Safety

17. Does fluoride in the water supply, at the levels recommended for the prevention of tooth decay, adversely affect human health?

Answer.

The overwhelming weight of scientific evidence supports the safety of community water fluoridation.

Fact.

For generations, millions of people have lived in areas where fluoride is found naturally in drinking water in concentrations as high or higher than the optimal level recommended to prevent tooth decay. Research conducted among these persons confirms the safety of fluoride in the water supply.[1-5]

As with other nutrients, fluoride is safe and effective when used and consumed as recommended. No charge against the benefits and safety of fluoridation has ever been substantiated by generally accepted scientific knowledge. A number of reviews on fluoride in drinking water have been issued over the years. For example, in 1951[6] the National Research Council (NRC), of the National Academies, issued its first report stating fluoridation was safe and effective. Additional reviews by the NRC followed in 1977[7] and 1993[8] with the most recent NRC review completed in 2006.[9] Additional reviews completed over the ten year period from 2007-2017 include:

2017 Australian Government. National Health and Medical Research Council (NHMRC). *Information Poper — Water Fluoridation: Dental and Other Human Health Outcomes.*[10]

2016 O'Mullane DM, Baez RJ, Jones S, Lennon MA, Petersen PE, Rugg-Gunn AJ, Whelton H, Whitford GM. *Fluoride and Oral Health.*[11]

2016 American Water Works Association. *Water Fluoridation Principles and Practices.* AWWA Manual M4. Sixth edition.[12]

2015 Water Research Foundation. *State of the Science: Community Water Fluoridation.*[13]

2015 The Network for Public Health Law. *Issue Brief: Community Water Fluoridation.*[14]

2015 Ireland Health Research Board. *Health Effects of Water Fluoridation: An Evidence Review.*[15]

2015 U.S. Department of Health and Human Services Federal Panel on Community Water Fluoridation. *U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries.*[16]

2014 Public Health England. *Water Fluoridation: Health Monitoring Report for England.*[17]

2014 Royal Society of New Zealand and the Office of the Prime Minister's Chief Science Advisor. *Health Effects of Water Fluoridation: a Review of the Scientific Evidence.*[18]

2013 U.S. Community Preventive Services Task Force. The Guide to Community Preventive Services. *Preventing Dental Caries: Community Water Fluoridation.*[19]

2011 European Commission of the European Union Scientific Committee on Health and Environmental Risks (SCHER). *Fluoridation.*[20]

2008 Health Canada. *Findings and Recommendations of the Fluoride Expert Panel.*[21]

2007 Australian Government National Health and Medical Research Council *A Systematic Review of the Efficacy and Safety of Fluoridation; Part A: Review Methodology and Results.*[22]

The overwhelming weight of scientific evidence supports the safety of community water fluoridation.

18. Are additional studies being conducted to determine the effects of fluorides in humans?

Answer.

Yes. Since its inception, fluoridation has undergone a nearly continuous process of re-evaluation. As with other areas of science, additional studies on the effects of fluorides in humans can provide insight as to how to make effective choices for the use of fluoride. The American Dental Association and the U.S. Public Health Service support this on-going research.

Fact.

For more than 70 years, detailed reports have been published on multiple aspects of fluoridation. The accumulated dental, medical and public health evidence concerning fluoridation has been reviewed and evaluated numerous times by academicians, committees of experts, special councils of governments and most of the world's major national and international health organizations. The consensus of the scientific community is that water fluoridation, at the level recommended to prevent tooth decay, safely provides oral health benefits which in turn supports improved general health. The question of possible secondary health effects caused by fluorides consumed in optimal concentrations throughout life has been the object of thorough medical investigations which have failed to show any impairment of general health throughout life.[10 22]

The consensus of the scientific community is that water fluoridation, at the level recommended to prevent tooth decay, safely provides oral health benefits which in turn supports improved general health.

In scientific research, there is no such thing as "final knowledge." New information is continuously emerging and being disseminated. Government agencies, such as the U.S. National Institutes of Health, National Institute of Dental and Craniofacial Research, and others continue to fund fluoride research. One example is the National Toxicology Program's systematic review using animal studies to evaluate potential neurobehavioral effects from exposure to fluoride during development which began in 2015 and continues in 2017.[23]

In 2011, the U.S. Department of Health and Human Services and the U.S. Environmental Protection Agency (EPA) issued a joint press release[24] outlining important steps the respective agencies were taking to ensure that standards and guidelines on fluoride in drinking water continue to ensure the safety of the public while supporting good dental health, especially in children. Those actions resulted in the 2015 report issued by the U.S. Public Health Service[16] regarding the recommended level of fluoride in drinking water and the EPA activity was informational to the 2016 EPA Six-Year Review 3[25] in which the Agency completed a detailed review of drinking water regulations including the regulation for naturally occurring fluoride in water.

19. Why did the U.S. Public Health Service issue a report in 2015 recommending 0.7 milligrams per liter (mg/L) as the optimal level for fluoride in drinking water for all temperature zones in the U.S.?

Answer.

The U.S. Public Health Service (USPHS) updated and replaced its 1962 Drinking Water Standards related to community water fluoridation to establish a single value of 0.7 mg/L as the optimal concentration of fluoride in drinking water. This concentration provides the best balance of protection from tooth decay while limiting the risk of dental fluorosis.[16]

Fact.

The previous U.S. Public Health Service recommendations for optimal fluoride concentrations were based on average ambient air temperatures of geographic areas and ranged from 0.7-1.2 mg/L. In 2011, the U.S. Department of Health and Human Services (HHS) issued a notice of intent in the *Federal Register*[26] proposing that community water systems adjust the amount of fluoride to 0.7 mg/L to achieve an optimal fluoride level.

The new guidance was based on several considerations that included:

- Scientific evidence related to effectiveness of water fluoridation on 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 in children across various ambient air temperatures.

As part of the process leading to the notice of intent, the U.S. Department of Health and Human Services (HHS) convened a federal interdepartmental, interagency panel of scientists to review the 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 U.S. Food and Drug Administration, the Agency for Healthcare Research and Quality, the Office of the Assistant Secretary for Health, U.S. Environmental Protection Agency, and the U.S. Department of Agriculture.[16]

A public comment period followed the publication of the notice of intent during which time more than 19,000 comments were received. The vast majority (more than 18,000) were variations on a letter submitted by an organization opposing community water fluoridation. Comments received were summarized and reported to the full federal panel. The panel then spent several years reviewing each comment in light of the best available science. After completing their extensive review, the panel did not alter the recommendation based on the following:

- Community water fluoridation remains an effective public health strategy for delivering fluoride to prevent tooth decay and is the most feasible and cost-effective strategy for reaching entire communities.
- In addition to drinking water, other sources of fluoride exposure have contributed to the prevention of dental caries and an increase in dental fluorosis prevalence.
- Caries preventive benefits can be achieved and the risk of dental fluorosis reduced at 0.7 mg/L.
- Recent data do not show a convincing relationship between water intake and outdoor air temperature. Thus, recommendations for water fluoride concentrations that differ based on outdoor temperature are unnecessary.[16]

In 2015 the USPHS published a final report establishing guidance for water systems that are actively fluoridating or those that may initiate fluoridation in the future.[16] For community water systems that add fluoride to their water, the USPHS recommends a uniform fluoride concentration of 0.7 mg/L (parts per million [ppm]) for the entire United States to maintain caries (tooth decay) prevention benefits and reduce the risk of dental fluorosis.

The USPHS further noted that surveillance of dental caries (tooth decay), dental fluorosis, and fluoride intake through the National Health and Nutritional Examination Survey will be done to monitor changes that might occur following implementation of the recommendation.[16]

20. What is the recommendation for the maximum level of naturally occurring fluoride in drinking water contained in the 2016 EPA Six-Year Review 3?

Answer.

As established by the U.S. EPA, the maximum allowable level of naturally occurring fluoride in drinking water is 4 milligrams/liter (mg/L or ppm). Under the Maximum Contaminant Level (MCL) standard, if the naturally occurring level of fluoride in a public water supply exceeds the MCL, the water supplier is required to lower the level of fluoride below the MCL — a process called defluoridation. The MCL is a federally enforceable standard.[27] (Additional details regarding the EPA maximum contaminant standards can be found in the Figure 3.)

Fact.

Under the Safe Drinking Water Act (SDWA),[27] the EPA is required to periodically review the existing National Primary Drinking Water Regulations (NPDWRs) "not less often than every 6 years." This review is a routine part of the EPA's operations as dictated by the SDWA.

In April 2002, the EPA announced the results of its preliminary revise/not revise decisions for 68 chemical NPDWRs as part of its first Six-Year Review of drinking water standards.[28] Fluoride was one of the 68 items reviewed. While the EPA determined that it fell under the "Not Appropriate for Revision at this Time" category, the agency asked the National Academies (NA) to update the risk assessment for fluoride. Prior to this time, the National Academies' National Research Council (NRC) completed a review of fluoride for the EPA which was published as "Health Effects of Ingested Fluoride" in 1993.[8]

The National Research Council's Committee on Toxicology created the Subcommittee on Fluoride in Drinking Water[9] which reviewed toxicologic, epidemiologic, and clinical data published since 1993, and exposure data on orally ingested fluoride from drinking water and other sources (e.g., food, toothpaste, dental rinses). Based on these reviews, the Subcommittee evaluated independently the scientific and technical basis of the U.S. Environmental Protection Agency's (EPA) maximum contaminant level goal (MCLG) of 4 milligram per liter (mg/L or ppm) and secondary maximum contaminant level (SMCL) of 2 mg/L in drinking water.

On March 22, 2006, almost three years after work began, the NRC issued a 500-page report titled *Fluoride in Drinking Water — A Scientific Review of the EPA's Standards*[9] to advise the EPA on the adequacy of its fluoride MCLG (maximum contaminant level goal) and SMCL (secondary maximum contaminant level) to protect children and others from adverse effects. (For additional information on the EPA maximum contaminant standards, please refer to Figure 3.) The report contained two major recommendations related to the MCLG:

> In light of the collective evidence on various health end points and total exposure to fluoride, the committee concludes that EPA's MCLG of 4 mg/L should be lowered. Lowering the MCLG will prevent children from developing severe enamel fluorosis and will reduce the lifetime accumulation of fluoride into bone that the majority of the committee concludes is likely to put individuals at increased risk of bone fracture and possibly skeletal fluorosis, which are particular concerns for subpopulations that are prone to accumulating fluoride in their bones.[9]
>
> To develop an MCLG that is protective against severe enamel fluorosis, clinical stage II skeletal fluorosis, and bone fractures, EPA should update the risk assessment of fluoride to include new data on health risks and better estimates of total exposure (relative source contribution) for individuals. EPA should use current approaches for quantifying risk, considering susceptible subpopulations, and characterizing uncertainties and variability.[9]

The 2006 NRC report[9] contained one major recommendation related to the Secondary Maximum Contaminant Level (SMCL):

> The prevalence of severe enamel fluorosis is very low (near zero) at fluoride concentrations below 2 mg/L. From a cosmetic standpoint, the SMCL does not completely prevent the occurrence of moderate enamel fluorosis. EPA has indicated that the SMCL was intended to reduce the severity and occurrence of the condition to 15% or less of the exposed population. The available data indicate that fewer than 15% of children will experience moderate enamel fluorosis of aesthetic concern (discoloration of the front teeth) at that concentration. However, the degree to which moderate enamel fluorosis might go beyond a cosmetic effect to create an adverse psychological effect or an adverse effect on social functioning is not known.[9]

Additionally, the Subcommittee identified data gaps and made recommendations for future research relevant to future revisions of the MCLG and SMCL for fluoride.[9]

It should be emphasized that the 2006 NRC report was not a review of fluoride as used in community water fluoridation. In fact, the 2006 NRC Report in Brief[29] states: "The committee did not evaluate the risks or benefits of the lower fluoride concentrations (0.7 to 1.2 mg/L) used in water fluoridation. Therefore, the committee's conclusions regarding the potential for adverse effects from fluoride at 2 to 4 mg/L in drinking water do not apply at the lower water fluoride levels commonly experienced by most U.S. citizens."[29]

In response to the recommendations noted above from the NRC report, in 2011, the EPA completed and peer-reviewed a quantitative dose-response assessment based on the available data for severe dental fluorosis as recommended by the NRC.[30] Additionally, the EPA completed and peer-reviewed a document on the environmental exposure of children and adults to fluoride and the relative source contribution for water which is needed in order to derive the MCLG from the dose-response assessment.[30] These efforts were being undertaken during Six-Year Review 2 and so no action on fluoride was taken during Six-Year Review 2.

In December 2016, the EPA announced the review results for the Agency's third Six-Year Review (called Six-Year Review 3),[25] in which the Agency completed a detailed review of 76 national primary drinking water regulations. The regulation for naturally occurring fluoride in water was examined as part of this review and is included among the list of regulated contaminants considered to be "Low priority and/or no meaningful opportunity" under "Not Appropriate for Revision at this Time."[25]

The announcement of the results of the EPA's Six-Year Review 3 in the *Federal Register*[31] indicates that, with the reviews of fluoride conducted since the first Six-Year Review (including but not limited to the 2006 NRC report and the EPA Fluoride Risk Assessment and Relative Source Contribution) and noting that other contaminants are of much greater concern, the EPA is recommending that no further action be taken at this time to change the current MCL/MCLG of 4 mg/L (the maximum level of naturally occurring fluoride allowed in drinking water).[31]

21. What is the Secondary Maximum Contaminant Level (SMCL) for naturally occurring fluoride in drinking water established by the EPA?

Answer.

The Secondary Maximum Contaminant Level (SMCL) for naturally occurring fluoride in water is 2 mg/L (or ppm). This is a non-enforceable federal standard.

Fact.

In addition to the MCL, the EPA has established a Secondary Maximum Contaminant Level (SMCL) of 2.0 mg/L and requires consumer notification by the water supplier if the naturally occurring fluoride level exceeds 2.0 mg/L. The SMCL, while not federally enforceable, is intended to alert families that regular consumption of water with natural levels of fluoride greater than 2.0 mg/L by young children could cause moderate to severe dental fluorosis in the developing permanent teeth.[32] The notice to be used by water systems that exceed the SMCL must contain the following points:

1. The notice is intended to alert families that children under nine years of age who are exposed to levels of fluoride greater than 2.0 mg/liter may develop dental fluorosis.

2. Adults are not affected because dental fluorosis occurs only when developing teeth are exposed to elevated fluoride levels.

3. The water supplier can be contacted for information on alternative sources or treatments that will insure the drinking water would meet all standards (including the SMCL).[32]

Figure 3. USEPA Standards and USPHS Recommendation for Fluoride in Drinking Water

U.S. Environmental Protection Agency (EPA) Standards for Fluoride in Drinking Water

The EPA standards for fluoride in drinking water apply to the ***naturally occurring*** fluoride in water. They are the:

- Maximum Contaminant Level Goal (**MCLG**) – 4 mg/L
- Maximum Contaminant Level (**MCL**) – 4 mg/L
- Secondary Maximum Contaminant Level (**SMCL**) – 2 mg/L

MCLG — The MCLG is the level of contaminants in drinking water at which no adverse health effects are likely to occur. This health goal is based solely on possible health risks and exposure over a lifetime with an adequate margin of safety. The current MCLG for fluoride is 4 mg/L and is set at this level to provide protection against the increased risk of crippling skeletal fluorosis.

MCL — The MCL is an enforceable standard which is set as close to the health goal as possible, considering the benefit to the public, the ability of public water systems to detect and remove contaminants using suitable treatment technologies and cost. In the case of fluoride, the MCL is set at the MCLG.

Under the MCL standard, if the naturally occurring level of fluoride in a public water supply exceeds 4 mg/L, the water supplier is required to lower the level of fluoride or defluoridate. Community water systems that exceed the fluoride MCL of 4 mg/L must notify persons served by that system as soon as practical, but no later than 30 days after the system learns of the violation.

SMCL — Secondary standards are non-enforceable guidelines regulating contaminants that may cause cosmetic effects (such tooth discoloration). The EPA recommends secondary standards to water systems but does not require systems to comply. However, states may choose to adopt them as enforceable standards. Tooth discoloration and/or pitting is caused by excess fluoride exposures during the formative period prior to eruption of the teeth in children. The level of the SMCL was set based upon a balancing of the beneficial effects of protection from tooth decay and the undesirable effects of excessive exposures leading to discoloration.

Under the SMCL, if water exceeds 2 mg/L, the water system is to notify consumers that regular consumption of water with fluoride above 2 mg/L, may increase the risk for fluorosis in young (under 9 years of age) children. Community water systems that exceed the fluoride secondary standard of 2 mg/L must notify persons served by that system as soon as practical but no later than 12 months from the day the water system learns of the exceedance.

U.S. Public Health Service (USPHS) Recommendation for Fluoride in Drinking Water

In 2015, the USPHS published a final report establishing guidance for water systems that are actively fluoridating or those that may initiate fluoridation in the future. For community water systems that add fluoride to their water, the USPHS recommends a uniform fluoride concentration of 0.7 mg/L for the entire United States to maintain caries (tooth decay) prevention benefits and reduce the risk of dental fluorosis.

Why is the EPA MCL of 4 mg/L different from the USPHS recommendation of 0.7 mg/L?

The two benchmarks have different purposes and are set under different authorities. The EPA MCL of 4 mg/L is set to protect against risks from exposure to too much fluoride. The USPHS recommended level of fluoride on 0.7 mg/L is set to promote the benefit of fluoride in preventing tooth decay while minimizing the chance for dental fluorosis.

Information Source: EPA Fact Sheet: Questions and Answers on Fluoride. 2011. Available at *https://www.epa.gov/dwsixyearreview/fact-sheet-questions-and-answers-fluoride*

Additional information on these topics con be found in this Section, Questions 19, 20 and 21.

22. Does the total intake of fluoride from air, water and foods in a community in the United States with drinking water fluoridated at the recommended level pose significant health risks?

Answer.

The total intake of fluoride from air, water and foods in a community in the United States with drinking water fluoridated at the recommended level does not pose significant health risks.

Fact.

Fluoride from the Air

The atmosphere normally contains negligible concentrations of airborne fluorides. Studies reporting the levels of fluoride in air in the United States suggest that ambient fluoride contributes very little to a person's overall fluoride intake.[9,30]

Fluoride from Water

For generations, millions of people have lived in areas where fluoride is found naturally in drinking water in concentrations as high as or higher than those recommended to prevent tooth decay. Research conducted among these people confirms the safety of fluoride in the water supply.[1,5]

A ten-year comparison study of long-time residents of Bartlett and Cameron, Texas, where the water supplies contained 8.0 and 0.4mg/L of fluoride, respectively, included examinations of organs, bones and tissues. Other than a higher prevalence of dental fluorosis in the Bartlett residents (8.0 mg/L fluoride), the study indicated that long-term consumption of fluoride from water and food sources (resident average length of fluoride exposure was 36.7 years), even at these levels more than 10 times higher than recommended for tooth decay prevention, resulted in no clinically significant physiological or functional effects.[5]

In the United States, the natural level of fluoride in ground water varies from very low levels to over 4 mg/L. Public water systems in the U.S. are monitored by the Environmental Protection Agency (EPA), which requires that public water systems not exceed a naturally occurring fluoride level of 4 mg/L.[31] The recommended level for fluoride in drinking water in the United States has been established at 0.7 mg/L by the U.S. Public Health Service.[16] This level has been established to reduce tooth decay while minimizing the occurrence of dental fluorosis.

Individuals living in a community with water fluoridation get a portion of their daily fluoride intake from fluoridated water and a portion from dietary sources which would include foods and other beverages. Water and water-based beverages are the chief source of dietary fluoride intake. Conventional estimates are that approximately 75% of dietary fluoride comes from water and water-based beverages.[33,34] When considering water fluoridation, an individual consuming one liter of water fluoridated at 0.7 mg/L receives 0.7 milligram of fluoride.

Fluoride in Foods

In looking at the fluoride content of foods and beverages over time, it appears that fluoride intake from dietary sources has remained relatively constant.[35] Except for products prepared (commercially or by the individual) or cooked with fluoridated water, the fluoride content of most foods and beverages is not significantly different between fluoridated and nonfluoridated communities. When fluoridated water is used to prepare or cook the samples, the fluoride content of foods and beverages is higher. This difference has remained relatively constant over time.[33,35]

Launched in 2004 and updated in 2005, the National Fluoride Database is a comprehensive, nationally representative database of the fluoride concentration in 427 foods across 27 food groups and beverages consumed in the United States.[34] This database for fluoride was designed for use by epidemiologists and health researchers to estimate fluoride intake and to assist in the investigation of the relationships between fluoride intake and human health. The database contains fluoride values for beverages, water, and some lower priority foods.[34]

The fluoride content of fresh solid foods in the United States generally ranges from 0.01 to 1.0 part per million.[35] The foods highest in fluoride are fish and shellfish, reflective of the fluoride found in ocean water, and the presence or absence of bone fragments such as those in sardines.[35] (Fluoride has an affinity for calcified tissues such as bones.) Cereals, baked goods, breads, and other grain products were estimated to have fluoride concentrations between 0.06 and 0.72 ppm. The majority of vegetables (leafy, root, legumes, green or yellow) have a relatively low fluoride concentration (ranging from 0.01 to 0.5 ppm)

with fruits generally having lower concentrations (ranging from 0.01 to 0.2 ppm) than in vegetables. Raisins are one exception in the fruit category with a higher fluoride concentration due to the use of certain pesticides and concentration through drying.[35]

Brewed teas can contain fluoride concentrations of 1 ppm to 6 ppm depending on the amount of dry tea used, the water fluoride concentration and the brewing time.[36] The fluoride value for unsweetened instant tea powder appears very high when reported as a dry powder because this product is extremely concentrated. However, when one teaspoon of the unsweetened tea powder is added to an eight ounce cup of tap water, the value for prepared instant tea is similar to the values reported for regular brewed tea.[34]

Foods and beverages commercially processed (cooked or reconstituted) in cities fluoridated to the recommended level generally contain higher levels of fluoride than those processed in nonfluoridated communities. These foods and beverages are consumed not only in the city where processed, but also are often distributed to and consumed in nonfluoridated areas.[37] This "halo" or "diffusion" effect results in increased fluoride intake by people in nonfluoridated communities, providing them increased protection against tooth decay.[38,39] As a result of the widespread availability of these various sources of fluoride, the difference between tooth decay rates in fluoridated areas and nonfluoridated areas is somewhat less than several decades ago but this difference is still significant. Failure to account for the diffusion effect results in an underestimation of the total benefit of water fluoridation especially in areas where large amounts of fluoridated products are brought into nonfluoridated communities.[38]

The average daily dietary intake of fluoride (expressed on a body weight basis) by children residing in communities with water fluoridated at 1.0 mg/L is 0.05 mg/kg/day (milligram per kilogram of body weight per day).[40] In communities without optimally fluoridated water, average intakes for children are about 50% lower.[40] Dietary fluoride intake by adults in communities where water is fluoridated at 1.0 mg/L averages 1.4 to 3.4 mg/day, and in nonfluoridated areas averages 0.3 to 1.0 mg/day.[40] With the 2015 recommendation that drinking water be fluoridated at 0.7 mg/L, average intakes would be 30% lower in fluoridated communities than when they were fluoridated at 1.0 mg/L.

23. How much fluoride is recommended to maximize the tooth decay prevention benefits of fluoride?

Answer.

As with all nutrients, the appropriate amount of daily fluoride intake varies with age and body weight. Fluoride is safe and effective when used and consumed properly.

Fact.

In 1997, the Food and Nutrition Board of the Institute of Medicine developed a comprehensive set of reference values for dietary nutrient intakes.[40] These new reference values, the Dietary Reference Intakes (DRI), replace the Recommended Dietary Allowances (RDA) which had been set by the National Academy of Sciences since 1941. The new values present nutrient requirements to optimize health and, for the first time, set maximum-level guidelines to reduce the risk of adverse effects from excessive consumption of a nutrient. Along with calcium, phosphorous, magnesium and vitamin D, DRIs for fluoride were established because of its proven preventive effect on tooth decay. (See Table 2 in this Question.)

