

[a]bsent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should . . . carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.

United States v. Mid-America Dairymen, Inc., 1997-1 Trade Cas. ¶ 61,508, at 71.980 (W.D. Mo. 1997).

Accordingly, with respect to the adequacy of the relief secured by the decree, a court may not "engage in an unrestricted evaluation of what relief would best serve the public." *United States v. BNS, Inc.*, 858 F.2d 456, 462 (9th Cir. 1988), citing *United States v. Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir. 1981); see also *Microsoft*, 56 F.3d at 1460-62. Precedent requires that

the balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is "within the reaches of the public interest." More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.²

The proposed Final Judgment, therefore, should not be reviewed under a standard of whether it is certain to eliminate every anticompetitive effect of a particular practice or whether it mandates certainty of free competition in the future. Court approval of a final judgment requires a standard more flexible and less strict than the standard required for a finding of liability. "[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is within the reaches of public interest."³

This is strong and effective relief that should fully address the likely

competitive harm posed by the proposed merger.

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: March 23, 1999.

Respectfully submitted,

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated October 1, 1998, and published in the **Federal Register** on October 9, 1998 (63 FR 54490), Ansys Diagnostics, Inc., 25200 Commercentre Drive, Lake Forest, California 92630, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Phencyclidine (7471)	II
1-Piperidinocyclohexane-carbonitrile (PCC) (8603)	II
Benzoyllecgonine (9180)	II

The firm plans to manufacture the listed controlled substances to produce standards and controls for in-vitro diagnostic drug testing systems.

DEA has considered the factors in Title 21, United States Code, section 823(a) and determined that the registration of Ansys Diagnostics, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Ansys Diagnostics, Inc. on a regular basis to ensure that the company's continued registration is consistent with the public interest. These investigations have included inspection and testing of the company's physical security systems, audits of the company's records, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy

Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: March 17, 1999.

John H. King,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 97-19]

Cadiz Thrift-T Drug, Inc., Termination of Registration

On June 3, 1997, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to Cadiz Thrift-T Drug, Inc. (Respondent) of Cadiz, Kentucky, notifying it of an opportunity to show cause as to why DEA should not revoke its DEA Certificate of Registration BC5009421 pursuant to 21 U.S.C. 824(a)(1), (2) and (4), and deny any applications for renewal of such registration as a retail pharmacy pursuant to 21 U.S.C. 823(f), for reason that the pharmacy "falsified an application for registration, an owner-operator of the pharmacy was convicted of a felony related to controlled substances, and your continued registration is inconsistent with the public interest. . . ."

By letter dated June 30, 1997, Respondent filed a request for a hearing, and following prehearing procedures, a hearing was held in Nashville, Tennessee on October 29 and 30, 1997, before Administration Law Judge Gail A. Randall. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing both parties filed proposed findings of fact, conclusions of law and argument. On July 31, 1998, Judge Randall issued her Opinion and Recommended Ruling, recommending that Respondent's DEA registration be revoked, but that the revocation be stayed for three years.

On August 20, 1998 both parties filed exceptions to the Opinion and Recommended Ruling of the Administrative Law Judge. In addition, on August 20, 1998, Respondent filed a Motion to Dismiss arguing that Respondent has ceased doing business

Cong. 2d Sess. 8-9 (1974), reprinted in U.S.C.A.N. 6535, 6538.

² *Bechtel*, 648 F.2d at 666 (citations omitted)(emphasis added); see *BNS*, 858 F.2d at 463; *United States v. National Broadcasting Co.*, 449 F. Supp. 1127, 1143 (C.D. Cal. 1978); *Gillette*, 406 F. Supp. at 716. See also *Microsoft*, 56 F.3d at 1461 (whether "the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest'")(citations omitted).

³ *United States v. American Tel. and Tel Co.*, 552 F. Supp. 131, 151 (D.D.C. 1982), *aff'd sub nom. Maryland v. United States*, 460 U.S. 1001 (1983), quoting *Gillette Co.*, 406 F. Supp. at 716 (citations omitted); *United States v. Alcan Aluminum Ltd.*, 605 F. Supp. 619, 622 (W.D. Ky. 1985).

and surrendered its DEA Certificate of Registration and as a result these proceedings are moot. The Government filed its Response to Motion to Dismiss on August 25, 1998, arguing that the record is closed and any consideration of new evidence "ought to be rejected." The Government also argued that if Respondent's motion is considered it should be denied based upon a prior DEA decision. On September 10, 1998, Jude Randall transmitted the record of these proceedings to the then-Acting Deputy Administrator.

