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Formal Ethics Complaint and Request for Investigation

**Presented to the Joint Meeting of
the Ethics Subcommittee of the Advisory Council to the CDC Director
and the CDC Public Health Ethics Committee**

August 9, 2007

EXECUTIVE SUMMARY

Statements made by CDC and disturbing new facts acknowledged in reports from key government agencies such as the National Research Council and the U.S. Dept. of Agriculture have now shown certain actions by the CDC Division of Oral Health and CDC Director to be in violation of fundamental principles of ethics. These unethical activities are occurring in CDC's efforts to promote water fluoridation, and they demonstrate that *the Oral Health Division has not in practice applied the Ethics Code that CDC promotes throughout the country*. In failing to integrate and respond with integrity to the ramifications of the new information coming from reputable government sources known to CDC staff, the Oral Health Division and CDC Director have directly negatively impacted U.S. citizens who have been misled by CDC officials. Because CDC assumes top-level authority for health information dissemination, these unethical actions are serious and egregious. Avoidance of embarrassment to the organization is an insufficient and unethical reason not to disclose and appropriately respond to information from its own agency and other government agencies that contradicts CDC's official position that fluoridation is safe and effective in preventing cavities. CDC's actions have resulted in implementation of faulty public health policy-making at the state level and by water districts.

These following acts of commission and omission are serious breaches of the public trust. On behalf of citizens who are unaware of these breaches, we submit this complaint and request a formal investigation, corrective action by the committees and CDC, dissemination of revised information, and discipline of the responsible parties. We ask the joint Ethics Committees for a timely and public response.

Specifically, CDC has:

- Elected to omit vital information in its information disseminated to the public concerning vulnerable population groups that are particularly susceptible to harm from fluoride;
- Chosen to ignore its own data showing disproportionate harm by dental fluorosis in minority populations and has not actively provided this information to these groups;
- Demonstrated a severe ethical lapse in failing to appropriately disseminate its own change in policy that parents of infants be aware of the risk of dental fluorosis in their children and may wish to use unfluoridated water to mix their babies' powdered milk formula;
- Justified fluoridation in terms that mislead Americans into confusing the fundamental concepts of *concentration* versus *dose*. This had led citizens to believe that a low *concentration* of fluoride in water cannot result in a harmful *dose* of the chemical, regardless of volume of water consumed and other sources of fluoride -- and in this context CDC has also failed to appropriately disclose that fluoride can accumulate harmfully in the body over time; and
- Misled the public concerning the results of studies about harm from ingested fluoride.

BACKGROUND:

Numerous recent reports of ethics and criminal violations by government officials have sparked a greater focus on ethical action and policies in government. The Centers for Disease Control has established two committees designed to ensure ethical actions by CDC employees.

CDC promotes use of the Public Health Leadership Society's ethics code *Principles of the Ethical Practice of Public Health* (see attachment 1), and in fact CDC provided funding and help in its development. But CDC is not ensuring that the ethics principles of this code are implemented in internal CDC departments. This is substantiated in the record of the proceedings of the Feb 27-28, 2007 joint meeting of the ethics subcommittee of the Advisory Council to the CDC Director and the CDC Public Health Ethics Committee (see excerpt in attachment 2). For example, in the minutes of the proceedings, CDC's Dr. Stephanie Bailey is recorded as saying that the uptake of the Code needs to be improved, and that the Code "is not translated to the internal practice of CDC."

CDC also states that two of its "core values" are *accountability* and *integrity* (see attachment 3). Now officials in the Oral Health Division must be held *accountable* for their lack of *integrity* in violating the trust given them as stewards of public health policy and disseminators of public health information. *At a minimum*, the unethical actions and omissions by the Oral Health Director and CDC Director violate Items 6 and 7 as listed in the Ethics Code, to wit:

- Item 6: "Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs…" The Code's accompanying explanatory document elaborates on this item by saying that "the information obtained by public health institutions is to be considered public property and made available to the public." (See the second page of attachment 4.)
- Item 7: "Public health institutions should act in a timely manner on the information they have within the resources and the mandate given to them by the public." The accompanying explanatory document for the Code says about this item that "Public health is active rather than passive, and information is not to be gathered for idle interest." (See the second page of attachment 4.)

There are numerous other violations of public health ethics that have occurred in this matter, but for the sake of brevity, we are only listing the two specific areas of the Ethics Code referenced. The average "man on the street" will see numerous other ethical violations in this matter. We are expectant that the two CDC Ethics Committees, after looking into this, will also readily see other violations of fundamental ethics principles AND will demonstrate a response commensurate with the severity of the harm done. We also wish to notify all CDC employees of good conscience who read this document and wish to tell what they know regarding unethical actions by CDC that they should be aware of the protections available to them from the U.S. Office of Special Counsel and under the Whistleblower Protections Act.

This formal complaint brings to light actions taken by the Director and staff of the Oral Health Division and the CDC Director to continue promoting water fluoridation to help prevent cavities while not disseminating vital, state-of-the-art information about harm from fluoridation.

SPECIFIC UNETHICAL ACTIONS:

1. *Integrity* demands telling the whole story of a matter, even when it might be tempting to selectively omit parts of the story that do not support one's positions or policies. Oral Health Director Dr. William Maas and his staff and CDC Director Gerberding continue to state that fluoridation is "safe for ALL" and that there is "extensive research" supporting fluoridation's safety (see attachment 5 from the Oral Health Division's web site). The vast majority of American citizens and health officials today are under the impression that water fluoridation and fluoride are "safe." Water districts and cities adopt this position by deferring to the opinion of County Health Departments; the County Health Departments defer to the opinion of State Health Departments; and the State Health Departments defer to CDC's Oral Health Division.

   The tremendous influence wielded by the Oral Health Division in this chain of deferred expertise points all the more to a need for ethical action by the Oral Health Division. Last year's National Research Council (NRC) report stated that there are population groups in our country that are particularly susceptible and vulnerable to harm from fluoride, and called for extensive research on the safety of fluoridation. Dr. Maas and Dr. Gerberding continue to state that fluoridation is "safe for ALL" and that "extensive research conducted over the past 60 years" has shown fluoridation to be safe, yet the NRC report lists diabetics, persons with kidney disease, seniors, children, athletes, and outdoor workers as "susceptible subpopulations." (See attachment 6). How can extensive research have shown fluoridation to be safe, when the NRC report acknowledges the need for a staggering amount of research studies, many of which are fundamental and basic in their nature? (See attachment 7.)

   HIV patient groups should be proactively and openly told by CDC that the report suggests research on adverse reactions in immunocompromised people exposed to water with 1 part per million fluoride, the concentration of fluoride in drinking water, but they have not been told this by CDC. Seniors should be told that fluoride accumulates in their bones, putting them at risk for the painful early stages of skeletal fluorosis (whose symptoms could be misdiagnosed as arthritis), but they have not been openly told this. Persons with diabetes inspidus or diabetes mellitus must be told they are in a susceptible population group. Similarly, outdoor workers in hot climates and parents of infants who use powdered milk formula for baby milk deserve to hear the state-of-the-art knowledge in the NRC report, yet CDC has unethically been silent about this, violating its moral and ethical responsibility to tell the *whole* story.

