



**Fluoride Action Network**  
fluoridealert.org

## Federal Court Rules That Water Fluoridation Poses an “Unreasonable Risk” to Children

*The ruling requires the EPA to take regulatory action to eliminate the risk, in a decision that could end the use of water fluoridation chemicals throughout the U.S.*

**San Francisco, CA (September 24, 2024)** — After a precedent-setting 7-year legal battle in federal court, an historic ruling by the *United States District Court of the Northern District of California* has ordered the U.S. Environmental Protection Agency (EPA) to take regulatory action to eliminate the “unreasonable risk” to the health of children posed by the practice of water fluoridation.

The verdict is a significant loss for the EPA and the promoters of fluoridation like the American Dental Association and the US Centers For Disease Control because the court found that their claims of safety—made for over 75 years—were in fact not supported by evidence.

Senior Judge Edward Chen wrote, “the Court finds that fluoridation of water at 0.7 milligrams per liter (“mg/L”) – the level presently considered “optimal” in the United States – poses an unreasonable risk of reduced IQ in children...the Court finds there is an unreasonable risk of such injury, a risk sufficient to require the EPA to engage with a regulatory response.”

"In all, there is substantial and scientifically credible evidence establishing that fluoride poses a risk to human health; it is associated with a reduction in the IQ of children and is hazardous at dosages that are far too close to fluoride levels in the drinking water of the United States... Reduced IQ poses serious harm. Studies have linked IQ decrements of even one or two points to, e.g., reduced educational attainment, employment status, productivity, and earned wages."

The ruling did not specify exactly what measures must be adopted by the EPA, but under the Toxic Substances Control Act (TSCA), once the court rules that a chemical poses an unreasonable risk, the EPA is [obligated by law](#) to restrict or eliminate the risk.

Judge Chen described a range of options for regulating fluoridation, including banning it, but he warned, “One thing the EPA cannot do, however, in the face of this Court’s finding, is to ignore that risk.”

[\*\*READ THE FULL RULING\*\*](#)

**Here are some notable excerpts from the ruling:**

pg 3: There is little dispute in this suit as to whether fluoride poses a hazard to human health. Indeed, **EPA's own expert agrees that fluoride is hazardous at some level of exposure. And ample evidence establishes that a mother's exposure to fluoride during pregnancy is associated with IQ decrements in her offspring.**

pg 5: The pooled benchmark dose analysis concluded that a 1-point drop in IQ of a child is to be expected for each 0.28 mg/L of fluoride in a pregnant mother's urine. **This is highly concerning, because maternal urinary fluoride levels for pregnant mothers in the United States range from 0.8 mg/L at the median and 1.89 mg/L depending upon the degree of exposure. Not only is there an insufficient margin between the hazard level and these exposure levels, for many, the exposure levels exceed the hazard level of 0.28 mg/L.**

pg 5: Even if the toxicologically determined hazard level of 0.28 mg/L were deemed insufficiently substantiated, **evidence in the record still establishes with little doubt that fluoridated drinking water presents a risk of injury to health.**

6: **The EPA's default margin of error requires a factor of 10 between the hazard level and exposure level due to variability in human sensitivities...**Here, an even greater margin (100x) is owed because the methodology (which yields the 4 mg/L hazard level) uses the lowest observed adverse effect level ("LOAEL"); this methodology adds an additional level of uncertainty (and hence the application of a 100x rather than 10x margin). But even if only the default 10x margin is required, the safe level of fluoride exposure would be 0.4 mg/L (4 mg/L (hazard level) divided by 10). **The "optimal" water fluoridation level in the United States of 0.7 mg/L is nearly double that safe level of 0.4 mg/L for pregnant women and their offspring.**

pg 77: **The scientific literature in the record provides a high level of certainty that a hazard is present;** fluoride is associated with reduced IQ. There are uncertainties presented by the underlying data regarding the appropriate point of departure and exposure level to utilize in this risk evaluation. But those uncertainties do not undermine the finding of an unreasonable risk; in every scenario utilizing any of the various possible points of departures, exposure levels and metrics, a risk is present in view of the applicable uncertainty factors that apply.

pg 78: **There is significant certainty in the data set regarding the association between fluoride and reduced IQ. Namely, there is a robust body of evidence finding a statistically significant adverse association between fluoride and IQ.** A large majority of the 72 epidemiological studies assessed by the NTP Monograph observed this relationship including all but one of the 19 high-quality studies, see ¶¶ 34-36, and literature published after the NTP Monograph cutoff date observed the same relationship, see ¶ 37 – and countervailing evidence, for various reasons described previously, are of little impact on this repeated, and consistently observed association between fluoride and reduced IQ, see ¶ 39. Moreover, complete consistency amongst studies is not expected. See Dkt. No. 414, Feb. 9, 20240, Trial Tr. at 1172:23-1173:6 (Savitz). Notably, notwithstanding inherent difficulties in observing this association at lower exposure levels, studies assessing such levels still observed a statistically significant relationship between fluoride and reduced IQ. See ¶¶ 42-44. Again, to put the breadth of evidence supporting this finding in perspective, the EPA has identified a LOAEL based upon far less in other contexts. For instance, in the EPA's risk evaluation of Methylene, conducted pursuant to Amended TSCA, the EPA used a LOAEL for developmental neurotoxicity, derived from the analysis of one study conducted upon

