collection contact Memuna Ifedirah at 410–786–6849).

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities (PRTFs) for Individuals Under Age 21 and Supporting Regulations; *Use:* Psychiatric residential treatment facilities are required to report deaths, serious injuries and attempted suicides to the State Medicaid Agency and the Protection and Advocacy Organization. They are also required to provide residents the restraint and seclusion policy in writing, and to document in the residents' records all activities involving the use of restraint and seclusion. *Form Number:* CMS–R–306 (OMB Control Number 0938–0833); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 390; *Total Annual Responses:* 1,466,795; *Total Annual Hours:* 431,062. (For policy questions regarding this collection contact Cindy Ruff at 410–786–5916).

Dated: April 28, 2015.

William N. Parham III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–10207 Filed 4–30–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Venkata J. Reddy, University of Minnesota: Based upon the evidence and findings of an investigation report by the University of Minnesota (UMN), an investigation conducted by another Federal agency, and additional information obtained by the Office of Research Integrity (ORI) during its oversight review of the UMN investigation, ORI found that Mr. Venkata J. Reddy, former Graduate Student, Department of Chemistry, UMN, engaged in research misconduct in research that was included in grant application R01 GM095559–01A1, submitted to the National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH).

ORI found by a preponderance of the evidence that the Respondent intentionally and knowingly engaged in research misconduct by falsifying and/or fabricating data that was provided to his mentor to include in grant application R01 GM095559–01A1 submitted to NIGMS, NIH, to obtain U.S. Public Health Service (PHS) funds. Specifically, ORI found that the Respondent falsified data included in Figures 4, 9, 11, 15, and 25 in R01 GM095559–01A1 for enantiomeric excess (''ee'') to falsely show a high degree of selectivity for one enantiomer over another by a cut-and-paste method and manipulation of the instrument to give the desired result. Respondent also falsified the underlying nuclear magnetic resonance spectroscopy (NMR) data for Compound 22 reported in Figure 15 in R01 GM095559–01A1 by a cut-and-paste method to manipulate the NMR spectra and give the desired result.

Dr. Reddy has been debarred by the Federal agency with joint jurisdiction for a period of five (5) years, ending on August 26, 2018. ORI has implemented the following administrative action to coincide with the government-wide debarment:

(1) Respondent is prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

Donald Wright,

Acting Director, Office of Research Integrity.

[FR Doc. 2015–10203 Filed 4–30–15; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries

AGENCY: Office of the Secretary, HHS.

SUMMARY: Through this final recommendation, the U.S. Public Health Service (PHS) updates and replaces its 1962 Drinking Water Standards related to community water fluoridation—the controlled addition of a fluoride compound to a community water supply to achieve a concentration optimal for dental caries prevention. For these community water systems that add fluoride, PHS now recommends an optimal fluoride concentration of 0.7 milligrams/liter (mg/L). In this guidance, the optimal concentration of fluoride in drinking water is the concentration that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis. The earlier PHS recommendation for fluoride concentrations was based on outdoor air temperature of geographic areas and ranged from 0.7–1.2 mg/L. This updated guidance is intended to apply to community water systems that currently fluoridate or that will initiate fluoridation, and is based on considerations that include:

- Scientific evidence related to the effectiveness of water fluoridation in caries prevention and control across all age groups,
- Fluoride in drinking water as one of several available fluoride sources,
- Trends in the prevalence and severity of dental fluorosis, and
- Current evidence on fluid intake of children across various outdoor air temperatures.

FOR FURTHER INFORMATION CONTACT: Barbara F. Gooch, DMD, MPH, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health, 4770 Buford Highway NE., MS F–80, Atlanta, GA 30341–3717; tel. 770–488–6054; fax 770–488–6080; email <*BGooch@cdc.gov*>.

SUPPLEMENTARY INFORMATION: Because fluoridation of public drinking water systems had been demonstrated as effective in reducing dental caries, the U.S. Public Health Service (PHS) provided recommendations regarding optimal fluoride concentrations in drinking water for community water systems in 1962 (U.S. DHEW, 1962). The U.S. Department of Health and Human Services (HHS) is releasing this updated PHS recommendation because of new data that address changes in the prevalence of dental fluorosis, the relationship between water intake and outdoor temperature in children, and the contribution of fluoride in drinking water to total fluoride exposure in the United States. Although PHS recommends community water fluoridation as an effective public health intervention, the decision to fluoridate water systems is made by state and local governments.

As of December 31, 2012, the Centers for Disease Control and Prevention (CDC) estimated that approximately 200 million people in the United States were served by 12,341 community water systems that added fluoride to water or purchased water with added fluoride from other systems. For many years, nearly all of these fluoridated systems used fluoride concentrations ranging from 0.8 to 1.2 mg/L; fewer than 1% of these systems used a fluoride concentration at 0.7 mg/L (Unpublished data, Water Fluoridation Reporting System, CDC, 2010). When water systems that add fluoride implement the new PHS recommendation (0.7 mg/L), the fluoride concentration in these systems will be reduced by 0.1 to 0.5 mg/L and fluoride intake from water will decline among most people served by these systems.

It is expected that implementation of the new recommendation will lead to a reduction of approximately 25% (range: 12%–42%) in fluoride intake from drinking water alone and a reduction of approximately 14% (range: 5%–29%) in total fluoride intake. These estimates are based on intake among young children at the 90th percentile of drinking water intake for whom drinking water accounts for 40%–70% of total fluoride intake (U.S. EPA, 2010a). Furthermore, these estimates are based on a weighted mean fluoride concentration of 0.94 mg/L in systems that added fluoride (or purchased water from systems that added fluoride) in 2009 (Unpublished data, Water Fluoridation Reporting System, CDC, 2009). Community water systems that contain naturally occurring fluoride at concentrations greater than 0.7 mg/L (estimated to serve about 11 million people) will not be directly affected by the new PHS recommendation.

Under the Safe Drinking Water Act, the U.S. Environmental Protection Agency (EPA) sets standards for drinking water quality (*42 U.S.C.* 300f *et seq.* (1974)). EPA is in the process of reviewing the maximum amount of fluoride allowed in drinking water. Upon completion of its review, EPA will determine if it is appropriate to revise the drinking water standard for fluoride. Currently, the enforceable standard is set at 4.0 mg/L to protect against severe skeletal fluorosis, a rare condition in the United States (NRC, 2006; U.S. EPA, 2010b). If the EPA determines that it is appropriate to revise the standard, any revisions could affect certain community water systems that have naturally occurring fluoride. More information about EPA's existing drinking water standards for fluoride can be found at: *http://water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm.*

Recommendation

For community water systems that add fluoride to their water, PHS recommends a fluoride concentration of 0.7 mg/L (parts per million [ppm]) to maintain caries prevention benefits and reduce the risk of dental fluorosis.

