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The National Toxicology Program on Wednesday Released a Draft Report Linking Prenatal and Childhood Fluoride Exposure to Reduced IQ in Children, After Public Health Officials Tried for Almost a Year to Block Its Publication.

by <u>Brenda Baletti</u>, *Ph.D.*, <u>The Defender</u> March 16, 2023

The National Toxicology Program (NTP) on Wednesday released a <u>draft report</u> linking prenatal and childhood fluoride exposure to reduced IQ in children, after public health officials tried for almost a year to block its publication.

The U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) initially blocked the NTP from releasing the report, according to emails obtained via a Freedom of Information Act (FOIA) request.

But a <u>court order</u> stemming from <u>a lawsuit</u> filed by Food and Water Watch against the U.S. Environmental Protection Agency (EPA) forced the report's release this week.

The NTP, an interagency program run by HHS that researches and

reports on environmental toxins, conducted a six-year systematic review to assess scientific studies on fluoride exposure and potential neurodevelopmental and cognitive health effects in humans.

The report, containing a monograph and a meta-analysis, went through two rounds of peer review by the National Academies of Sciences, Engineering, and Medicine. Comments from reviewers and HHS and NTP's responses also were included in the report released Wednesday.

According to its website, the NTP "removed the hazardous classification of fluoride" in response to comments in the peer-review process. Yet, the report states:

"Our meta-analysis confirms results of previous meta-analyses and extends them by including newer, more precise studies with individual-level exposure measures.

"The data support a consistent inverse association between fluoride exposure and children's IQ ...

"The results were robust to stratifications by risk of bias, gender, age group, outcome assessment, study location, exposure timing, and exposure type (including both drinking water and urinary fluoride)."

"These findings fly in the face of the empty, unscientific claims U.S. health officials have propagated for years, namely that water fluoridation is safe and beneficial," said Robert F. Kennedy, Jr., Children's Health Defense chairman and chief litigation counsel. "It's past time to eliminate this neurotoxin from our water supply."

The controversial report will play a key role in determining the outcome of a lawsuit brought in 2017 by several nonprofits against the EPA to end fluoridation of drinking water, plaintiffs' attorney Michael Connett told The Defender.

"We had to fight hard to have this report even made public," Connett said. "They [CDC and HHS] buried this. If they had gotten their way, this report would have never even seen the light of day," Connett said.

Since the trial began in 2020, U.S. District Judge <u>Edward</u> <u>Chen</u> has been waiting for the NTP to complete a systematic review of fluoride's neurotoxicity before ruling on the case.

Groups like the <u>American Dental Association</u> publicly pressured the NTP to "exclude any neurotoxin claims" from the reports.

Connett said during the trial, the EPA repeatedly claimed that the plaintiffs' allegations about toxicity could not be verified because there was no "systematic review."

The documents released Wednesday fill that gap.

Connett said:

"So now what do we have? We have a systematic review by one of the pioneering, leading, most authoritative research groups on toxicology in the world.

"They just completed a systematic review that took them six years to complete, so if that's not enough to demonstrate a hazard under the toxic substances control act, then how would any citizen group ever be able to meet the standard?"

The findings: fluoride and lowered IQ in children

According to the NTP report:

"The current bodies of experimental animal studies and human mechanistic evidence do not provide clarity on the association between fluoride exposure and cognitive or neurodevelopmental human health effects."

Yet, the report's summary contradicts this statement by

summarizing the evidence informing this conclusion, stating that nearly all studies examined for this literature review found evidence of cognitive or developmental issues associated with fluoride.

According to the report, 8 of the 9 "high-quality studies examining cognitive or neurodevelopmental outcomes reported associations with fluoride exposure."

Of the 19 high-quality studies assessing the association between fluoride and IQ in children, 18 reported an association between higher fluoride exposure and lower IQ in children. Forty-six of the 53 low-quality studies also found evidence of that association.

The meta-analysis also states:

"The body of evidence from studies on adults is also limited and provides low confidence that fluoride exposure is associated with adverse effects on adult cognition. There is, however, a large body of evidence on IQ effects in children."

