



WATER FLUORIDATION Issue Brief

Introduction

On April 27, 2015, the U.S. Department of Health and Human Services (HHS) issued a final rule recommending that drinking water in all regions of the country be fluoridated at 0.7 milligrams per liter.¹ This rule replaces the previous version that recommended different levels across the nation, from 0.7 mg/L to 1.2 mg/L, determined by climate.² The issuance of the new recommendations provides an opportunity for public health professionals to review the public health impact of community water fluoridation and to clarify the complementary roles that federal, state and local government agencies play in water fluoridation. Some messages commonly used by fluoridation opponents—for example, “the FDA has never approved [fluoride]”—reflect a misunderstanding of the oversight roles played by various government actors.³ Clarifying these roles and understanding the rationale for the new HHS recommendations can help reduce confusion and encourage public dialogue that focuses on the scientific evidence.

Background

Water Fluoridation Process

Water fluoridation is the adjustment of fluoride levels in a water system to prevent tooth decay.⁴ Virtually all water systems have some natural amount of fluoride but at levels lower than recommended by HHS.⁵ Therefore, to attain the level of fluoride recommended by HHS, the vast majority of water departments must increase the fluoride content in their water. Most water departments do this by adding hydrofluorosilicic acid (HFSA) to their water, but sodium fluoride and sodium fluorosilicate can also be used. All additives that are used to fluoridate water must meet the National Sanitation Foundation/American National Standards Institute (NSF/ANSI) and American Water Works Association standards.⁶

About four percent of the population on community water systems (CWS) in the United States is served by water that has natural fluoride levels at or above the 0.7 to 1.2 mg/L range recommended by HHS.⁷ In these communities, natural fluoride concentrations can exceed recommended levels, and in some instances, communities may be required to remove fluoride from their drinking water.⁸ EPA, which sets *maximum* levels for fluoride in drinking water, has designated activated alumina and reverse osmosis as the “best technology generally available” for removing fluoride from water systems, though other technologies may also be used to reduce fluoride in certain circumstances.⁹



Public Health Impact of Water Fluoridation

Community water fluoridation has been hailed by the Centers for Disease Control and Prevention (CDC) as one of ten “great public health achievements” of the Twentieth Century.¹⁰ In 1945, Grand Rapids, Michigan became the first city in the world to fluoridate its water.¹¹ Fluoridation spread quickly, and by 1975, almost 50 percent¹² of people in the United States received water with fluoride at or above the recommended levels.¹³ Since that time, the percentage of people receiving water with fluoride concentrations at or above the recommended range in the U.S. has continued to grow: increasing among individuals on CWS to 65 percent in 2000 and to 75 percent in 2012.¹⁴


As water fluoridation spread, oral health in the U.S. improved dramatically. Early studies comparing cities with fluoridated water to non-fluoridated cities found that community water fluoridation reduced dental caries among children by 50 to 70 percent.¹⁵ More recent studies reflect the increased use of fluoride toothpaste and other dental care in non-fluoridated communities, but still find that water fluoridation reduces the risk of dental caries by about 25 percent.¹⁶ Moreover, because fluoridated water diffuses into non-fluoridated communities through processed foods and bottled beverages, many studies may actually underestimate the benefits of water fluoridation.¹⁷ A study published in 2013 found that adults who resided for more than 75 percent of their lifetimes in fluoridated communities had significantly lower rates of tooth decay than adults who had resided less than 25 percent of their lives in such communities.¹⁸ One of the study’s co-authors said the research “means that more people benefit from water fluoridation than previously thought.”¹⁹ Poorer and minority children may disproportionately benefit from water fluoridation because they are less likely to have access to other preventive dental care.

Water fluoridation is also the most cost-effective method for preventing dental caries. A recent study that modeled a variety of interventions for preventing early childhood caries (ECC) in New York found that water fluoridation had the greatest potential for saving money among a range of strategies that were tested for young children receiving Medicaid.²⁰ The CDC estimates that, on average, a dollar spent fluoridating water saves \$38 in dental costs.²¹ Water fluoridation has generally been found to be cost saving even for smaller communities, which have higher per capita fluoridation costs.²²

