Thu Sep 18 13:15:12 EDT 2014
Wachter.Eric@epamail.epa.gov
FW: FOR YOUR REVIEW - HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries - Comments requested by COB, Tuesday, September 30
To: CMS.OEX@epamail.epa.gov; Gaines.Cynthia@epamail.epa.gov

From: Wagner, Debra (CDC/OD/OCS) [mailto:dgx3@cdc.gov]
Sent: Wednesday, September 17, 2014 2:17 PM
To: East, Janet (HHS/OASH); Brewer, Ann (NIH/OD) [E]; Varnado, Martina (FDA/OC); Perry, Wendy (AHRQ); sally.liska@osec.usda.gov; Wachter, Eric
Cc: Malliou, Ekaterini (OS/IOS); Cox, Pamela J. (CDC/OD/OCS)
Subject: FOR YOUR REVIEW - HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries - Comments requested by COB, Tuesday, September 30

Good afternoon everyone,

CDC is requesting that you review the attached document "HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries" and provide any comments by COB, Tuesday, September 30. We intend to publish the recommendations in Public Health Reports. The recommendations are currently written in a regulation format that is used by the Federal Register. The format will be adjusted when the recommendations are submitted to Public Health Reports for publication. We do intend to publish a Federal Register Notice announcing the new recommendations when they are published. These recommendations have gone through the external peer review process. I can provide the responses to the peer review comments if you would like to review them.

Appendix A lists the members of the HHS Federal Panel on Community Water Fluoridation. This panel was involved in the drafting of the recommendations. This may help in your review.

If you have any concerns about the recommendations and would like to discuss with CDC, please contact me and we can arrange a conference call to discuss any issues.

Janet – would you please pass this to the Office of the Surgeon General for review? I don't have a contact for them.

Summary of the recommendation: Through this final recommendation, the Department of Health and Human Services (HHS) updates and replaces the 1962 U.S. Public Health Service Drinking Water Standards related to recommendations for fluoride concentrations in drinking water to prevent dental caries. HHS now recommends that community water systems adjust the amount of fluoride to 0.7 mg/L to achieve an optimal fluoride level. For the purpose of this guidance, the optimal concentration of fluoride in drinking water is that concentration that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis. The earlier U.S. Public Health Service recommendations for fluoride concentrations were based on ambient outdoor air temperature of geographic areas and ranged from 0.7–1.2 mg/L. Community water fluoridation is the adjusting and monitoring of fluoride in drinking water to reach the optimal concentration (Truman BI, *et al.*, 2002).

This updated guidance is intended to apply to community water systems that are currently fluoridating or will initiate fluoridation, and is based on considerations that include:

- Scientific evidence related to 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.
- Current evidence on fluid intake of children across various outdoor air temperatures.

Thanks

Debra

Debra Wagner, MSPH

LCDR, USPHS

Management/Program Analyst

Division of Executive Secretariat

Office of the Chief of Staff

Centers for Disease Control and Prevention

1600 Clifton Road NE, MS D-14

Atlanta, GA 30329

404-639-1267

billing code: [CAN 9213242]

department of health and human services

HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: Through this final recommendation, the Department of Health and Human Services (HHS) updates and replaces the 1962 U.S. Public Health Service Drinking Water Standards related to recommendations for fluoride concentrations in drinking water to prevent dental caries. HHS now recommends that community water systems adjust the amount of fluoride to 0.7 mg/L to achieve an optimal fluoride level. For the purpose of this guidance, the optimal concentration of fluoride in drinking water is that concentration that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis. The earlier U.S. Public Health Service recommendations for fluoride concentrations were based on outdoor air temperature of geographic areas and ranged from 0.7?1.2 mg/L. Community water fluoridation is the adjusting and monitoring of fluoride in drinking water to reach the optimal concentration (Truman BI, *et al.*, 2002).

This updated guidance is intended to apply to community water systems that are currently fluoridating or will initiate fluoridation, and is based on considerations that include:

? Scientific evidence related to 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.

? Current evidence on fluid intake of children across various outdoor air temperatures.

FOR FURTHER INFORMATION CONTACT: Barbara F. Gooch, DMD, MPH, Associate Director for Science, 770-488-6054, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention, 4770 Buford Highway, NE, MS F-80, Atlanta, GA 30341-3717.

SUPPLEMENTARY INFORMATION:

Because fluoridation of public drinking water systems had been demonstrated as effective in reducing dental caries, the U.S. Public Health Service provided recommendations regarding optimal fluoride concentrations in drinking water for community water systems (CWS) in 1962 (U.S. DHEW, 1962). HHS is updating and replacing these recommendations because of new data that address changes in the prevalence of dental fluorosis, the relationship between outdoor temperature and fluid intake in children, and the contribution of fluoride in drinking water to total fluoride exposure in the United States. As of December 31, 2012, the Centers for Disease Control and Prevention (CDC) estimated that approximately 200 million people were served by 12,341 community water systems that added fluoride to water or purchased water with added fluoride from other systems. In December 2010 (prior to publication of the proposed change in the recommended concentration), unpublished data from the Water Fluoridation Reporting System found that less than 1% of these community water systems had a fluoride concentration at 0.7 mg/L, When water systems implement the new HHS recommendation (0.7 mg/L), the recommended fluoride concentration in adjusted systems will be reduced by 0.1 to 0.5 mg/L and fluoride intake from water will decline among most persons served by these systems.

