February 14, 2011

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U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
Community Water Fluoridation Comments
Division of Oral Health
National Center for Chronic Disease Prevention and Health Promotion
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Submitted to: CWFcomments@cdc.gov

Subject: Proposed federal cap on fluoride in water will not protect public health

Comments on proposed HHS recommendation for fluoride concentration in drinking water for prevention of dental caries

Dear Dr. Koh:

The Environmental Working Group applauds the U.S. Department of Health and Human Services proposal, announced January 7 2011, to reduce the recommended maximum fluoride in drinking water from 1.2 parts per million (ppm) to 0.7 ppm, a 42 percent decrease.

Yet we have found that significant body of scientific evidence supports an even more dramatic reduction to protect the health of infants, children and others who are most vulnerable to the surprising array of health problems associated with this common water additive. We urge that you substantially reduce your recommended limit for fluoride in tap water in light of these facts.

Nearly 200 million Americans drink tap water containing fluoride added by water utilities, because of fluoride's reported ability to help reduce tooth decay (CDC 2008). But ingested fluoride can damage the teeth as well, at close to or the same concentrations once thought to protect against cavities.

In 2006 the National Research Council, among the nation's most prestigious scientific advisory bodies, called for a reassessment of the safety of fluoride in drinking water. It advised setting health-based upper limits to prevent fluoride-induced tooth and bone problems, including bone fractures, skeletal fluorosis, a painful sometimes crippling condition, and tooth enamel pitting and staining, known as dental fluorosis (NRC 2006).

The council also noted an emerging body of science that implicates fluoride in other serious health problems, including neurotoxicity, hormone disruption and the rare bone cancer osteosarcoma.

Since the vast majority Americans drink tap water with added fluoride and because researchers are constantly developing more evidence of fluoride's toxic effects, your department's efforts to reduce Americans' exposure to excessive fluoride are welcome and overdue.

As you know, the Environmental Protection Agency is also making an effort to reduce fluoride exposures. On January 7, the EPA announced that it had completed a new fluoride risk assessment and launched a review to determine whether its drinking water regulations for fluoride should be tightened. In a related announcement on January 10, the EPA granted a 2004 petition filed by several public health organizations, including the Environmental Working Group, to end the use of a fluoride-based pesticide. The EPA's action was based on new exposure assessment which found that some children are already ingesting unsafe levels of fluoride from fluoridated tap water alone; if they consumed yet more fluoride from pesticide-coated food, they would be well past the safe limit.

Yet government actions to date may not be sufficient. EWG urges you to lower your proposed upper limit for fluoride in tap water and to complete your proposal swiftly, for these reasons:

- **Infants and children drinking water with fluoride at the new HHS-proposed limit of 0.7 ppm will be exposed to more fluoride than the EPA deems safe**. It is unacceptable for HHS to recommend exposing children to unsafe amounts of fluoride.
  - Up to 21 percent of infants could be overexposed to fluoride at HHS's proposed new limit. This calculation is based on EWG's analysis of actual amounts of water consumed by babies in their first year of life, as reported by the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey (CDC 2010), relative to EPA's new proposed safe amount, the reference dose (RfD), of 0.08 milligrams of fluoride per kilogram of body weight per day (EPA 2011a; EPA 2011b).
  - EPA's own risk assessment finds that more than 10 percent of children between the ages of 6 months and 6 years who drink fluoridated water will ingest potentially unsafe amounts during a critical period of bone and tooth development (EPA 2011b).

