Board of Health: Public Comment and Supplement to our Petition to protect the Public from Harm:

Bill Osmunson DDS MPH November 7, 2024

Washington Action for Safe Water

Money Marketing supports fluoridation. Science disagrees. Fluoridation harms fetuses, infants,

Bobby NBC (1).mp4

children, youth and adults. Listen to RFK's 26 second interview.

C:\Users\14254\Downloads\Bobby NBC.mp4

Fluoridation hit the media with Trump saying he will ban fluoridation. Dictators do that. But dictators also force mass medication. The Board of Health should not be comatose on science until the President recommends stopping fluoridation.

The Board for 75 years has refused the science and laws on fluoridation's lack of benefit and harm and we have provided science for 18 years with 20 petitions to protect our most vulnerable for 14 years.

You do not have a single randomized controlled trial on the benefit of fluoridation.

You do not have a single safety study on fluoride's effect on the developing human brain, thyroid or any cell of the human body.

The National Toxicology Program did not report any safe dosage of fluoride.

The Court was clear, fluoridation is an unreasonable risk. And brain damage is only one risk.

The National Research Council 18 years ago listed about a dozen risks of concern and for 18 years the Board of Health has ignored all of them, failed to study the risks and harmed the developing brains, teeth, bones, thyroid glands, enzymatic system, kidneys, stomach, intestines, heart, and the mitochondria of every cell for most of one, actually three generations, without any warning or caution.

The Board relies on marketing and endorsements from those making the most money on products. Money can cause both conscious and subconscious bias and serious greed. In other words, money cherry picks the evidence, cherry picks reviewers of science, cherry picks authorities, and cherry picks conclusions. Money drives America and our Health Care.

I sold fluoride to patients and applied it to their teeth, thinking I was benefiting my patients. I treated and profited from split, cracked, fractured brittle teeth, not realizing too much fluoride had contributed to the harm. For dentists, fluoridation is a win, win for our bank accounts. And the Board trusts the Fluoridation profiteers for unbiased evidence? That's nonsense and is harming the public.

The Board's words matter, at least for those who trust the Board, such as city authorities.

My attempt in the past has been to find evidence which is concise and reasonably current. New Board members and growing evidence necessitates more inclusion of evidence from the NTP and Court.

The National Toxicology Program Report on Fluoride neurotoxicity.

In late 2015, I nominated fluoride for cancer, thyroid and developmental neurotoxicity for NTP to review. They accepted developmental neurotoxicity; however, both cancer and thyroid are almost as persuasive with scientific studies of harm and should be reviewed by NTP.

The following is a brief concise and accurate report of the NTP report.

I. A brief overview of the NTP report, the final report and some of the politics blocking the report until the court ordered the release. A very important read.

National Toxicology Program Finds No Safe Level of Fluoride in Drinking Water; Water Fluoridation Policy Threatened

March 21, 2023 | Cheikhani

After a 6-year long systematic review of fluoride's impact on the developing brain, a court order has led to the National Toxicology Program (NTP) making public their finalized report that was blocked by US Department of Health and Human Services (HHS) leadership and concealed from the public for the past 10 months. The NTP reported 52 of 55 studies found decreases in child IQ associated with increase in fluoride, a remarkable 95% consistency. The NTP's report says:

"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."

A meta-analysis is when information from all the relevant studies are combined to get a fuller and unbiased overall picture, rather than just looking at individual studies in isolation.

The NTP's meta-analysis also put the magnitude of harm into perspective:

"[R]esearch 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."

So, while an average drop of 5 IQ points in a population might sound small it is huge from a public health perspective. Furthermore, the NTP acknowledged there was the potential for some people to be more susceptible than average, so those people could lose much more than 5 IQ points. Those susceptible individuals could lose 10, 15, 20 or more IQ points which would likely cause profound lifetime negative consequences.

The five independent peer-reviewers of the NTP report all voted to accept the review's main conclusion and lauded the report. Their comments include: "what you have done is state-of-the-art"; "the analysis itself is excellent, and you thoroughly addressed comments"; "Well done!"; "Findings… were interpreted objectively".

The newly released documents include comments from the NTP's own experts confirming that the report's conclusion that fluoride can lower IQ does apply to communities with water fluoridation

programs. NTP report says the evidence is not just in those who drink water with higher fluoride concentrations exceeding the World Health Organization (WHO) recommended maximum level of 1.5 mg/L. Furthermore, the WHO guideline was set in 1984 to protect against more severe forms of dental fluorosis and neurotoxicity was never considered. Few neurotoxicity studies even existed in 1984.

In numerous responses to comments by reviewers of the report, the NTP made clear that they had found evidence that exposures of at least some people in areas with fluoridated water at 0.7 mg/L were associated with lower child IQ.

For example, when an unnamed government fluoridation proponent claimed:

"The data do not support the assertion of an effect below 1.5 mg/L…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…because fluoride is also found in certain foods, dental products, some pharmaceuticals, and other sources… Even in the optimally fluoridated cities…individual exposure levels…suggest widely varying total exposures from water combined with fluoride from other sources."

Additional NTP responses about the review's relevance to water fluoridation programs:

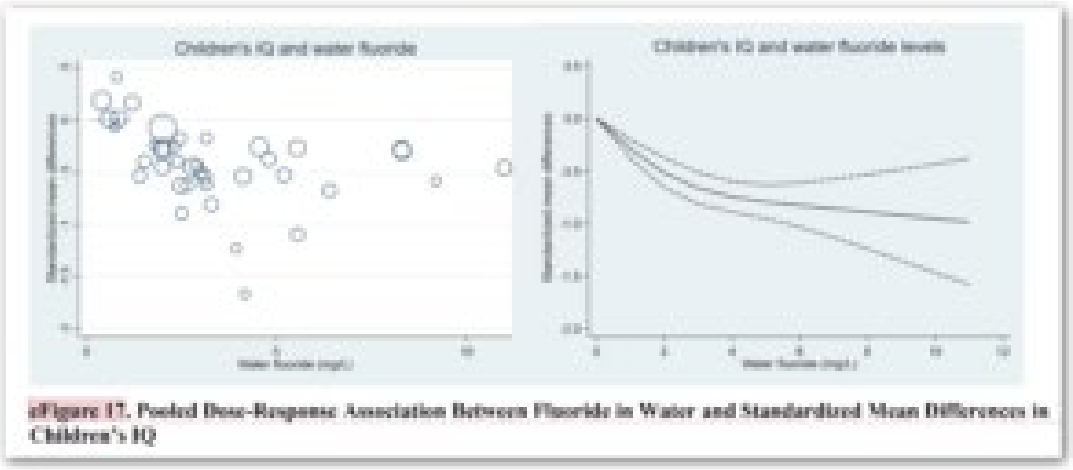
"We have no basis on which to state that our findings are not relevant to some children or pregnant people in the United States."

"Several of the highest quality studies showing lower IQs in children were done in optimally fluoridated (0.7 mg/L) areas…many urinary fluoride measurements exceed those that would be expected from consuming water that contains fluoride at 1.5 mg/L."

The NTP also responded to commenters asking whether their meta-analysis had identified any safe exposure threshold, below which there would be no loss of IQ.

The NTP responded that they found "no obvious threshold" for either total fluoride exposure or water fluoride exposure, referring to a graph in the meta-analysis (NTP's eFigure 17 reproduced below) showing that as water fluoride concentration increased from 0.0 to 1.5 mg/L there was a steep drop in IQ of about 7 points (expressed as "standardized mean difference" units in the graphs). An external peer-reviewer commented on the size of the IQ loss:

"Wow … that is substantial … That's a big deal." {p 1060}



eFigure 17. Pooled Dose-Response Association Between Fluoride in Water and Standardized Mean Differences in Children's IQ

The graph uses standardized mean difference (SMD) units where each -1.0 SMD is equivalent to about -15 IQ points.

In the left-hand graph each circle represents a study. Several have mean water fluoride below 1.5 mg/L. The right-hand graph shows the relationship between fluoride concentration and loss of IQ when all the studies are pooled. This analysis, based on many studies, is strong evidence that fluoride is associated with a substantial loss of IQ at levels of exposure common in people drinking artificially fluoridated water, and there is no observable threshold indicating a "safe" dose.

The NTP's experts further stated that the science showing neurotoxic harm "is a large, consistent and growing database."

Overall, the report provides strong evidence that fluoride is associated with a substantial loss of IQ at levels of exposure common in people drinking fluoridated water.

STAY TUNED! We will be sending out additional bulletins on the NTP report in the coming days.

PLEASE SHARE THIS BULLETIN WITH YOUR LOCAL MEDIA OUTLETS.

See our other press releases on the NTP report below:

March 15: Suppressed Government Report Finding Fluoride Can Reduce Children's IQ Made Public Under EPA Lawsuit

II. The EPA Lawsuit under the Toxic Substance Control Act (This data is provided by FAN and appropriately referenced.

The report of the court proceedings below is followed by earlier evidence. If you must cut to the chase, be sure to read The Judgment

EPA Lawsuit

Under the Toxic Substances Control Act (TSCA) of 1976, a group of non-profits and individuals petitioned the U.S. Environmental Protection Agency (EPA) in 2016 to end the addition of fluoridation chemicals into U.S. drinking water due to fluoride's neurotoxicity. The EPA rejected the petition. In response the groups sued the EPA in Federal Court in 2017. Evidence on fluoride's neurotoxicity was heard by the Court in two phases: a 7-day trial in June 2020, and a 14-day trial in February 2024. As of May 2024, a judgment from the court has yet to be rendered.

Official Court link: Food and Water Watch et al. v. United States Environmental Protection Agency et al.

The Petition

In 2017, Dr. Paul Connett PhD and Dr. Bill Hirzy PhD, on behalf of the Fluoride Action Network (FAN), Food and Water Watch (FWW), Moms Against Fluoridation (MAF), as well as several individuals, served the EPA with a petition calling on the agency to ban the addition of fluoridation chemicals to public water supplies due to the risks these chemicals pose to the brain.

The Petition was submitted under Section 21 of the Toxic Substances Control Act (TSCA) because it authorizes EPA to prohibit the "particular use" of a chemical that presents an unreasonable risk to the general public or susceptible subpopulations. TSCA also gives EPA the authority to prohibit drinking water additives.

The Initial Hearings

EPA denied the petition on February 27, 2017, claiming that: "The petition has not set forth a scientifically defensible basis to conclude that any persons have suffered neurotoxic harm as a result of exposure to fluoride in the U.S. through the purposeful addition of fluoridation chemicals to drinking water or otherwise from fluoride exposure in the U.S." FAN and other plaintiffs then sued the EPA and won a series of favorable court hearings in 2017 and 2018 on plaintiff's standing and trial discovery, while defeating several motions by EPA attempting to dismiss the case.

In late 2019 both FAN and EPA submitted motions for summary judgment in the case in the hopes that the judge would rule on the evidence submitted to the court without the need for a lengthy trial. On December 30, 2019 the Court released its order denying both plaintiffs' and defendant's motions for summary judgment. This means that our case will go forward. Trial is scheduled for two weeks beginning April 20, 2020 and will run for two weeks.

Attorney Michael Connett: "this is the first time in its 43-year history that citizens have been able to successfully bring a suit to court under provisions in TSCA"

Pre-Trial

On March 17, 2020 the Court postponed the April 2020 fluoride lawsuit trial dates due to the coronavirus outbreak. The trial will now be held June 8-19 by Zoom webinar (instead of in person at the courtroom).

In a May 2020 pre-trial hearing, the Court cleared the way for three international experts in neurotoxicity (Dr. Howard Hu, Dr. Philippe Grandjean, and Dr. Bruce Lanphear) to testify on the risks of fluoride in public water supplies on behalf of the plaintiffs. The court also ruled that the purported benefits of community water fluoridation cannot be part of the trial, restricting testimony to the toxic risks under the Toxic Substances Control Act (TSCA) Read the May 2020 trial declarations from our 4 witnesses:

Philippe Grandjean, MD, PhD
Howard Hu, MD, MPH, ScD
Bruce Lanphear, MD, MPH
Kathleen Thiessen, PhD

The First Fluoride Trial (June 8 - 19, 2020)

The first trial in the TSCA fluoride lawsuit took place in June 2020 over Zoom webinar. The trial lasted two weeks and featured testimony from FAN's expert witnesses (Drs Hu, Lanphear, Grandjean, and Thiessen) who are subject matter experts on developmental neurotoxicity and risk assessment, pitted against EPA's witnesses.

Shockingly, EPA did not rely on its own agency experts to defend its position that fluoride is not neurotoxic to humans. Instead it hired an outside consulting company, Exponent, a firm deployed by corporations to deny and downplay the health impacts of chemicals in litigation. Exponent experts attempted to cast doubt on fluoride's neurotoxic effects even as the EPA's own scientists, under subpoena by the plaintiffs, said new research does indeed warrant "an update to the fluoride assessment".

"I think it's a reason for doing an update to the fluoride assessment" - Dr. Joyce Donohue, EPA Office of Water, on recent NIH-funded studies showing fluoride harms the developing brain.

FAN attorney, Michael Connett, gave the opening statement in the trial - a summary of the case that fluoride presents a neurotoxic hazard (a threat to the brain); that this hazard is a risk at doses experienced in fluoridated communities (.7ppm); and that this

risk is an “unreasonable risk” as defined by TSCA. The EPA is represented by lawyers from the Department of Justice (DOJ). The DOJ argued in their opening statement that establishing fluoride as a neurotoxic hazard requires a systematic review and without that, FAN’s case falls.

The first fact witness called by the plaintiffs (FAN) was Dr. Joyce Donohue who has worked in the EPA’s Office of Water since the 1996 and has been their spokesperson on fluoride. Her testimony in the trial was based on a video recording of her deposition in 2019. From this deposition our attorney was able to yield two key concessions:

a) The EPA as of 2019 had no studies to provide a pregnant woman to show her fetus was safe from neurotoxicity. In fact the EPA only had studies showing harm to the fetus.

b) Dr. Donohue recommends EPA and other regulatory bodies do risk assessments of fluoride with neurotoxicity as an end point. All EPA risk assessments on fluoride to date have been based on potential damage to teeth and bones.

FAN’s first expert witness called was Dr. Howard Hu, MD, MPH, ScD, the lead author on a series of key NIH-funded research papers on fluoride and developmental neurotoxicity. Hu’s credentials are very impressive. Dr. Hu came across as knowledgeable and credible and was able to summarize the importance of his research, stressing the importance of a loss of 3 or 4 IQ points at the population level while drawing a striking parallel to lead’s neurotoxicity.
FAN’s second expert witness, Danish scientist and neurotoxicity expert Philippe Grandjean, MD, DMSc, took the stand on day two. Grandjean is the author of the book Only One Chance, in which he warns of the dangers of exposing children to neurotoxicants during early development, especially during the fetal stage. According to many who watched his testimony, Dr. Grandjean left no doubt that fluoridation poses a threat to the brains of children and easily debunked the EPA’s paid experts’ arguments.

FAN asked Dr. Grandjean to do a review of the literature since his famous 2012 meta-analysis to include the most recent US government-funded studies. Grandjean did this review but he went one step further and quantified the risk of IQ loss from fluoride to children based upon the Bashash 2017 and the Green 2019 (Canadian study) mother-offspring studies. For this analysis Grandjean did what is called a Benchmark Dose study (using methods that he and his colleagues have pioneered, and used by the EPA). He concluded that a safe reference dose (RfD) be no higher than 0.15 mg per day to protect against a loss of one IQ point. This is well below fluoride exposure levels experienced by pregnant women (and passed to the fetus) in the Bashash and Green studies.
FAN’s next expert witness was renowned clinical scientist and professor, Dr. Bruce Lanphear… who’s work on lead….. Dr. Lanphear explained that there was no safe level of fluoride exposure with regard to neurotoxicity, and that the effects seen in recent studies are “equal to what we saw with lead in children.”

Next the court watched the deposition video of CDC Oral Health Division Director, Casey Hannan, who confirmed his agency agreed with the National Research Council's 2006 findings that fluorides "interfere with the function of the brain and body by direct and indirect means," among many other stunning admissions, yet did nothing to act upon or study these findings.
Next up in the trial was fact witness Dr. Kristina Thayer, Director of the US EPA's Chemical and Pollutant Assessment Division. Dr. Thayer confirmed the vulnerability of the developing brain to environmental toxins as well as fluoride's known neurotoxicity "at some level."

The next expert witness was veteran risk assessment scientist Kathleen Thiessen, PhD, who was a member of the 2006 NRC committee that reviewed fluoride, and authored around a third of the report. Dr. Thiessen confirmed that the EPA was ignoring the neurotoxic risk from fluoridation because doing so would require them to effectively ban the practice. She also compared the amount of evidence of neurotoxicity from fluoride to other toxins the EPA currently did regulate as neurotoxic, saying "the amount of evidence for fluoride is considerably larger."
The EPA then called their first expert witness, Dr. Joyce Tsuji, PhD from corporate consulting firm Exponent. This is the same scientists-for-hire firm the tobacco industry used to deny lung cancer risk. Dr. Tsuji's answers repeatedly contradicted the testimony from her pre-trial deposition. Eventually FAN attorney Michael Connett was able to get Dr. Tsuji to admit on the stand that "there is enough literature for us to be concerned" about fluoride's neurotoxicity.

The EPA then called their second expert witness, Dr. Ellen Chang (also from Exponent), to discuss the human fluoride/IQ studies. She spent much of her time attacking the quality of the studies linking fluoride to lowered IQ. FAN attorney Michael Connett was successful in exposing Dr. Chang's blatant bias and, in a defining moment at trial, was able to get her to admit that the fluoride/IQ studies from Till (2020), Green (2019), and Bashash (2017) were the most rigorous neurotoxicity studies to date.

Next up was Dr Tala Henry, Director of the EPA's Risk Assessment Division, who has 25 years of risk assessment experience at the agency. Her testimony focused on the many hurdles presented to those who attempt a risk assessment and risk evaluation of a chemical. FAN's attorney Michael Connett dealt a destructive blow to Dr. Henry during cross-examination came when he asked: "you held the plaintiffs to a burden of proof that EPA has not held a single chemical under section 6 [of the Toxic Substances Control Act] before, correct?". Henry replied, "by the words on the page, I guess that's true". The EPA closed its case with a short video segment of Dr. Joyce Donohue, the predominant fluoride expert in the EPA's Office of Water. If anything, this video strengthened our case and did not weaken it.

The last day of trial featured a dramatic moment, as the federal judge surprised everyone by recognizing the key plank in our case, undermining the key argument in the EPA's case. The judge said:
"So much has changed since the petition was filed…two significant series of studies – respective cohort studies – which everybody agrees is the best methodology. Everybody agrees that these were rigorous studies and everybody agrees that these studies would be part of the best available scientific evidence."
The EPA appears to have applied a standard of causation, which from my read of TSCA is not accurate. It's not a proper allocation. It's not the proper standard.'

After closing statements, Judge Chen shared his views on the case and made recommendations. Chen asked the parties whether they could discuss the possibility of an amended petition and re-assessment by the EPA, or start a new petition and have the EPA conduct a proper review. To many observers, it felt as though Chen was intimating that FAN had essentially won the case, but he was giving the EPA a chance to right their original wrongs.

The ending of the first fluoride trial was somewhat unexpected as the judge asked the two parties to work out an agreement. The Court specifically urged the EPA to independently re-assess the hazard posed by fluoridation chemicals and the Judge assigned August 6, 2020 for a status hearing to reconnect with the two sides. When the parties met on August 6, EPA claimed that they "didn't have the resources to do a risk assessment," and were going to let the court record stand without taking any further action. The judge continued to insist the EPA reconsider their position, and also said he wanted to review the updated National Toxicology Program's (NTP) review of fluoride's neurotoxicity, which was due to be released soon.

In August 2020, the Court placed the case in abeyance (on hold) in part to consider the pending findings from the pending NTP report on fluoride neurotoxicity.