mouse pups (Fredriksson et al., 1992). See Methylene Risk Evaluation at 262. Compare this with 6 (water fluoride) and 9 (urinary fluoride), high-quality, epidemiological studies of human populations underlying the 4 mg/L LOAEL underlying the POD here. Dkt. No. 431-2, Trial Ex. 68 at 39, 41 (eTable 4). **The scientific literature in the record provides a high level of certainty that a hazard is present; fluoride is associated with reduced IQ. The qualitative evidence is superior.**

pg 76: **The size of the affected population is vast.** Approximately 200 million Americans have fluoride intentionally added to their drinking water at a concentration of 0.7 mg/L. See Dkt. No. 421 at 206-07 (undisputed). Other Americans are indirectly exposed to fluoridated water through consumption of commercial beverages and food manufactured with fluoridated water

pg 76: Approximately two million pregnant women, and over 300,000 exclusively formula-fed babies are exposed to fluoridated water. **The number of pregnant women and formula-fed babies alone who are exposed to water fluoridation each year exceeds entire populations exposed to conditions of use for which EPA has found unreasonable risk;** the EPA has found risks unreasonable where the population impacted was less than 500 people.

The Fluoride Action Network's attorney, Michael Connett, said, "The Court has done what EPA has long refused to do: applied EPA's risk assessment framework to fluoride. It's a historic decision. And, as we await EPA's rulemaking proceeding, policymakers would be well advised to ask: "Should we really be adding a neurotoxicant to our drinking water?"

## Background

The lawsuit was brought under the Toxic Substances Control Act of 1976 (TSCA) which allows citizens to petition the EPA to evaluate whether a chemical presents an unreasonable risk to public health and should be regulated. It also empowers citizen groups to challenge the EPA in court after denial of a petition. TSCA gives EPA the authority to prohibit "the particular use" of a chemical substance if it's found to present an unreasonable risk to the general public or susceptible subpopulations.

FAN submitted a Citizens Petition under Section 21 of TSCA to the EPA in November 2016 requesting a ban on the addition of fluoridation chemicals to water. When the EPA denied our Petition, FAN filed suit in federal court in 2017, joined by consumer advocacy groups, *Food and Water Watch* and *Moms Against Fluoridation*, public health associations, the *American Academy of Environmental Medicine*, and the *International Academy of Oral Medicine and Toxicology*, as well as several individuals representing themselves and/or their children, including Brenda and Ko Staudenmaier and Kristie Lavelle.

After a two-week bench trial held via Zoom in June 2020, the trial was placed in abeyance as the court awaited the finalization of the National Toxicology Program's (NTP) systematic review of fluoride neurotoxicity. However, in 2022, pressure from pro-fluoridation interest groups led to NTP's report being [blocked](#) from public release by top officials in the U.S. Department of Health & Human Services. [Plaintiffs submitted documents](#) obtained via the Freedom of Information Act exposing this intervention to the court. This discovery led to a legal agreement forcing [the report](#) to be made public and prompting Chen to rule that the trial should go forward using the draft report from the NTP.

A second, and final, phase of the bench trial was held over several weeks during the winter of 2024. And just last month, the [NTP finally published](#) the first part of their report, finding a "large

body” of evidence that fluoride exposure is “consistently associated with lower IQ in children.” An accompanying NTP meta-analysis is soon to be published in a peer-reviewed journal.

- Click here for [a timeline of the lawsuit](#).
- Click here for FAN's [comprehensive webpage on the lawsuit](#)

## **Precedent-Setting**

This is the first time a citizen's petition has gone to trial, and it's the first time a citizen group has won a trial against EPA under TSCA Section 21. Our case and our victory will undoubtedly [create opportunities](#) for citizen and environmental watchdog groups to use the same blueprint as FAN in the future to force the EPA to adequately regulate chemicals that pose an unreasonable risk to public health.

This trial was also the first time citizen groups have successfully obtained a full objective review of the science on fluoridation, in a courtroom, with experts under oath, under TSCA's provisions that create a level playing field between the citizen groups and the EPA defending a chemical. Under most statutes, when citizens sue a federal agency, the courts give deference to the views of the agency. But in this lawsuit, under a special provision of TSCA, the court does not give deference to the EPA. Congress specifically added this level playing field because it recognized EPA can be too slow to address harmful chemical exposures.

## **Next Steps**

The court has ordered EPA to initiate a rulemaking proceeding to come up with a new regulation that will restrict or eliminate the risk posed by fluoridation chemicals to the developing brain.

According to Stuart Cooper, FAN's Executive Director, “The ONLY way to effectively eliminate the risk is to end fluoridation. Communities are currently adding this neurotoxin to the public water supplies voluntarily. The harm is needlessly self-inflicted, but this also means the solution is simple: ban the use of fluoridation chemicals.”

The EPA may appeal to the *Court of Appeals for the Ninth Circuit*, or they could take a few years to develop rules.

Attorney Connett says, “In our view, attempts by the EPA to appeal or delay this ruling will only result in harm to hundreds of thousands of additional children, particularly those whose families are unable to afford expensive reverse osmosis or distillation filtration of their tap water.”

Policymakers at the local and state level do not need to wait to take action. The federal government doesn't mandate fluoridation, and thus local and state decision makers can take action immediately. The ruling provides a very thorough opinion by the federal court, and is based upon extensive scientific research and expert testimony.

Cooper added, “The public didn't sign up to have a chemical added to public drinking water that could adversely affect the brain. And while a cavity can easily be filled, damage to the brain is permanent, and the consequences are lifelong. There are no second chances when it comes to impaired brain development.”

## **CONTACT:**

media@fluoridealert.org