Rationale

Importance of Community Water Fluoridation

Community water fluoridation is a major factor responsible for the decline in prevalence (occurrence) and severity of dental caries (tooth decay) during the second half of the 20th century (CDC, 1999). For adolescents, the prevalence of dental caries in at least one permanent tooth (excluding third molars) decreased from 90% among those aged 12–17 years in the 1960's (Kelly JE, 1975) to 60% among those aged 12–19 years in 1999–2004 (Dye B, *et al.,* 2007); during that interval, the number of permanent teeth affected by dental caries (*i.e.,* decayed, missing and filled) declined from 6.2 to 2.6, respectively. Adults also have benefited from community water fluoridation; the average number of affected teeth decreased from 18 among 35- to 44-year-old adults in the 1960s to 10 among 35- to 49-year-old adults in 1999–2004 (Kelly JE, *et al.,* 1973; Dye B, *et al.,* 2007). Although data were not age-adjusted, age groups in the 1999–2004 survey used a higher upper age limit, and both caries prevalence and number of teeth affected increased with age; thus, these comparisons may underestimate caries decline over time.

Although there have been notable declines in tooth decay, it remains one of the most common chronic diseases of childhood (U.S. DHHS, 2000; Newacheck PW *et al.,* 2000). In 2009–2010, national survey data showed that untreated dental caries among children varied by race/ethnicity and federal poverty level. About one in four children living below 100% of the federal poverty level had untreated decay (Dye BA *et al.,* 2012). Untreated tooth decay can result in pain, school absences, and poorer school performance (Lewis C, *et al.,* 2010; Detty AMR, *et al.,* 2014; Jackson SL, *et al.,* 2011; Seirawan H, *et al.,* 2012).

Systematic reviews of the scientific evidence related to fluoride have concluded that community water fluoridation is effective in decreasing dental caries prevalence and severity (McDonagh MS, *et al.,* 2000a; McDonagh MS, *et al.,* 2000b; Truman BI, *et al.,* 2002; ARCPOH 2006; Griffin SO, *et al.,* 2007; Yeung, 2008; CPSTF, 2013). Effects included significant increases in the proportion of children who were caries-free and significant reductions in the number of teeth or tooth surfaces with caries in both children and adults (McDonagh MS, *et al.,* 2000b; ARCPOH 2006; Griffin SO, *et al.,* 2007; Yeung, 2008; CPSTF, 2013). When analyses were limited to studies conducted after the introduction of other sources of fluoride, especially fluoride toothpaste, beneficial effects across the lifespan from community water fluoridation were still apparent (McDonagh MS, *et al.,* 2000b; Griffin SO, *et al.,* 2007; Slade, *et al.,* 2013).

Fluoride in saliva and dental plaque works to prevent dental caries primarily through topical remineralization of tooth surfaces (Koulourides T, 1990; Featherstone JDB, 1999). Consuming fluoridated water and beverages, and foods prepared or processed with fluoridated water, throughout the day maintains a low concentration of fluoride in saliva and plaque that enhances remineralization. Although other fluoride-containing products are available and contribute to the prevention and control of dental caries, community water fluoridation has been identified as the most cost-effective method of delivering fluoride to all members of the community regardless of age, educational attainment, or income level (CDC, 1999; Burt BA, 1989). Studies continue to find that community water fluoridation is cost-saving (Truman B, *et al.,* 2002; O'Connell JM, *et al.,* 2005; Campain AC, *et al.,* 2010; Cobiac LJ and Vos T, 2012).

Trends in Availability of Fluoride Sources

Community water fluoridation and fluoride toothpaste are the most common sources of non-dietary fluoride in the United States (CDC, 2001b). Community water fluoridation began in 1945, reaching 49% of the U.S. population by 1975 and 67% by 2012 (*http://www.cdc.gov/fluoridation/statistics/2012stats.htm; http://www.cdc.gov/nohss/FSGrowth_text.htm*). Toothpaste containing fluoride was first marketed in the United States in 1955 (USDHEW, 1980). By 1983, more than 90% of children and adolescents 5–19 years of age, and almost 70% of young children 2–4 years of age, reportedly used fluoride toothpaste (Ismail AI, *et al,* 1987). By 1986, more than 90% of young children 2–4 years of age also were reported to use fluoride toothpaste (NCHS, 1988). And by the 1990s, fluoride toothpaste accounted for more than 90 percent of the toothpaste market (Burt BA and Eklund SA, 2005). Other products that provide fluoride now include mouth rinses, dietary fluoride supplements, and professionally applied fluoride compounds. More detailed explanations of these products are published elsewhere. (CDC, 2001b; ADA, 2006; USDHHS, 2010)

More information on major sources of ingested fluoride and their relative contributions to total fluoride exposure in the United States is presented in an EPA report (U.S. EPA 2010a). To protect the majority of the population, EPA uses the 90th percentile of drinking water intake for all age groups in calculating the relative contribution for each fluoride source. The EPA definition of ''drinking water'' includes tap water ingested alone or with beverages and certain foods reconstituted in the home. Among children aged 6 months to 14 years, drinking water accounts for 40%–70% of total fluoride intake; for adults, drinking water provides 60% of total fluoride intake. Toothpaste that has been swallowed inadvertently is estimated to account for about 20 percent of total fluoride intake in very young children (1–3 years of age) (U.S. EPA 2010a). Other major contributors to total daily fluoride intake are commercial beverages and solid foods.

Dental Fluorosis

Fluoride ingestion while teeth are developing can result in a range of visually detectable changes in the tooth enamel called dental fluorosis. Changes range from barely visible lacy white markings in milder cases to pitting of the teeth in the rare, severe form. The period of possible risk for fluorosis in the permanent teeth, excluding the third molars, extends from birth through 8 years of age when the pre-eruptive maturation of tooth enamel is complete (CDC, 2001b; Massler M and Schour I, 1958; Avery, 1987). The risk for and severity of dental fluorosis depends on the amount, timing, frequency, and duration of the exposure (CDC, 2001b). When communities first began adding fluoride to their public water systems in 1945, drinking water and local foods and beverages prepared with fluoridated water were the primary sources of fluoride for most children (McClure FJ, 1943; U.S. EPA, 2010b). At that time, only a few systems fluoridated their water, minimizing the amount of fluoride contributed by processed water to commercial foods and beverages. Since the 1940s, other sources of ingested fluoride such as fluoride toothpaste (if swallowed) and dietary fluoride supplements have become available. Fluoride intake from these products, in addition to water, other beverages, and infant formula prepared with fluoridated water, have been associated with increased risk of dental fluorosis (Levy SL, *et al.,* 2010; Wong MCM, *et al.,* 2010; Ismail AI and Hasson H, 2008; Osuji OO *et al.,* 1988; Pendrys DG *et al.,* 1994; Pendrys DG and Katz RV 1989; Pendrys DG, 1995). Both the 1962 PHS recommendations and the current updated recommendation for fluoride concentration in community drinking water were set to achieve reduction in dental caries while minimizing the risk of dental fluorosis.

