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A federal judge rejected the EPA's argument that the exact level at which fluoride is hazardous is too unclear to determine if the chemical presents an unreasonable risk, and ruled the agency must take regulatory action.

by <u>Brenda Baletti</u>, Ph.D., <u>The Defender</u> September 25, 2024

In a decision that could end the practice of water fluoridation in the U.S., a federal judge late Tuesday <u>ruled</u> that water fluoridation at current U.S. levels poses an "unreasonable risk" of reduced IQ in children.

The U.S. Environmental Protection Agency (EPA) can no longer ignore that risk, and must take regulatory action, Judge Edward Chen of the U.S. District Court of the Northern District of California wrote in the long-awaited landmark decision.

More than 200 million Americans <u>drink water treated with fluoride</u> at the "optimal" level of 0.7 milligrams per liter (mg/L). However, Chen ruled that a preponderance of scientific evidence shows this level of fluoride exposure may damage human health, particularly that of pregnant mothers and young children.

The verdict delivers a major blow to the EPA, public health agencies like the Centers for Disease Control and Prevention

(CDC) and professional lobbying groups like the American Dental Association (ADA), which have staked their reputations on the claim that water fluoridation is one of the greatest public health achievements of the 20th century and an unqualified public good.

Fluoride proponents refused to <u>reexamine that stance</u> despite mounting scientific evidence from <u>top</u> <u>researchers</u> and <u>government agencies</u> of fluoride's neurotoxic risks, particularly for infants' developing brains.

Instead, they attempted to weaken and <u>suppress the</u> <u>research</u> and <u>discredit the scientists</u> carrying it out.

Rick North, board member of Fluoride Action Network, one of the plaintiffs in the lawsuit, told The Defender, "What's false is the CDC claiming that fluoridation is one of the 10 greatest health achievements of the 20th century. What's true is that ending fluoridation will be one of the 10 greatest health achievements of the 21st century."

"The judge did what EPA has long refused to do, and that is to apply the <u>EPA standard risk assessment framework</u> to fluoride," said Michael Connett, attorney for the plaintiffs. "In so doing, the court has shown that the widespread exposure to fluoride that we now have in the United States is unreasonably and precariously close to the levels that we know cause harm."

The EPA can appeal Tuesday's decision. The <u>agency</u> told The Defender it is reviewing the decision and has no comment at this time. The U.S. Department of Justice, which represents the EPA in the lawsuit, also said it has no comment.

EPA's argument 'not persuasive'

The ruling concludes a <u>historic lawsuit</u> — one that has dragged on for seven years — brought against the EPA by environmental and consumer advocacy organizations like the <u>Fluoride Action</u>
Network, <u>Moms Against Fluoridation</u> and <u>Food & Water Watch</u>,

along with individual parents and children.

It is the first lawsuit to go to a federal trial under the <u>Toxic Substances Control Act</u> (TSCA), as amended by Congress in 2016. The TSCA allows U.S. citizens to petition the EPA to evaluate whether a chemical presents an unreasonable risk to public health and should be regulated.

If the EPA denies a TSCA citizen petition — which the agency did when the plaintiffs asked it to reexamine water fluoridation in 2016 — the petitioners are entitled to a "de novo" judicial review of the science without the deference to the agency typically afforded it in legal cases.

Chen's 80-page ruling, issued six months after <u>closing</u> <u>arguments</u> in February, offers a careful and detailed articulation of the EPA's review process for chemicals that pose a hazard to human health and evaluates and summarizes the extensive scientific data presented at trial.

Chen wrote, "EPA's own expert agrees that fluoride is hazardous at some level." He cited a key report issued by the U.S. Department of Health and Human Services (HHS) National Toxicology Program (NTP), which undertook a systematic review of all available scientific research at the time of publication.

The report "concluded that fluoride is indeed associated with reduced IQ in children, at least at exposure levels at or above 1.5 mg/L," Chen wrote.

The NTP also reported that although there are technical challenges to measuring fluoride's <u>toxic</u> effects at low levels, "scientists have observed a statistically significant association between fluoride and adverse effects in children even at such 'lower' exposure levels," Chen wrote.

He said that despite recognizing that fluoride is hazardous, the EPA's defense rested largely on the fact that the exact

level at which it is hazardous is too unclear for the agency to determine whether the chemical presents an unreasonable risk.

This argument is "not persuasive," Chen wrote.