- **It is likely that many more Americans than EPA estimates risk consuming excessive fluoride.** Because the RfD proposed by EPA (2011a) examines only adverse dental effects of fluoride or the other risks of fluoride toxicity, the truly safe dose of fluoride would be likely much lower than EPA's current estimates. Furthermore, EPA's assessment contains certain shortcomings that, if remedied, would demonstrate that fluoride risks occur at smaller doses and that greater numbers of people are being overexposed to the chemical. Among them:
  - EPA's new proposed reference dose accounts only for severe dental fluorosis, and fails to consider the full range of health problems associated with fluoride. EPA has failed to address evidence from recent research findings that associates fluoride with bone cancer, neurotoxicity and hormone disruption (see attachment to this letter for further detail).
  - EPA has failed to include any safety margin (uncertainty factor) in its proposed reference dose. It has not recognized that many aspects of fluoride toxicity, especially neurotoxicity and endocrine toxicity, are not yet sufficiently understood and that significant data gaps exist in the published literature even on well-studied effects such as dental fluorosis. For

example, the 1942 study on which EPA bases its reference dose was based on only white children (Dean 1942). More recent research indicates that other racial and ethnic groups, including black children, may be more vulnerable than whites to fluoride damage. (Martinez-Mier 2010).

- Many groups besides infants and children may be vulnerable to health problems arising from excessive exposure to fluoride. These include diabetics, athletes and people with kidney disease. It is not clear that HHS has considered the safety of these individuals as it has crafted its guidelines.
- Concerned that children and adults who drink large amounts of water are exposed to fluoride above the current reference dose, three NRC committee members and an EPA scientist proposed a revised drinking water standard of "at most" 0.4 ppm, or 43 percent lower than the HHS proposal (Limeback 2007).

- **Proven alternatives to tap-water fluoridation exist, including fluoride-containing toothpaste and other dental care products.** Benefits of toothpaste and other topical applications of fluoride are clear. Tap water fluoridation, however, is an entirely different matter. As they drink water, people ingest all the fluoride it contains. The chemical then circulates throughout the body. The European Union's Scientific Committee on Health and Environmental Risks (SCHER) recently reviewed water fluoridation and drew a conclusion far different from that of HHS, observing that there was "no obvious advantage" for water fluoridation, compared to toothpaste and other topical applications. A key study cited by HHS to justify water fluoridation reached a similar conclusion but HHS appears to have misinterpreted it (Griffin 2007). This study, Centers for Disease Control and Prevention Division of Oral Health review of fluoride found that exposure to fluoride, whether in water or toothpaste – reduces cavities by about 25 percent (Griffin 2007).

Tens of millions of children at crucial developmental stages are exposed daily to fluoride in tap water. Adults also face substantial daily exposures to this chemical. The potential risks to tooth and bone development and other serious toxicities are unacceptable when fluoride can be applied topically with greater safety.

We urge you to act expeditiously to lower the proposed maximum limit of fluoride in tap water, to expand research efforts to determine the benefits and toxicity of fluoride and to intensify your efforts to educate the public on the proper use of toothpaste and other topically-applied fluoride treatments.

Sincerely,

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ATTACHMENTS

Fluoride Policy and Toxicity – Detailed Comments on HHS Fluoride Proposal
Environmental Working Group
February 2011

References

ATTACHMENT

Fluoride Policy and Toxicity – Detailed Comments on HHS Fluoride Proposal

Washington, D.C.
February 2011

Environmental Working Group is a non-profit public health, environmental research and advocacy organization based in Washington, DC and Oakland, Calif. Our staff scientists conduct research and analysis on an array of public health and environmental issues including chemical contamination of food, water, consumer products and the environment. We are writing to offer technical analysis in support of the Department of Health and Human Services proposed guidance to reduce fluoride levels in drinking water to a maximum of 0.7 mg/L, the lowest end of the current recommended range for fluoridation (0.7-1.2 mg/L) (HHS 2011). This key step, announced January 7, 2011, represents an overdue action by the federal agencies to modernize water fluoridation guidelines.

EWG supports a coordinated federal effort to ensure that cumulative fluoride exposures for Americans are sufficient to strengthen teeth but do not harm health. The benefits of topical fluoride in dental treatments or toothpaste are clear. The fluoride is not intended to be ingested. Tap water fluoridation, however, is an entirely different matter because the dental benefits appear marginal in light of the most recent science. Almost all of the fluoride exposure is due to ingested fluoride, via water or food.