The monograph and meta-analysis found that fluoride exposure at levels equivalent to 1.5 mg/L is associated with lower IQ in children. The abstract concludes:

"This review finds, with moderate confidence, that higher fluoride exposure (e.g., represented by populations whose total fluoride exposure approximates or exceeds the World Health Organization Guidelines for Drinking-water Quality of 1.5 mg/L of fluoride) is consistently associated with lower IQ in children."

Levels of fluoride found in drinking water in the U.S. are typically 0.7 mg/L, which is lower than the 1.5 mg/L levels found to be neurotoxic by the reports.

On that basis, HHS' review of the reports recommended the NTP

revise its assessment such that, "all conclusory statements in this document should be explicit that any findings from the included studies only apply to water fluoride concentrations above 1.5 mg/L."

The NTP responded:

"We do not agree with this comment. Our assessment considers fluoride exposures from all sources, not just water.

As discussed in the pre-publication 2022 NTP Monograph, because fluoride is also found in certain foods, dental products, some pharmaceuticals, and other sources, individual behaviors are likely an important determinant of actual exposures."

Rick North, former CEO of the American Cancer Society's Oregon division and <u>Fluoride Action Network</u> board member told The Defender that "people consume large amounts of fluoride through tea and other drinks and processed foods made with fluoridated water, not to mention pesticide ingestion and fluoride from air pollution."

He also said that people's fluoride exposure can depend on how much water they drink.

"Think about it," North said. "Your level of risk depends upon, incredibly, how thirsty you are. That's how absurd the entire premise of water fluoridation is," he said.

The NTP confirmed that people exposed to levels of fluoride lower than 1.5 mg/L in the water system could have high levels of fluoride in their systems. It stated:

"Even in the optimally fluoridated cities [fluoridated at 0.7 mg/L] in Canada studied by <u>Green et al. (2019)</u>, individual exposure levels, as documented by repeated urinary measurements, suggest widely varying total exposures from water combined with fluoride from other sources."

It added, "our moderate confidence conclusion is primarily based on studies with total fluoride exposure that approximates or exceeds what is generally associated with consumption of optimally fluoridated water [0.7 mg/L] in the United States."

"We have stressed in our monograph that our conclusions apply to total fluoride exposures rather than to exposures exclusively through drinking water."

"What the NTP is pointing to here is that in some communities, where the dose of fluoride in the water is 0.7 mg/L, the NTP has found levels of fluoride found to be associated with lower IQ," Connett told The Defender.

Also, different people have different risk levels, he said. <u>Pregnant women</u> and bottle-fed babies, for example, are some of the populations at highest risk.

On this point, the NTP responded to a different HHS critique, writing, "We have no basis on which to state that our findings are not relevant to some children or pregnant people in the United States."

"The margin of safety here just doesn't exist — it is precariously small," Connett said. He added that the lawsuit is "basically a risk assessment of fluoride."

Under the <u>Toxic Substances Control Act</u> (TSCA), which is the law at stake in the lawsuit, the <u>EPA carries out risk</u> <u>assessments</u> for potential toxins.

To do a risk assessment, the EPA first identifies a hazard and determines at what dose — what level of human exposure — that hazard harms human health.

Then the agency determines in a given case whether the margin between the existing hazard levels and the human exposure levels is unacceptably close, which would make a toxin pose a risk to human health.

Connett said that in EPA's previous risk assessments for other <u>chemicals</u>, such as <u>methylene chloride</u> or <u>bromopropane</u>, evaluated according to the <u>2020 risk evaluation</u> method that guides this case, the agency found the hazard level exceeds the human exposure level by much higher margins — "usually in a range of ten to 20 times higher," yet it has deemed those chemicals to present an unreasonable risk to human health.

In other words, the substances were found to be toxic to humans at levels significantly lower than what people may be exposed to in regular use, yet the EPA determined them to be risks.

When it makes that determination, the EPA must then <u>take</u> <u>steps</u> to mitigate the risk.