It is expected that implementation of the new recommendation will lead to a reduction of

approximately 25% (range: 12% to 42%) in fluoride intake from drinking water alone and a reduction of approximately 14% (range: 5% to 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). Further, these estimates are based on a weighted mean fluoride concentration of 0.94 mg/L in adjusted systems (including those purchasing water from adjusted systems) in 2009 (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 HHS recommendation. The U.S. Environmental Protection Agency (EPA) is in the process of reviewing the maximum amount of fluoride allowed in drinking water. Upon completion of its review, EPA will determine whether it is appropriate to revise the drinking water standard for fluoride. Currently, this enforceable standard is set at 4.0 mg/L to protect against exposure to too much fluoride. If the EPA determines that it is appropriate to revise these standards, any such revisions could impact certain community water systems that have naturally occurring fluoride. More information about EPA?s existing drinking water standards for fluoride can be found at the following EPA Web site:
http://water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm

Recommendation

HHS?recommends that community water systems that fluoridate their water adjust the fluoride concentration to 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). Comparing data from national surveys in the early 1970s and 1999-2004, the prevalence of dental caries in at least one permanent tooth (excluding third molars) among adolescents has decreased from 90% to 60% and the average number of teeth affected by dental caries (*i.e.*, decayed, missing and filled) from 6.2 to 2.6 (Kelly JE, 1975; Dye B, *et al*, 2007). Adults also have benefited from community water fluoridation. Among adults, aged 35?44 years, the average number of affected teeth decreased from 18 in the early 1960s to 10 among adults, aged 35?49 years, in 1999-2004 (Kelly JE, *et al*, 1967; Dye B, *et al*, 2007). 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).

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; ANHMRC 2007; 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 works to prevent dental caries primarily through topical remineralization of tooth surfaces when small amounts of fluoride, specifically in saliva and accumulated plaque, are present frequently in the mouth (Koulouirides T, 1990; Featherstone JDB, 1999). Consuming fluoridated water and beverages and foods prepared or processed with fluoridated water routinely introduces a low concentration of fluoride into the mouth. 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, and almost 70% of young children, 2 ? 4 years,

children and adolescents, 5 ? 19 years, and almost 70% of young children, 2 ? 4 years, reportedly used fluoride toothpaste (Ismail AI, *et al,* 1987). By 1986, more than 90% of young children, 2 ? 4 years, also were reported to use fluoride toothpaste (NCHS, 1988). 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 all sources of fluoride and their relative contribution to total fluoride exposure in the United States is presented in a report by EPA (U.S. EPA 2010a). In order to protect the majority of the population, EPA uses the 90th percentile of drinking water intake for all age groups. Among children ages 6 months to 14 years, drinking water accounts for 40% to 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) (U.S. EPA 2010a, page 102). Other major contributors to total daily fluoride intake are commercial beverages and solid foods (including milk and non-reconstituted fruit juice).

Dental Fluorosis

Fluoride ingestion while teeth are developing can result in a range of visually detectable changes in the tooth enamel (Aoba T and Fejerskov O, 2002) 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 about 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, appendix D). At that time, only a few systems fluoridated their water, minimizing the amounts 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 and 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 USPHS 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 the very mild or mild forms. Data on prevalence of dental fluorosis come from the National Health and Nutrition Examination Survey (NHANES), 1999?2004 (Beltr?n-Aguilar ED, *et al*, 2010a). NHANES assessed the prevalence and severity of dental fluorosis among persons aged 6 to 49 years. Twenty-three percent had dental fluorosis, of which the vast majority was very mild or mild. Approximately 2% (95% CI: 1.45, 2.47) of persons had moderate dental fluorosis, and

Approximately 2% (95% CI: 1.45, 2.47) of persons had moderate dental fluorosis, and less than 1% (95% CI: 0.1, 0.4) had severe fluorosis. Prevalence was higher among younger persons 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?15 year olds in 1999?2004 also were compared to estimates from the Oral Health of United States Children Survey, 1986?87 (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 versus schoolchildren), findings support the hypothesis that there has been an increase in dental fluorosis that was very mild or greater between the two surveys. In 1986?87 and 1999?2004 the prevalence of dental fluorosis was 23% and 41%, respectively, among adolescents aged 12 to 15. (Beltr?n-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%) have increased. Estimates limited to severe fluorosis among adolescents in both surveys, however, were statistically unreliable because of too few cases in the samples.

The higher prevalence of dental fluorosis in younger persons in 1999-2004 probably reflects the increase in fluoride exposures (intake) across the U.S. population, primarily through community water fluoridation and increased use of fluoride toothpaste.

Children are at risk for fluorosis in the permanent teeth from birth through 8 years of age. Adolescents who were 12 ? 15 years when they participated in the national surveys of 1986-87 and 1999-2004 would have been at risk for dental fluorosis from 1971 ? 1983 and from 1984 - 2000, respectively. While the percentage (number) of the US population

and from 1984 - 2000, respectively. While the percentage (number) of the US population receiving fluoridated water increased from 29% (56,069,100) to 44% (88,475,684) in the 5-year period between 1964 to 1969, the rate of expansion was slower thereafter when children in these national surveys were at risk.
http://www.cdc.gov/nohss/fsgrowth.htm

By 1985, the percentage (number) of the US population receiving fluoridated water reached 55% (130,172,334); an increase of about 10 percentage points since 1969. By 2000 this percentage (number) was 57%, (161,924,080); an increase of just 2 percentage points since 1985. Although the percentage point increases in more recent years appear small, it is important to note that the total size of the U.S. population also continued to expand. Small percentage point changes reflect increases of more than 40 million people receiving fluoridated water from 1969 to 1985 and more than 30 million from 1985 to 2000.