The perspective of the European Union health agency, European Commission Directorate-General for Health & Consumers Scientific Committee on Health and Environmental Risks (EU SCHER), differs from that of the HHS. It concludes that there are no benefits of fluoride ingestion over topical application (EU SCHER 2010) since, as demonstrated by numerous studies, anti-caries benefits of fluoride treatment are limited to its contact with the surface of the teeth (Aoba 2002, Limeback 1999).

As outlined in the US EPA's Dose-Response Analysis for Non-Cancer Effects, when water fluoridation is the chief strategy for dental protection, there is an incredibly slim margin between what HHS considers to be the recommended intake for caries protection and the level that results in moderate or serious fluorosis in a fraction of susceptible children (EPA 2011a). Fluoride provided through topical treatments can be targeted by age and largely averts systemic circulation, associated concerns for bone development, and potential impacts to the endocrine system, thyroid, and neurodevelopment.

Evidence suggests that decreasing Americans' systemic exposure to fluoride could improve public health, particularly for infants and young children (Beltran-Aguilar 2010). Both EPA and the EU SCHER find a strong potential for excessive fluoride exposure from treated water alone for formula-fed infants and young children (EPA 2011b, EU SCHER 2010). The EU concludes that "scientific evidence for the protective effect of topical fluoride application is strong, while the respective data for systemic application via drinking water is less convincing" (EU SCHER

2010). EWG is particularly concerned that EPA's determination of a safe intake for fluoride includes no modifying factors to account for individual susceptibility or the uncertainties in the study used to derive the risk value for dental severe fluorosis.

EWG urges HHS to further and substantially reduce the proposed recommended limit for fluoride in tap water in light of current science and recognized gaps in the understanding of the full range of fluoride toxicity.

We note five significant shortcomings in current HHS and EPA fluoride policies and assessments that must be remedied if public health is to be protected:

- **HHS must establish its proposal based on an independent, updated risk analysis and benefit analysis.** In EPA's new risk assessment (on which the HHS bases its latest proposal) EPA dismissed data that suggested that maximum daily fluoride intakes should be below the current but outdated 1997 dietary guidelines of the Institute of Medicine that promote fluoride for dental protection (EPA 2011a). In any standard "risk-benefit" analysis, risks and benefits must be assessed independently, which EPA has not done. EPA's toxicity assessment also fails to use traditional uncertainty factors to assure that public exposures are safely below the levels that may cause harm

- **HHS must reduce its proposed maximum limit for fluoride in drinking water in light of the numerous gaps and deficiencies in EPA's toxicity assessment on which the HHS proposal is based.**

- **HHS currently proposed reduction of fluoride levels in water will not protect young children and other sensitive groups from unsafe levels of fluoride ingestion.**

- **Water fluoridation guidelines should take into account the fact that fluoride ingestion is not necessary to obtain reported anti-caries effects.**

- **HHS and EPA guidance and regulations should consider the potential toxicity of fluoride to bone, neurodevelopment and hormonal systems, and an association between fluoride exposure and osteosarcoma.**

Details and rationale for these recommendations are provided below.

1. Health agencies must fully assess fluoride risks independent of dental benefits.

The HHS recommendation to lower fluoride levels in water is based on concerns of fluoride toxicity, and EWG is concerned that the EPA toxicity assessment is not sufficiently protective. When assessing the risk of fluoride toxicity EPA intentionally chose model inputs that would justify the continued use of water fluoridation instead of a proper and protective assessment of potential health risks of fluoride ingestion.

The Institute of Medicine's 1997 dietary recommendations state that daily fluoride intake should be at least 0.05 mg fluoride per kilogram of bodyweight (mg/kg-day) for dental caries prevention (IOM 1997). When evaluating fluoride toxicity, EPA chose not to consider data that would raise concerns about the IOM guideline, and indeed justified its final maximum safe exposure level (or "reference dose") of 0.08 mg/kg-day as one that assures a "reasonable difference in exposure between it and the IOM [guideline]" (EPA 2011a). Given that fluoride ingestion does not appear to be necessary for protecting teeth (as discussed in detail below), federal agencies should clearly evaluate the risks of fluoride ingestion independently of presumed dental benefits.

