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Fluoride in Drinking Water: A Review of Fluoridation and Regulation Issues

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Summary

According to the Centers for Disease Control and Prevention (CDC), 67% of the 246 million people in the United States who receive their water from a public water system received fluoridated water in 2000. One of the CDC's national health goals is to increase the proportion of the U.S. population served by community water systems with "optimally" fluoridated drinking water to 75% by 2010. The decision to add fluoride to a water supply is made by local or state governments. The U.S. Public Health Service (PHS) has recommended an optimal fluoridation level in the range of 0.7 to 1.2 milligrams per liter (mg/L) for the prevention of tooth decay.

The fluoridation of drinking water often generates both strong support and opposition within communities. This practice is controversial because fluoride has been found to have beneficial effects at low levels and is intentionally added to many public water supplies; however, at higher concentrations, it is known to have toxic effects. Fluoridation opponents have expressed concern regarding potential adverse health effects of exposure to fluoride, and some view the practice as an undemocratic infringement on individual freedom. The medical and public health communities generally have recommended water fluoridation, citing it as a safe, effective, and equitable way to provide dental health protection community-wide.

The use of dental products containing fluoride (such as toothpaste and rinses) has increased significantly since the PHS recommended optimal levels for water fluoridation, and many people now may be exposed to more fluoride than had been anticipated. Consequently, questions have emerged as to whether current water fluoridation practices and levels offer the most appropriate ways to provide the expected beneficial effects of fluoride while avoiding adverse effects (primarily tooth mottling or dental fluorosis) that may result from exposure to too much fluoride. Moreover, research gaps and scientific uncertainty regarding the health effects of long-term exposure to higher levels of fluoride add controversy to decisions regarding drinking water fluoridation.

Although fluoride is added to water to strengthen teeth, some communities must treat their water to remove excess amounts of naturally occurring fluoride. The Environmental Protection Agency (EPA) regulates the amount of fluoride that may be present in public drinking water supplies to protect against fluoride's adverse health effects. In 1986, EPA issued a drinking water regulation for fluoride that includes an enforceable standard of 4 mg/L to protect against adverse effects on bone structure (skeletal fluorosis). EPA acknowledged that the standard did not protect infants and young children against mild or moderate dental fluorosis, which is considered a cosmetic effect rather than a health effect. To address concerns, EPA included in the regulation a secondary (advisory) standard of 2 mg/L to protect children against dental fluorosis and adverse health effects. Currently, EPA is reviewing the fluoride regulation and has asked the National Academy of Sciences (NAS) to assess the currently available health and toxicity data for fluoride. The NAS study may resolve some of the questions regarding the risks and benefits of exposure to fluoride in drinking water. This report will be updated as warranted.

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Introduction

The fluoridation of drinking water often generates both strong support and opposition within communities. The decision to fluoridate a water supply is made by the state or local municipality and is not mandated by any federal agency. Opponents have expressed concern regarding potential adverse health effects of exposure to fluoride, and some view the practice as an undemocratic infringement on individual freedom. The medical and public health communities generally recommend water fluoridation, citing it as a safe, effective, and equitable way to provide dental health protection community-wide.

With the increased use of products containing fluoride, such as toothpaste and rinses, questions have emerged as to whether current fluoridation practices and levels offer the most appropriate way to provide the beneficial effects of fluoride while avoiding adverse effects (such as tooth mottling or dental fluorosis) that can result from exposure to too much fluoride. Moreover, research gaps regarding the potential health effects of long-term exposure to higher levels of fluoride add controversy to decisions regarding water fluoridation.

Although many communities add fluoride to drinking water to strengthen teeth, some communities must treat their water to remove excess amounts of fluoride, which is often present naturally in water. The Environmental Protection Agency (EPA) regulates the amount of fluoride that may be present in public drinking water supplies to protect against fluoride's adverse health effects.

This report discusses the documented benefits and potential adverse effects associated with the fluoridation of drinking water supplies. It also discusses the regulation of fluoride in drinking water to protect against adverse health effects from exposure to higher levels of fluoride, and it reviews the status of federal efforts to update the health risk assessment for fluoride. The following review of issues related to fluoride in drinking water presents information from research published in peer-reviewed scientific journals, reports and statements of federal agencies (including the Centers for Disease Control and Prevention [CDC] and the U.S. Public Health Service [PHS]) and the World Health Organization, studies by the National Research Council of the National Academy of Sciences, and other sources.