Available data do not support detailed examination of changes in the percent of the children and adolescents using fluoride toothpaste. As 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, were reportedly using fluoride toothpaste (Ismail AI, *et al*, 1987) and by 1986 more than 90% of young children were also using fluoride toothpaste (NCHS, 1988). 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, page 102).

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

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% Confidence Interval of 1.87 mg/L (US EPA 2010b, p. 93). 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. These findings are consistent with an increase in exposures from other sources of fluoride and support the HHS Panel conclusion that a drinking water concentration 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.

EPA assessments of fluoride (U.S. EPA, 2010a; US EPA, 2010b) responded to findings of the National Research Council (NRC) of the National Academies of Science (NRC, 2006). At EPA?s request, the NRC had reviewed new data on fluoride published since its previous report (NRC 1993) and issued a 2006 report recommending update of EPA 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?s report focused on the potential for adverse effects from naturally occurring fluoride at 2 to 4 mg/L in drinking water, and did not examine benefits or risks that might occur at lower concentrations of fluoride used for community water fluoridation (0.7 to 1.2 mg/L) (NRC, 2006, p. 11). For its recommendation, HHS 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

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 aged 6 to 17 years (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 to 1.2 mg/L. In contrast, the percentage of children with at least very mild dental fluorosis increased with increasing fluoride concentrations in water. The published report did not report standard errors.

In Hong Kong a small decrease of about 0.2 mg/L in the mean fluoride concentration in drinking water in 1978 was associated with a detectable reduction in fluorosis prevalence by the mid-1980s (Evans RW and Stamm JW, 1991). 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 those from the 1986?1987 survey of U.S. schoolchildren, suggest that risk of fluorosis can be reduced and caries prevention maintained toward the lower end (*i.e.*, 0.7 mg/L) of the 1962 USPHS recommendations for fluoride concentrations of community water systems.

Relationship of Fluid Intake and Outdoor Temperature among Children and Adolescents in the United States:

in the United States:

The 1962 USPHS 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—and 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; Beltr?n-Aguilar ED, *et al*, 2010b). One study conducted among children using nationally representative data from 1988 to 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 1999 to 2004 also found no association between total water intake and outdoor temperature among children or adolescents (Beltr?n-Aguilar ED, *et al*, 2010b), additional analyses of these data detected a statistically significant but small association between plain water intake and outdoor temperature (Beltr?n-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.

Process

The U.S. Department of Health and Human Services (HHS) convened a federal inter-departmental, inter-agency panel of scientists (Appendix A) to review scientific evidence relevant to the 1962 USPHS 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 Centers for Disease Control and Prevention, the National Institutes of Health, the Food and Drug Administration, the Agency for Healthcare Research and Quality, the Office of the Assistant Secretary for Health, the U.S. Environmental Protection Agency, 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 U.S. 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 U.S. This relationship had formed the basis for the 1962 recommendation.

Recent systematic reviews of evidence on 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;ANHMRC 2007; Yeung 2008; CPSTF, 2013).

Both publications provided an update to 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 with concurrent controls. Random assignment of individuals usually is not feasible for studies of water fluoridation, because the intervention uses 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 in fluoridated or non-fluoridated communities (Griffin SO, et al, 2007). Studies in these systematic reviews were not limited to the United States.

HHS Panel scientists accepted an extensive review of fluoride in drinking water by the National Research Council (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 drinking water concentrations of 4.0 mg/L (the MCLG established by EPA) is likely to increase bone fracture rates in the population, compared to exposures at 1.0 mg/L (NRC, 2006 p.7). Fluoride concentrations used for water fluoridation have been substantially lower than those EPA has established to ensure the safety of water (USDHEW, 1962; NRC, 2006).

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

Federal Register document (USDHHS, 2011). Guidance is advisory, not regulatory, in nature.

OVERVIEW OF PUBLIC COMMENTS: The public comment period for the Proposed HHS Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries lasted for ninety-three (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 in order 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 either 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, approximately 18,500 (96 percent) were nearly identical to a letter submitted by an organization opposing community water fluoridation (CWF), 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 CWF; 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 HHS panel) reviewed all unique responses and used an electronic list of descriptors to categorize their contents. Comments were summarized and reported to the full HHS Federal Panel, along with examples reflecting a range of differing opinions regarding the new recommendation. The following sections summarize frequent comments and provide the HHS 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 have reviewed and evaluated the best available science. After review, the HHS Federal Panel concluded that public comments submitted do not alter the proposed HHS recommendation to lower the fluoride concentration in drinking water for prevention of dental caries.

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 should 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.

and endocrine disruption.