Despite the contribution of community water fluoridation to oral health, tooth decay remains a public health problem in the United States. Over 90 percent of adults in the U.S. have had dental caries, and 21 percent of children aged 6 to 11 have had caries in their permanent teeth.²³ In a poll conducted in September 2013, 33 percent of adults said that either they or a family member had a toothache or another problem with their teeth or gums “that needs to be addressed.”²⁴ The fluoridation savings that CDC’s research identified are especially noteworthy given the short- and long-term costs associated with dental treatments. For example, Americans spent \$111 billion on dental care in 2012, and the lifetime cost of treating one decayed molar can be as much as \$6,105.²⁵ Left untreated, tooth decay can result in extreme pain and edentulism (loss of one’s teeth).²⁶ Edentulism is associated with a variety of adverse health outcomes, including poorer nutrition, and may aggravate or increase the risk of other chronic conditions.²⁷

The CDC and ADA both consider water fluoridation to be safe,²⁸ but it is associated with an increased prevalence of dental fluorosis.²⁹ Dental fluorosis results from exposing developing teeth to excess fluoride—typically, this means exposure between ages 0 and 8.³⁰ In its mild forms, fluorosis is a cosmetic condition, characterized by white spots on tooth surfaces. Nearly all dental fluorosis in the United States is very mild to mild.³¹ Very mild to mild fluorosis has been associated with lower rates of tooth decay,³² and is often not noticeable,³³ though it may cause cosmetic concerns for some individuals.³⁴ Mild forms of fluorosis do not cause pain or affect the health or function of teeth.³⁵

Among individuals aged 6 to 49 in the United States, less than three percent have moderate or severe forms of fluorosis.³⁶ Severe fluorosis is characterized by pitting of the tooth enamel and may increase individuals’ risk of dental caries.³⁷ Severe fluorosis is very rare among individuals whose water is optimally fluoridated and who are not exposed to other risk factors, such as fluoride supplements. In fact, according to the National Research Council, even at 2 mg/L (i.e. almost 3



times the concentration now recommended by HHS), “the prevalence of severe fluorosis is very low (near zero).”³⁸ Moreover, a 2014 study of 4,584 school-aged children in North Carolina concluded that tooth decay “is a much bigger public health concern than enamel fluorosis. The prevalence of fluorosis is less than caries, and it had no impact on the [oral health-related quality of life] of children or their families.”³⁹

Because of its safety and health benefits, community water fluoridation remains a public health priority. Recognizing this need, the Healthy People initiative, a collaboration of federal agencies setting science-based objectives to improve the nation’s health, aims to increase the percentage of the US population that is served by CWS and receives optimally fluoridated water to 80 percent by 2020.⁴⁰

Legal Framework Governing Water Fluoridation

State and local governments are responsible for deciding whether to fluoridate public water systems. The federal government plays a complementary role by setting maximum limits for fluoride in drinking water and issuing voluntary recommendations on optimal fluoridation levels.⁴¹ Although the CDC endorses the safety and effectiveness of fluoridated water, neither the CDC nor other federal agencies require states or communities to fluoridate their water.⁴² Through the Food and Drug Administration (FDA), the federal government also provides advisory opinions on fluoride’s health effects and regulates the maximum amount of fluoride that can be in bottled water and the labeling related to that fluoride. There is, in short, no federal mandate to fluoridate water, and the main regulatory role of the federal government is to make sure naturally-occurring fluoride levels in drinking water are not too high.

State and Local Role

States’ authority to fluoridate community water is based on their inherent authority to protect public health and safety. This authority, also known as states’ “police power,” was reserved to the states by the Tenth Amendment.⁴³ States may exercise this authority directly or delegate it to subsidiary, local governments.⁴⁴ State delegations of police power can be very broad: for example, a city’s authority to fluoridate its water may be inferred from its broader authority to protect the health and welfare of its inhabitants.⁴⁵

In the case of community water fluoridation, most states have delegated their authority to local governments, and, therefore, the decision to fluoridate CWS is usually made at the county, township or municipal level. Of the over 280 million Americans whose homes are connected to CWS, just over 210 million (75 percent) receive water that is fluoridated to the optimal level.⁴⁶ Forty-four of the 50 largest cities in the United States supply fluoridated water to their residents, and that proportion should increase soon as San Jose, California prepares to implement a policy to fluoridate its drinking water over the next several years.⁴⁷ Portland, Oregon, which recently voted against fluoridation, is the largest city not to fluoridate.