2. HHS must reduce its proposed maximum limit for fluoride in drinking water in light of the numerous gaps and deficiencies in EPA's toxicity assessment on which the HHS proposal is based.

HHS cannot assure the safety of water fluoridation of 0.7 ppm because EPA's toxicity assessment is not sufficiently protective for the entire population. EPA's reference doses for toxic chemicals traditionally incorporate a safety factor to account for uncertainties in our understanding of toxic effects, weaknesses in key studies and the fact that people vary widely in their sensitivity to toxic chemicals. Federal agencies are highly invested in water fluoridation, and we believe this may have influenced EPA to deviate from its standard practices of risk assessment. The 2011 non-cancer toxicity assessment did not employ a safety factor when calculating a reference dose for fluoride, a highly unusual step reserved for very well studied pollutants. EWG strongly advises HHS and EPA to reduce fluoride exposures in order to provide greater protection against dental fluorosis and other adverse effects of fluoride, particularly based on the following shortcomings in EPA's risk assessment:

- The 1942 Dean study used to evaluate determine the risk of fluorosis based on drinking water studied only white children (Dean 1942). Recent studies show clear differences in fluoride exposure and elevated rates of dental fluorosis for African American children relative to white children (Martinez-Mier 2010). EWG strongly advises HHS and EPA to use an uncertainty factor greater than 1 so as to fully account for individual susceptibility to fluorosis.

- The Dean study did not collect water ingestion information from individual study participants, leaving EPA to make crude assumptions about typical drinking water intake for individuals with fluorosis. This introduces another source of potential uncertainty about the inter-individual variation in sensitivity to fluorosis.

- Three NRC committee members and one EPA scientist proposed a revised drinking water standard of "at most" 0.4 ppm (Limeback 2007). Their method accounted for stage II skeletal fluorosis, dental fluorosis, and bone fractures. By applying very modest safety margins from 1 to 10 to the "no effect" doses reported or estimated for the above effects, the authors calculated health-based limits of from 0.1 to 0.33 ppm fluoride in tap water.

3. HHS currently proposed water level of 0.7 ppm will not protect young children and other sensitive groups from unsafe levels of fluoride ingestion.

Even with a weak assessment of fluoride toxicity, EPA still concludes that "it is likely that some children 8 and younger are exposed to too much fluoride at least occasionally while their teeth are forming because of their high fluoride intake relative to their body weight and/or because of high natural levels of fluoride in their local drinking water" (EPA 2011b).

Estimates of fluoride ingestion vary widely, but all assessments identify formula-fed babies as at a particular risk for overexposure (EU SCHER 2010, EPA 2011b). In the first 3 months of life formula fed babies will drink nearly 10 times as much water as an adult does, on a bodyweight adjusted basis (EPA 2004). Using individual formula and bodyweight data from CDC's NHANES study data (CDC 2010) we estimate that about 20 percent of babies 0 to 12 months will exceed EPA's reference dose based on water alone, in cities where water contains the HHS-recommended level of 0.7 ppm fluoride[1].

EPA's 2011 exposure analysis does not report findings for formula-fed babies as a group. But EPA data suggests that babies at the 90th percentile for water consumption could be at the reference dose based on water intake alone, suggesting that the 10 percent with even greater water consumption would exceed the RfD. EWG calculates that a 6 month old boy of average weight, at the 90th percentile of water consumption would ingest fluoride levels equivalent to the reference dose from fluoridated water alone. Babies at this age are beginning to eat other foods that would provide an additional source of fluoride.[2]

Older children may receive too much fluoride from water or dental treatments. EPA's exposure modeling suggests that more than 10 percent of and young children (ages 1 to 6 years) who drink of water with average amounts of fluoride will exceed the reference dose (EPA 2011b). However we note that children who have higher than average intake of fluoride from other sources will also exceed this guideline. This includes children who live in areas with high levels of naturally-occurring fluoride in water, those who brush their teeth more than once daily, who ingest more than average amounts of toothpaste, or who use any mouthwash or fluoride supplements (EPA 2011b). Additional subgroups of concern include people who drink lots of water (i.e. pregnant women, diabetics and athletes), and people with kidney disease who accumulate more fluoride in their bones.