Results of two national surveys indicate that the prevalence of dental fluorosis has increased since the 1980s, but mostly in very mild or mild forms. Data on prevalence of dental fluorosis come from the National Health and Nutrition Examination Survey (NHANES), 1999–2004 (Beltrán-Aguilar ED, *et al.,* 2010a). NHANES assessed the prevalence and severity of dental fluorosis among people aged 6 to 49 years. Twenty-three percent (95% confidence interval [CI]: 20.1, 26.1) had dental fluorosis, of which the vast majority was very mild or mild. Approximately 2% (95% CI: 1.5, 2.5) of people had moderate dental fluorosis, and less than 1% (95% CI: 0.1, 0.4) had severe fluorosis. Prevalence of dental fluorosis that was very mild or greater was higher among young people and ranged from 41% (95% CI: 36.3, 44.9) among adolescents aged 12–15 years to 9% (95% CI: 6.1, 11.4) among adults, aged 40–49 years.

The prevalence and severity of dental fluorosis among 12- to 15-year-olds in 1999–2004 also were compared with estimates from the Oral Health of United States Children survey, 1986–1987 (USDHHS, 1989), which was the first national survey to include measures of dental fluorosis. Although these two national surveys differed in sampling and representation (household vs. schoolchildren), findings support the hypothesis that there was an increase in dental fluorosis that was very mild or greater during the time between the two surveys. In 1986–1987 and 1999–2004, the prevalence of dental fluorosis was 23% and 41%, respectively, among adolescents aged 12 to 15 years. (Beltrán-Aguilar ED, *et al.,* 2010a). Similarly, the prevalence of very mild fluorosis (17.2% and 28.5%), mild fluorosis (4.1% and 8.6%), and moderate and severe fluorosis combined (1.3% and 3.6%) among 12- to 15-year-old adolescents during 1986–1987 and 1999–2004, respectively, all showed increases. Estimates limited to severe fluorosis among adolescents in both surveys, however, were statistically unreliable because there were too few cases among survey participants examined. The higher prevalence of dental fluorosis in young people in 1999–2004 may reflect increases in fluoride exposures (intake) across the U.S. population.

Children are at risk for fluorosis in the permanent teeth from birth through 8 years of age. Adolescents who were 12–15 years of age when they participated in the national surveys of 1986–1987 and 1999–2004 would have been at risk for dental fluorosis from 1971–1983 and from 1984–2000, respectively.

By 1969, the percentage (number) of the U.S. population receiving fluoridated water was 44% (88,475,684). By 1985, this percentage (number) increased about 10 percentage points, reaching 55% (130,172,334). By 2000, this percentage (number) was 57% (161,924,080). Although the percentage point increases in more recent years appear small (2 percentage points from 1985 to 2000), it is important to note that the total size of the U.S. population also continued to expand during the time period. As a result, the 10-percentage-point increase from 1969 to 1985 reflects an increase of more than 40 million people receiving fluoridated water whereas the 2-percentage-point increase from 1985 to 2000 represents an increase of more than 30 million people.

Available data do not support additional detailed examination of changes in the percentage of children and adolescents using fluoride toothpaste. As previously described in Trends in Availability of Fluoride Sources, by 1983, more than 90% of children and adolescents, 5–19 years, and almost 70% of young children, 2–4 years of age, were reportedly using fluoride toothpaste (Ismail AI, *et al.,* 1987); by 1986 more than 90% of young children were also using fluoride toothpaste (NCHS, 1988). As mentioned, recent EPA estimates indicate that toothpaste swallowed inadvertently accounts for about 20 percent of total fluoride intake in very young children (U.S. EPA 2010a).

More information on fluoride concentrations in drinking water and the risk of severe dental fluorosis in children is presented in a report by EPA (U.S. EPA 2010b). EPA's scientific assessments considered new data on dental fluorosis and updated exposure estimates to reflect current conditions. Based on original data from a study that predated widespread water fluoridation in the United States, EPA determined that the benchmark dose for a 0.5% prevalence of severe dental fluorosis was a drinking water fluoride concentration of 2.14 mg/L, with a lower 95% CI of 1.87 mg/L (U.S. EPA 2010b). Categorical regression modeling (U.S. EPA, 2011 presentation) also indicated that the concentration of fluoride in water associated with a 1% prevalence of severe dental fluorosis decreased over time (1940–2000). These findings are consistent with an increase in exposures from other sources of fluoride and support the conclusion that a fluoride concentration in drinking water of 0.7 mg F/L would reduce the chance of dental fluorosis—especially severe dental fluorosis—in the current context of multiple fluoride sources.

The two EPA assessments of fluoride (U.S. EPA, 2010a; U.S. EPA, 2010b) responded to earlier findings of the National Research Council (NRC) of the National Academies of Science (NRC, 2006). The NRC had reviewed new data on fluoride at EPA's request and in 2006 recommended that EPA update health and exposure assessments to consider all sources of fluoride and to take into account dental effects—specifically, pitting of teeth (*i.e.,* severe dental fluorosis) in children. The NRC identified severe dental fluorosis as an adverse health effect, because pitting of the enamel compromises its protective function. The NRC's report focused on the potential for adverse effects from naturally occurring fluoride at 2–4 mg/L in drinking water; it did not examine benefits or risks that might occur at lower concentrations typically used for community water fluoridation (0.7 to 1.2 mg/L) (NRC, 2006). For this PHS recommendation, Panel scientists did review the balance of benefits and potential for unwanted effects of water fluoridation at those lower levels (U.S. EPA, 2010b).

Relationship Between Dental Caries and Fluorosis at Varying Water Fluoridation Concentrations

The 1986–1987 Oral Health of United States Children survey has been the only national survey that assessed the child's water fluoride exposure, thus allowing linkage of that exposure to measures of caries and fluorosis (USDHHS, 1989). An additional analysis of data from this survey examined the relationship between dental caries and fluorosis at varying water fluoride concentrations for children and adolescents (Heller KE, *et al.,* 1997). Findings indicate that there was a gradual decline in dental caries as fluoride content in water increased from negligible to 0.7 mg/L. Reductions plateaued at concentrations from 0.7–1.2 mg/L. In contrast, the percentage of children with at least very mild dental fluorosis increased from 13.5% (standard error [SE] = 1.9) to 41.4% (SE = 4.4) as fluoride concentrations in water increased from <0.3 mg/L to >1.2 mg/L.

In Hong Kong, a small decrease of about 0.2 mg/L in the mean fluoride concentration in drinking water in 1978 (from 0.82 mg/L to 0.64 mg/L) was associated with a detectable reduction in fluorosis prevalence by the mid-1980s, from 64% (SE = 4.1) to 47% (SE = 4.5), based on the upper right central incisor only. Across all age groups, more than 90 percent of fluorosis cases were very mild or mild (Evans RW and Stamm JW, 1991). The study did not include measures of fluoride intake. Concurrently, dental caries prevalence did not increase (Lo ECM, *et al.,* 1990). Although not fully generalizable to the current U.S. context, these findings, along with findings from the 1986–1987 survey of U.S. schoolchildren, suggest that the risk of fluorosis can be reduced and caries prevention maintained toward the lower end (*i.e.,* 0.7 mg/L) of the 1962 PHS recommendations for community water fluoridation.