Justice Delayed

The Court requested on the last day of the trial that FAN submit a new petition to the EPA to allow them another 90-day opportunity to respond to our original 2016 petition with the addition of all the new studies on fluoride neurotoxicity published between 2017-2020. The Court also requested that FAN include petitioners who were pregnant or planning a pregnancy in light of the science linking early-life exposure to fluoridated water to adverse neurodevelopmental effects in these new studies.

On November 4, 2020, FAN filed a supplement to our original petition to the EPA.
The supplement asked that EPA reconsider their denial of our 2016 Petition.
The supplement has done everything the Court asked us to do with a new petition.
The supplement also responds to the issue of standing by identifying nine members of Food & Water Watch "who are currently pregnant, women who are actively seeking to become pregnant, and/or mothers of infants".

In December 2020, the EPA filed a last ditch motion to attempt to dismiss our landmark case, arguing that plaintiffs lacked standing; a motion they had previously made and were denied. The Court denied the EPA motion as being premature and procedurally improper. The trial will continue, in abeyance, as the Court awaits the EPA's response to FAN's updated petition and an updated draft of the National Toxicology Programs (NTP) monograph on fluoride's neurotoxicity, expected early in 2021.

In January 2021, the EPA denies FAN's supplemental petition, setting the stage for additional hearings and filings in the TSCA fluoride lawsuit. An April 2021 status hearing with the Court focused on FAN's amended petition to the EPA, which the Judge recommended before he placed the trial in abeyance. The amended version has a more detailed list of plaintiffs and includes recent studies that were not a part of the trial. The Court grants FAN's motion to supplement our pleadings to introduce additional evidence on standing, which should satisfy the Judge's prior concerns on this issue and ensure that the case is resolved on the merits.

The Judge reiterates that he is keen to read the NTP's finalized report on fluoride's neurotoxicity as well as other new science on the issue, including an upcoming pooled analysis of the NIH-funded birth cohort studies. To consider this new science, the Judge discussed having a "phase 2 trial" where Plaintiffs and EPA can introduce additional expert testimony on the NTP report and other developments. In June 2021, FAN attorney Michael Connett informs the Court of a new landmark study by Grandjean et al., confirming that very low levels of fluoride exposure during pregnancy impairs the brain development of the child. The paper's authors concluded in the Benchmark Dose (BMD) analysis that a maternal urine fluoride concentration of 0.2mg/L was enough to lower IQ by 1 point. The judge was waiting to see this analysis as well as the final version of the NTP review before moving forward with the case.

In a January 2022 status hearing, the Judge reiterates his desire to wait until the NTP publishes the final version of their review on fluoride's neurotoxicity before continuing with the trial. The NTP report had been delayed, with speculation brewing that dental interests were actively influencing the report's final publication.

In September 2022, FAN filed a motion to lift the pause on the trial in response to the indefinite postponement of the NTP fluoride review. The final publication of the NTP review was expected at the end of 2021, then promised again in early 2022, with May 2022 being the long-awaited release date. May 2022 came and went without any sign of the NTP report.

In October 2022, FAN attorney Michael Connett introduced evidence from Freedom of Information Act (FOIA) documents showing that political pressures had prevented NTP from releasing its long-delayed report [link to new NTP page]. The Court promptly granted our motion to lift the stay on the trial and permit additional discovery into the NTP review.

EPA's objections to using any version of the NTP report besides the "final" version during the trial was based on their concern that the NTP's findings would be made public prematurely. To circumvent this objection, the Court placed the NTP's review under protective order so that it was only made available to the parties involved, the Court, and expert witnesses. The Court urged both parties to come together and find a way to get the current NTP review into the Court's hands "voluntarily," while also leaving the door open for FAN attorney Michael Connett to use "subpoenas or a motion to compel," the release of the long-delayed report.

In December 2022, after extensive negotiations, the Department of Justice (DOJ) agreed to produce a copy of NTP's suppressed report on fluoride. The report is produced under a strict protective order.
FAN Attorney Michael Connett shared with the Court FAN's desire to see the final NTP review from May 2022 available to the public, as well as the communications and criticisms from the CDC and HHS that led to it being blocked. Connett pointed out that FAN had evidence obtained through FOIA requests showing that the American Dental Association (ADA) was already given the NTP review so they could work to discredit it, and therefore there is no justifiable reason for the EPA to continue hiding it from the public.

In January 2023 the Court ruled against EPA's request for additional delay of the trial, acknowledging that "justice delayed is justice denied". The Court sets a timeline for the final phase leading to a verdict.

In February 2023, after being served a subpoena by our attorneys, the NTP agreed to publicly produce their final report that was intended to be published in May of 2022, along with communications between various federal agencies and the NTP about the report. This allows the public to finally see the report and accompanying documents that were blocked from being published by the leadership at U.S. Health and Human Services (HHS) in May of 2022. Internal CDC emails discovered through FOIA by FAN show that the publication was blocked at the last second due to interference from Assistant Health Secretary, Rachel Levine.
The NTP fluoride review was issued in two parts, a monograph and a meta-analysis. The meta-analysis found that 52 of 55 studies found lower IQ with higher fluoride exposures, demonstrating remarkable consistency. Of the 19 studies rated higher quality, 18 found lowering of IQ. The meta-analysis could not detect any safe exposure, including at levels common from drinking artificially fluoridated water.

In March 2023 the Court denied EPA's motion to prevent FAN from conducting depositions into the suppression of the NTP report. Dates are set for the final phase of the TSCA fluoride lawsuit - January 29 thru February 13, 2024.

FAN learned at an October 2023 status hearing the start date for the last phase of our fluoride trial would be pushed back two days to January 31st, 2024. The expiration of the CARES Act means that our attorneys will present live, in-person from the federal courthouse in San Francisco during the second phase of the trial. The trial will be live streamed on Zoom for the public to view.

In a January 2024 pre-trial hearing, FAN attorney Michael Connett introduced evidence that key a EPA witness lied under oath.

The Second Fluoride Trial (January 31 – February 20, 2024)

The second trial in the TSCA fluoride lawsuit took place January 31 – February 13, 2024, at the Federal Courthouse in San Francisco and was live-streamed on Zoom. The trial lasted two weeks and featured testimony from the same FAN expert witnesses seen in the first fluoride trial – Drs. Hu, Lanphear, Grandjean, and Thiessen.

Central to the crux of the case, Connett focused on EPA's admittance that they did not use the appropriate EPA guidelines in their risk evaluation of fluoride and did not follow the Toxic Substances Control Act (TSCA) statutes when evaluating whether fluoride posed an unreasonable risk to the developing brain. Not only did EPA fail to follow TSCA and agency risk assessment rules, but they went further by admitting that they held fluoride to a higher standard than any other chemical. This included the EPA's insistence in discounting high-dose fluoride studies, while EPA has never disregarded higher-dose studies when identifying a hazard with any other chemical.

Connett also honed in on the National Toxicology Program's (NTP) systematic review of fluoride neurotoxicity, and a large body of animal data showing brain harm from fluoride. The NTP review found a large number of studies have been published on fluoride and human IQ. In total they identified 72 human studies of which 64 found a connection between fluoride and IQ deficits. 18 of the 19 studies deemed high quality found that fluoride lowered IQ, a 95% consistency. Connett flagged recent research relied upon by EPA that did not find neurotoxic effects from fetal fluoride exposures as deeply suspicious. He said the authors of these studies were long-time promoters of water fluoridation, compared to FAN expert witnesses, who have all worked with the EPA and have been relied upon as experts on the regulation of environmental toxins by governments around the world and are subject-matter experts on fluoride.

Connett discussed how the exposure level at which a chemical presents a risk for toxic effects (a threshold level) varies substantially across the human population, but the point of a regulatory action is to protect the most vulnerable people in the population. Connett stressed to the Court that "TSCA commands us to protect the vulnerable". Connett then wrapped up by pointing out that roughly two million pregnant women and 400,000 formula-fed babies exposed to fluoride in water are at risk and that TSCA requires the EPA to consider injuries that chemicals pose to sensitive and highly exposed people. The EPA focused their opening statement on the talking point that "the dose

makes the poison," suggesting, in contrast to the actual published research, that there is insufficient compelling evidence that fluoride is a neurotoxin at the current levels used for fluoridation in the U.S. and that therefore water fluoridation doesn't pose a risk to children. EPA named the expert witnesses it will call in the case: David Savitz, Ph.D., who chaired NASEM's committee that peer reviewed the NTP's systematic review; EPA risk assessment expert, Stan Barone, Jr., PhD; and and Jesus Ibarluzea, PhD, authored of the flawed "Spanish" study.

FAN attorney Michael Connett then called our first expert witness to the stand, Howard Hu, MD, MPH, ScD. Dr. Hu has authored more than 320 papers in peer-reviewed journals and published several landmark studies on fluoride and the brain. He also advises the EPA and collaborates with its scientists on issues related to lead exposure.

Connett asked Dr. Hu how he would compare the peer review process that his fluoride studies underwent with other studies he's published. Hu responded that his fluoride studies are "probably the most extensive peer review process I've experienced." Hu also discussed his concerns about the Spanish study the EPA used as a basis to argue fluoride is not toxic at low levels, and criticized the EPA's opening statements, saying that the EPA was presenting data as black and white.

Hu then compared his Canada MIREC cohort study and Hu's more recent MADRES cohort study from the U.S. Both indicate higher levels of fluoride in the urine of pregnant mothers in the third trimester. Hu remarked that the third trimester increase is reminiscent of what we saw with lead: fluoride is stored in the mother's bones and during the third trimester, when fetal bone growth accelerates, the mother's body transfers calcium from her bones, along with any present toxins like fluoride, to the fetus.

Dr. Hu was interviewed by independent journalist Derrick Broze after the first day of court adjourned:
Next up was FAN expert witnesses Bruce Lanphear, MD, MPH, who has studied the impact of toxic chemicals, including lead and pesticides, on children's brain development for over 20 years. Lanphear testified that his research has been almost exclusively funded by federal agencies, including the EPA and the Centers for Disease Control and Prevention (CDC). In fact, Dr. Lanphear's research was cited by the EPA as the principle study upon which the agency based its current regulatory standards for lead in air and water.

Lanphear discussed the findings and methodology used for several landmark human studies funded and vetted by the National Institutes of Health (NIH) on fluoride and the brain that he co-authored. Lanphear stated that out of the 350+ studies he's published, his study was one of the two most rigorously reviewed and scrutinized studies prior to publication in his career due to the "implications for public health policy." His study found a linear dose-response relationship between fluoride and IQ, meaning that the

lowered IQ effect occurred with any level of fluoride exposure and increased as the exposure increased.

There was then discussion of another study he co-authored which found that consumption of infant formula reconstituted with fluoridated water led to excessive fluoride intake and lower IQ scores for both boys and girls compared to their breastfed counterparts who received very low intakes of fluoride. Lanphear also pointed out that studies have consistently found that children in poorer areas were often exposed to more toxins, and the effects of fluoride exposures for their mothers during pregnancy and for the children during formula feeding could compound these effects, making the poor particularly vulnerable to fluoride's effects.

In his testimony, Lanphear addressed the variability of findings in different studies - some find sex-differentiated responses to fluoride and others don't, or some find neurotoxicity at lower levels and some at higher levels. Lanphear said that the same variability exists in toxicity studies for lead, where some studies find greater effects in boys and others in girls. The overall indication is that lead, like fluoride, is toxic and that other factors drive sex differentiation in a particular context.

The discussion then focused on how fluoride could increase hypothyroidism rates in pregnant women, impacting fetal brain development, and how these effects were both increased if the mother was iodine deficient. Lanphear co-authored key studies on these subjects. He pointed out that the 2006 National Research Council report recognized that fluoride was a thyroid disruptor. He also noted that iodine deficiency has been increasing in the United States. FAN attorney Michael Connett asked, "Is there any dispute that hypothyroidism can lead to a lower IQ?" Lanphear: "No."

Lanphear wrapped up his testimony by discussing his work measuring maternal urinary fluoride concentrations of pregnant women. He testified that an average woman living in a fluoridated community has fluoride levels in their urine twice as high as an average woman living in a non-fluoridated community. Connett asked, "What is the cause of this difference?" Lanphear responded, "Fluoridated drinking water."

Journalist Derrick Broze interviewed Dr. Lanphear after his testimony on day two of the trial:
The third expert witness called by FAN was Philippe Grandjean, MD, DMSc. Dr. Grandjean is a physician, a scientist, an internationally known expert in environmental epidemiology, an author, and both a professor of environmental health at the Harvard School of Public Health and the head of the Environmental Medicine Research Unit at the University of Southern Denmark.

Grandjean testified that he has been given grants and/or contracts to advise the EPA, the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA), the World Health Organization (WHO), and numerous other government bodies for over 25

years. Dr. Grandjean said he had even been retained by the Department of Justice, which is representing the EPA in our trial, as an expert witness on environmental toxins.

Grandjean is the author or co-author of some 500 scientific papers and is perhaps best known worldwide for his research on the neurotoxicity of mercury, which involved studying the IQ of children born to mothers whose diet was high in mercury. This work led to defining the EPA's safe regulatory levels for mercury in the diet and inspired downward revisions of methyl mercury exposure limits internationally.

Dr. Grandjean has authored or co-authored several studies and reviews on fluoride's neurotoxicity, as well as the first benchmark dose analysis on fetal fluoride exposure which found that a maternal urine fluoride concentration of 0.2 mg/L, which studies show is exceeded 4 to 5 times in pregnant women living in fluoridated communities, was enough to lower IQ by 1 point. In his testimony, Grandjean confirmed that the fluoride the mother is absorbing will pass into the child's brain. "You only get one chance to develop a brain. Once it's harmed, there's nothing you can do." Grandjean says.

Attorney Connett showed a quote from EPA scientist Kristina Thayer, who provided testimony in the first phase of the trial. Dr. Thayer said she believes that animal data supports the biological plausibility of fluoride causing neurotoxic effects in humans. Grandjean agreed with Thayer's opinion. Connett asked Grandjean about the EPA's opening statement in which they claimed that Chinese fluoride studies were looking only at very high levels of fluoride exposure. Grandjean insisted this was not the case, saying that even at lower levels there was evidence of cognitive impacts from fluoride, confirming outright that he felt neurotoxicity was definitely a hazard of fluoride exposure.

Connett then asked about NTP's May 2022 final draft report, which included Grandjean's own studies and found lower IQ in children exposed to fluoride during fetal development. Connett specifically asked about the EPA's claim that the NTP's findings were "driven by studies looking at fluoride levels of 7.0 ppm and higher." Dr. Grandjean replied, "They must have a misunderstanding because that's certainly not correct." He then agreed with the NTP authors' statements that some of the higher-quality studies that found harm were done in optimally fluoridated communities.

Dr. Grandjean then confirmed that over a lifetime of dealing with evidence on neurotoxicants, "Fluoride probably has the largest body of evidence of any of our known or suspected neurotoxicants." Agreeing with NTP's finding that the consistency of association of lower IQ in children in five different countries rules out the possibility that there is a common factor other than fluoride exposure that can account for this outcome, Dr. Grandjean stated: "When it comes to fluoride, we have a massive amount of evidence. There is something very serious going on here that we must take seriously."

Journalist Derrick Broze interviewed Dr. Grandjean after his testimony on day three of the trial:
Next to take the stand was EPA's expert witness Stanley Barone, Ph.D., a risk assessment scientist from the EPA Office of Chemical Safety and Pollution Prevention, testifying as FAN's fact witness to establish EPA's methods for risk evaluation under the Toxic Substances Control Act(TSCA).

Through questioning, Barone explained the EPA's risk assessment method - the method FAN says EPA is failing to apply in the case of fluoride. As an EPA developmental toxicologist, Barone was heavily involved in TSCA's first 10 risk evaluations. Before the trial, the plaintiffs asked Barone to establish the risk evaluation process for the record.

Connett questioned Barone on key elements of the hazard assessment. He asked Barone to confirm that to determine whether a chemical is a hazard - step one in the risk assessment process - there is no need to prove causation. Barone agreed that to establish that a chemical is a hazard, EPA requires proof of association, not causation.

Next, Connett asked Barone whether EPA had ever made a different hazard evaluation for high-dose versus low-dose exposure in any of the risk evaluations it had done to date under TSCA. Barone said he was confused by the question. Judge Chen interjected to pose the question himself. "In the hazard evaluation, is it a binary decision?" Barone said it was. In other words, a chemical poses a hazard or it doesn't. The EPA doesn't differentiate between high and low doses in determining whether something is a hazard. Barone also confirmed that once something has been confirmed as a hazard, medium- and high-quality studies are then used to identify a hazard level. These are points our attorney laid out in his opening remarks.

In what would become a defining moment in the trial, Dr. Barone testified that in his estimation we should have a margin of safety of at least 10x for fluoride to protect the most vulnerable in society. The current margin of safety between fluoridated water at 0.7 ppm and the level that NTP found neurotoxicity, 1.5 ppm, is only 2x. EPA would backpedal from this admission throughout the rest of the trial. Some observers might say this moment forced the EPA to change strategy mid-trial.

FAN attorneys then called to the witness stand Dr. Brian Berridge, DVM, DACVP, Ph.D., who oversaw the completion of the NTP's work, to discuss the NTP fluoride review and the peer-review process.

In December 2023, EPA moved to exclude Berridge's testimony from the trial, arguing it would speak to the political influence exerted to stop the NTP report's publication, rather than to the scientific findings in the report, which are central to the trial. EPA attorneys argued Berridge's testimony would be "unfairly prejudicial" to the agency. Although Berridge commented in an email, obtained by FAN via a FOIA request, that there was an ongoing attempt to modify the report to satisfy interested actors and to

obstruct its publication, FAN did not call on him to speak to that issue, but rather on the integrity of the scientific process in the report's production. In a blow to EPA, Judge Chen said he woul allow Berridge's testimony.

Dr. Berridge testified at trial that he signed off on the May 2022 version of the NTP fluoride review as a final and complete report that was ready for publication.

Read more: What Dr. Berridge Couldn't Tell The Court

FAN Attorney Michael Connett then called veteran risk assessment scientist, Dr. Kathleen Thiessen as the next expert witness. Connett establishes that Dr. Thiessen is the author of a large portion of the 2006 NRC fluoride review, and that she also worked on the 2009 review. Connett asked Thiessen if there is any reasonable doubt that neurotoxicity is a hazard of fluoride exposure. Thiessen replied that "neurotoxicity is a hazard of fluoride exposure, the evidence is abundant".

Connett then asked several questions comparing the NTP review process to the EPA review process, Thiessen says the EPA has not been as open and transparent. That the NTP's communication of its conclusions about fluoride's toxicity was more transparent.

Day six of the second trial in the fluoride lawsuit started off with a bang, as FAN attorneys shared with the Court a new systematic review by Canadian researchers, published the night before, linking fluoride exposure at very low levels to lower IQ in children.

Canada's public health agency, Health Canada, commissioned a team of scientists to study the effects of fluoride on human health, but the agency did not publish the review. The peer-reviewed journal Critical Reviews in Toxicology instead independently published the study. The researchers calculated the "point of departure" for the effects of fluoride on IQ - also known as the "hazard level," the lowest point at which a toxic effect is observed - and found it to be 0.179 milligrams per liter (mg/L) in water.

Levels of fluoride found in drinking water in the U.S. and Canada typically are in the higher range of 0.7 mg/L. The NTP report set the hazard level at 1.5 mg/L, and one of the key studies at the center of the trial set the level even lower than 0.2 mg/L.

Even at a hazard level of 1.5 mg/L, exposure levels for fluoride carry significant risk under TSCA's guidelines, but this new level identified by Canadian researchers would set a risk level even further below current exposure levels.

The findings are important to the trial because the identified hazard level was quite low and also because the authors calculated their hazard level in terms of water fluoridation levels, which they extrapolated from the urinary fluoride levels used in most studies.

