobacco as defined in part 897 of this chapter.

11. New part 897 is added to read as follows:

#### PART 897—CIGARETTES AND SMOKELESS TOBACCO

##### Subpart A—General Provisions

###### Sec.

897.1 Scope.

897.2 Purpose.

897.3 Definitions.

##### Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

897.10 General responsibilities of manufacturers, distributors, and retailers.

897.12 Additional responsibilities of manufacturers.

897.14 Additional responsibilities of retailers.

897.16 Conditions of manufacture, sale, and distribution.

**Subpart C—Labels**

- 897.24 Established names for cigarettes and smokeless tobacco.
- 897.25 Statement of intended use and age restriction.

**Subpart D—Labeling and Advertising**

- 897.30 Scope of permissible forms of labeling and advertising.
- 897.32 Format and content requirements for labeling and advertising.
- 897.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

Authority: Secs. 502, 510, 518, 519, 520, 701, 704, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360h, 360i, 360j, 371, 374, 393).

**Subpart A—General Provisions****§ 897.1 Scope.**

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine.

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of Title 21, unless otherwise noted.

**§ 897.2 Purpose.**

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

**§ 897.3 Definitions.**

(a) *Cigarette* means any product which contains nicotine, is intended to be burned under ordinary conditions of use, and consists of:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (a)(1) of this section.

(b) *Cigarette tobacco* means any product that consists of loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette. Unless otherwise stated, the

requirements pertaining to cigarettes shall also apply to cigarette tobacco.

(c) *Distributor* means any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

(d) *Manufacturer* means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product.

(e) *Nicotine* means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl)pyridine or  $C_{10}H_{14}N_2$ , including any salt or complex of nicotine.

(f) *Package* means a pack, box, carton, or container of any kind in which cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers.

(g) *Point of sale* means any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco for personal consumption.

(h) *Retailer* means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

(i) *Smokeless tobacco* means any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral cavity.

**Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age****§ 897.10 General responsibilities of manufacturers, distributors, and retailers.**

Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part.

**§ 897.12 Additional responsibilities of manufacturers.**

In addition to the other responsibilities under this part, each manufacturer shall remove from each point of sale all self-service displays, advertising, labeling, and other items that the manufacturer owns that do not comply with the requirements under this part.

**§ 897.14 Additional responsibilities of retailers.**

In addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:

(a) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;

(b)(1) Except as otherwise provided in § 897.16(c)(2)(i) and in paragraph (b)(2) of this section, each retailer shall verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(2) No such verification is required for any person over the age of 26;

(c) Except as otherwise provided in § 897.16(c)(2)(ii), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);

(d) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use; and

(e) Each retailer shall ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part.

**§ 897.16 Conditions of manufacture, sale, and distribution.**

(a) *Restriction on product names.* A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

(b) *Minimum cigarette package size.* Except as otherwise provided under this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) *Vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale.* (1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include vending machines and self-service displays.

(2) Exceptions. The following methods of sale are permitted:

(i) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail; and

(ii) Vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(d) *Free samples.* No manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes or smokeless tobacco.

(e) *Restrictions on labels, labeling, and advertising.* No manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with subparts C and D of this part, and other applicable requirements.

### Subpart C—Labels

#### § 897.24 Established names for cigarettes and smokeless tobacco.

Each cigarette or smokeless tobacco package shall bear, as provided in section 502 of the act, the following established name: "Cigarettes", "Cigarette Tobacco", "Loose Leaf Chewing Tobacco", "Plug Chewing Tobacco", "Twist Chewing Tobacco", "Moist Snuff", or "Dry Snuff", whichever name is appropriate.

#### § 897.25 Statement of intended use and age restriction.

Each cigarette or smokeless tobacco package, that is offered for sale, sold, or otherwise distributed shall bear the following statement: "Nicotine-Delivery Device for Persons 18 or Older".

### Subpart D—Labeling and Advertising

#### § 897.30 Scope of permissible forms of labeling and advertising.

(a)(1) A manufacturer, distributor, or retailer may, in accordance with this subpart D, disseminate or cause to be

disseminated advertising or labeling which bears a cigarette or smokeless tobacco brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification, in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, and placards; in nonpoint-of-sale promotional material (including direct mail); in point-of-sale promotional material; and in audio or video formats delivered at a point-of-sale.

(2) A manufacturer, distributor, or retailer intending to disseminate, or to cause to be disseminated, advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in paragraph (a)(1) of this section, shall notify the agency 30 days prior to the use of such medium. The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The manufacturer, distributor, or retailer shall send this notice to the Division of Drug Marketing, Advertising, and Communications, 5600 Fishers Lane (HFD-40), rm. 17B-20, Rockville, MD 20857.

(b) No outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, may be placed within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., a public park with equipment such as swings and seesaws, baseball diamonds, or basketball courts), elementary school, or secondary school.

(c) This subpart D does not apply to cigarette or smokeless tobacco package labels.

#### § 897.32 Format and content requirements for labeling and advertising.

(a) Except as provided in paragraph (b) of this section, each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self-service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer,

distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

(1) Audio format shall be limited to words only with no music or sound effects.

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

(c) Each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, advertising permitted under this subpart D, shall include, as provided in section 502 of the act, the product's established name and a statement of its intended use as follows: "Cigarettes—A Nicotine-Delivery Device for Persons 18 or Older", "Cigarette Tobacco—A Nicotine-Delivery Device for Persons 18 or Older", or "Loose Leaf Chewing Tobacco", "Plug Chewing Tobacco", "Twist Chewing Tobacco", "Moist Snuff" or "Dry Snuff", whichever is appropriate for the product, followed by the words "A Nicotine-Delivery Device for Persons 18 or Older".

#### § 897.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

(a) No manufacturer and no distributor of imported cigarettes or smokeless tobacco may market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item (other than cigarettes or smokeless tobacco) or service, which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

(b) No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other than cigarettes or smokeless tobacco) to any person

purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any

brand of cigarettes or smokeless tobacco. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors,

or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

Dated: August 22, 1996.

William B. Schultz,

*Deputy Commissioner for Policy.*

David A. Kessler,

*Commissioner of Food and Drugs.*

Donna E. Shalala,

*Secretary of Health and Human Services.*

NOTE: The following Annex will not appear in the Code of Federal Regulations.

**BILLING CODE 4160-01-F**