Background

Fluoride is a naturally occurring substance and is present in virtually all water, usually at very low levels. Higher concentrations of naturally occurring fluoride often

are associated with well water, where fluoride has dissolved from the rock formations into the groundwater.[1] Communities began fluoridating water supplies in the 1940s, after scientists discovered that higher levels of fluoride in a community water supply were associated with fewer dental caries (cavities) among the residents.[2]

In 2004, the Surgeon General reported that more than 170 million (67%) of the people in the United States who received their water from a public water system received fluoridated water.[3] This represented a 5% increase from 1992, when 62% of individuals served by public water systems were provided with fluoridated water.[4]

Many public health agencies and professional health organizations advocate the addition of a small amount of fluoride to drinking water to help strengthen teeth and prevent dental caries. Although this practice has been controversial in some communities, the CDC, the American Medical Association, the American Dental Association (ADA), the American Academy of Pediatric Dentistry, and others recommend fluoridation of public water supplies as an effective way to protect dental health. This approach is advocated for its ability to provide community-wide benefits, particularly in poorer communities where children may be less likely to receive adequate dental care.[5]

The CDC considers the reduction in tooth decay from fluoridation one of the top public health achievements of the 20th Century.[6] In 2002, the CDC reported that

> [d]uring the second half of the 20th century, a major decline in the prevalence and severity of dental caries resulted from the identification of fluoride as an effective method of preventing caries. Fluoridation of the public water supply is the most equitable, cost-effective, and cost-saving method of delivering fluoride to the community.[7]

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[1] Fluoride also occurs in many foods, including meat, potatoes, fish, sugar, milk, and legumes. The amount in brewed tea ranges from 1 to 6 milligrams per liter (mg/L), depending on brewing strength and time. Also, fluorides are used industrially and may be present in the environment as a result of inadequate pollution control.

[2] National Cancer Institute, *Cancer Facts: Fluoridated Water*, National Institutes of Health.

[3] Dr. Richard Carmona, U.S. Surgeon General, Su*rgeon General's Statement on Community Water Fluoridation*, Department of Health and Human Services, 2004.

[4] Centers for Disease Control and Prevention, "Populations Receiving Optimally Fluoridated Public Drinking Water — United States, 2000," *Morbidity and Mortality Weekly Report*, vol. 51, no. 7, Feb. 21, 2002, pp. 144-147.

[5] Centers for Disease Control and Prevention, "Achievements in Pubic Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries," *Morbidity and Mortality Weekly Report*, vol. 48, no. 41, Oct. 22, 1999, pp. 933-940. Available online at [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4841a1.htm]; visited Feb. 3, 2006.

[6] Centers for Disease Control and Prevention, "Ten Great Public Health Achievements — United States, 1900-1999," *Morbidity and Mortality Weekly Report*, vol. 48, no. 12, Apr. 2, 1999, pp. 241-243. See [http://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm].

[7] Centers for Disease Control and Prevention, *Populations Receiving Optimally Fluoridated*

(continued...)

One of the CDC's national health goals for 2010 is to increase the proportion of the U.S. population served by community water systems with "optimally" fluoridated drinking water to 75%.[8] The optimal fluoridation level recommended by the U.S. Public Health Service for decay prevention is in the range of 0.7 to 1.2 milligrams per liter (mg/L).

The World Health Organization (WHO) has identified dental caries (cavities) as a worldwide epidemic and recommends adding fluoride to drinking water where naturally occurring levels of fluoride are below optimal levels.[9] The WHO states that the goal of community-based public health programs "should be to implement the most appropriate means of maintaining a constant low level of fluoride in as many mouths as possible."[10] According to the WHO,

> [w]ater fluoridation in low fluoride-containing water supplies helps to maintain optimal dental tissue development and dental enamel resistance against caries attack during the entire life span.... People of all ages, including the elderly, benefit from community water fluoridation. For example, the prevalence of caries on root surfaces of teeth is inversely related to fluoride levels in the drinking water: in other words, within the non-toxic range for fluoride, the higher the level of fluoride in water, the lower the level of dental decay. This finding is important because with increasing tooth retention and an aging population, the prevalence of dental root caries would be expected to be higher in the absence of fluoridation.[11]

The recommended beneficial amount of fluoride can be obtained from a variety of sources other than water (e.g., fluoride toothpastes, rinses, and supplements). However, health officials generally have recommended fluoridation of community water supplies, citing socioeconomic reasons that may vary among countries and communities. The WHO explains this preference as follows:

> The consensus among dental experts is that fluoridation is the single most important intervention to reduce dental caries, not least because water is an essential part of the diet for everyone in the community, regardless of their motivation to maintain oral hygiene or their willingness to attend or pay for dental treatment. In some developed countries, the health and economic benefits

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[7] (...continued)
Public Drinking Water, pp. 144.