Relationship of Water Intake and Outdoor Temperature Among Children and Adolescents in the United States

The 1962 PHS recommendations stated that community drinking water should contain 0.7–1.2 mg/L (ppm) fluoride, depending on the outdoor air temperature of the area. These temperature-related guidelines were based on studies conducted in two communities in California in the early 1950s. Findings indicated that a lower fluoride concentration was appropriate for communities in warmer climates because children drank more water on warm days (Galagan DJ, 1953; Galagan DJ and Vermillion JR, 1957; Galagan DJ, *et al.,* 1957). Social and environmental changes, including increased use of air conditioning and more sedentary lifestyles, have occurred since the 1950s—thus, the assumption that children living in warmer regions drink more tap water than children in cooler regions may no longer be valid (Heller, *et al.,* 1999).

Studies conducted since 2001 suggest that children's water intake does not increase with increases in outdoor air temperature (Sohn W, *et al.,* 2001; Beltrán-Aguilar ED, *et al.,* 2010b). One study conducted among children using nationally representative data from NHANES 1988–1994 did not find an association between either total or plain water intake and outdoor air temperature (Sohn W, *et al.,* 2001). Although a similar study using nationally representative data from NHANES 1999–2004 also found no association between total water intake and outdoor temperature among children or adolescents (Beltrán-Aguilar ED, *et al.,* 2010b), additional analyses of these data detected a small but statistically significant association between plain water intake and outdoor temperature (Beltrán-Aguilar ED, *et al.,* manuscript for Public Health Reports). Temperature explained less than 1% of the variation in plain water intake; thus, these findings support use of one target concentration for community water fluoridation in all temperature zones of the United States, a standard far simpler to implement than the 1962 temperature-based recommendations. In these analyses, ''plain water'' was defined as from the tap or bottled water and ''total water'' included water from or mixed with other beverages, such as juice, soda, sport drinks, and non-dairy milk, as well as water from or mixed with foods (Beltrán-Aguilar ED, *et al.,* manuscript for Public Health Reports).

Process

HHS convened a federal inter-departmental, inter-agency panel of scientists (Appendix A) to review scientific evidence relevant to the 1962 PHS Drinking Water Standards for fluoride concentrations in drinking water in the United States and to update these recommendations based on current science. Panelists included representatives from the CDC, the National Institutes of Health, the Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality, the Office of the Assistant Secretary for Health, the EPA, and the U.S. Department of Agriculture. The Panel evaluated recent systematic reviews of the effectiveness of fluoride in drinking water to prevent dental caries, as well as published reports about the epidemiology of dental caries and fluorosis in the United States and the relationship of these conditions with varying water fluoridation concentrations. The Panel also reviewed existing recommendations for fluoride in drinking water and newer data on the relationship between water intake in children and outdoor air temperature in the United States—a relationship that had served as the basis for the 1962 recommendation.

Recent systematic reviews of evidence on the effectiveness of community water fluoridation were from the Community Preventive Services Task Force (CPSTF), first published in 2001 and updated in 2013, and the Australian National Health and Medical Research Council in 2007 (Truman BI, *et al.,* 2002; CPSTF, 2013). Both reviews updated a comprehensive systematic review of water fluoridation completed by the National Health Service Centre for Reviews and Dissemination, University of York, in 2000 (McDonagh MS *et al.,* 2000a, McDonagh MS *et al.,* 2000b). In these reviews, estimates of fluoridation effectiveness in preventing caries were limited to children and adolescents and based on comparative studies. Random assignment of individuals usually is not feasible for studies of water fluoridation, because the intervention occurs in the community water system. Another systematic review examined the effectiveness of water fluoridation in preventing dental caries in adults. Findings were based primarily on cross-sectional studies of lifelong residents of communities with fluoridated or non-fluoridated water (Griffin SO, et al, 2007). Studies in these systematic reviews were not limited to the United States.

Panel scientists accepted an extensive review of fluoride in drinking water by the NRC (NRC, 2006) as the summary of hazard. The NRC review focused on potential adverse effects of naturally occurring fluoride at 2–4 mg/L in drinking water; it found no evidence substantial enough to support effects other than severe dental fluorosis at these levels. A majority of NRC Committee members also concluded that lifetime exposure to fluoride at a drinking water concentration of 4.0 mg/L (the enforceable standard established by EPA) is likely to increase bone fracture rates in the population, compared with exposures at 1.0 mg/L (NRC, 2006). Fluoride concentrations used for water fluoridation have been substantially lower than the enforceable standard EPA established to protect against severe skeletal fluorosis (USDHEW, 1962; NRC, 2006).

Conclusions of the Panel were summarized, along with their rationale, in the **Federal Register** document (USDHHS, 2011). PHS guidance is advisory, not regulatory, in nature.

Overview of Public Comments: The public comment period for the Proposed Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries lasted for 93 days; it began with publication of the **Federal Register** notice on January 13, 2011, and was extended from its original deadline of February 14, 2011, to April 15, 2011 to allow adequate time for interested organizations and members of the public to respond. Duplicate comments (*e.g.,* electronic and paper submissions from the same source) were counted as one comment. Although the 51 responses received electronically or postmarked after the deadline (midnight ET, April 15, 2011) were not reviewed, all other comments were considered carefully.

Approximately 19,300 responses were received; of these responses, approximately 18,500 (96 percent) were nearly identical to a letter submitted by an organization opposing community water fluoridation, often originating from the Web site of that organization; hereafter, these responses are called ''standard letters.'' Of the remaining 746 unique responses, 79 anecdotes described personal experiences, often citing potentially harmful effects, and 18 consisted of attachments only. Attachments to the unique submissions were examined to ensure that they addressed the recommendation, and to determine whether they supported it, opposed it as too low, or opposed it as too high. Although nearly all responses came from the general public, comments also were submitted by organizations, such as those representing dental, public health, or water supply professionals; those that advocate cessation of community water fluoridation; or commercial companies.

Of the unique responses, most opposed the recommendation as still too high and presented multiple concerns. Four CDC scientists (who did not serve on the inter-agency Federal Panel) reviewed all unique responses and used an electronic list of descriptors to categorize their contents. Comments were summarized and reported to the full Federal Panel, along with examples reflecting a range of differing opinions regarding the new recommendation. The following sections summarize frequent comments and provide the Federal Panel's response, divided into three categories: Comments that opposed the recommendation as still too high, comments that opposed the recommendation as too low to achieve prevention of dental caries, and comments that supported the recommendation. Data on the approximate numbers of comments received in support of and opposed to the new recommendation are provided for informational purposes. Responses to these comments are based primarily on conclusions of evidence-based reviews and/or expert panels that reviewed and evaluated the best available science.

Comments That Opposed the Recommendation as Too High

Nearly all submissions opposed community water fluoridation at any concentration; they stated that the new recommendation remains too high, and most asked that all fluoride be removed from drinking water. These submissions include the standard letters (~18,500) and unique responses (~700 said the new level was too high; of these ~500 specifically asked for all fluoride to be removed). Nearly all of these submissions listed possible adverse health effects as concerns specifically, severe dental fluorosis, bone fractures, skeletal fluorosis, carcinogenicity, lowered IQ and other neurological effects, and endocrine disruption.