EPA discounts the magnitude of these effects by stating that only 0.5 percent of overexposed children will develop severe fluorosis. However an estimated 40 percent of American adolescents have detectable dental fluorosis (Beltran-Aguilar 2010). Effects range from minor

[1] We examined infant water consumption including any water used to mix formula for babies 0 to 12 months using data from CDC's NHANES data for 2007-2008. We calculated a fluoride dose based on that individuals' body weight and fluoride concentrations of 0.7 ppm

[2] EPA estimates that children age 6 months to 1 year in the 90th percentile for water consumption take in 0.84 mg/day of fluoride from water at 0.87 ppm. We calculate this to be 0.68 mg/day when water has the HHS guideline of 0.7 ppm. Average bodyweight for a 6 month-old boy is approximately 8 kg. 0.68 mg/day / 8 kg = 0.085 mg/kd-day

discoloration to severe pitting and weakening of tooth enamel. EWG urges that every attempt be made to minimize the risk of fluorosis as a precautionary measure, since fluoride levels sufficient to cause changes in tooth structure could have similar, subclinical effects on bone, as well as other poorly characterized toxicological concerns. The EU notes that no threshold has been identified for dental or bone fluorosis (EU SCHER 2010).

4. Water fluoridation guidelines should take into account the fact that fluoride ingestion is not necessary to obtain reported anti-caries effects.

We urge HHS to consider the benefits and drawbacks of water fluoridation in comparison to other methods of fluoride application. The federal agencies' action on fluoride is based on an assurance that fluoride risks are concentrated on a small subgroup of children who are at an elevated risk of severe fluorosis. We question the comprehensiveness of this assessment, and also believe that these are unacceptable risks since sufficient fluoride can be delivered to teeth with methods that result in lesser system ingestion.

A CDC review of fluoride effectiveness found comparable anti-caries benefits for fluoride deliver via topical treatment or water fluoridation (Griffin 2007). Studies find that the sustained use of a pea-size amount of fluoridated toothpaste achieves substantial reduction in dental caries, with minimum risk of fluorosis. A 2010 study of children drinking unfluoridated water found a 40 percent reduction in caries with no detectable fluorosis in middle school aged children living in Bergen Norway. On the contrary children given fluoride lozenges had caries reduction but a 6.58-fold increase in mild to moderate enamel fluorosis (Pendrys 2010).

Fluoride benefits vary by age. There is no evidence to support fluoride exposure for the developing fetus and infants age 0 to 6 months (Leverett 1997, ADA 2011). On the contrary exposures during this period may be harmful. Most studies as well as exhaustive reviews by EPA and the European SCHER find that formula-fed babies in regions with water fluoridation ingest too much fluoride over their first year of life (Hujoel 2009, EPA 2011, EU SCHER 2010). For this reason parents should be cautioned to mix infant formula with fluoride-free water, although this practice is uncommon.

In the United States approximately 95 percent of toothpaste sold contains fluoride, making this a common and effective method for delivering fluoride to teeth. By weight, toothpaste has approximately 1,500 times more fluoride than water with the HHS guideline (~1,000 ppm vs 0.7 ppm), however EPA's exposure assessment suggests that even accounting for improper uses far less fluoride from toothpaste will reach systemic circulation compared to the amount ingested in water (EPA 2011b).

The European Union differs from the HHS, in that it finds that there is no obvious advantage to water fluoridation compared to topical treatment for adults and children whose permanent teeth are in (EU SCHER 2010). Thus topical treatments could be a better delivery mechanism for fluoride when the impacts to teeth bone and other types of toxicity are fully accounted for.

5. HHS and EPA guidance and regulations should consider the potential toxicity of fluoride to bone, neurodevelopment and hormonal systems, and an association between fluoride exposure and osteosarcoma.