2. In August of 2005, CDC's MMWR publication described trends in dental health in an article entitled "Surveillance for Dental Caries, Dental Sealants, Tooth Retention, Edentulism, and Enamel Fluorosis --- United States, 1988--1994 and 1999—2002." In the report, but ignored by CDC, is the startling fact that African Americans and perhaps Mexican Americans are being disproportionately harmed by moderate and severe dental fluorosis, a permanent staining or pitting of the teeth that occurs when young children receive an over-exposure to fluoride before their permanent teeth erupt from beneath their gums. (See attachment 8.) See attachment 9 for photos of dental fluorosis from the website www.fluoridealert.org. Dr.'s Maas and Gerberding have not openly shown photos of moderate and severe dental fluorosis to Americans in general, and have avoided notifying minority groups in particular of the existence and cause of their disproportionately-experienced fluorosis-damaged teeth.

   Americans who are fortunate to be able to do so may spend over $100,000 over a lifetime for teeth veneers and veneer replacements to cover damage caused by fluorosis. Other less fortunate citizens with moderate or severe dental fluorosis are apparently expected to simply

"live with it." Our citizens have a moral right to hear about and see what is causing their damaged teeth, their loss of self-esteem, and the expensive repair expenditures they may incur. CDC knows that average citizens, and especially disproportionately harmed groups, do not have visual examples and complete information about moderate and severe dental fluorosis, yet unethically does not act to provide the photos and information to the public.

Further, CDC is in breach of Presidential Executive Order 12898 which states that "to the greatest extent practicable and permitted by law…each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States."

3. CDC has for decades promoted the safety and benefit of fluoridated water for infants and children, but early this year quietly changed its statements about fluoridated water and infant formula *without openly notifying the public* by even the use of a press release. This year CDC responded to the National Research's Council's statement that infants in our country are receiving 3-4 times the dose of fluoride as are adults, on a body weight basis. On its Internet site, CDC now states that parents of infants may wish to use low fluoride water (typically meaning, unfluoridated city water) when mixing powdered milk formula. (See attachment 10). At a minimum, a press release should have been issued, as CDC has done for hundreds of other news stories it truly and *with integrity* wants the public to hear, but no press release was issued and no other outreach endeavors utilized. Millions of parents of infants deserve to hear this information and cannot be expected to find this news where it is buried on the Oral Health web site. Without even a press release, how will mothers of newborns hear this information? How will families with limited English ability know about it? And are low-income families that cannot afford unfluoridated bottled water or an expensive home water filtration system expected to use fluoridated water for baby formula, even if they desire not to do so?

   In our society we find pages of drug side-effects warnings for medications advertised in magazines, yet CDC has not held itself to the same standard by openly and actively telling parents of babies the "downside" of fluoride: that it causes or contributes to dental fluorosis.

4. CDC states the following "Key Fact About Community Water Fluoridation" on its web site: **"**Water fluoridation is the addition of fluoride to adjust the natural concentration of a community's water supply to the level recommended by the U.S. Public Health Service for optimal dental health -- 0.7 to 1.2 parts per million (equivalent to about 1 inch in 16 miles or 1 cent in $10,000)." (See attachment 11.)

   The above-cited use of "one inch" and "one cent" are examples of untruths covered by analogies. CDC's use of these analogies is unethical because CDC unethically and improperly confuses Americans with a statement of *concentration* of fluoride instead of *dose*; CDC omits to say that small *concentrations* of fluoride, when ingested, *accumulate* in a person's body (as *dose*). CDC does not say that for persons with well-functioning kidneys, slightly less of half of all fluoride ingested remains in the body, nor that toxic dose level is based on cumulative amount ingested over time -- the total number of pennies or inches over time, to use the analogy terms.

   CDC also does not tell the public that the U.S. Dept. of Agriculture has been concerned enough about Americans' total fluoride dose so as to recently develop software and a fluoride-

in-foods database to begin to monitor Americans' total fluoride intake. USDA states that, "Assessments of fluoride intake are critical to ensure adequacy to prevent dental caries and to prevent excessive fluoride intake resulting in dental and skeletal fluorosis." (See attachment 12.) The National Research Council report on fluoride in 2006 stated that, "The elderly are another population of concern because of their long-term accumulation of fluoride into their bones." (See attachment 6). CDC also omits to say that only four inches (in the16 mile analogy) is the maximum water concentration the government allows, meaning that the difference between toxic dose (4 parts per million) and therapeutic dose (approximately 1 part per million) is only three "inches" -- a shockingly small margin of safety strangely provided to fluoride and not other chemicals, and one that does not adequately take into account Americans' multiple other sources of fluoride ingestion today, in addition to water.

CDC's use of the deceptive and misleading analogies shown here is strikingly illustrative of an overall pattern of unethical strategy to not disclose cumulative dose concerns and the true nature of fluoride's effects on the body.

5. CDC has misled the public about the conclusions of studies and systematic reviews that CDC says support the idea that fluoride is safe and effective. For example, CDC states on its web site that the York University systematic review in 2000 "concluded" that fluoride is "safe and effective." (See attachment 13.) Dr. Gerberding has also cited the York review as having documented comprehensively the safety of fluoride. Yet the chair of the advisory group for the systematic review last year stated his concern that the results of the review have been widely misrepresented. He flatly stated, "The review did not show fluoridation to be safe." (See attachment 14.)

   This same deceptive pattern of improper assertions concerning reports showing fluoride and fluoridation to be safe is also seen in CDC's statement about the National Research Council fluoride report. CDC stated that, "The report addresses the safety of high levels of fluoride in water that occur naturally, and *does not question the use of lower levels of fluoride to prevent tooth decay*." (emphasis added, see attachment 15.) CDC also says in its statement, "The National Research Council Committee … found that the current EPA (allowable level for fluoride in drinking water) should be lowered to better protect people from health risks associated with high natural fluoride levels."

   CDC unethically deceptively uses the official tasking given to the NRC committee (it wasn't to review water fluoridation, but the effectiveness of current permissible regulatory water fluoride levels) *to infer that the report does not have relevant information useful to citizens about fluoridation*. CDC incorrectly says that the reason NRC suggested lowering the maximum amount of fluoride allowed in water is to protect people from high *natural* fluoride levels, but the report assesses both *artificial and natural* fluoride exposures. Therefore the NRC report does, in fact, have significant pertinent information relating to fluoridation.

   The NRC report documents the significant gaps in our knowledge of fluoride's effects at the levels used *in fluoridation*. Two examples are the report showing a need for research on low doses of fluoride on kidney and liver enzyme function, and on adverse reactions in persons with compromised immune systems to 1 part per million (ppm) in drinking water. A risk assessment expert who served on the NRC panel has also publicly stated her personal belief that the report is relevant to many aspects of the water fluoridation debate. She states that the safety margin between 1 ppm fluoridated water and the maximum allowed 4 ppm is "very low," considering Americans' wide range of water consumption. (See p. 2 of attachment 16).

CONCLUSION:

There are numerous unethical practices demonstrated by CDC in its efforts to avoid admitting harm from fluoridation at all costs. Not all of these practices are listed here in this Complaint, but the CDC Ethics Committees may find it useful to also examine the CDC representative's statements to water districts in an American Water Works Association webcast after the NRC report was issued; CDC's inference that fluoridation is safe because fluoride is "naturally" present in water (CDC leaves out that arsenic also occurs "naturally"); CDC's refusal to provide specific answers in writing to certain key questions asked about fluoridation by U.S. and state legislators; CDC's giving of responsibility to healthcare providers to ascertain total fluoride dose for individuals, but CDC not appropriately notifying healthcare providers of the need to do so, of the near impossibility of doing so, and that seniors, diabetics, kidney patients, and other populations are more susceptible to harm from fluoride; and concerns of other countries that refuse to fluoridate, especially their ethical concerns about providing medication in water without obtaining informed consent.