In response to these concerns, HHS again reviewed the scientific information cited to support actions announced in January 2011 by the Department of Health and Human Services (U.S. DHHS, 2011) and the United States Environmental Protection Agency (U.S. EPA, 2010a; U.S. EPA, 2010b)—and again considered carefully whether 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 HHS 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 will 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 appears in the very mild or mild form?as barely visible lacy white markings or spots on the enamel (Beltr?n-Aguilar, ED, *at al.*, 2010a). The U.S. 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). It is rare in the United States, and its prevalence could not be estimated among adolescents in a national survey because samples included too few cases for statistical reliability (Beltr?n-Aguilar, ED, et al, 2010a). The NRC review noted that prevalence of severe dental fluorosis is near zero at fluoride concentrations below 2 mg/L (NRC, 2006, p. 10). In addition, the most recent review of CWF by the Community Preventive Services Task Force concluded that ?there is no evidence that CWF results in severe dental fluorosis?

concluded that ?there is no evidence that CWF results in severe dental fluorosis? (CPSTF, 2013).

Standard letter submissions also expressed concern that infants fed formula reconstituted with fluoridated drinking water will 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, some parents may choose to use low-fluoride bottled water to mix infant formula?these bottled waters are labeled as de-ionized, purified, demineralized, or distilled, and do not contain any added fluoride (FDA requires the label to indicate when it does). 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). HHS?s recommendation to lower the fluoride concentration for community water fluoridation should decrease fluoride exposure during the time of enamel formation, from birth through eight years of age (CDC, 2001b; Avery, 1987; Massler M and Schour I, 1958) for most permanent teeth, 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 over 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

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, p 6). 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? (NRC, 2006, p 6) 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, p 6).

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, stage III skeletal fluorosis (NRC, 2006). In response, the EPA Dose-Response Analysis for Non-Cancer Effects (U.S. EPA, 2010b) 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 prevent severe dental fluorosis among children. 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 increased relative risk of bone fractures in susceptible populations when compared to populations consuming concentrations of 1 mgF/L (U.S. EPA, 2010b, p. 86). 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 (N?sman P, *et al.*, 2013).

The fluoride intake estimated by U.S. EPA to prevent 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, p.105) EPA compared its

and an increased risk of bone fractures.? (U.S. EPA, 2010b, p.105) EPA compared its own risk assessments for skeletal effects to those made both by the NRC in 2006 and by the World Health Organization in 2002. EPA concluded that its own recommendation is protective compared to each of these other benchmarks. (U.S. EPA, 2010b, p. 105) 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, page 107).

Carcinogenicity

Some unique comments (~100) mentioned concern 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 males and estimated fluoride exposure from drinking water. 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 drinking water concentrations of locations in the reported residence history. The later study incorporating more reliable measures of exposure 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; ANHMRC 2007; 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.

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 in 2011, used a weight-of-evidence approach (SCHER, 2010) and concluded that epidemiological studies do 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, do 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 been clearly 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 lowered 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 lowered IQ among children exposed to fluoride in drinking water at mean concentrations of 2.5?4.1 mg/L?several times the new HHS recommendation. The NRC (NRC, 2006) found that ?the significance of these Chinese studies is uncertain? (p. 208) because important procedural details were omitted, yet also stated that findings warrant additional research on the effects of fluoride on intelligence. 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

nervous system changes, and called for more research ?to clarify the effect of fluoride on brain chemistry and function? (NRC, 2006, p. 8). These recommendations should be considered in the context of the NRC review, that 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, p. 11).

A recent meta-analysis of studies conducted in rural China, including those considered by the NRC report, identified an association between high fluoride exposure (drinking water concentrations ranging up to 11.5 mg/L) and lower IQ scores; study authors noted the low quality of included studies and called for studies based on measures of exposure at the individual-level over time (Choi, *et al.,* 2012). Subsequently, a review cited this meta-analysis to support its identification of ?raised fluoride concentrations? in drinking water as a potential developmental neurotoxicant (Grandjean and Landrigan, 2014).

The European review (SCHER, 2010) also considered the neurotoxicity of fluoride in water; it determined that there is not enough evidence from well-controlled studies to conclude whether fluoride in drinking water at concentrations used for community fluoridation may impair the IQ of children. 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 a fluoridated area, during early childhood and IQ measured repeatedly during childhood and at age 38 years (Broadbent, *et al.*, 2014).

While additional research may address identified gaps in knowledge, HHS seeks to protect health by lowering the recommended fluoride concentration. This action maintains the benefits of community water fluoridation at the same time it reduces the

maintains the benefits of community water fluoridation at the same time it reduces the chance of unwanted effects.

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 (NRC, 2006) considered potential association between fluoride exposure (2?4 mg/L) and changes in the thyroid, parathyroid, and pineal glands in experimental animals and humans. The report noted that available studies of the effects of fluoride exposure on endocrine function have limitations, e.g., many studies did not measure actual hormone concentrations; 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 epidemiologic 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, p 266). A review did not find evidence that consuming drinking water with fluoride at the level used in CWF 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 benefits of CWF 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; these studies were included in systematic reviews of the effectiveness of community water fluoridation (McDonagh, *et al.*, 2000b; Truman BI, *et al.*, 2002;

community water fluoridation (McDonagh, *et al.*, 2000b; Truman BI, *et al.*, 2002; ANHMRC 2007; Yeung 2008; 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 children and low-income children will not be protected by the recommendation, since they have experienced more tooth decay than other racial and ethnic groups, despite exposure to fluoride through drinking water and other sources. Data from the National Health and Nutrition Examination Surveys (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 and ethnic groups. For example, in 1999?2004, compared with 1988?1994, the percentage of adolescents ages 12?19 who had experienced dental caries in their permanent teeth, by race and ethnicity, was 54% in African-Americans (down from 63%), 58% in non-Hispanic whites (down from 68%), and 64% in Mexican-Americans (down from 69%) (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 (down from 72%). Although disparities in caries prevalence among these adolescent groups remain, each 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. This change represented an increase of more than 36 million people.
http://www.cdc.gov/nohss/fsgrowth.htm