The findings also are significant because David Savitz, Ph.D., professor of epidemiology at Brown University and the EPA's first witness, was part of the expert panel that advised Health Canada on how to interpret this study and other data. The expert panel that included Savitz concluded there wasn't enough evidence to lower the amount of fluoride in drinking water based on its neurocognitive effects.

Next, EPA's first key witness, David Savitz, Ph.D. took the stand. Dr. Savitz is a professor of epidemiology at Brown University School of Public Health. He worked with the National Academies of Sciences, Engineering, and Medicines (NASEM) in reviewing the draft NTP fluoride report.

Over nearly three days of testimony, Savitz downplayed the link between fluoride and IQ loss in children. Savitz's testimony supported the EPA's three key arguments:
Data on fluoride's neurotoxic effects for children at current levels of water fluoridation is mixed or uncertain and therefore no action should be taken.
There are limitations to the NTP's conclusions, published in draft form last year, linking fluoride exposure and IQ loss in children at 1.5 milligrams per liter (mg/L).
More recent studies not considered by the NTP cast doubt on the NTP's findings.
However attorney Michael Connett and even Judge Chen pushed back on his conclusions. Connett underscored in his cross-examination that Savitz is an expert in epidemiology but has no experience researching fluoride.

Savitz testified that the Health Canada panel he was on determined that data showing IQ loss in children at existing water fluoridation levels contained too much "uncertainty" to set a hazard level for drinking water, so they advised Health Canada not to change its fluoridation levels.

Under cross-examination, Savitz told the court he sat on that panel at the same time that the EPA was paying him $500 per hour — totaling between $137,000 to $150,000 for 275-300 hours of work — as a litigation expert for the EPA in this trial examining that very question. Judge Chen asked Savitz if Health Canada knew he was serving as an expert witness in this case when they invited him to the panel. Savitz said the agency did.

Regarding his work reviewing the NTP fluoride report, Savitz said NASEM determined the first draft of the NTP's report, which classified fluoride as a neurotoxin, fell short of providing "a clear and convincing argument" that supported its assessment. Savitz told the court he didn't think NTP's conclusions were "wrong" but that they were stated in a way that could be "misused" as a tool for setting or changing water policy on water fluoridation. Savitz said he thought that after the revisions, the communication was "tempered" and "more consistent".

Savitz testified that because two of the four major cohort studies discussed in the trial (MIREC and ELEMENT), found a statistically significant effect of fluoride on IQ at low

levels, and two did not (Odenseand INMA), there was too much uncertainty to definitively conclude that it posed a danger at current levels of water fluoridation. Judge Chen asked, “I take it the converse would also apply? Which is that given this mix [of results] you can’t foreclose that there is an effect at U.S. drinking levels?” Savitz conceded this was true.

Judge Chen asked, given Savitz’s response and the NTP’s findings, if it makes sense to assume that there is a concern about current drinking water levels. Chen also asked Savitz if he took issue with NTP’s conclusion that there is an association between fluoride exposure and lowered IQ at 1.5 mg/L - just over two times current fluoridation levels. Savitz said he had no reason to challenge it, but he hadn’t corroborated it.

Savitz said another flaw was that the NTP used high-quality ecological studies - studies of endemic fluoride in other countries - as some evidence to show the effects of fluoride and that those could be confounded by other variables. Chen pointed out that the studies would have controlled for that issue. Savitz conceded they did.

On cross-examination, Connett also pointed out that in Savitz’s own work on arsenic in China, his team studied endemic arsenic at high concentrations to show evidence for arsenic’s toxic effects. They also used that data to consider toxic exposure levels in the U.S., using the same methods NTP scientists and other researchers were using endemic fluoride data, which Savitz criticized.

Connett also asked Savitz if he believed his own statements on uncertainty by quoting from Savitz’s textbook, “Interpreting Epidemiological Evidence: Connecting Research to Applications.” Savitz wrote in the book that “to claim we have insufficient evidence does not resolve the problem for those who make public health decisions, because inaction is an action.”

Throughout his testimony, Savitz maintained there was no strong evidence for the neurotoxic effects of fluoride exposure at “low levels,” which extended up to 2 mg/L. On cross-examination, Connett presented him with data from the NTP report and also from at least one key study showing this link. Savitz conceded he hadn’t read those studies. In fact, in addition to the NTP report, he said he had read only about 10 studies on fluoride and neurotoxicity. EPA’s risk analyst Dr. Stanley Barone took the stand again as the final in-person witness in nine days of testimony at the Phillip Burton Federal Courthouse in San Francisco. FAN attorneys called Dr. Barone earlier to comment on the EPA’s risk analysis methodology even though he’s an expert witness for the EPA. The EPA called him back to testify to the quality of the evidence on fluoride and IQ for a hazard assessment.

Dr. Barone admitted in his testimony that fluoride is neurotoxic at relatively low levels and that EPA’s key expert on fluoride’s neurotoxicity, David Savitz, conceded flaws in his

own study as our landmark fluoride trial drew to a close. Fluoride causes “neurotoxic harm,” and does so at relatively low levels, Barone admitted under cross-examination.

Barone said there simply isn’t enough data available for EPA to implement its risk assessment process for fluoride. Pharmacokinetic modeling that predicts how a chemical will be absorbed and metabolized by the body, hasn’t yet been done, he said. But on cross-examination, Attorney Michael Connett forced Barone to concede several of the FAN’s key points.

“You do not dispute that fluoride is capable of causing neurodevelopment harm, correct?” Connett asked. “I do not,” Barone said, adding that he said that in his deposition.

“You agree that the current evidence is suggestive that low-dose fluoride causes neurodevelopmental effects? Correct?” Connett asked. Barone said the “hazard ID” - the level at which a toxin causes effects - “is probably in the suggestive range but is highly uncertain.”
“You agree that fluoride is associated with neurotoxic effects at water fluoride levels exceeding two parts per million?” Connett asked. After first evading the question, Barone conceded.

Connett asked if Barone agreed there should be a “benchmark margin of uncertainty” of 10 for fluoride neurotoxicity. That means the lowest allowable human exposure level should be at least 10 times the hazard level, which Barone conceded may be approximately 2 parts per million. Barone said that is generally true for toxic chemicals under TSCA.

Water fluoridation levels in the U.S. are currently 0.7 parts per million, also referred to as milligrams per liter (mg/L), which would place them well above the allowable level if they were regulated through TSCA’s norms.

Barone also conceded that the NTP’s report linking fluoride to neurotoxicity at 1.5 mg/L is a rigorous, high-quality review and that the NTP is one of the world leaders in doing such reviews.

“Do you feel comfortable as a risk assessor,” Connett asked, “exposing pregnant women to a level of fluoride that is so high that the kidney is oversaturated?” Barone avoided answering, commenting instead on other foods containing fluoride.

Connett asked a second time, “Are you comfortable then with a pregnant woman having so much fluoride in her circulating system that their kidney has lost the ability to efficiently process it?”

EPA lawyers objected to the question as “vague and argumentative” but Chen overruled.

Barone then sat in silence for several seconds before responding, “Again, putting this in context, my comfort level I don’t think is germane.”

Connett then turned to the question of the “data gap” or “uncertainty” that Barone and other EPA experts have argued is the basis for not requiring the agency to regulate fluoride.

Connett asked Barone if he agreed that uncertainty about the threshold level at which a chemical causes harm is not a basis for deciding not to do a risk assessment - the process that would likely lead to chemical regulation. Barone agreed but said the weight of the evidence was key. Connett also asked him if he personally agreed that the EPA should “use health protective assumptions” (i.e. an uncertainty factor of 10) when data is lacking. He said he did.

Chen intervened to ask Barone why the EPA couldn’t do its risk assessment with the given information, using a “lowest observed effect level,” or LOEL. “I mean here we have a phenomenon where I think everybody agrees, as you put it, something’s going on,” Chen said, adding:
“And knowing that the EPA is to use health-protective assumptions when the information is lacking, why can’t one approach it from the low-level approach? We seem to know that there’s some level in which something’s going on. There’s adverse effects. We may debate where it is, but wouldn’t it be proper to use even a conservative estimate of LOEL?”
Barone insisted, as he did in earlier testimony, that the data are unclear. But he also conceded the EPA does often use the LOEL in risk assessment. Throughout Barone’s testimony, Connett drew concessions from Barone through “impeachment” — meaning Barone gave responses under cross-examination that contradicted statements he made in his earlier deposition. Connett read from Barone’s deposition testimony to demonstrate he was misrepresenting his responses.

To wrap up the trial and move forward with closing arguments, Judge Chen privately reviewed the recorded deposition of Jesús Ibarluzea, Ph.D., EPA’s final witness.

Dr. Ibarluzea is the author of the “Spanish study” that found fluoride increased IQ in boys by an implausible 15 points. 15 IQ points is enough to turn an average person into a genius, which no chemical has ever been found to do, calling the findings of his study into serious question.

Dr. Ibarluzea pulled out of testifying publicly in the trial after his study was scrutinized by plaintiffs for its ridiculously unbelievable findings.

At the close of the expert testimony, a scheduling change occurred. The Judge ordered that closing statements from both FAN and EPA now take place with a one-week delay,

setting a February 20, 2024, closing date. The judge wanted time to watch deposition videos, look over evidence, and prepare a series of key questions for attorneys.

Closing Arguments

On February 20, 2024, rather than delivering summary closing arguments, attorneys for FAN and EPA responded for nearly three hours to the Judge's detailed questions on technical aspects of the link between low-level fluoride exposure and lower IQ scores in children. The two sides also debated the role of uncertainty in risk assessment.

During the trial, top scientific experts who advised the EPA on understanding and setting hazard levels for other major environmental toxins and who conducted gold-standard "cohort" studies on the link between fluoride and low IQ in children testified for FAN.

They explained the NTP's findings and presented evidence from their own research showing neurotoxic risks - particularly to pregnant women, formula-fed infants and children- posed by water fluoridation.

EPA witnesses conceded fluoride does have neurotoxic effects at relatively low levels but countered that the risk assessment process under TSCA is highly complex and there is too much uncertainty in the data on fluoride's toxicity at current levels of water fluoridation to do a proper risk assessment and regulate the chemical.

It is now up to Judge Chen to decide if the EPA should be required to create a rule banning water fluoridation in the U.S. "Because the regulatory agencies have failed to do their job for decades," plaintiffs' attorney Michael Connett told Brenda Baletti of The Defender, "the court is now in the position of having to do it for them."

"It's not a job the court takes lightly," he said. "It's not a job the court wanted to do, but I think it's a job the court is prepared to do."

The Judgment

On September 24, 2024 the court ruled on behalf of the Fluoride Action Network and the plaintiffs. A U.S. federal court has now deemed fluoridation an "unreasonable risk" to the health of children, and the EPA will be forced to regulate it as such.

The decision is written very strongly in our favor.

Below is an excerpt from the introduction of the ruling:

"The issue before this Court is whether the Plaintiffs have established by a preponderance of the evidence that the fluoridation of drinking water at levels typical in the United States poses an unreasonable risk of injury to health of the public within the meaning of Amended TSCA. For the reasons set forth below, the Court so finds. Specifically, 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…One thing the EPA cannot do, however, in the face of this Court's finding, is to ignore that risk."

Toxic Substances Control Act (TSCA) Lawsuit Timeline Summary

November 2016 — **Watchdog organizations serve the U.S. Environmental Protection Agency (EPA) with a petition calling on the agency to ban the addition of fluoridation chemicals to public water supplies due to the risks these chemicals pose to the brain.**

February 2017 — EPA denies the petition.

April 2017 — **Fluoride Action Network (FAN) and other organizations sue EPA.**

November 2017 — Court holds hearing on EPA's Motion to Dismiss.

December 2017 — Court rules in plaintiffs' favor, denying EPA's motion to dismiss, noting: "the purpose of citizen petitions is to ensure the EPA does not overlook unreasonable risks to health or the environment."

EPA files a motion asking the Court to limit the scope of evidence to the administrative record.

February 2018 — Court rules in plaintiffs' favor, denying the EPA's motion to limit review to the administrative record, thus allowing use of important new scientific studies published since the case was initiated.

October 2018 — Court denies EPA's motion to prevent plaintiffs from deposing an EPA representative on EPA's fluoride safety standards.

April 2019 — Court denies EPA's motion to prevent plaintiffs from deposing additional EPA scientists. Court also denies EPA's motion to prevent plaintiffs from obtaining documents regarding National Toxicology Program (NTP) review of fluoride.

September 2019 — Court denies EPA's motion to delay the trial.

December 2019 — Court denies EPA's motion for summary judgment. This means our case will go forward. Trial is scheduled for two weeks beginning April 20, 2020 and will run for two weeks.

April 2020 — Trial postponed on 3/17/20 due to the coronavirus outbreak.

May 2020 — Pre-trial hearing. Court denies EPA's motion to prevent plaintiffs' experts from testifying at trial. Court grants plaintiffs motion to exclude the issue of fluoride's purported benefits at trial, agreeing that benefits are not relevant to risk evaluations under TSCA.

Trial declarations from plaintiffs' witnesses submitted.

June 2020 — **Court holds a 7-day trial, marking the first time in TSCA's 45 year history that citizen groups have taken a TSCA petition all the way to a federal trial.**

August 2020 — The Court places the case "in abeyance" in part to consider the pending findings from the NTP.

November 2020 — Plaintiffs file supplemental petition to EPA asking the Agency to reconsider its denial.

January 2021 — EPA denies plaintiffs' supplemental petition.

April 2021 — Court grants plaintiffs' motion to supplement their pleadings to introduce additional evidence on standing.

June 2021 — Plaintiffs file motion to lift pause on the trial.

January 2022 — Status hearing. The Judge reiterates his desire to wait until the NTP publishes the final version of their review on fluoride's neurotoxicity before continuing with the trial.

October 2022 — **Plaintiffs introduce evidence showing that political pressures have prevented NTP from releasing its long awaited report. Court grants plaintiffs' motion to lift the stay and permit additional discovery into the NTP review.**

December 2022 — After extensive negotiations, the Department of Justice agrees to produce a copy of NTP's suppressed report on fluoride. The report is produced under a strict protective order.

January 2023 — Status hearing. Court rules against EPA's request for additional delay of the trial, acknowledging that "justice delayed is justice denied". Court sets a timeline for the final phase leading to a verdict.

March 2023 — Court denies EPA's motion to prevent plaintiffs from conducting depositions into the suppression of the NTP report.

October 2023 — Status hearing. The expiration of the CARES Act means that our attorneys will present live from the federal courthouse in San Francisco during the second phase of the trial.

January 16 2024 — Pre-trial hearing. Plaintiffs introduce evidence that key EPA witness lied under oath. The trial will be live streamed on Zoom.

January 31 - February 14 2024 — **Second Phase of Fluoride Trial**

Thanks to Derrick Broze of the Conscious Resistance and Brenda Baletti of Children's Health Defense for their contributions to this detailed overview of the TSCA fluoride lawsuit.

Although I do not expect you to read all the links, certainly some of this information is critical for a thorough understanding of the legal action in the TSCA trial on fluoridation.

Plaintiffs needed five things to win our TSCA lawsuit 1. We need to prove in court that neurotoxicity is a hazard of fluoride exposure. 2. We need to prove in court that this hazard is a risk at the doses ingested in fluoridated areas. 3. We need to prove in court this risk is unreasonable.

Previous to the above report of the court proceedings:

Federal Trial Update: New Supplement To Our TSCA Petition Submitted To Court
November 7, 2020 | Cheikhani
As you might recall, the Court requested on the last day of the trial that we submit a new Petition to the Environmental Protection Agency (EPA) to allow them the opportunity to respond to our original 2016 Petition in regards to the new studies that were published between 2017-2020. The Court also requested that we include Petitioners who were pregnant or planning a pregnancy in light of the science linking early-life exposure to fluoridated water to adverse neurodevelopmental effects in these new studies.
Yesterday's meeting with the Judge
At the very short meeting convened by the Judge, lawyers representing both sides were in attendance. Lead attorney Michael Connett told the Court that he filed, on November 4, a Supplement to our original Petition with the EPA. The Supplement asks that EPA reconsider their denial of our 2016 Petition. The reasons are set forth in the Supplement and its 9 attachments (all listed below). The Supplement has done everything the Court asked us to do with a new Petition. The Supplement also responds to the issue of Standing by identifying nine members of Food & Water Watch "who are currently pregnant, women who are actively seeking to become pregnant, and/or mothers of infants…"
We believe that this is an important and highly readable document and we urge our supporters to read it in full. However, if time is short we have presented excerpts below.
Background to the Supplement
"On November 22, 2016, the undersigned Petitioners submitted a Citizen Petition under Section 21 of the Toxic Substances Control Act ("TSCA"), requesting that the EPA prohibit the addition of fluoridation chemicals to drinking water in order to protect the public, including susceptible subpopulations, from fluoride's neurotoxic risks. After the EPA denied this petition, the Petitioners brought suit in the Northern District of California to challenge

EPA's denial. Following a bench trial in June of 2020, the Court stated that EPA had used an incorrect standard in assessing the evidence that the Petitioners had presented. ..
The Court also noted that much of the evidence that the Petitioners relied upon at trial—including recent studies funded by the National Institutes of Health (NIH)— was not yet available at the time EPA denied the Petition. (Appendix A at 4.) In light of these facts, the Court asked Petitioners to re-submit evidence to the EPA in order to give the Agency an opportunity to give the evidence a "second look" using the "proper standard" at the administrative level, which the Court 'urged' the EPA to do."
"Pursuant to the Court's request, the Petitioners are hereby submitting this Supplement to their Petition and requesting that EPA reconsider its denial of the Petition based on the information presented herein."

EPA HAS THE AUTHORITY TO RECONSIDER ITS DENIAL OF A SECTION 21 PETITION

"EPA has the inherent authority to reconsider its denials of Section 21 petitions, as the EPA itself has repeatedly acknowledged. The EPA has explained that: "Although TSCA does not expressly provide for requests to reconsider EPA denials of Section 21 petitions, 'the courts have uniformly concluded that administrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so.'" … As the EPA has explained, "the power to reconsider is inherent in the power to decide." Id. at 24 (quoting Albertson v. FCC, 182 F.2d 397, 399 (D.C. Cir. 1950)) …"

GROUNDS FOR PETITIONERS' REQUEST FOR RECONSIDERATION

1. EPA Used an Incorrect and Impermissibly Stringent Standard of Proof

"At the close of trial in June 2020, the Court observed that EPA has subjected Petitioners' evidence to an incorrect standard of proof. As the Court noted, "EPA appears to have applied a standard of causation … It's not the proper standard." (6/17 Trial Tr. 1131:5-9.)
"TSCA commands that EPA protect against "unreasonable risk," which exists when human exposure to a toxicant is unacceptably close to the estimated hazard level. (6/10 Trial Tr. 471:11-472:9.) At trial, EPA confirmed that 'EPA does not require that human exposure levels exceed a known adverse effect level to make an unreasonable risk determination under TSCA.' (Appendix H at 4.) Thus, EPA does not require proof that human exposures under a given condition of use cause the hazard. In fact, Dr. Tala Henry agreed at trial that EPA has "never once in any of its risk evaluations to date under Section 6 used a causation standard." (6/16 Trial Tr. 987:6-8.) Despite this, Dr. Henry admitted that EPA held Petitioners to a burden of proof where Petitioners needed to prove that human exposure to fluoride in water at 0.7 mg/L causes neurotoxicity. (6/16 Trial Tr. 985-15-987:2.) Dr. Henry thus made the extraordinary admission that EPA 'held the plaintiffs to a burden of proof that EPA has not held a single chemical under Section 6 before.' (6/16 Trial Tr. 987:16-19.)…"

2. Each of the Limitations that EPA Identified with the Fluoride/IQ Studies in the Petition Have Now Been Addressed by High Quality Studies Funded by the NIH

"In its denial of the Petition, the EPA criticized the human studies that Petitioners cited on three primary grounds: (1) the studies were cross-sectional and thus 'affected by antecedent consequent bias';1 (2) the studies failed to adjust for potential confounding factors; and (3) the studies failed to adequately establish a dose-response relationship between fluoride and neurotoxicity. (Fed Reg, Vol. 82, No. 37, p. 11882-83). …

"Following EPA's denial of the Petition in February 2017, a series of prospective cohort studies funded by the National Institutes of Health (NIH) were published which evaluate the impact of individualized measurements of prenatal and early-infant fluoride exposure on standardized measures of neurobehavioral performance between ages 4 and 12 (Bashash 2017, Bashash 2018, Green 2019, Till 2020)."