[8] U.S. Department of Health and Human Services, *Healthy People 2010 — Understanding and Improving Health*, 2nd ed., Washington, DC, U.S. Government Printing Office, November 2000, pp. 21-28.

[9] World Health Organization, Water Sanitation and Health, *World Water Day 2001: Oral Health: Dental Caries, a Worldwide Epidemic*, Health and Sanitation Unit and Oral Health Program. Available online at [http://www.who.int/water_sanitation_health/oralhealth/en/index1.html]; visited Feb. 3, 2006.

[10] World Health Organization, *Risks to Oral Health and Intervention: Fluoride*. See [http://www.who.int/oral_health/action/risks/en/index1.html]; visited Feb. 3, 2006.

[11] Ibid.

> of fluoridation may be small, but particularly important in deprived areas, where water fluoridation may be a key factor in reducing inequalities in dental health.[12]

Despite such recommendations, fluoridation is far from universally practiced. Worldwide, an estimated 350 million people receive artificially fluoridated water, and another 50 million drink water that is naturally fluoridated at or near the optimal level.[13] Australia, Canada, Chile, Columbia, Israel, Malaysia, and Singapore are among the countries where water is fluoridated. Of the Western European countries, Ireland, Spain, and the United Kingdom fluoridate drinking water. Most other Western European countries have ceased, or never practiced, water fluoridation for various reasons, including the availability of other sources of fluoride (especially toothpaste), the availability of free school-based dental care programs in some countries, broader public skepticism about the safety and efficacy of fluoridation, and greater political opposition. In several Latin American countries, where centralized water supplies are often lacking, fluoridated salt is the chosen method of providing dental protection across disparate communities. Fluoridated salt also is available in some European countries, including Austria, France, Germany, Hungary, and Switzerland.[14]

Questions About the Safety and Benefits of Fluoridation

Water fluoridation has generated less opposition in the United States than in Europe. However, notwithstanding recommendations from many governmental and professional health organizations, this practice continues to generate controversy in some communities. Research gaps concerning the effects of long-term exposure to increased levels of fluoride fuel this debate, and decades into this practice, the safety and efficacy of water fluoridation continues to be questioned, debated, and studied.

Dental Fluorosis. Some oppose water fluoridation because of a concern that even recommended "optimal" levels of fluoridation may cause dental fluorosis in children. Dental fluorosis is caused by excessive fluoride intake while teeth are developing, and it is during this period before teeth erupt that dental tissues are very sensitive to fluoride (typically during a child's first eight years).[15] Mild dental fluorosis is characterized by opaque white or stained patches in the dental enamel. More severe fluorosis is characterized by pitting of tooth enamel. Since the 1960s, the U.S. Public Health Service has recommended an "optimal" fluoride concentration

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[12] World Health Organization, *Naturally Occurring Hazards*. Available online at [http://www.who.int/water_sanitation_health/naturalhazards.html#fluoride]; visited Feb. 3, 2006.

[13] British Fluoridation Society and the UK Public Health Association, *One in a Million: The Facts about Water Fluoridation*, 2nd ed., 2004, p. 71.

[14] Marthaler, T. M. Salt Fluoridation in Europe, Comparisons with Latin America, Department of Preventive Dentistry, Periodontology and Cariology, University of Zurich, available at [http://www.sph.emory.edu/PAMM/SALT2000/marthaler.pdf]; visited Feb. 7, 2006.

[15] Institute of Medicine. *Dietary reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, National Academy Press, 1997, p. 298.

in water of 0.7 to 1.2 mg/L. This level was designed to "maximize prevention of caries while limiting the prevalence of dental fluorosis to about 10% of the population, virtually all of it mild to very mild."[16]

Because of the increased use of fluoridated dental products and the tendency for young children to swallow these products, concern over dental fluorosis and other potential effects of fluoride exposure has increased. Questions have arisen as to whether current fluoridation practices and levels offer the most appropriate ways to provide the beneficial effects of fluoride while avoiding adverse effects that can result from ingesting too much fluoride. As noted by the National Research Council (NRC) of the National Academy of Sciences,

> In addition to fluoride in drinking water, people also can ingest fluoride in toothpaste, mouth rinse, and dietary fluoride supplements or in beverages and foods prepared with fluoridated water. As a result, many Americans might ingest more "incidental" fluoride than was anticipated by the PHS [Public Health Service] and by EPA in recommending standards for drinking water.[17]

A 2002 study reported that estimates of fluorosis prevalence among schoolchildren in the 1980s were 18% or 26%, depending on the analytical index used. The authors further estimated that based on these findings and further studies, approximately 2% of U.S. schoolchildren may experience "perceived esthetic problems" that could be attributable to currently recommended levels of fluoride in drinking water combined with fluoride toothpaste consumption.[18] The authors reported that data were not available for fluoridated toothpaste and diluted infant formula consumption and that, consequently, the risk of fluorosis attributable to fluoridation of public water supplies may be overestimated if fluoride consumption was higher in fluoridated areas.[19] The researchers concluded that in determining the optimal fluoridation policy, the prevalence of dental fluorosis