Cost-Effectiveness of Community Water Fluoridation

Some unique comments (~200) called attention to the cost of water fluoridation, or stated

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 finished 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 5000 or fewer, updated to 2010 dollars using the Consumer Price Index), it remains only a fraction of the cost of one dental filling. The annual per person cost savings for those ages 6 to 65 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 U.S. 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).

Toxicity of Fluoride

Unique comments (~300) expressed concern that fluoride is a toxin, poison, dangerous chemical or 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 (CWF). All additives used to treat water, including those used for CWF, are subject to a system of standards, testing, and certification involving participation of the American Water Works Association (AWWA), the National Sanitation Foundation (NSF), 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* (U.S. EPA, 2000) by an ANSI-accredited laboratory. All fluoride products evaluated against Standard 60 are tested to ensure that

laboratory. 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 website, http://www.nsf.org/newsroom_pdf/NSF_Fact_Sheet_on_Fluoridation.pdf, found that no contaminants exceeded the concentration allowed by the ANSI/NSF 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 (Crosby, 1969; Finney, *et al;*, 2006, U.S. EPA, 2000) and thus, are comparable to the fluoride ion produced by other additives, such as sodium fluoride. At the pH of drinking water, usually between 6.5 and 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). ANSI/NSF Standards provide criteria to develop an allowable concentration when no MCL has been established by the EPA. Using this protocol, NSF 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 calculated allowable concentration.
http://www.nsf.org/newsroom_pdf/NSF_Fact_Sheet_on_Fluoridation.pdf
A recent European report (SCHER, 2010) also considered health and environmental risks associated with 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.

Ethics of Community Water Fluoridation

All standard letters and some (~200) unique comments stated that water fluoridation is unethical mass medication of the population. In order to determine if a public health action that may encroach on individual preferences is ethical, a careful analysis of its benefits and its 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; ANHMRC 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 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 U.S. 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 and reduce the risk of dental fluorosis among children. In addition,

preventive benefits and reduce the risk of dental fluorosis among children. In addition, given the documented increases in other sources of fluoride (e.g., from processed foods and beverages, toothpaste inadvertently swallowed), reducing the recommended water fluoride concentration to 0.7 mg/L will compensate for those additional sources of fluoride?water fluoridation is the fluoride source easiest to control.

Comments that Supported the Recommendation

Some submissions specifically endorsed lowering the concentration of fluoride in drinking water for 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, HHS 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, e.g., maintaining the Water Fluoridation Reporting System; offering 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) 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) were at 1.0 mg/L or greater and less than 1% at 0.7 mg/L. By summer

from such systems) were at 1.0 mg/L or greater and less than 1% at 0.7 mg/L. By summer 2011, only 6 months after publication of the draft notice, 68% of that population were at 0.7 mg/L and about 28% were at 1.0 mg/L or greater.

Following broad implementation of the new recommendation, enhanced surveillance over 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 (currently in the field) adds 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 (toothpaste, prescription drops and tablets) As findings from these—and future—examinations become available, they can be accessed through the CDC website (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 of drinking water, cannot occur until permanent teeth erupt into the mouths of children who drank that water during the period of tooth development. HHS agencies continue to give priority to 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 ages 2?7 as a biomarker for dental fluorosis of the permanent teeth at ages 10?15 (Buzalaf MAR, *et al.*, 2012).

Summary and Conclusions

HHS acknowledges the concerns of commenters, and appreciates the efforts of all who

HHS 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 HHS 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 risk of dental fluorosis reduced at 0.7 mg/L, the lowest concentration in the range of the 1962 USPHS recommendation.

? 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: .

Sylvia M. Burwell *Secretary.*

References

American Dental Association. Council on Scientific Affairs. Professionally applied topical fluoride ? evidence-based clinical recommendations. J Am Dent Assoc 2006;137:1151-1159.

American Dental Association (ADA), Council on Scientific Affairs. Evidence-based clinical recommendations regarding fluoride intake from reconstituted infant formula and enamel fluorosis. J Am Dent Assoc 2011; 142:79-87.

Aoba T, Fejerskov O. Dental fluorosis: Chemistry and biology. Critical Reviews in Oral Biology & Medicine 2002;13(2):155-70.

Australian Research Centre for Population Oral Health (ARCPOH). The use of fluorides in Australia: Guidelines. Aust Dent J 2006; 51:195-199.

Australian National Health and Medical Research Council (ANHMRC). NHMRC Public Statement: The Efficacy and Safety of Fluoridation 2007.
http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/eh41_statement_efficacy_safety_fluoride.pdf
Avery JK, ed. Oral development and histology. Baltimore, Williams and Wilkins, c1987. Xiii + 380 p. (p 130-131).Bassin EB, Wypij D, Davis RB, Mittleman MA. Age-specific fluoride exposure in drinking water and osteosarcoma (United States). Cancer Causes Control 2006; 17:421-428.