"These NIH-funded studies address each of EPA's three criticisms of the studies in the Petition…"

3. The National Toxicology Program Has Concluded that Fluoride Is a Presumed Human Neurotoxicant that Lowers IQ in Children

"Petitioners' contention that fluoride is a neurotoxicant has gained powerful new support from the National Toxicology Program's (NTP) recently revised systematic review and meta-analysis…"

A. NTP Agrees that Fluoride Is a Likely Neurodevelopmental Hazard to Humans

"On September 16, 2020, the NTP released its Draft Monograph on the Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects. The Monograph is a revised version of a draft issued in October 2019, and incorporates the recommendations made by a committee of the National Academy of Sciences (NAS). After making the changes recommended by the NAS, the NTP reconfirmed its conclusion that 'fluoride is presumed to be a cognitive neurodevelopmental hazard to humans.' (p. 2) …"

B. The Relationship Between Fluoride and Neurotoxic Effects Is Unlikely to Be Explained by Confounding or Other Issues of Methodology and Bias

"The NTP reached its hazard conclusion for fluoride after carefully considering issues of study quality and bias, including potential confounding, publication bias, translation bias, and the validity of exposure and outcome assessments. Each of these methodological issues were raised at trial by EPA to question the confidence in the numerous studies reporting neurotoxicity from fluoride exposure. Importantly, the NTP's report makes clear that none of the issues identified by EPA at trial warrant a downgrade in the confidence that fluoride is a human neurotoxicant. In other words, the issues identified by EPA at trial do not explain the overwhelmingly consistent association between fluoride and neurotoxic harm…"

C. The NTP Identified a Large Number of Low Risk-of-Bias Studies Linking Fluoride to Neurotoxicity

"… In total, the NTP identified 31 human studies on fluoride and neurodevelopment that it found to have a relatively low potential for bias (p. 25) and the vast majority of these studies found significant associations between fluoride and adverse effects. This highlights that the association between fluoride and neurotoxicity is not the artifact of poor study design or bias, as EPA argued at trial."

D. The NTP Has Judged the New Zealand Studies that EPA Has Relied Upon to Be at High Risk of Bias

E. The Animal Data Supports the Conclusion that Fluoride Produces Neurodevelopmental Effects

F. The NTP's Recently Retired Director Has Called for Measures to Protect Pregnant Women and Bottle-Fed Babies from the Neurotoxic Effects of Fluoride

"The relevance of the NTP's findings to water fluoridation has recently been highlighted by none other than the recently retired director of the NTP, Dr. Linda Birnbaum. On October 7,

2020, shortly after the NTP released its revised Monograph, Dr. Birnbaum issued a public statement calling for measures to protect pregnant women and bottle-fed babies from the neurotoxic effects of fluoride. Dr. Birnbaum noted that the NTP's conclusion is 'consequential,' given that "about 75 percent of Americans on community water systems have fluoride in their water.'…"

G. Limitations and Weaknesses of NTP's Report

"The NTP Monograph provides an exceptionally comprehensive review of the scientific literature on fluoride neurotoxicity, and provides ample support for its conclusion that fluoride is a neurotoxicant that reduces IQ. There are, however, some limitations and weaknesses with the NTP's analysis that Petitioners wish to bring to the EPA's attention…"

H. Even with Its Limitations, the NTP Monograph Demonstrates that Water Fluoridation Poses an Unreasonable Risk of Neurodevelopmental Harm

"Even with its limitations, the NTP Monograph demonstrates that neurotoxicity is an unreasonable risk of water fluoridation…"

4. Pooled BMD Analysis of the NIH-Funded Birth Cohort Data Confirms that Pregnant Women in Fluoridated Areas Are Exceeding the Dose Associated with IQ Loss

"A team of scientists, including the authors of the NIH-funded studies, have recently completed a pooled benchmark dose (BMD) analysis of the maternal urinary fluoride data from the ELEMENT and MIREC datasets (Grandjean, et al. 2020, in review)… Given that BMD analysis is EPA's preferred method for determining toxicity values and risk estimates, the new pooled analysis provides compelling grounds for EPA to reconsider its denial of the Petition. The analysis, which became publicly available on November 4, 2020, is attached as Appendix G…"

5. Millions of Americans Are at Risk of Harm as a Result of EPA's Failure to Regulate Fluoridation, Including Petitioners

"… Each year, there are approximately 2.5 million pregnancies in fluoridated areas; in utero exposures are thus widespread. (Appendix B at p. 78 ¶ 406.) Many of those exposed in utero will also be exposed during the sensitive neonatal period, with upwards of 1.9 million infants living in fluoridated areas being fed formula at least part of the time, including 400,000 infants who are exclusively formula-fed for their first six months. (Id.) Petitioner Organizations have members who fall within these zones of danger…"

6. EPA Erred in Considering the Purported Dental Benefits of Fluoridation in its Denial of the Petition

"In its denial of the Petition, EPA cited the purported dental benefits of fluoridation as a basis for its denial. This was improper because the Amended TSCA statute forbids risk evaluations from considering 'costs and other nonrisk factors.' 15 U.S.C. § 2620(b)(4)(B(ii). …"

7. EPA Erred in Claiming that Petitioners Failed to Adequately Identify the Chemicals at Issue

"… During the litigation on this matter, the Court considered and rejected each of these arguments, and held that the Petitioners had adequately identified the chemicals at issue, and that there was no merit to EPA's contention that it 'would become obligated to address all conditions of use of the category.'"

List of Documents submitted:

SUPPLEMENT: Petitioners' request to EPA to reconsider their denial of their original TSCA Petition of November 22, 2016. http://fluoridealert.org/wp-content/uploads/tsca.supplement.11-4-20.pdf

Appendix A: Excerpt of Court's August 10, 2020 Order. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-a.11-4-20.pdf

Appendix B: Petitioners' Summary of the Trial Record. Food & Water Watch, et al. v. U.S. Environmental Protection Agency Case No. 17-cv-02162. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-b.11-4-20.pdf

Appendix C: The NIH-funded Studies (Bashash et al. 2017 and 2018; Till et al. 2018 and 2020; Green et al. 2019). http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-c.11-4-20.pdf

Appendix D: National Toxicology Program's Revised Monograph on Fluoride Neurotoxicity. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-d.11-4-20.pdf

Appendix E: Dr. Linda Birnbaum's Statement on the NTP Report. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-e.11-4-20.pdf

Appendix F: Additional Details on the Limitations of the NTP Review. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-f.11-4-20.pdf

Appendix G: Pooled BMD Analysis of the ELEMENT and MIREC Datasets. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-g.11-4-20.pdf

Appendix H: Undisputed Material Facts from Trial and Court's Ruling on Dental Benefits. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-h.11-4-20.pdf

Appendix I: The Court's Order Dismissing EPA's Order to Dismiss.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-i.11-4-20.pdf

A. Most recent. The link to the actual court order is included and must be considered as evidence for the Board.

Federal Court Orders EPA to Regulate Fluoridation of Drinking Water under TSCA

Beveridge & Diamond | Oct 19, 2024 | By Mark N. Duvall

In a groundbreaking decision, a federal district court has ordered the U.S. Environmental Protection Agency (EPA) to regulate the "unreasonable risk" it found to be posed by the fluoridation of drinking water. The order came in the long-running case *Food & Water Watch, Inc. v. EPA*, No. 17-cv-02162-EMC, 2024 WL 4291497 (N.D. Cal. Sept. 24, 2024).

While the court did not specify what EPA must now do, its decision could significantly impact municipal drinking water systems and public health. Supported by the Centers for Disease Control and Prevention, EPA has permitted public water systems to fluoridate their drinking water as a critical measure to control tooth decay for decades. More than three-quarters of the U.S. population today gets their drinking water from fluoridated public sources.

The court order also has substantial implications for the regulated chemical industry and EPA's regulatory processes under the Toxic Substances Control Act (TSCA). This is the first instance of a court ordering EPA to "initiate a proceeding" under TSCA Section 6(a) in response to a citizen petition denied by EPA and subsequently appealed under Section 21 to a federal court. Both industry and the federal government have previously argued that Section 21 does not authorize a court to order *rulemaking* but rather a fact-gathering risk evaluation process akin to that normally required under TSCA for chemicals that EPA itself has identified as potentially presenting unreasonable risks under their conditions of use, in part because Section 21 requires a lower standard of evidence than is required of the usual risk evaluation process. A federal court has now implicitly disagreed with that argument, ordering that EPA "initiate rulemaking" to manage the risks it found to be posed by water fluoridation.

Background

EPA permits public drinking water systems to fluoridate drinking water up to certain levels under the Safe Drinking Water Act. EPA has established an enforceable maximum contaminant level (MCL) for fluoride in drinking water at 4.0 milligrams per liter (mg/L), effectively ensuring that community water systems limit fluoridation to levels that EPA has determined present no known or anticipated adverse effects on human health.

EPA has also set a "secondary" standard for fluoride at 2.0 mg/L or 2.0 ppm. Secondary standards are non-enforceable federal guidelines that address potential cosmetic effects (such as skin or tooth discoloration) or aesthetic effects (such as taste, odor, or color) in drinking water, which state or local governments may implement.

The U.S. Department of Health and Human Services (HHS) recommends the fluoridation of drinking water at 0.7 mg/L to achieve the benefits of preventing tooth decay.

Nevertheless, in 2016, a group of NGOs petitioned EPA under TSCA Section 21 to ban the fluoridation of drinking water entirely, arguing that fluoride has neurotoxic effects when ingested even at the "optimal" concentration identified by HHS and so presents an "unreasonable risk to human health."
EPA denied that petition in 2017, and, pursuant to Section 21, the NGOs appealed that denial to the federal district court for the Northern District of California. The district court judge in the case is Edward Chen, who previously had directed EPA to adopt a TSCA Section 8(a) reporting rule for asbestos in another case that contested EPA's denial of a Section 21 petition. *Asbestos Disease Awareness Org.* v. *EPA,* 508 F. Supp. 3d 707 (N.D. Cal. 2020).

In 2019, Judge Chen denied EPA's motion for summary judgment that had argued that the NGOs were required to comply with all requirements of both Section 6(b) (e.g., provide information equivalent to a risk evaluation) and Section 26 (e.g., provide information reflecting the weight of the scientific evidence). The court did so in part by citing that Sections 6(b) and 26 are not directly incorporated into Section 21, although their provisions may be looked to

for guidance. *Food & Water Watch, Inc. v. EPA*, No. 17-cv-02162-EMC, 2019 WL 8261655 (N.D. Cal. Dec. 30, 2019). Extensive discovery and a trial followed.

TSCA Proceedings

Under TSCA Section 21, any person may petition EPA to "initiate a proceeding" for the issuance, amendment, or repeal of a rule under Section 6(a). 15 U.S.C. § 2620(a). If EPA grants the petition, EPA must start an appropriate rulemaking process to consider the petitioner's requests. However, if EPA denies the petition—as it did here—it must publish a notice detailing the reasons for the denial. If EPA denies or does not respond to a petition within 90 days, then the petitioner may initiate a civil action in federal district court to compel EPA to "initiate a proceeding" for the requested rulemaking, if the court determines, without consideration of costs, that the subject chemical presents an unreasonable risk to human health or the environment under the conditions of use. The resulting rule under Section 6(a) could impose a variety of controls—ranging from a label warning to an outright ban—to manage the chemical's identified risks.

Since Congress substantially overhauled TSCA in 2016, it has not been clear what it would mean to "initiate a proceeding" for a Section 6(a) rule. The statute now generally requires prioritization and risk evaluation as critical predicates to rulemaking, and EPA's risk evaluations must be made according to the "weight of the scientific evidence" and "consistent with the best available science." 15 U.S.C. § 2625(h)-(i). However, under Section 21, a court only needs to decide whether the chemical substance presents an unreasonable risk "by a preponderance of the evidence," arguably a lesser scientific standard. 15 U.S.C. § 2620(b)(4)(B). Section 21 also only enables EPA and a specific petitioner or petitioners to present evidence, whereas the full risk evaluation process that would usually inform Section 6 rulemaking involves more than three years' worth of public participation and comment. Until now, no court had addressed whether a court ordering EPA to "initiate a proceeding" under Section 21 would require EPA to begin the full risk evaluation process or jump directly to rulemaking to manage those risks.

Without substantial analysis, Judge Edward Chen has now provided an answer. He found that the evidence suggests that HHS's "optimal" level of drinking water fluoridation—0.7 milligrams per liter, well below EPA's maximum and target concentrations—"poses an unreasonable risk of reduced IQ in children." The Court then ordered EPA to "initiate *rulemaking* pursuant to Subsection 6(a) of TSCA." Order at 2, 79 (emphasis added). Nevertheless, in a footnote, the Court left the door open for EPA to conduct additional analysis or seek additional information to "put a finer point on [the] risk posed by the condition of use before taking regulatory action." *Id.* at 67 n.33. Thus, it remains unclear to what extent EPA must now begin to draft regulations on the addition of fluoride to drinking water or may instead engage in the deliberative risk evaluation process.

Impacts and Next Steps

This order could significantly impact the chemical industry and municipal drinking water systems. If courts uphold that a TSCA Section 21 citizen's petition can be leveraged to force EPA to skip the statutory chemical prioritization and risk evaluation processes and jump directly to rulemaking, then EPA's chemical regulatory program could foreseeably be overwhelmed by competing priorities. Chemical manufacturers, processors, and users could also potentially face overbroad restrictions due to EPA's having to regulate certain chemicals on the basis of less (and potentially less comprehensive) information.

Drinking water utilities may also want to closely track this issue, which could significantly impact their operations.

Although the district court ordered EPA to initiate rulemaking to address the level of fluoride in drinking water, it remains to be seen what steps EPA will take next. The possibilities include, among others, that EPA will request more information from the public as part of the initiation of rulemaking; that it will appeal the case to the Ninth Circuit (including the district court's earlier ruling about the scope of Section 21); and that it will attempt to move the entire matter to the Office of Water under TSCA Section 9(b) on the basis that the risk

identified by the court “could be eliminated or reduced to a sufficient extent by actions taken under the authorities” of the Office of Water. Stay tuned.

Original article online at: https://natlawreview.com/article/federal-court-orders-epa-regulate-fluoridation-drinking-water-under-tsca

Sincerely,

Bill Osmunson DDS MPH

Washington Action for Safe Water

_____
From: bill teachingsmiles.com
Sent: 11/7/2024 8:01:10 AM
To: DOH WSBOH
Cc:
Subject: Public Comment for November and Supplement to #21 Petition for Rule Change

attachments\9D2C7B0C09284AB1_11 24 PC II.docx

External Email

Board of Health: Public Comment and Supplement to our Petition to protect the Public from Harm:
Bill Osmunson DDS MPH November 7, 2024
Washington Action for Safe Water
Money Marketing supports fluoridation. Science disagrees. Fluoridation harms fetuses, infants, children, youth and adults. Listen to RFK's 26 second interview.
C:\Users\14254\Downloads\Bobby NBC.mp4
Fluoridation hit the media with Trump saying he will ban fluoridation. Dictators do that. But dictators also force mass medication. The Board of Health should not be comatose on science until the President recommends stopping fluoridation.
The Board for 75 years has refused the science and laws on fluoridation's lack of benefit and harm and we have provided science for 18 years with 20 petitions to protect our most vulnerable for 14 years.
You do not have a single randomized controlled trial on the benefit of fluoridation.
You do not have a single safety study on fluoride's effect on the developing human brain, thyroid or any cell of the human body.
The National Toxicology Program did not report any safe dosage of fluoride.
The Court was clear, fluoridation is an unreasonable risk. And brain damage is only one risk.
The National Research Council 18 years ago listed about a dozen risks of concern and for 18 years the Board of Health has ignored all of them, failed to study the risks and harmed the developing brains, teeth, bones, thyroid glands, enzymatic system, kidneys, stomach, intestines, heart, and the mitochondria of every cell for most of one, actually three generations, without any warning or caution.
The Board relies on marketing and endorsements from those making the most money on products. Money can cause both conscious and subconscious bias and serious greed. In other words, money cherry picks the evidence, cherry picks reviewers of science, cherry picks authorities, and cherry picks conclusions. Money drives America and our Health Care.
I sold fluoride to patients and applied it to their teeth, thinking I was benefiting my patients. I treated and profited from split, cracked, fractured brittle teeth, not realizing too much fluoride had contributed to the harm. For dentists, fluoridation is a win, win for our bank accounts. And the Board trusts the Fluoridation profiteers for unbiased evidence? That's nonsense and is harming the public.
The Board's words matter, at least for those who trust the Board, such as city authorities.
My attempt in the past has been to find evidence which is concise and reasonably current. New Board members and growing evidence necessitates more inclusion of evidence from the NTP and Court.

The National Toxicology Program Report on Fluoride neurotoxicity.
In late 2015, I nominated fluoride for cancer, thyroid and developmental neurotoxicity for NTP to review. They accepted developmental neurotoxicity; however, both cancer and thyroid are almost as persuasive with scientific studies of harm and should be reviewed by NTP.
The following is a brief concise and accurate report of the NTP report.

1. A brief overview of the NTP report, the final report and some of the politics blocking the report until the court ordered the release. A very important read.