> should be weighed against fluoridation's lifetime benefits and the feasibility and associated costs of alternative solutions such as educating parents of preschoolers about appropriate toothpaste use and lowering the current fluoride content of children's toothpaste. Given that fluorosis results from fluoride exposure during a narrow age range and that the benefits accrue over the entire life span, educating parents as to the appropriate use of fluoride toothpaste or reducing the

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[16] National Research Council, *Health Effects of Ingested Fluoride*, Subcommittee on Health Effects of Ingested Fluoride, Committee on Toxicology, Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Academy Press, 1993, p. 5. Note: Researchers have found dental fluorosis to have a clear dose-response relationship — increasing in severity and prevalence at higher concentrations — with effects generally ranging from mild or very mild at roughly 0.7 to 1.0 mg/L, to pronounced discoloration and pitting of teeth occurring at 5 to 7 mg/L and higher.

[17] Ibid.

[18] Griffin, Susan O., Eugenio D. Beltran, Stuart A. Lockwood, and Laurie K. Barker, *Esthetically Objectionable Fluorosis Attributable to Water Fluoridation*, Community Dental Oral Epidemiology, 2002, vol. 30, pp. 199-209. The prevalence of "perceived esthetic problems" was assessed by evaluating fluorosis in the teeth at the front of the mouth.

[19] Ibid. pp. 199, 208-209.

> fluoride content of children's toothpaste as some have suggested may be more efficient than altering current fluoridation policy.[20]

The NRC agreed with this conclusion in principal; however, it determined that this approach may not be feasible in practice:

> The most effective approach to stabilizing the prevalence and severity of dental fluorosis, without jeopardizing the benefits to oral health, is likely to come from more judicious control of fluoride in foods, processed beverages, and dental products, rather than a reduction in the recommended concentrations of fluoride in drinking water. But applying such a policy would be formidable; reduction of fluoride concentrations in drinking water would be easier to administer, monitor, and evaluate.[21]

Although dental fluorosis is considered to be a cosmetic effect, not a health effect, it may be objectionable to many and, therefore, does factor in the fluoridation debate.[22]

Health Effects. Researchers continue to study the potential adverse health effects associated with exposure to low levels of fluoride. Many studies have examined the potential toxic effects of long-term ingestion of fluoride in drinking water. These studies generally show that fluoride ingestion primarily produces effects on skeletal tissues (skeletal fluorosis) and that these effects are more severe as exposure to fluoride increases above a threshold. Very mild skeletal fluorosis is characterized by slight increases in bone mass. The most severe form of this condition, "crippling skeletal fluorosis," involves bone deformities, calcification of ligaments, and immobility. Epidemiological data suggest that crippling skeletal fluorosis might occur in humans who drink water containing more than 10 mg/L of fluoride for 10 to 20 years.[23] This condition is extremely rare in the United States and is not considered a public health concern.

Bone Fracture Incidence. A related question that has been the subject of scientific debate and research concerns whether water fluoridation increases the risk of bone fracture in older women. A number of ecological studies conducted in the 1980s and 1990s compared rates of fracture, specific for age and gender, between

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[20] Ibid. p. 209.

[21] National Research Council, *Health Effects of Ingested Fluoride*, pp. 47-48.

[22] In setting a standard for fluoride in drinking water, the U.S. Environmental Protection Agency (EPA) considered dental fluorosis to be a cosmetic effect, not an adverse health effect, and set the standard at a level that was not intended to protect against mild dental fluorosis. This issue is discussed below in the section on the federal regulation of fluoride in drinking water.

[23] National Research Council, *Health Effects of Ingested Fluoride*, p. 59. The severity of fluorosis varies among individuals and is complicated by factors such as malnutrition, calcium deficiency, and impaired kidney function (the kidneys clear much of the fluoride that is ingested). India has a high incidence of fluorosis because water supplies in large areas of the country contain high levels of naturally occurring fluoride. Fluorosis is also widely prevalent in China, the Middle East, North Africa, and other parts of Africa.

fluoridated and nonfluoridated communities. Several of these studies found that exposure to fluoridated water increased the risk of fracture, a few studies showed that water fluoridation reduced the risk of fracture, and several studies found no effect.[24] However, a weakness of these studies is that they were based on community-level data and lacked data on individuals.