The Adequate Intake (AI) establishes a goal for intake to sustain a desired indicator of health without causing side effects. In the case of fluoride, the AI is the daily intake level required to reduce tooth decay without causing moderate dental fluorosis. The AI for fluoride intake from all sources (fluoridated water, foods, beverages, fluoride dental products and dietary fluoride supplements) is set at 0.05 mg/kg/day. Using the established AI of 0.05 mg/kg, the amount of fluoride for optimal health to be consumed each day has been calculated by sex and age group (expressed as average weight).[40]

The Tolerable Upper Intake Level (UL) establishes a maximum guideline. The UL is higher than the AI and is not the recommended level of intake. The UL is the estimated maximum intake level that should not produce unwanted effects on health. The UL for fluoride intake from all sources (fluoridated water, foods, beverages, fluoride dental products and dietary fluoride supplements) is set at 0.10 mg/kg/day (milligram per kilogram of body weight per day) for infants, toddlers, and children through eight years of age. For older children and adults, who are no longer at risk for dental fluorosis, the UL for fluoride is set at

Table 2. Reference Intakes for Fluoride			
Food and Nutrition Board of the Institute of Medicine 1997[40]			
Age Group	**Reference Weights kg (lbs)***	**Adequate Intake (mg/day)**	**Tolerable Upper Intake (mg/day)**
Infants 0-6 months	7 (16)	0.01	0.7
Infants 7-12 months	9 (20)	0.5	0.9
Children 1-3 years	13 (29)	0.7	1.3
Children 4-8 years	22 (48)	1.0	2.2
Children 9-13 years	40 (88)	2.0	10.0
Boys 14-18 years	64 (142)	3.0	10.0
Girls 14-18 years	57 (125)	3.0	10.0
Males 19 years and over	76 (166)	4.0	10.0
Females 19 years and over	61 (133)	3.0	10.0
* Value based on data collected during 1988 94 as part of the Third National Health and Nutrition Examination Survey (NHANES III) in the United States.[40]			

10 mg/day regardless of weight. Using the established ULs for fluoride, the amount of fluoride that can be consumed each day to reduce the risk of moderate enamel fluorosis for children through age eight, has been calculated by sex and age group (expressed as average weight).[40] (See Table 2.)

As a practical example, daily intake of 2 mg of fluoride is adequate for a 9- to 13-year-old child weighing 88 pounds (40 kg). This was calculated by multiplying 0.05 mg/kg/day (AI) times 40 kg (weight) to equal 2 mg. At the same time, that 88 pound (40kg) child could consume 10 mg of fluoride a day as a tolerable upper intake level.

Children living in a community with water fluoridation get a portion of their daily fluoride intake from fluoridated water and a portion from dietary sources which would include foods and other beverages. When considering water fluoridation, an individual must consume one liter of water fluoridated at 0.7 mg/L to receive 0.7 milligrams (0.7 mg) of fluoride. Children under six years of age, on average, consume less than one-half liter of drinking water a day.[35] Therefore, children under six years of age would consume, on average, less than 0.35 mg of fluoride a day from drinking optimally fluoridated water (at 0.7 mg/L).

If a child lives in a nonfluoridated area and is determined to be at high risk for tooth decay, the dentist or physician may prescribe dietary fluoride supplements.[41] As shown in Table 1 "Dietary Fluoride Supplement Schedule" (See Benefits Section, Question 12.), the current dosage schedule recommends supplemental fluoride amounts that are below the AI for each age group.[41] The dosage schedule was designed to offer the benefit of decay reduction with a margin of safety to prevent mild to moderate enamel fluorosis. For example, the AI for a child 3 years of age is 0.7 mg/day. The recommended dietary fluoride supplement dosage for a child 3 years of age in a nonfluoridated community is 0.5 mg/day. This provides leeway for some fluoride intake from processed foods and beverages, and other sources.

Tooth decay rates are declining in many population groups because children today are being exposed to fluoride from a wider variety of sources than decades ago.[16] Many of these sources are intended for topical use only; however, some fluoride is ingested inadvertently by children.[42,43] By reducing the inappropriate ingestion of fluoride from toothpaste, the risk of dental fluorosis can be reduced without jeopardizing the benefits to oral health.

For example, it has been reported in a number of studies that young children inadvertently swallow an average of 0.30 mg of fluoride from fluoride toothpaste at each brushing.[44] [48] If a child brushes twice a day, 0.60 mg of fluoride could be ingested inappropriately. This could slightly exceed the Adequate Intake (AI) values from Table 2. The 0.60 mg consumption is 0.10 mg higher than the AI value for children 6 to 12 months and is 0.10 mg lower than the AI for children from 1-3 years of age.[40] Although toothpaste is not meant to be swallowed, children could consume the daily recommended Adequate Intake amount of fluoride from toothpaste alone. In order to decrease the risk of dental fluorosis, the American Dental Association (ADA) recommends:[49]

- For children younger than 3 years, caregivers should begin brushing children's teeth as soon as they begin to come into the mouth by using fluoride toothpaste in an amount no more than a smear or the size of a grain of rice (Figure 4). Brush teeth thoroughly twice per day (morning and night) or as directed by a dentist or physician. Supervise children's brushing to ensure that they use the appropriate amount of toothpaste.

- For children 3 to 6 years of age, caregivers should dispense no more than a pea-sized amount (Figure 4) of fluoride toothpaste. Brush teeth thoroughly twice per day (morning and night) or as directed by a dentist or physician. Supervise children's brushing to minimize swallowing of toothpaste.[49]

Additional information on this topic can be found in this Section, Question 29.

Figure 4. Examples of Toothpaste Amounts for Children[49]

For children under three years old, use no more than a smear or grain of-rice sized amount of fluoride toothpaste.

For children three to six years old, use only a pea sized amount of fluoride toothpaste.

It should be noted that the amounts of fluoride discussed here are intake, or ingested, amounts. When fluoride is ingested, a portion is retained in the body and a portion is excreted.

Addition information on this topic can be found in this Section, Question 25.

24. Is there a need for prenatal dietary fluoride supplementation?

Answer.

There is no scientific basis to suggest any need to increase a woman's daily fluoride intake during pregnancy or breastfeeding to protect her health. At this time, scientific evidence is insufficient to support the recommendation for prenatal fluoride supplementation for decay prevention for infants.

Fact.

The Institute of Medicine determined that, "No data from human studies document the metabolism of fluoride during lactation. Because fluoride concentrations in human milk are very low (0.007 to 0.011 ppm) and relatively insensitive to differences in the fluoride concentrations of the mother's drinking water, fluoride supplementation during lactation would not be expected to significantly affect fluoride intake by the nursing infant or the fluoride requirement of the mother."[40]

A 2005 a randomized, double blind study[50] compared the amount of fluoride incorporated into primary teeth exposed to prenatal and post natal fluoride supplements to primary teeth that were exposed to only postnatal fluoride. The study concluded that teeth exposed to prenatal and postnatal fluoride supplements had no additional measurable fluoride other than that attributable to postnatal fluoride alone.[50] This study confirmed the findings of a 1997 randomized, double blind study that evaluated the effectiveness of prenatal dietary supplementation which concluded that the data did not support the hypothesis that prenatal fluoride had a strong decay preventive effect on primary teeth.[51]

25. When fluoride is ingested, where does it go?

Answer.
Much of the ingested fluoride is excreted. Of the fluoride retained, almost all is found in calcified (hard) tissues, such as bones and teeth.

Fact.
After ingestion of fluoride, such as drinking a glass of fluoridated water, the majority of the fluoride is absorbed from the stomach and small intestine into the blood stream. This causes a short-term increase in fluoride levels in the blood. Fluoride is distributed through the body by plasma (a component of blood) to hard and soft tissues. Following ingestion, the fluoride plasma levels increase quickly and reach a peak concentration within 20-60 minutes. The concentration declines rapidly, usually approximating the baseline levels within three to six hours, due to the uptake of fluoride by calcified tissues and excretion in urine. In adults, approximately 50% of the fluoride absorbed each day becomes associated with calcified tissues within 24 hours while the remainder is excreted in the urine. Approximately 99% of the fluoride present in the body is in calcified tissues (mainly bone).[52]

Ingested or systemic fluoride becomes incorporated into forming tooth structures. Fluoride ingested regularly during the time when teeth are developing is deposited throughout the tooth structure and contributes to long lasting protection against tooth decay.[53-57]

Additional information on this topic can be found in the Benefits Section, Question 2.

An individual's age and stage of skeletal development will affect the rate of fluoride retention. The amount of fluoride taken up by bone and retained in the body is inversely related to age. A greater percentage of fluoride is absorbed in young bones than in the bones of older adults.[52] However, once fluoride is absorbed into bones, it is released back into plasma (a component of blood) when fluoride levels in plasma fall. This absorption and release cycle continues throughout the life span.[52]

26. Will drinking water that is fluoridated at the recommended level adversely affect bone health?

Answer.
According to the best available science, drinking water that has been fluoridated at the recommended level does not have an adverse effect on bone health.

Fact.
Several systematic reviews have concluded that fluoride at the level used in community water fluoridation has no adverse effect on bone health. A systematic review published in 2000 concluded that there was no clear association between water fluoridation and hip fracture.[59] Twenty-nine studies that looked at the association between bone fracture/bone development and water fluoridation were included in the review. The evidence regarding other types of bone fractures was similar.[59] A systematic review published in 2017[10] concurred with the earlier review concluding that there is evidence that fluoridated water at recommended levels is not associated with bone fracture.[10]

In addition to the systematic reviews, a number of individual studies have investigated the bone health of individuals residing in communities with fluoride in drinking water at the recommended levels and higher than recommended levels. Most of these studies have focused on whether there exists a possible link between fluoride and bone fractures. Additionally, the possible association between fluoride and bone cancer has been studied. None of the studies provide a legitimate reason for altering public health policy regarding fluoridation and bone health concerns.

The following studies, listed in chronological order, add to the body of evidence indicating that there is no association between consumption of optimally fluoridated water and bone fracture.

The Iowa Fluoride Study/Iowa Bone Development Study[60] looked at the association of fluoride intake with bone measures (bone mineral content and bone mineral density) in a cohort of Iowa children. Assessment of the participants' dietary fluoride intake had been ongoing since birth with parents completing detailed fluoride questionnaires at numerous time periods through 15 years of age. These children had combined fluoride intake estimated from a number of sources including water, other beverages, selected

foods, dietary fluoride supplements and fluoride toothpaste. Estimated fluoride intake was noted during different time periods and cumulatively from birth to 15 years of age. The findings indicate that fluoride exposures at typical levels for most U.S. adolescents in fluoridated areas do not have significant effects on bone mineral measures. These findings are generally comparable with those from the analyses of this cohort at age 11 years.[61] During the intervening 4 years, cohort members generally experienced a substantial increase in bone mass accrual. For example, mean whole-body bone mineral content showed mean increases of approximately 61% in females and 96% in males. Despite the acceleration of bone growth near puberty, the associations between fluoride intake and bone outcome measures remained weak and none was significant after adjustment for other variables.[60]

In one of the largest studies of its kind with nearly half a million subjects, Swedish researchers looked at residents' chronic consumption of various levels of fluoride and the risk of hip fracture. All individuals born in Sweden between January 1, 1900 and December 31, 1919, alive and living in their municipality of birth at the time of the start of follow-up, were eligible for the study. Information on the study population was linked to the Swedish health registers. Estimated individual drinking water fluoride exposure was stratified into 4 categories: very low, < 0.3 mg/L; low, 0.3 to 0.69 mg/L; medium, 0.7 to 1.49 mg/L; and high, ≥ 1.5 mg/L. Published in 2013, the researchers found Swedish residents chronically exposed to various levels of fluoride in drinking water did not show any differences in rates of either hip fracture or low-trauma osteoporotic hip fracture due to fluoride exposure.[62]

A study published in 2005 evaluated the bone mineral density levels and rate of bone fracture of 1,300 women living in three separate communities. To be included in the study, the women had to be ambulatory. The ages of the women ranged from 20 years to 92 years. The size and demographics of the three communities were similar. One part of the study looked at whether fluoride was associated with adverse bone-related outcomes. The study measured fluoride serum levels, fluoride exposure, and bone metabolism as related to fluoride exposure and fluoride's interaction with other important bone factors including age, menopause status and medications. The study concluded that long-term exposure to fluoride was not associated with adverse effects on bone health.[63]

A study published in 2001[64] examined the risk of bone fractures, including hip fractures associated with long-term exposure to fluoridated water in six Chinese populations. The water fluoride concentrations ranged from 0.25 to 7.97 mg/L. A total of 8,266 male and female subjects, all of whom were 50 years old or older participated in the study. The results showed an interesting and potentially important finding regarding overall bone fractures. Whereas there appeared to be a trend for higher fracture rates from 1.00 to 4.00 mg/L, the fracture rate in the 1.00 to 1.06 mg/L category was lower than the rate in the category with the lowest fluoride intake (0.25 to 0.34 mg/L). The study concluded that long-term fluoride exposure from drinking water containing 4.32 mg/L or more increases the risk of overall bone fracture, as well as hip fracture, while water fluoride levels of 1.0 to 1.06 mg/L decreased the risk of overall fractures relative to negligible fluoride in water.[64] (Note that 4.32 mg/L is more than six times the fluoride level currently recommended for community water fluoridation in the United States).

While a number of studies reported findings at a population level, both the Hillier and Phipps studies published in 2000, examined risk on an individual, rather than a community basis, taking into account other risk factors such as medications, age of menopause, alcohol consumption, smoking, dietary calcium intake and physical activity. Using these more rigorous study designs, these two studies reported no effect of the risk of hip fracture[65] and no increase in the risk of hip fracture in those drinking fluoridated water,[66] respectively.

According to the best available science, drinking water that has been fluoridated at the recommended level does not have an adverse effect on bone health.

27. What is dental fluorosis or enamel fluorosis?

Answer.

Dental fluorosis is a change in the appearance of the tooth enamel that only occurs when younger children consume too much fluoride, from all sources, over long periods when teeth are developing under the gums.[36] In the United States, most commonly these changes are not readily apparent to the affected individual or casual observer and require a trained specialist to detect. This type of dental fluorosis found in the United States has no effect on tooth function and can make the teeth more resistant to decay.[67] Photographs of mild dental fluorosis can be viewed at *https://www.ADA.org/en/member-center/oral-health-topics/fluoride-topical-and-systemic-supplements*. (Note that mild dental fluorosis is generally less evident than on these photographs. This is because the teeth were dried very well to improve the photography and this makes the mild dental fluorosis stand out, but if the tooth had saliva on it as it usually does, then it would be less noticeable.)

Fact.

The crown of the tooth (the part covered in enamel) is formed under the gums before the teeth erupt. Enamel formation of permanent teeth, other than third molars (wisdom teeth), occurs from about the time of birth until approximately eight years of age.[68] Because dental fluorosis occurs only while teeth are forming under the gums, teeth that have erupted are not at risk for dental fluorosis; therefore, older children and adults are not at risk for the development of dental fluorosis.[69] It should be noted that there are many other developmental changes that affect the appearance of tooth enamel which are not related to fluoride intake. In other words, not all opaque or white blemishes on teeth are caused by fluoride. Furthermore, dental fluorosis occurs among some people in all communities, even in communities that do not have community water fluoridation, or that have a low natural concentration of fluoride in their drinking water.[70-72]

Classification of Dental Fluorosis

Dental fluorosis has been classified in a number of ways. One of the most widely used classifications was developed by Dean in 1942.[73] (See Table 3.)

In using Dean's Fluorosis Index, each tooth in an individual's mouth is rated according to the fluorosis index in Table 3. The individual's dental fluorosis score is based upon the most severe form of fluorosis recorded for two or more teeth. Dean's Fluorosis Index, which has been used since 1942, remains popular for prevalence studies in large part due to its simplicity and the ability to make comparisons with findings from a number of earlier studies.[74]

In 2010, a report by the U.S. National Center for Health Statistics described the prevalence and changes in prevalence and severity of dental fluorosis in the United States and among adolescents between 1986 1987 and 1999 2004.[75] According to the report, in 1999 to 2004, 40.7% of adolescents had dental fluorosis. It should be noted that dental fluorosis can occur not only from fluoride intake from water but also from fluoride products, such as toothpaste, mouthrinses and excessive use of fluoride supplements during the ages when teeth are forming. A 1994 analysis of five studies showed that the amount of dental fluorosis attributable to water fluoridation at 1.0 mg/L was approximately 13%.[76] In other words, at that time the amount of dental fluorosis would have been reduced by only 13% if water was not fluoridated. Now it would be less of a reduction, since fluoridation uses the lower level of 0.7 mg/L. The majority of dental fluorosis in the U.S. is caused by the inappropriate ingestion of fluoride products.[76]

The vast majority of dental fluorosis in the United States is the very mild or mild type. This type of dental fluorosis is not readily apparent to the affected individual or casual observer and often requires a trained specialist to detect. In contrast, the moderate and severe forms of dental fluorosis, characterized by esthetically (cosmetically) objectionable changes in tooth color and surface irregularities, respectively, are not common in the United States. Most investigators regard even the more advanced forms of dental fluorosis as a cosmetic effect rather than a functional adverse effect.[40] In 1993, the U.S. Environmental Protection Agency, in a decision supported by the U.S. Surgeon General, determined that objectionable dental fluorosis is a cosmetic effect with no known health effects.[77] However, in 2003, the EPA requested that the National Research Council (NRC) evaluate the adequacy of its MCLG for fluoride to protect public health. A committee was convened to review recent evidence and eventually developed the 2006 report titled, *Fluoride in Drinking Water — A Scientific Review of the EPA's Standards*.[9] As part of that report, a majority of the committee members found severe dental fluorosis to be an adverse health

effect based on suggestive but inconclusive evidence that severe dental fluorosis (characterized by pitting of the enamel) increased the risk of tooth decay. All members of the committee agreed that the condition damages the tooth and that the EPA standard should prevent the occurrence of this unwanted condition. The prevalence of severe enamel fluorosis is very low below 2 mg/L of fluoride in drinking water in the U.S.[9]

Additional information on this topic can be found in this Section, Questions 20 and 21.

The vast majority of dental fluorosis in the United States is the very mild or mild type. This type of dental fluorosis is not readily apparent to the affected individual or casual observer and often requires a trained specialist to detect.

Limited research on the psychological effects of dental fluorosis on children and adults has been conducted. However, a 2009 literature review that assessed the relationships between perceptions of dental appearance/oral health related quality of life (OHRQoL) and dental fluorosis concluded that very mild to mild dental fluorosis has little impact and in some cases evidence suggested enhanced quality of life with mild dental fluorosis.[78] When evaluating the oral health related quality of life of children by tooth decay (cavities) and dental fluorosis experience, a 2007 study concluded that cavities were associated with a negative impact while mild dental fluorosis had a positive impact on children's and parents' quality of life.[79]

Very mild to mild dental fluorosis has no effect on tooth function and can make the tooth enamel more resistant to decay. A study published in 2009[67] investigated the relationship between dental fluorosis and tooth decay in U.S. schoolchildren. The study concluded that teeth with dental fluorosis were more resistant to tooth decay than were teeth without dental fluorosis. Not only should the cavity preventive benefits of fluoridation be considered when evaluating policy to introduce or retain water fluoridation, but the cavity preventive benefits of mild dental fluorosis should also be considered.[67]

Very mild to mild dental fluorosis has no effect on tooth function and can make the tooth enamel more resistant to decay.

A report published in 2010[75] described the prevalence (total percentage of cases in a population) of dental fluorosis in the United States and discussed the changes in the prevalence and severity of dental fluorosis among adolescents between 1986-1987 and 1999-2004. The report used data from the National Health and Nutrition Examination Survey (NHANES) 1999-2004 and the 1986-1987 National Survey of Oral Health in U.S. School Children. The data represented persons from 6 to 49-years of age and varied races and ethnicities including non-Hispanic black and Mexican-American persons. The oral exams for both surveys were conducted by trained dental examiners and included a dental fluorosis assessment of permanent teeth. The Dean's Fluorosis Index was used to determine the prevalence and severity of dental fluorosis.

The data published in 2010[75] showed that less than one-quarter of persons aged 6-49 in the United States had some form of dental fluorosis. For the remaining three-quarters of persons in this age group, 60.6% were unaffected by dental fluorosis and 16.5% were classified as having questionable dental fluorosis. The percent distribution of the types of dental fluorosis in persons aged 6-49 years observed was:

Very mild fluorosis	16.0%
Mild fluorosis	4.8%
Moderate fluorosis	2.0%
Severe fluorosis	less than 1%

While moderate and severe dental fluorosis comprise less than 3% of dental fluorosis in all persons aged 6-49, the prevalence of moderate or severe dental fluorosis in this age group comprised a very small portion (less than 10%) of the total number of all cases of dental fluorosis. In other words, approximately 90% of all dental fluorosis observed was very mild to mild form.[75]

In regards to dental fluorosis in adolescents, children aged 12-15 years in 1999-2004 had higher prevalence of dental fluorosis compared with the same aged children in 1986-1987.[75]

In reviewing this report,[75] it should be noted that dental fluorosis was not assessed in NHANES 1988-1994 and so it was not possible to compare the NHANES 1999-2002 to the earlier NHANES report. The only other previously collected national data on dental fluorosis were the 1986-1987 National Institute of Dental Research (NIDR) National Survey of Oral Health in U.S. School Children. Differences in study design between NIDR 1986-1987 and NHANES 1999-2002 should be considered when drawing inferences about changes in prevalence and severity of enamel fluorosis.[75] Examples of differences in these two surveys include but are not limited to:

- NIDR survey is a school-based survey while the NHANES is a household survey.
- NHANES did not collect residential histories; NIDR did gather residential histories but it is unknown if NIDR reported dental fluorosis data only for those with a single residence history.
- NIDR collected water samples from schools for fluoride analysis; NHANES did not collect water samples for analysis until the 2013-14 survey cycle.

As defined in Table 3, very mild dental fluorosis is characterized by small opaque, paper-white areas covering less than 25% of the tooth surface. The risk of teeth forming with the very mildest form of dental fluorosis must be weighed against the benefit that the individual will have fewer cavities thus saving dental treatment costs, avoiding patient discomfort and reducing tooth loss.[81,82] In addition, the risk of dental fluorosis can be viewed as an alternative to having tooth decay,[83] which is a disease that causes cosmetic problems, pain, missed school and work, and can lead to infection and, in advanced cases, life-threatening health effects. This is in contrast to dental fluorosis which is not a disease and is not life-threatening.

The risk of teeth forming with the very mildest form of dental fluorosis must be weighed against the benefit that the individual will have fewer cavities thus saving dental treatment costs, avoiding patient discomfort and reducing tooth loss.

Table 3. Dental Fluorosis Classification by H.T. Dean – 1942[75]

Classification	Criteria-Description of Enamel
Normal	Smooth, glossy, pale creamy-white translucent surface
Questionable	A few white flecks or white spots
Very Mild	Small opaque, paper-white areas covering less than 25% of the tooth surface
Mild	Opaque white areas covering less than 50% of the tooth surface
Moderate	All tooth surfaces affected; marked wear on biting surfaces; brown stain may be present
Severe	All tooth surfaces affected; discrete or confluent pitting; brown stain prsent

28. Is it safe to use fluoridated water to reconstitute infant formula?

Answer.
It is safe to use fluoridated water to reconstitute infant formula.

Fact.
Fluoridated water can be used to prepare infant formula. However, if the child is exclusively consuming infant formula reconstituted with fluoridated water, there could be an increased chance of mild dental fluorosis.[86] To lessen this chance, parents can use low-fluoride bottled water some of the time to mix infant formula. These bottled waters are labeled as de-ionized, purified, demineralized, or distilled. However, parents should be aware that using these types of waters exclusively means an infant does not receive the amount of fluoride the Institute of Medicine indicated is required to prevent tooth decay.[40] On the other hand, the exclusive use of nonfluoridated water to reconstitute infant formula will not guarantee that an infant will not develop dental fluorosis. The chance of development of dental fluorosis exists through approximate eight years of age when the permanent teeth are still forming under the gums. Fluoride intake from other sources during this time such as toothpaste, mouthrinse and dietary fluoride supplements also contributes to the chance of dental fluorosis for children living in nonfluoridated and fluoridated communities.[84]

In response to the report of the National Research Council (NRC) *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*[9] in November 2006, and with an abundance of caution, the ADA issued the *Interim Guidance on Fluoride Intake for Infants and Young Children* (Interim Guidance). **The Interim Guidance is no longer current and has been replaced**. Unfortunately, those opposed to fluoridation continue to publicize and use the Interim Guidance in efforts to halt fluoridation.

The *Interim Guidance* was replaced in January 2011 by the ADA *Evidence-Based Clinical Recommendations Regarding Fluoride Intake From Reconstituted Infant Formula and Enamel Fluorosis A Report of the American Dental Association Council on Scientific Affairs*.[84] The report encourages clinicians to follow the American Academy of Pediatrics guidelines for infant nutrition which advocates exclusive breastfeeding until the child is aged 6 months and continued breastfeeding until the child is at least 12 months of age, unless specifically contraindicated. Additionally, the ADA report, designed for use by clinical practitioners, offers the following suggestions to practitioners to use in advising parents and caregivers of infants who consume powdered or liquid concentrate infant formula as the main source of nutrition:[84]

- Suggest the continued use of powdered or liquid concentrate infant formulas reconstituted with optimally fluoridated drinking water while being cognizant of the potential risk of enamel fluorosis development.[89]

- When the potential risk of enamel fluorosis development is a concern, suggest ready-to-feed formula or powdered or liquid concentrate formula reconstituted with water that either is fluoride free or has low concentrations of fluoride.[84]

It should be noted that the Centers for Disease Control and Prevention,[85] as well as other agencies, such as the U.S. Department of Health and Human Services,[86] American Public Health Association,[87] and health departments such as the New York State Health Department[88] provide similar information regarding the use of fluoridated water to reconstitute infant formula.

29. What can be done to reduce the occurrence of dental fluorosis in the U.S.?

Answer.
The vast majority of enamel fluorosis in the United States can be prevented by limiting the ingestion of topical fluoride products (such as toothpaste) and recommending the appropriate use of dietary fluoride supplements — without denying young children the decay prevention benefits of community water fluoridation.