The evidence showing unethical practice by CDC in this matter is readily observable to an objective observer. A "reasonable man" (a legal concept used in court cases involving contract disputes and other legal matters) will find CDC's actions to be disingenuous, unethical, and we believe even legally compensable for damages incurred. We hope CDC will hold its own staff accountable to the same Ethics Code it encourages in public health agencies around the country. Americans have a right to hear the *whole* story about fluoride. The world is *not* flat, and fluoride is *not* "safe and effective for all."

Sincerely,

Dr. Lillie B. Fessenden Daniel G. Stockin, MPH

The Lillie Center, Inc.

Principles of the Ethical Practice of Public Health

1. Public health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes.

2. Public health should achieve community health in a way that respects the rights of individuals in the community.

3. Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members.

4. Public health should advocate and work for the empowerment of disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.

5. Public health should seek the information needed to implement effective policies and programs that protect and promote health.

6. Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community's consent for their implementation.

7. Public health institutions should act in a timely manner on the information they have within the resources and the mandate given to them by the public.

8. Public health programs and policies should incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community.

9. Public health programs and policies should be implemented in a manner that most enhances the physical and social environment.

10. Public health institutions should protect the confidentiality of information that can bring harm to an individual or community if made public. Exceptions must be justified on the basis of the high likelihood of significant harm to the individual or others.

11. Public health institutions should ensure the professional competence of their employees.

12. Public health institutions and their employees should engage in collaborations and affiliations in ways that build the public's trust and the institution's effectiveness.

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ethics could show how the Code should be interpreted in particular situations. Rather than re-writing the Code, he advised "making it live."

- Dr. Salaam Semann recommended conferring with the organizations who are not using the Code, but who they hoped would use it, to find out why they are not using it. For example, CDC staff are not largely aware of the Code and may not know how to use it. She wondered about how CDC could facilitate increasing use of the Code and filtering it to the public health community.
- Dr. Thomas pointed out that many national public health organizations have adopted the Code, but CDC has not.
- Dr. Stephanie Bailey, Office of the Director, agreed that the Code does not need to be revised, but its uptake needs to be improved. The Code is not translated to the internal practice of CDC. Case studies of the Code's use have been shared through APHA and public health law conferences, but these have not been captured.
- Dr. Barrett said that the PHEC stresses the importance of the Code and provides the Code to its members to provide to their Center-level staff. PHEC developed a framework document to describe its work and refers to the Code as "guiding values" for the committee's activities and for public health. They do need to share more information about the Code, and providing specific examples of the code's use via case studies of its implementation would be useful.
- Dr. Dixon observed that the narrative components of the Code and bases for action include the importance of science. It is important for people in public health to understand what works. They have an obligation to do continuing evaluation of the effects that they are having by the actions that they take in communities.
- Dr. Gamble has used the code for teaching. It is important to show how the Code is used. For example, one of the principles of the Code is advocating for the empowerment of disenfranchised communities. She used the code in a special session of APHA in the context of a health department that wants outcomes; however, programs that address disparities are typically costly and may not show outcomes quickly. Local health departments might choose a program that might not have the biggest outcome just to show effectiveness. These tensions are very real in the world. She felt that describing cases in which the Code was used will increase its uptake and use.
- Dr. Macklin asked the group to reflect on how the Subcommittee and PHEC can assist.
- Dr. Thomas asked the group to share any case studies that could be helpful. A number of case studies from the Code were collected at APHA last year, but more would be welcomed.
- Dr. Roger Bernier recently participated in public engagement discussions regarding priorities for pandemic influenza vaccine and community control measures for pandemic influenza. There did not seem to be awareness of the Public Health Ethics Code in these discussions, and he himself did not feel the need to refer to it and did not have a sense of how the Code could be helpful. He wondered about the practical value of the Code. Codes are expected to be broad, but it is not clear how ethics principles and framework are useful in practical public health. Demonstrations of the practical use of the Code are needed. It is not always clear how ethical theories and frameworks, as well as values and principles, are helpful in dealing with dilemmas. Models in ethical decision-making provide a series of steps in working with ethical issues. None of these measures had entered the discussions of the day as they wrestled with ethical issues. He struggled with how general principles and codes help with the execution of practical public health work.
- Dr. Arras has never used a code to help him think through an issue, but the Public Health Ethics Code is one of the best he has seen and has a better chance of being practically helpful because it links ethical principles with public health functions. It is unrealistic, however, to think that a code of ethics will help people work their way through a problem. Most codes are written too broadly, and even when they are written specifically, competing

CDC Mission

To promote health and quality of life by preventing and controlling disease, injury, and disability.

CDC seeks to accomplish its mission by working with partners throughout the nation and the world to

- monitor health,
- detect and investigate health problems,
- conduct research to enhance prevention,
- develop and advocate sound public health policies,
- implement prevention strategies,
- promote healthy behaviors,
- foster safe and healthful environments,
- provide leadership and training.

Those functions are the backbone of CDC's mission. Each of CDC's component organizations undertakes these activities in conducting its specific programs. The steps needed to accomplish this mission are also based on scientific excellence, requiring well-trained public health practitioners and leaders dedicated to high standards of quality and ethical practice.

CDC Pledge

CDC pledges to the American people:

> To be a diligent steward of the funds entrusted to it.
>
> To provide an environment for intellectual and personal growth and integrity.
>
> To base all public health decisions on the highest quality scientific data, openly and objectively derived.
>
> To place the benefits to society above the benefits to the institution.
>
> To treat all persons with dignity, honesty, and respect.

CDC Core Values

Accountability — As diligent stewards of public trust and public funds, we act decisively and compassionately in service to the people's health. We ensure that our research and our services are based on sound science and meet real public needs to achieve our public health goals.

Respect — We respect and understand our interdependence with all people, both inside the agency and throughout the world, treating them and their contributions with dignity and valuing individual and cultural diversity. We are committed to achieving a diverse workforce at all levels of the organization.

Integrity — We are honest and ethical in all we do. We will do what we say. We prize scientific integrity and professional excellence.

Source: http://www.cdc.gov/about/organization/mission.htm

Notes on the Individual Ethical Principles

1. This Principle gives priority not only to prevention of disease or promotion of health, but also at the most fundamental levels. Yet the principle acknowledges that public health will also concern itself with some immediate causes and some curative roles. For example, the treatment of curable infections is important to the prevention of transmission of infection to others. The term “public health” is used here and elsewhere in the Code to represent the entire field of public health, including but not limited to government institutions and schools of public health.

2. This Principle identifies the common need in public health to weigh the concerns of both the individual and the community. There is no ethical principle that can provide a solution to this perennial tension in public health. We can highlight, however, that the interest of the community is part of the equation, and for public health it is the starting place in the equation; it is the primary interest of public health. Still, there remains the need to pay attention to the rights of individuals when exercising the police powers of public health.

3. A process for input can be direct or representative. In either case, it involves processes that work to establish a consensus. While democratic processes can be cumbersome, once a policy is established, public health institutions have the mandate to respond quickly to urgent situations. Input from the community should not end once a policy or program is implemented. There remains a need for the community to evaluate whether the institution is implementing the program as planned and whether it is having the intended effect. The ability for the public to provide this input and sense that it is being heard is critical in the development and maintenance of public trust in the institution.