The Deputy Administrator concludes that it is proper to consider Respondent's Motion to Dismiss since it was filed before the record was transmitted to him and because it raises the issue of whether there is even a viable DEA registration capable of revocation in this matter. Accordingly, the Deputy Administrator has considered the record in its entirety, including Respondent's Motion to Dismiss and the Government's response thereto, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth.

Respondent was issued DEA Certificate of Registration BC5009421 on August 23, 1996. On June 30, 1997, DEA issued Respondent an Order to Show Cause proposing to revoke its DEA registration. Specifically, the Order to Show Cause alleged that:

1. On July 27, 1993, [Respondent] renewed its DEA registration, AC1370597, as a retail pharmacy at a registration location of 11 Hospital Street, Cadiz, Kentucky. The registrant held Kentucky Pharmacy permit #P01465. At that time, David C. Smith was the chief pharmacist, as well as a co-owner and corporate president.

2. On August 4, 1994, the DEA Louisville Resident Office conducted an inspection of the records of [Respondent], owned and operated by David C. Smith. The audit revealed that there were shortages and overages of Schedule II, III, and IV controlled substances. Such discrepancies indicate a failure to keep complete and accurate records in violation of 21 CFR 1304-21.

3. On or about September 15, 1994, David C. Smith admitted to an inspector of the Kentucky Board of Pharmacy that the pharmacy had dispensed or refilled prescriptions for patients without physician authorization.

4. On or about November 16, 1994, the Kentucky Board of Pharmacy entered an *Agreed Order* suspending the pharmacist's license of David C. Smith for three months.

5. Pursuant to an *Information* before the United States District Court for the Western District of Kentucky, David C. Smith was charged with two counts of distributing the Schedule IV controlled substances Xanax and propoxyphene on May 20, 1993, in violation of 21 U.S.C. 841(a)(1). On or about July 19, 1996, David C. Smith entered a plea

agreement with the United States Attorney, agreeing to plead guilty to both felony counts.

6. Thomas C. Smith submitted, on behalf of [Respondent], an application for a DEA registration as a retail pharmacy dated July 30, 1996. The registered location was designated as 11 Hospital Street, Cadiz, Kentucky. The applicant indicated that it held Kentucky Pharmacy permit #P01465. Thomas C. Smith is a co-owner and corporate officer, and the father of David C. Smith. The DEA subsequently issued registration number BC5009421 to [Respondent].

7. The July 30, 1996, application contained a material falsification by indicating "no" to a question which asked, in part, "has any officer, partner, stockholder or proprietor... ever had a State professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation." The corporation and its officers knew that on or about November 16, 1994, the Kentucky Board of Pharmacy entered an *Agreed Order* suspending the pharmacist's license of David C. Smith, President and chief pharmacist of [Respondent], for three months.

8. [Respondent's] Certificate of Registration, AC1370597, expired on August 31, 1996, and was not renewed.

9. On or about September 2, 1996, [Respondent] submitted information to the Kentucky Pharmacy Board indicating a "change in ownership." As a result, Kentucky Pharmacy permit #P01465 was "closed" and a new Kentucky Pharmacy permit #06246 was issued to [Respondent]. The DEA was not notified in accordance with the requirements of 21 CFR § 1307.14.

10. On November 25, 1996, David C. Smith, pursuant to the earlier plea agreement, was sentenced to two years probation by the United States District Court for the Western District of Kentucky.

11. [Respondent] has continued to employ David C. Smith as pharmacist-in-charge in violation of 21 CFR 1301.76(a).

Following a hearing regarding the allegations raised in the Order to Show Cause, Judge Randall issued her Opinion and Recommended Ruling on July 31, 1998, recommending that Respondent's registration be revoked but that the revocation be stayed for three years upon the condition that David Smith not be allowed to work in Respondent pharmacy without a DEA waiver of 21 CFR 1301.76(a).