Fact.
Tooth decay has decreased substantially in the United States because more children today are benefitting from access to fluoride which is available from a wider variety of sources than decades ago. Many of these sources are intended for topical use only; however, when they are used, some fluoride is inadvertently swallowed by children.[42,43,89] Inappropriate ingestion of topical fluoride can be minimized, thus reducing the risk for dental fluorosis without reducing decay prevention benefits.

Fluoride Toothpaste

Fluoride toothpastes are effective in helping to prevent tooth decay but have been identified as a major risk factor for enamel fluorosis when used inappropriately.[42,43,89]

In order to decrease the risk of dental fluorosis, the American Dental Association (ADA) recommends:[49]

- For children younger than 3 years, caregivers should begin brushing children's teeth as soon as they begin to come into the mouth by using fluoride toothpaste in an amount no more than a smear or the size of a grain of rice. (See Figure 4 in Question 23.) Brush teeth thoroughly twice per day (morning and night) or as directed by a dentist or physician. Supervise children's brushing to ensure that they use the appropriate amount of toothpaste.

- For children 3 to 6 years of age, caregivers should dispense no more than a pea-sized amount (Figure 4) of fluoride toothpaste. Brush teeth thoroughly twice per day (morning and night) or as directed by a dentist or physician. Supervise children's brushing to minimize swallowing of toothpaste.

The reason for including age information on directions for use for fluoride toothpaste is because it takes into account the ages during which teeth are most susceptible to dental fluorosis (during the time when the teeth are forming under the gums). Additionally, until approximately six years of age, children have not developed the full ability to spit and not swallow toothpaste. Inadvertently swallowing toothpaste during brushing can increase the risk of dental fluorosis. After age eight, the enamel formation of permanent teeth (with the exception of the third molars) is basically complete;[68] therefore, the risk of developing dental fluorosis is over. Because dental fluorosis occurs while teeth are forming under the gums, individuals whose teeth have erupted are not at risk for enamel fluorosis.

Additional information on this topic can be found in this Section, Question 27.

Numerous studies have established a direct relationship between young children brushing with more than a pea-sized amount of fluoride toothpaste and the risk of very mild or mild dental fluorosis in both fluoridated and nonfluoridated communities.[42,43,48,71,89] It was noted that 34% of the dental fluorosis cases in a nonfluoridated community were explained by children having brushed with fluoride toothpaste more than once per day during the first two years of life.[90] In the optimally fluoridated community, 68% of the fluorosis cases were explained by the children using more than a pea-sized amount of toothpaste during the first year of life.[90] However, recognizing that the risk tooth decay can start before a child's first birthday, it is considered important to begin using a fluoride toothpaste when the child's first tooth appears in the mouth.[49]

Dietary Fluoride Supplements

A systematic review published in 2006 concluded that the use of supplements during the first six years of life, and especially during the first three years, is associated with a significant increase in dental fluorosis.[91]

Dietary fluoride supplements should only be prescribed for children at high risk for tooth decay who live in nonfluoridated areas.[41]

Dietary fluoride supplements should be prescribed according to the dosage schedule found in the *Evidence-based Clinical Recommendations on the Prescription of Dietary Fluoride Supplements for Caries Prevention: A Report of the American Dental Association Council on Scientific Affairs published in 2010.*[41] The current dietary fluoride supplement schedule[41] is shown in the Benefits Section, Question 12, Table 1.

Determination of the level of risk for tooth decay is accomplished through the use of a professional caries risk assessment that assists the health provider identify and assess factors that could contribute to the development of cavities.[41] A child's caries (cavity) risk should be assessed on a routine basis because risk status can be affected by changes in the child's development, home conditions, dietary regimen and oral hygiene practices. Additional information on caries risk assessments can be found on the ADA website.[92] Because of the many sources of fluoride in the diet, proper prescribing of fluoride supplements can be complex. It is suggested that all sources of fluoride be evaluated with a thorough fluoride history before supplements are prescribed for a child.[41] This evaluation should include testing of the home water supply if the fluoride concentration is unknown. Families on community water systems should contact their water supplier to ask about the fluoride level. Consumers with private wells should have the water tested yearly to accurately determine the fluoride content.

Additional information on this topic can be found in the Benefits Section, Question 4.

Dietary fluoride supplements can be considered for infants and children aged 6 months to 16 years. Compliance with the daily administration of the supplement will enhance the cavity prevention benefits. Providers should consider and monitor the ability of the caregiver and child to adhere to the schedule. If compliance is an issue, another mode of fluoride delivery should be considered.[41]

Use of Over the Counter Fluoride-Containing Dental Products in the Home

Parents, caretakers and health care professionals should judiciously monitor use of all fluoride-containing dental products by children under age six. As is the case with any therapeutic product, more is not always better. The same is true for most products found in the medicine cabinet; care should be taken to adhere to label directions on fluoride prescriptions and over-the-counter products (e.g., fluoride toothpastes and rinses).

The ADA recommends the use of fluoride mouthrinses, but not for children less than six years of age because they may swallow the rinse.[93] These products should be stored out of the reach of children. Additional information regarding the use of mouthrinses can be found on the ADA website.[93]

Drinking Water That Has Been Fluoridated at the Recommended Levels

In 2015, the U.S. Public Health Service made a recommendation on the level of fluoride to be used in water fluoridation (0.7mg/L) to provide the best balance of protection from tooth decay while limiting the risk of dental fluorosis.[16]

Additional information on this topic can be found in this Section, Question 19.

Drinking Water With High Levels of Naturally Occurring Fluoride

In areas where naturally occurring fluoride levels in ground water are higher than 2 mg/L, the U.S. EPA has recommended that consumers should consider action to lower the risk of dental fluorosis for young children such as providing drinking water from an alternative source.[32]

Families with young children on community water systems should contact their water suppliers to ask about the fluoride level in their drinking water. Consumers with private wells should have the water tested yearly to accurately determine the fluoride content. Consumers should consult with their dentist regarding water-testing results and discuss appropriate dental health care measures.

In homes where young children (with developing permanent teeth) are faced with consuming water with a fluoride level greater than 2 mg/L, families should use an alternative primary water source that contains the recommended level of fluoride for drinking and cooking.[32]

Additional information on this topic can be found in this Section, Question 21.

30. Why is there a warning label on a tube of fluoride toothpaste?

Answer.

The U.S. Food and Drug Administration (FDA) has established regulations for warning labels for a number of over-the-counter items it considers safe and effective including fluoride toothpaste.

Fact.

The FDA has published regulations regarding warning labels for over-the-counter (OTC) drugs in the Code of Federal Regulations (CFR).[94] All the non-prescription drugs covered by these regulations must display the general warning "Keep out of the reach of children" in bold type. The regulations outline three additional warning statements (based on the most likely route of exposure) to be listed on the label in the event the drug is misused. While they vary slightly, they all include the following language: "...get medical help or contact a Poison Control Center right away."[94]

In the CFR, the FDA has outlined the drug categories to be covered by these warning labels.[95] Some of the 26 categories include antacids, allergy treatment products, antiperspirants, cold remedies, ophthalmic products and dentifrices and dental products such as analgesics, antiseptics, etc.[95]

A specific FDA regulation[96] applies to "Anticaries Drug Products for Over-The-Counter Human Use" which provides the exact language for the warning label to be used on "fluoride dentifrice (gel, paste, and powder) products." The regulation requires the following language appear on these products under the heading "Warning":

> "Keep out of reach of children under 6 years of age. [highlighted in bold type] If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away."[96]

The over-the-counter (OTC) drugs listed in these regulations are generally recognized as safe and effective by the FDA.[94] Fluoride toothpaste is just one of a long list of OTC products that carries a warning label.

The over-the-counter (OTC) drugs listed in these regulations are generally recognized as safe and effective by the FDA. Fluoride toothpaste is just one of a long list of OTC products that carries a warning label.

While the FDA has required such label language since 1997, the ADA has required manufacturers seeking the ADA Seal of Acceptance to place a label on fluoride toothpaste since 1991 to help ensure proper use and thereby reduce the risk of dental fluorosis. At that time, the ADA required the label to include: "Do not swallow. Use only a pea-sized amount for children under six. To prevent swallowing, children under six years of age should be supervised in the use of toothpaste."

Additionally, to ensure children's safety, the ADA limits the total amount of fluoride allowed in any one tube of ADA-Accepted toothpaste. If a child were to ingest an entire tube of fluoride toothpaste at one time, the total fluoride content of a single tube is not enough to cause a fatal event. In fact, because of some of the (non-fluoride) additives in toothpaste, a child attempting to ingest a tube of toothpaste would most likely vomit before they could eat enough to become seriously ill.

31. Is fluoride, as provided by community water fluoridation, a toxic substance?

Answer.

No. Fluoride in water at the recommended level is not toxic according to the best available scientific evidence.

Fact.

Toxicity is related to dose. While large doses of fluoride could be toxic, it is important to recognize the difference between the effect of a massive dose of an extremely high level of fluoride versus the fluoride level currently recommended for public water systems. Like many common substances essential to life and good health — salt, iron, vitamins A and D, chlorine, oxygen and even water itself — fluoride can be toxic in massive quantities. Fluoride at the much lower recommended concentrations (0.7 mg/L) used in community water fluoridation is not harmful or toxic.[16]

Fluoride at the much lower recommended concentrations (0.7 mg/L) used in community water fluoridation is not harmful or toxic.

The single dose (consumed all at one time) of fluoride that could cause acute fluoride toxicity is 5 mg/kg of body weight (11mg/kg of body weight of sodium fluoride).[97] This dose is considered the probably toxic dose (PTD) which "is defined as the minimum dose that could cause serious or life-threatening systemic signs and symptoms and that should trigger immediate therapeutic intervention and hospitalization."[97] Acute fluoride toxicity occurring from the ingestion of optimally fluoridated water is impossible.[97] With water fluoridated at 1 mg/L, an individual would need to drink five (5) liters of water for every kilogram of body weight. For example, for an adult male (155 pound/70.3 kilogram man), it would require that he consume more than 350 liters (nearly 93 gallons) of water at one time to reach an acute fluoride dose. With optimally fluoridated water now set at 0.7 mg/L, it would take almost 30% more, or nearly 120 gallons (more than 1,900 eight ounce glasses) of water at one time to reach the acute dose.

Chronic fluoride toxicity can develop after 10 or more years of exposure to very high levels of fluoride, levels much higher than what is associated with drinking water fluoridated at recommended levels. The primary functional adverse effect associated with long-term excess fluoride intake is skeletal fluorosis.[40,58] The development of skeletal fluorosis and its severity is directly related to the level and duration of fluoride intake. For example, the ingestion of water naturally fluoridated at approximately 5 mg/L or greater for 10 years or more is needed to produce clinical signs of osteosclerosis (a mild form of skeletal fluorosis that can be seen as a change in bone density on x-rays) in the general population. In areas naturally fluoridated at 5 mg/L, daily fluoride intake of 10 mg/day would not be uncommon.[40] A survey of X-rays from 170,000 people in Texas and Oklahoma whose drinking water had naturally occurring fluoride levels of 4 to 8 ppm revealed only 23 cases of osteosclerosis and no cases of crippling skeletal fluorosis.[98] Evidence of advanced skeletal fluorosis, or crippling skeletal fluorosis, was not seen in communities in the United States where water supplies contained up to 20 mg/L of naturally occurring fluoride.[40,99] In these communities, "daily fluoride intake of 20 mg/day would not be uncommon."[40] Crippling skeletal fluorosis is extremely rare in the United States and is not associated with water fluoridated at the recommended level.[40,58]

Additional information on this topic can be found in this Section, Question 26.

The Environmental Protection Agency (EPA) identifies the most serious hazardous waste sites in the nation. These sites make up the Superfund: National Priorities List (NPL) and are the sites targeted for long-term federal cleanup activities.[100] The Agency for Toxic Substances and Disease Registry (ATSDR) prepares toxicological profiles for hazardous substances that describe the effects of exposure from chemicals found at these sites and acute releases of these hazardous substances.[101] The ATSDR provides answers to the most frequently asked questions about exposure to hazardous substances found around hazardous waste sites and the effects of exposure on human health. The Toxicological Profile for Fluorides, Hydrogen Fluoride and Fluorine indicates that subsets of the population could be unusually susceptible to the toxic effects of fluoride and its compounds at high doses, such as what might be encountered in the cleanup of a chemical spill. However, there are no data to suggest that exposure to the low levels of fluoride associated with community water fluoridation would result in adverse effects in these potentially susceptible populations.[101] The ATSDR's Public Health Statement on Fluorides states that "when used appropriately, fluoride is effective in preventing and controlling dental caries."[102]

While large doses of fluoride could be toxic, it is important to recognize the difference in the effect of a massive dose of an extremely high level of fluoride versus the recommended amount of fluoride found in optimally fluoridated water. The implication that fluoride in large doses and fluoride in trace amounts have the same effect is completely unfounded. Many substances in widespread use are very beneficial in small amounts while toxic in large quantities.

The possibility of adverse health effects from continuous low level consumption of fluoride over long periods has been studied extensively. As with other nutrients, fluoride is safe and effective when used and consumed properly. No charge against the safety of fluoridation has ever been substantiated by generally accepted scientific knowledge. After more than 70 years of research and practical experience, the best available scientific evidence indicates that fluoridation of community water supplies is safe.

After more than 70 years of research and practical experience, the best available scientific evidence indicates that fluoridation of community water supplies is safe.

32. Does drinking water fluoridated at the recommended levels cause or accelerate the growth of cancer?

Answer.

According to the best available scientific evidence, there is no association between cancer rates in humans and drinking water that is fluoridated at the recommended levels.

Fact.

Since community water fluoridation was introduced in 1945, more than 50 epidemiologic studies in different populations and at different times have failed to demonstrate an association between fluoridation and the risk of cancer.[1] Studies have been conducted

in the United States,[103 108] Japan,[109] the United Kingdom,[110-112] Canada[113] and Australia.[114] In addition, over the years, a number of independent bodies from around the world have conducted extensive reviews of the scientific literature and concluded that there is no relationship between fluoridation and cancer.[1,2,4,59,115] At the beginning of the Safety Section in Question 17, a number of recent reviews are listed that have also concluded there is no relationship between fluoridation and cancer.[10,11,13,15-18,20,21] Clearly, the best available science indicates there is no association between fluoridation and cancer.

Clearly, the best available science indicates there is no association between fluoridation and cancer.

Many of the questions about a possible association between fluoride and cancer center around a form of bone cancer called osteosarcoma. This topic is covered in the next question.

In October 2011, the California Office of Environmental Health Hazard Assessment (OEHHA) through its Carcinogen Identification Committee (CIC) determined that fluoride does not cause cancer. The review was part of California's Proposition 65 listing process.[116] Proposition 65 was enacted in 1986 with the intent to protect California citizens and the State's drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm and to inform citizens about exposure to such chemicals. It requires the Governor to publish, at least annually, a list of chemicals known to the state to cause cancer or reproductive toxicity. The OEHHA administers meetings of the CIC and the list of items to be reviewed through the Proposition 65 process. On May 29, 2009, fluoride was selected by OEHHA for review by the CIC. Due to widespread exposure to fluoride, it was identified as one of five high priority chemicals to be evaluated. A public comment period followed. On July 8, 2011, as the next step in the Proposition 65 process, the CIC released a hazard identification document, "Evidence on the Carcinogenicity of Fluoride and its Salts". It was used by the CIC in its deliberations on whether fluoride should be listed as a carcinogen under Proposition 65. A second public comment period followed. At a public meeting on October 12, 2011, the CIC heard additional testimony and then voted on the question, "Do you believe that it has been clearly shown, through scientifically valid testing according to generally accepted principles, that fluoride causes cancer?" The CIC's vote was unanimous (6-0) that fluoride had not been clearly shown to cause cancer.[117]

On its website, the American Cancer Society (ACS) provides a page titled, "Water Fluoridation and Cancer Risk."[118] In question and answer format, the ACS provides basic information regarding fluoridation as well as information on a number of studies that examined the possible association between fluoridation and cancer — many of which are referenced in the opening paragraph of this Safety Section. Near the bottom of the ACS web page, under the header "Assessments by Expert Groups" is this paragraph:

> The general consensus among the reviews done to date is that there is no strong evidence of a link between water fluoridation and cancer. However, several of the reviews noted that further studies are needed to clarify the possible link.[118]

33. Does fluoridated water cause osteosarcoma?

Answer.
No. The best available scientific evidence shows that fluoridated water does not cause osteosarcoma.

Fact.
In 2016, the American Society of Clinical Oncology estimated that a total of 1,000 people, including 450 children and teens younger than 20, would be diagnosed with osteosarcoma (a form of bone cancer) in the United States during the year. About 2% of all childhood cancers are osteosarcoma which most often affects those between the ages of 10 and 30. Osteosarcoma is about 50% more common in boys than girls. The 5-year survival rate for children and teens with osteosarcoma that is only in one place at the time of diagnosis is 70%.[119]

In 2014, researchers from England published the largest study ever conducted examining the possible association between fluoride in drinking water and risk of osteosarcoma or Ewing sarcoma. Analyzing 2,566 osteosarcoma cases and 1,650 Ewing's sarcoma cases from 1980 to 2005, the study found that higher

levels of natural or adjusted fluoride in drinking water in Great Britain (England, Scotland and Wales) had no impact on the incidence of either osteosarcoma or Ewing's sarcoma in people aged 0–49. Water fluoride levels ranged from near zero to a maximum of approximately 1.26 ppm.[120]

A case-control study[121] published in 2011 found no significant association between the fluoride levels in bone and osteosarcoma risk. Led by a Harvard researcher, the study analyzed fluoride levels in bone samples from 137 patients with primary osteosarcoma and bone samples from 51 patients with other newly-diagnosed malignant bone tumors who served as a control group. Conducted in nine U.S. hospitals over an eight-year period (1993 and 2000), the study was considered the most extensive to date on the issue. The vast majority of fluoride in the body is located in calcified tissue such as bone. The study hypothesized that if chronic exposure to fluoride was a risk factor for osteosarcoma, then those cases would have a significantly higher level of fluoride in bone than the controls. This was not the case. The major advantage of this study was the ability to use actual bone fluoride levels as a measure of fluoride intake rather than estimating fluoride exposure. Focusing on fluoride intake from water as a primary source of fluoride, in earlier studies[122,123] members of the research team noted the difficulty in obtaining accurate information on fluoride levels of drinking water at the subjects' homes. Even when accurate information could be obtained, that information did not reflect actual consumption of water by the study subjects. Funding for the study came from three agencies of the National Institutes of Health — the National Cancer Institute, the National Institute of Environmental Health Sciences and the National Institute of Dental and Craniofacial Research.[121]

The best available scientific evidence shows that fluoridated water does not cause osteosarcoma (a form of bone cancer).

34. Does fluoride, as provided by community water fluoridation, inhibit the activity of enzymes in humans?

Answer.

The best available scientific evidence demonstrates that the recommended levels of fluoride in drinking water, has no effect on human enzyme activity.

Fact.

Enzymes are organic compounds that promote chemical change in the body. The best available scientific evidence has not indicated that water fluoridated at the recommended levels has any influence on human enzyme activity. There are no available data to indicate that, in humans drinking water fluoridated at the recommended levels, the fluoride affects enzyme activities with toxic consequences.[124] The World Health Organization report, *Fluorides and Human Health* states, "No evidence has yet been provided that fluoride ingested at 1 ppm in the drinking water affects intermediary metabolism of food stuffs, vitamin utilization or either hormonal or enzymatic activity."[125]

In 2006, the National Research Council Report stated that the available data were not sufficient to draw any conclusions about potential effects or risks to liver enzymes from low-level long-term fluoride exposures such as those seen with community water fluoridation.[9]

The concentrations of fluoride used in laboratory studies to produce significant inhibition of enzymes are hundreds of times greater than the concentration present in body fluids or tissues.[126] While fluoride could affect enzymes in an artificial environment outside of a living organism in the laboratory, it is unlikely that adequate cellular levels of fluoride to adversely alter enzyme activities would be attainable in a living organism. The two primary physiological mechanisms that maintain a low concentration of fluoride ion in body fluids are the rapid excretion of fluoride by the kidneys and the uptake of fluoride by calcified tissues.[52]

35. Does the ingestion of optimally fluoridated water adversely affect the thyroid gland or its function?

Answer.

The best available scientific evidence indicates optimally fluoridated water does not have an adverse effect on the thyroid gland or its function.

Fact.

A number of systematic reviews completed in the last ten years have looked at a possible association between exposure to fluoride and thyroid function.

In 2017, the Australian National Health and Medical Research Council's systematic review *Information Paper — Water Fluoridation: Dental and Other Human Health Outcomes*[10] concluded, "There is no reliable evidence of an association between water fluoridation and current Australian levels and thyroid function." (Current recommendations for fluoride levels in drinking water in Australia are a range of 0.6 to 1.1 mg/L depending on climate.)[10]

A scientific evaluation of fluoridating agents of drinking water was done by the Scientific Committee on Health and Environmental Risks (SCHER) as requested by the European Commission (EC). The EC is the European Union's (EU) executive body with responsibility to manage EU policy. The final report, *Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water,* was released in 2011. It stated that "A systematic evaluation of the human studies does not suggest a potential thyroid effect at realistic exposures to fluoride."[20]

In 2015, the *U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries*[16] was released. It referred to the 2006 National Research Council's report, *Fluoride in Drinking Water — A Scientific Review of the EPA's Standards,*[9] stating:

> The 2006 NRC review considered a potential association between fluoride exposure (2-4 mg/L) and changes in the thyroid, parathyroid, and pineal glands in experimental animals and humans. The report noted that available studies of the effects of fluoride exposure on endocrine function have limitations. For example, many studies did not measure actual hormone concentrations, and several studies did not report nutritional status or other factors likely to confound findings. The NRC called for better measurement of exposure to fluoride in epidemiological studies and for further research "to characterize the direct and indirect mechanisms of fluoride's action on the endocrine system and factors that determine the response, if any, in a given individual."[9]

On March 22, 2006, during the press webcast[127] for the release of the 2006 National Research Council (NRC) Report,[9] John Doull, M.D., Ph.D., Professor Emeritus of Pharmacology and Toxicology, University of Kansas Medical Center, Kansas City and Chair of the NRC Committee was asked about the conclusions reached on fluoride and the endocrine system (which includes the thyroid). Dr. Doull replied:

> The Endocrine Chapter (of the NRC Report) is a relatively new chapter. It has not been extensively reviewed previously and our feeling was that we needed to provide a baseline of all the adverse effects and a lot of the systems that hadn't really been looked at very closely. We have a chapter for example on the central nervous system which has not been reviewed in detail previously. We went through all those effects in the endocrine chapter, the thyroid effect, the parathyroid effect, calcitonin to see whether there were sufficient evidence for us to include any of those effects as specific adverse effects at 4 mg/L and the conclusion of our Committee was that those were all things we needed to worry about. Those were all things that we made recommendations for additional research. **But, none of them reached the level where we considered them to be signs of adverse effects at the 4 mg/L level**. (Emphasis added.)[127]

A population-based Canadian study[128] was released in 2017 that examined the association between fluoride exposure and thyroid conditions. Data for the analysis came from Cycles 2 (2009-2011) and 3 (2012-2013) of Statistics Canada's Canadian Health Measures Survey (CHMS). The CHMS' target population is all Canadian residents between the ages of 3 and 79 living in all ten Canadian provinces. It collects health information by an individual in-home interview followed by a clinical exam conducted in a mobile clinic. The researchers' reported findings suggest that, at the population level in Canada, fluoride exposure does not contribute to impaired thyroid functioning during a time when multiple sources of fluoride exposure, including community water

fluoridation, exist. It was additionally noted that the findings could be broadly relevant to other countries with similar populations and water fluoridation.[128]

In 2015, a study was published in which the authors claimed to have found a positive association between fluoride levels in drinking water and hypothyroidism. Drawing immediate criticism, the published critiques noted that a major weakness of this study was the failure to consider a number of potential confounding factors. The only confounders taken into consideration were age, sex and socioeconomic status. While acknowledging that iodine intake is associated with thyroid health, the authors failed to consider iodine as a factor along with the impacts of smoking and medications. The strong conclusion of the paper was not supported by the work of the authors or other published literature.[130-133]

In addition, two studies have explored the association between fluoridated water and cancer of the thyroid gland. Both studies found no association between optimal levels of fluoride in drinking water and thyroid cancer.[106,110]

36. Does water fluoridation affect the pineal gland causing the early onset of puberty?

Answer.
The best available scientific evidence indicates that water fluoridation does not cause the early onset of puberty.