In response to these concerns, PHS again reviewed the scientific information cited to support actions announced in January 2011 by the HHS (U.S. DHHS, 2011) and the EPA (U.S. EPA, 2010a; U.S. EPA, 2010b)—and again considered carefully whether or not the proposed recommendations and standards on fluoride in drinking water continue to provide the health benefits of community water fluoridation while minimizing the chance of unwanted health effects from too much fluoride. After a thorough review of the comments opposing the recommendation, the Federal Panel did not identify compelling new information to alter its assessment that the recommended fluoride concentration (0.7 mg/L) provides the best balance of benefit to potential harm.

Dental Fluorosis

The standard letters stated that the new recommendation would not eliminate dental fluorosis and cited its current prevalence among U.S. adolescents. In national surveys cited by the initial **Federal Register** notice, however, more than 90 percent of dental fluorosis in the United States is the very mild or mild form, most often appearing as barely visible lacy white markings or spots on the enamel (Beltrán-Aguilar, ED, *at al.,* 2010a). EPA considers the severe form of dental fluorosis, with staining and pitting of the tooth surface, as the ''adverse health effect'' to be prevented (U.S. EPA, 2010b). Severe dental fluorosis is rare in the United States, and its prevalence could not be estimated among adolescents in a national survey because there were too few cases among the survey participants examined to achieve statistical reliability (Beltrán-Aguilar, ED, et al, 2010a). The NRC review noted that prevalence of severe dental fluorosis was near zero at fluoride concentrations below 2 mg/L (NRC, 2006, p. 10). In addition, the most recent review of community water fluoridation by the Community Preventive Services Task Force concluded that ''there is no evidence that community water fluoridation results in severe dental fluorosis'' (CPSTF, 2013).

Standard letter submissions also expressed concern that infants fed formula reconstituted with fluoridated drinking water would receive too much fluoride. If an infant is consuming only infant formula mixed with fluoridated water, there may be an increased chance for permanent teeth (when they erupt at ~ age 6) to have mild dental fluorosis (ADA, 2011). To lessen this chance, parents may choose to use low-fluoride bottled water some of the time to mix infant formula, *e.g.,* bottled waters labeled as de-ionized, purified, demineralized, or distilled, and without any fluoride added after purification treatment (FDA requires the label to indicate when fluoride is added). Such guidance currently is found on the Web sites of both CDC (*http://www.cdc.gov/fluoridation/safety/infant_formula.htm*) and the American Dental Association (*http://www.mouthhealthy.org/en/az-topics/f/fluorosis.aspx*). The PHS recommendation to lower the fluoride concentration for community water fluoridation should decrease fluoride exposure during the time of enamel formation, from birth through 8 years of age for most permanent teeth (CDC, 2001b; Avery, 1987; Massler M and Schour I, 1958), and further lessen the chance for children's teeth to have dental fluorosis, while keeping the decay prevention benefits of fluoridated water.

Bone Fractures and Skeletal Fluorosis

Some unique comments (~100) cited fractures or other pathology of bone, while the standard letters expressed concern about skeletal fluorosis (*i.e.,* a bone disease caused by excessive fluoride intake for a long period of time that in advanced stages can cause pain or damage to bones and joints) and suggested that symptoms of stage II skeletal fluorosis (*i.e.,* a clinical stage associated with chronic pain) are identical to those of arthritis (*i.e.,* sporadic pain and stiffness of the joints). The NRC review found no recent studies to evaluate the prevalence of skeletal fluorosis in U.S. populations exposed to fluoride at the current maximum level of 4.0 mg/L (NRC, 2006). On the basis of existing epidemiologic literature, the NRC concluded that stage III skeletal fluorosis (*i.e.,* a clinical stage associated with significant bone or joint damage) ''appears to be a rare condition in the United States'' and stated that the committee ''could not determine whether stage II skeletal fluorosis is occurring in U.S. residents who drink water with fluoride at 4 mg/L'' (NRC, 2006).

The NRC also recommended that EPA consider additional long-term effects on bone in adults—stage II skeletal fluorosis and bone fractures—as well as the health endpoint that had been evaluated previously (*i.e.* stage III skeletal fluorosis) (NRC, 2006). In response, the EPA Dose-Response Analysis for Non-Cancer Effects noted that, although existing data were inadequate to model the relationship of fluoride exposure and its impact on bone strength, skeletal effects among adults are unlikely to occur at the fluoride intake level estimated to protect against severe dental fluorosis among children (U.S. EPA, 2010b). The EPA report concluded that exposure to concentrations of fluoride in drinking water of 4 mg/L and above appears to be positively associated with the increased relative risk of bone fractures in susceptible populations when compared with populations consuming fluoride concentrations of 1 mg/L (U.S. EPA, 2010b). Recently, a large cohort study of older adults in Sweden reported no association between long-term exposure to drinking water with fluoride concentrations up to 2.7 mg/L and hip fracture (Näsman P, *et al.,* 2013).

The fluoride intake estimated by EPA to protect against severe dental fluorosis among children during the critical period of enamel formation was determined to be ''likely also protective against fluoride-related adverse effects in adults, including skeletal fluorosis and an increased risk of bone fractures'' (U.S. EPA, 2010b). EPA compared its own risk assessments for skeletal effects with those made both by the NRC in 2006 and by the World Health Organization in 2002. EPA concluded that its own dose recommendation is protective compared with each of these other benchmarks and, thus, is ''applicable to the entire population since it is also protective for the endpoints of severe fluorosis of primary teeth, skeletal fluorosis, and increased risk of bone fractures in adults'' (U.S. EPA, 2010b).

Carcinogenicity

Some unique comments (~100) mentioned concerns regarding fluoride as a carcinogen, and the standard letters called attention to one study (Bassin, *et al.,* 2006) that reported an association between osteosarcoma (*i.e.,* a type of bone cancer) among young males and estimated fluoride exposure from drinking water, based on residence history. The study examined an initial set of cases from a hospital-based case-control study of osteosarcoma and fluoride exposure. Findings from subsequent cases (Kim, *et al.,* 2011) were published in 2011. This later study assessed fluoride exposure using actual bone fluoride concentration—a more accurate and objective measure than previous estimates based on reported fluoride concentrations in drinking water at locations in the reported residence history. The later study showed no significant association between bone fluoride levels and osteosarcoma risk (Kim, *et al.,* 2011). This finding is consistent with systematic reviews (McDonagh, 2000b; Parnell, 2009; ARCPOH, 2006, Yeung, 2008) and three recent ecological studies (Comber, *et al.,* 2011; Levy and Leclerc, 2012; Blakey K, *et al.,* 2014) that found no association between incidence of this rare cancer and the fluoride content of community water. Although study authors acknowledged the statistical and methodological limitations of ecological analyses, they also noted that their findings were consistent with the hypothesis that low concentrations of fluoride in water do not increase the risk of osteosarcoma development.