Subsequently, on August 20, 1998, Respondent filed a Motion to Dismiss with attachments indicating that Respondent was sold on May 24, 1998 and its DEA Certificate of Registration was surrendered to DEA. Respondent argued that these proceedings are moot since Respondent pharmacy is no longer in business and is not using the DEA registration that is the subject of these proceedings. In its response to Respondent's motion, the Government argued that "the issue regarding

Respondent's continued registration is not rendered moot by any unilateral decision of Respondent's officers to discontinue their corporate form of business." The Government further argued that "once an order to show cause has been initiated, there is continued jurisdiction over a registration consistent with DEA precedent." In support of its arguments, the Government cited the case of *Park and King Pharmacy*, 52 FR 13,136 (1987), where the then-Administrator revoked the DEA registration even though the pharmacy was sold in the midst of the proceedings.¹ The then-Administrator found that a registration subject to ongoing administrative proceedings cannot be unilaterally terminated pursuant to 21 CFR 1301.62² by the registrant by discontinuing business. Specifically, the then-Administrator noted that "permitting a registrant to terminate his registration unilaterally, during the eleventh hour of a proceeding to revoke that registration, would permit the registrant to avoid any of the collateral effects of revocation and could require the Administrator to grant the individual another full evidentiary hearing should he decide to re-establish his business or professional practice and apply for a new registration shortly thereafter."

In addition, the then-Administrator found in *Park and King Pharmacy* that 21 CFR 1301.37(a)³ "effectively precludes an applicant's abrupt and unilateral termination of proceedings by requiring the Administrator's permission for withdrawal of an application at any time after issuance of the Order to Show Cause." The then-Administrator reasoned that it is the "application" and not the applicant that is the subject of the proceedings and found that it is similarly the "registration," and not the registrant who possessed it, that becomes the subject of revocation proceedings. As a result, the then-Administrator concluded that a registration cannot be withdrawn without the Administrator's prior approval.

The Government in its response to Respondent's motion also argued that Respondent did not "surrender" its DEA registration but merely tendered it to

¹ In *Park and King Pharmacy*, the pharmacy's DEA registration also expired during the proceedings, however that aspect of the case will not be discussed here since it is not relevant to the issues in this proceeding.

² At the time of the decision in *Park and King Pharmacy* the provision regarding the termination of a registration was found in 21 CFR 1301.62. That provision has since been renumbered and can now be found in 21 CFR 1301.52.

³ This provision has since been renumbered as 21 CFR 1301.16(a).

DEA for retirement, "and that no action has been taken, nor is any action contemplated . . . for reason that Respondent's registration record currently has an administrative code "O" placed on it, which forecloses all administrative action pending the outcome of a show cause proceeding. Accordingly, DEA has not accepted this tender."

The Deputy Administrator agrees with the Government that the chronology of this case is similar to that of *Park and King Pharmacy*. Respondent was sold after the Order to Show Cause was issued. Therefore, according to the decision in *Park and King Pharmacy*, Respondent's registration should not be considered terminated and should be capable of revocation. However, the Deputy Administrator is troubled by the decision in *Park and King Pharmacy*. The Deputy Administrator can find nothing in the statute or regulations nor any other notice to the public that a registration does not terminate upon the sale of a pharmacy if an Order to Show Cause has been issued. Pursuant to 21 CFR 1301.16, permission is needed to amend or withdraw an application once an Order to Show Cause has been issued, but there is no similar provision regarding a registration. Therefore, no permission is needed to terminate a registration. In fact, 21 CFR 1301.52(a) specifically states that, "the registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice." (emphasis added)

The Deputy Administrator recognizes the then-Administrator's concerns in *Park and King Pharmacy* that to permit termination after an Order to Show Cause has been issued allows a registrant to avoid the consequences of a revocation. However, pursuant to 21 CFR 1301.52(a) a registration automatically terminates when a pharmacy ceases legal existence or discontinues business or professional practice. The Deputy Administrator can find no authority to support the prevention of a termination, and therefore finds no authority to support the then-Administrator's conclusion in *Park and King Pharmacy* that a registration does not terminate upon the sale of a pharmacy if an Order to Show Cause has been issued.