4. This Principle speaks to two issues: ensuring that all in a community have a voice; and underscoring that public health has a particular interest in those members of a community that are underserved or marginalized. While a society cannot provide resources for health at a level enjoyed by the wealthy, it can ensure a decent minimum standard of resources. The Code cannot prescribe action when it comes to ensuring the health of those who are marginalized because of illegal behaviors. It can only underscore the principle of ensuring the resources necessary for health to all. Each institution must decide for itself what risks it will take to achieve that.

5. This Principle is a mandate to seek information to inform actions. The importance of information to evaluate programs is also implied.

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Notes on the Individual Ethical Principles

6. This Principle is linked to the third one about democratic processes. Such processes depend upon an informed community. The information obtained by public health institutions is to be considered public property and made available to the public. This statement is also the community-level corollary of the individual-level ethical principle of informed consent. Particularly when a program has not been duly developed with evaluation, the community should be informed of the potential risks and benefits, and implementation of the program should be premised on the consent of the community (though this principle does not specify how that consent should be obtained).

7. Public health is active rather than passive, and information is not to be gathered for idle interest. Yet the ability to act is conditioned by available resources and opportunities, and by competing needs. Moreover, the ability to respond to urgent situations depends on having established a mandate to do so through the democratic processes of Ethical Principle number three.

8. Public health programs should have built into them a flexibility that anticipates diversity in those needs and perspectives having a significant impact on the effectiveness of the program. Types of diversity, such as culture and gender, were intentionally not mentioned. Any list would be arbitrary and inadequate.

9. This Principle stems from the assumptions of interdependence among people, and between people and their physical environment. It is like the ethical principle from medicine, “do no harm,” but it is worded in a positive way.

10. This statement begs the question of which information needs to be protected and what the criteria are for making the information public. The aims of this statement are modest: to state explicitly the responsibility inherent to the “possession” of information. It is the complement to Ethical Principles 6 and 7, about acting on and sharing information.

11. The criteria for professional competence would have to be specified by individual professions, such as epidemiology and health education.

12. This statement underscores the collaborative nature of public health while also stating in a positive way the need to avoid any conflicts of interest that would undermine the trust of the public or the effectiveness of a program.

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Fluoridation – FAQs

Is community water fluoridation safe?

Yes. Extensive research conducted over the past 60 years has shown that fluoridation of public water supplies is a safe and effective way to reduce tooth decay for all community residents. More recent reviews of the safety of water fluoridation include a comprehensive review of the scientific literature by the U.S. Public Health Service in 1991 and the University of York in 2000. The overall value and safety of community water fluoridation has been endorsed by the Centers for Disease Control and Prevention, by the U.S. Surgeon General's report Oral Health in America (May 2000), and by the U.S. Task Force on Community Preventive Services in 2001. Community water fluoridation also has been endorsed by numerous public health and professional organizations, including the American Dental Association, the American Medical Association, the American Association of Public Health, U.S. Public Health Service, and the World Health Organization

of structural or psychological effects. There are no studies since 1993 to assess the prevalence of enamel fluorosis at 2 mg/L, but previous reports have shown a distinct increase (approximately 15%) in moderate enamel fluorosis around 2 mg/L. Thus, the SMCL will not completely prevent the occurrence of moderate enamel fluorosis. As noted above, SMCL was intended to reduce the severity and occurrence of the condition to 15% or less of the exposed population. The available data indicates that less than 15% of children would experience moderate enamel fluorosis of aesthetic concern (discoloration of the front teeth). 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.

While a few cases of sever enamel fluorosis occasionally have been reported in populations exposed at 2 mg/L, it appears that other sources of exposure to fluoride or other factors contributed to the condition. For example, similar rates of severe enamel fluorosis were reported in populations exposed to negligible amounts of fluoride in drinking water and in populations exposed at 2 mg/L (Selwitz et al. 1995; Kumar and Swango 1999; Nowjack-Raymer et al. 1995). Thus, the committee concludes that the SMCL of 2 mg/L adequately protects the public from the most severe stage of the condition (enamel pitting).

Skeletal Fluorosis

Few new data are available on skeletal fluorosis in populations exposed to fluoride in drinking water at 2 mg/L. Thus, the committee's evaluation was based on new estimates of the accumulation of fluoride into bone (iliac crest/pelvis) at that concentration (on average 4,000 to 5,000 mg/kg ash) and historical information on stage II skeletal fluorosis (4,300 to 9,200 mg/kg ash). A comparison of the bone concentrations indicates that lifetime exposure at the SMCL could lead to bone fluoride concentrations that historically have been associated with stage II skeletal fluorosis. However, as noted above, the existing epidemiologic evidence is insufficient for determining whether stage II skeletal fluorosis is occurring in U.S. residents, so no quantitative conclusions could be made about risks or safety at 2-mg/L exposures.

Bone Fracture

There were few studies to assess bone fracture risk in populations exposed to fluoride at 2 mg/L in drinking water. The best available study was from Finland, which provided data that suggested an increased rate of hip fracture in populations exposed to fluoride at >1.5 mg/L (Kurttio et al. 1999). However, this study alone is not sufficient to base judgment of fracture risk for people exposed to fluoride at 2 mg/L in drinking water. Thus, no quantitative conclusions could be drawn about fracture risk or safety at the SMCL.

Susceptible Subpopulations

Populations in need of special consideration when determining the MCLG and SMCL for fluoride include those at risk because their exposure to fluoride is greater than that of the average person or because they are particularly vulnerable to the effects of fluoride. The first category

includes people who consume much larger volumes of water than assumed by EPA, such as athletes and outdoor workers, who consume large volumes of water to replace fluids lost because of strenuous activity, and people with medical conditions that cause them to consume excessive amounts of water (e.g., diabetes insipidus). Individuals who consume well over 2 L of water per day will accumulate more fluoride and reach critical bone concentrations before the average water drinker exposed to the same concentration of fluoride in drinking water. In Chapter 2, it was estimated that for high-water-intake individuals, drinking water would contribute 92% to 98% of the exposure to fluoride at 4 mg/L and 86% to 96% at 2 mg/L. Another consideration is individuals who are exposed to other significant sources of fluoride, such as occupational, industrial, and therapeutic sources.

There are also environmental, metabolic, and disease conditions that cause more fluoride to be retained in the body. For example, fluoride retention might be affected by environments or conditions that chronically affect urinary pH, including diet, drugs, altitude, and certain diseases (e.g., chronic obstructive pulmonary disease) (reviewed by Whitford 1996). It is also affected by renal function, because renal excretion is the primary route of fluoride elimination. Age and health status can affect renal excretion. Individuals with renal disease are of particular concern because their ability to excrete fluoride can be seriously inhibited, causing greater uptake of fluoride into their bones. However, the available data are insufficient to provide quantitative estimates of the differences between healthy individuals and people with renal disease.
Another category of individuals in need of special consideration includes those who are particularly susceptible or vulnerable to the effects of fluoride. For example, children are vulnerable for developing enamel fluorosis, because the condition occurs only when there is exposure while teeth are being formed (the pre-eruption stages). Thus, children up to the age of 8 are the susceptible subpopulation of concern for that end point. The elderly are another population of concern because of their long-term accumulation of fluoride into their bones. There are also medical conditions that can make people more susceptible to the effects of fluoride.