Fact.
The pineal gland is an endocrine gland located in the brain which produces melatonin.[133] Endocrine glands secrete their products into the bloodstream and body tissues and help regulate many kinds of body functions. The hormone, melatonin, plays a role in sleep, aging and reproduction.[134]

A single researcher has published one study in a peer-reviewed scientific journal regarding fluoride accumulation in the pineal gland. The purpose of the study was to discover whether fluoride accumulates in the pineal gland of older adults. This limited study, conducted on only 11 cadavers whose average age at death was 82 years, indicated that fluoride deposited in the pineal gland was significantly linked to the amount of calcium in the pineal gland.[135] It would not be unexpected to see higher levels of calcium in the pineal gland of older individuals as this would be considered part of a normal aging process. As discussed in Question 25, approximately 99% of the fluoride present in the body is associated with hard or calcified tissues.[52] The study concluded fluoride levels in the pineal gland were not indicators of long-term fluoride exposure.[135]

The same researcher had theorized in her 1997 dissertation, portions of which are posted on numerous internet sites opposed to fluoridation, that the accumulation of fluoride in children's pineal glands leads to an earlier onset of puberty. However, the researcher notes in the dissertation that there is no verification that fluoride accumulates in children's pineal glands. Moreover, a study conducted in Newburgh (fluoridated) and Kingston (nonfluoridated), New York found no statistically significant difference between the onset of menstruation for girls living in a fluoridated versus nonfluoridated area.[136] The National Research Council's 2006 report, *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*, stated that a connection between fluoride pineal function in humans remains to be demonstrated."[9]

37. Can fluoride, at the levels found in drinking water that is fluoridated to the recommended levels, alter immune function or produce an allergic reaction (hypersensitivity)?

Answer.
There is no scientific evidence of any adverse effect from fluoridation on any specific immunity, nor have there been any medically confirmed reports of allergic reaction from drinking or being in contact with optimally fluoridated water.

Fact.
There is no scientific evidence linking health conditions related to immune function such as HIV or AIDS (acquired immune deficiency syndrome) with community water fluoridation.[137]

There are no confirmed cases of allergy to fluoride, or of any positive skin testing in human or animal models.[138] A committee of the National Academy of Sciences evaluated clinical reports of possible allergic responses to fluoride in 1977 and stated, "The reservation in accepting (claims of allergic reaction) at face value is the lack of similar reports in much larger numbers of people who have been exposed to considerably more fluoride than was involved in the

original observations."[7] The World Health Organization also judged these cases to represent "a variety of unrelated conditions" and found no evidence of allergic reactions to fluoride.[139,140]

38. Is fluoride, as provided by community water fluoridation, a genetic hazard?

Answer.
The best available scientific evidence indicates that drinking water fluoridated at the recommended levels is not a genetic hazard.

Fact.
Chromosomes are the DNA-containing bodies of cells that are responsible for the determination and transmission of hereditary characteristics. A single chromosome contains many genes which are the functional hereditary units that occupy a fixed location on a chromosome. Many studies have examined the possible effects of fluoride on chromosome damage.

In 1993, the National Research Council (NRC) of the National Academies issued a report[8] that supported the conclusion that drinking optimally fluoridated water is not a genetic hazard. In a statement summarizing its research[8], the NRC stated, "in vitro data indicate that:

1. the genotoxicity of fluoride is limited primarily to doses much higher than those to which humans are exposed,
2. even at high doses, genotoxic effects are not always observed, and
3. the preponderance of the genotoxic effects that have been reported are of the types that probably are of no or negligible genetic significance."[8]

The lowest dose of fluoride reported to cause chromosomal changes in mammalian cells was approximately 170 times that normally found in human cells in areas where drinking water was fluoridated at 1.0 mg/L, which indicates a large margin of safety.[8] (Note that this would be 242 times greater with fluoridation now set at 0.7 mg/L.)

In its subsequent 2006 report,[9] the NRC stated after reviewing the evidence available since its 1993 report, that the weight of evidence from studies on rodents indicated a very low probability that fluoride presents a risk of genetic mutation for humans.[9]

In addition, the 2006 NRC report[9] indicated that the results of human studies related to fluoride and its effect on genotoxicity since its 1993 report are inconsistent and do not strongly indicate the presence or absence of genotoxic potential for fluoride. Continued research and evaluation are recommended.[9]

39. Does fluoride at the levels found in water fluoridation affect human reproduction, fertility or birth rates?

Answer.
According to the best available scientific evidence, water fluoridation does not have an adverse effect on human reproduction, fertility or birth rates.

Fact.
In 2011, the European Commission requested the European Scientific Committee on Health and Environmental Risks (SCHER) perform a critical review of fluoridating agents of drinking water. A portion of that report looked at reproductive issues. The report concluded that there is no new evidence from human studies indicating that fluoride in drinking water influences male and female reproductive capacity.[20]

In its 2006 report,[9] the National Research Council (NRC) indicated that since 1990, the quality and number of reproductive and developmental studies using laboratory animals have improved significantly. These high-quality studies indicate adverse reproductive and developmental effects occur only at levels of fluoride much higher than 4 mg/L.[9] The NRC also indicated that a few studies conducted with human populations have suggested that fluoride might be associated with alterations in reproductive hormones and fertility. However, the report continued on to explain that limitations in study design, such as the lack of control of reproductive variables, make these studies of little value for risk evaluation.[9]

A study examining the relative risk of stillbirths and congenital abnormalities (facial clefts, Down syndrome and neural tube defects) found no evidence that fluoridation had any influence on the rates of congenital abnormalities or stillbirths.[141] The study, conducted in 2003, analyzed data from two population based registries to identify all stillbirths and congenital abnormalities occurring in northeastern England between 1989 and 1998 and compared the rates of stillbirths and

specific congenital abnormalities in fluoridated and nonfluoridated communities. The study found no significant association between the occurrence of stillbirths or specific congenital abnormalities and fluoride levels in drinking water.[141]

40. For women, does drinking water fluoridated at the recommended levels create a risk for their children to be born with Down syndrome?

Answer.
There is no known association between the consumption of drinking water fluoridated at the recommended levels and Down syndrome.

Fact.
All people with Down syndrome have an extra, critical portion of chromosome 21 present in all or some of their cells. This additional genetic material alters the course of development and causes the characteristics associated with Down syndrome. The cause of the extra full or partial chromosome is still unknown. Maternal age is the major factor that has been linked to an increased chance of having a baby with Down syndrome. There is no definitive scientific research that indicates that Down syndrome is caused by environmental factors or the parents' activities before or during pregnancy.[142]

However, those opposed to fluoridation sometimes still assert that consuming fluoridated tap water can cause Down syndrome.

In 2014, the systematic review published by Public Health England reviewed the literature and concluded that there was no evidence of a difference in the rate of Down syndrome in fluoridated and nonfluoridated areas.[17]

A number of studies have looked at this issue in the past. Several are summarized below.

A detailed study of approximately 2,500 children born with Down syndrome was conducted in Massachusetts. A rate of 1.5 cases per 1,000 births was found in both fluoridated and nonfluoridated communities, providing strong evidence that fluoridation does not increase the risk of Down syndrome.[143]

Another large population-based study with U.S. national data relating to nearly 1.4 million births showed no association between water fluoridation and the incidence of congenital malformations including Down syndrome.[144]

A comprehensive study of Down syndrome births was conducted in 44 U.S. cities over a two-year period. Rates of Down syndrome were comparable in both fluoridated and nonfluoridated cities.[145]

41. Does ingestion of water fluoridated at recommended levels have any effect on intelligence (IQ) in children or neurological impact?

Answer.
The best available science-based evidence does not establish a causal relationship between consumption of water fluoridated at recommended levels and lowered intelligence (IQ) or behavioral disorders in children.

Fact.
A number of systematic reviews and individual studies provide evidence that consumption of optimally fluoridated water at levels recommended in the U.S. (0.7 mg/L) does not lower IQ or cause behavior problems in children. The following conclusions from a number of systematic reviews and individual studies support the safety of community water fluoridation.

A number of systematic reviews and individual studies provide evidence that consumption of optimally fluoridated water at levels recommended in the U.S. (0.7 mg/L) does not lower IQ or cause behavior problems in children.

In 2017, the Australian National Health and Medical Research Council's systematic review *Information paper — Water Fluoridation: Dental and Other Human Health Outcomes*[10] concluded, "The evidence from a single study of acceptable quality shows that there is no association between water fluoridation at current Australian levels and the cognitive function of children or adults." (Current recommendations for fluoride levels in drinking water in Australia are a range of 0.6 to 1.1 mg/L depending on climate.)[10]

The report, *Health Effects of Water Fluoridation: An Evidence Review*, issued in 2015 by the Ireland Health Research Board noted,[15] "There was only one study carried out in a non-endemic or CWF area (like Ireland) that examined fluoride and IQ. This was a prospective cohort study (whose design is appropriate to infer causality) in New Zealand. The study concluded that there was no evidence of a detrimental effect on IQ as a result of exposure to CWF (community water fluoridation)."[15]

In 2014, a scientific review, *Health effects of water fluoridation: A review of the scientific evidence*,[18] commissioned by the New Zealand Prime Minister's Chief Science Advisor and the President of the Royal Society of New Zealand concluded: "There is no convincing evidence of neurological effects at fluoride concentrations achieved by CWF."[18]

At the request of the European Commission, the Scientific Committee on Health and Environmental Risks (SCHER) conducted a critical review[20] of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water. Their report of May 2011 reviewed animal and human studies concluding that "there is not enough evidence to conclude that fluoride in drinking water at concentrations permitted in the EU may impair the IQ of children. SCHER also agreed that a biological plausibility for the link between fluoridated water and IQ has not been established."[20]

As noted in the preceding paragraphs, at least three systematic reviews[10,15,18] indicated that there was only one high-quality prospective cohort study that addressed the issue of IQ. Published in 2014, a study[146] conducted in New Zealand followed a group of more than 1,000 people born in the early 1970s and measured childhood IQ at the ages of 7, 9, 11 and 13 years and adult IQ at the age of 38 years. Early life exposure to fluoride from a variety of sources was recorded and adjustments were made for factors potentially influencing IQ. Childhood factors associated with IQ variation included socio-economic status of parents, birth weight and breastfeeding, as well as secondary and tertiary educational achievement, which is associated with adult IQ. This detailed study revealed no evidence that exposure to water fluoridation in New Zealand affects neurological development or IQ. (Recommended levels of fluoride used in New Zealand's fluoridation program range from 0.7 mg/L to 1.0 mg/L.)[146]

Those opposed to water fluoridation have promoted studies that reportedly show fluoridation causes lower intelligence (IQ) in children. The studies cited are often from China, Mexico, India or Iran where social, nutritional and environmental conditions are significantly different from those in the United States. The vast majority of these studies have not been published in peer-reviewed English language journals. The consensus of those who have reviewed these studies is that the quality of these studies does not stand up to scientific scrutiny. The studies are of low quality, have a high risk of bias and use a study design unsuited to prove or disprove theories. They take no or little account of other factors that are known to cause a lowering of IQ (also called confounders) such as nutritional status, socioeconomic status, iodine deficiency and consumption of other harmful elements in ground water (arsenic or lead).

At the request of the U.S. EPA, a report on fluoride in drinking water issued in 2006 by the National Research Council[9] noted that the significance of the Chinese studies reviewed was "uncertain." "Most of the papers were brief reports and omitted important procedural details...Most of the studies did not indicate whether the IQ tests were administered in a blinded manner. Some of the effects noted in the studies could have been due to stress induced by the testing conditions. Without detailed information about the testing conditions and the tests themselves, the committee was unable to assess the strength of the studies."[9]

In England in 2009, the South Central Strategic Health Authority requested an independent critical appraisal of 19 papers and one abstract that reported an association between fluoride in drinking water and IQ in countries outside England. The appraisal[147] noted that the study design and methods used by many of the researchers in these studies had serious limitations. The researchers also exhibited a lack of a thorough consideration of confounding factors as a source of bias in the results. From these studies alone, it was "uncertain how fluoride was responsible for any impairment in intellectual development." Significant differences were noted in conditions between the communities studied and conditions in England. For example, some studies noted high levels of naturally occurring fluoride in drinking water and exposure to fluoride from other sources including the practice of burning high fluoride coal to heat poorly ventilated homes in China. Additionally, in many cases, there were stark differences in other environmental conditions and socioeconomic characteristics.[147]

In November 2016, those opposed to fluoridation filed a legal petition[148] with the U.S. Environmental Protection Agency (EPA) in Washington, D.C. calling for the EPA to ban the addition of fluoridating chemicals to public drinking water on the grounds that a large body of animal, cellular, and human research showed that fluoride is neurotoxic at doses within the range now seen in fluoridated communities in the U.S. (0.7 mg/L). The EPA responded to the petition in February 2017 noting, "After careful consideration, EPA denied the TSCA section 21 petition, primarily because EPA concluded that the petition has not set forth a scientifically defensible basis to conclude that any persons have suffered neurotoxic harm as a result of exposure to fluoride in the U.S. through the purposeful addition of fluoridation chemicals to drinking water or otherwise from fluoride exposure in the U.S."[148] As allowed under the TSCA process, the petitioners filed a lawsuit challenging the EPA ruling in April 2017 in the U.S. District Court for the Northern District of California at San Francisco. In late 2017, a federal judge denied an EPA motion to dismiss the lawsuit.

In 2017 a study from Mexico City[149] received some coverage in the popular press. The authors concluded higher urinary fluoride levels of pregnant women were associated with lower scores on tests of cognitive function in their children. This was an observational study that by definition could only show a possible association between fluoride exposure and IQ — not cause and effect. This small study did not adequately address a number of potential confounders that might explain the possible association such as breast feeding, maternal age, gestational age, birth weight and education as well as exposures to lead, mercury, arsenic and iodine that affect IQ and other measures of cognitive ability. Unlike conditions in the U.S., the pregnant women participating in the study were exposed to varied fluoride levels from naturally occurring fluoride in the water supply (in some cases at levels almost twice as high as the level recommended for community water fluoridation in the U.S.) and fluoridated salt.[149]

Additional research on this topic is underway through the National Toxicology Program's systematic review using animal studies to evaluate potential neurobehavioral effects from exposure to fluoride during development. Initiated in 2015, work continued in 2017.[23]

42. Does drinking fluoridated water increase the level of lead in the blood or cause lead poisoning in children?

Answer.

The best available scientific evidence has not shown any association between water fluoridation and blood lead levels.

Fact.

A number of reviews and data analyses indicate no association between water fluoridation and blood lead levels.

In 2011, the European Commission requested that the European Scientific Committee on Health and Environmental Risks (SCHER) perform a critical review of fluoridating agents of drinking water. The committee concluded that "it is highly unlikely that there would be an increased release of lead from pipes due to hexafluorosilicic acid.[20] Hexafluorosilicic acid is another name for fluorosilicic acid which is one of the additives used to fluoridate water in the U.S.

Additional information on this topic can be found in the Fluoridation Practice Section, Question 49.

A 2006 study analyzed data from the Third National Health and Nutrition Examination Survey (1988-1994) and the 1992 Fluoridation Census to evaluate the relationship between water fluoridation and lead concentrations in children. The study concluded that the results did not support that the silicofluorides used in community water systems caused higher lead concentrations in children.[150]

According to the Centers for Disease Control and Prevention,[151] the average blood lead levels of young children in the U.S. have continued to decline since the 1970s primarily due to lead poisoning prevention laws such as the phase-out of leaded paint and leaded gasoline. The primary remaining sources of childhood lead exposure are deteriorated leaded paint, house dust contaminated by leaded paint and soil contaminated by leaded paint and/or decades of industrial and motor vehicle emissions. Besides exposure to lead paint in older homes, lead water pipes and fixtures also can be found in homes built before 1978. In some areas of the county, folk remedies and pottery also add to lead exposure.[151] Findings from the National Health and Nutrition

Examination Surveys (NHANES) from 1976-1980 to 2003-2008 show that the percentage of children aged 1- to 5-years-old having high lead blood levels (≥10 µg/dL) declined dramatically from 88.2% to 0.9%.[152] During that same time period (1976 to 2008), the percentage of the U.S. population receiving fluoridated water rose from approximately 48.8% to 64.3%.[153] Moreover, in the 1991-1994 NHANES, the overall (all age groups) prevalence of high lead blood levels (≥10 µg/dL) was 2.2% but decreased to 0.7% by the 1999-2002 survey.[151] While antifluoridationists claim that fluoridated water increases lead blood levels in children, the fact is that since 1976 while the use of water fluoridation has increased, the percentage of children in the U.S. with high lead blood levels actually has continued to decreased substantially. This demonstrates that the claim made by those opposed to water fluoridation that fluoride in water increases lead concentrations in children is unfounded. It should be noted that approximately 95% of the primary sources of adult lead exposure are occupational.[154] In general, adult blood lead levels have continued to decline over recent decades due largely to improved prevention measures in the workplace and changes in employment patterns.[154]

Those opposed to water fluoridation sometimes claim that there is an increase in acidity when fluoride is added to water and that the acidic water in the system leaches lead from pipes and fixtures. The process of adding fluoride to water has minimal impact on the acidity or pH of drinking water. Under some water quality conditions, a small increase in the acidity of drinking water that is already slightly acidic can be observed after treatment with alum, chlorine, fluorosilicic acid or sodium fluorosilicate. In such cases, additional water treatment to adjust the pH to neutralize the acid in water distribution systems is standard practice in water plants.[155] Water facilities typically maintain a pH of between 7.0 and 8.0 as standard practice indicating that the water leaving the plant is slightly alkaline and non-acidic.[156]

Despite this information, antifluoridationists continue to exploit their unfounded claims that fluoridation can lead to an increased uptake of lead by children. A 1999 study[157] charged that fluorosilicic acid and sodium silicofluoride did not disassociate completely when added to water systems and could be responsible for lower pH (more acidic) levels of drinking water, leaching lead from plumbing systems and increasing lead uptake by children. In response to the study, scientists from the EPA reviewed the basic science that was the foundation for the claim that silicofluorides leach lead from water pipes and found that many of the chemical assumptions made in the original ecological study were scientifically unjustified.[158] Fluoride additives do disassociate very quickly and completely release fluoride ions into the water. The research from the 1999 study was inconsistent with accepted scientific knowledge and the authors of that study failed to identify or account for those inconsistencies. The EPA scientists discounted the 1999 study and said there were no credible data to suggest any link between fluoridation and lead. Overall, the EPA scientists concluded that "...no credible evidence exists to show that water fluoridation has any quantifiable effects on the solubility, bioavailability, bioaccumulation, or reactivity of lead compounds."[158]

43. Does drinking water fluoridated at recommended levels cause Alzheimer's disease?

Answer.

The best available scientific evidence has not indicated an association between drinking optimally fluoridated water and Alzheimer's disease.

Fact.

Scientists believe the causes of late-onset Alzheimer's, the most common form of the disease, include a combination of age-related brain changes, genetic, lifestyle, and environmental factors. The importance of any one of these factors in increasing or decreasing the risk of developing Alzheimer's could differ from person to person. Early-onset Alzheimer's is less common (fewer than 10% of Alzheimer's cases) with the first signs of the disease typically appearing between an individual's 30s and mid-60s. It is believed to be caused primarily by gene changes passed down from parent to child.[159]

A study published in 1998[160] raised concerns about the potential relationship between fluoride, aluminum and Alzheimer's disease. However, several flaws in the study's experimental design precluded any definitive conclusions from being drawn.[161] Concerns were noted about a number of aspects of the protocol including, but not limited to, the high percentage of the test rodents dying during the study and that

the researchers failing to account for the high levels of aluminum and fluoride in the chow fed to all test rodents.[161] For decades, a small number of researchers have implicated aluminum in the development of late-onset Alzheimer's disease. However, the "Aluminum Hypothesis" has been abandoned by the majority of mainstream scientists.[162]

In 2000, a study[163] investigated the relationships between trace elements in drinking water and the thought processes of 1,016 subjects over the age of 65 living in two rural areas of China. In today's U.S. society, people are very mobile and tend to live in multiple places during their lifetimes. In contrast, the rural residents of China rarely move and so in this study the researchers were able to assume that this elderly population had used the same water and food sources throughout their lifetimes. The researchers evaluated the effects on thought processes of seven elements (cadmium, calcium, fluoride, iron, lead, selenium and zinc) found in the water sources at the two study sites. The study assessed thought processes in three areas (memory, language and attention) using a Chinese translation of the Community Screening Interview for Dementia. Taking into account the effects of the seven trace elements, the authors concluded that fluoride is not significantly related to impairment of thought processes such as is seen in Alzheimer's disease.[163]

44. Does drinking water fluoridated at recommended levels cause or contribute to heart disease?

Answer.

Drinking water fluoridated at recommended levels is not a risk factor for heart disease.

Fact.

The American Heart Association identifies aging, male gender, heredity, cigarette and tobacco smoke, high blood cholesterol levels, high blood pressure, physical inactivity, obesity and diabetes mellitus as major risk factors for cardiovascular disease.[164]

The American Heart Association's website notes: "No evidence exists that adjusting the fluoride content of public water supplies to a level of about one part per million has any harmful effect on the cardiovascular system."[165]

A number of historical studies have evaluated urban mortality in relation to fluoridation status. Researchers from the National Heart, Lung and Blood Institute of the National Institutes of Health examined a wide range of data from communities that had naturally high levels, optimal levels and low levels of fluoride in water. The results of their analysis published in 1972[166] concluded, "Thus, the evidence from comparison of the health of fluoridating and nonfluoridating cities, from medical and pathological examination of persons exposed to a lifetime of naturally occurring fluorides or persons with high industrial exposures, and from broad national experience with fluoridation all consistently indicate no adverse effect on cardiovascular health."[166] Two additional studies were published in 1978. In the first study,[104] the mortality trends from 1950-70 were studied for 473 cities in the United States with populations of 25,000 or more. Findings showed no relationship between fluoridation and heart disease death rates over the 20-year period.[104] In the second study,[105] the mortality rates for approximately 30 million people in 24 fluoridated cities were compared with those of 22 nonfluoridated cities for two years. No evidence was found of any harmful health effects, including heart disease, attributable to fluoridation.[105]

The misinterpretation of the results of a study by those opposed to fluoridation[167] led the opposition to claim that "research highlights the fact that mass fluoride exposure may be to blame for the cardiovascular disease epidemic that takes more lives each year than cancer."[167] In fact, the study published in Nuclear Medicine Communications in January 2012[168] examines the possible benefits of using a sodium fluoride isotope marker in testing to determine the presence of atherosclerosis and risk for coronary disease. In this case, fluoride's affinity for calcified tissue aided in the location of calcium deposited in arterial walls which could be associated with an increased risk of coronary artery disease. The study made no reference to any relationship between the consumption of fluoridated water and heart disease.[168]

45. Is the consumption of water fluoridated at recommended levels harmful to kidneys?

Answer.

Consuming water fluoridated at recommended levels has not been shown to cause or worsen kidney disease.

Fact.

Approximately 60% of the fluoride absorbed daily by adults (45% for children) is removed from the body by the kidneys.[52] Because the kidneys are constantly exposed to various fluoride concentrations, any health effects caused by fluoride would likely manifest themselves in kidney cells. However, several large community-based studies of people with long-term exposure to drinking water with fluoride concentrations up to 8 ppm have failed to show an increase in kidney disease.[5,136,169]

In a report issued in 1993 by the National Research Council (NRC), the Subcommittee on Health Effects of Ingested Fluoride stated that the threshold dose of fluoride in drinking water which causes kidney effects in animals is approximately 50 ppm — more than 12 times the maximum level allowed in drinking water by the Environmental Protection Agency. Therefore, they concluded that "ingestion of fluoride at currently recommended concentrations is not likely to produce kidney toxicity in humans."[8] Furthermore, the NRC report on fluoride in drinking water issued in 2006 concluded that there were no published studies that demonstrate that drinking water fluoridated at recommended levels can damage kidneys. The report further concluded that fluoride concentrations need to be higher than 4 ppm to affect kidney tissues and function.[9]

A review of scientific studies completed in 2007 for Kidney Health Australia (KHA),[170] summarized findings from the recent literature related to the health effects of fluoridated water for people with chronic kidney disease (CKD). The purpose of the review was to provide an up to date summary of studies on the topic so that KHA, the leading organization in Australia that promotes kidney and urinary tract health, could develop a fluoride position paper. The review concluded that while studies on the topic are limited, "there is no evidence that consumption of optimally fluoridated drinking water increases the risk of developing CKD." For those people who have CKD, the report stated that "there is no evidence that consumption of optimally fluoridated drinking water poses any health risks for people with CKD, although only limited studies addressing this issue are available." There is limited evidence that people with advanced CKD (stages 4 or 5) "who ingest substances with a high concentration of fluoride may be at risk of fluorosis." Accordingly, the report recommended that it would be "prudent" for patients with advanced CKD to monitor fluoride intake and avoid fluoride-rich substances. These conclusions are the basis for KHA's position statement on fluoride which was released in 2007.[170] The position statement was updated in 2011 and concluded that "there has been no new published evidence to contradict the 2007 KHA Position Statement."[171]

According to information on their website, the National Kidney Foundation is the leading organization in the U.S. dedicated to the awareness, prevention and treatment of kidney disease. A paper titled *Fluoride Intake in Chronic Kidney Disease* dated April 15, 2008,[172] developed by the National Kidney Foundation (NKF) and posted on the NKF website includes the following points under the header "Analysis and Recommendations":

- Dietary advice for patients with CKD should primarily focus on established recommendations for sodium, potassium, calcium, phosphorus, energy/calorie, protein, fat, and carbohydrate intake. Fluoride intake is a secondary concern.