Beltr?n-Aguilar ED, Barker L, Dye BA. Prevalence and Severity of Enamel Fluorosis in the United States, 1999-2004. NCHS data brief no 53. Hyattsville, MD: National Center for Health Statistics. 2010a. Available at:
http://www.cdc.gov/nchs/data/databriefs/db53.htm.

Beltr?n-Aguilar ED, Barker L, Sohn W. Total water intake: Lack of association between daily temperature and children?s water intake in the United States, 1999-2004. 2010b.
http://www.cdc.gov/fluoridation/factsheets/totalwaterintake.htm.

Beltr?n-Aguilar ED, Barker L, Sohn W, Wei L. Water intake by outdoor temperature among children aged 1?10 years: Implications for community water fluoridation in the United States. [Manuscript for submission to Public Health Reports.]

Blakey K, Feltbower RG, Parslow RC, James PW, *et al.* Is fluoride a risk factor for bone cancer? Small area analysis of osteosarcoma and Ewing sarcoma diagnosed among 0-49-year-olds in Great Britain, 1980-2005. Int. J. Epidemiol 2014;43:224-234.

Broadbent JM, Thomson WM, Ramrakha S, Moffitt TE, *et al.* Community water fluoridation and intelligence: Prospective study in New Zealand. Am J Public Health 2014 [May 15 Published online ahead of print**].**

Burt BA (Ed). Proceedings for the workshop: Cost-effectiveness of caries prevention in dental public health, Ann Arbor, Michigan, May 17--19, 1989. J Public Health Dent 1989;49(special issue):331-7.

Burt BA, Eklund SA. Dentistry, Dental Practice, and the Community. 6th ed. St. Louis, MO: Elsevier Saunders; 2005.

Buzalaf MAR, Massaro CS, Rodrigues MHC, Fukushima R, *et al.* Validation of fingernail fluoride concentration as a predictor of risk for dental fluorosis. Caries Res

fingernail fluoride concentration as a predictor of risk for dental fluorosis. Caries Res 2012;46:394-400.

Campain AC, Marino RJ, Wright FAC, Harrison D, Bailey DL, Morgan MV. The impact of changing dental needs on cost savings from fluoridation. Aust Dent J 2010; 55:37-44.

Centers for Disease Control and Prevention. Recommendations for using fluoride to prevent and control dental caries in the United States. MMWR Recommendations and Reports 2001b;50(RR-14).

Centers for Disease Control and Prevention. Achievements in Public Health, 1900-1999: Fluoridation of drinking water to prevent dental caries. MMWR 1999;48(41):933-40.

Centers for Disease Control and Prevention. Water Fluoridation Reporting System, 2009, 2010. (Unpublished data.)

Choi AL, Sun G, Zhang Y, Grandjean P. Developmental fluoride neurotoxicity: A systematic review and meta-analysis. Environ Health Perspect 2012;120:1362-8 (DOI:10.1289/ehp.1104912).

Cobiac LJ, Vos T. Cost-effectiveness of extending the coverage of water supply fluoridation for the prevention of dental caries in Australia. Community Dent Oral Epidemiol 2012;40:369-76.

Comber H, Deady S, Montgomery E, Gavin A. Drinking water fluoridation and osteosarcoma incidence on the island of Ireland. Cancer Causes Control 2011; 22:919-24.

Community Preventive Services Task Force (CPSTF). Preventing dental caries: Community water fluoridation. April 2013. Available at: http://www.thecommunityguide.org/oral/fluoridation.html

Crosby NT. Equilibria of fluorosilicate solutions with special reference to the fluoridation of public water supplies. J Appl Chem 1969; 19:100-102.

Dye B, Tan S, Smith V, Lewis BG, Barker LK, Thornton-Evans G, Eke P, Beltr?n-Aguilar ED, Horowitz AM, Li C-H. (2007). Trends in oral health status, United States, 1988-1994 and 1999-2004. Vital and Health Statistics Series 11 No. 248.

Evans RW, Stamm JW. Dental fluorosis following downward adjustment of fluoride in drinking water. J Public Health Dent 1991;51(2):91-8.

Featherstone JDB. Prevention and reversal of dental caries: role of low level fluoride. Community Dent Oral Epidemiol 1999;27:31-40.

Finney WF, Wilson E, Callender A, Morris MD, Beck LW. Re-examination of hexafluorosilicate hydrolysis by fluoride NMR and pH measurement. Environ Sci Technol 2006; 40:8:2572-7.

Galagan DJ, Vermillion JR. Determining optimum fluoride concentrations. Public Health Rep 1957;72:491-3.

Galagan DJ. Climate and controlled fluoridation. J Am Dent Assoc 1953;47:159-70.

Galagan DJ, Vermillion JR, Nevitt GA, Stadt ZM, Dart RE. Climate and fluid intake.

Galagan DJ, Vermillion JR, Nevitt GA, Stadt ZM, Dart RE. Climate and fluid intake. Public Health Rep 1957;72:484-90.

Grandjean P, Landrigan PJ. Neurobehavioral effects of developmental toxicity. Lancet Neurol 2014; 13:330-38.

Griffin SO, Jones K, Tomar SL. An economic evaluation of community water fluoridation. J Public Health Dent 2001;61:78-86.