Relative Source Contribution

At the time the MCLG was established for fluoride, a reference dose was not available and the MCLG was calculated directly from available data rather than as an apportioned part of the reference dose. In Chapter 2, the committee shows that at 4 mg/L, drinking water is the primary contributor to total fluoride exposure, ranging from 72% to 94% for average-waterintake individuals and from 92% to 98% for high-water-intake individuals. At 2 mg/L, drinking water contributes 57% to 90% for average-water-intake individuals and 86% to 96% for highwater-intake individuals. Thus, it is important that future revisions to the MCLG take into consideration that water is a significant, and sometimes the most significant, source of exposure to fluoride.

Excerpts from: "Fluoride in Drinking Water: A Scientific Review of EPA's Standards" (National Research Council, 2006)

NRC's RESEARCH RECOMMENDATIONS:

"Fluoride should be included in nationwide biomonitoring surveys and nutritional studies; in particular, analysis of fluoride in blood and urine samples taken in these surveys would be valuable." p9

"To assist in estimating individual fluoride exposure from ingestion, manufacturers and producers should provide information on the fluoride content of commercial foods and beverages." p71

"The concentrations of fluoride in human bone as a function of exposure concentration, exposure duration, age, sex, and health status should be studied." p9

"Information is particularly needed on fluoride plasma and bone concentrations in people with small-to-moderate changes in renal function as well as in those with serious renal deficiency." p9

"More research is needed on the relation between fluoride exposure and dentin fluorosis and delayed tooth eruption patterns." p9

"A systematic study of clinical stage II and stage III skeletal fluorosis should be conducted to clarify the relationship between fluoride ingestion, fluoride concentration in bone, and clinical symptoms. " p10

"More studies of communities with drinking water containing fluoride at 2 mg/L or more are needed to assess potential bone fracture risk at these higher concentrations." p10

"Carefully conducted studies of exposure to fluoride and emerging health parameters of interest (e.g., endocrine effects and brain function) should be performed in populations in the United States exposed to various concentrations of fluoride." p10

"Better characterization of exposure to fluoride is needed in epidemiology studies investigating potential effects. Important exposure aspects of such studies would include the following: collecting data on general dietary status and dietary factors that could influence exposure or effects, such as calcium, iodine, and aluminum intakes." p72

"To permit better characterization of current exposures from airborne fluorides, ambient concentrations of airborne hydrogen fluoride and particulates should be reported on national aregional scales, especially for areas of known air pollution or known sources of airborne fluorides. Additional information on fluoride concentrations in soils in residential and recreational areas near industrial fluoride sources also should be obtained" p71-72

"The possibility of biological effects of SiF6, as opposed to free fluoride ion, should be examined." p72

"The biological effects of aluminofluoride complexes should be researched further, including the conditions (exposure conditions and physiological conditions) under which the complexes can be expected to occur and to have biological effects." p72

"Thus, more studies are needed on fluoride concentrations in soft tissues (e.g., brain, thyroid, kidney) following chronic exposure." p83

"Research is needed on fluoride plasma and bone concentrations in people with small to moderate changes in renal function as well as patients with serious renal deficiency. Other potentially sensitive populations should be evaluated, including the elderly, postmenopausal women, and people with altered acid-base balance." P83

attachment (7) three pages

"More work is needed on the potential for release of fluoride by the metabolism of organofluorines." p83

"More research is needed on bone concentrations of fluoride in people with altered renal function, as well as other potentially sensitive populations (e.g., the elderly, post-menopausal women, people with altered acid-balance), to better understand the risks of musculoskeletal effects in these populations." p147

"the relationship between fertility and fluoride requires additional study." p161

"Two small studies have raised the possibility of an increased incidence of spina bifida occulta in fluorosis-prone areas in India; larger, well-controlled studies are needed to evaluate that possibility further." p164

"More research is needed to clarify fluoride's biochemical effects on the brain." p186

"The possibility has been raised by the studies conducted in China that fluoride can affect intellectual abilities. Thus, studies of populations exposed to different concentrations of fluoride in drinking water should include measurements of reasoning ability, problem solving, IQ, and short- and long-term memory." p187

"Studies of populations exposed to different concentrations of fluoride should be undertaken to evaluate neurochemical changes that may be associated with dementia. Consideration should be given to assessing effects from chronic exposure, effects that might be delayed or occur late-in-life, and individual susceptibility." p187

"Further effort is necessary to characterize the direct and indirect mechanisms of fluoride's action on the endocrine system and the factors that determine the response, if any, in a given individual. Such studies would address the following...

identification of those factors, endogenous (e.g., age, sex, genetic factors, or preexisting disease) or exogenous (e.g., dietary calcium or iodine concentrations, malnutrition), associated with increased likelihood of effects of fluoride exposures in individuals. consideration of the impact of multiple contaminants (e.g., fluoride and perchlorate) that affect the same endocrine system or mechanism." p223

"The effects of fluoride on various aspects of endocrine function should be examined particularly with respect to a possible role in the development of several diseases or mental states in the United States. Major areas for investigation include the following:

thyroid disease (especially in light of decreasing iodine intake by the U.S. population); nutritional (calcium-deficiency) rickets; calcium metabolism (including measurements of both calcitonin and PTH); pineal function (including, but not limited to, melatonin production); and development of glucose intolerance and diabetes." p224 "Studies are needed to evaluate gastric responses to fluoride from natural sources at concentrations up to 4 mg/L and from artificial sources." p. 258

"Additional studies should be carried out to determine the incidence, prevalence, and severity of renal osteodystrophy in patients with renal impairments in areas where there is fluoride at up to 4 mg/L in the drinking water." p. 258

"The effect of low doses of fluoride on kidney and liver enzyme functions in humans needs to be carefully documented in communities exposed to different concentrations of fluoride in drinking water." p258

"In addition, studies could be conducted to determine what percentage of immunocompromised subjects have adverse reactions when exposed to fluoride in the range of 1-4 mg/L in drinking water." p259

"It is paramount that careful biochemical studies be conducted to determine what fluoride concentrations occur in the bone and surrounding interstitial fluids from exposure to fluoride in drinking water at up to 4 mg/L, because bone marrow is the source of the progenitors that produce the immune system cells." p 259

"Further research on a possible effect of fluoride on bladder cancer risk should be conducted." p288

"in vivo human genotoxicity studies in U.S. populations or other populations with nutritional and sociodemographic variables similar to those in the United States should be conducted." p288

Surveillance for Dental Caries, Dental Sealants, Tooth Retention, Edentulism, and Enamel Fluorosis --- United States, 1988--1994

TABLE 23. Enamel fluorosis* among persons aged 6–39 years, by selected characteristics — United States, National Health and Nutrition Examination Survey, 1999–2002