Pregnant women exposed to fluoride in water at levels exceeding the hazard level

The EPA requires a margin of error by a factor of at least 10 to exist between the hazard level for a toxin and the acceptable human exposure level. "Put differently, only an exposure that is below 1/10th of the hazard level would be deemed safe under Amended TSCA, given the margin of error required," Chen wrote.

That means that even if the hazard level were 4 mg/L - well above the 1.5 mg/L identified by the NTP - the safe level of fluoride exposure would be 0.4 mg/L, well below the current "optimal" fluoride level in the U.S., Chen wrote.

The much lower probable hazard level established by highquality studies indicates that many pregnant women in the U.S. are already exposed to fluoride in water at levels exceeding the hazard level.

"Under even the most conservative estimates of this level, there is not enough of a margin between the accepted hazard level and the actual human exposure levels to find that fluoride is safe," Chen concluded.

"Simply put, the risk to health at exposure levels in United States drinking water is sufficiently high to trigger regulatory response by the EPA under Amended TSCA."

The law dictates that the EPA must take regulatory action, but it does not specify what that action has to be. EPA regulatory actions can range from notifying the public of risks to banning chemicals.

Philippe Grandjean, M.D., Ph.D., adjunct professor in environmental health at Harvard and chair of environmental medicine at the University of Southern Denmark, top researcher on fluoride's neurotoxicity and expert witness for plaintiffs in the case told The Defender he thought the court's decision was "well-justified."

He said the ruling made it incumbent on the EPA to go beyond simply ending water fluoridation.

"EPA will have to consider what to do in the southwestern parts of the country where the fluoride content of groundwater is too high due to minerals in the soil containing fluoride," he said. "And then there is the question about ingestion of toothpaste."

The CDC and the ADA did not immediately respond to The Defender's request for comment.

More than 70 years of controversy

For more than seven decades, U.S. public health officials have steadfastly supported <u>water fluoridation</u>, claiming the practice is a key strategy for maintaining and improving dental health.

Proponents of water fluoridation, with help from the mainstream press, often attempted to cast those questioning fluoride's benefits and raising concerns about its safety as conspiracy theorists.

The EPA in 1975 recommended adding fluoride to water at an optimal level of 1.2 mg/L for its dental benefits, but recommended a maximum level of 4 mg/L, the ruling said.

As more evidence has emerged about fluoride's adverse <u>health</u> <u>effects</u>, including skeletal fluorosis, recommended levels were revised.

<u>Surgeon General Vivek Murthy</u>, officially lowered the

recommended dosage for water fluoridation in 2015 from 0.7-1.2 mg/L to 0.7 mg/L after considering "adverse health effects" along with alleged benefits.

However, evidence that fluoride poses a neurotoxic risk has existed for decades.

In 2017, after the EPA rejected their <u>citizen petition</u> to end <u>fluoridation of drinking water</u> in the U.S. based on evidence of health risks, namely neurotoxicity, the plaintiffs <u>filed the lawsuit</u>.

A seven-day trial took place in federal court in San Francisco in June 2020, but Chen put the proceedings on hold pending the release of the NTP's systematic review of research available on the neurotoxic effects of fluoride.

The NTP sought to publish its report — which consisted of a "state of the science" monograph and a meta-analysis — in May 2022, but dental officials at the CDC and the National Institutes of Health National Institute of Dental and Craniofacial Research pressured HHS Assistant Secretary for Health Rachel Levine to prevent the review from being published.

The <u>ADA also sought to suppress</u> the report.

Levine told the NTP to not publish the report but to put it on hold and allow for further review.

<u>Plaintiffs submitted documents</u> obtained via the Freedom of Information Act exposing this intervention to the court. The revelation prompted Chen to rule that the trial should go forward using the draft report from the NTP.

The trial resumed in January in San Francisco, with arguments presented over the course of two weeks.

The <u>NTP's monograph was finalized and published</u> last month on its website. The meta-analysis is forthcoming in a peer-

reviewed journal.

Connett said that Congress created the citizen petition provision in TSCA as a counterweight to bureaucratic lethargy and as a check on the EPA.

The statute, he said, is a powerful tool for overcoming politicized science.

"When science becomes fossilized in political inertia, the citizen petition provision of TSCA is a very powerful tool for citizens," Connett said. "Through this case, we have been able to effectuate what Congress had envisioned with this part of the statute."

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