- Individuals with CKD should be notified of the potential risk of fluoride exposure by providing information on the NKF website including a link to the Report in Brief of the National Research Council and the Kidney Health Australia position paper. The risk is likely greatest in areas with naturally high water fluoride levels.

- The NKF has no position on the optimal fluoridation of water. The oral health of people with CKD is certainly of interest to the NKF, but balancing the overall benefits and risks of fluoride exposure is the primary concern.[172]

Many people with kidney failure depend on hemodialysis (treatment with an artificial kidney machine) for their survival. During hemodialysis, the patient's blood is exposed to large amounts of water each week (280–560 quarts). Therefore, procedures have been designed to ensure that the water utilized in the process contain a minimum of dissolved substances that could diffuse indiscriminately into

the patient's bloodstream.[173] Both KHA and the NKF recommend careful monitoring of hemodialysis systems to ensure proper mechanical function.[170,172] Since the composition of water varies in different geographic locations in the United States, the U.S. Public Health Service recommends dialysis units use techniques such as reverse osmosis and de-ionization to remove excess iron, magnesium, aluminum, calcium, and other minerals, as well as fluoride, from tap water before the water is used for dialysis.[173]

46. What are some of the erroneous health claims made against water fluoridation?

Answer.

From sources such as the internet, newsletters, social media and personal anecdotes in emails, it is frequently claimed that community water fluoridation causes the following adverse health effects:

- AIDS
- Allergic Reactions (e.g.,loss of hair, skin that burns and peels after contact with fluoridated water)
- Accelerated Aging
- Alzheimer's disease
- Arthritis
- Asthma
- Austism
- Behavioral Problems (e.g., attention deficit disorders)
- Bone Disease (e.g.,osteoporosis increased bone/ hip fractures)
- Cancer (all types including osteosarcoma or bone cancer)
- Chronic Bronchitis
- Colic (acute abdominal pain)
- Cystic Fibrosis
- Down Syndrome
- Emphysema
- Enzyme Effects (gene-alterations)
- Flatulence (gas)
- Gastrointestinal Problems (irritable bowel syndrome)
- Harmful Interactions with Medications
- Heart Disease
- Increased Infant Mortality
- Low Birth Weight for Infants
- Kidney Disease
- Lead Poisonings
- Lethargy (lack of energy)
- Lower IQ scores
- Malpositioned Teeth
- Parkinson's Disease
- Calcification of the Pineal Gland (causing early puberty) (chronic insomnia);
- Reproductive issues (damaged sperm) (reduced fertility)
- Skin Conditions (redness, rash/welts, itching)
- Sudden Infant Death Syndrome (SIDS)
- Thyroid Problems (goiter and obesity due to hypothyroidism)

AND

- Tooth Decay

Fact.

As discussed throughout this document, the best available scientific evidence consistently has indicated that fluoridation of community water supplies is safe and effective. The possibility of any adverse health effects from continuous low-level consumption of fluoride has been and continues to be studied extensively. Of the thousands of credible scientific studies on fluoridation, none has shown health problems associated with the consumption of optimally fluoridated water.

Of the thousands of credible scientific studies on fluoridation, none has shown health problems associated with the consumption of optimally fluoridated water.

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47. Who regulates drinking water additives in United States?

Answer.

The United States Environmental Protection Agency (EPA) regulates drinking water additives.

Fact.

In 1974, Congress passed the Safe Drinking Water Act (SDWA) which protects the public's health by regulating the nation's public drinking water supply.[1] The SDWA, as amended in 1986 and 1996,[1] requires the Environmental Protection Agency (EPA) to ensure the public is provided with safe drinking water.[1] On June 22, 1979, the Food and Drug Administration (FDA) and the EPA entered into a Memorandum of Understanding (MOU) to clarify their roles and responsibilities in water quality assurance.[2] The stated purpose of the MOU is to "avoid the possibility of overlapping jurisdiction between the USEPA and FDA with respect to control of drinking water additives." The two agencies agreed that the Safe Drinking Water Act's passage in 1974 implicitly repealed FDA's jurisdiction over drinking water as a 'food' under the Federal Food, Drug and Cosmetic Act (FFDCA). Under the MOU, EPA enjoys exclusive regulatory authority over drinking water provided by public water systems, including any additives in such water. FDA retains jurisdiction over bottled drinking water under Section 410 of the FFDCA and "over water (and substances in water) used in food or food processing once it enters the food processing establishment."[2]

While drinking water from the tap is regulated by the EPA, bottled water is regulated by the FDA which has established standards for its quality.[2] The FDA has noted that fluoride can occur naturally in source waters used for bottled water or may be added by a bottled water manufacturer. Recognizing the benefit of fluoride in water, the FDA has stated that bottled water that meets specific standards of identity and quality set forth by FDA, and the provisions of the authorized health claim related to fluoride, may be labeled with the following health claim: "Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]."[3]

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From time to time, states and communities have had to deal with legislation or ballot initiatives aimed at requiring the approval of the FDA before any agent can be added to community water systems. Often referred to as the Fluoride Product Quality Control Act, Water Product Quality Ordinance or Pure Water Ordinance, the legislation is specifically used by those opposed to water fluoridation as a tool to prevent water systems from providing community water fluoridation. Often this legislation does not specifically

mention fluoride or fluoridation. Those supporting this type of legislation may claim that they are not against water fluoridation but are proponents of pure water and do not want anything added to water that has not been approved by the FDA. On the surface, this may appear to be a "common sense" approach. However, its only real purpose is to defeat efforts to provide water fluoridation. That is because this proposed legislation would require the FDA — which does NOT regulate public water systems — to approve any water additive. By mistakenly (and perhaps craftily) naming the wrong federal agency, the probable outcome is to stop or prevent water fluoridation.

48. What standards have been established to ensure the safety of fluoride additives used in community water fluoridation in the United States?

Answer.
The three fluoride additives used in the U.S. to fluoridate community water systems (sodium fluoride, sodium fluorosilicate, and fluorosilicic acid) meet safety standards established by the American Water Works Association (AWWA) and NSF International (NSF).[4]

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Fact.
Additives used in water treatment meet safety standards prepared in response to a request by the Environmental Protection Agency to establish minimum requirements to ensure the safety of products added to water for its treatment, thereby ensuring the public's health.[4] Specifically, fluoride additives used in water fluoridation meet standards established by the American Water Works Association (AWWA) and NSF International (NSF).[4] Additionally, the American National Standards Institute (ANSI) endorses both AWWA and NSF standards for fluoridation additives and includes its name on these standards.[4]

The American Water Works Association[5] is an international nonprofit scientific and educational society dedicated to providing total water solutions to assure the effective management of water. Founded in 1881, the AWWA is the largest organization of water supply professionals in the world. The membership represents the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water. AWWA unites the diverse water community to advance public health, safety, the economy, and the environment.[5]

NSF International,[6] an independent, accredited organization, is dedicated to being the leading global provider of public health and safety-based risk management solutions. Manufacturers, regulators and consumers look to NSF to develop public health standards and certifications that help protect food, water, consumer products and the environment. Its professional staff includes microbiologists, toxicologists, chemists, engineers, and environmental and public health professionals. Founded in 1944 as the National Sanitation Foundation, NSF's mission is to protect and improve global human health.[6]

The American National Standards Institute (ANSI)[7] is a private, non-profit organization that administers and coordinates the U.S. voluntary standardization and conformity assessment system. The Institute's mission is to enhance both the global competitiveness of U.S. business and the U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems, and safeguarding their integrity.[7]

The AWWA documents provide manufacturers, suppliers and purchasers with standards for the manufacturing, quality and verification for each of the three fluoride additives listed below. The AWWA standards set the physical, chemical and impurities standards including information on verification of the standard requirements and requirements for delivery.[4]

- ANSI/AWWA B701 Sodium Fluoride
- ANSI/AWWA B702 Sodium Fluorosilicate
- ANSI/AWWA B703 Fluorosilicic Acid[4]

NSF/ANSI Standard 60[4,6] provides for purity of drinking water additives as it limits an additive's contribution of harmful contaminants to drinking water. The Standard also provides for safety assurances from production through distribution to ensure product quality is maintained. Additionally, the Standard requires documentation of the purity of the additives including specific criteria for products imported from other countries. NSF/ANSI Standard 61[4,6] is a related standard that provides guidance for equipment/products used in water treatment plants that come in contact with drinking water. Both NSF/ANSI standards were developed by a consortium of associations including NSF, AWWA, the Association of State Drinking Water Administrators and the Conference of State Health and Environmental Managers with support from the U.S. Environmental Protection Agency.[4]

Fluoride additives, like all of the more than 40 additives typically used in water treatment, are "water grade" additives. All additives used at the water plant are classified as water grade additives meeting NSF Standard 60 requirements. Examples of other "water grade" additives which are commonly used in water plant operations are chlorine (gas), ferrous sulfate, hydrochloric acid, sulfur dioxide and sulfuric acid.[8]

Sometimes antifluoridationists express the view that they are not really opposed to fluoridation, but are opposed to the use of "industrial grade" fluoride additives. They may even go so far as to state that they would support fluoridation if the process was implemented with pharmaceutical grade fluoride additives that were approved by the U.S. Food and Drug Administration (FDA). On the surface, this may appear to be a "common sense" approach. In fact, this is usually a ploy whose only real purpose is to stop fluoridation. First, the EPA, not the FDA, has regulatory authority for additives used in public water systems. Second, and perhaps most importantly, the U.S. Pharmacopeia (USP) monograph on sodium fluoride does not provide for certification of quality by an independent credentialing body.[4,9] Third, the USP and The National Formulary (USP-NF) standards used to formulate prescription drugs are not appropriate for water fluoridation additives as they could actually allow higher levels of contaminants to be introduced into drinking water than is allowed by the current EPA standards.[4,9] According to the CDC:[9]

> The USP does not provide specific protection levels for individual contaminants, but establishes a relative maximum exposure level for a group of related contaminants. Some potential impurities have no restrictions by the USP, including arsenic, some heavy metals regulated by the U.S. EPA, and radionuclides. Given the volumes of chemicals used in water fluoridation, a pharmaceutical grade of sodium fluoride for fluoridation could potentially contain much higher levels of arsenic, radionuclides, and regulated heavy metals than an NSF/ANSI Standard 60-certified product.

Additional information about this topic can be found in this Section, Question 49.

Lastly, USP-grade sodium fluoride product is more likely to result in water plant personnel being exposed to fluoride dust as it is more powder-like than the preferred AWWA-grade sodium fluoride which is crystalline and so minimizes dusting when handled.[4]

Additional information about this topic can be found in this Section, Question 52.

49. Does fluoridating the community water supply raise concerns about lead, arsenic and other toxic contaminants to the water supply?

Answer.

No. The concentrations of contaminants in drinking water as a result of fluoridation do not exceed, but are in fact, well below regulatory standards set to ensure the public's safety.

Fact.

Fluorosilicic acid is used to fluoridate the majority of community water systems in the United States.[10] Because the additive is derived from ore mined from the earth, fluorosilicic acid may contain minute amounts of contaminants such as lead and arsenic. However, existing regulations and standards require that these contaminants, and others, be at levels considered acceptable by the U.S. Environmental Protection Agency when the fluorosilicic acid or other fluoridation additives are diluted to produce optimally fluoridated water.[6] NSF International and the American National Standards Institute (NSF/ANSI) Standard 60 as well as AWWA standards are applicable to all fluoride additives.[4,6]

Testing of fluoride additives provides evidence that the levels of these contaminants do not exceed, but are in fact, well below regulatory standards set to ensure the public's safety. NSF has prepared a detailed fact sheet, *NSF Fact Sheet on Fluoridation Products* (2013)[11] that provides the documented quality of fluoride additives based on product samples analyzed. The NSF reports that the majority of fluoridation products as a class, based on NSF test results, do not add measurable amounts of arsenic, lead, or other heavy metals, or radionuclides to drinking water.[9,11]

50. Have fluoride additives been tested for safety?

Answer.

The claim is sometimes made that no studies on safety exist on the additives used in water fluoridation. This statement is a ruse because the scientific community does not study the health effects of the concentrated additives; studies are done on the health effects of the treated water.

Fact.

A 1999 study[12] charged that fluorosilicic acid and sodium silicofluoride did not disassociate (break down) completely when added to water systems and may be responsible for lower pH (acid) levels of drinking water, leaching lead from plumbing systems and increasing lead uptake by children. Scientists from the U.S. Environmental Protection Agency (EPA) evaluated the disassociation of fluoride additives[13] and concluded that at the typical pH level of drinking water (which is normally slightly alkaline) and the fluoride levels used in drinking water, the fluoride additives quickly and completely broke down to fluoride ions and silica.

Published in 2006,[14] researchers at the University of Michigan verified for the EPA that theoretical predictions that hexafluorosilicate completely hydrolyzed (broke down) when added to water separating into free fluoride ions and silica ions were confirmed. The research demonstrated that there was no hexafluorosilicate that could be measured in the finished water.[14]

While sodium fluoride was the first additive used in water fluoridation, the use of silicofluoride additives (sodium fluorosilicate and fluorosilicic acid) began in the late 1940s. By 1951, silicofluorides had become the most commonly used fluoride additives in water fluoridation.[15] Many of the early studies on the health effects of fluoridation were completed in communities that were using the silicofluoride additives, most generally fluorosilicic acid.[16-21] However, at that time, the additives used to fluoridate were not always identified in research reports. As the body of research on fluoridation grew, it became evident that there were no adverse health effects associated with water fluoridation regardless of which fluoride additive was used. Additionally, over time, a number of comprehensive reviews of the health effects of fluoridation were published. These reviews which support the safety of water fluoridation include many studies conducted in large fluoridated communities which used the silicofluoride additives.[22-29]

There is now more than 70 years of practical experience that lends additional credence to the best available science that concludes that fluoridation is safe.

51. What is the source of the additives used to fluoridate water supplies in the United States?

Answer.

The majority of fluoridation additives used in the United States are derived from the mineral apatite (a component of calcium phosphate).

Fact.

About 95% of the fluoridation additives used in water fluoridation are by-products which come from the processing of calcium phosphate into phosphate fertilizer. About 4% are derived from the processing of calcium fluoride and the remaining 1% derived from the production of high-purity silica.*

In the production of phosphate fertilizer, calcium phosphate ore (which contains apatite) is mixed with sulfuric acid resulting in a calcium sulfate (gypsum) slurry. The gaseous phosphoric acid released from this process is collected by vacuum extraction, condensed and then desiccated (dried) and formed into phosphate fertilizer pellets. Fluoride is a trace constituent (3-7%) of the mineral apatite found in calcium phosphate ore. Silica tetrafluoride is also released as a gas in the creation of the calcium sulfate slurry and is collected by vacuum extraction along with the gaseous phosphoric acid. In about half the phosphate fertilizer plants in the U.S., the silica tetrafluoride gas is condensed and

processed along with the phosphoric acid and becomes a trace component of the phosphate fertilizer. In the other plants, the silica tetrafluoride gas is separated from the phosphoric acid. Roughly 60% of the fluoride recovered from processing calcium phosphate ore is sold for use as fluoridation additives. The fluoridation additive produced by this process is fluorosilicic acid. While most of the product is sold as fluorosilicic acid, some of the product is partially neutralized to sodium fluorosilicate salt and some is fully neutralized to sodium fluoride salt. In the U.S., 77% of the fluoridation additives used are fluorosilicic acid, 15% are sodium fluorosilicate and 8% are sodium fluoride.*

About 4% of the fluoridation additives used are derived from the processing of calcium fluoride into hydrogen fluoride using a gas separation technique to recover the fluorosilicic acid from the hydrogen fluoride.*

About 1% of the fluoridation additives used are derived from the production of high-purity silica. Fluorosilicic acid is produced as part of the purification of the silica.*

**The preceding paragraphs were developed using references 4, 30 through 35 and personal communication from Mr. Kip Duchon, P.E., national fluoridation engineer, CDC.*

From time to time, opponents of fluoridation allege that fluoridation additives are by-products of the phosphate fertilizer industry in an effort to suggest the additives are not safe. By definition, by-products are materials produced as a result of producing something else. In the chemical industry, a byproduct (secondary product) is anything other than the principal product produced. The fact that a product is a secondary product of a manufacturing process should not suggest the item is bad, harmful or a waste product. On the contrary, by-products may have certain characteristics which make them valuable resources. In the production of phosphate fertilizer, the fluoridation additive, fluorosilicic acid, is a by-product along with gypsum.[36] Gypsum is commonly use in manufacturing wall board used in construction. The production of orange juice provides another example of valuable by-products. In addition to orange juice, various by-products are obtained from oranges during juice production that are used in cleaners, fragrances and flavorings.[37]

Fluoridation additives are valuable by-products produced as a result of producing phosphate fertilizer. To ensure the public's safety, additives used in water fluoridation meet standards of the American Water Works Association (AWWA) and NSF International (NSF).[4]

52. Does the process of water fluoridation present unusual safety concerns for water systems and water facility operators?

Answer.

No. With proper monitoring, maintenance, water facility operator training and systems planning, water fluoridation is a safe and reliable process.

Fact.

Water facilities and water facility operators perform a valuable public service by carefully adjusting the level of fluoride in water to improve the oral health of the community. Facilities and personnel are subject to a number of regulations designed to ensure safety.

Employers must conform to Occupational Safety and Health Administration (OSHA) requirements.[38] OSHA's mission is to assure safe and healthful workplaces by setting and enforcing standards, and by providing training, outreach, education and assistance. Under the OSH Act, employers are responsible for providing a safe and healthful workplace. Employers must comply with all applicable OSHA standards.[38]

Additionally, in order to assist in protecting the professionals who produce sustainable supplies of high-quality drinking water, the American Water Works Association publishes detailed guidance on safety and safe working conditions for water plant personnel.[39]

Furthermore, OSHA requires that Safety Data Sheets (SDS), previously known as Material Safety Data Sheets (MSDS), be readily available to all employees for potentially harmful substances handled in the workplace under the Hazard Communication regulation.[40] A SDS may include instructions for the safe use and potential hazards associated with a particular material and are typically made available in the area where the material is stored or used. Information contained in a SDS focuses on the potential hazards of working with the material in an occupational setting. Adherence to the SDS guidelines for handling fluoride additives helps to ensure the

recommended level of fluoride in drinking water flows through the water system while maintaining water operator safety. In the case of fluoride, the potential hazards faced by a water facility employee in dealing with concentrated fluoride additives before they enter the water system are not related to the level of fluoride in water as used by consumers. The information found in the SDS for fluoride additives is not applicable to water with fluoride at the recommended level. Therefore, SDS sheets should not be used by consumers to gauge potential hazards of community water fluoridation.

As part of safety procedures, water facility personnel receive training on the management of the additives in water plants. While the recommended fluoride level found in drinking water has been proven safe, water facility operators and engineers may be exposed to much higher fluoride levels when handling fluoride additives at the water treatment facility.[4] Fluoride additives present risks comparable to other water additives in common use at water facilities, such as hypochlorite, quicklime, aluminum sulfate, sodium hydroxide and ferrous sulfate. In some cases, the fluoride additives are much less dangerous than many other additives, including chlorine gas commonly used in many water plants.[39]

Today's equipment allows water facility personnel to easily monitor and maintain the desired fluoride concentration. Automatic monitoring technology is also available that can help to ensure that the fluoride concentration of the water remains within the recommended range.[4]

It is important that the water facility personnel responsible for monitoring the addition of fluoride to the water supply are appropriately trained and that the equipment used for this process is adequately maintained.[4] With over 70 years of experience and thousands of water systems adding fluoride every day, water facility personnel have an excellent safety record related not only to their personal safety but in providing safe drinking water to their customers.

53. Does fluoridation present difficult engineering problems?

Answer.

No. Adding fluoride products to water is no different than adding other commonly used water treatment additive products using the same equipment and techniques.

Fact.

Fluoride additives used to adjust the fluoride level in drinking water are compatible with other water treatment processes often using the same type of equipment and other standard materials designed for the safe handling of other water treatment additive products in drinking water treatment facilities. Fluoride additives are introduced to the water supply as liquids. There are many control devices, some in use for decades and some newer equipment, that allow water facility personnel to easily monitor and maintain the desired fluoride level as well as levels of other water treatment additives and naturally occurring substances that may be in the water. Automatic monitoring technology is available that can help to ensure that the fluoride concentration of the water remains within the recommended range.[4]

When added to community water supplies, the concentrated fluoride additives become greatly diluted. For example, typically fluorosilicic acid is diluted approximately 315,000 times to reach the recommended target concentration of 0.7 mg/L. The exact dilution factor depends on the concentration of the fluoride additive and the amount of additive being used to reach the concentration of 0.7mg/L. At 0.7mg/L (or 0.7 parts per million), seven-tenths of one part of fluoride is diluted in is diluted in 999,999.3 parts of water. To place this concentration in perspective, the following comparisons can be of assistance.

1 inch in approximately 23 miles
1 minute in approximately 1,000 days
1 cent in approximately $14,000
1 seat in more than 34 Wrigley Field baseball parks (seating capacity 41,268)

With more than 70 years of experience with water fluoridation, there is considerable guidance on sound engineering practices to design, construct, operate and maintain water fluoridation systems. By design, and with proper maintenance and testing, water

systems can provide the recommended level of fluoride within a narrow control range of the target of 0.7mg/L.[41,42] Additional design features such as the use of a day tank (that holds only one day's supply of fluoride) can limit the amount of fluoride that can be added to a water system in a 24-hour period and is the most reliable method to ensure overfeed protection.[4] The State Office of Drinking Water, or similar state agency, will normally establish engineering requirements for safety. Additional standards and references on best engineering practice are available from the American Water Works Association and the Centers for Disease Control and Prevention.[4,43]

54. Does fluoride at levels used in fluoridation corrode water pipes?

Answer.

No. Allegations that fluoridation causes corrosion of water pipes are not supported by the best available scientific evidence.

Fact.

The process of adding fluoride to water has minimal impact on the acidity or pH of drinking water and therefore will not corrode water pipes. Corrosion of drinking water pipes is related primarily to induced electrical current between dissimilar metals. Other contributing factors include the dissolved oxygen concentration, water temperature, acidity/alkalinity (pH), hardness, salt concentration, hydrogen sulfide content and the presence of certain bacteria. Under some water quality conditions, a small increase in the acidity of drinking water that is already slightly acidic may be observed after treatment with alum, chlorine, fluorosilicic acid or sodium fluorosilicate. In such cases, further water treatment to adjust the pH to neutralize the acid for corrosion control in water distribution systems is standard procedure in water plants.[44]

The process of adding fluoride to water has minimal impact on the acidity or pH of drinking water and therefore will not corrode water pipes.

Note that the Water Quality Report or Consumer Confidence Report that all water systems must make available to customers on a yearly basis, may list the pH of the system's finished water.[45] Control of neutral pH (7.0) is essential as part of corrosion control requirements. Water facilities typically maintain a pH of between 7.0 and 8.0 as good practice indicating that the water leaving the plant is slightly alkaline and non-acidic.[46]

55. Does fluoride at levels used in water fluoridation corrode glass, concrete or other surfaces in water plants?

Answer.

No. A correctly engineered and maintained system will not result in damage to the water plant.

Fact.

Fluorosilicic acid in a concentrated form can be corrosive if not correctly handled. The concentrated fluorosilicic acid is 75% water, and 25% fluorosilicic acid. Up to 1% of the fluorosilicic acid can be other acids including hydrogen fluoride. Hydrogen fluoride is volatile near room temperature so it will evaporate from the solution if the system is not properly engineered and maintained. The evaporation process occurs at an extremely slow rate. Less than 1% of fluorosilicic acid will be lost over a month from the evaporation of hydrogen fluoride. However, only a small release of hydrogen fluoride may be very corrosive to concrete, glass, and electrical components.[30]

If a water system is reporting problems with corrosion from evaporating hydrogen fluoride in the storage room or fluoride handling room (i.e. the glass in the facility has become "frosted"), the system is being inadequately maintained. The storage tank and other locations in the fluorosilicic acid feed system may not be sealed or correctly vented and hydrogen fluoride gas can be released (leaked) at those points All fluoride products storage, handling, and feed systems should be vented to the outside of the building and the system and piping should be pressure tested (low pressure is sufficient) to identify possible locations of leaks. Leaks should be promptly corrected.[30]

With no system leaks and proper venting to outside the building, there will be no corrosion problems.[30]

56. Does fluoridated water harm the environment?

Answer.
No. Scientific evidence supports the fluoridation of public water supplies as safe for the environment and beneficial for people.