In fact in *AML Corporation, d/b/a G & O Pharmacy, and G & O Pharmacy*, 61 Fed. Reg. 8973 (1996), decided subsequent to *Park and King Pharmacy*, the then-Deputy Administrator concluded that a pharmacy's registration terminated upon the sale of the pharmacy even though the sale

occurred in the midst of administrative proceedings regarding the registration.⁴ The then-Deputy Administrator noted "that pursuant to 21 CFR 1301.62, the transfer of ownership of G & O Pharmacy to AML effectively terminated all authority granted under DEA Certificate of Registration, AG2999691, previously issued to G & O Pharmacy."

Accordingly, the Deputy Administrator concludes that DEA Certificate of Registration BC5009421, previously issued to Cadiz Thrif/T Drug, Inc. terminated as of May 24, 1998, when it discontinued business upon its sale to Hospital Street Pharmacy, Inc. Therefore there is no viable DEA Certificate of Registration capable of revocation as proposed in the June 3, 1997 Order to Show Cause. This order is effective immediately.

Dated: March 15, 1999.

Donnie R. Marshall,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Michael W. Dietz, D.D.S., Revocation of Registration

On September 23, 1998, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to Michael W. Dietz, D.D.S. (Respondent) of Cookeville, Tennessee, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration AD6561307 pursuant to 21 U.S.C. 824(a) (3) and (4), and deny any pending applications for renewal of such registration pursuant to 21 U.S.C. 823(f). Specifically, the Order to Show Cause alleged that:

"1. [Dr. Dietz'] continued registration is inconsistent with the public interest, as that term is issued in 21 U.S.C. § 823(f) and § 824(a)(4), as evidenced by, but not limited to, the following:

(a) On or about April 19, 1997, [Dr. Dietz] sold cocaine, a Schedule II controlled substance, to another person, and such sale was for no legitimate medical purpose and not in the usual course of [his] professional practice.

(b) On or about April 26, 1997, [Dr. Dietz] again sold cocaine to the same person, and such sale was for no legitimate medical purpose and not in the usual course of [his] professional practice.

(c) On or about May 7, 1997, [Dr. Dietz] and this same person used cocaine, and such use was for no legitimate medical practice and not in the usual course of [his] professional practice.

(d) On or about May 9, 1997, [Dr. Dietz] agreed to sell and attempted to deliver cocaine to this same person, and such sale and attempted deliver were for no legitimate medical purpose and not in the usual course of [his] professional practice.

2. On May 19, 1997, [Dr. Dietz] was indicted in the State of Tennessee, Putnam County, for two felony counts of unlawfully and knowingly selling cocaine, two felony counts of unlawfully and knowingly delivering cocaine, two felony counts of unlawfully and knowingly possessing cocaine with the intent to sell or deliver cocaine, two felony counts of unlawfully and knowingly conspiring to sell cocaine and one felony count of unlawfully and knowingly conspiring to possess cocaine with the intent to sell or deliver such cocaine. These criminal charges were based upon the allegations enumerated above.

3. Based upon the above events, the State of Tennessee, Department of Health, Tennessee Board of Dentistry, revoked [Dr. Dietz'] dental license, effective May 19, 1997. As a result, [Dr. Dietz is] no longer authorized by State law to handle controlled substances in the state in which [he is] registered with DEA. 21 U.S.C. § 824(a)(3).

By letter dated October 15, 1998, Respondent waived his opportunity for a hearing and submitted a written statement regarding his position on the issues raised in the Order to Show Cause. Therefore, the Deputy Administrator finds that Respondent has waived his opportunity for a hearing and hereby enters his final order in this matter based upon the investigative file and Respondent's written statement pursuant to 21 CFR 1301.43 (c) and (e) and 1301.46.

The Deputy Administrator finds that in an Order effective May 27, 1998, the State of Tennessee, Department of Health, Board of Dentistry (Board) revoked indefinitely Respondent's license to practice dentistry.¹ In his letter dated October 15, 1998, Respondent stated that "as a result of the actions taken by the Tennessee Board of Dentistry, I do not require a DEA Certificate of Registration at this time. I respectfully request a suspension of my Registration until re-licensure occurs. Respondent further stated that he "fully expect[s] re-instatement of my dental license during the spring [Board] meeting of 1999."

The Deputy Administrator finds that based upon the record before him, Respondent is not currently licensed to

⁴In that case, the Government also sought to revoke the new pharmacy's DEA registration and the proceedings were consolidated.

¹The Deputy Administrator can find no Board order revoking Respondent's dental license effective May 19, 1997, as alleged in the Order to Show Cause.