That can also be the finding in this case. According to a <u>pretrial document</u>, both sides in the case agreed to the "undisputed fact" that the "EPA does not require that human exposure levels exceed a known adverse effect level to make an unreasonable risk determination under TSCA."

The NTP documents also raised flags about the implications of seemingly small neurotoxic effects:

"Research on other neurotoxicants has shown that subtle shifts in IQ at the population level can have a profound impact on the number of people who fall within the high and low ranges of the population's IQ distribution.

"For example, a 5-point decrease in a population's IQ would nearly double the number of people classified as intellectually disabled."

Top HHS and CDC officials tried to 'water down' and

block the report

In 2016, a group of six nonprofit organizations and several individuals <u>petitioned the EPA</u> to end <u>fluoridation of drinking</u> <u>water</u> in the U.S. based on evidence of health risks associated with fluoride, namely neurotoxicity.

The EPA rejected the petition.

In response, <u>Food and Water Watch</u>, Fluoride Action Network and others sued the EPA in 2017, seeking an end to water fluoridation.

The plaintiffs argued that water fluoridation violates the EPA's <u>Toxic Substances Control Act</u> and that fluoride is neurotoxic and <u>lowers children's IQ</u>.

They based their initial claims on dozens of <u>studies</u> and <u>reviews</u> demonstrating fluoride's neurotoxicity. Studies have also linked fluoride to a variety of other <u>health</u> <u>risks</u> in both children and adults, and evidence shows it to be an <u>endocrine disruptor</u>.

The EPA denied water fluoridation causes harm.

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

The report, slated for release in May 2022, was delayed several times and sent for several rounds of peer review.

"The people on the [NTP] committee were experts in their fields who put years into this study, going back and forth with one external review after another," North said. "You couldn't ask for more peer review than what it already had. There were constant attempts to delay it, to water it down."

In late October 2022, Judge Chen ended the stay on the NTP

review, <u>ruling that</u> the parties involved could view the NTP review in its unpublished form to better inform his final decision.

However, due to concerns from the EPA, he also ruled the report could not be made public unless the NTP released it.

In December 2022, the plaintiffs filed several exhibits with Judge Chen, including a redacted version of the NTP's assessment of fluoride's neurotoxicity and <u>internal emails</u> between the CDC and the NTP obtained through FOIA demonstrating that HHS blocked the release of the long-delayed review, the plaintiffs argued.

The documents showed that on May 11, NTP notified the agencies that it was going to <u>release the report</u> on May 18, but the CDC opposed the release.

Emails also indicated that HHS Assistant Secretary for Health Rachel Levine was going to "get involved," and, "the May 18 release date for [the monograph] is almost certainly not going to happen," the Defender reported.

Connett said:

"It was only because we were tipped off by someone with knowledge on the inside that something was amiss that we went and did extensive FOIA requests and we were able to get documents showing that the NTP scientists considered this report to be complete and ready for publication last May, May of 2022."

North said it was clear the agencies were blocking the release of the report, which was ready for publication.

"This was a clear case of stonewalling," North said. "The National Toxicology Program, after over six years of research and numerous outside peer reviews, had completed its state-of-the-science report."

Connett added:

"We have emails showing that Levine is the one who put it on hold. Rachel Levine said not to publish this report at this time. Then we got the FOIA emails showing that and NTP said they may not publish this [the report] at all. They may not publish it in final form but we did get them to agree to at least post a draft report. They will consider it a draft report."

On January 20, Judge Chen <u>denied the EPA's request</u> to add another six-month period to the stay he lifted in his October ruling.

The monograph and meta-analysis released yesterday on the NTP's website are both labeled "draft."

"Unfortunately, fluoridation promoters and high-level government officials have continued to label it a draft," North said. "It wasn't."

Experts associated with the lawsuit against the EPA will now analyze and interpret the report in future hearings and then Judge Chen will rule.

The next hearing date is scheduled for April 11, 2023. At that time, the judge will set a date for the next phase of the trial.

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