Fact.
Fluoride is naturally occurring in the environment and is the 13th most abundant element in the earth's crust. It is found in naturally in all water sources as noted below.[47]

Rain — between 0.1 to 0.2 mg/L
Streams and lakes — between 0.1 to 0.3 mg/L
Groundwaters — between 0.1 to 10 mg/L
Oceans and seawater — between 1.2 to 1.4 mg/L

A comprehensive literature review published in 2004 revealed no negative environmental impacts as a result of water fluoridation.[48] A 1990 study concluded that fluoridation has little or no impact on surrounding aquatic environment or soil.[49] Historically, issues surrounding problems with fluoride and the environment have involved incidents related to serious industrial pollution or accidents.[49]

Under the Washington's State Environmental Protection Act (SEPA), a study was conducted in Tacoma-Pierce County to investigate the environmental consequences of adding optimal levels of fluoride to drinking water. Noting that the amount of fluoride in the water does not reach levels that are harmful to plants or animals, the SEPA study concluded that there are "no probable significant adverse environmental impacts."[50]

There is no evidence that the recommended level of fluoride in drinking water has any adverse effect on gardens, lawns or plants.[50]

Additional information regarding water fluoridation additives and engineering issues can be found on the CDC's fluoridation website, "Water Operators and Engineers" at ***https://www.cdc.gov/fluoridation/engineering/index.htm.***

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Public Policy

57. What is public health?

Answer.

Public health promotes and protects the health of people and the communities where they live, learn, work and play. Public health measures improve the quality of life for members of the community.

Fact.

Public health has numerous definitions and dimensions. It can encompass issues of research, education, regulation, policy and more. It focuses on the health of entire populations that can vary in size from as small as a local neighborhood to a small-sized community and a large-sized city. It also can focus on populations with a state, national or even global perspective. But how does public health affect our everyday lives? Individuals are touched by public health measures every day without giving them a second thought. For example, garbage pick-up and disposal prevent the spread of disease. The stoplight at a busy intersection protects motorists and pedestrians from injury. Building sidewalks in communities provides the option for people to walk to help control their weight and improve their heart health. Smoke-free laws help prevent lung cancer. All of these are public health in action.

Community water fluoridation is another example of a public health measure.

- Optimally fluoridated water is accessible to the entire community regardless of socioeconomic status, educational attainment or other social variables.[1]
- Individuals do not need to take special action or otherwise change their behavior to obtain the benefits of fluoridation.
- Frequent exposure to small amounts of fluoride over time makes fluoridation effective through the life span in helping to prevent tooth decay.[2]
- Community water fluoridation is more cost-effective and cost-saving than other forms of fluoride treatments or applications.[3,4]

During the 20th century, the health and life expectancy of persons residing in the United States improved dramatically. Since 1900, the average life span of persons in the United States lengthened by greater than 30 years; 25 years of this gain are attributable to advances in public health. Many notable public health achievements occurred during the 1900s. In a series of reports during 1999, the *Morbidity and Mortality Weekly Report (MMWR)* profiled 10 public health achievements chosen to highlight the contributions of public health and to describe the impact of these contributions on the health and well being of persons in the United States.[5]

Ten Great Public Health Achievements — United States, 1900-1999[5]

- Vaccination
- Motor-vehicle safety
- Safer workplaces
- Control of infectious diseases
- Decline in deaths from coronary heart disease and stroke
- Safer and healthier foods
- Healthier mothers and babies
- Family planning
- Fluoridation of drinking water
- Recognition of tobacco use as a health hazard

In discussing the contribution of fluoridation, the October 22,1999 MMWR[6] noted fluoridation of community drinking water was a major factor responsible for the decline in tooth decay during the second half of the 20th century. Although other fluoride-containing products are available, water fluoridation remains the most equitable and cost-effective method of delivering fluoride to all members of communities, regardless of age, educational attainment, or income level.[6]

58. Is water fluoridation a valuable public health measure?

Answer.

Yes. Community water fluoridation is a public health measure that benefits people of all ages and is a public health program that saves money for families and the health care system. Because fluoridation reaches large numbers of people where they live, learn, work and play, it is more effective than other forms of fluoride delivery. Water fluoridation reaches everyone in the community regardless of age, race, education, income level or access to routine dental care. Because of the important role it has played in the reduction of tooth decay, the Centers for Disease Control and Prevention (CDC) has proclaimed community water fluoridation one of 10 great public health achievements of the 20th century.[5,6]

Community water fluoridation is a public health measure that benefits people of all ages and is a public health program that saves money for families and the health care system.

Fact.

Throughout decades of research and more than 70 years of practical experience, fluoridation of public water supplies has been responsible for dramatically improving the public's oral health status.

It has been said that those who cannot remember the past are condemned to repeat it. As generations pass, details from life in the 1930s and 1940s fade. The oral health of Americans suffered greatly during the time of the Great Depression and into the era of World War II. There were no public health programs in place that addressed tooth decay and the loss of teeth was viewed as an eventuality. In fact, as World War II approached, those joining the U.S. Army were required to have six back teeth (three on the top and three on the bottom) that opposed each other to serve the function of chewing food and six front teeth (three on the top and three on the bottom) that opposed each other for the purpose of biting into food. The number of men disqualified for dental reasons far exceeded all expectations as "dental disease" became the most common reason for military deferment. One out of eleven registrants examined was disqualified for military service due to dental issues.[7] After Pearl Harbor it was apparent that the manpower needed to fight a global war could be obtained only if dental standards for induction were drastically relaxed. By March 1942, the standards had been revised so that a man who was "well nourished, of good musculature, and free from gross dental infections" but who was completely edentulous (without any teeth) could be inducted if his condition was corrected or could be corrected with dentures.[7]

Because fluoridation reaches large numbers of people where they live, learn, work and play, it is more effective than other forms of fluoride delivery.

In January 1945, a community water fluoridation trial began in Grand Rapids, Michigan followed within months by trials in Newburgh, NY (May 1945), Brantford, Ontario (June 1945) and Evanston, IL (February 1947). Reductions in tooth decay were dramatic leading to the rapid adoption of fluoridation in cities across the U.S. As a result, tooth decay declined sharply during the second half of the 20th century. Tooth loss was no longer considered inevitable.

Former U.S. Surgeon General, Dr. Luther Terry, called fluoridation as vital a public health measure as immunization against disease, pasteurization of milk and purification of water.[8]

Another former U.S. Surgeon General, Dr. C. Everett Koop, wrote:

> ...this preventive measure (fluoridation) is the single most important commitment that a community can make to the oral health of its children and to future generations. I urge all health officials and concerned citizens to join me in supporting this commitment and in the task of achieving water fluoridation for all community drinking water supplies which lack the fluoride content needed for the prevention of dental caries.[9]

In 1999, because of the dramatic role it played in the reduction of tooth decay, the Centers for Disease Control and Prevention (CDC) proclaimed community water fluoridation one of 10 great public health achievements of the 20th century.[5,6]

In May 2000, U.S. Surgeon General Dr. David Satcher issued the first ever Surgeon General's report on oral health titled, *Oral Health in America: A Report of the Surgeon General*.[10] In 2001, Dr. Satcher issued a statement on fluoridation in which he noted:

> ...community water fluoridation continues to be the most cost-effective, practical and safe means for reducing and controlling the occurrence of dental decay in a community...water fluoridation is a powerful strategy in efforts to eliminate health disparities among populations.[11]

In the 2003 *National Call to Action to Promote Oral Health*,[12] U.S. Surgeon General Dr. Richard Carmona called on individuals and groups who are most concerned and in a position to act to apply strategies to enhance the adoption and maintenance of proven community-based interventions such as community water fluoridation.[12] In his 2004 *Statement on Community Water Fluoridation*,[13] Dr. Carmona wrote:

> While we can be pleased with what has already been accomplished, it is clear that there is much yet to be done. Policymakers, community leaders, private industry, health professionals, the media, and the public should affirm that oral health is essential to general health and well-being and take action to make ourselves, our families, and our communities healthier. I join previous Surgeons General in acknowledging the continuing public health role for community water fluoridation in enhancing the oral health of all Americans.[13]

In 2013, U.S. Surgeon General Dr. Regina M. Benjamin wrote:[14]

> ...As Surgeon General I have been working hard to encourage individuals and communities to make healthy choices because I believe it is better to prevent illness and disease rather than treat it after it occurs. Community water fluoridation is one of the most effective choices communities can make to prevent health problems while actually improving the oral health of their citizens... Fluoridation's effectiveness in preventing tooth decay is not limited to children, but extends throughout life, resulting in fewer and less severe cavities. In fact, each generation born since the implementation of water fluoridation has enjoyed better dental health than the generation that preceded it...[14]

U.S. Surgeon General Dr. Vivek H. Murthy issued a video statement supporting community water fluoridation in December 2015.[15] In his video and written statement on fluoridation issued in 2016,[15,16] Surgeon General Murthy emphasized:

> Our progress on this issue over the past 70 years has been undeniable. But we still have work to do. Because we know that so much of our health is determined by zip code rather than genetic code. That's why creating a culture of disease prevention through community efforts — and ensuring health equity for all — is one of my highest priorities. Community water fluoridation helps us meet these goals; as it is one of the most cost-effective, equitable, and safe measures communities can take to prevent tooth decay and improve oral health.[15,16]

Today, the focus in achieving and maintaining health is on prevention. Established by the U.S. Department of Health and Human Services, Healthy People 2020[17] provides a science-based, comprehensive set of ambitious, yet achievable, ten-year national objectives for improving the health of the public. Included under oral health is an objective to expand the fluoridation of public water supplies. Objective 13 states that at least 79.6% of the U.S. population served by community water systems should be receiving the benefits of optimally fluoridated water by the year 2020.[18] Data from the CDC indicate that in 2014, 74.4% of the U.S. population on public water systems, or a total of 211.4 million people, had access to fluoridated water.[19]

Established by the U.S. Department of Health and Human Services in 1996, the Community Preventive Services Task Force develops and disseminates guidance on which community-based health promotion and disease prevention intervention approaches work, and which do not work, based on available scientific evidence. The Task Force issues findings based on systematic reviews of effectiveness and economic evidence. The Guide to Community Preventive Services ("The Community Guide") is a collection of evidence-based findings of the Community Preventive Services Task Force and is designed to assist decision makers in selecting interventions to improve health and prevent disease.[20]

The Community Guide reviews are designed to answer three questions:

1. What has worked for others and how well?
2. What might this intervention approach cost, and what am I likely to achieve through my investment?
3. What are the evidence gaps?[20]

The Community Preventive Services Task Force recommends community water fluoridation to reduce tooth decay.[21]

Reports have been released by the U.S. Department of Health and Human Services that encourage the use of preventive interventions to improve the overall and oral health of the nation.[22,23] Specific to oral health, two reports issued in 2011 by the Institute of Medicine acknowledge water fluoridation is an effective intervention for the prevention of tooth decay. *Advancing Oral Health in America*[24] referred to water fluoridation as an effective prevention intervention, while *Improving Access to Oral Health Care for Vulnerable and Underserved Populations*[25] acknowledged that evidence regarding community water fluoridation programs continues to validate its effectiveness, safety and cost-saving benefits.

59. Does water fluoridation reduce disparities in dental health?

Answer.

Yes, evidence indicates water fluoridation helps to reduce the disparities in dental health at the community level. Populations with lower socioeconomic status (SES) who live in fluoridated communities have less tooth decay than their peers in nonfluoridated communities.

Fact.

In the first ever Surgeon's General Report on Oral Health issued in May 2000, U.S. Surgeon General David Satcher noted that community water fluoridation is safe and effective in preventing dental caries in both children and adults. Fluoridation benefits all residents served by community water supplies regardless of their social or economic status.[10] In 2001, Dr. Satcher issued a statement on fluoridation in which he noted:

> ...community water fluoridation continues to be the most cost-effective, practical and safe means for reducing and controlling the occurrence of dental decay in a community...water fluoridation is a powerful strategy in efforts to eliminate health disparities among populations.[11]

"...water fluoridation is a powerful strategy in efforts to eliminate health disparities among populations."

Established by the U.S. Department of Health and Human Services, Healthy People 2020 provides a science-based, comprehensive set of ambitious, yet achievable, ten-year national objectives for improving the health of the public and reducing health disparities.[17] Starting with Healthy People 2000, one of the overarching goals of Healthy People has focused on disparities. With Healthy People 2020, that goal was expanded to achieve health equity, eliminate disparities, and improve the health of all groups.[25] Healthy People 2020 provides the following definitions.

> *Health disparity* — a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic

group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion.[25]

Health equity the attainment of the highest level of health for all people. Achieving health equity requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health and health care disparities.[25]

The association between social class and disparities in dental health has been established through extensive studies and reviews.[26-28] Studies in communities both with and without fluoridated water consistently have shown higher levels of tooth decay in lower socioeconomic groups. Additional studies have evaluated the differences in children's tooth decay experience among socioeconomic groups and the effect that community water fluoridation has had on that experience.[29-35] In areas with water fluoridation, children with low socioeconomic status (SES) had greater cavity experience than those with high SES. However, the tooth decay rates were higher for children with low SES who had no exposure to fluoridation compared to children with low SES who had exposure to fluoridated water.[29-35] These studies demonstrate the positive effects that fluoridation has in reducing oral health disparities.

In 2011, a report by the Institute of Medicine, *Improving Access to Oral Health Care for Vulnerable and Underserved Populations*,[36] acknowledged that evidence regarding community water fluoridation programs continues to validate its effectiveness, safety and cost-saving benefits.

Under the topic "Oral Health," Healthy People 2020 includes an objective to expand the fluoridation of public water supplies. Objective 13 states that at least 79.6% of the U.S. population served by community water systems should be receiving the benefits of optimally fluoridated water by the year 2020.[18] Data from the CDC indicate that in 2014, 74.4% of the U.S. population on public water systems, or a total of 211.4 million people, had access to fluoridated water.[19] Conversely, approximately 25% or more than 72.7 million people on public water systems do not receive the decay preventing benefits of fluoridation — a powerful strategy communities can implement in efforts to eliminate health disparities.

60. Along with the American Dental Association, who supports community water fluoridation?

Answer.

Many organizations, such as the National Dental Association, Hispanic Dental Association, American Academy of Pediatrics, American Medical Association, American Public Health Association and the World Health Organization also have policies that support community water fluoridation.

Many organizations, such as the National Dental Association, Hispanic Dental Association, American Academy of Pediatrics, American Medical Association, American Public Health Association and the World Health Organization also have policies that support community water fluoridation.

Fact.

The American Dental Association (ADA) adopted its original resolution in support of fluoridation in 1950[37] and has repeatedly reaffirmed its position publicly and in its House of Delegates based on its continuing evaluation of the safety and effectiveness of fluoridation.[27]

The National Dental Association (NDA) is the largest and oldest organization of minority oral health professionals in the world.[39] Representing more than 7,000 minority dentists, nationally and abroad,[39] the NDA seeks to provide continued advancement of the highest quality of oral health care and safety for the public.[40] In 2012, the NDA adopted the following position:[40]

> It is therefore, the position of the National Dental Association that Community Water Fluoridation is safe, beneficial and cost-effective and should be encouraged and supported under the following conditions:
>
> - Community water supplies should contain the optimal fluoride levels as recommended by the U.S. Public Health Service (a range from 0.7 – 1.2 parts per million)
> - Local communities and dental societies should be in agreement with and support the fluoridation project in their communities.

- Appropriate resources monitoring capabilities should be available to ensure that the appropriate water fluoride monitoring infrastructures are in place at all times in the impacted communities.[40]

In a policy position released in 2012,[41] the Hispanic Dental Association (HDA) noted that the HDA mission works toward the elimination of oral health disparities in the Hispanic community and that the benefits of fluoridation are critical to HDA's endorsement. The HDA position statement[41] includes the following item:

> Therefore, it is the position of the Hispanic Dental Association to:
>
> 1. Endorse community water fluoridation in all communities — especially the Hispanic and underserved communities — as a safe, beneficial and cost-effective public health measure based on science for preventing dental caries and to aid in the reduction of oral health disparities.[41]

As part of its core values[42] the American Academy of Pediatrics (AAP) is dedicated to promoting optimal health and wellbeing for every child. With a strong emphasis on policy, advocacy and education,[42] the AAP is a strong advocate for community water fluoridation. In support of water fluoridation[43] the AAP states:

> Water fluoridation is a community-based intervention that optimizes the level of fluoride in drinking water, resulting in preeruptive and posteruptive protection of the teeth. Water fluoridation is a cost-effective means of preventing dental caries, with the lifetime cost per person equaling less than the cost of 1 dental restoration.[43]

The American Medical Association's (AMA) mission is to promote the art and science of medicine and the betterment of public health.[44] Its House of Delegates first endorsed fluoridation in 1951[45] and the AMA reaffirmed its support for water fluoridation in 2011.[46]

The American Public Health Association (APHA) champions the health of all people and all communities and speaks out for public health issues and policies backed by science.[47] It has supported community water fluoridation as a safe and effective public health measure for the prevention of tooth decay since 1950.[48] The APHA reaffirmed its support in 2008 by stating that it strongly endorses and recommends "the fluoridation of all community water systems as a safe and effective public health measure for the prevention of tooth decay."[49]

The goal[50] at the World Health Organization (WHO) is to build a better, healthier future for people all over the world. The WHO, which initially adopted policy recommending the practice of water fluoridation in 1969,[51] reaffirmed its support for fluoridation in 1994[52] stating:

> Providing that a community has a piped water supply, water fluoridation is the most effective method of reaching the whole population, so that all social classes benefit without the need for active participation on the part of individuals.[52]

In 2004, the WHO once again affirmed its support stating that "Water fluoridation, where technically feasible and culturally acceptable, has substantial public health benefits."[53] In 2007, the Sixtieth World Health Assembly adopted *WHA60.17-Oral health action plan for promotion and integrated disease prevention*[54] which urges member states to:

> (4) for those countries without access to optimal levels of fluoride, and which have not yet established systematic fluoridation programmes, to consider the development and implementation of fluoridation programmes, giving priority to equitable strategies such as the automatic administration of fluoride, for example, in drinking-water, salt or milk, and to the provision of affordable fluoride toothpaste;[54]

In 2016, WHO officials wrote:

> The use of fluoride is a major breakthrough in public health. Controlled addition of fluoride to drinking water supplies in communities where fluoride concentration is below optimal levels to have a cariostatic effect began in the 1940s and since then extensive research has confirmed the successful reduction in dental caries in many countries.[55]

Additionally a list of more than 35 organizations with positions/policies supporting community water fluoridation can be viewed on ADA's website at ***www.ADA.org/fluoride*** in the section marked "Fluoridation Links." Each organization is listed with a link to their specific fluoridation position/policy. Below are just a few of the organizations listed on the website.

- American Association of Dental Research
- American Association of Public Health Dentistry
- American Water Works Association
- Association of State and Territorial Dental Directors
- Centers for Disease Control and Prevention
- International Association of Dental Research
- National Institute of Dental and Craniofacial Research

Many organizations in the United States and around the world recognize the benefits of community water fluoridation. The ADA has developed a list of "National and International Organizations that Recognize the Public Health Benefits of Community Water Fluoridation for Preventing Dental Decay." Please see the ADA website at ***www.ADA.org/fluoride*** for the most current listing as well as information on reproduction and distribution of the list.

However, support for fluoridation doesn't end with a list of organizations. In many cases, local newspaper editorial boards support fluoridation. Perhaps the most notable of these efforts occurred when the 2013 Pulitzer Prize for Journalism — Editorial Writing[56] was awarded to Tim Nickens and Daniel Ruth of the *Tampa Bay Times*, St. Petersburg, Florida, for their diligent campaign that helped reverse a decision to end fluoridation of the water supply for the 700,000 residents of the newspaper's home (Pinellas) county. Copies of their 10 editorials from 2012 can be viewed at ***http://www.pulitzer.org/winners/tim-nickens-and-daniel-ruth***.

61. Has the legality of water fluoridation been upheld by the courts?

Answer.

Yes. Fluoridation has been thoroughly tested in the United States' court system, and found to be a proper means of furthering public health and welfare. No court of last resort has ever determined fluoridation to be unlawful. Moreover, fluoridation clearly has been held not to be an unconstitutional invasion of religious freedom or other individual rights guaranteed by the First, Fifth or Fourteenth Amendments to the U.S. Constitution. And while cases decided primarily on procedural grounds have been won and lost by both pro- and anti-fluoridation interests, to ADA's knowledge, no final ruling in any of those cases has found fluoridation to be anything but safe and effective.

Fact.

The legality of fluoridation in the United States has been thoroughly tested in our court systems. Fluoridation is viewed by the courts as a proper means of furthering public health and welfare.[57] No court of last resort has ever determined fluoridation to be unlawful. The highest courts of more than a dozen states have confirmed the constitutionality of fluoridation.[58] In 1984, the Illinois Supreme Court upheld the constitutionality of the state's mandatory fluoridation law, resolving 16 years of court action at a variety of judicial levels.[59] Moreover, the U.S. Supreme Court has denied review of fluoridation cases thirteen times, citing that no substantial federal or constitutional questions were involved.[58]

Fluoridation is viewed by the courts as a proper means of furthering public health and welfare. No court of last resort has ever determined fluoridation to be unlawful.

It has been the position of the American courts that a significant government interest in the health and welfare of the public generally overrides individual objections to public health regulation.[58] Consequently, the courts have rejected the contention that fluoridation ordinances are a deprivation of religious or individual freedoms guaranteed under the Constitution.[58,60] In reviewing the legal aspects of fluoridation, the courts have dealt with this concern by ruling that: (1) fluoride is a nutrient, not a medication, and is present naturally in the environment; (2) no one is forced to drink fluoridated water as alternative sources are available; and (3) in cases where a person believes that fluoridation interferes with religious beliefs, there is a difference between the freedom to believe, which is absolute, and the freedom to practice beliefs, which may be restricted in the public's interest.[61,62]

Fluoridation is the adjustment of the level of a naturally occurring mineral found in water in order to prevent tooth decay. Courts have consistently ruled that water fluoridation is not a form of compulsory mass medication or socialized medicine.[58,61,63] In fact, water that has been fortified with fluoride is similar to fortifying salt with iodine, milk with vitamin D and orange juice with calcium — none of which are medications.

In recent years, challenges to fluoridation have been dismissed for a variety of reasons, including that plaintiffs admitted they could not establish injury by virtue of fluoridation and that state law supporting fluoridation prevailed over local attempts to oppose fluoridation.

Interestingly, pro- and anti- fluoridation interests have each won and lost legal challenges regarding which state or local agency has regulatory authority over fluoridation, which of course varies by state and locality.

State law variances have also led to different rulings on other issues, such as whether downstream end-users of fluoridation must be given an opportunity to vote on whether to fluoridate. While cases decided primarily on procedural grounds have been won and lost by both pro- and anti- fluoridation interests, to the ADA's knowledge no final ruling in any of those cases has found fluoridation to be anything but safe and effective.

For additional information regarding the legal status of community water fluoridation in the United States, refer to *The Fluoride Legislative User Information Database* (FLUID) which is a comprehensive database containing historical information on legal cases decided by U.S. courts. The database also contains current information on federal and state policies regarding community water fluoridation. The website can be accessed at: *http://fluidlaw.org*

62. Why does opposition to community water fluoridation continue?

Answer.

Public health controversies sometimes exist regarding public health interventions. In public health there can be tension between "public good" and "individual freedoms." Because public health deals with populations it is all but impossible to resolve issues to achieve approval from 100 percent of the individuals within the population. When looking at fluoridation, some individuals opposed to fluoridation are sincere in their beliefs. Others ignore what constitutes reputable scientific evidence as defined by the vast majority of the scientific community and choose instead to base their beliefs on personal opinions and studies with flawed methodologies.

Fact.

Fluoridation is considered beneficial by the overwhelming majority of the health and scientific communities as well as the general public. A vast body of scientific literature endorses water fluoridation as a safe means of reducing the incidence of tooth decay. Support for fluoridation among scientists and health professionals, including physicians and dentists, is nearly universal. Recognition of the benefits of fluoridation by the American Dental Association, the American Medical Association, the American Academy of Pediatrics, governmental agencies and other national health and civic organizations continues as a result of published, peer-reviewed research.

Fluoridation has a long history of being a political issue, as well as a scientific one, with opposition including activists from both the right and the left of the political spectrum. In the late 40s, opposition to fluoridation began to appear nationwide. Reportedly, one of the first public votes on fluoridation occurred in 1950 in Stevens Point, Wisconsin,[64] when a local activist initiated a campaign to stop the introduction of what he called "poison" into the water system. The campaign quickly moved from being a discussion of the science to a political campaign that included the involvement of a large number of civic groups, unofficial public petitions, calls for a debate, campaign rallies and numerous letters to the editor that "kept typesetters busy preparing for print the thousands of words that poured into the editor's desk." After 1950 when the U.S. Public Health Service and ADA endorsed fluoridation, proponents became more organized in their efforts to promote fluoridation while the opposition capitalized on the political nature of the struggle and used lessons learned in Stevens Point.

Of the small faction that opposes water fluoridation for philosophical reasons, freedom of choice probably is one of the most frequently cited issues. People take the stance that society should not "force" individuals to act in ways that are beneficial to their own health or the health of others. They are opposed to "government interference" in their lives.[65] Some individuals are opposed to community action on any health issue, others are opposed due to environmental or economic concerns and some are opposed because they are simply misinformed.