Characteristic	Unaffected		Questionable		Very mild		Mild		Moderate/Severe	
	%†	SE§	%	SE	%	SE	%	SE	%	SE
Age group (yrs)										
6–11	59.81	4.07	11.80	2.50	19.85	2.12	5.83	0.73	2.71	0.59
12–15	51.46	3.51	11.96	1.84	25.33	1.98	7.68	0.93	3.56	0.59
16–19	58.32	3.30	10.21	1.70	20.79	1.78	6.65	0.67	4.03	0.77
20–39	74.86	2.28	8.83	1.23	11.15	1.22	3.34	0.58	1.81	0.39
Sex										
Male	67.65	2.63	9.99	1.45	15.65	1.52	4.58	0.54	2.12	0.39
Female	66.97	2.84	9.83	1.34	15.58	1.36	4.84	0.61	2.78	0.49
Race/Ethnicity¶										
White, non-Hispanic	69.69	3.13	10.43	1.62	14.09	1.56	3.87	0.60	1.92	0.48
Black, non-Hispanic	56.72	3.30	10.40	2.16	21.21	2.16	8.24	0.82	3.43	0.54
Mexican-American	65.25	3.89	8.95	1.29	15.93	2.24	5.05	0.72	4.82**	1.81
Poverty status††										
<100% FPL	68.02	3.21	10.67	1.64	14.28	1.73	4.07	0.69	2.97	0.66
100%–199% FPL	66.92	2.91	9.11	1.79	16.11	1.46	5.21	0.78	2.65	0.56
≥200% FPL	66.88	2.75	10.73	1.33	15.56	1.56	4.83	0.50	2.00	0.37
Total	**67.40**	**2.65**	**9.91**	**1.35**	**15.55**	**1.37**	**4.69**	**0.49**	**2.45**	**0.40**

* Using Dean's index. All estimates are adjusted by age (single years) and sex to the U.S. 2000 standard population, except sex, which is adjusted only by age.
† Weighted prevalence estimates.
§ Standard error.
¶ Calculated using "other race/ethnicity" and "other Hispanic" in the denominator.
** Unreliable estimate: the standard error is 30% the value of the point estimate, or greater.
†† Percentage of the Federal Poverty Level (FPL), which varies by income and number of persons living in the household.

http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5403a1.htm

Dental Fluorosis Examples

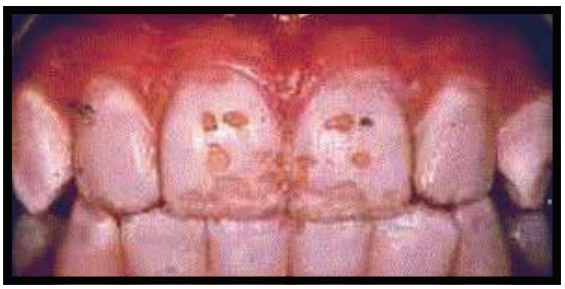
Mild Fluorsis
Photo by David Kennedy DDS

Mild/Moderate Fluorosis
Photo by Elke Babiuk

Severe Fluorosis
Photo Source Unknown

Severe Fluorosis
Photo by Hardy Limeback, DDS

Severe Fluorosis
Photo by John Colquhoun, DDS



Severe Fluorosis
Photo Source Unknown

Photos taken from www.fluoridealert.org

Attachment (9)

Fluoridation – Safety – Infant Formula

What type of water does CDC recommend for mixing infant formula?

Parents should follow the advice of the formula manufacturer and their child's doctor for the type of water appropriate for the formula they are using. Parents and caregivers of infants fed primarily with formula from concentrate who are concerned about the effect that mixing their infant's formula with fluoridated water may have in developing enamel fluorosis can lessen this exposure by mixing formula with low fluoride water most or all of the time. This may be tap water, if the public water system is not fluoridated (check with your local water utility). If tap water is fluoridated or has substantial natural fluoride (0.7 mg/L or higher), a parent may consider using a low-fluoride alternative water source. Bottled water known to be low in fluoride is labeled as purified, deionized, demineralized, distilled, or prepared by reverse osmosis. Most grocery stores sell these types of low-fluoride water. Ready to feed (no-mix) infant formula typically has little fluoride and may be preferred for use at least some of the time.

Why is there a focus on infant formula as a source of fluoride?

Infant formula manufacturers take steps to assure that infant formula contains low fluoride levels—the products themselves are not the issue. Although formula itself has low amounts of fluoride, when infant formula concentrate is mixed with fluoridated water and used as the primary source of nutrition, it may introduce fluoride at levels above the amount recommended to minimize the risk for fluorosis. Infants consume little other than breast milk or formula during the first four to six months of life, and continue to have a high intake of liquids during the entire first year. Therefore, proportional to body weight, fluoride intake from liquids is generally higher for younger or smaller children than for older children, adolescents, or adults. Mixing concentrate with fluoridated tap water on an occasional basis is unlikely to be of much risk. However, when used consistently as the primary source of nutrition over longer periods of the first year, a child may receive enough fluoride to increase his/her chances of developing very mild or mild fluorosis.

http://www.cdc.gov/fluoridation/safety/infant_formula.htm

Oral Health Resources – Press Release – Community Water Fluoridation Lacking

Key Facts About Community Water Fluoridation

- Water fluoridation is the addition of fluoride to adjust the natural concentration of a community's water supply to the level recommended by the U.S. Public Health Service for optimal dental health—0.7 to 1.2 parts per million (equivalent to about 1 inch in 16 miles or 1 cent in $10,000).

http://www.cdc.gov/OralHealth/pressreleases/wf_lacking.htm

National Fluoride Database and Intake Assessment Study

The Nutrient Data Laboratory (NDL), a part of the Agricultural Research Service, and the University of Minnesota Nutrition Coordinating Center (NCC) are collaborating on the National Fluoride Database and Intake Assessment Study (NFDIAS). The NFDIAS was supported by the National Institute of Dental & Craniofacial Research and the National Heart, Lung, & Blood Institute of the National Institutes of Health. The University of Iowa College of Dentistry cooperated with NDL to conduct fluoride analyses for both the USDA National Fluoride Database and for the NCC Software Demonstration Study. The Virginia Polytechnic Institute Food Analysis Laboratory Control Center worked with NDL to receive, composite and ship food and beverage samples for analysis. Fluoride data from other studies and from the scientific literature have been evaluated and incorporated along with analytical data from the NFDIAS study to create the USDA National Fluoride Database of Selected Beverages and Foods released, October 2004, online at USDA-NDL's Web site. The database provides the fluoride level of 400 separate food and beverage items. It will be incorporated into a computer-based food and beverage intake survey tool now being developed by researchers at the University of Minnesota NCC. That tool will be used to assess the amount of fluoride consumed by individuals from dietary and nondietary sources, including fluoride supplements and toothpastes.

Fluoride is added to many municipal water supplies and, therefore, finds its way into water-based beverages and foods in the United States. Its role in prevention of dental caries is well recognized. Fluoride has an affinity for calcified tissues and attention is being given to fluoride exposure and prevention of bone health, disease, and fracture. Fluoride is among those nutrients for which Dietary Reference Intakes have been established. An Adequate Intake level has been set for fluoride at 3 milligrams (mg) daily for women and 4 mg daily for men. Until now, scant data existed on the quantity of fluoride in the national food supply and, therefore, on overall dietary fluoride intake among individuals. Assessments of fluoride intake are critical to ensure adequacy to prevent dental caries and to prevent excessive fluoride intake resulting in dental and skeletal fluorosis. The fluoride database will, for the first time, enable researchers to estimate consumers' day-to-day fluoride intake. It will also serve as an important data resource for nutrition-related research, planning, and policy nation-wide and when incorporated into NCC's computer-based fluoride intake assessment tool will contribute to assessment studies of fluoride intake in humans including dental and skeletal fluorosis, dental caries, bone health, and osteoporosis.