Griffin SO, Regnier E, Griffin PM, Huntley V. Effectiveness of fluoride in preventing caries in adults. J Dent Res 2007;86:410-415.

Heller KE, Eklund SA, Burt BA. Dental caries and dental fluorosis at varying water fluoride concentrations. J Public Health Dent 1997;57:136-43.

Heller KE, Sohn W, Burt BA, Eklund SA. Water consumption in the United States in 1994-96 and implications for water fluoridation policy. J Public Health Dent 1999;59:3-11.

Ismail AI, Burt BA, Hendershot GE, Jack S, Corbin SB. Findings from the dental care supplement of the National Health Interview Survey, 1983. J Am Dent Assoc 1987;114:617-21.

Ismail AI, Hasson H. Fluoride supplements, dental caries and fluorosis: A systematic review. J Am Dent Assoc 2008;139:1457-1468.

Kelly JE. Decayed, missing and filled teeth among youths 12-17 years. Vital and Health Statistics Series 11, No. 144, 1975. DHEW Publication No. (HRA) 75-1626.

Kelly JE, Harvey CR. Basic dental examination findings of persons 1--74 years. In: Basic data on dental examination findings of persons 1-74 years, United States, 1971-1974. Vital and Health Statistics Series 11, No. 214, 1979. DHEW Publication No. (PHS) 79-1662.

Kelly JE, Van Kirk LE, Garst CC. Decayed, missing, and filled teeth in adults. Vital and Health Statistics Series 11, No. 23. 1973. DHEW Publication No. (HRA) 74-1278. Reprinted from Public Health Service publication series No. 1000, 1967.

Kim FM, Hayes C, Williams PL, Whitford GM, Joshipura KJ, Hoover RN, Douglass CW, National Osteosarcoma Etiology Group. An assessment of bone fluoride and osteosarcoma. J Dent Res 2011; 90:1171-1176.

Koulourides T. Summary of session II: fluoride and the caries process. J Dent Res 1990;69(Spec Iss):558.

Levy M, Leclerc B-S. Fluoride in drinking water and osteosarcoma incidence rates in the continental United States among children and adolescents. Cancer Epid 2012; 36:e83-e88.

Levy SM, Broffitt B, Marshall TA, Eichenberger-Gilmore JM, Warren JJ. Associations between fluorosis of permanent incisors and fluoride intake from infant formula, other dietary sources and dentifrice during early childhood. J Am Dent Assoc 2010;141:1190-1201.

Lo ECM, Evans RW, Lind OP. Dental caries status and treatment needs of the permanent dentition of 6 ? 12 year-olds in Hong Kong. Community Dent Oral Epid 1990;18:9-11.

Lu Y, Sun ZR, Wu LN, Wang X, Lu W, Liu SS. Effect of high-fluoride water on intelligence in children. Fluoride 2000; 33:74-8.

Ludlow M, Luxton G, Mathew T. Effects of fluoridation of community water supplies for people with chronic kidney disease. Nephrol Dial Transplant 2007; 22:2763-2767.

Massler M and Schour I. 1958. Atlas of the mouth in health and disease.2nd ed., 6th printing 1982. Chicago: American Dental Association.

McClure FJ. Ingestion of fluoride and dental caries. Am J Dis Child 1943;66:362-9.

McDonagh MS, Whiting PF, Wilson PM, Sutton AJ, Chestnutt I, Cooper J, Misso K, Bradley M, Treasure E, Kleijnen J. Systematic review of water fluoridation. Br Med J 2000a;321:855-859.

McDonagh MS, Whiting PF, Bradley M. et al. A systematic review of public water fluoridation. NHS Centre for Reviews and Dissemination. University of York, September 2000b. Available at: http://www.york.ac.uk/inst/crd/CRD_Reports/crdreport18.pdf

N?sman P, Ekstrand J, Granath F, Ekbom A, Fored CM. Estimated drinking water fluoride exposure and risk of hip fracture: A cohort study. J Dent Res 2013;92:1029-34.

National Center for Health Statistics, S. Jack and B. Bloom. 1988. Use of dental services and dental health: United States, 1986. Vital and Health Statistics. Series 10, No. 165. DHHS Pub No. (PHS) 88-1593. Public Health Service. Washington: U.S. Government Printing Office.
http://www.cdc.gov/nchs/data/series/sr_10/sr10_165.pdf

National Research Council of the National Academies, Committee on Fluoride in Drinking Water, Board on Environmental Studies and Toxicology (NRC). Fluoride in drinking water; a scientific review of EPA?s standards. The National Academies Press, c2006.

National Research Council, Subcommittee on Health Effects of Ingested Fluoride, Board on Environmental Studies and Toxicology (NRC). Health Effects of Ingested Fluoride. National Academy Press, 1993.

Newacheck PW, Hughes DC, Hung YY, Wong S, Stoddard JJ. The unmet health needs of America?s children. Pediatrics 2000;105(4 Pt 2):989-97.

Osuji OO, Leake JL, Chipman ML, Nikiforuk G, Locker D, Levine N. Risk factors for dental fluorosis in a fluoridated community. J Dent Res 1988;67:1488-92.