National Toxicology Program Finds No Safe Level of Fluoride in Drinking Water; Water Fluoridation Policy Threatened
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fn
toxicology-program-finds-no-safe-level-of-fluoride-in-drinking-water-water-fluoridation-policy-
threatened%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

March 21, 2023 | Cheikhani
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fauthor%2Fch

After a 6-year long systematic review of fluoride's impact on the developing brain, a court order has led to the National Toxicology Program (NTP) making public their finalized report
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fntp.niehs.nih.gov%2Fntp%2Fabou
that was blocked
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Farticles%2Fnt
will-make-blocked-neurotoxicity-report-public-after-fan-legal-action%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C1
by US Department of Health and Human Services (HHS) leadership and concealed from the public for the past 10 months. The NTP reported 52 of 55 studies found decreases in child IQ associated with increase in fluoride, a remarkable 95% consistency. The NTP's report says:
"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."
A meta-analysis is when information from all the relevant studies are combined to get a fuller and unbiased overall picture, rather than just looking at individual studies in isolation.
The NTP's meta-analysis also put the magnitude of harm into perspective:
"[R]esearch 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."
So, while an average drop of 5 IQ points in a population might sound small it is huge from a public health perspective. Furthermore, the NTP acknowledged there was the potential for some people to be more susceptible than average, so those people could lose much more than 5 IQ points. Those susceptible individuals could lose 10, 15, 20 or more IQ points which would likely cause profound lifetime negative consequences.
The five independent peer-reviewers of the NTP report all voted to accept the review's main conclusion and lauded the report. Their comments include: "what you have done is state-of-the-art"; "the analysis itself is excellent, and you thoroughly addressed comments"; "Well done!"; "Findings… were interpreted objectively".
The newly released documents include comments from the NTP's own experts confirming that the report's conclusion that fluoride can lower IQ
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Farticles%2Fsu
government-report-finding-fluoride-can-reduce-childrens-iq-made-public-under-epa-lawsuit%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C
does apply to communities with water fluoridation programs. NTP report says the evidence is not just in those who drink water with higher fluoride concentrations exceeding the World Health Organization (WHO) recommended maximum level of 1.5 mg/L. Furthermore, the WHO guideline was set in 1984 to protect against more severe forms of dental fluorosis and neurotoxicity was never considered. Few neurotoxicity

studies even existed in 1984.
In numerous responses to comments by reviewers of the report, the NTP made clear that they had found evidence that exposures of at least some people in areas with fluoridated water at 0.7 mg/L were associated with lower child IQ.
For example, when an unnamed government fluoridation proponent claimed:
"The data do not support the assertion of an effect below 1.5 mg/L…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…because fluoride is also found in certain foods, dental products, some pharmaceuticals, and other sources… Even in the optimally fluoridated cities…individual exposure levels…suggest widely varying total exposures from water combined with fluoride from other sources."
Additional NTP responses about the review's relevance to water fluoridation programs:
"We have no basis on which to state that our findings are not relevant to some children or pregnant people in the United States."
"Several of the highest quality studies showing lower IQs in children were done in optimally fluoridated (0.7 mg/L) areas…many urinary fluoride measurements exceed those that would be expected from consuming water that contains fluoride at 1.5 mg/L."
The NTP also responded to commenters asking whether their meta-analysis had identified any safe exposure threshold, below which there would be no loss of IQ.
The NTP responded that they found "no obvious threshold" for either total fluoride exposure or water fluoride exposure, referring to a graph in the meta-analysis (NTP's eFigure 17 reproduced below) showing that as water fluoride concentration increased from 0.0 to 1.5 mg/L there was a steep drop in IQ of about 7 points (expressed as "standardized mean difference" units in the graphs). An external peer-reviewer commented on the size of the IQ loss:
"Wow … that is substantial … That's a big deal." {p 1060}
The graph uses standardized mean difference (SMD) units where each -1.0 SMD is equivalent to about -15 IQ points.
In the left-hand graph each circle represents a study. Several have mean water fluoride below 1.5 mg/L. The right-hand graph shows the relationship between fluoride concentration and loss of IQ when all the studies are pooled. This analysis, based on many studies, is strong evidence that fluoride is associated with a substantial loss of IQ at levels of exposure common in people drinking artificially fluoridated water, and there is no observable threshold indicating a "safe" dose.
The NTP's experts further stated that the science showing neurotoxic harm "is a large, consistent and growing database."
Overall, the report provides strong evidence that fluoride is associated with a substantial loss of IQ at levels of exposure common in people drinking fluoridated water.
STAY TUNED! We will be sending out additional bulletins on the NTP report in the coming days.
PLEASE SHARE THIS BULLETIN WITH YOUR LOCAL MEDIA OUTLETS.
See our other press releases on the NTP report below:
March 15: Suppressed Government Report Finding Fluoride Can Reduce Children's IQ Made Public Under EPA Lawsuit
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Farticles%2Fsu
government-report-finding-fluoride-can-reduce-childrens-iq-made-public-under-epa-lawsuit%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C

2. The EPA Lawsuit under the Toxic Substance Control Act (This data is provided by FAN and appropriately referenced.

The report of the court proceedings below is followed by earlier evidence. If you must cut to the chase, be sure to read The Judgment <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fkey-topics%2Fepa-lawsuit%2F%23judgement&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208

EPA Lawsuit

The First Fluoride Trial (June 2020) <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fkey-topics%2Fepa-lawsuit%2F%23june-2020&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e

Justice Delayed (2020-2024) <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fkey-topics%2Fepa-lawsuit%2F%23justice-2020-2024&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e

The Second Fluoride Trial (February 2024) <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fkey-topics%2Fepa-lawsuit%2F%23february-2024&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e

The Judgment <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fkey-topics%2Fepa-lawsuit%2F%23judgement&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208

Under the Toxic Substances Control Act (TSCA) of 1976, a group of non-profits and individuals petitioned the U.S. Environmental Protection Agency (EPA) in 2016 to end the addition of fluoridation chemicals into U.S. drinking water due to fluoride's neurotoxicity. The EPA rejected the petition. In response the groups sued the EPA in Federal Court in 2017. Evidence on fluoride’s neurotoxicity was heard by the Court in two phases: a 7-day trial in June 2020, and a 14-day trial in February 2024. As of May 2024, a judgment from the court has yet to be rendered.

Official Court link: Food and Water Watch et al. v. United States Environmental Protection Agency et al. <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.cand.uscourts.gov%2Ffood-and-water-watch-v-us-epa%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d

The Petition
In 2017, Dr. Paul Connett PhD and Dr. Bill Hirzy PhD, on behalf of the Fluoride Action Network (FAN), Food and Water Watch (FWW), Moms Against Fluoridation (MAF), as well as several individuals, served the EPA with a petition <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Fepa-petition.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C
calling on the agency to ban the addition of fluoridation chemicals to public water supplies due to the risks these chemicals pose to the brain.

The Petition was submitted under Section 21 of the Toxic Substances Control Act (TSCA) because it authorizes EPA to prohibit the "particular use" of a chemical that presents an unreasonable risk to the general public or susceptible subpopulations. TSCA also gives EPA the authority to prohibit drinking water additives.

The Initial Hearings

EPA denied <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.federalregister.gov%2Fdocu 03829%2Ffluoride-chemicals-in-drinking-water-tsca-section-21-petition-reasons-for-agency-response&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11 the petition on February 27, 2017, claiming that: "The petition has not set forth a scientifically defensible basis to conclude that any persons have suffered neurotoxic harm as a result of exposure to fluoride in the U.S. through the purposeful addition of fluoridation chemicals to drinking water or otherwise from fluoride exposure in the U.S."

FAN and other plaintiffs then sued <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Flawsuit.complaint.4-18-17.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0 the EPA and won a series <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fresearchers% trial%2Fthe-timeline%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C of favorable court hearings in 2017 and 2018 on plaintiff's standing and trial discovery, while defeating several motions by EPA attempting to dismiss the case.

In late 2019 both FAN and EPA submitted motions for summary judgment in the case in the hopes that the judge would rule on the evidence submitted to the court without the need for a lengthy trial. On December 30, 2019 the Court released its order <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca.court-order.dec-30-2019.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11 denying both plaintiffs' and defendant's motions for summary judgment. This means that our case will go forward. Trial is scheduled for two weeks beginning April 20, 2020 and will run for two weeks.

Attorney Michael Connett: "this is the first time in its 43-year history that citizens have been able to successfully bring a suit to court under provisions in TSCA"

Pre-Trial

On March 17, 2020 the Court postponed the April 2020 fluoride lawsuit trial dates due to the coronavirus outbreak. The trial will now be held June 8-19 by Zoom webinar (instead of in person at the courtroom).

In a May 2020 pre-trial hearing, the Court cleared the way for three international experts in neurotoxicity (Dr. Howard Hu, Dr. Philippe Grandjean, and Dr. Bruce Lanphear) to testify on the risks of fluoride in public water supplies on behalf of the plaintiffs. The court also ruled that the purported benefits of community water fluoridation cannot be part of the trial, restricting testimony to the toxic risks under the Toxic Substances Control Act (TSCA) Read the May 2020 trial declarations from our 4 witnesses:

Philippe Grandjean, MD, PhD <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-trial-Grandjean-Declaration.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Howard Hu, MD, MPH, ScD <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-trial-Hu-Declaration.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Bruce Lanphear, MD, MPH
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-trial-Lanphear-declaration.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Kathleen Thiessen, PhD
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-trial-Thiessen-Declaration.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

The First Fluoride Trial (June 8 - 19, 2020)
The first trial in the TSCA fluoride lawsuit took place in June 2020 over Zoom webinar. The trial lasted two weeks and featured testimony from FAN's expert witnesses (Drs Hu, Lanphear, Grandjean, and Thiessen) who are subject matter experts on developmental neurotoxicity and risk assessment, pitted against EPA's witnesses.

Shockingly, EPA did not rely on its own agency experts to defend its position that fluoride is not neurotoxic to humans. Instead it hired an outside consulting company, Exponent, a firm deployed by corporations to deny and downplay the health impacts of chemicals in litigation. Exponent experts attempted to cast doubt on fluoride's neurotoxic effects even as the EPA's own scientists, under subpoena by the plaintiffs, said new research does indeed warrant "an update to the fluoride assessment".
"I think it's a reason for doing an update to the fluoride assessment" - Dr. Joyce Donohue, EPA Office of Water, on recent NIH-funded studies showing fluoride harms the developing brain.
FAN attorney, Michael Connett
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.sirillp.com%2Fprofile%2Fmic
connett%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C
, gave the opening statement in the trial - a summary of the case that fluoride presents a neurotoxic hazard (a threat to the brain); that this hazard is a risk at doses experienced in fluoridated communities (.7ppm); and that this risk is an "unreasonable risk" as defined by TSCA. The EPA is represented by lawyers from the Department of Justice (DOJ). The DOJ argued in their opening statement that establishing fluoride as a neurotoxic hazard requires a systematic review and without that, FAN's case falls.

The first fact witness
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fth
tsca-trial-day-1-june-8-2020%2F%3FeType%3DEmailBlastContent%26eId%3Dd2727b36-379f-4a5a-835c-f8ed8c91c5e0&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%
called by the plaintiffs (FAN) was Dr. Joyce Donohue who has worked in the EPA's Office of Water since the 1996 and has been their spokesperson on fluoride. Her testimony in the trial was based on a video recording of her deposition in 2019. From this deposition our attorney was able to yield two key concessions:

a) The EPA as of 2019 had no studies to provide a pregnant woman to show her fetus was safe from neurotoxicity. In fact the EPA only had studies showing harm to the fetus.

b) Dr. Donohue recommends EPA and other regulatory bodies do risk assessments of fluoride with neurotoxicity as an end point. All EPA risk assessments on fluoride to date have been based on potential damage to teeth and bones.

FAN's first expert witness
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fth
tsca-trial-day-1-june-8-2020%2F%3FeType%3DEmailBlastContent%26eId%3Dd2727b36-379f-4a5a-835c-f8ed8c91c5e0&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%
called was Dr. Howard Hu, MD, MPH, ScD, the lead author on a series of key NIH-funded

research papers on fluoride and developmental neurotoxicity. Hu's credentials are very impressive. Dr. Hu came across as knowledgeable and credible and was able to summarize the importance of his research, stressing the importance of a loss of 3 or 4 IQ points at the population level while drawing a striking parallel to lead's neurotoxicity.
FAN's second expert witness <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-trial-Grandjean-Declaration.pdf%3FeType%3DEmailBlastContent%26eId%3Dd2727b36-379f-4a5a-835c-f8ed8c91c5e0%26eType%3DEmailBlastContent%26eId%3D492bbd66-0721-4212-a207-8c2a94d3d2a4&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%, Danish scientist and neurotoxicity expert Philippe Grandjean, MD, DMSc, <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-trial-Grandjean-Declaration.pdf%3FeType%3DEmailBlastContent%26eId%3Dd2727b36-379f-4a5a-835c-f8ed8c91c5e0%26eType%3DEmailBlastContent%26eId%3D492bbd66-0721-4212-a207-8c2a94d3d2a4&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f% took the stand on day two. Grandjean is the author of the book Only One Chance, <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fglobal.oup.com%2Facademic%2F one-chance-9780190239732%3Fcc%3Dus%26lang%3Den%26&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2 in which he warns of the dangers of exposing children to neurotoxicants during early development, especially during the fetal stage. According to many who watched his testimony, Dr. Grandjean left no doubt that fluoridation poses a threat to the brains of children and easily debunked the EPA's paid experts' arguments.

FAN asked Dr. Grandjean to do a review of the literature since his famous 2012 meta-analysis <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker% to include the most recent US government-funded studies. Grandjean did this review but he went one step further and quantified the risk of IQ loss from fluoride to children based upon the Bashash 2017 <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker% and the Green 2019 <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker% (Canadian study) mother-offspring studies. For this analysis Grandjean did what is called a Benchmark Dose study (using methods that he and his colleagues have pioneered, and used by the EPA). He concluded that a safe reference dose (RfD) be no higher than 0.15 mg per day to protect against a loss of one IQ point. This is well below fluoride exposure levels experienced by pregnant women (and passed to the fetus) in the Bashash and Green studies.
FAN's next expert witness <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fb 11-20%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0 was renowned clinical scientist and professor, Dr. Bruce Lanphear… who's work on lead….. Dr. Lanphear explained that there was no safe level of fluoride exposure with regard to neurotoxicity, and that the effects seen in recent studies are "equal to what we saw with lead in children."
Next the court watched the deposition video of CDC Oral Health Division Director, Casey Hannan, who confirmed his agency agreed with the National Research Council's 2006 findings that fluorides "interfere with the function of the brain and body by direct and indirect means," among many other stunning admissions, yet did nothing to act upon or study these findings.
Next up in the trial was fact witness Dr. Kristina Thayer, Director of the US EPA's Chemical and Pollutant Assessment Division. Dr. Thayer confirmed the vulnerability of the developing brain to environmental toxins as well as fluoride's known neurotoxicity "at some level."

The next expert witness was veteran risk assessment scientist Kathleen Thiessen, PhD, who was a member of the 2006 NRC committee <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fresearchers%
362c-43c4-88e0-
17ad6dcf6c18&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%
that reviewed fluoride, and authored around a third of the report. Dr. Thiessen confirmed that the EPA was ignoring the neurotoxic risk from fluoridation because doing so would require them to effectively ban the practice. She also compared the amount of evidence of neurotoxicity from fluoride to other toxins the EPA currently did regulate as neurotoxic, saying "the amount of evidence for fluoride is considerably larger."
The EPA then called their first expert witness, Dr. Joyce Tsuji, PhD from corporate consulting firm Exponent. This is the same scientists-for-hire firm the tobacco industry used to deny lung cancer risk <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fbusiness-ethics.com%2F2016%2F12%2F13%2F1724-big-companies-in-legal-scrapes-turn-to-science-for-hire-giant-
exponent%2F%3FeType%3DEmailBlastContent%26eId%3Dc452729b-dd53-4386-aa0c-
a6f814bc35aa&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%
. Dr. Tsuji's answers repeatedly contradicted the testimony from her pre-trial deposition. Eventually FAN attorney Michael Connett was able to get Dr. Tsuji to admit on the stand that "there is enough literature for us to be concerned" about fluoride's neurotoxicity.

The EPA then called their second expert witness, Dr. Ellen Chang (also from Exponent), to discuss the human fluoride/IQ studies. She spent much of her time attacking the quality of the studies linking fluoride to lowered IQ. FAN attorney Michael Connett was successful in exposing Dr. Chang's blatant bias and, in a defining moment at trial, was able to get her to admit that the fluoride/IQ studies from Till (2020), Green (2019), and Bashash (2017) were the most rigorous neurotoxicity studies to date.

Next up was Dr Tala Henry, Director of the EPA's Risk Assessment Division, who has 25 years of risk assessment experience at the agency. Her testimony focused on the many hurdles presented to those who attempt a risk assessment and risk evaluation of a chemical. FAN's attorney Michael Connett dealt a destructive blow to Dr. Henry during cross-examination came when he asked: "you held the plaintiffs to a burden of proof that EPA has not held a single chemical under section 6 [of the Toxic Substances Control Act] before, correct?". Henry replied, "by the words on the page, I guess that's true". The EPA closed its case with a short video segment of Dr. Joyce Donohue, the predominant fluoride expert in the EPA's Office of Water. If anything, this video strengthened our case and did not weaken it.

The last day of trial featured a dramatic moment, as the federal judge surprised everyone by recognizing the key plank in our case, undermining the key argument in the EPA's case. The judge said:
"So much has changed since the petition was filed…two significant series of studies – respective cohort studies – which everybody agrees is the best methodology. Everybody agrees that these were rigorous studies and everybody agrees that these studies would be part of the best available scientific evidence."
The EPA appears to have applied a standard of causation, which from my read of TSCA is not accurate. It's not a proper allocation. It's not the proper standard.'

After closing statements, Judge Chen shared his views on the case and made recommendations. Chen asked the parties whether they could discuss the possibility of an amended petition and re-assessment by the EPA, or start a new petition and have the EPA conduct a proper review. To many observers, it felt as though Chen was intimating that FAN had essentially won the case, but he was giving the EPA a chance to right their original wrongs.

The ending of the first fluoride trial was somewhat unexpected as the judge asked the

two parties to work out an agreement. The Court specifically urged the EPA to independently re-assess the hazard posed by fluoridation chemicals and the Judge assigned August 6, 2020 for a status hearing to reconnect with the two sides. When the parties met on August 6, EPA claimed that they "didn't have the resources to do a risk assessment," and were going to let the court record stand without taking any further action. The judge continued to insist the EPA reconsider their position, and also said he wanted to review the updated National Toxicology Program's (NTP) review of fluoride's neurotoxicity, which was due to be released soon.

In August 2020, the Court placed the case in abeyance (on hold) in part to consider the pending findings from the pending NTP report on fluoride neurotoxicity.

Justice Delayed

The Court requested on the last day of the trial that FAN submit a new petition to the EPA to allow them another 90-day opportunity to respond to our original 2016 petition with the addition of all the new studies on fluoride neurotoxicity published between 2017-2020. The Court also requested that FAN include petitioners who were pregnant or planning a pregnancy in light of the science linking early-life exposure to fluoridated water to adverse neurodevelopmental effects in these new studies.

On November 4, 2020, FAN filed a supplement <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca.supplement.11-4-20.pdf%3FeType%3DEmailBlastContent%26eId%3D628cf9ee-6fd1-471d-a1a2-d986dbfe943e&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%
to our original petition to the EPA. The supplement asked that EPA reconsider their denial of our 2016 Petition. The supplement has done everything the Court asked us to do with a new petition. The supplement also responds to the issue of standing by identifying nine members of Food & Water Watch "who are currently pregnant, women who are actively seeking to become pregnant, and/or mothers of infants".

In December 2020, the EPA filed a last ditch motion to attempt to dismiss our landmark case, arguing that plaintiffs lacked standing; a motion they had previously made and were denied. The Court denied <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca.court-order.jan-13-2021.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11
the EPA motion as being premature and procedurally improper. The trial will continue, in abeyance, as the Court awaits the EPA's response to FAN's updated petition and an updated draft of the National Toxicology Programs (NTP) monograph on fluoride's neurotoxicity, expected early in 2021.

In January 2021, the EPA denies FAN's supplemental petition, setting the stage for additional hearings and filings in the TSCA fluoride lawsuit. An April 2021 status hearing with the Court focused on FAN's amended petition to the EPA, which the Judge recommended before he placed the trial in abeyance. The amended version has a more detailed list of plaintiffs and includes recent studies that were not a part of the trial. The Court grants <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca-court-order.may-11-2021.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11
FAN's motion to supplement our pleadings to introduce additional evidence on standing, which should satisfy the Judge's prior concerns on this issue and ensure that the case is resolved on the merits.

The Judge reiterates that he is keen to read the NTP's finalized report on fluoride's neurotoxicity as well as other new science on the issue, including an upcoming pooled analysis of the NIH-funded birth cohort studies. To consider this new science, the Judge discussed having a "phase 2 trial" where Plaintiffs and EPA can introduce additional

expert testimony on the NTP report and other developments. In June 2021, FAN attorney Michael Connett informs the Court of a new landmark study <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker% by Grandjean et al., confirming that very low levels of fluoride exposure during pregnancy impairs the brain development of the child. The paper's authors concluded in the Benchmark Dose (BMD) analysis that a maternal urine fluoride concentration of 0.2mg/L was enough to lower IQ by 1 point. The judge was waiting to see this analysis as well as the final version of the NTP review before moving forward with the case.

In a January 2022 status hearing, the Judge reiterates his desire to wait until the NTP publishes the final version of their review on fluoride's neurotoxicity before continuing with the trial. The NTP report had been delayed, with speculation <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fb 19-
21%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0 brewing that dental interests were actively influencing the report's final publication.