A critical review of fluoride and fluoridating agents of drinking water, accepted by the European Commission's Scientific Committee on Health and Environmental Risks (SCHER) in 2010, used a weight-of-evidence approach and concluded that epidemiological studies did not indicate a clear link between fluoride in drinking water and osteosarcoma or cancer in general. In addition, the committee found that the available data from animal studies, in combination with the epidemiology results, did not support classifying fluoride as a carcinogen (SCHER, 2010). Finally, the Proposition 65 Carcinogen Identification Committee, convened by the Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, determined in 2011 that fluoride and its salts have not clearly been shown to cause cancer (OEHHA CA, 2011).

IQ and Other Neurological Effects

The standard letters and approximately 100 unique responses expressed concern about fluoride's impact on the brain, specifically citing lower IQ in children. Several Chinese studies (Xiang, *et al.,* 2003; Lu, *et al.,* 2000; Zhao, *et al.,* 1996) considered in detail by the NRC review reported lower IQ among children exposed to fluoride in drinking water at mean concentrations of 2.5–4.1 mg/L—several times higher than concentrations recommended for community water fluoridation. The NRC found that ''the significance of these Chinese studies is uncertain'' because important procedural details were omitted, but also stated that findings warranted additional research on the effects of fluoride on intelligence (NRC, 2006).

Based on animal studies, the NRC committee speculated about potential mechanisms for nervous system changes and called for more research ''to clarify the effect of fluoride on brain chemistry and function'' (NRC, 2006). These recommendations should be considered in the context of the NRC review, which limited its conclusions regarding adverse effects to water fluoride concentrations of 2–4 mg/L and did ''not address the lower exposures commonly experienced by most U.S. citizens'' (NRC, 2006). A recent meta-analysis of studies conducted in rural China, including those considered by the NRC report, identified an association between high fluoride exposure (*i.e.,* drinking water concentrations ranging up to 11.5 mg/L) and lower IQ scores; study authors noted the low quality of included studies and the inability to rule out other explanations (Choi, *et al.,* 2012). A subsequent review cited this meta-analysis to support its identification of ''raised fluoride concentrations'' in drinking water as a developmental neurotoxicant (Grandjean and Landrigan, 2014).

A review by SCHER also considered the neurotoxicity of fluoride in water and determined that there was not enough evidence from well-controlled studies to conclude if fluoride in drinking water at concentrations used for community fluoridation might impair the IQ of children (SCHER, 2010). The review also noted that ''a biological plausibility for the link between fluoridated water and IQ has not been established'' (SCHER, 2010). Findings of a recent prospective study of a birth cohort in New Zealand did not support an association between fluoride exposure, including residence in an area with fluoridated water during early childhood, and IQ measured repeatedly during childhood and at age 38 years (Broadbent, *et al.,* 2014).

Endocrine Disruption

All of the standard letters and some of the unique comments (~100) expressed concern that fluoride disrupts endocrine system function, especially for young children or for individuals with high water intake. The 2006 NRC review considered a potential association between fluoride exposure (2–4 mg/L) and changes in the thyroid, parathyroid, and pineal glands in experimental animals and humans (NRC, 2006). The report noted that available studies of the effects of fluoride exposure on endocrine function have limitations. For example, many studies did not measure actual hormone concentrations, and several studies did not report nutritional status or other factors likely to confound findings. The NRC called for better measurement of exposure to fluoride in epidemiological studies and for further research ''to characterize the direct and indirect mechanisms of fluoride's action on the endocrine system and factors that determine the response, if any, in a given individual'' (NRC, 2006). A review did not find evidence that consuming drinking water with fluoride at the level used in community water fluoridation presents health risks for people with chronic kidney disease (Ludlow, *et al.,* 2007).

Effectiveness of Community Water Fluoridation in Caries Prevention

In addition to citing potential adverse health effects, the standard letters stated that the benefits of community water fluoridation have never been documented in any randomized controlled trial. There are no randomized, double-blind, controlled trials of water fluoridation because its community-wide nature does not permit randomization of individuals to study and control groups or blinding of participants. However, community trials have been conducted, and these studies were included in systematic reviews of the effectiveness of community water fluoridation (McDonagh, *et al.,* 2000b; Truman BI, *et al.,* 2002; CPSTF, 2013). As noted, these reviews of the scientific evidence related to fluoride have concluded that community water fluoridation is effective in decreasing dental caries prevalence and severity.

Standard letters also stated that African-American and low-income children would not be protected by the recommendation, as they have experienced more tooth decay than other racial/ethnic groups, despite exposure to fluoride through drinking water and other sources. Data from the NHANES (Dye B, *et al.,* 2007) do not support this statement and, instead, document a decline in the prevalence and severity of dental caries (tooth decay) across racial/ethnic groups. For example, in 1999–2004, compared with 1988–1994, the percentage of adolescents aged 12–19 years who had experienced dental caries in their permanent teeth, by race/ethnicity, was 54% in African-American (down from 63%), 58% in non-Hispanic white (down from 68%), and 64% in Mexican-American (down from 69%) adolescents (Dye B, *et al.,* 2007). For adolescents whose family income was less than 100% of the federal poverty level, a similar decline occurred: 66% had experienced dental caries in 1999–2004, down from 72% in 1988–1994. Although disparities in caries prevalence among these adolescent groups remain, the prevalence for each group was lower in 1999–2004 than in 1988–1994. Concurrent with these reductions in the prevalence of dental caries, the percentage (number) of the U.S. population receiving fluoridated water increased from 56% (144,217,476) in 1992 to 62% (180,632,481) in 2004 (*http://www.cdc.gov/nohss/fsgrowth.htm).* This change represented an increase of more than 36 million people.

Cost-Effectiveness of Community Water Fluoridation

Some unique comments (~200) called attention to the cost of water fluoridation or stated that it was unnecessary or inefficient given the availability of other fluoride modalities and the amount of water used for purposes other than drinking. Cost-effectiveness studies that included costs incurred in treating all community water with fluoride additives still found fluoridation to be cost-saving (Truman, *et al.,* 2002, Griffin, *et al.,* 2001). Although the annual per-person cost varies by size of the water system (from $0.50 in communities of 20,000 or more to $3.70 for communities of 5,000 or fewer, updated to 2010 dollars using the Consumer Price Index [CPI]), it remains only a fraction of the cost of one dental filling. The annual per person cost savings for those aged 6 to 65 years ranged from $35.90 to $28.70 for larger and smaller communities, respectively (Griffin, *et al.,* 2001, updated to 2010 dollars using CPI-dental services). Studies in the United States and Australia also have documented the cost-effectiveness of community water fluoridation (Truman BI, *et al.,* 2002; O'Connell JM *et al.,* 2005; Campain AC *et al.,* 2010; Cobiac LJ and Vos T, 2012).