Opposition to fluoridation has existed since the initiation of the first programs in 1945 and continues today despite over 70 years of practical experience

showing fluoridation to be safe and effective. An article[55] that appeared in the local newspaper shortly after the first fluoridation program was implemented in Grand Rapids, Michigan, noted that the fluoridation program was slated to commence January 1, but did not actually begin until January 25. Interestingly, health officials in Grand Rapids began receiving complaints of physical ailments, including "teeth falling out and enamel peeling off their teeth," attributed to fluoridation from citizens weeks before fluoride was actually added to the water.[66] In 1992 a community in Finland opted to stop their fluoridation program at the end of the year in December. However, it was discontinued at the end of November without the public being told. Public surveys conducted in November and December and again in March the following year revealed the occurrence and mean number of symptoms (the most common being itching and dryness of skin) were fairly similar during the periods of actual and supposed fluoridation indicating the symptoms were not caused by fluoride in the water. Interestingly, those who claimed to be able to taste the fluoride in the water made this claim equally often during actual and supposed fluoridation. A significant reduction in the symptoms occurred after those responding to the surveys became aware that fluoridation had stopped. The authors concluded that the prevalence rates of the symptoms were connected to the psychological rather than the physical effects of exposure to fluoride in water.[67]

Over time, antifluoridation leaders and organizations have come and gone, but their basic beliefs have remained the same. These include: fluoride is toxic and causes numerous harmful health effects; fluoride does not prevent tooth decay; fluoridation is costly; and fluoridation interferes with freedom of choice and infringes on individual rights.

Opinions are seldom unanimous on any scientific subject. In fact, there really is no such thing as "final knowledge," since new information is continuously emerging and being disseminated. As such, the benefit evidence must be continually weighed against risk evidence. Health professionals, decision makers and the public should be cooperating partners in the quest for accountability where decisions are based on proven benefits measured against verified risks.[68] Dentists are a valuable source of accurate information regarding water fluoridation for both their patients and their communities.

63. What are the tactics fluoridation opponents use to provoke opposition to water fluoridation?

Answer.

Fluoridation opponents use numerous tactics to disseminate misinformation and raise the fears of the public about the safety of water fluoridation. Routinely, they use scare techniques,[69] present half-truths, downplay the significance of science-based evidence and use selective reporting of results and studies to support their false allegations.[59]

Fact.

While many of the arguments against fluoridation have remained relatively constant over the years, antifluoridationists have used different approaches that play upon the popular concerns of the public at the time.[65] For example, in the 1950s fluoridation was said to be a Communist plot. With America's growing concern for environmental issues in the 1960s, fluoridation was called pollution. After the Vietnam War in the 1970s, the antifluoridationists capitalized on the popularity of conspiracy theories by portraying fluoridation as a conspiracy between the U.S. government, the dental-medical establishment and industry. As the population became more concerned about their health in the 1980s, antifluoridationists claimed fluoridation caused AIDS and Alzheimer's disease. In the 1990s, claims of hip fractures and cancer were designed to resonate with aging baby boomers. With the new millennium, overexposure and toxicity, in association with lead poisoning, surfaced as common themes. Since the economic crisis of 2008, discussions about the cost of fluoridation are more commonplace. In the 2010s, neurotoxicity became a constant theme with charges of lower IQ and autism. Over the years, none of these approaches have ever really disappeared, but instead are often recycled as antifluoridationists choose which approach will have the greatest effect on the intended audience.[65]

The internet has breathed new life into the antifluoridation effort bringing the antifluoridation message into voters' homes.[71,72] With just a click of the mouse, search engines can locate a large number of websites denouncing fluoridation, which can give the impression that this is a one-sided argument. Individuals who look to the internet as a source of valid and reliable information often fail to recognize that these sites frequently contain personal opinion rather than scientific fact. Newspaper stories,

press releases and letters to the editor are often posted as documentation of the "science" behind antifluoridationists' claims. All too often, the public accepts this type of information as true simply because it is in print. Opposition videos are available from national antifluoridation organizations and are shared at no cost via vehicles such as YouTube making it possible for every campaign to bring an antifluoridationist to the community. Social media such as Facebook and Twitter are used to spread antifluoridation messaging to the public and to assist in organizing local efforts. These venues have allowed the small faction of antifluoridationists to be linked across the country and around the world and promote their message quickly, repeatedly and economically.

Spreading misinformation impacts public policy and costs society in immeasurable ways. The opponents' claims and opinions can escalate to emotional arguments that, in the end, can delay, or prevent the introduction of a water fluoridation program or stop an existing program.[70] More people, especially those involved in policy decisions, need to be better informed about these tactics. In making decisions that affect the health of the community, it is important to distinguish between someone's personal opinion disguised as science and information based on the best available scientific evidence. It is perfectly acceptable to have your own opinion but it is unacceptable to have your own "facts" derived from something less than reputable science.

In making decisions that affect the health of the community, it is important to distinguish between someone's personal opinion disguised as science and information based on the best available scientific evidence.

In 1993 the U.S. Supreme Court issued a landmark decision that many view as likely to restrict the use of information inferred as science in the federal courts and in those state courts which adopt this reasoning. The Court determined that while "general acceptance" is not needed for scientific evidence to be admissible, federal trial judges have the task of ensuring that an expert's testimony rests on a reasonable foundation and is relevant to the issue in question.[73] According to the Supreme Court, many considerations will bear on whether the expert's underlying reasoning or methodology is scientifically valid and applicable in a given case. The Court set out four criteria that judges could use when evaluating scientific testimony:

1. whether the expert's theory or technique can be (and has been) tested, using the scientific method,

2. whether it has been subject to peer review and publication (although failing this criteria alone is not necessarily grounds for disallowing the testimony),

3. its known or potential error rate and the existence and maintenance of standards in controlling its operation and

4. whether it has attracted widespread acceptance within a relevant scientific community, since a known technique that has been able to attract only minimal support may properly be viewed with skepticism.[73]

The scientific validity and relevance of claims made by opponents of fluoridation might be best viewed when measured against these criteria.[73] The techniques used by antifluoridationists are well known and have been discussed at length in a number of published articles that review the tactics used by antifluoridationists.[58,65,68-70,74-77] Examples of a few of the techniques can be viewed in Figure 5.

Figure 5. Opposition Tactics

Targeting Politicians and Community Leaders: Antifluoridation websites contain draft letters to be sent to newspaper publishers, water departments, and community public officials warning them of their "liability" should they support or endorse water fluoridation. Leaders are urged to remain "neutral" and allow fluoridation decisions to be put to a public vote, therefore, relieving the leaders of any and all responsibility in the matter. Antifluoridationists use the time gained to conduct a public referendum to bombard the public with misinformation designed to turn public opinion against fluoridation.

Unproven Claims: Antifluoridationists have repeatedly claimed fluoridation causes an entire laundry list of human illnesses, including AIDS, Alzheimer's disease, cancer, Down Syndrome, genetic damage, heart disease, lower intelligence, kidney disease, osteoporosis and hip fractures. None of these claims has a basis in fact. These allegations are often repeated so frequently during campaigns that the public assumes they must be true. Their appearance in print, even if only in letters to the editor of the local newspaper, reinforces the allegation's credibility. With just a small amount of doubt established, the opposition slogan, "If in doubt, vote it out," often rings true with voters.

Innuendo: The statement, "Fifty years ago physicians and dentists posed for cigarette ads," is an example of innuendo or, more specifically, guilt by association. Even though fluoridation is not mentioned, individuals are expected to make the connection that the medical community changed its position on smoking so it is possible health professionals are wrong about fluoridation, too.

Outdated Studies and Statements from "Experts": Antifluoridation websites often offer a list of "respected medical professionals and scientists" who have spoken out against fluoridation. One of those often quoted is Dr. Charles Gordon Heyd who is noted to be a Past President of the American Medical Association (AMA). What is not disclosed is the source of the quote or that Dr. Heyd was President of the AMA in 1936 – almost ten years before water fluoridation trials began. His decades-old quote certainly does not represent the current AMA position of support for water fluoridation and is characteristic of antifluoridationists' use of items that are out of date. Additionally, antifluoridationists have claimed that fourteen Nobel Prize winners have "opposed or expressed reservations about fluoridation." It should be noted that the vast majority of these individuals were awarded their prizes from 1929 through 1958.

Statements Out of Context: One of the most repeated antifluoridation statements is, "Fluoride is a toxic chemical. Don't let them put it in our water." This statement ignores the scientific principle that toxicity is related to dosage and not just to exposure to a substance. Examples of other substances that can be harmful in the wrong amounts, but beneficial in the correct amounts, are salt, vitamins A and D, iron, iodine, aspirin and even water itself.

Conspiracy Theories: Hardly a fluoridation campaign goes by without those opposed to fluoridation bringing up any number of conspiracy theories about fluoridation. Whether it is the claim that scientists from the original atomic bomb program secretly shaped and guided the early Newburgh, NY, fluoridation trial or that chemtrails are a government plot to spread fluoride, these claims have no basis in fact. Even the belief that fluoridation was a communist plot to destroy America was famously parodied in the 1964 movie Dr. Strangelove. Over the decades, those opposed to fluoridation have used propaganda schemes and conspiracy theories that reflected the social and political environment of the times. Today, "follow the money" is a common theme as the opposition claims that the beverage industry, the companies supplying fluoride additives and others are financially backing researchers, as well as dental and medical groups, who are promoting fluoridation. None of these claims has a basis in fact.

Treating Correlation as Causation: Many people have heard the phrase that "correlation does not imply causation." In other words, just because two events seem to fluctuate in tandem does not prove that they are meaningfully related to one another. For example, statistics show that sales of ice cream increase in warm summer months. Statistics also show that crime goes up in large cities in the summer. However, it would be ludicrous to draw the conclusion that ice cream causes an increase in crime. Yet this is exactly the type of logic exercised in some arguments and studies promoted by those opposed to fluoridation. For example, the opposition often points to Kentucky as having a large portion of the population on public water supplies receiving fluoridated water. And that's correct. In 2014, Kentucky was ranked the number one state in the U.S. as 99.9% of its public water systems were fluoridated. But the opposition also points to the fact that Kentucky suffers from a large number of people who have lost their teeth. They draw the conclusion that this proves fluoridation does not work — without looking at other factors that influence this outcome. For example, while there is a large number of public water systems that are fluoridated, Kentucky has a large rural population that does not have access to public water supplies. Additionally, and perhaps most importantly, Kentucky's population has a high rate of tobacco use which is known to be a risk factor for periodontal (gum) disease which can lead to the loss of teeth.

64. Where can valid, evidence-based information about water fluoridation be found on the internet?

Answer.

There are many reputable sites on the internet that provide information on fluorides and fluoridation including the American Dental Association as well as other reputable health and science organizations and government agencies. These sites provide information that is consistent with the best available scientific evidence.

Fact.

One of the most widely respected sources for information regarding fluoridation and fluorides is the American Dental Association's (ADA) Fluoride and Fluoridation website at *www.ADA.org/fluoride*. (See Figure 6.) From the ADA website individuals can link to other fluoridation websites such as:

- Centers for Disease Control and Prevention at *www.cdc.gov/fluoridation*
- The Community Guide at *https://www.thecommunityguide.org*
- Fluoride Science at *http://fluoridescience.org*

The internet contains numerous sources of information on fluoridation. However, not all "science" posted on the internet is based on scientific fact. Searching the internet for "fluoride" or "water fluoridation" directs individuals to numerous websites. Some of the content found in the sites is scientifically sound. Other less scientific sites look highly technical, but contain information based on science that is unconfirmed or has not gained widespread acceptance. In many cases, the information is largely opinion. While everyone is entitled to their opinion, they are not entitled to make that opinion appear as scientific fact. Commercial interests, such as the sale of water filters, are often promoted.

Today's technology can put the world at your fingertips but search engine technology can influence what is returned in searches. The first time the search for "fluoridation" is made, it is likely that the returns will include both pro- and anti- fluoridation websites. When you click to view a website, the search engine takes note and on subsequent searches for the same term, the search engine will return items similar to what you chose initially. For example, if you choose a pro-fluoridation website initially, the next time you search for "fluoridation," the search engine will likely return a selection of other pro-fluoridation websites for your review. Of course the converse is also true. Clicking on anti-fluoridation websites will allow you to see a search ladened with similar anti-fluoridation sites.

Figure 6. ADA Fluoride and Fluoridation Web Page

FLUORIDATION AT YOUR FINGERTIPS!

http://www.ADA.org/fluoride

- ADA Fluoridation Resources
- ADA Fluoridation Videos
- ADA Fluoridation News Stories
- ADA Policy and Statements
- Links to Additional Fluoridation Websites

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65. Why does community water fluoridation sometimes lose when it is put to a public vote?

Answer.
Voter apathy or low voter turnout due to the vote being held as a special election or in an "off" year, confusing ballot language (a "no" vote translates to support for fluoridation), blurring of scientific issues, the use of scare tactics by those opposed to fluoridation, long campaigns that lead to "fluoridation fatigue," lack of leadership by elected officials and a lack of political campaign skills among health professionals are some of the reasons fluoridation votes are sometimes unsuccessful.

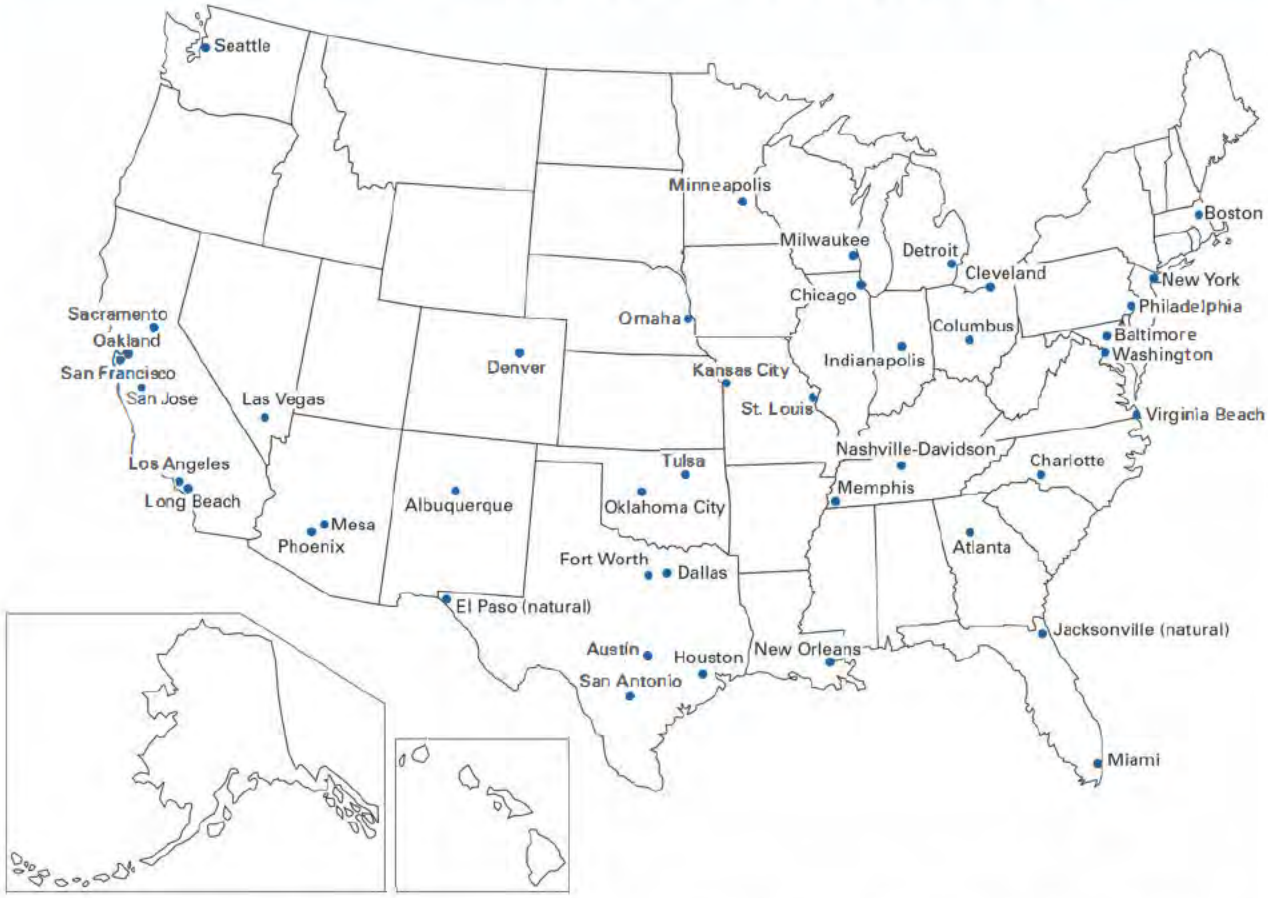
Fact.
The fact is that fluoridation votes in the U.S. are more often successful than not. In 2016, it was common to see those opposed to fluoridation make statements such as "450 communities had rejected fluoridation since 2000" or similar statements using different numbers. What is not made clear is that the number of communities in these statements is a global number. Many of these communities are outside the United States.[78] In fact from 2000 through 2016, more than 515 U.S. communities in 42 states voted to adopt or retain successful fluoridation programs.[79] In the five years from 2012 to 2016, U.S. communities voted in favor of fluoridation programs by a two to one margin.[78,79]

The fact is that fluoridation votes in the U.S. are more often successful than not...In the five years from 2012 to 2016, U.S. communities voted in favor of fluoridation programs by a two to one margin.

Since 2000, nearly 50 million people have been added to the population on public water systems in the United States that enjoys the benefit of optimally fluoridated water.[80] In 2000, 65% of the public on public water systems received fluoridated water.[81] In 2014, the percentage had increased nearly 10% to 74.4% of the population.[19] But despite the continuing growth of fluoridation in this country over the past several decades, millions of people in the U.S. do not yet receive the protective benefit of fluoride in their drinking

Figure 7. Largest Fluoridated Cities

Two cities (Jacksonville, Florida and El Paso, Texas) are naturally fluoridated.*



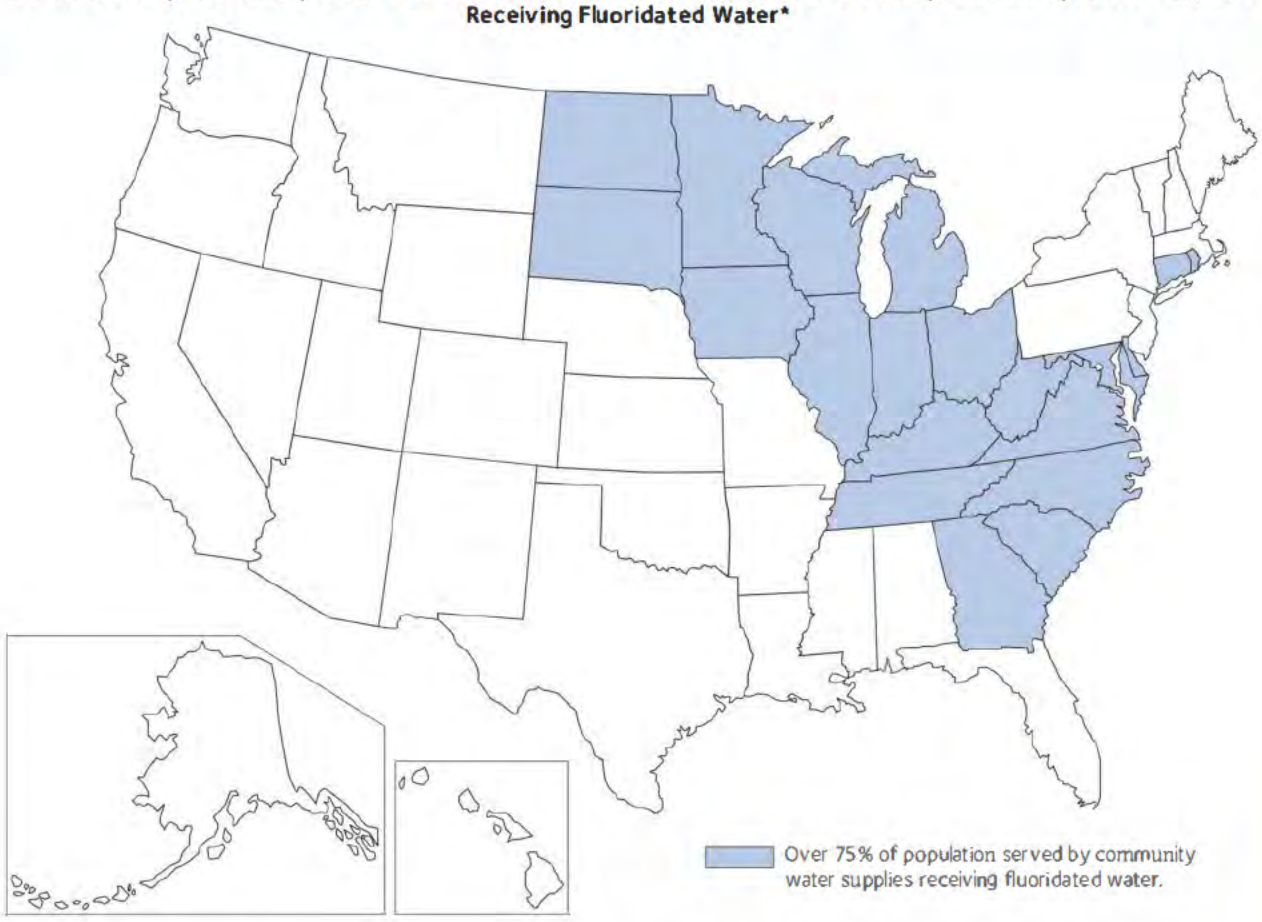
* Data compiled by the American Dental Association and Centers for Disease Control and Prevention/Division of Oral Health. Information current as of October 2017.

water. Centers for Disease Control and Prevention (CDC) data from 2014 indicated more than 25% of the population served by public water systems did not have access to fluoridated water.[19] In 2017, 44 of the 50 largest cities were fluoridated.[82] Of the 44 cities, 42 were fluoridated by adjustment and two had naturally occurring fluoride at the recommended levels (Figure 7). The remaining six largest nonfluoridated cities (in order of population largest to smallest) were: Portland, Oregon; Albuquerque, New Mexico; Tucson, Arizona; Fresno, California; Colorado Springs, Colorado; and Wichita, Kansas. In October 2017, the Albuquerque Bernalillo County Water Utility Authority authorized budget monies to restore fluoridation to their customers. It is estimated that fluoridated water will be available in six to eight months.

In 2010, recognizing the ongoing need to improve health and well-being, the U.S. Department of Health and Human Services revised national health objectives to be achieved by the year 2020.[17] Included under oral health was an objective to significantly expand the fluoridation of public water supplies. Specifically, Objective 13 of Healthy People 2020 states that at least 79.6% of the U.S. population served by community water systems should be receiving the benefits of optimally fluoridated water by the year 2020.[18] This replaced the Healthy People 2010 objective of 75%.[83] As of 2014, twenty states met or exceeded the 2020 objective.[19] (See Figure 8.) Although water fluoridation reaches some residents in every state the coverage is uneven. Data from 2014 indicated that 26 states provided fluoridation benefits to 75% or more of their residents on community water systems while eight states were at or below 50%.[19] (See Figure 9.)