In September 2022, FAN filed <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca-plaintiffs.motion-to-lift-stay.sept-12-2022.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11 a motion to lift the pause on the trial in response to the indefinite postponement of the NTP fluoride review. The final publication of the NTP review was expected at the end of 2021, then promised again in early 2022, with May 2022 being the long-awaited release date. May 2022 came and went without any sign of the NTP report.

In October 2022, FAN attorney Michael Connett introduced evidence from Freedom of Information Act (FOIA) documents showing that political pressures had prevented NTP from releasing its long-delayed report [link to new NTP page]. The Court promptly granted <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca-court-order.abeyance-lifted.oct-28-2022.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11 our motion to lift the stay on the trial and permit additional discovery into the NTP review.

EPA's objections to using any version of the NTP report besides the "final" version during the trial was based on their concern that the NTP's findings would be made public prematurely. To circumvent this objection, the Court placed the NTP's review under protective order so that it was only made available to the parties involved, the Court, and expert witnesses. The Court urged both parties to come together and find a way to get the current NTP review into the Court's hands "voluntarily," while also leaving the door open for FAN attorney Michael Connett to use "subpoenas or a motion to compel," the release of the long-delayed report.

In December 2022, after extensive negotiations, the Department of Justice (DOJ) agreed to produce <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca.plaintiffs-filed-redacted-notice.12-15-22.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0 a copy of NTP's suppressed report on fluoride. The report is produced under a strict protective order.
FAN Attorney Michael Connett shared with the Court FAN's desire to see the final NTP review from May 2022 available to the public, as well as the communications and criticisms from the CDC and HHS that led to it being blocked. Connett pointed out that FAN had evidence obtained through FOIA requests showing that the American Dental Association (ADA) was already given the NTP review so they could work to discredit it, and therefore there is no justifiable reason for the EPA to continue hiding it from the

public.

In January 2023 the Court ruled against EPA's request for additional delay of the trial, acknowledging that "justice delayed is justice denied". The Court sets a timeline for the final phase leading to a verdict.

In February 2023, after being served a subpoena <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2F2023_02_14_Order-re-NTP-BSC-Materials.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7 by our attorneys, the NTP agreed to publicly produce their final report that was intended to be published in May of 2022, along with communications between various federal agencies and the NTP about the report. This allows the public to finally see the report and accompanying documents that were blocked from being published by the leadership at U.S. Health and Human Services (HHS) in May of 2022. Internal CDC emails discovered through FOIA by FAN show that the publication was blocked <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Ff emails-expose-fluoridation-promoters%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f% at the last second due to interference <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FPlainitffs-Opp-Brief_FILED.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f from Assistant Health Secretary, Rachel Levine.
The NTP fluoride review was issued <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fs government-report-finding-fluoride-can-reduce-childrens-iq-made-public-under-epa-lawsuit%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C in two parts, a monograph and a meta-analysis. The meta-analysis found that 52 of 55 studies found lower IQ with higher fluoride exposures, demonstrating remarkable consistency <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fg report-finds-no-safe-level-of-fluoride-in-water-fluoridation-policy-threatened%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f% . Of the 19 studies rated higher quality, 18 found lowering of IQ. The meta-analysis could not detect any safe exposure, including at levels common from drinking artificially fluoridated water.

In March 2023 the Court denied EPA's motion to prevent FAN from conducting depositions into the suppression of the NTP report. Dates are set for the final phase of the TSCA fluoride lawsuit - January 29 thru February 13, 2024.

FAN learned at an October 2023 status hearing the start date for the last phase of our fluoride trial would be pushed back two days to January 31st, 2024. The expiration of the CARES Act means that our attorneys will present live, in-person from the federal courthouse in San Francisco during the second phase of the trial. The trial will be live streamed on Zoom for the public to view.

In a January 2024 pre-trial hearing, FAN attorney Michael Connett introduced evidence <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fe witness-lied-under-oath%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11 that key a EPA witness lied under oath.
The Second Fluoride Trial (January 31 – February 20, 2024)
The second trial in the TSCA fluoride lawsuit took place January 31 – February 13, 2024, at the Federal Courthouse in San Francisco and was live-streamed on Zoom. The trial lasted two weeks and featured testimony from the same FAN expert witnesses seen in the first fluoride trial – Drs. Hu, Lanphear, Grandjean, and Thiessen.

Central to the crux of the case, Connett focused on EPA's admittance that they did not use the appropriate EPA guidelines in their risk evaluation of fluoride and did not follow the Toxic Substances Control Act (TSCA) statutes when evaluating whether fluoride posed an unreasonable risk to the developing brain. Not only did EPA fail to follow TSCA and agency risk assessment rules, but they went further by admitting that they held fluoride to a higher standard than any other chemical. This included the EPA's insistence in discounting high-dose fluoride studies, while EPA has never disregarded higher-dose studies when identifying a hazard with any other chemical.

Connett also honed in on the National Toxicology Program's (NTP) systematic review of fluoride neurotoxicity <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fn toxicology-program-finds-no-safe-level-of-fluoride-in-drinking-water-water-fluoridation-policy-threatened%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f% , and a large body of animal data showing brain harm from fluoride. The NTP review found a large number of studies have been published on fluoride and human IQ. In total they identified 72 human studies of which 64 found a connection between fluoride and IQ deficits. 18 of the 19 studies deemed high quality found that fluoride lowered IQ, a 95% consistency. Connett flagged recent research relied upon by EPA that did not find neurotoxic effects from fetal fluoride exposures as deeply suspicious. He said the authors of these studies were long-time promoters of water fluoridation, compared to FAN expert witnesses, who have all worked with the EPA and have been relied upon as experts on the regulation of environmental toxins by governments around the world and are subject-matter experts on fluoride.

Connett discussed how the exposure level at which a chemical presents a risk for toxic effects (a threshold level) varies substantially across the human population, but the point of a regulatory action is to protect the most vulnerable people in the population. Connett stressed to the Court that "TSCA commands us to protect the vulnerable". Connett then wrapped up by pointing out that roughly two million pregnant women and 400,000 formula-fed babies exposed to fluoride in water are at risk and that TSCA requires the EPA to consider injuries that chemicals pose to sensitive and highly exposed people. The EPA focused their opening statement on the talking point that "the dose makes the poison," suggesting, in contrast to the actual published research, that there is insufficient compelling evidence that fluoride is a neurotoxin at the current levels used for fluoridation in the U.S. and that therefore water fluoridation doesn't pose a risk to children. EPA named the expert witnesses it will call in the case: David Savitz, Ph.D., who chaired NASEM's committee that peer reviewed the NTP's systematic review; EPA risk assessment expert, Stan Barone, Jr., PhD; and and Jesus Ibarluzea, PhD, authored of the flawed "Spanish" study.

FAN attorney Michael Connett then called our first expert witness to the stand, Howard Hu, MD, MPH, ScD. <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fts fluoride-trial-witness-spotlight%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7 Dr. Hu has authored more than 320 papers in peer-reviewed journals and published several landmark studies on fluoride and the brain. He also advises the EPA and collaborates with its scientists on issues related to lead exposure.

Connett asked Dr. Hu how he would compare the peer review process that his fluoride studies underwent with other studies he's published. Hu responded that his fluoride studies are "probably the most extensive peer review process I've experienced." Hu also discussed his concerns about the Spanish study the EPA used as a basis to argue fluoride is not toxic at low levels, and criticized the EPA's opening statements, saying that the

EPA was presenting data as black and white.

Hu then compared his Canada MIREC <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.mirec-canada.ca%2Fen%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44> cohort study and Hu's more recent MADRES <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmadres.usc.edu%2Fwelcome%2F> cohort study from the U.S. Both indicate higher levels of fluoride in the urine of pregnant mothers in the third trimester. Hu remarked that the third trimester increase is reminiscent of what we saw with lead: fluoride is stored in the mother's bones and during the third trimester, when fetal bone growth accelerates, the mother's body transfers calcium from her bones, along with any present toxins like fluoride, to the fetus.

Dr. Hu was interviewed by independent journalist Derrick Broze <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftheconsciousresistance.com%2F%> after the first day of court adjourned:
Next up was FAN expert witnesses Bruce Lanphear, MD, MPH, who has studied the impact of toxic chemicals, including lead and pesticides, on children's brain development for over 20 years. Lanphear testified that his research has been almost exclusively funded by federal agencies, including the EPA and the Centers for Disease Control and Prevention (CDC). In fact, Dr. Lanphear's research was cited by the EPA as the principle study upon which the agency based its current regulatory standards for lead in air and water.

Lanphear discussed the findings and methodology used for several landmark human studies funded and vetted by the National Institutes of Health (NIH) on fluoride and the brain that he co-authored <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker%>. Lanphear stated that out of the 350+ studies he's published, his study was one of the two most rigorously reviewed and scrutinized studies prior to publication in his career due to the "implications for public health policy." His study found a linear dose-response relationship between fluoride and IQ, meaning that the lowered IQ effect occurred with any level of fluoride exposure and increased as the exposure increased.

There was then discussion of another study <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker%> he co-authored which found that consumption of infant formula reconstituted with fluoridated water led to excessive fluoride intake and lower IQ scores for both boys and girls compared to their breastfed counterparts who received very low intakes of fluoride. Lanphear also pointed out that studies have consistently found that children in poorer areas were often exposed to more toxins, and the effects of fluoride exposures for their mothers during pregnancy and for the children during formula feeding could compound these effects, making the poor particularly vulnerable to fluoride's effects.

In his testimony, Lanphear addressed the variability of findings in different studies - some find sex-differentiated responses to fluoride and others don't, or some find neurotoxicity at lower levels and some at higher levels. Lanphear said that the same variability exists in toxicity studies for lead, where some studies find greater effects in boys and others in girls. The overall indication is that lead, like fluoride, is toxic and that other factors drive sex differentiation in a particular context.

The discussion then focused on how fluoride could increase hypothyroidism rates in pregnant women, impacting fetal brain development, and how these effects were both increased if the mother was iodine deficient. Lanphear co-authored key studies <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2> on these subjects. He pointed out that the 2006 National Research Council report <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fresearchers%> recognized that fluoride was a thyroid disruptor. He also noted that iodine deficiency has

been increasing in the United States. FAN attorney Michael Connett asked, "Is there any dispute that hypothyroidism can lead to a lower IQ?" Lanphear: "No."

Lanphear wrapped up his testimony by discussing his work <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker% measuring maternal urinary fluoride concentrations of pregnant women. He testified that an average woman living in a fluoridated community has fluoride levels in their urine twice as high as an average woman living in a non-fluoridated community. Connett asked, "What is the cause of this difference?" Lanphear responded, "Fluoridated drinking water."

Journalist Derrick Broze interviewed Dr. Lanphear after his testimony on day two of the trial:
The third expert witness called by FAN was Philippe Grandjean, MD, DMSc. <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FPhillipe-Grandjean-Spotlight-Final.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11c Dr. Grandjean is a physician, a scientist, an internationally known expert in environmental epidemiology, an author, and both a professor of environmental health at the Harvard School of Public Health and the head of the Environmental Medicine Research Unit at the University of Southern Denmark.

Grandjean testified that he has been given grants and/or contracts to advise the EPA, the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA), the World Health Organization (WHO), and numerous other government bodies for over 25 years. Dr. Grandjean said he had even been retained by the Department of Justice, which is representing the EPA in our trial, as an expert witness on environmental toxins.

Grandjean is the author or co-author of some 500 scientific papers and is perhaps best known worldwide for his research on the neurotoxicity of mercury, which involved studying the IQ of children born to mothers whose diet was high in mercury. This work led to defining the EPA's safe regulatory levels for mercury in the diet and inspired downward revisions of methyl mercury exposure limits internationally.

Dr. Grandjean has authored or co-authored several studies <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.sciencedirect.com%2Fscienc and reviews on fluoride's neurotoxicity, <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fehjournal.biomedcentral.com%2F 019-0551-x&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e217 as well as the first benchmark dose analysis <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2 on fetal fluoride exposure which found that a maternal urine fluoride concentration of 0.2 mg/L, which studies show is exceeded 4 to 5 times in pregnant women living in fluoridated communities, was enough to lower IQ by 1 point. In his testimony, Grandjean confirmed that the fluoride the mother is absorbing will pass into the child's brain. "You only get one chance to develop a brain. Once it's harmed, there's nothing you can do." Grandjean says.

Attorney Connett showed a quote from EPA scientist Kristina Thayer, who provided testimony in the first phase of the trial. Dr. Thayer said she believes that animal data supports the biological plausibility of fluoride causing neurotoxic effects in humans. Grandjean agreed with Thayer's opinion. Connett asked Grandjean about the EPA's opening statement in which they claimed that Chinese fluoride studies were looking only at very high levels of fluoride exposure. Grandjean insisted this was not the case, saying that even at lower levels there was evidence of cognitive impacts from fluoride, confirming outright that he felt neurotoxicity was definitely a hazard of fluoride exposure.

Connett then asked about NTP's May 2022 final draft report, which included Grandjean's own studies and found lower IQ in children exposed to fluoride during fetal development. Connett specifically asked about the EPA's claim that the NTP's findings were "driven by studies looking at fluoride levels of 7.0 ppm and higher." Dr. Grandjean replied, "They must have a misunderstanding because that's certainly not correct." He then agreed with the NTP authors' statements that some of the higher-quality studies that found harm were done in optimally fluoridated communities.

Dr. Grandjean then confirmed that over a lifetime of dealing with evidence on neurotoxicants, "Fluoride probably has the largest body of evidence of any of our known or suspected neurotoxicants." Agreeing with NTP's finding that the consistency of association of lower IQ in children in five different countries rules out the possibility that there is a common factor other than fluoride exposure that can account for this outcome, Dr. Grandjean stated: "When it comes to fluoride, we have a massive amount of evidence. There is something very serious going on here that we must take seriously."

Journalist Derrick Broze interviewed Dr. Grandjean after his testimony on day three of the trial:
Next to take the stand was EPA's expert witness Stanley Barone, Ph.D., a risk assessment scientist from the EPA Office of Chemical Safety and Pollution Prevention, testifying as FAN's fact witness to establish EPA's methods for risk evaluation under the Toxic Substances Control Act <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.epa.gov%2Flaws-regulations%2Fsummary-toxic-substances-control-act&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e21 (TSCA).

Through questioning, Barone explained the EPA's risk assessment <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.epa.gov%2Frisk&data=05% method - the method FAN says EPA is failing to apply in the case of fluoride. As an EPA developmental toxicologist, Barone was heavily involved in TSCA's first 10 risk evaluations. Before the trial, the plaintiffs asked Barone to establish the risk evaluation process for the record.

Connett questioned Barone on key elements of the hazard assessment. He asked Barone to confirm that to determine whether a chemical is a hazard - step one in the risk assessment process - there is no need to prove causation. Barone agreed that to establish that a chemical is a hazard, EPA requires proof of association, not causation.

Next, Connett asked Barone whether EPA had ever made a different hazard evaluation for high-dose versus low-dose exposure in any of the risk evaluations it had done to date under TSCA. Barone said he was confused by the question. Judge Chen interjected to pose the question himself. "In the hazard evaluation, is it a binary decision?" Barone said it was. In other words, a chemical poses a hazard or it doesn't. The EPA doesn't differentiate between high and low doses in determining whether something is a hazard. Barone also confirmed that once something has been confirmed as a hazard, medium- and high-quality studies are then used to identify a hazard level. These are points our attorney laid out in his opening remarks.

In what would become a defining moment in the trial, Dr. Barone testified that in his estimation we should have a margin of safety of at least 10x for fluoride to protect the most vulnerable in society. The current margin of safety between fluoridated water at 0.7 ppm and the level that NTP found neurotoxicity, 1.5 ppm, is only 2x. EPA would backpedal from this admission throughout the rest of the trial. Some observers might say this moment forced the EPA to change strategy mid-trial.

FAN attorneys then called to the witness stand Dr. Brian Berridge, DVM, DACVP, Ph.D.,

who oversaw the completion of the NTP's work, to discuss the NTP fluoride review and the peer-review process.

In December 2023, EPA moved to exclude <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-Motion-Exclude-Testimony-Brian-Berridge.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C> Berridge's testimony from the trial, arguing it would speak to the political influence exerted to stop the NTP report's publication, rather than to the scientific findings in the report, which are central to the trial. EPA attorneys argued Berridge's testimony would be "unfairly prejudicial" <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fwp-content%2Fuploads%2FEPA-Motion-Exclude-Testimony-Brian-Berridge.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C> to the agency. Although Berridge commented in an email, obtained by FAN via a FOIA request, that there was an ongoing attempt to modify the report <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fde-fluoride-neurotoxicity-closer-final-publication%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%> to satisfy interested actors and to obstruct its publication, FAN did not call on him to speak to that issue, but rather on the integrity of the scientific process in the report's production. In a blow to EPA, Judge Chen said he woul allow Berridge's testimony <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fde-rejects-epa-bid-exclude-witness-fluoride-lawsuit%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C> .

Dr. Berridge testified at trial that he signed off on the May 2022 version of the NTP fluoride review as a final and complete report that was ready for publication.

Read more: What Dr. Berridge Couldn't Tell <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fde-brian-berridge-fluoride-trial-public-health%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C1> The Court

FAN Attorney Michael Connett then called veteran risk assessment scientist, Dr. Kathleen Thiessen as the next expert witness. Connett establishes that Dr. Thiessen is the author of a large portion of the 2006 NRC fluoride review, and that she also worked on the 2009 review. Connett asked Thiessen if there is any reasonable doubt that neurotoxicity is a hazard of fluoride exposure. Thiessen replied that "neurotoxicity is a hazard of fluoride exposure, the evidence is abundant".

Connett then asked several questions comparing the NTP review process to the EPA review process, Thiessen says the EPA has not been as open and transparent. That the NTP's communication of its conclusions about fluoride's toxicity was more transparent.

Day six of the second trial in the fluoride lawsuit started off with a bang, as FAN attorneys shared with the Court a new systematic review by Canadian researchers, published the night before, linking fluoride exposure at very low levels to lower IQ in children.

Canada's public health agency, Health Canada, commissioned a team of scientists to study the effects of fluoride on human health, but the agency did not publish the review. The peer-reviewed journal Critical Reviews in Toxicology instead independently published the study. <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.tandfonline.com%2Fdoi%2F> The researchers calculated the "point of departure" for the effects of fluoride on IQ - also

known as the "hazard level," the lowest point at which a toxic effect is observed - and found it to be 0.179 milligrams per liter (mg/L) in water.

Levels of fluoride found in drinking water in the U.S. and Canada typically are in the higher range of 0.7 mg/L. The NTP report set the hazard level at 1.5 mg/L, and one of the key studies <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F341 at the center of the trial set the level even lower than 0.2 mg/L.

Even at a hazard level of 1.5 mg/L, exposure levels for fluoride carry significant risk under TSCA's guidelines, but this new level identified by Canadian researchers would set a risk level even further below current exposure levels.

The findings are important to the trial because the identified hazard level was quite low and also because the authors calculated their hazard level in terms of water fluoridation levels, which they extrapolated from the urinary fluoride levels used in most studies.

The findings also are significant because David Savitz, Ph.D., professor of epidemiology at Brown University and the EPA's first witness, was part of the expert panel that advised Health Canada on how to interpret this study and other data. The expert panel that included Savitz concluded there wasn't enough evidence to lower the amount of fluoride in drinking water based on its neurocognitive effects.

Next, EPA's first key witness, David Savitz, Ph.D. took the stand. Dr. Savitz is a professor of epidemiology at Brown University School of Public Health. He worked with the National Academies of Sciences, Engineering, and Medicines (NASEM) in reviewing the draft NTP fluoride report.