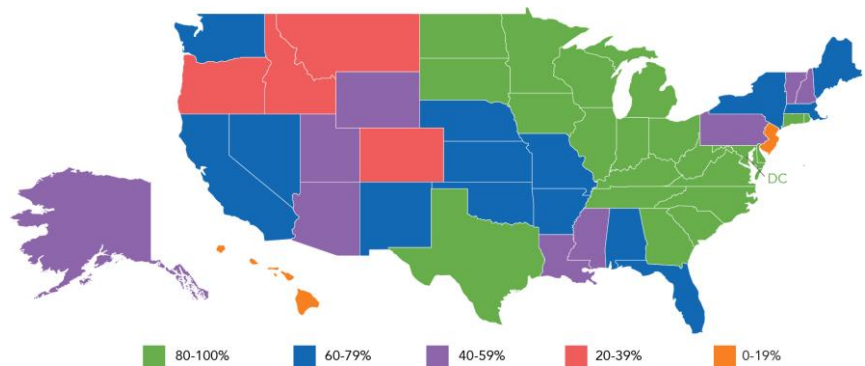
Thirteen states have passed statutes or issued regulations setting statewide fluoridation requirements.⁴⁸ Even in these states, however, some local governments retain control over fluoridation due to exemptions in the state laws. Nine of the 13 states, for example, exempt communities under a certain size, though there is considerable variation among these states as to the population thresholds that are covered.⁴⁹ Nevada’s requirement, for example, only applies to counties with at least 700,000 people and to water systems that serve at least 100,000 people.⁵⁰ South Dakota’s, by contrast, applies to all communities with 500 or more people.⁵¹ Other states provide exemptions based on lack of funding or on communities’ affirmative decision to opt out of the requirement.⁵²

Perhaps because of these exemptions, some of these 13 states still have relatively low fluoridation coverage: Louisiana, for example, whose statute contains size and funding exemptions as well as an opt-out provision, ranked 45th, with only 43 percent of its CWS population receiving fluoridated water in 2012; California, whose statute also contained size and

funding exemptions but no opt-out provision, ranked 34th, with 64 percent of its CWS population receiving fluoridated water. On the other hand, five of these 13 states ranked in the top 10 for fluoridation rates in 2012: Kentucky (99.9 percent) ranked first; Minnesota (98.8 percent) ranked second; Illinois (98.5 percent) ranked third; Georgia (96.3 percent) ranked sixth; and South Dakota (93.6 percent) ranked tenth.⁵³

The wide variation in state and local laws is matched by wide variation in fluoridation coverage across states. As Figure 1 illustrates, by 2012, 21⁵⁴ states and the District of Columbia met or exceeded the Healthy People 2020 national fluoridation objective of 80 percent for individuals on CWS. There were also, however, 14 states with fluoridation coverage under 60 percent, five of which provide optimal fluoride to less than 40 percent of the population on community water systems. The low coverage of fluoridation in these states highlights a promising public health opportunity.

Figure 1



Overcoming political opposition to fluoridation will likely be challenging, however. Fluoridation opponents have adopted a variety of techniques that can create confusion among the public and impede laws promoting fluoridation. In New Jersey, which has the second lowest rate of fluoridation in the country, health advocates have also faced opposition from the New Jersey Utilities Association. New Jersey water utilities have made it difficult for many communities to fluoridate their own water systems because the utilities, which typically serve several communities, often require all the communities to approve fluoridation rather than allowing individual communities to decide for themselves.⁵⁵


Federal Role in Water Fluoridation

The federal government does not mandate water fluoridation, but it is responsible for making sure that levels of fluoride are not too high in CWS or in bottled water. EPA sets maximum levels for fluoride concentration allowed in CWS and can regulate which additives can be used to fluoridate water systems. FDA regulates fluoride in bottled water but has no authority to regulate CWS. HHS issues voluntary recommendations on optimal fluoridation levels for preventing tooth decay; HHS's role and rationale for its recommendations will be discussed in the final section of this Issue Brief.