To improve understanding of this issue, a 2000 study published in the *British Medical Journal* looked at fluoride exposure and fractures in individual women. The results of this study suggested that water fluoridation may reduce the risk of fractures of the hip and vertebrae in older white women (the subjects of the study).[25] The authors noted the potential public health importance of this finding, stating that "[i]f fluoridation does reduce the incidence of hip fracture, it may be one of the most cost effective methods of reducing the incidence of fractures related to osteoporosis."[26]

Cancer: Human Epidemiology. A possible link asserted in the 1970s between water fluoridation and increased cancer mortality raised health concerns and heightened controversy over the practice of fluoridation. Some researchers had reported that cancer mortality was higher in areas with fluoridated drinking water than in nonfluoridated areas.[27] These findings were refuted subsequently by other investigators who identified problems with the study's research methodology.[28] However, because of the importance of this question, researchers have continued to examine the possibility of an association between fluoridated water and cancer in humans.

Independent expert panels performed extensive reviews of the available scientific studies in 1982 and 1985. The panels agreed that the studies provided "no credible evidence for an association between fluoride in drinking water and risk of cancer."[29] According to the National Research Council, all but one of these studies were ecological studies; that is, they were either geographic correlation or time-line studies that looked at exposures at the community level rather than individual exposures.[30] Consequently, the interpretation of the data was complicated by an inability to measure individual fluoride exposures over long periods of time, or to

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[24] National Research Council, *Health Effects of Ingested Fluoride*, pp. 60-61.

[25] Phipps, Kathy R., Eric S. Orwoll, Jill D. Mason, Jane A. Cauley, "Community Water Fluoridation, Bone Mineral Density, and Fractures: Prospective Study of Effects in Older Women," *British Medical Journal*, Oct. 7, 2000, vol. 321, pp. 860-864.

[26] Ibid. p. 863.

[27] Yiamouyannis, J. and D. Burk, "Fluoridation and Cancer: Age Dependence of Cancer Mortality Related to Artificial Fluoridation," *Fluoride*, no. 10, 1977, pp. 102-123.

[28] National Research Council, *Health Effects of Ingested Fluoride*, p. 16.

[29] Ibid. p. 110.

[30] Epidemiological studies look for associations between the occurrence of disease and exposure to known or suspected causes. In ecological studies, the unit of observation is the population or community; the specific exposures of individuals are not assessed.

measure exposure to other known risk factors such as smoking or other cancer-causing substances.[31]

In another examination of this issue, scientists at the National Cancer Institute (NCI) evaluated the relationship between drinking water fluoridation and the number of cancer deaths in the United States by county. After examining more than 2.2 million cancer death records, NCI researchers concluded that "there was no indication of increased cancer risk associated with fluoridated drinking water."[32] The NRC concluded in 1993 that "[t]he large number of epidemiological studies [more than 50] combined with their lack of positive finding implies that if any link exists, it must be very weak."[33]

Cancer: Animal Studies. In 1990, the National Toxicology Program (NTP) published the results of studies on the potential carcinogenicity of fluoride in rats and mice.[34] The studies found no evidence of carcinogenic activity in female rats or mice at very high concentrations (100-175 mg/L) but found "equivocal evidence" of carcinogenicity in male rats. Osteosarcomas (bone cancers) were observed in 1 of 50 male rats receiving 100 mg/L sodium fluoride and 3 of 50 rats receiving 175 mg/L.[35] From this study, NTP researchers concluded that levels of sodium fluoride below 175 mg/L in drinking water over a two-year period would not be expected to cause any bone cancers in rats or mice. Although extrapolation of data from animals to humans is controversial in the scientific community, it is generally thought that optimally fluoridated drinking water (roughly 1 mg/L) would not be expected to cause cancer in humans. The result of the NTP study (i.e., equivocal evidence of carcinogenicity) was not substantiated in a subsequent study of rats using higher fluoride doses.

In response to the concerns raised by the NTP research, EPA requested that the National Research Council (NRC) review the available toxicological and exposure data on fluoride and determine whether the current drinking water standard of 4 mg/L was sufficient to protect public health. In 1993, the National Research Council (NRC) completed an extensive literature review concerning the association between fluoridated drinking water and increased cancer risk. Although the NRC concluded

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[31] U.S. Department of Health and Human Services, Public Health Service, Ad-hoc Subcommittee on Fluoride, Committee to Coordinate Environmental Health and Related Programs, Review of Fluoride: Benefits and Risks, Executive Summary, Febrary 1991, p. 9.

[32] National Cancer Institute, Cancer Facts: Fluoridated Water, 2000. Details discussed in National Research Council, *Health Effects of Ingested Fluoride, Carcinogenicity of Fluoride*. pp. 109-112.