Over nearly three days of testimony, Savitz downplayed the link between fluoride and IQ loss in children. Savitz's testimony supported the EPA's three key arguments:
Data on fluoride's neurotoxic effects for children at current levels of water fluoridation is mixed or uncertain and therefore no action should be taken.
There are limitations to the NTP's conclusions, published in draft form <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fntp.niehs.nih.gov%2Fsites%2Fdef last year, linking fluoride exposure and IQ loss in children at 1.5 milligrams per liter (mg/L).
More recent studies not considered by the NTP cast doubt on the NTP's findings.
However attorney Michael Connett and even Judge Chen pushed back on his conclusions. Connett underscored in his cross-examination that Savitz is an expert in epidemiology but has no experience researching fluoride.

Savitz testified that the Health Canada panel he was on determined that data showing IQ loss in children at existing water fluoridation levels contained too much "uncertainty" to set a hazard level for drinking water, so they advised Health Canada not to change its fluoridation levels.

Under cross-examination, Savitz told the court he sat on that panel at the same time that the EPA was paying him $500 per hour — totaling between $137,000 to $150,000 for 275-300 hours of work — as a litigation expert for the EPA in this trial examining that very question. Judge Chen asked Savitz if Health Canada knew he was serving as an expert witness in this case when they invited him to the panel. Savitz said the agency did.

Regarding his work reviewing the NTP fluoride report, Savitz said NASEM determined the first draft of the NTP's report, which classified fluoride as a neurotoxin, fell short of providing "a clear and convincing argument" that supported its assessment. Savitz told the court he didn't think NTP's conclusions were "wrong" but that they were stated in a way that could be "misused" as a tool for setting or changing water policy on water

fluoridation. Savitz said he thought that after the revisions, the communication was "tempered" and "more consistent".

Savitz testified that because two of the four major cohort studies discussed in the trial (MIREC <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2 and ELEMENT <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsph.umich.edu%2Fcehc%2Feleme), found a statistically significant effect of fluoride on IQ at low levels, and two did not (Odense <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2 and INMA <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.sciencedirect.com%2Fscienc), there was too much uncertainty to definitively conclude that it posed a danger at current levels of water fluoridation. Judge Chen asked, "I take it the converse would also apply? Which is that given this mix [of results] you can't foreclose that there is an effect at U.S. drinking levels?" Savitz conceded this was true.

Judge Chen asked, given Savitz's response and the NTP's findings, if it makes sense to assume that there is a concern about current drinking water levels. Chen also asked Savitz if he took issue with NTP's conclusion that there is an association between fluoride exposure and lowered IQ at 1.5 mg/L - just over two times current fluoridation levels. Savitz said he had no reason to challenge it, but he hadn't corroborated it.

Savitz said another flaw was that the NTP used high-quality ecological studies - studies of endemic fluoride in other countries - as some evidence to show the effects of fluoride and that those could be confounded by other variables. Chen pointed out that the studies would have controlled for that issue. Savitz conceded they did.

On cross-examination, Connett also pointed out that in Savitz's own work on arsenic in China, his team studied endemic arsenic at high concentrations to show evidence for arsenic's toxic effects. They also used that data to consider toxic exposure levels in the U.S., using the same methods NTP scientists and other researchers were using endemic fluoride data, which Savitz criticized.

Connett also asked Savitz if he believed his own statements on uncertainty by quoting from Savitz's textbook, "Interpreting Epidemiological Evidence: Connecting Research to Applications." Savitz wrote in the book that "to claim we have insufficient evidence does not resolve the problem for those who make public health decisions, because inaction is an action."

Throughout his testimony, Savitz maintained there was no strong evidence for the neurotoxic effects of fluoride exposure at "low levels," which extended up to 2 mg/L. On cross-examination, Connett presented him with data from the NTP report and also from at least one key study showing this link. Savitz conceded he hadn't read those studies. In fact, in addition to the NTP report, he said he had read only about 10 studies on fluoride and neurotoxicity. EPA's risk analyst Dr. Stanley Barone took the stand again as the final in-person witness in nine days of testimony at the Phillip Burton Federal Courthouse in San Francisco. FAN attorneys called Dr. Barone earlier to comment on the EPA's risk analysis methodology even though he's an expert witness for the EPA. The EPA called him back to testify to the quality of the evidence on fluoride and IQ for a hazard assessment.

Dr. Barone admitted in his testimony that fluoride is neurotoxic at relatively low levels and that EPA's key expert on fluoride's neurotoxicity, David Savitz, conceded flaws in his own study as our landmark fluoride trial drew to a close. Fluoride causes "neurotoxic harm," and does so at relatively low levels, Barone admitted under cross-examination.

Barone said there simply isn't enough data available for EPA to implement its risk assessment process for fluoride. Pharmacokinetic modeling that predicts how a chemical will be absorbed and metabolized by the body, hasn't yet been done, he said. But on cross-examination, Attorney Michael Connett forced Barone to concede several of the FAN's key points.

"You do not dispute that fluoride is capable of causing neurodevelopment harm, correct?" Connett asked. "I do not," Barone said, adding that he said that in his deposition.

"You agree that the current evidence is suggestive that low-dose fluoride causes neurodevelopmental effects? Correct?" Connett asked. Barone said the "hazard ID" - the level at which a toxin causes effects - "is probably in the suggestive range but is highly uncertain."
"You agree that fluoride is associated with neurotoxic effects at water fluoride levels exceeding two parts per million?" Connett asked. After first evading the question, Barone conceded.

Connett asked if Barone agreed there should be a "benchmark margin of uncertainty" of 10 for fluoride neurotoxicity. That means the lowest allowable human exposure level should be at least 10 times the hazard level, which Barone conceded may be approximately 2 parts per million. Barone said that is generally true for toxic chemicals under TSCA.

Water fluoridation levels in the U.S. are currently 0.7 parts per million, also referred to as milligrams per liter (mg/L), which would place them well above the allowable level if they were regulated through TSCA's norms.

Barone also conceded that the NTP's report linking fluoride to neurotoxicity at 1.5 mg/L is a rigorous, high-quality review and that the NTP is one of the world leaders in doing such reviews.

"Do you feel comfortable as a risk assessor," Connett asked, "exposing pregnant women to a level of fluoride that is so high that the kidney is oversaturated?" Barone avoided answering, commenting instead on other foods containing fluoride.

Connett asked a second time, "Are you comfortable then with a pregnant woman having so much fluoride in her circulating system that their kidney has lost the ability to efficiently process it?"

EPA lawyers objected to the question as "vague and argumentative" but Chen overruled.

Barone then sat in silence for several seconds before responding, "Again, putting this in context, my comfort level I don't think is germane."

Connett then turned to the question of the "data gap" or "uncertainty" that Barone and other EPA experts have argued is the basis for not requiring the agency to regulate fluoride.

Connett asked Barone if he agreed that uncertainty about the threshold level at which a chemical causes harm is not a basis for deciding not to do a risk assessment - the process that would likely lead to chemical regulation. Barone agreed but said the weight of the evidence was key. Connett also asked him if he personally agreed that the EPA should "use health protective assumptions" (i.e. an uncertainty factor of 10) when data is lacking. He said he did.

Chen intervened to ask Barone why the EPA couldn't do its risk assessment with the given information, using a "lowest observed effect level," or LOEL. "I mean here we have a phenomenon where I think everybody agrees, as you put it, something's going on,"

Chen said, adding:
"And knowing that the EPA is to use health-protective assumptions when the information is lacking, why can't one approach it from the low-level approach? We seem to know that there's some level in which something's going on. There's adverse effects. We may debate where it is, but wouldn't it be proper to use even a conservative estimate of LOEL?"
Barone insisted, as he did in earlier testimony, that the data are unclear. But he also conceded the EPA does often use the LOEL in risk assessment. Throughout Barone's testimony, Connett drew concessions from Barone through "impeachment" — meaning Barone gave responses under cross-examination that contradicted statements he made in his earlier deposition. Connett read from Barone's deposition testimony to demonstrate he was misrepresenting his responses.

To wrap up the trial and move forward with closing arguments, Judge Chen privately reviewed the recorded deposition of Jesús Ibarluzea, Ph.D., EPA's final witness.

Dr. Ibarluzea is the author of the "Spanish study" that found fluoride increased IQ in boys by an implausible 15 points. 15 IQ points is enough to turn an average person into a genius, which no chemical has ever been found to do, calling the findings of his study into serious question.

Dr. Ibarluzea pulled out of testifying publicly in the trial after his study was scrutinized <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fde
final-witnesses-neurotoxicity-fluoride-
trial%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11c
by plaintiffs for its ridiculously unbelievable findings.

At the close of the expert testimony, a scheduling change occurred. The Judge ordered that closing statements from both FAN and EPA now take place with a one-week delay, setting a February 20, 2024, closing date. The judge wanted time to watch deposition videos, look over evidence, and prepare a series of key questions for attorneys.
Closing Arguments
On February 20, 2024, rather than delivering summary closing arguments, attorneys for FAN and EPA responded for nearly three hours to the Judge's detailed questions on technical aspects of the link between low-level fluoride exposure and lower IQ scores in children. The two sides also debated the role of uncertainty in risk assessment.

During the trial, top scientific experts who advised the EPA on understanding and setting hazard levels for other major environmental toxins and who conducted gold-standard "cohort" studies on the link between fluoride and low IQ in children testified for FAN.

They explained the NTP's findings and presented evidence from their own research showing neurotoxic risks - particularly to pregnant women,
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F352
formula-fed infants
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F317
and children
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F318
- posed by water fluoridation.

EPA witnesses conceded fluoride does have neurotoxic effects at relatively low levels but countered that the risk assessment process under TSCA is highly complex and there is too much uncertainty in the data on fluoride's toxicity at current levels of water fluoridation to do a proper risk assessment and regulate the chemical.

It is now up to Judge Chen to decide if the EPA should be required to create a rule banning water fluoridation in the U.S. "Because the regulatory agencies have failed to do their job for decades," plaintiffs' attorney Michael Connett told Brenda Baletti of The

Defender, “the court is now in the position of having to do it for them.”

“It’s not a job the court takes lightly,” he said. “It’s not a job the court wanted to do, but I think it’s a job the court is prepared to do.”
The Judgment
On September 24, 2024 the court ruled on behalf of the Fluoride Action Network and the plaintiffs. A U.S. federal court has now deemed fluoridation an “unreasonable risk” to the health of children, and the EPA will be forced to regulate it as such.
The decision
<https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2F2024%2F09%2FCourt-Ruling.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C1
is written very strongly in our favor.
Below is an excerpt from the introduction of the ruling:
"The issue before this Court is whether the Plaintiffs have established by a preponderance of the evidence that the fluoridation of drinking water at levels typical in the United States poses an unreasonable risk of injury to health of the public within the meaning of Amended TSCA. For the reasons set forth below, the Court so finds. Specifically, 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…One thing the EPA cannot do, however, in the face of this Court’s finding, is to ignore that risk.”
Thanks to Derrick Broze
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftheconsciousresistance.com%2F%
of the Conscious Resistance and Brenda Baletti
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fau
baletti%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C1
of Children’s Health Defense for their contributions to this detailed overview of the TSCA fluoride lawsuit.

Although I do not expect you to read all the links, certainly some of this information is critical for a thorough understanding of the legal action in the TSCA trial on fluoridation.

Plaintiffs needed five things to win our TSCA lawsuit 1. We need to prove in court that neurotoxicity is a hazard of fluoride exposure. 2. We need to prove in court that this hazard is a risk at the doses ingested in fluoridated areas. 3. We need to prove in court this risk is unreasonable.

Previous to the above report of the court proceedings:

Federal Trial Update: New Supplement To Our TSCA Petition Submitted To Court
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fb
6-
20%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0

November 7, 2020 | Cheikhani
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fauthor%2Fch

As you might recall, the Court requested on the last day of the trial
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT737286
bb86-4901-8757-55a6a2f75cd2%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

that we submit a new Petition to the Environmental Protection Agency (EPA) to allow them the opportunity to respond to our original 2016 Petition in regards to the new studies that were published between 2017-2020. The Court also requested that we include Petitioners who were pregnant or planning a pregnancy in light of the science linking early-life exposure to fluoridated water to adverse neurodevelopmental effects in these new studies.

Yesterday's meeting with the Judge

At the very short meeting convened by the Judge, lawyers representing both sides were in attendance. Lead attorney Michael Connett told the Court that he filed, on November 4, a Supplement to our original Petition with the EPA. The Supplement asks that EPA reconsider their denial of our 2016 Petition. The reasons are set forth in the Supplement and its 9 attachments (all listed below). The Supplement has done everything the Court asked us to do with a new Petition. The Supplement also responds to the issue of Standing by identifying nine members of Food & Water Watch "who are currently pregnant, women who are actively seeking to become pregnant, and/or mothers of infants…"

We believe that this is an important and highly readable document and we urge our supporters to read it in full. However, if time is short we have presented excerpts below.

Background to the Supplement

"On November 22, 2016, the undersigned Petitioners submitted a Citizen Petition under Section 21 of the Toxic Substances Control Act ("TSCA"), requesting that the EPA prohibit the addition of fluoridation chemicals to drinking water in order to protect the public, including susceptible subpopulations, from fluoride's neurotoxic risks. After the EPA denied this petition, the Petitioners brought suit in the Northern District of California to challenge EPA's denial. Following a bench trial in June of 2020, the Court stated that EPA had used an incorrect standard in assessing the evidence that the Petitioners had presented. .. The Court also noted that much of the evidence that the Petitioners relied upon at trial—including recent studies funded by the National Institutes of Health (NIH)—was not yet available at the time EPA denied the Petition. (Appendix A at 4.) In light of these facts, the Court asked Petitioners to re-submit evidence to the EPA in order to give the Agency an opportunity to give the evidence a "second look" using the "proper standard" at the administrative level, which the Court 'urged' the EPA to do."

"Pursuant to the Court's request, the Petitioners are hereby submitting this Supplement to their Petition and requesting that EPA reconsider its denial of the Petition based on the information presented herein."

EPA HAS THE AUTHORITY TO RECONSIDER ITS DENIAL OF A SECTION 21 PETITION

"EPA has the inherent authority to reconsider its denials of Section 21 petitions, as the EPA itself has repeatedly acknowledged. The EPA has explained that: "Although TSCA does not expressly provide for requests to reconsider EPA denials of Section 21 petitions, 'the courts have uniformly concluded that administrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so.'" … As the EPA has explained, "the power to reconsider is inherent in the power to decide." Id. at 24 (quoting Albertson v. FCC, 182 F.2d 397, 399 (D.C. Cir. 1950)) …"

GROUNDS FOR PETITIONERS' REQUEST FOR RECONSIDERATION

1. EPA Used an Incorrect and Impermissibly Stringent Standard of Proof

"At the close of trial in June 2020, the Court observed that EPA has subjected Petitioners' evidence to an incorrect standard of proof. As the Court noted, "EPA appears to have applied a standard of causation … It's not the proper standard." (6/17 Trial Tr. 1131:5-9.)

"TSCA commands that EPA protect against "unreasonable risk," which exists when human exposure to a toxicant is unacceptably close to the estimated hazard level. (6/10 Trial Tr. 471:11-472:9.) At trial, EPA confirmed that 'EPA does not require that human exposure levels exceed a known adverse effect level to make an unreasonable risk determination under TSCA.' (Appendix H at 4.) Thus, EPA does not require proof that human exposures under a given condition of use cause the hazard. In fact, Dr. Tala Henry agreed at trial that EPA has "never once in any of its risk evaluations to date under Section 6 used a causation standard." (6/16 Trial Tr. 987:6-8.) Despite this, Dr. Henry

admitted that EPA held Petitioners to a burden of proof where Petitioners needed to prove that human exposure to fluoride in water at 0.7 mg/L causes neurotoxicity. (6/16 Trial Tr. 985-15-987:2.) Dr. Henry thus made the extraordinary admission that EPA 'held the plaintiffs to a burden of proof that EPA has not held a single chemical under Section 6 before.' (6/16 Trial Tr. 987:16-19.)…"

2. Each of the Limitations that EPA Identified with the Fluoride/IQ Studies in the Petition Have Now Been Addressed by High Quality Studies Funded by the NIH

"In its denial of the Petition, the EPA criticized the human studies that Petitioners cited on three primary grounds: (1) the studies were cross-sectional and thus 'affected by antecedent consequent bias';1 (2) the studies failed to adjust for potential confounding factors; and (3) the studies failed to adequately establish a dose-response relationship between fluoride and neurotoxicity. (Fed Reg, Vol. 82, No. 37, p. 11882-83). …

"Following EPA's denial of the Petition in February 2017, a series of prospective cohort studies funded by the National Institutes of Health (NIH) were published which evaluate the impact of individualized measurements of prenatal and early-infant fluoride exposure on standardized measures of neurobehavioral performance between ages 4 and 12 (Bashash 2017, Bashash 2018, Green 2019, Till 2020)."

"These NIH-funded studies address each of EPA's three criticisms of the studies in the Petition…"

3. The National Toxicology Program Has Concluded that Fluoride Is a Presumed Human Neurotoxicant that Lowers IQ in Children

"Petitioners' contention that fluoride is a neurotoxicant has gained powerful new support from the National Toxicology Program's (NTP) recently revised systematic review and meta-analysis…"

A. NTP Agrees that Fluoride Is a Likely Neurodevelopmental Hazard to Humans

"On September 16, 2020, the NTP released its Draft Monograph on the Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects. The Monograph is a revised version of a draft issued in October 2019, and incorporates the recommendations made by a committee of the National Academy of Sciences (NAS). After making the changes recommended by the NAS, the NTP reconfirmed its conclusion that 'fluoride is presumed to be a cognitive neurodevelopmental hazard to humans.' (p. 2) …"

B. The Relationship Between Fluoride and Neurotoxic Effects Is Unlikely to Be Explained by Confounding or Other Issues of Methodology and Bias

"The NTP reached its hazard conclusion for fluoride after carefully considering issues of study quality and bias, including potential confounding, publication bias, translation bias, and the validity of exposure and outcome assessments. Each of these methodological issues were raised at trial by EPA to question the confidence in the numerous studies reporting neurotoxicity from fluoride exposure. Importantly, the NTP's report makes clear that none of the issues identified by EPA at trial warrant a downgrade in the confidence that fluoride is a human neurotoxicant. In other words, the issues identified by EPA at trial do not explain the overwhelmingly consistent association between fluoride and neurotoxic harm…"

C. The NTP Identified a Large Number of Low Risk-of-Bias Studies Linking Fluoride to Neurotoxicity

"… In total, the NTP identified 31 human studies on fluoride and neurodevelopment that it found to have a relatively low potential for bias (p. 25) and the vast majority of these studies found significant associations between fluoride and adverse effects. This highlights that the association between fluoride and neurotoxicity is not the artifact of poor study design or bias, as EPA argued at trial."