Safety of Fluoride Additives

Unique comments (~300) expressed concern that fluoride is poison and an industrial waste product; standard letters noted the lack of specific data on the safety of silicofluoride compounds used by many water systems for community water fluoridation. All additives used to treat water, including those used for community water fluoridation, are subject to a system of standards, testing, and certification involving participation of the American Water Works Association, NSF International, and the American National Standards Institute (ANSI)—entities that are nonprofit, nongovernmental organizations. Most states require that water utilities use products that have been certified against *ANSI/NSF Standard 60: Drinking Water Treatment Chemicals—Health Effects* (hereinafter, Standard 60) by an ANSI-accredited laboratory (U.S. EPA, 2000). All fluoride products evaluated against Standard 60 are tested to ensure that the levels of regulated impurities present in the product will not contribute to the treated drinking water more than 10% of the corresponding Maximum Contaminant Level (MCL) established by EPA for that contaminant (U.S. EPA, 2000). Results from 2000–2011, reported on the NSF International Web site (*http://www.nsf.org/newsroom_pdf/NSF_Fact_Sheet_on_Fluoridation.pdf)* found that no contaminants exceeded the concentration allowed by Standard 60.

Although commenters expressed concerns about silicofluorides, studies have shown that these compounds achieve virtually complete dissolution and ionic disassociation at concentrations added to drinking water and thus, are comparable to the fluoride ion produced by other additives, such as sodium fluoride (Crosby, 1969; Finney, *et al;,* 2006, U.S. EPA, 2000). At the pH of drinking water, usually 6.5–8.5, and at a fluoride concentration of 1 mg/L, the degree of hydrolysis of hexafluorosilicic acid has been described as ''essentially 100%'' (U.S. EPA, 2000). Standard 60 provides criteria to develop an allowable concentration when no MCL has been established by the EPA. Using this protocol, NSF International calculations showed that a sodium fluorosilicate concentration needed to achieve 1.2 mg F/L would result in 0.8 mg/L of silicate, or about 5% of the allowable concentration calculated by NSF International. (*http://www.nsf.org/newsroom_pdf/NSF_Fact_Sheet_on_Fluoridation.pdf*).

SCHER also considered health and environmental risks associated with the use of silicofluoride compounds in community water fluoridation and concurred that in water they are rapidly hydrolyzed to fluoride, and that concentrations of contaminants in drinking water are well below guideline values established by the World Health Organization (SCHER, 2010).

Ethics of Community Water Fluoridation

All standard letters and some unique comments (~200) stated that water fluoridation is unethical mass medication of the population. To determine if a public health action that may encroach on individual preferences is ethical, a careful analysis of its benefits and risks must occur. In the case of water fluoridation, the literature offers clear evidence of its benefits in reducing dental decay (McDonagh MS, *et al.,* 2000a; McDonagh MS, *et al.,* 2000b; Truman BI, *et al.,* 2002; ARCPOH, 2006; Griffin SO, *et al.,* 2007; Yeung, 2008; CPSTF, 2013), with documented risk limited to dental fluorosis (U.S. EPA, 2010a; U.S. EPA, 2010b; McDonagh MS, *et al.,* 2000a; ARCPOH, 2006; CPSTF, 2013).

Several aspects of decision-making related to water fluoridation reflect careful analysis and lend support to viewing the measure as a sound public health intervention. State and local governments decide whether or not to implement water fluoridation, after considering evidence regarding its benefits and risks. Often, voters themselves make the final decision to adopt or retain community water fluoridation. Although technical support is available from HHS, federal agencies do not initiate efforts to fluoridate individual water systems. In addition, court systems in the United States have thoroughly reviewed legal challenges to community water fluoridation, and have viewed it as a proper means of furthering public health and welfare (*http://fluidlaw.org*).

Comments That Opposed the Recommendation as Too Low

Several unique comments said that 0.7mg/L is too low to offer adequate protection against tooth decay. Evidence, however, does suggest that 0.7 mg/L will maintain caries preventive benefits. Analysis of data from the 1986–1987 Oral Health of United States Children survey found that reductions in dental caries plateaued between 0.7–1.2 mg/L of fluoride (Heller KE *et al.,* 1997). In addition, fluoride in drinking water is only one of several available fluoride sources, such as toothpaste, mouth rinses, and professionally applied fluoride compounds.

Comments That Supported the Recommendation

Some submissions specifically endorsed lowering the concentration of fluoride in drinking water for the prevention of dental caries. Other commenters asked for guidance on the operational range for implementing the recommended concentration of 0.7 mg/L and on consistent messaging regarding the recommended change. Currently, CDC is reviewing available data and collaborating with organizations of water supply professionals to update operational guidance. In addition, CDC continues to support local and state infrastructure needed to implement and monitor the recommendation. Examples of this support include maintenance of the Water Fluoridation Reporting System; provision of training opportunities for water supply professionals; assisting state and local health agencies with health promotion and public education related to water fluoridation; and funding (in coordination with other Federal agencies, including the National Institute of Dental and Craniofacial Research) for research and surveillance activities related to dental caries, dental fluorosis, and fluoride intake.

Monitoring Implementation of the New Recommendation

Unpublished data from the Water Fluoridation Reporting System show how rapidly the proposed change in recommended concentration has gained acceptance. In December 2010, about 63% of the population on water systems adjusting fluoride (or buying water from such systems) was at 1.0 mg/L or greater and fewer than 1% at 0.7 mg/L. By summer 2011, only 6 months after publication of the draft notice, 68% of that population was at 0.7 mg/L and about 28% was at 1.0 mg/L or greater.

Following broad implementation of the new recommendation, enhanced surveillance during the next decade will detect changes in the prevalence and severity of dental caries and of dental fluorosis that is very mild or greater, nationally and for selected socio-demographic groups. For example, the 2011–2012 NHANES included clinical examination of children and adolescents by dentists to assess decayed, missing and filled teeth; presence of dental sealants; and dental fluorosis. The 2013–2014 examination added fluoride content of home water (assessed using water taken from a faucet in the home), residence history (needed to estimate fluoride content of home tap water for each child since birth), and questions on use of other fluoride modalities (*e.g.,* toothpaste, prescription drops, and tablets). As findings from these and future examinations become available, they can be accessed through the CDC Web site (*http://www.cdc.gov/nchs/nhanes/nhanes_products.htm*).

Definitive evaluation of changes in dental fluorosis prevalence or severity, associated with reduction in fluoride concentration in drinking water, cannot occur until permanent teeth erupt in the mouths of children who drank that water during the period of tooth development. HHS agencies continue to give priority to the development of valid and reliable measures of fluorosis, as well as technologies that could assess individual fluoride exposure precisely. A recent study documented the validity of fingernail fluoride concentrations at age 2–7 years as a biomarker for dental fluorosis of the permanent teeth at age 10–15 years (Buzalaf MA, *et al.,* 2012).

