

Fluoride in Drinking Water May be Dangerous to Children's Health

by Kenneth J. Warren

Our public health system encourages fluoride use to prevent cavities. Dentists advise patients with multiple occurrences of tooth decay to brush their teeth with more concentrated fluoride toothpaste, to take fluoride tablets, or to undergo fluoride treatments. Aware of the public perception that use of fluoride products combats tooth decay, manufacturers of toothpaste and mouthwash tout the benefits of fluoride in their products. And public health officials credit the addition of fluoride to drinking water with vast improvements in dental health, especially among populations that do not regularly visit dentists. The continuation of this practice, however, is now in doubt.

In our enthusiasm for the benefits of fluoride, we have minimized the risks that its use entails, particularly to children. Scientific studies have demonstrated that at certain concentrations fluoride may cause severe enamel fluorosis evidenced by discoloration of the teeth. Excessive exposure to fluoride also causes skeletal fluorosis associated with calcification of tendons and ligaments, osteosclerosis and skeletal deformities. Observation and research have revealed additional potential harms warranting rigorous scientific study.

In August 2024, the U.S. Department of Health and Human Services National Toxicology Program (NTP) partly filled this scientific gap. NTP undertook a systematic review of the scientific literature on the quality of evidence linking fluoride exposure to neurodevelopment and cognition effects. NTP's peer-reviewed Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopment and Cognition concluded that aggregate fluoride exposure from all sources in an amount equivalent to 1.5 mg/L in drinking water is consistently associated with lower IQ in children. NTP found the data to be insufficient to determine whether a fluoride level of 0.7 mg/L in drinking water would negatively affect children's IQ.

The uncertainty regarding whether 0.7 mg/L of fluoride in drinking water adversely affects children raises important questions of whether it is medically advisable, or even ethical, to add fluoride to public drinking water consumed by pregnant mothers and children. Fluoridization of drinking water in the United States began in 1945. In 1975, the U.S. Public Health Service (Service) set its recommended optimal concentration of fluoride in drinking water at 1.2 mg/L. Thereafter, faced with increasing evidence that fluoride causes adverse health effects, in 2006 the Service lowered the recommended optimal concentration to 0.7 mg/L of fluoride. This remains the Service's current recommendation. Recognizing that in some locations background levels of drinking water contain concentrations of fluoride that may exceed the 0.7mg/L "optimal" level, the U.S. Environmental Protection Agency (the EPA) has set a maximum contaminant level (MCL) of 4 mg/L and an unenforceable secondary MCL of 2 mg/L for fluoride in drinking water. The NTP Monograph should cause the EPA to reconsider its MCL.

The NTP Monograph likewise invigorates litigation challenging the addition of fluoride to drinking water. In 2016, Food and Water Watch, Inc. and other environmental groups and individuals petitioned the EPA pursuant to the Toxic Substances Control Act (TSCA) to examine whether fluoride poses an unreasonable risk of injury to health or the environment. In 1976, Congress enacted TSCA to regulate the safety of chemical substances and mixtures used in the United States. In 2016, Congress adopted the Lautenberg amendments to TSCA which, in part, require the EPA to regulate the manufacture or use of chemical substances that pose an unreasonable risk of harm to health or the environment. 15 U.S.C. Section 2605(a). Petitioners cited the Lautenberg Amendment in their request to the EPA to regulate fluoride.

The EPA denied the petition. Thereafter, plaintiffs commenced an action in the U.S. District Court for the Northern District of California seeking a determination that the government's prescribed optimal level of fluoridation presents an unreasonable risk of injury to the health of children. See 15 U.S.C. Section 2605(a) and 2620(b)(4)(B)(ii). As required by TSCA, the court performed a de novo review and considered, but did not defer to, the position of

the EPA. At trial, plaintiffs presented expert testimony and studies to demonstrate the link between cognitive impairment and fluoride ingestion. The court agreed, ruling that adding .07 mg/L of fluoride to drinking water poses an unreasonable risk of harm to children. The court ordered the EPA to initiate rulemaking to protect this susceptible group. See *Food & Water Watch v. United States Environmental Protection Agency*, 2024 WL 4291497 (N.D. Cal. Sept. 24, 2024). In its opinion, the court discussed the considerable body of studies and other evidence showing that the recommended fluoride levels pose a risk to children's health. The court utilized the EPA's established risk evaluation methodology which requires the risk assessor to evaluate the hazard posed by a chemical and the level at which a chemical poses the hazard. The assessor then compares the hazard level adjusted by safety factors to the exposure level. If this comparison reveals that the chemical poses a risk, the assessor evaluates whether the risk is reasonable. When performing its analysis, the court gave considerable weight to NTP's Monograph.

The court determined the plaintiffs satisfied the hazard assessment step of the risk evaluation by presenting scientific evidence showing that exposure to fluoride is associated with the adverse effect of reduced IQ in children. Evidence demonstrated these effects particularly in boys, even at exposure levels less than 1.5 mg/L. The court further found the "weight-of-the-scientific evidence" regarding fluoride's association with reduced IQ to be sufficient.

The court next identified the level at which fluoride ceases to be safe, *i.e.*, a "point of departure" or "hazard level." Because the total exposure of pregnant mothers to fluoride rather than solely fluoride in the drinking water causes adverse effects, the court expressed the hazard level based on maternal urinary fluoride rather than drinking water intake. Similarly, the court assessed the exposure levels of pregnant mothers by examining their maternal urinary fluoride levels. Recognizing that approximately half of the total fluoride intake comes from drinking water, the court found maternal urinary levels to be probative of fluoride from drinking water consumption.

The court next determined that a risk exists by comparing the hazard level with the human exposure level. To perform this comparison, the EPA's standard risk assessment methodology first requires applying safety factors, also called uncertainty factors, to the hazard level to ensure that exposure to the chemical is safe. Here the testimony showed that application of an uncertainty factor of 10 or 100 would be appropriate because, among other things, the relationship between fluoride intake and urinary concentrations may vary among individuals. The exposure level exceeded the hazard level adjusted by uncertainty factors and thus risk of cognitive harm to children exists.

In the ultimate step in the risk evaluation process, the court concluded that the risk is unreasonable. The risk of IQ reduction is severe and greater than the IQ loss the EPA has cited to support identifying other substances such as lead as posing an unreasonable risk. Exposure to fluoride is continuous, and approximately 200 million Americans drink water to which water purveyors have intentionally added at a concentration of 0.7 mg/L. Approximately two million pregnant women, and over 300,000 exclusively formula-fed babies are exposed to fluoridated water. These and all children under the age of seven are particularly vulnerable to fluoride exposure and are susceptible populations for TSCA purposes.

Based on these findings, the court concluded that the typical level of community water fluoridation in the United States, 0.7 mg/L, presents an unreasonable risk of injury to health. Following a judicial finding of unreasonable risk, TSCA requires the EPA to commence rulemaking to eliminate such risk by imposing requirements that may include, among others, mandating warnings, establishing permissible fluoride concentrations in drinking water, or banning fluoride distribution or use. See 15 U.S.C. Section 2605(a)(1)-(7). Preserving the benefits of fluoride use while eliminating the unreasonable risk to children may be a formidable task. It remains to be seen what action the EPA will take in response to the court's decision.

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