[33] Ibid. p. 121.

[34] National Toxicology Program, *Toxicology and Carcinogenesis Studies of Sodium Fluoride in 344/N Rats and B6C3F1 Mice,* Department of Health and Human Services, National Institutes of Health, Technical Report 393, NIH Publ. No. 91-2848, 1990, p. 447.

[35] By NTP definition, equivocal evidence of carcinogenic activity is a category for uncertain findings by studies that are interpreted as showing a marginal increase in cancers that may be related to the administration of a chemical.

that the data did not demonstrate an association between fluoridated drinking water and cancer, it did suggest that more research should be undertaken.[36]

In 2002, EPA noted that new studies regarding the effects of fluoride on bone had been published since the fluoride standard was promulgated and that a new analysis of the data was warranted. EPA again requested the NRC to review the toxicological and epidemiological data on fluoride, to update the fluoride risk assessment, and to evaluate the scientific basis and adequacy of EPA's drinking water standards for fluoride.[37] The NRC study is pending. (See the section below on the regulation of fluoride.)

Efficacy. The benefits of water fluoridation to oral health also has received scrutiny. An overall reduction in caries has been observed in both fluoridated and nonfluoridated communities in the United States, and some more recent studies have suggested that water fluoridation has become less important and effective in preventing caries when compared with the findings of earlier studies. Some of this research has attributed the smaller differences in caries prevalence between fluoridated and nonfluoridated communities to the widespread use of fluoride toothpaste and other preventive dental care, and to better nutrition.[38]

Several studies have suggested that the traditional measure of the benefits of water fluoridation may understate its total effectiveness. The authors of a 2001 study determined that the benefit of caries reduction from fluoridation is diffused to adjacent nonfluoridated communities through the export of bottled beverages and processed foods to those communities.[39] When this effect was accounted for, the authors found a beneficial effect from water fluoridation that was closer to the findings of studies conducted in the 1970s and earlier.[40] The results of a 1979-1980 national survey found a 33% difference in the prevalence of dental caries among children in fluoridated and nonfluoridated regions in the United States, whereas a 1986-1987 national survey identified an overall 18% difference in caries prevalence. The National Institutes of Health analyzed the 1986-1987 results and reported that when the effect of topical fluoride was controlled, the difference between fluoridated and nonfluoridated areas increased to 25%. The authors concluded that the results

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[36] National Research Council, *Health Effects of Ingested Fluoride*, pp. 121-123.

[37] U.S. Environmental Protection Agency, "National Primary Drinking Water Regulations: EPA's Review of Existing Drinking Water Standards and Request for Public Comment," 67 *Federal Register* 19069, Apr. 17, 2002.

[38] See, for example, Seppa, L., et al. "Caries Occurrence in a Fluoridated and a Nonfluoridated Town in Finland: A Retrospective Study Using Longitudinal Data from Public Dental Records," *Caries Research*, 2002, vol. 36, no. 5, pp. 308-314.

[39] Griffin, Susan O., Barbara F. Gooch, Stuart A. Lockwood, and Scott Tomar. "Quantifying the Diffused Benefit from Water Fluoridation in the United States," *Community Dentistry and Oral Epidemiology*, 2001, vol. 29, pp. 120-129.

[40] Ibid. p. 128.

suggested that water fluoridation continued to play a dominant role in the decline in caries.[41]

In 2000, British researchers published the results of their systematic review of 214 studies on the safety and efficacy of water fluoridation. The researchers found that water fluoridation was associated with an increased proportion of children without caries and a reduction in the number of teeth with caries, but the overall reductions were smaller than had been reported in earlier studies.[42] The review also concluded that at a fluoride level of 1 mg/L, an estimated 12.5% of exposed individuals would have fluorosis that could be considered aesthetically concerning.[43] In reviewing the 214 studies, the authors found no other adverse effects associated with the fluoridation of drinking water. However, they noted that, overall, the studies were of low to moderate quality and recommended better research.[44]

Other Considerations. Aside from questions of safety and efficacy, social and political concerns may influence decisions about water fluoridation. A central issue for some who oppose fluoridation of the public water supply is lack of choice. Consumers who prefer not to drink fluoridated water are unable to exercise that choice without treating their tap water or buying bottled water. Some view a state or community fluoridation requirement as intrusive and object to receiving water that is not free of additives, other than those needed to make water safe. (In contrast, disinfectants, such as chlorine, generally have been accepted as necessary to protect public health by eliminating pathogens). In this view, decisions regarding dental health-care practices should be made by individuals and families and not imposed by the government. To the extent that research gaps exist regarding potential adverse effects of increased exposures to fluoride because of its presence in multiple sources (e.g., water, beverages, toothpaste and rinses), the conflict between individual choice and public policy is likely to continue.