To access the new database on the Internet, go to: www.nal.usda.gov/fnic/foodcomp and click on the Special Interest Database "Fluoride" under Food Composition Products.

Read more about the research in the *November* issue of *Agricultural Research* magazine, on the World Wide Web at: *www.ars.usda.gov/is/AR/archive/nov04/fluoride1104.htm*

USDA, Agricultural Research Service
Beltsville Human Nutrition Research Center
Nutrient Data Laboratory
10300 Baltimore Ave
Bldg 005, Rm 107 BARC-West
Beltsville, MD 20705-2350

For food composition information, access:
www.nal.usda.gov/fnic/foodcomp

Or contact NDL by
telephone: 301-504-0630
fax: 301-504-0632
email: ndinfo@rbhnrc.usda.gov

March 2005

Systematic Reviews: Assessing the Weight of the Evidence

An important resource used to assess the safety of a health care strategy such as water fluoridation are systematic reviews of scientific literature. Systematic reviews are helpful because they:

- Seek to collect evidence from all published studies on a subject.
- Use carefully-designed methods to critically examine scientific evidence.
- Use national and international panels of experts in various health and scientific disciplines, including many experts outside of oral health, including medicine, biophysics, chemistry, toxicological pathology, and epidemiology.
- Assess the quality of individual studies and summarize the strength of the entire body of evidence.
- Summarize information regarding other evidence.
- Identify and summarize research gaps and make recommendations for further research.

Systematic reviews have been conducted by several scientific and public health organizations over the past two decades. All have concluded that community water fluoridation is a safe and effective method for reducing tooth decay across all ages.

United States Public Health Service Review of Fluoride: Benefits and Risks, 1991
Comprehensive review and evaluation of the public health benefits and risks of fluoride from drinking water and other sources.

Institute of Medicine Dietary Reference Guidelines, 1997*
Describes the dietary reference intakes for specific nutrients known to be beneficial to health including fluoride.

National Research Council

The NRC released its current report, *Fluoride in Drinking Water: A Scientific Review of EPA's Standard*, on March 22, 2006. The National Research Council's (NRC) previous report, entitled *Health Effects of Ingested Fluoride,* was issued in 1993. It examined the possible toxic effects of ingested fluoride and concluded:

- Fluoride at recommended concentrations is not likely to produce a number of unwanted health effects that had been claimed by opponents of water fluoridation.
- The maximum contaminant level (MCL) set by the Environmental Protection Agency (EPA) at 4 mg/L was an appropriate interim standard, even though fluoride at this level might cause moderate or even severe dental fluorosis in a small percentage of the population.

The full 1993 report can be found at http://www.nap.edu/books/030904975X/html/R1.html.*

University of York

A systematic review of public water fluoridation was released in 2000 by the National Health Service (NHS) Centre for Reviews and Dissemination, University of York, United Kingdom. This looked at the evidence on positive and negative effects of community water fluoridation. They identified five objectives and evaluated the studies relating to each objective. Based on the best available research they found that:

- Community water fluoridation reduces tooth decay.
- Fluoridation is still effective even with the use of many other sources of fluoride.
- There is no clear association between fluoridation and bone fractures or cancer.
- There appears to be no difference between benefits from natural and artificial fluoridation.
- There is an association between the water fluoride concentration and the occurrence of enamel fluorosis.
- No clear evidence of other potential negative health effects were found.

The full report can be found at http://www.york.ac.uk/inst/crd/fluores.htm.*

Published Date: 26 July 2006 **Location:** Yorkshire

Chewing over the facts about fluoride and our dental health

From: Professor Trevor Sheldon, Department of Health Studies, Innnovation Centre, York Science Park, University Road, York.

IN my capacity as chair of the Advisory Group for the systematic review on the effects of water fluoridation recently conducted, I am concerned that the results of the review have been widely misrepresented (Yorkshire Post, July 22).
The review was exceptional in this field in that it was conducted by an independent group to the highest international scientific standards, and a summary has been published in the British Medical Journal. It is particularly worrying then that statements which mislead the public about the review's findings have been made in press releases and briefings by the British Dental Association, the British Medical Association, the National Alliance for Equity in Dental Health and the British Fluoridation Society. I should like to correct some of these errors.
1. While there is evidence that water fluoridation is effective at reducing caries, the quality of the studies was generally moderate and the size of the estimated benefit, only of the order of 15 per cent, is far from "massive".
2. The review found water fluoridation to be significantly associated with high levels of dental fluorosis, which was not characterised as, "just a cosmetic issue".
3. The review did not show water fluoridation to be safe. The quality of the research was too poor to establish with confidence whether or not there are potentially important adverse effects in addition to the high levels of fluorosis. The report recommended that more research was needed.
4. There was little evidence to show that water fluoridation has reduced social inequalities in dental health.
5. The review could come to no conclusion as to the cost-effectiveness of water fluoridation or whether there are different effects between natural or artificial fluoridation.
6. Probably because of the rigour with which this review was conducted, these findings are more cautious and less conclusive than in most previous reviews.
7. The review team was surprised that in spite of the large number of studies carried out over several decades, there is a dearth of reliable evidence with which to inform policy. Until high-quality studies are undertaken providing more definite evidence, there will continue to be legitimate scientific controversy over the likely effects and costs of water fluoridation.

http://www.yorkshirepost.co.uk/viewarticle.aspx?sectionid=101&articleid=1651774

CDC Statement on the 2006 National Research Council (NRC) Report on Fluoride in Drinking Water

CDC recommends community water fluoridation as a safe, effective, and inexpensive way to prevent tooth decay (dental caries) among populations living in areas with adequate community water supply systems. Similar to many vitamins and minerals we consume for our health, fluoride should be taken in the proper amount. Past comprehensive reviews of the safety and effectiveness of fluoride in water have concluded that water fluoridation is safe and effective. Fluoride is present naturally in most water at a very low level, and more than 170 million people on public water systems in the United States enjoy the benefits of having their water adjusted to the optimal level (0.7–1.2 mg/L, or 0.7–1.2 parts per million [ppm]) for preventing tooth decay.

Some water has naturally occurring fluoride at levels much higher than the optimal. A recent report, *Fluoride in Drinking Water: A Scientific Review of EPA's Standards* from the National Research Council (NRC), released on March 22, 2006, addresses safe maximum fluoride levels. The report addresses the safety of high levels of fluoride in water that occur naturally, and does not question the use of lower levels of fluoride to prevent tooth decay.

This new report was prompted as part of a routine, periodic review by the Environmental Protection Agency (EPA), the federal agency that is responsible for all regulated contaminants in drinking water, including fluoride. As part of its congressionally authorized mission, to protect the health of the public, the EPA sets standards for safe drinking water. Drinking water can contain many minerals, compounds, and organisms, some of which are considered "contaminants" under EPA's regulations. There currently are 96 contaminants that are regulated under the Safe Drinking Water Act; fluoride is included as a naturally occurring mineral.

The purpose of the review of fluoride was to determine the adequacy of current guidelines set by the EPA on the maximum allowable concentration of fluoride in drinking water to protect children and others from adverse health effects. The National Research Council (NRC) Committee found that the current EPA maximum contaminant level goal (MCLG) of 4 milligrams of fluoride per Liter (mg/L) of drinking water should be lowered to better protect people from health risks associated with high natural fluoride levels. The report recommended that the EPA update its risk assessment in order to determine the appropriate level for the MCLG.

