Comments on the HHS recommendation released April 27, 2015

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In April 2015, the Department of Health and Human Services (HHS) released a new Public Health Service Recommendation for the fluoride concentration to be used in drinking water for prevention of dental caries (HHS 2015). The new recommendation of 0.7 mg/L (0.7 ppm) fluoride in drinking water replaces earlier temperature-based guidelines for fluoride concentrations ranging from 0.7-1.2 mg/L (0.7-1.2 ppm). The new recommendation was proposed in January 2011 and made official in April 2015.

A reduction in the fluoride concentration in drinking water for many (not all) locations in the U.S. is a step in the right direction and an admission that fluoride concentrations have been too high. However, as described in my February 2011 comments to HHS, the new recommendation is still inadequate in terms of protecting the health of the U.S. population, will not achieve the expected reduction in the nationwide prevalence of dental fluorosis, will not improve dental health, and maintains HHS in the position of recommending indiscriminate administration of a drug to the U.S. population, without individual evaluation of need, appropriate dose, efficacy, or side effects.

The proposed recommendation (January 2011) was based on a pair of EPA reports (EPA 2010a; 2010b; refs. 4 and 7 in HHS 2015). As detailed in my April 2011 comments to EPA, the EPA's new reference dose (RfD, 0.08 mg/kg/day) does not meet EPA's standards for a reference dose, in terms of protecting the human population, including sensitive subgroups, from deleterious effects. The new RfD is intended to protect against severe dental fluorosis, but it does not protect against many other "known or anticipated effects" (from EPA's definition of the MCLG[1], or health-based standard) which are likely to occur at lower exposures. EPA did not consider the documented associations of dental fluorosis with increased risk of adverse health effects (thyroid disease, decreased IQ, bone fracture). EPA inappropriately included an assumption of benefit in its risk assessment, preserving an intake of 0.05 mg/kg/day as desirable and excluding possible adverse health effects below an intake of 0.07 mg/kg/day, against the recommendation of one of EPA's external peer reviewers (EPA 2010c). EPA's exposure estimate excluded children up to 6 months old, even though these children, if fed formula prepared with fluoridated tap water, have the highest exposures with respect to body weight. EPA also failed to include sensitive population subgroups, such as those with high water intake, impaired renal function, or exposure

[1] The Maximum Contaminant Level Goal (MCLG) is a non-enforceable health goal which is set at a level at which no known or anticipated adverse effect on the health of persons occurs and which allows an adequate margin of safety (EPA 2009). For fluoride, both the MCLG and the enforceable standard (Maximum Contaminant Level, or MCL) are set at 4 mg/L (4 ppm).

to other sources of fluoride. EPA's characterization of uncertainty was inadequate in a number of respects.

The 2015 Public Health Reports document just released (HHS 2015), describing the HHS final recommendation, continues to be based on the 2010 EPA reports (refs. 4 and 7), without addressing any of the concerns listed above. (Presumably HHS would have cited revised EPA reports if those exist.) The HHS report refers to EPA's estimates of fluoride intake among "young children" (p. 2) without mentioning EPA's failure to include the youngest children. The HHS report refers (p. 3) to EPA's finding that drinking water accounts for 40-70% of total fluoride intake among children aged 6 months to 14 years, but fails to note that for bottle-fed infants, tap water could account for at least 80-90% of total fluoride intake. HHS three times (pp. 3, 4, 7) refers to children being at risk for development of fluorosis from birth through 8 years of age, without mentioning that EPA's reference dose, at best, is not protective for children younger than 6 months old. In addition, the HHS conclusion (p. 11) that other sources of fluoride besides drinking water contribute to dental fluorosis downplays the fact that fluoridated tap water is by far the largest single source of fluoride for most people, and elimination of that source would be the single most effective means of preventing dental fluorosis and any other adverse health effect of fluoride.

HHS (2015) describes the comments received from 19,300 persons and organizations, but specifically says (p. 6) that they "did not identify compelling new information to alter its assessment." No changes appear to have been made. However, every one of my comments to HHS in 2011 still holds, and more recent publications (e.g., Choi et al. 2012; 2013; 2015; Mullenix 2014; Peckham et al. 2015; Malin and Till 2015; Ko and Thiessen 2015) all call into question various parts of the HHS document.

HHS (2015) apparently has not considered any "compelling" old information either. As described in my 2011 comments to HHS, the paper that HHS uses as the basis for its new recommendation of 0.7 mg/L (Heller et al. 1997, based on 1986-1987 survey data) contains data that indicate that the new recommendation will not have a large impact on the fluorosis prevalence in the U.S. population and that also show no significant difference in caries experience with respect to water fluoride concentration. Apart from questions about what took so long for HHS to make a new recommendation based on data from 1986-1987, the data (as opposed to the text of Heller et al. 1997) do not support the HHS recommendation. (EPA's analysis was based on even older literature.)

It is interesting, given the HHS statement that there is little difference in children's water intake (now) between hot and cool parts of the U.S., that the HHS recommendation proposes to bring the concentration in the northern states down by as much as 0.5 mg/L, while making little or no change for the southern states. HHS has not provided data indicating that dental fluorosis is worse in northern states than southern states. HHS does state that nearly all fluoridated systems in 2010 used concentrations between 0.8 and 1.2 mg/L, without mentioning that in some areas (parts of Arizona, Florida, and Texas), the concentration should already have been 0.7 mg/L; some (or many?) systems were fluoridating too high by the old recommendations. (As an aside, probably many localities that have been fluoridating at 1.0 mg/L should have been using lower concentrations, based on the old recommendations.)