Regulation of Fluoride in Drinking Water

This section discusses the regulation of fluoride in drinking water to protect against adverse health effects associated with exposure to higher, typically naturally occurring levels of fluoride (compared with the recommended levels used in artificial fluoridation to protect dental health). It reviews the current federal standards for fluoride in drinking water, EPA's steps to review the standards, and related efforts to update the assessment of health risks associated with fluoride ingestion.

Fluoride poses challenges to regulators because it is intentionally added to water supplies for its beneficial effects at low levels, whreas at higher concentrations, it has

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[41] Brunelle, J.A. and J.P. Carlos, "Recent Trends in Dental Caries in U.S. Children and the Effect of Water Fluoridation," National Institute of Dental Research National Institutes of Health, *Journal of Dental Research*, February 1990, vol. 69, pp. 723-727.

[42] McDonagh, Marian S., Penny F. Whiting, et al., "Systematic Review of Water Fluoridation," *British Medical Journal*, Oct. 7, 2000, vol. 321, pp. 855-864.

[43] Ibid. p. 855.

[44] Ibid. p. 859.

toxic effects and is regulated as a drinking water contaminant. Moreover, the range between the amounts that are considered beneficial and excessive is narrower for fluoride than for many trace minerals.[45]

Under the authority of the Safe Drinking Water Act (SDWA), the Environmental Protection Agency (EPA) regulates the amount of fluoride that may be present in public water supplies to protect against fluoride's adverse health effects. In 1986, EPA issued the current national primary drinking water regulation for fluoride. This regulation includes an enforceable maximum contaminant level for fluoride of 4 mg/L, specifically to protect against effects on the bone (skeletal fluorosis).[46] This standard was controversial, as it replaced an interim standard of 1.4 to 2.4 mg/L that was established to protect against moderate dental fluorosis.[47] The SDWA requires EPA to conduct periodic reviews of existing drinking water regulations, and EPA has initiated a review of the fluoride standard to determine whether it needs revision.[48]

When setting the fluoride standard, EPA acknowledged that the standard does not protect infants and young children against moderate dental fluorosis, which EPA considers a cosmetic effect, rather than an adverse health effect. The Agency set a secondary standard for fluoride at 2 mg/L that is intended to protect children against dental fluorosis and adverse health effects.[49] Because of concerns regarding dental fluorosis, EPA does not recommend that infants consume water containing 4 mg/L fluoride and requires that all families who receive water from a public water system with more than 2 mg/L receive a public notification recommending that alternate sources of water be used for infants and children (40 CFR 143.5).

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[45] Many trace minerals share the property of having a health benefit at low levels but toxicity at higher levels (e.g., copper, chromium, manganese, selenium, and zinc). Although certain amounts of fluoride help make tooth enamel resistant to caries, fluoride has not been classified as an essential nutrient. In 1997, the National Academy of Science established Dietary Reference Intakes (DRI) for fluoride as a nutrient. The DRI included age- and gender-specific tolerable upper intake levels (UL) to indicate the highest average daily intake level likely to pose no risk of adverse effect to most individuals. The NAS also established Adequate Intake (AI) values for fluoride. AI values are set when the data do not permit determination of a Recommended Dietary Allowance (RDA).

[46] 51 *Federal Register* 11396, Apr. 2, 1986.

[47] 51 *Federal Register* 11410, Apr. 2, 1986.

[48] SDWA §1412(b)(9) requires the EPA Administrator, not less often than every six years, to review and revise, as appropriate, each national primary drinking water regulation. Since 1996, the law has specified that any revision must maintain or provide for greater protection of human health.

[49] Under the Safe Drinking Water Act, EPA sets national *primary* drinking water regulations that include enforceable, health-based standards (maximum contaminant levels) that limit the amount of a regulated substance that may be present in water provided by public water systems. EPA also sets national *secondary* standards that establish nonmandatory water quality standards for substances. Secondary standards are established as guidelines to help public water systems manage drinking water for aesthetic (e.g., taste and odor), cosmetic (e.g., tooth discoloration), and technical (e.g., corrosivity) effects.