High fluoride concentration in drinking water endangers the health of millions of people worldwide, especially in certain areas of India, China and Africa. According to the World Health Organization, chronic ingestion of large amounts of fluoride has been linked to a variety of adverse health effects, most notably dental problems and crippling skeletal fluorosis (WHO 2006). Fluoride stimulates the division and growth of osteoblasts, a cell type responsible for bone formation; exposure of bone cells to fluorides also results in generation of reactive oxygen species that are toxic to cells (Gazzano 2010). Clinically, fluoride effects on the bone tissue result in increased bone density, which leads to joint stiffness and pain as well as a higher risk of bone fractures (NRC 2006).

Overall, advanced skeletal fluorosis and its associated health consequences appear to be relatively rare among residents of North American and Western European countries. However, a recent Iowa Fluoride Study/Iowa Bone Development Study demonstrated that there is some association between exposure to fluoride from multiple sources, including fluoridated water, and elevated bone mineral density in young boys (Levy 2009), indicating that bone fluorosis risks in the US remain a concern and should be taken into account in fluoride risks assessment. It is well established that bone fluoride concentrations increase with both magnitude and length of exposure and there has been no published evidence for a threshold for adverse effects on bone structure at lower exposures to fluoride (EU SCHER 2010). Research is needed to clarify any impacts to bone development caused by fluoride concentrations at or below 1 ppm.

Furthermore, the National Research Council report observed that, "because fluoride stimulates osteoblast proliferation, there might be a theoretical risk that it might induce a malignant change in the expanding cell population" (NRC 2006). This hypothesis is supported by epidemiological studies that found an elevated risk of osteosarcoma, a rare but deadly bone cancer, in young boys and teenagers exposed to fluoridated water (Eyre 2009), as reviewed below.

Link between fluoride and osteosarcoma

Three high quality, targeted epidemiological studies found that exposure to fluoride in tap water during the mid-childhood growth spurt between ages 5 and 10 increases the incidence of osteosarcoma in boys ages 10 through 19 (Bassin 2006, Cohn 1992, HHS 1991). A study published in 2009 found that mean serum fluoride concentration was significantly higher in patients with osteosarcoma (Sanhu 2009). In contrast, epidemiological studies that have failed to find this association do not examine the relationship between age of exposure to fluoride and the incidence of bone cancer in young males (Chilvers 1983, Kinlen 1975, Moss 1995, Operskalski 1987).

The link between fluoride in tap water and bone cancer in boys is supported by significant biological evidence. Half of ingested fluoride is deposited in bones, where it acts as a mitogen that stimulates cellular proliferation in the growing ends of the bones where osteosarcoma occurs

(NRC 2006). Fluoride's capacity to induce DNA damage, including sister chromatid exchange, suggests that it can cause genotoxic effects in bone cells where it is actively deposited (Gruber 1991; Whitford 1996). Animal studies add further credence to the potential link between fluoride and bone cancer in males; 2 animal cancer bioassays conducted with fluoride both show rare bone tumors, many of which were malignant, in male test animals (Maurer 1990; Maurer 1993).

Fluoride neurotoxicity

Multiple research groups around the world convincingly demonstrated fluoride neurotoxicity in studies with laboratory animals where fluoride causes memory impairment, structural and biochemical changes and neurodegeneration (Basha 2011, Bhatnagar 2002, Chouhan 2008, Grandjean 2006, Mullenix 1995, Pereira 2011, Zhu 2011). In line with this experimental evidence, the question of fluoride's effects on the nervous system and behavior in people has been actively researched over the past two decades (NRC 2006). Reports from China, India, and Iran have found that children in high fluoride areas had significantly lower Intelligence Quotient (IQ) compared to children in low fluoride areas (Seraj 2006, Tang 2008, Trivedi 2007, Xiang 2003). These studies examined adjacent areas with drinking water sources naturally high or low in fluoride. The high-fluoride areas in these studies had fluoride concentration similar to some naturally fluoridated areas in the U.S., indicating the relevance of these findings to the U.S. public health. Of note, after reviewing the overall database on fluoride neurotoxicity, the NRC report concluded that the "consistency of study results appears significant enough to warrant additional research on the effects of fluoride on intelligence" (NRC 2006).