EPA

Under the Safe Drinking Water Act of 1974, the U.S. Environmental Protection Agency (EPA) is responsible for ensuring water safety.⁵⁶ EPA ensures water safety by setting a maximum allowable fluoride concentration for CWS. The current maximum level allowed by EPA is 4 mg/L, but this standard is under review.⁵⁷ EPA also has set a secondary maximum contaminant level (SMCL) for fluoride of 2 mg/L to reduce the incidence of dental fluorosis.⁵⁸ Water systems that exceed the SMCL must inform their customers about the risk of dental fluorosis for children. They must also recommend that children under nine years old use alternative sources of drinking water and that caregivers consult with a dental professional on how to reduce total fluoride exposure.⁵⁹ As of 1992, about 1.6 million people in the United States received water that had natural fluoride concentrations above 2 mg/L.⁶⁰

In addition to setting maximum fluoride concentrations in drinking water, EPA can also regulate which additives can be used to fluoridate CWS. In 2013, EPA responded to a petition seeking to prohibit public water systems from using H2SFA,



which is the most common additive currently used to fluoridate water and is much less expensive than alternatives. A prohibition on HSFA, therefore, could have prompted many communities to consider stopping fluoridation of their water systems. The petition raised concern that HFSA contained arsenic and lead, but EPA's review rejected this claim because the evidence presented by the petitioner did "not adequately support a conclusion that HFSA, when used as a fluoridation agent, presents or will present an unreasonable risk to health or the environment."⁶¹ In denying the petition, EPA also noted that the petitioners conflated annual risks with lifetime risks and, therefore, overestimated the cancer risks of HSFA by 70 times.⁶² The scientist whose estimate the petition was based on later acknowledged his mistake.⁶³

FDA

FDA sets maximum levels for fluoride in bottled water. FDA's limits vary according to whether the water is 1) imported or packaged in the U.S. and 2) has been fortified with additional fluoride. For imported water, FDA has set a maximum fluoride concentration of 1.4 mg/L for naturally fluoridated water and 0.8 mg/L for water with added fluoride. For water packaged in the U.S., FDA regulations set maximum fluoride levels according to the average ambient temperature of the region in which the bottled water is sold. In colder climates, bottled water may contain higher concentrations of fluoride under the theory that people drink less water when it is cold. As the next section discusses, recent studies suggest this is no longer true. FDA may, therefore, revise its fluoride regulations.

FDA also regulates labeling on bottled water. In 2006, FDA approved a request allowing marketers of bottled water with fluoride levels of more than 0.6 mg/L and no more than 1.0 mg/L to include language on their labels noting that consuming fluoridated water "may reduce the risk" of tooth decay.⁶⁴ More recently, FDA wrote a letter to California to oppose a move by state officials that could have required products containing fluoride to bear a label warning that the "product contains a chemical known to the State of California to cause cancer."⁶⁵ The FDA letter noted that "available data do not support a conclusion that exposure to fluoride in FDA-regulated products causes cancer."⁶⁶ The letter also stated that adding a cancer warning on FDA-regulated products that contain fluoride "would misbrand these products in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and, therefore, would be preempted."⁶⁷


The fact that FDA does not regulate CWS may cause confusion for some Americans. Legislation and ballot initiatives have been proposed in some states and communities that would require FDA to approve any agent that is added to a CWS within the state or community. If passed, these initiatives would make it impossible to fluoridate the water systems since FDA does not have authority to approve fluoride in CWS. As noted earlier, the safety of water system additives is assured by the NSF/ANSI standards and the EPA's oversight.

Rationale for New HHS Recommendations

HHS recommends the fluoride level at which CWS should be fluoridated. As previously noted, these recommendations are voluntary, and the decision as to whether a community fluoridates is made at the state or local level.

In 1962, the U.S. Public Health Service, a part of HHS, recommended that each CWS be fluoridated at a specific level between 0.7 and 1.2 mg/L, depending on that community's ambient air temperature. At that time, evidence suggested that children who lived in warmer climates consumed more water.⁶⁸ Therefore, the Public Health Service recommended that fluoride concentration levels be set according to each region's annual average of maximum daily temperature. For example, the lower end of the range (at or just above 0.7 mg/L) was recommended for CWS in warmer climates such as Florida and Texas.⁶⁹

On April 27, 2015, HHS finalized a recommendation it had first proposed in January 2011—namely, that all communities fluoridating their drinking water do so at a concentration of 0.7 mg/L.⁷⁰ Thus, under the new recommendations, fluoridation in the warmest communities would stay the same, while fluoridation in colder climates would be reduced.



The rationale for the new recommendations is twofold. First, recent studies indicate that water intake no longer varies by climate, a change that may be attributable to wider use of air conditioning.⁷¹ Second, the increased use of fluoridated toothpaste, mouthwashes, and professionally applied varnishes and gels means that the higher concentrations of water fluoridation are no longer necessary to prevent tooth decay.⁷² The new recommendations are intended to maximize dental health while minimizing dental fluorosis.