Summary and Conclusions

PHS acknowledges the concerns of commenters and appreciates the efforts of all who submitted responses to the **Federal Register** notice describing its recommendation to lower the fluoride concentration in drinking water for the prevention of dental caries. The full Federal Panel considered these responses in the context of best available science but did not alter its recommendation that the optimal fluoride concentration in drinking water for prevention of dental caries in the United States should be reduced to 0.7 mg/L, from the previous range of 0.7–1.2 mg/L, based on the following information:

- Community water fluoridation remains an effective public health strategy for delivering fluoride to prevent tooth decay and is the most feasible and cost-effective strategy for reaching entire communities.
- In addition to drinking water, other sources of fluoride exposure have contributed to the prevention of dental caries and an increase in dental fluorosis prevalence.
- Caries preventive benefits can be achieved and the risk of dental fluorosis reduced at a fluoride concentration of 0.7 mg/L.
- Recent data do not show a convincing relationship between water intake and outdoor air temperature. Thus, recommendations for water fluoride concentrations that differ based on outdoor temperature are unnecessary.

Surveillance of dental caries, dental fluorosis, and fluoride intake will monitor changes that might occur, following implementation of the recommendation.

Dated: April 24, 2015.

Sylvia M. Burwell,

Secretary.

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Appendix A—HHS Federal Panel on Community Water Fluoridation

Peter Briss, MD, MPH—Panel Chair, Medical Director, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

William Bailey, DDS, MPH (*former Panel member*), Acting Director (2011–2013), Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

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Leila T. Beker, Ph.D., RD, Interdisciplinary Scientist, Infant Formula and Medical Foods Review Team, Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services

Eugenio Beltrán-Aguilar, DMD, MPH, DrPH (*former Panel member*), Senior Epidemiologist, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Mary Beth Bigley, DrPH, MSN, ANP (*former Panel member*), Acting Director, Office of Science and Communications, Office of the Surgeon General, U.S. Department of Health and Human Services

Linda Birnbaum, Ph.D., DABT, ATS, Director, National Institute of Environmental Health Sciences and National Toxicology Program, National Institutes of Health, U.S. Department of Health and Human Services

John Bucher, Ph.D., Associate Director, National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, U.S. Department of Health and Human Services

Amit Chattopadhyay, PhD. *(former Panel member)*, Epidemiologist, Office of Science and Policy Analysis, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services

Joyce Donohue, Ph.D., Health Scientist, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency

Elizabeth Doyle, Ph.D., Chief, Human Health Risk Assessment Branch, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency

Isabel Garcia, DDS, MPH, Deputy Director, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services

Barbara Gooch, DMD, MPH, Associate Director for Science, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Jesse Goodman, MD, MPH, Chief Scientist and Deputy Commissioner for Science and Public Health, Food and Drug Administration, U.S. Department of Health and Human Services

J. Nadine Gracia, MD, MSCE *(former Panel member)*, Chief Medical Officer (2009–2011), Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Susan O. Griffin, Ph.D., Health Economist, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Laurence Grummer-Strawn, Ph.D., Chief, Maternal and Child Nutrition Branch, Division of Nutrition, Physical Activity, and Obesity, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Jay Hirschman, MPH, CNS, Director, Special Nutrition Staff, Office of Research and Analysis, Food and Nutrition Service, U.S. Department of Agriculture

Frederick Hyman, DDS, MPH, Dental Officer, Division of Dermatology and Dental Products, Center for Drug Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services

Timothy Iafolla, DMD, MPH, Supervisory Science Policy Analyst, Office of Science and Policy Analysis, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services

William Kohn, DDS *(former Panel member)*, Director (2010–11), Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services
Arlene M. Lester, DDS, MPH, CAPT, United States Public Health Service, Regional Minority Health Consultant, Office of the Secretary, US Department of Health and Human Services
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Richard Manski, DDS, MBA, Ph.D., Senior Scholar, Center for Financing, Access and Cost Trends, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services
Ana Maria Osorio, MD, MPH, Senior Advisor for the Public Health Service, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services
Benson Silverman, MD *(former panel member, deceased)*, Staff Director, Infant Formula and Medical Foods, Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services
Thomas Sinks, Ph.D., Deputy Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the Presidential Commission for the Study of Bioethical Issues

AGENCY: Presidential Commission for the Study of Bioethical Issues, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues (the Commission) will conduct its twenty-first meeting on May 27, 2015. At this meeting, the Commission will discuss the role of deliberation and deliberative methods to engage the public and inform debate in bioethics, and how to integrate pubic dialogue into the bioethics conversation; bioethics education as a forum for fostering deliberative skills, and preparing students to participate in public dialogue in bioethics; goals and methods of bioethics education; and integrating bioethics education across a range of professional disciplines and educational levels.

DATES: The meeting will take place Wednesday, May 27, 2015, from 9 a.m. to approximately 5 p.m.

ADDRESSES: University of Pennsylvania Henry Jordan Medical Education Center, 5th Floor Lobby, 3400 Civic Center Boulevard, Philadelphia, PA 19104.

FOR FURTHER INFORMATION CONTACT: Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005. Telephone: 202–233–3960. Email: *Hillary.Viers@bioethics.gov.* Additional information may be obtained at *www.bioethics.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act of 1972, Public Law 92–463, 5 U.S.C. app. 2, notice is hereby given of the twenty-first meeting of the Commission. The meeting will be open to the public with attendance limited to space available. The meeting will also be webcast at *www.bioethics.gov.*

Under authority of E. O. 13521, dated November 24, 2009, the President established the Commission. The Commission is an expert panel of not more than 13 members who are drawn from the fields of bioethics, science, medicine, technology, engineering, law, philosophy, theology, or other areas of the humanities or social sciences. The Commission advises the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Commission seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.

The main agenda items for the Commission's twenty-first meeting are to discuss the role of deliberation and deliberative methods to engage the public and inform debate in bioethics, and how to integrate pubic dialogue into the bioethics conversation; bioethics education as a forum for fostering deliberative skills, and preparing students to participate in public dialogue in bioethics; goals and methods of bioethics education; and integrating bioethics education across a range of professional disciplines and educational levels. The draft meeting agenda and other information about the Commission, including information about access to the webcast, will be available at *www.bioethics.gov.*

The Commission welcomes input from anyone wishing to provide public comment on any issue before it. Respectful debate of opposing views and active participation by citizens in public exchange of ideas enhances overall public understanding of the issues at hand and conclusions reached by the Commission. The Commission is particularly interested in receiving comments and questions during the meeting that are responsive to specific sessions. Written comments will be accepted at the registration desk and comment forms will be provided to members of the public in order to write down questions and comments for the Commission as they arise. To accommodate as many individuals as possible, the time for each question or comment may be limited. If the number of individuals wishing to pose a question or make a comment is greater than can reasonably be accommodated during the scheduled meeting, the Commission may make a random selection.

Written comments will also be accepted in advance of the meeting and are especially welcome. Please address written comments by email to *info@bioethics.gov,* or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, should notify Esther Yoo by telephone at (202) 233–3960, or email at *Esther.Yoo@bioethics.gov* in advance of the meeting. The Commission will make every effort to accommodate persons who need special assistance.

Dated: April 22, 2015.

Lisa M. Lee,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.