Hormone disruption

Summarizing the current state of the science, the National Research Council described fluoride as an endocrine disruptor with especially significant effects on the thyroid and parathyroid hormone function (NRC 2006). Effects of fluoride on the thyroid was first reported 150 years ago and fluoride has been historically used as a thyroid-suppressing medication for patients with Graves's disease and symptoms of hyperthyroidism (Galletti 1957, Gedalia 1963). Fluoride toxicity to the thyroid function in laboratory animals is also well documented (Wang 2009). In people, 10 epidemiological studies conducted between 1941 and 1999 found an association between endemic goiter (enlargement of the thyroid gland) and fluoride exposure in countries as diverse as India, South Africa, Kenya, England, and Nepal. Fluoride anti-thyroid effects appear to be especially severe in cases of iodine deficiency, a condition that is on the rise in the United States (NRC 2006).

In addition to targeting the thyroid, fluoride exposure may pose especial risk to the pineal gland, a part of the brain responsible for the production of melatonin and maintenance of day-night cycles, sleep patterns and other important physiologic functions. The pineal gland undergoes calcification with age and higher calcification is associated with decreased melatonin production (Mahlberg 2009). As with other calcifying tissues, the pineal gland accumulates fluoride: an aged pineal gland has 600 times more fluoride compared to the muscle tissue (Luke 2001). In animal studies, fluoride impact on the pineal gland caused lower melatonin production, earlier sexual maturation, and altered day-night activity cycle (Luke 1997).

Today, many people living in communities with fluoridated tap water are ingesting doses of fluoride that fall within the range of doses shown to alter thyroid function, elevate the levels of thyroid-stimulating hormone, calcitonin and parathyroid hormone, impair glucose tolerance and increase prevalence of goiter (NRC 2006). Hormonal effects may also underlie reported findings of fluoride reproductive and developmental toxicity (Freni 1994, Kumar 2010, Ortiz-Perez 2003). In general, studies of the health status of people in communities with water fluoridation primarily focused on effects such as dental fluorosis and the full scope of the potential adverse impact of fluoride on the endocrine system remains to be assessed.

Conclusion: Federal agencies must quickly enact measures to protect Americans from excessive fluoride and provide the public, water system operators, and dental professionals with clear information risks, benefits, and optimum dental care

The January 2011 HHS announcement and EPA scientific reviews are a welcome first step in reforming fluoride policies. As the NRC noted in 2006, the current drinking water standards of 2 and 4 ppm are clearly inadequate adequately (NRC 2006). Fluoride exposures at these levels pose excessive risks of severe dental fluorosis, as well as potential skeletal effects, hormone disruption, IQ deficits and other negative impacts to health.

The reduction in the target level of fluoride for public water systems to 0.7 ppm will reduce the potential for over-exposure, particularly for infants and young children. However given the scope of water fluoridation in the United States, EWG urges a more complete assessment of fluoride risks, as well as alternative methods of treating teeth. The European Union's review of the same body of evidence draws very different conclusions about the risk-benefit tradeoffs for fluoridation (EU SCHER 2010), and this view deserves careful consideration by US decision-makers.

Even with HHS' proposed reduction in the target range for water fluoridation, several subpopulations will remain at risk for excess fluoride. These include formula-fed infants who receive no dental benefit from fluoride exposure. Young children also exceed EPA's exposure guidelines in many cases, especially given widespread confusion about the proper use of fluoridated toothpaste for young children, especially those who cannot reliably rinse and spit excess toothpaste (EPA 2011b). Parents must be carefully advised to avoid fluoridated toothpaste for children under the age of 2 (FDA 2009), and that only pea-sized amounts of child-strength toothpaste should be used for older children. EPA notes that some subpopulations, including individuals with kidney disease, are more vulnerable to the effects of fluoride. Finally people who drink lots of tap water, and those who reside in regions with higher fluoride levels are at risk for excess fluoride intake regardless of their other dental habits.

Thank you for addressing the safety of current fluoridation practices, and for considering these comments.

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