The NRC Committee evaluated many health effects that have the potential to be associated with fluoride in drinking water. The NRC concluded that only three adverse health effects warranted consideration in developing regulatory standards for high levels of fluoride in drinking water—severe enamel fluorosis from exposure to these high levels between birth to 8 years of age, and the potential risk for bone fractures and the more severe forms of skeletal fluorosis after lifetime exposure. Severe skeletal fluorosis is a rare condition in the United States.

This report is important for people living in areas with high concentrations of natural fluoride greater than 2 mg/L or 2 ppm. This represents approximately one half of one percent of the U.S. population. The EPA estimates that approximately 220,000 Americans receive water from public water systems with fluoride levels that are equal to or exceed 4 mg/L. The Committee concluded that people who consume water with this high fluoride content over a lifetime, when compared to people consuming water with 1 mg/L, are likely to be at increased risk for bone fractures. Another 1.4 million people in the United States drink water from community water supplies that have a natural fluoride level ranging from 2.0 mg/L to 3.9 mg/L. The Committee found that water at 2 mg/L or greater may put children 8 years old and younger at increased risk for severe enamel fluorosis, a condition that causes staining and pitting of the enamel surface of teeth. In

communities with fluoride levels greater than 2 mg/L, CDC recommends that parents and caregivers of children 8 years and younger should provide children with drinking water from an alternative water source. At levels less than 2 mg/L (equivalent to 2 ppm), the committee found that the prevalence of severe enamel fluorosis was very low (near zero).

The findings of the NRC report are consistent with CDC's assessment that water is safe and healthy at the levels used for water fluoridation (0.7–1.2 mg/L). CDC reviews the latest scientific literature on an ongoing basis and maintains an active national community water fluoridation quality assurance program. CDC promotes research on the topic of fluoride and its effect on the public's health. CDC's recommendation remains the same—that community water fluoridation is safe and effective for preventing tooth decay. Water fluoridation should be continued in communities currently fluoridating and extended to those without fluoridation.

CDC has previously recommended steps to prevent moderate and severe enamel fluorosis. These recommendations were made in the August 17, 2001, *MMWR* report, *Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States* and can be found at http://www.cdc.gov/OralHealth/waterfluoridation/guidelines/index.htm. In addition to using an alternate water source for children 8 years and younger if the primary drinking water source has naturally occurring fluoride above 2 mg/L, these recommendations include: seeking professional advice on use of fluoride toothpaste for children younger than 2 years; using a pea-sized amount of fluoride toothpaste and supervising toothbrushing for children younger than age 6; prescribing fluoride supplements judiciously; and using fluoride mouth rinses appropriately.

Consumers wishing to know the fluoride concentration in their water can contact their local water utility, or local, county or state health department. Currently, 32 states provide information on water systems that is available to the public through the My Water's Fluoride section of the CDC Web site.

Date last reviewed: 07/25/2007
Content source: Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion

SENES Oak Ridge Inc.
Center for Risk Analysis
F. Owen Hoffman, Ph.D., President

Specialists in Energy, Nuclear and Environmental Sciences.
Custom Applications in Human Health and Ecological Assessment.

May 2, 2006

Daniel G. Stockin, MPH
Senior Operations Officer
The Lillie Center, Inc.
P.O. Box 1951
Brentwood, TN 37024

Dear Mr. Stockin,

Thank you for your interest in the recent National Research Council report on the toxicology of fluoride; as you know I had the privilege of serving on the committee that prepared this report. As a resident of Tennessee for 25 years, I appreciate your concern regarding the significance of the NRC report for water districts in Tennessee that are evaluating the safety and desirability of starting or continuing water fluoridation.

As you are aware, the NRC report did not evaluate the safety or benefits of water fluoridation, which were outside the scope of our committee's assignment. However, we also did not say that the practice of fluoridation is safe or that fluoride concentrations in water of 0.7-1.2 mg/L are safe—we did not evaluate that. We did specifically address the safety of the Maximum Contaminant Level Goal (MCLG) of 4 mg/L, and we concluded, unanimously, that the MCLG is not protective of human health. We said that the MCLG should be lowered, but we did not derive or suggest a new value for the MCLG.

Our conclusion that the MCLG of 4 mg/L is not protective was based largely on health effects that have long been considered specific to fluoride and significant enough to warrant protection, namely dental fluorosis and skeletal fluorosis. We parted ways with previous reviews of fluoride by saying that severe dental fluorosis is an adverse health effect, not merely a cosmetic effect, that stage II as well as stage III skeletal fluorosis is an adverse health effect, and that a fluoride concentration of 4 mg/L is likely not protective with respect to an increased risk of bone fracture. We indicated that at 2 or 4 mg/L, bone fluoride concentrations can reach the ranges historically associated with stage II and III skeletal fluorosis. We were not able to rule out a carcinogenic effect of fluoride. We reported that fluoride exposure is plausibly associated with a number of other health effects, including neurotoxicity, gastrointestinal problems, and endocrine problems, and that even though these effects are not necessarily specific to fluoride exposure, the associations cannot be ruled out and need further study.

For dental fluorosis, skeletal fluorosis, and risk of bone fracture, the committee considered studies in which populations were exposed to concentrations of fluoride in drinking water of around 4 mg/L; because there were sufficient studies at the exposure level of interest, we did not

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Attachment (16) two pages

examine the whole range of possible fluoride exposures. From those studies we concluded that 4 mg/L is not protective of those effects; only when the fluoride concentration in water is below 2 mg/L does the prevalence of severe dental fluorosis approach zero. For some of the other health effects mentioned above, the committee examined studies over a wider range of exposures, depending on what information was available. Some of those studies do include exposure levels that would be associated with water fluoride concentrations of around 1 mg/L. The committee also provided a very thorough analysis of overall fluoride exposures in the U.S., which are largely driven by drinking water and beverages made with tap water. We identified population subgroups who are at higher risk than usual of problems due to fluoride exposure, due to factors such as very high water consumption rates or increased retention of fluoride in the body.

I personally feel that the NRC report is relevant to many aspects of the water fluoridation debate, even though the committee did not directly address water fluoridation, in terms of either risks or benefits. For instance, the report discusses the wide range of drinking water intake among members of the population, which means that groups with different fluoride concentrations in their drinking water may still have overlapping distributions of individual fluoride exposure. In other words, the range of individual fluoride exposures at 1 mg/L will overlap the range of individual exposures at 2 mg/L or even 4 mg/L. Thus, even without consideration of differences in individual susceptibility to various effects, the margin of safety between 1 and 4 mg/L is very low. The report also discusses a number of health effects plausibly associated with fluoride exposure that should be considered in any future risk assessment for fluoride, besides the effects that have historically been attributed to fluoride. Several issues pertaining to use of silicofluorides in municipal water are brought up, although it was outside the committee's scope to address them in detail. Recent information provided on the relationship between outdoor temperatures and drinking water consumption suggests that the historical guidelines for setting water fluoride levels should be revisited. The report attempts to draw together much of what is known about the effects of fluoride exposure on human health and to identify the sizeable areas that are still not fully understood, for example, the molecular mechanisms by which fluoride exerts its effects.

I encourage you to read the report yourself, and to encourage your contacts at the various water districts to read it. I hope that you and your contacts will feel free to call me or send me an e-mail if I can be of any further help to you.

Sincerely,

Kathleen M. Thiessen, Ph.D.
Senior Scientist
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