Following increased concern regarding the potential carcinogenicity of fluoride related to the results of the 1990 NTP animal study, EPA requested the National Research Council (NRC) to review the available toxicological and exposure data on fluoride and to assess the sufficiency of the current drinking water standard. The NRC concluded that the national primary drinking water standard for fluoride (4 mg/L) was "appropriate as an interim standard" to protect public health. However, the NRC noted that because EPA had promulgated the drinking water regulation for fluoride in 1986, the use of fluoride in dental products had increased and, as a result, many Americans might ingest more "incidental" fluoride than was anticipated by the Public Health Service and by EPA when recommending standards for drinking water.[50] Moreover, the NRC found inconsistencies in the fluoride toxicity data base and gaps in knowledge, and it recommended further research in the areas of fluoride intake, dental fluorosis, bone strength, and carcinogenicity. The NRC further recommended that EPA's fluoride standard should be reviewed and, if necessary, revised when results of new research become available.[51]

Toward that end, in 1998, EPA commissioned an evaluation of the exposure data for fluoride, including data on amounts in water, foods, and dental products. In 2002, EPA published the results of its review of existing drinking water standards, including the fluoride standard.[52] The Agency noted that new studies on fluoride's effects on bone had been published since EPA issued the fluoride standard in 1986. EPA had conducted a literature search to identify reports of the clinical, toxicological, and epidemiological data on fluoride and the skeletal system. The results of that search indicated that a review of the new data was justified as part of the regulatory review process. Consequently, EPA requested the NRC to conduct a review of the data and to update the fluoride health risk assessment and to review EPA's relative source contribution assumptions.[53] The NRC agreed to evaluate the scientific basis for EPA's primary and secondary fluoride standards and to advise EPA on the adequacy of its secondary standard to protect to protect children and others from adverse effects.

The NRC is nearing publication of its assessment of the toxicologic risk of fluoride in drinking water. The results of the NRC assessment are expected to help EPA determine whether the primary and secondary fluoride standards need to be revised. Even if the NRC confirms EPA's earlier assessment of fluoride toxicity and health effects, the Agency still might revise the standard. One reason for potential revision is that when EPA developed the current standards, the Agency considered drinking water to be the only source of exposure for fluoride. Since then, sources of fluoride exposure have increased, and EPA would consider fluoride intake from

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[50] Ibid.

[51] Ibid. p. 11.

[52] U.S. Environmental Protection Agency, "National Primary Drinking Water Regulations: Announcement of the Results of EPA's Review of Existing Drinking Water Standards and Request for Public Comment," 67 *Federal Register* 19030, Apr. 17, 2002.

[53] EPA based the current standard on the assumption that drinking water was the only source of fluoride exposure; thus, water's relative source contribution was considered to be 100%. In revising the standard, EPA would consider other sources of exposure also.

sources other than drinking water. This consideration alone may lead to a lowering of the health-based primary standard and the esthetics-based secondary standard for fluoride. EPA's position on this issue is not yet known, and it may take some time for EPA to evaluate and respond to the NRC study.

Conclusion

The use of dental products containing fluoride (such as toothpaste and rinses) has increased significantly in recent years. As a result, many people now may be taking in more fluoride than was anticipated when the Public Health Service recommended optimal levels for water fluoridation and when EPA issued its regulation establishing limits for fluoride in drinking water. Consequently, questions have emerged as to whether current water fluoridation practices offer the most appropriate ways to provide the expected beneficial effects of fluoride while avoiding potential adverse effects that may result from exposure to too much fluoride. Moreover, research gaps and scientific uncertainty regarding the health effects of long-term exposure to higher levels of fluoride add controversy to decisions regarding drinking water fluoridation.

Although the purpose of the National Research Council study is to advise EPA on the adequacy of its primary and secondary drinking water standards for fluoride, the assessment of the available science is likely to also be valuable to those who are interested in evaluating the currently recommended levels for water fluoridation and to communities that are assessing whether or not to fluoridate their public water supplies.

Opposition to water fluoridation often has been driven by concerns about the health risks of exposure to fluoride in drinking water; however, social and political concerns also influence decisions about water fluoridation. A central issue for some fluoridation opponents is lack of choice, and they oppose the addition of any chemicals to the water supply other than those needed to make water safe. In contrast, many public health professionals and government officials believe that water fluoridation offers the most equitable and cost-effective way to protect dental health across socially and economically diverse communities. The conflict between individual liberty and social policy is one that is unlikely to be fully resolved by more research. Additional scientific evidence can help inform the decision to fluoridate a community's water, but such choices often are not made purely on the basis of science.

Congress has expressed interest in water fluoridation issues in the past, particularly as questions have arisen regarding the benefits and risks of this practice. However, because fluoridation decisions are made at the state and local level, and perhaps also because of the documented benefits of fluoridation, Congress has not been at the forefront of the water fluoridation debate. In contrast, Congress does have a key role pursuant to EPA's regulation of fluoride in public drinking water supplies under the Safe Drinking Water Act. The findings of the NRC study of the toxicological risk of fluoride and the appropriateness of the EPA's drinking water standards for fluoride may generate new congressional oversight and legislative attention