HHS does discuss the use of fluoridated water in preparation of infant formula (p. 7), admitting that this leads to an increased chance of fluorosis. However, rather than acknowledging that this

means that fluoridated water is not "safe" for all members of the population, HHS puts the burden on parents to obtain "guidance" from the CDC or ADA websites and to obtain alternative water for preparation of the formula. This is inappropriate and impractical, especially given that use of tap water for preparation of infant formula is more likely to be associated with lower socioeconomic status (lower income, less education). Reconstituted formula is typically cheaper than ready-to-feed formula, and parents mixing their own formula are less likely to be able to afford alternatives to tap water. In addition, many low income women do not breast-feed their infants.

The HHS report does not mention sensitive subgroups, e.g., those with high water intake, impaired renal function, or exposure to other sources of fluoride. These groups were also left out of the EPA reports on which the HHS recommendation is based.

HHS fails to mention (pp. 2, 6) that the NRC's 2006 report specifically stated that EPA's health-based standard[2] of 4 mg/L is not protective (NRC 2006). HHS inappropriately "accepted" the NRC report as "the summary of hazard." The NRC report specifically says that it has not evaluated or made judgments about the benefits, safety, or efficacy of artificial water fluoridation. For many health endpoints, the NRC report considered only or primarily the evidence concerning safety at the level of EPA's MCLG (4 mg/L). The NRC report concluded that 4 mg/L is not safe—not protective of human health—without identifying a "safe" level. This conclusion was based on the best-known (and hardest to deny) effects: dental fluorosis, skeletal fluorosis, and increased risk of bone fracture. However, for some endpoints, the whole dose response range (all available information) was considered, and the NRC report clearly shows overlap between expected exposure levels of the U.S. population (especially sensitive subgroups) and average intakes that have been associated with some adverse effects. A concentration of 0.7 mg/L (the HHS recommendation) is not "substantially lower" (p. 6 of the HHS report) than the EPA's enforceable standard (4 mg/L) that the NRC concluded was not protective.[3] In addition, as noted previously, the HHS recommendation does not allow for sensitive subgroups and admittedly (p. 7) does not protect infants from dental fluorosis. The Surgeon General's Perspectives paper (Murthy 2015) that accompanies the HHS report also mischaracterizes the findings of the NRC report, failing to point out that the NRC found that 4 mg/L is not protective and claiming that 2-4 mg/L is "much higher"[4] than the 0.7-1.2 mg/L range in the 1962 fluoridation recommendations.

HHS fails to mention that caries rates have been declining independently of fluoridation. This has been documented or discussed by various authors (e.g., Diesendorf 1986; Colquhoun 1993; Ko and Thiessen 2015). Ko and Thiessen (2015) also point out serious flaws in CDC's analysis of the cost-effectiveness of water fluoridation and in several other papers used to support the HHS recommendation (e.g., refs. 21, 24, 27, 31, 32, 88 in HHS 2015). The economic analysis,

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[2] The health-based standard is the MCLG (see footnote 1).

[3] The new recommended concentration (0.7 mg/L) is less than a factor of 6 below the enforceable standard (4 mg/L), a level which the NRC concluded was not protective. A factor of 6 between "not safe" and "recommended" does not allow an adequate margin of safety even for people with average exposures, let alone for people with high exposures or impaired excretion.

[4] Between 4 mg/L and the previous recommended range of 0.7-1.2 mg/L there is a factor of 3.3-5.7. As described in footnote 3, this is an inadequate margin of safety between "unsafe" (4 mg/L) and "recommended" (0.7-1.2 mg/L). A range of 2-4 mg/L cannot responsibly be considered "much higher" than the then-recommended range of 0.7-1.2 mg/L or the new recommendation of 0.7 mg/L.

among other things, fails to include the cost of treating cosmetically objectionable dental fluorosis.

HHS defends the lack of randomized studies of the effectiveness of fluoridation (p. 5), while criticizing the quality of studies that found adverse effects (no "compelling new information," p. 6). However, HHS cites studies in support of its recommendation that have major shortcomings. For example, the osteosarcoma study (Kim et al. 2011, ref. 74) does not refute the earlier study (Bassin et al. 2006, ref. 73); Bassin et al. did an age-dependent analysis of fluoride exposure, while Kim et al. specifically say that "if risk [of osteosarcoma] is related to exposures at a specific time in life, rather than total accumulated dose, this metric [bone fluoride concentration] would not be optimal." Thus, by definition, Kim et al. could not refute Bassin et al. In addition, Kim et al. (2011) found "no significant association between bone fluoride levels and osteosarcoma risk," while also admitting that "the median age of controls was higher than that of cases" by more than a factor of two. For cases to have had similar bone fluoride levels as controls twice their age indicates that cases had to have had substantially higher fluoride exposures, a detail not admitted by Kim et al. (2011) or HHS (2015). One of "three recent ecological studies that found no association" between fluoridation and osteosarcoma (HHS 2015, pp. 7-8, ref. 76, referring to Comber et al. 2011) acknowledged that they could not evaluate the importance of age-specific exposure (i.e., they could not refute Bassin et al. 2006) and estimated that at least a 70% increase in risk of osteosarcoma would be necessary for it to have been detected in their study (i.e., Comber et al. could not have detected a 50-60% increase in osteosarcoma risk). HHS (2015) also cites Broadbent et al. (2015, ref. 86 in HHS 2015) as showing no association between fluoride exposure and IQ, without mentioning that the "fluoridated" and "nonfluoridated" groups probably had very similar total fluoride exposures (see Menkes et al. 2014 for further discussion of Broadbent et al. 2015).

In summary, while a step in the right direction, the new Public Health Service Recommendation for fluoride concentrations in drinking water is still not adequate in terms of protecting the health of the U.S. population.

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