Figure 8. States Meeting National Goal

States Meeting the Healthy People 2020 Goal Of 79.6% of the Population Served by Community Water Supplies Receiving Fluoridated Water*



* Data Source: Centers for Disease Control and Prevention/Division of Oral Health. "National Fluoridation Statistics" 2014. Available at *https://www.cdc.gov/fluoridation/statistics/2014stats.htm*

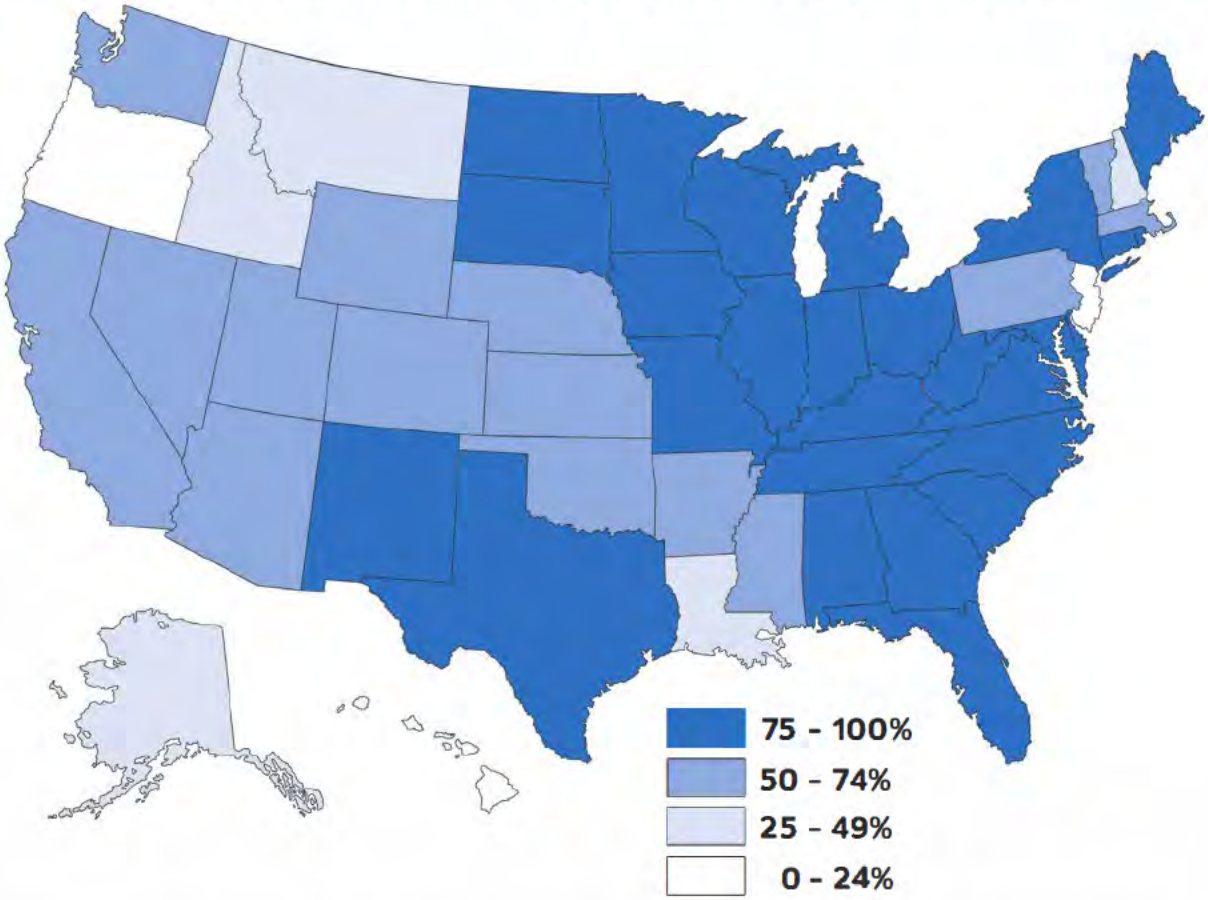
Fluoridation campaigns can vary greatly from community to community. To paraphrase an old saying, "If you've seen one fluoridation campaign, you've seen one fluoridation campaign." A number of factors commonly come into play when fluoridation is put to a public vote and does not succeed. Among those factors are a lack of funding, public and professional apathy, the failure of many legislators and community leaders to take a stand because of perceived controversy, low voter turnout and the difficulty faced by an electorate in evaluating scientific information in the midst of emotional charges by opponents. Voters are often unaware of the fluoride content of their water. Unfortunately, citizens sometimes mistakenly believe their water contains the recommended level of fluoride when, in fact, it does not. On the other hand, people sometimes say they have great teeth and don't need fluoridation when in fact, the major reason they have such good teeth is because they've had the benefit of fluoride in the water their entire lives. And, in some cases, because fluoridation campaigns often become political campaigns, there are political factors that can sway a vote that have nothing at all to do with fluoridation.

Clever use of emotionally charged "scare" propaganda by fluoride opponents creates fear, confusion and doubt within a community when voters consider the use of fluoridation.[84,85]

Defeats of referenda or the discontinuance of fluoridation have occurred most often when a small, vocal and well organized group has used a barrage of fear-inspiring allegations designed to confuse the electorate. In addition to attempts to influence voters, opponents have threatened community leaders with

Figure 9. State Fluoridation Status

Percentage of population on community water systems receiving fluoridated water.*



* Data Source: Centers for Disease Control and Prevention/Division of Oral Health. "National Fluoridation Statistics" 2014. Available at *https://www.cdc.gov/fluoridation/statistics/2014stats.htm*

personal litigation.[86] While no court of last resort has ever ruled against fluoridation, community leaders can be swayed by the threat of litigation due to the cost and time involved in defending even a groundless suit, not to mention threats of political fallout. The American Dental Association (ADA) knows of no cases in which community leaders have been found liable for their pro-fluoridation efforts. In no instance has fluoridation been discontinued because it was proven harmful in any way.[85 87]

Defeats of referenda or the discontinuance of fluoridation have occurred most often when a small, vocal and well organized group has used a barrage of fear inspiring allegations designed to confuse the electorate.

Adoption of fluoridation is ultimately a decision of state or local decision makers, whether determined by elected officials, health officers or the voting public. Fluoridation can be enacted through state legislation, administrative regulation, ordiance or a public referendum. While fluoridation is not legislated at the federal level, it is legislated at the state and local level. As with any public health measure, a community has the right and obligation to protect the health and welfare of its citizens, even if it means overriding individual objections to implement fluoridation.

Those opposed to fluoridation sometimes comment that "the government is forcing fluoridation" on the community. But who is "the government?" The fact is that since fluoridation is implemented by state or local votes (by city councils or public vote), the people are "the government." Voters elect officials at the

state and local level to act on their behalf. Voters participate directly in public votes on fluoridation.

Each spring as part of the yearly ADA/ASTDD/CDC Community Water Fluoridation Awards program, the ADA, Association of State and Territorial Dental Directors and the CDC Division of Oral Health compile a list of water systems/communities in the United States that have adopted or retained community water fluoridation in the previous year.[88] This list is posted on the ADA website at *http://www.ADA.org/fluoride*. The ADA has also compiled a master list of U.S. communities voting to adopt or retain fluoridation programs dating from 1998 which is also available on the ADA website.[79] From 2000 through 2016, more than 515 U.S. communities in 42 states have voted to adopt or retain fluoridation. The size of these water systems/communities varies greatly — from those with a few thousand residents to the Metropolitan Water District of Southern California which provides fluoridated water to more than 18 million people.[79]

The primary source for technical assistance with fluoridation efforts is the ADA's Council on Advocacy for Access and Prevention (CAAP) at the ADA. Additional support for fluoridation is available from the ADA's Division of Legal Affairs, Division of Communications and Department of State Government Affairs. Dental and health professionals seeking technical assistance can reach CAAP at (b) (6)

66. Is community water fluoridation accepted by other countries?

Answer.

According to the British Fluoridation Society,[89] as of November 2012, approximately 377.7 million people in 25 countries worldwide were supplied with water fluoridated by adjustment. Additionally, the number of people receiving naturally fluoridated water at the optimum level is approximately 57.4 million. Worldwide, the estimated number of people with access to optimally fluoridated water is 435.1 million and it continues to grow each year. A second study estimates the number at 437.2 million.[90]

According to the British Fluoridation Society, as of November 2012, approximately 377.7 million people in 25 countries worldwide were supplied with water fluoridated by adjustment.

Fact.

The value of water fluoridation is recognized internationally. Countries and geographic regions with water fluoridated by adjustment include the U.S., Argentina, Australia, Brazil, Brunei, Canada, Chile, China (Special Administrative Region of Hong Kong), Fiji, Guatemala, Guyana, the Irish Republic, Israel, Malaysia, New Zealand, Panama, Papua New Guinea, Peru, Republic of Korea (South Korea), Serbia, Singapore, Spain, the United Kingdom and Vietnam.[89] Major cities (outside the U.S.) with fluoridated water include Adelaide, Auckland, Bilbao, Birmingham, Brisbane, Buenos Aires, Cork, Dublin, Edmonton, Ho Chi Minh City (Saigon), Kuala Lumpur, Melbourne, Newcastle upon Tyne, Perth, Rio de Janeiro, San Paolo, Santiago, Seville, Sydney, Toronto, Wellington and Winnipeg.[89]

Thorough investigations of fluoridation, conducted in a number of countries in addition to the U.S. including Australia, England, Ireland, New Zealand as well as by the European Commission and the World Health Organization, support the safety and effectiveness of water fluoridation.[90-95]

Considering the extent to which fluoridation has already been implemented throughout the world, the lack of documentation of adverse health effects is remarkable testimony to its safety.[91-94, 96] The World Health Organization (WHO) has endorsed the practice of water fluoridation since 1969.[51] In 1994, an expert committee of the WHO published a report which reaffirmed its support of fluoridation as being safe and effective in the prevention of tooth decay, and stated that "provided a community has a piped water supply, water fluoridation is the most effective method of reaching the whole population, so that all social classes benefit without the need for active participation on the part of individuals."[52] In 2004, the WHO once again affirmed its support.[53] In 2007, the Sixtieth World Health Assembly recommended that countries without access to optimal levels of fluoride or systemic fluoridation programs should consider initiating fluoridation programs.[54]

A scientific evaluation of fluoride was conducted by the Scientific Committee on Health and Environmental Risks (SCHER) upon request by the European Commission (EC).[85] The EC is the European Union's (EU) executive body with responsibility to manage EU policy. The Committee was asked to critically evaluate any new evidence on the hazard profile, health effects and human exposure to fluoride. The final report,

Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water was released in 2011.[95] It stated that exposure to levels of fluoride used for fluoridation of drinking water is not expected to lead to unacceptable risks to the environment. Additionally, the report concluded there was insufficient evidence or no evidence that fluoridation was linked to endemic skeletal fluorosis, osteosarcoma, lower IQs in children, thyroid or reproductive problems.[95]

There are parts of the world where water fluoridation is not common. In some of these instances water fluoridation is not feasible due to the lack of a central water supply, the existence of other more life-threatening health needs, the lack of trained technical personnel or sufficient funds for start-up and maintenance costs. In some cases where water fluoridation has not been implemented, countries have chosen to institute salt fluoridation programs.

67. Is community water fluoridation banned in Europe?

Answer.

No country in Europe bans community water fluoridation.

Fact.

Under European Union (EU) law and regulations, the individual Member States can decide whether to or not to fluoridate water. Members of the European Union (EU) construct their own water quality regulations within the framework of the Drinking Water Directive[97] adopted in 1998 which outlines the quality of water intended for human consumption. They can also decide whether to or not to add fluoride to milk or salt products. There is no EU-wide obligation to add fluoride to any product consumed by humans including water nor is there an EU-wide obligation not to add fluoride to any product including water.[87]

The Directive provides maximum admissible concentrations for many substances, one of which is fluoride. The Directive does not require or prohibit fluoridation; it merely requires that the fluoride concentration in water does not exceed the maximum permissible concentration of 1.5 mg/L.[97]

Many fluoridation systems that used to operate in Eastern and Central Europe did not function properly and when the Iron Curtain fell in 1989-90, fluoridation stopped because of obsolete technical equipment and lack of knowledge as to the benefits of fluoridated water.[88]

Water fluoridation is not practical in some European countries because of complex water systems with numerous water sources. As an alternative to water fluoridation, many European countries have opted for the use of dietary fluoride supplements or salt fluoridation.

Basel, Switzerland is one such example.[98] Those opposed to water fluoridation claimed a large victory when Basel voted to cease water fluoridation in 2003. The facts are that Basel was the lone city with fluoridated water surrounded by communities that used fluoridated salt. In the mid-1990s, trade barriers that had prevented fluoridated salt from being sold to those living in Basel fell and soon it was evident that residents were receiving fluoride from salt as well as through drinking water. The government voted to cease water fluoridation in 2003 in light of availability and use of fluoridated salt in the community. Basel, Switzerland did not stop providing fluoride. Officials simply chose another type of fluoridation — salt fluoridation.[98]

Again, no European country bans fluoridation. It has simply not been implemented for a variety of technical, legal, financial or political reasons.

Those opposed to fluoridation sometimes comment that "97% of western Europe has rejected water fluoridation," although frequently the line becomes "most of Europe has rejected water fluoridation." But what is not mentioned is that there are a number of countries in Europe that have opted to use fluoridated salt or milk fluoridation. (Additional information on this topic can be found in Benefits Section, Question 14.) Letters have appeared on the internet reportedly from officials in foreign countries who comment negatively regarding their country's position on fluoridation. However, from the letters it is apparent the writers are responding to a question that is not publically available and that was designed to illicit a negative response. Additionally the credentials of the respondents do not provide any insight as to what relationship, if any, they have with the governmental bodies who have jurisdiction over fluoridation practices in their respective countries. These letters should not be construed as any country's official position on fluoridation.

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Cost

68. Is water fluoridation a cost-effective and cost-saving method of preventing tooth decay?

Answer.

Yes. When compared to the cost of other prevention programs, water fluoridation is the most cost-effective means of preventing tooth decay for both children and adults in the United States. A number of studies over the past 15 years have attempted to place a specific dollar value on the benefit of fluoridation. These studies, conducted in different years (and therefore using different dollar values), encompassing different communities/populations and different methodologies have two conclusions in common: 1) for systems that serve more than 1,000 people, the economic benefit of fluoridation exceeds the cost and 2) the benefit-cost ratios increased as the size of the populations increase largely due to economies of scale.

Fact.

The cost of community water fluoridation varies for each community depending on the following factors.[1]

1. Size of the community (population and water usage);
2. Number of fluoride injection points where fluoride additives will be added to the water system;
3. Amount and type of equipment used to add and monitor fluoride additives;
4. Amount and type of fluoride additive needed to reach the target fluoride level of 0.7 mg/L; its price, cost of transportation and storage; and
5. Expertise and preferences of personnel at the water plant.

In 2016, a study[2] led by researchers from the Colorado School of Public Health created a model of fluoridation program costs, savings, net savings and return on investment for the 2013 U.S. population with access to optimally fluoridated water systems that served 1,000 or more people. The researchers found that savings associated with individuals avoiding tooth decay in 2013 as a result of fluoridation were estimated at $6.8 billion, or $32.19 per person, for the more than 211 million people who had access to fluoridated water through community water systems serving more than 1,000 people that year. Based on the estimated cost of the systems to fluoridate ($324 million), the net savings from fluoridation was estimated at $6.5 billion and the estimated return on investment (ROI) averaged 20 to 1 across water systems of all sizes (from 1,000 to over 100,000 people with a ROI range of 15.5 to 26.2). However, it was noted that the cost per person to fluoridate can vary significantly among different sizes of communities based on a number of the factors outlined in the previous paragraph. Because of those variables, the researchers urged communities to inform their policy decisions by identifying their specific water system's annual cost and comparing that cost to the annual estimated per person savings ($32.19) in averted treatment costs. The researchers noted that in 2013, while 211 million people had access to fluoridated water, more than 78 million people had access to a public water system that served 1,000 or more people that was not fluoridated. The study findings suggest that if those water systems had been fluoridated, an additional $2.5 billion could have been saved as a result of reductions in tooth decay.[2]

The economic benefits of fluoridation were also reconfirmed in a systematic review[3] conducted in 2013 by the Community Preventive Services Task Force which sought to update their prior review conducted in 2002[4] which also found that fluoridation saved money. The 2013 review concluded that recent

evidence continues to indicate the economic benefit of fluoridation programs exceeds their cost. The review also noted that benefit-cost ratio increases with the population of the community.

Because of the decay reducing effects of fluoride, the need for restorative dental care is typically lower in fluoridated communities. Therefore, an individual residing in a fluoridated community will typically pay for fewer dental restorative services (such as fillings) during a lifetime. A study[5] published in 2005, estimated the cost and treatment savings resulting from community water fluoridation programs in Colorado. The study also estimated the added savings if communities without water fluoridation initiated a fluoridation program. The study estimated a community fluoridation program generated treatment savings through prevented tooth decay of $61 for every $1 spent to fluoridate the community's water. On a state level, results indicated an annual savings of nearly $150 million associated with the water fluoridation programs and projected a nearly $50 million annual savings if the remaining 52 nonfluoridated water systems in Colorado were to implement water fluoridation programs.[5]

There are various types of dental restorations (fillings) commonly used for the initial treatment of tooth decay (cavities) including amalgam (silver) and composite resins (tooth-colored). In the 2016 study noted earlier[2], the most commonly used treatment was a two-surface composite resin restoration in posterior (back) permanent teeth. Considering the fact that in the United States the fee[6] for a two-surface composite resin restoration in a permanent tooth placed by a general dentist typically ranges from $165-$305*, fluoridation clearly demonstrates significant cost savings. An individual can enjoy a lifetime of fluoridated water for less than the cost of one dental filling.

An individual can enjoy a lifetime of fluoridated water for less than the cost of one dental filling.

*The Survey data should not be interpreted as constituting a fee schedule in any way, and should not be used for that purpose. Dentists must establish their own fees based on their individual practice and market considerations. The American Dental Association discourages dentists from engaging in any unlawful concerted activity regarding fees or otherwise.

When it comes to the cost of treating dental disease, everyone pays. Not just those who need treatment, but the entire community — through higher health insurance premiums and higher taxes. Cutting dental care costs by reducing tooth decay is something a community can do to improve oral health and save money for everyone. With the escalating cost of health care, fluoridation remains a community public health measure that saves money and so benefits all members of the community.

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The economic importance of fluoridation is underscored by the fact that the cost of treating dental disease frequently is paid not only by the affected individual, but also by the general public through services provided by health departments, community health clinics, health insurance premiums, the military and other publicly supported medical programs.[7] For example, results from a New York State study published in 2010[8] that compared the number of Medicaid claims in 2006 for cavity-related procedures in fluoridated and nonfluoridated counties showed a 33.4% higher level of claims for fillings, root canals and extractions in nonfluoridated counties as compared to such claims in fluoridated counties.[8]

Fluoridation contributes much more to overall health than simply reducing tooth decay. It prevents needless infection, pain, suffering and loss of teeth and saves vast sums of money in dental treatment cost — particularly in cases where dental care is received through surgical intervention in a hospital or through hospital emergency services.

In a study[9] conducted in Louisiana, Medicaid-eligible children (ages 1-5) residing in communities without fluoridated water were three times more likely than Medicaid-eligible children residing in communities with fluoridated water to receive dental treatment in a hospital and the cost of dental treatment per eligible child was approximately twice as high. In addition

to community water fluoridation status, the study took into account per capita income, population and number of dentists per county.[9]

By preventing tooth decay, fluoridation also plays a role in reducing visits to hospital emergency rooms (ERs) for toothaches and other related dental problems where treatment costs are high. Most hospitals do not have the facilities or staff to provide comprehensive or even emergency dental care. Many patients receive only antibiotics or pain mediation but the underlying dental problem is not addressed. In too many cases, the patient returns to the ER in a few days with the same problem or worse.

School-based dental disease prevention activities such as fluoride mouthrinse or tablet programs, professionally applied topical fluorides, dental health education and placement of dental sealants are beneficial but have not been found to be as cost-effective in preventing tooth decay as community water fluoridation.[10] In 1985, the National Preventive Dentistry Demonstration Program[10] analyzed various types and combinations of school-based preventive dental services to determine the cost and effectiveness of these types of prevention programs. Ten sites from across the nation were selected. Five of the sites had fluoridated water and five did not. Over 20,000 second and fifth graders participated in the study over a period of four years. Students were examined and assigned by site to one or a combination of the following groups:

- biweekly in class brushing and flossing plus a home supply of fluoride toothpaste and dental health lessons (ten per year);
- in-class daily fluoride tablets (in nonfluoridated areas);
- in-school weekly fluoride mouthrinsing;
- in-school professionally applied topical fluoride;
- in-school professionally applied dental sealants, and
- a control.[10]

After four years, approximately 50% of the original students were examined again. The study affirmed the value and effectiveness of community water fluoridation. At the sites where the community water was fluoridated, students had fewer cavities, as compared to those sites without fluoridated water where the same preventive measures were implemented. In addition, while sealants were determined to be an effective prevention method, the cost of a sealant program was substantially more than the cost of fluoridating the community water demonstrating fluoridation as the most cost-effective preventive option.[10]

In an effort to balance budgets, decision makers sometimes make economic choices that amount to being "penny wise and pound foolish." In other words, they cut an expense today that appears to be a sure money saver. But they fail to take a long-term view (or see the big picture) on the consequences of that action. They fail to see how money spent now can provide greater savings in the future. A decision to eliminate funding for a successful community water fluoridation program would be an example of that kind of action. Often decision makers are swayed by the promise of an alternative fluoride delivery system without considering who it will cover (and who it will not cover), how it will be administered and what it will cost. Examples of these alternative fluoride delivery programs include school-based fluoride mouthrinse programs, fluoride supplements, fluoride varnish and other professionally applied topical fluorides. Often dental health education programs including dispensing "free" toothbrushes and fluoridated toothpaste are mentioned as an alternative to fluoridation. All of these programs can be beneficial but are not as cost-effective as fluoridation programs because they typically require additional personnel to facilitate the programs, action on the part of the recipient and have much higher administrative and supply costs. Additionally, these programs typically target only children and so do not provide decay preventing benefits to adults. Fluoridation benefits all members of the community — children and adults — and is more cost-effective.

The CDC's "Health Impact in 5 Years" (HI-5) initiative[11] launched in 2016 highlights community-wide approaches that have evidence reporting 1) positive health impacts, 2) results in five years and 3) cost-effectiveness or cost savings over the lifetime of the population or earlier. Fluoridation is one of the community approaches included in the HI-5 Initiative as it has great potential to help keep people healthy as it reaches all members of a community where they live, learn, work, and play. Documenting the impact

of fluoridation can be challenging partially because the beneficial effect is not immediately apparent.[12] Cost savings from fluoridation would be expected to increase over several years' time. The most notable decrease in tooth decay would be anticipated in young children who received the benefits of fluoridation over their lifetime in both their primary teeth and as their adult teeth begin to appear when the children are approximately six years old. More immediate savings could be realized in recently fluoridated communities as children who had once received fluoride supplements would no longer require these prescriptions which are typically recommended for children from six months to 16 years of age, whose primary drinking water source is not fluoridated and have been determined to be at high risk for tooth decay.

Benefits from the prevention of tooth decay can include:

- freedom from dental pain
- a more positive self-image
- fewer missing teeth
- fewer cases of poorly aligned tooth aggravated by tooth loss
- fewer teeth requiring root canal treatment
- reduced need for crown, bridges, dentures and implants
- less time lost from school or work because of dental pain or visits to the dentist

While some of these types of benefits are difficult to measure economically, they are extremely important.[13,14]

Fluoridation remains the most cost-effective and practical form of preventing tooth decay in the United States and other countries with established municipal water systems. It is one of the very few public health measures that actually saves more money than it costs.[13,15-17]

69. Why fluoridate an entire water system when the vast majority of the water is not used for drinking?

Answer.

It is more practical and less costly to fluoridate an entire water supply than to attempt to treat only the water that will be consumed.

Fact.

Water systems treat all the water supplied to communities to the same high standards, for disinfection, clarity or fluoridation, whether the water is to be used for washing dishes, washing a car, watering lawns, preparing food or drinking. Although not all that water needs to be disinfected, clarified or fluoridated, it is more practical and cost efficient to treat all the water delivered to the customer to the same standard.

Fluoride is only one of more than 40 different chemicals/additives that can be used to treat water in the United States. Many are added for aesthetic or convenience purposes such as to improve the odor or taste, prevent natural cloudiness or prevent staining of clothes or porcelain.[18] The cost of additives for fluoridating a community's water supply is very low on a per capita basis; therefore, it is practical to fluoridate the entire water supply. It would be prohibitively expensive and impractical for a community to have two water systems — one that provided drinking water and another for all other water use (watering lawns, laundry, flushing toilets).

Many organizations that are concerned about water use, conservation and quality support the practice of water fluoridation. For example, the American Water Works Association, an international nonprofit scientific and educational association dedicated to the improvement of drinking water quality and supply, supports the practice of fluoridation of public water supplies.[19]

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From: Christopher H. Fox
Sent: Tue, 22 Sep 2020 20:47:01 +0000
To: Horsford, Jonathan (NIH/NIDCR) [E]
Cc: Stredrick, Denise (NIH/NIDCR) [E]; Ventura, Jeff (NIH/NIDCR) [E]; Iafolla, Timothy (NIH/NIDCR) [E]; Meister, Alissa (NIH/NIDCR) [E]; Lindsey Horan; Makyba Charles-Ayinde
Subject: RE: call for independent probe of Canadian research linking fluoride and lower IQ

All,

Another news outlet had a link to a dropbox with the letter, if you are interested in reading the concern:

https://www.dropbox.com/s/7u0c92nciwsg2nf/York%20University%20September%2021%2C%202020%20%281%29.docx?dl=0

Chris

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From: Horsford, Jonathan (NIH/NIDCR) [E] < (b) (6)
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To: Christopher H. Fox < (b) (6)
Cc: Stredrick, Denise (NIH/NIDCR) [E] < (b) (6) Ventura, Jeff (NIH/NIDCR) [E] < (b) (6) Iafolla, Timothy (NIH/NIDCR) [E] < (b) (6) Meister, Alissa (NIH/NIDCR) [E] < (b) (6)
Subject: RE: call for independent probe of Canadian research linking fluoride and lower IQ

EXTERNAL EMAIL
Interesting, thanks for sharing.

D. Jonathan Horsford, Ph.D.
Acting Deputy Director
NIDCR, NIH
Cell: (b) (6)

From: Christopher H. Fox < (b) (6)
Sent: Tuesday, September 22, 2020 9:31 AM
To: Horsford, Jonathan (NIH/NIDCR) [E] < (b) (6)
Subject: call for independent probe of Canadian research linking fluoride and lower IQ

FYI:

https://nationalpost.com/health/international-experts-call-for-independent-probe-of-canadian-research-linking-fluoride-and-lower-iq/wcm/4e2b0c79-57ed-47ad-8685-bf8d17b98847/amp/

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