O?Connell JM, Brunson D, Anselmo T, Sullivan PW. Costs and savings associated with community water fluoridation programs in Colorado. Prev Chronic Dis 2005. Available from: http://www.cdc.gov/pcd/issues/2005/nov/05_0082.htm

Office of Environmental Health Hazard Assessment, Carcinogen Identification Committee, State of California (OEHHA CA). Meeting synopsis and presentations from 10/12/11. http://oehha.ca.gov/prop65/public_meetings/cic101211synop.html

10/12/11. http://oehha.ca.gov/prop65/public_meetings/cic101211synop.html

Parnell C, Whelton H, O?Mullane D. Water fluoridation. European Archives of Paediatric Dent 2009; 10:141-8

Pendrys DG, Katz RV, Morse DR. Risk factors for enamel fluorosis in a fluoridated population. Am J Epidemiol 1994;140:461-71.

Pendrys DG, Katz RV. Risk for enamel fluorosis associated with fluoride supplementation, infant formula, and fluoride dentifrice use. Am J Epidemiol 1989;130:1199-208.

Pendrys DG. Risk for fluorosis in a fluoridated population: implications for the dentist and hygienist. J Am Dent Assoc 1995;126:1617-24.

Scientific Committee on Health and Environmental Risks, European Commission Directorate-General for Health and Consumers (SCHER). Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water. c2010. http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_139.pdf

Slade GD, Sanders AE, Do L, Roberts-Thompson K, Spencer AJ. Effects of fluoridated drinking water on dental caries in Australian adults. J Dent Res 2013; 92:376-82.

Sohn W, Heller KE, Burt BA. Fluid consumption related to climate among children in the United States. J Public Health Dent 2001;61:99-106.

Truman BI, Gooch BF, Evans CA Jr. (Eds). The Guide to Community Preventive Services: Interventions to prevent dental caries, oral and pharyngeal cancers, and sports-related craniofacial injuries. Am J Prev Med 2002;23(1 Supp):1-84.

U.S. Department of Health and Human Services. Oral health of United States children. The National Survey of Dental Caries in U.S. School Children: 1986-1987. NIH Publication No. 89-2247, 1989.

U.S. Department of Health and Human Services. Oral Health in America; A Report of the Surgeon General. Rockville, MD: USDHHS, National Institute of Dental and Craniofacial Research, National Institutes of Health, 2000.

U.S. Department of Health and Human Services. Food and Drug Administration. 21 CFR Part 355. Anticaries drug products for over-the-counter human use. Code of Federal Regulations 2010: 306-311.

U.S. Department of Health and Human Services. Proposed HHS recommendation for fluoride concentration in drinking water for prevention of dental caries. Federal Register 2011;76:2383-2388.

U.S. Department of Health, Education, and Welfare. Public Health Service drinking water standards, revised 1962. Washington, DC: Public Health Service Publication No. 956, 1962.

U.S. Department of Health, Education, and Welfare. Food and Drug Administration. Anticaries drug products for over-the-counter human use--establishment of a monograph;

Notice of proposed rulemaking. Fed Regist. 1980;45(62):20666-20691. To be codified at 21 CFR Part 355.

U.S. Environmental Protection Agency, Office of Water. Information Sheet: Hexafluorosilicic acid and sodium hexafluorosilicate. Sept 2000. 4 p.

U.S. EPA (U.S. Environmental Protection Agency). 2010a. *Fluoride: Exposure and Relative Source Contribution Analysis*. Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, Washington, DC. EPA 820-R-10-015.
Available at:
http://water.epa.gov/action/advisories/drinking/fluoride_index.cfm.

U.S. EPA (U.S. Environmental Protection Agency). 2010b. *Fluoride: Dose-response Analysis for Non-cancer Effects*. Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, Washington, DC. EPA 820-R-10-019.
Available at: http://water.epa.gov/action/advisories/drinking/fluoride_index.cfm.
U.S. Environmental Protection Agency, Office of Water. EPA Dose-Response and Exposure Assessments for Fluoride. Presentation at the National Oral Health Conference, Pittsburgh, PA, April 11, 2011.

Wong MCM, Glenny AM, Tsang BWK, Lo ECM, Worthington HV, Marinho VCC. Topical fluoride as a cause of dental fluorosis in children. *Cochrane Database of Systematic Reviews* 2010, Issue 1. Art. No.: CD007693.
DOI:10.1002/14651858.CD007693.pub2.

Yeung CA. A systematic review of the efficacy and safety of fluoridation. Evidence-Based Dent 2008;9:39-43.

Xiang Q, Liang Y, Chen L, Wang C, *et al.* Effect of fluoride in drinking water on children?s intelligence. Fluoride 2003;36:84-94.

Zhao LB, Liang GH, Zhang DN, Wu XR. Effect of a high fluoride water supply on children?s intelligence. Fluoride 1996;29:190-2.

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

Laurie K. Barker, MSPH
Statistician
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

Leila T. Beker, PhD, 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 Beltr?n-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, PhD, 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, PhD
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
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, PhD
Health Scientist
Health and Ecological Criteria Division
Office of Science and Technology
Office of Water
U.S. Environmental Protection Agency

Elizabeth Doyle, PhD
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, PhD
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, PhD
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
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
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

Nicholas S. Makrides, DMD, MA, MPH
CAPT, U.S. Public Health Service
Federal Bureau of Prisons
U.S. Department of Justice

Richard Manski, DDS, MBA, PhD
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, PhD
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