In November 2013, a CDC official estimated that roughly one-third of the U.S. communities that adjust the fluoride in their water systems (i.e., fluoridate) would need to lower it if they chose to meet HHS's new recommended level. Many CWS have already reduced their fluoride concentrations based on the preliminary 2011 recommendation, viewing the move as an opportunity to save money by purchasing lower quantities of fluoride additives.⁷³

Conclusion

Community water fluoridation has greatly improved oral health in the United States. Misinformation about how fluoride is regulated and about the safety and benefits of fluoridated water, however, continues to impede fluoridation efforts in many parts of the country. The issuance of the new HHS recommendations provides an opportunity for public health officials to clarify the complementary roles that federal, state, and local governments play in water fluoridation and to highlight the tremendous contribution that water fluoridation has made to public health.

SUPPORTERS



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- 12 Throughout this Issue Brief, we rely on CDC's fluoridation rates. CDC's rates appear to be calculated by summing the estimated population receiving optimally fluoridated water (i.e., water in which the fluoride concentration has been adjusted) with the estimated population receiving water that has natural fluoride concentrations at or above the optimal level. Therefore, a small percentage of the people that are included in these rates may actually be receiving water with higher than optimal fluoride concentrations. According to Kip Duchon, National Fluoridation Engineer at CDC, 3.9 percent of people on CWS receive water with natural fluoride levels at or above the level recommended by HHS; less than 0.5 percent of individuals on CWS receive water with fluoridation levels above EPA's Secondary Maximum Contaminant Level of 2 mg/l, and less than 0.1% receive water exceeding EPA's Primary Maximum Contaminant Level of 4 mg/L.
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- 106) (concluding that “In the more recent studies with methodological improvements to assess impact on quality of life, mild dental fluorosis clearly was not a concern. In fact, sometimes it was associated with improved oral health-related quality of life, probably due to the public’s greater emphasis on white teeth.”
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- ⁵² Cal. Health & Safety Code § 116409(a) (West 2013); La. Rev. Stat. Ann. § 40:5.11 (West 2012).
- ⁵³ CDC (2013) cost savings, *supra* note 14.
- ⁵⁴ As noted earlier, 3.9 percent of individuals whom CDCs counts as receiving fluoridated water receive water with natural fluoride levels at or above the level recommended by HHS. Since the 2020 goal of 80 percent is for “optimally fluoridated water,” the percentage of individuals receiving “optimally fluoridated water” in each state may be a bit lower than the rates given by the CDC. According to the CDC, the top 20 states have fluoridation rates of 84 percent or above, so they would probably meet or exceed the 2020 goal even if individuals receiving water with fluoride levels above the recommended level were excluded from the numerator. Texas’s 2012 rate, however, is 79.6 percent, so it is possible that it has not yet met CDC’s target rate for optimally fluoridated water.
- ⁵⁵ Zernike, K. (2012, March 2). In New Jersey, a battle over a fluoridation bill, and the facts. *New York Times*. Retrieved from http://www.nytimes.com/2012/03/03/nyregion/in-new-jersey-a-battle-over-fluoridation-and-the-facts.html?pagewanted=all&_r=0.
- ⁵⁶ Pub. L. 93-523, 88 Stat. 1660.
- ⁵⁷ U.S. Environmental Protection Agency. (2013, July 23). Water: basic Information about regulated drinking water contaminants. Retrieved from EPA website <http://water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm>.
- ⁵⁸ *Id.*
- ⁵⁹ Special Notice Exceedance of the SMCL for Fluoride. 40 C.F.R. § 141.208 (2014).
- ⁶⁰ National Research Council. (2006). Fluoride in drinking water: a scientific review of EPA’s standards. Washington, D.C.: National Academies Press.
- ⁶¹ Hydrofluorosilicic Acid in Drinking Water; TSCA Section 21 Petition; Reasons for Agency Response, 78 Fed. Reg. 155, 48846 (2013, August 12).
- ⁶² *Id.*

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- 63 Main, D. (2013, August 16). EPA rejects petition to change fluoride source in US drinking water. *Livescience*. Retrieved from <http://www.livescience.com/38952-epa-arsenic-petition-response.html>.
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- 72 Fed. Reg., *supra* note 2.
- 73 Duchon K., *supra* note 7.