D. The NTP Has Judged the New Zealand Studies that EPA Has Relied Upon to Be at High Risk of Bias

E. The Animal Data Supports the Conclusion that Fluoride Produces Neurodevelopmental Effects

F. The NTP's Recently Retired Director Has Called for Measures to Protect Pregnant Women and Bottle-Fed Babies from the Neurotoxic Effects of Fluoride

"The relevance of the NTP's findings to water fluoridation has recently been highlighted by none other than the recently retired director of the NTP, Dr. Linda Birnbaum. On

October 7, 2020, shortly after the NTP released its revised Monograph, Dr. Birnbaum issued a public statement calling for measures to protect pregnant women and bottle-fed babies from the neurotoxic effects of fluoride. Dr. Birnbaum noted that the NTP's conclusion is 'consequential,' given that "about 75 percent of Americans on community water systems have fluoride in their water.'…"

G. Limitations and Weaknesses of NTP's Report

"The NTP Monograph provides an exceptionally comprehensive review of the scientific literature on fluoride neurotoxicity, and provides ample support for its conclusion that fluoride is a neurotoxicant that reduces IQ. There are, however, some limitations and weaknesses with the NTP's analysis that Petitioners wish to bring to the EPA's attention…"

H. Even with Its Limitations, the NTP Monograph Demonstrates that Water Fluoridation Poses an Unreasonable Risk of Neurodevelopmental Harm

"Even with its limitations, the NTP Monograph demonstrates that neurotoxicity is an unreasonable risk of water fluoridation…"

4. Pooled BMD Analysis of the NIH-Funded Birth Cohort Data Confirms that Pregnant Women in Fluoridated Areas Are Exceeding the Dose Associated with IQ Loss

"A team of scientists, including the authors of the NIH-funded studies, have recently completed a pooled benchmark dose (BMD) analysis of the maternal urinary fluoride data from the ELEMENT and MIREC datasets (Grandjean, et al. 2020, in review)… Given that BMD analysis is EPA's preferred method for determining toxicity values and risk estimates, the new pooled analysis provides compelling grounds for EPA to reconsider its denial of the Petition. The analysis, which became publicly available on November 4, 2020, is attached as Appendix G…"

5. Millions of Americans Are at Risk of Harm as a Result of EPA's Failure to Regulate Fluoridation, Including Petitioners

"… Each year, there are approximately 2.5 million pregnancies in fluoridated areas; in utero exposures are thus widespread. (Appendix B at p. 78 ¶ 406.) Many of those exposed in utero will also be exposed during the sensitive neonatal period, with upwards of 1.9 million infants living in fluoridated areas being fed formula at least part of the time, including 400,000 infants who are exclusively formula-fed for their first six months. (Id.) Petitioner Organizations have members who fall within these zones of danger…"

6. EPA Erred in Considering the Purported Dental Benefits of Fluoridation in its Denial of the Petition

"In its denial of the Petition, EPA cited the purported dental benefits of fluoridation as a basis for its denial. This was improper because the Amended TSCA statute forbids risk evaluations from considering 'costs and other nonrisk factors.' 15 U.S.C. § 2620(b)(4)(B(ii). …"

7. EPA Erred in Claiming that Petitioners Failed to Adequately Identify the Chemicals at Issue

"… During the litigation on this matter, the Court considered and rejected each of these arguments, and held that the Petitioners had adequately identified the chemicals at issue, and that there was no merit to EPA's contention that it 'would become obligated to address all conditions of use of the category.'"

List of Documents submitted:

SUPPLEMENT: Petitioners' request to EPA to reconsider their denial of their original TSCA Petition of November 22, 2016.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.11-4-20.pd
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT30220b
d1d9-4837-b610-8c8e0f0c89c0%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%
f

Appendix A: Excerpt of Court's August 10, 2020 Order.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-a.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT70670b
55a3-4362-9915-9db0cc0126bc%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix B: Petitioners' Summary of the Trial Record. Food & Water Watch, et al. v. U.S. Environmental Protection Agency Case No. 17-cv-02162.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-b.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT1199bf6
4ce7-4b56-8458-4a4d27fc63cc%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix C: The NIH-funded Studies (Bashash et al. 2017 and 2018; Till et al. 2018 and 2020; Green et al. 2019).
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-c.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FTd30ac1
4fa4-481e-9063-2553cf488d7a%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix D: National Toxicology Program's Revised Monograph on Fluoride Neurotoxicity.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-d.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FTa4c5ef1
3c7f-44c3-96d3-96d49aa701a3%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix E: Dr. Linda Birnbaum's Statement on the NTP Report.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-e.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT743013
4881-4426-9d3d-5beb65673220%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix F: Additional Details on the Limitations of the NTP Review.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-f.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FTcac135
e30f-4271-b373-bebe827d486b%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix G: Pooled BMD Analysis of the ELEMENT and MIREC Datasets.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-g.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FTf514a77
7b58-4c67-a0e6-c7749903f17a%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix H: Undisputed Material Facts from Trial and Court's Ruling on Dental Benefits.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-h.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT5e0f709
fd59-4416-a8c5-54f84e099b3d%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix I: The Court's Order Dismissing EPA's Order to Dismiss.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-i.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT9121f55
d265-49b7-80ea-ff21dbcff114%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

1. Most recent. The link to the actual court order is included and must be considered as evidence for the Board.

Federal Court Orders EPA to Regulate Fluoridation of Drinking Water under TSCA
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fnews%2Ffede
court-orders-epa-to-regulate-fluoridation-of-drinking-water-under-

tsca%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d

Beveridge & Diamond | Oct 19, 2024 | By Mark N. Duvall

In a groundbreaking decision, a federal district court has ordered <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.cand.uscourts.gov%2Fwp-content%2Fuploads%2F2024%2F09%2F17-cv-2162-Food-_-Water-Watch-Inc.-et-al.-v.-EPA-et-al-Opinion.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C the U.S. Environmental Protection Agency (EPA) to regulate the "unreasonable risk" it found to be posed by the fluoridation of drinking water. The order came in the long-running case Food & Water Watch, Inc. v. EPA, No. 17-cv-02162-EMC, 2024 WL 4291497 (N.D. Cal. Sept. 24, 2024).

While the court did not specify what EPA must now do, its decision could significantly impact municipal drinking water systems and public health. Supported <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.cdc.gov%2Ffluoridation%2Fa by the Centers for Disease Control and Prevention, EPA has permitted public water systems to fluoridate their drinking water as a critical measure to control tooth decay for decades. More than three-quarters of the U.S. population today gets their drinking water from fluoridated public sources.

The court order also has substantial implications for the regulated chemical industry and EPA's regulatory processes under the Toxic Substances Control Act (TSCA). This is the first instance of a court ordering EPA to "initiate a proceeding" under TSCA Section 6(a) in response to a citizen petition denied by EPA and subsequently appealed under Section 21 to a federal court. Both industry and the federal government have previously argued that Section 21 does not authorize a court to order rulemaking but rather a fact-gathering risk evaluation process akin to that normally required under TSCA for chemicals that EPA itself has identified as potentially presenting unreasonable risks under their conditions of use, in part because Section 21 requires a lower standard of evidence than is required of the usual risk evaluation process. A federal court has now implicitly disagreed with that argument, ordering that EPA "initiate rulemaking" to manage the risks it found to be posed by water fluoridation.

Background

EPA permits public drinking water systems to fluoridate drinking water up to certain levels under the Safe Drinking Water Act. EPA has established an enforceable maximum contaminant level <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ecfr.gov%2Fcurrent%2Ftitle 40%2Fchapter-I%2Fsubchapter-D%2Fpart-141%2Fsubpart-G%2Fsection-141.62&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0 (MCL) for fluoride in drinking water at 4.0 milligrams per liter (mg/L), effectively ensuring that community water systems limit fluoridation to levels that EPA has determined present no known or anticipated adverse effects on human health.

EPA has also set a "secondary" standard <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ecfr.gov%2Fcurrent%2Ftitle 40%2Fchapter-I%2Fsubchapter-D%2Fpart-143%2Fsubpart-A%2Fsection-143.3&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e for fluoride at 2.0 mg/L or 2.0 ppm. Secondary standards are non-enforceable federal guidelines that address potential cosmetic effects (such as skin or tooth discoloration) or aesthetic effects (such as taste, odor, or color) in drinking water, which state or local governments may implement.

The U.S. Department of Health and Human Services (HHS) recommends <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.federalregister.gov%2Fdocu 637%2Fproposed-hhs-recommendation-for-fluoride-concentration-in-drinking-water-for-prevention-of-dental&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0 the fluoridation of drinking water at 0.7 mg/L to achieve the benefits of preventing tooth decay.

Nevertheless, in 2016, a group of NGOs petitioned <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.epa.gov%2Fpetitions%2Fsup

documents-fluoride-chemicals-drinking-water-section-21-petition&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d
EPA under TSCA Section 21 to ban the fluoridation of drinking water entirely, arguing that fluoride has neurotoxic effects when ingested even at the "optimal" concentration identified by HHS and so presents an "unreasonable risk to human health." EPA denied <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.epa.gov%2Fpetitions%2Fsup
documents-fluoride-chemicals-drinking-water-section-21-petition&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d
that petition in 2017, and, pursuant to Section 21, the NGOs appealed that denial to the federal district court for the Northern District of California. The district court judge in the case is Edward Chen, who previously had directed EPA to adopt a TSCA Section 8(a) reporting rule for asbestos in another case that contested EPA's denial of a Section 21 petition. Asbestos Disease Awareness Org. v. EPA, 508 F. Supp. 3d 707 <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcasetext.com%2Fcase%2Fasbesto
disease-awareness-org-v-wheeler-1&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e217
(N.D. Cal. 2020).

In 2019, Judge Chen denied EPA's motion for summary judgment that had argued that the NGOs were required to comply with all requirements of both Section 6(b) (e.g., provide information equivalent to a risk evaluation) and Section 26 (e.g., provide information reflecting the weight of the scientific evidence). The court did so in part by citing that Sections 6(b) and 26 are not directly incorporated into Section 21, although their provisions may be looked to for guidance. Food & Water Watch, Inc. v. EPA, No. 17-cv-02162-EMC, 2019 WL 8261655 (N.D. Cal. Dec. 30, 2019). Extensive discovery and a trial followed.

TSCA Proceedings

Under TSCA Section 21, any person may petition EPA to "initiate a proceeding" for the issuance, amendment, or repeal of a rule under Section 6(a). 15 U.S.C. § 2620(a). If EPA grants the petition, EPA must start an appropriate rulemaking process to consider the petitioner's requests. However, if EPA denies the petition—as it did here—it must publish a notice detailing the reasons for the denial. If EPA denies or does not respond to a petition within 90 days, then the petitioner may initiate a civil action in federal district court to compel EPA to "initiate a proceeding" for the requested rulemaking, if the court determines, without consideration of costs, that the subject chemical presents an unreasonable risk to human health or the environment under the conditions of use. The resulting rule under Section 6(a) could impose a variety of controls—ranging from a label warning to an outright ban—to manage the chemical's identified risks.

Since Congress substantially overhauled TSCA in 2016, it has not been clear what it would mean to "initiate a proceeding" for a Section 6(a) rule. The statute now generally requires prioritization and risk evaluation as critical predicates to rulemaking, and EPA's risk evaluations must be made according to the "weight of the scientific evidence" and "consistent with the best available science." 15 U.S.C. § 2625(h)-(i). However, under Section 21, a court only needs to decide whether the chemical substance presents an unreasonable risk "by a preponderance of the evidence," arguably a lesser scientific standard. 15 U.S.C. § 2620(b)(4)(B). Section 21 also only enables EPA and a specific petitioner or petitioners to present evidence, whereas the full risk evaluation process that would usually inform Section 6 rulemaking involves more than three years' worth of public participation and comment. Until now, no court had addressed whether a court ordering EPA to "initiate a proceeding" under Section 21 would require EPA to begin the full risk evaluation process or jump directly to rulemaking to manage those risks.

Without substantial analysis, Judge Edward Chen has now provided an answer. He found that the evidence suggests that HHS's "optimal" level of drinking water fluoridation—0.7 milligrams per liter, well below EPA's maximum and target concentrations—"poses an unreasonable risk of reduced IQ in children." The Court then ordered EPA to "initiate rulemaking pursuant to Subsection 6(a) of TSCA." Order at 2, 79 (emphasis added). Nevertheless, in a footnote, the Court left the door open for EPA to conduct additional analysis or seek additional information to "put a finer point on [the] risk posed by the condition of use before taking regulatory action." Id. at 67 n.33. Thus, it remains unclear

to what extent EPA must now begin to draft regulations on the addition of fluoride to drinking water or may instead engage in the deliberative risk evaluation process.

Impacts and Next Steps

This order could significantly impact the chemical industry and municipal drinking water systems. If courts uphold that a TSCA Section 21 citizen's petition can be leveraged to force EPA to skip the statutory chemical prioritization and risk evaluation processes and jump directly to rulemaking, then EPA's chemical regulatory program could foreseeably be overwhelmed by competing priorities. Chemical manufacturers, processors, and users could also potentially face overbroad restrictions due to EPA's having to regulate certain chemicals on the basis of less (and potentially less comprehensive) information. Drinking water utilities may also want to closely track this issue, which could significantly impact their operations.

Although the district court ordered EPA to initiate rulemaking to address the level of fluoride in drinking water, it remains to be seen what steps EPA will take next. The possibilities include, among others, that EPA will request more information from the public as part of the initiation of rulemaking; that it will appeal the case to the Ninth Circuit (including the district court's earlier ruling about the scope of Section 21); and that it will attempt to move the entire matter to the Office of Water under TSCA Section 9(b) on the basis that the risk identified by the court "could be eliminated or reduced to a sufficient extent by actions taken under the authorities" of the Office of Water. Stay tuned.

Original article online at: https://natlawreview.com/article/federal-court-orders-epa-regulate-fluoridation-drinking-water-under-tsca
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnatlawreview.com%2Farticle%2Ff
court-orders-epa-regulate-fluoridation-drinking-water-under-
tsca&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e2

Sincerely,
Bill Osmunson DDS MPH
Washington Action for Safe Water

_____
From: Garry Blankenship
Sent: 10/14/2024 7:43:11 AM
To: hcinfo.infosc@canada.ca,DOH
WSBOH,OADS@cdc.gov,sheriff@co.clallam.wa.us,Berry, Allison 2
(DOHi),shahidafatin@gmail.com,ncarr@cityofpa.us,gbsjrmd@sisna.com,mark.ozias,Randy.Johnson@Clallan

Cc:
Subject: Fwd: The Takada paper shows very clearly that the COVID vaccines are not safe

External Email

---------- Original Message ----------
From: Steve Kirsch's newsletter <stevekirsch@substack.com>
To: hisgarness@comcast.net
Date: 10/13/2024 8:38 PM PDT
Subject: The Takada paper shows very clearly that the COVID vaccines are not safe

<https://eotrx.substackcdn.com/open?token=eyJtIjoiPDIwMjQxMDE0MDMzODQ1LjMuNzU2ZDgzZmFjOTM0

For myocarditis, the ROR was 15 for Pfizer and 54 for Moderna. That means Pfizer is very unsafe and Moderna is a train wreck.

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AymKCVB2IBo&data=05%7C02%7Cwsboh%40sboh.wa.gov%7Ce1f631b758eb42b8a8f208dcec5e8486%7C
for more

The Takada paper shows very clearly that the COVID vaccines are not safe
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For myocarditis, the ROR was 15 for Pfizer and 54 for Moderna. That means Pfizer is very unsafe and Moderna is a train wreck.

Steve Kirsch
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2F%40stevekirsch

Oct 14

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Executive summary

A new paper by Takada
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F736
a3cc-4693-9658-
f86eaed048e9%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0
, published on August 3, 2024 shows the ROR for myocarditis for Pfizer was 15 and it was 54 for Moderna.

That means the Pfizer vaccine isn't safe, and the Moderna vaccine is 3.6 worse. 54 is a train wreck. You can't give a drug with an ROR of 54. That's insane.

The health authorities should be educating the public on the RORs for the most serious adverse events.

Yet they are silent. Worldwide.

ROR: Reporting Odds Ratio

ROR is a measure used in pharmacovigilance to assess the association between a drug and a specific adverse event by comparing the odds of that event occurring with the drug of interest versus with other drugs.

The formula for calculating ROR is:

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Where:

* A: Number of reports of the specific adverse event for the drug of interest.
* B: Number of reports of other events for the drug of interest.
* C: Number of reports of the specific adverse event for all other drugs.
* D: Number of reports of other events for all other drugs.

In this calculation, the ROR compares proportions rather than accounting for the absolute number of doses given.

Therefore, a drug with an ROR of 15 (like Pfizer) means that the odds of an adverse event occurring for that drug are 15X higher compared to the average odds for other drugs.

That is not safe. That is not even close to safe. That is a disaster.

What it means

The proportion of adverse event reports in the Japanese version of VAERS were 15X higher than the typical drug in the database. But the reports, relative to the total number of reports filed, were 54 times higher for Moderna which is 3.6X higher than Pfizer.

This suggests that:

1. The safety profile of the vaccines do not resemble, in any way, that of a placebo

2. With respect to myocarditis, if you are FORCED to take a vaccine and looking to avoid serious cardiac issues, you'd be a fool to choose Moderna

3. If you are holding Moderna stock, you should get rid of it. Note: it could take the financial market years to figure this stuff out.

Where is the ROR analysis by brand for serious adverse events? Have you seen it?

The health officials should be doing ROR by brand for the top 20 most serious adverse events for the COVID vaccines and informing the public. Why are they not doing this? Do all of them work for pharmaceutical companies?

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The ROR for myocarditis in VAERS

The ROR is 16 in the US VAERS database. In short, the COVID shots are not safe.

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dbff8071696b%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

Summary

The FDA and CDC are working to protect the drug companies, not the public.

This paper makes that crystal clear.

I've reached out to my network to produce an ROR report on all the top symptoms from the VAERS data and I'll promote to the public how the CDC and FDA have misled them. They deserve to be recognized for their hard work.

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If you enjoy Steve Kirsch's newsletter, share it with your friends and earn rewards when they subscribe.

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548 Market Street PMB 72296, San Francisco, CA 94104

From: bill teachingsmiles.com
Sent: 11/8/2024 10:19:56 AM
To: DOH WSBOH
Cc:
Subject: November Public Comment: Rulemaking WAC 246 290-22

External Email

Public Comment for November 2024. RE: Agenda Item #8
Bill Osmunson DDS MPH
Washington Action for Safe Water

When I started working at my last dental office, they were making over $200,000 a year selling fluoride.
Fluoridation appears to be increasing complete tooth fractures from about 2% of visits without fluoridation to about 7% of visits with fluoridation, add cosmetic treatments and fluoridation is a cash cow for us dentists.
Looking back, I was clearly making money both selling fluoride and treating the harm caused by fluoride. A win, win for my pocket book.
Fluoridation gets even more lucrative. The Board and authorities are some PR firms for dentists. No marketing expenses and powerful government authoritative endorsements.
And insurance companies pay or help pay for the sales and for the treatment.
And we feel we are doing so much good for those poor children.

The fluoridation lobby is seriously biased, both conscious and sub-conscious with known clear conflict of interest.
The Board has relied on money rather than science in promoting fluoridation. (Riches vs Risk)
The Board has refused to obey the law which requires the Board to hold a forum.
The Board has refused to obey Federal law which requires FDA approval for drugs. (Banned)
Neither the NSF, nor any Federal Authority EPA, CDC, FDA, nor any of the three fluoride raw manufacturers under sworn testimony in deposition said they had a single safety study on fluoride - - and in thousands of pages of evidence, neither does the Board.
Trusting money is not science.
The Board does not have a single Randomized Controlled Trial on benefit. Not one.
The Board has failed to include the cost of treating harm in their cost benefit claims. They only consider observation of alleged benefit - - a shocking lack of ethics and science.
The Board has failed to determine a dosage which prevents dental caries nor a dosage a person is ingesting from all sources (not just fluoride in water).
The Board has failed to provide or recommend a label or patient's doctor's oversight.
The Board has failed to provide a margin of safety.
The Board has failed to follow the Safe Drinking Water Act.
The Board has failed to recommend a pharmaceutical grade product.
The Board has failed to recommend Good Drug Manufacturing Practices.
The Board has failed to follow the science of harm to the developing brain, now confirmed by the National Toxicology Program and the U. S. Court.
The Board has failed, in light of current research, to carefully consider the National Research Council list of health risks, which 18 years ago included:

1. Tooth damage,
2. Rheumatoid and osteoarthritic-like pain,
3.

Bone cancer, Bone fractures
4. Thyroid reduction -Diabetes -Obesity

5. Kidney damage
6. Reproductive problems
7. Lower IQ --developmental neurotoxicity
8. Allergies (overactive immune system)
9. Gastrointestinal disorders.

Any review of fluoridation must be science based, rather than just money, and inclusive of all streams of evidence.
We have no conflict of interest and are not paid to provide our time to the Board. Our only concern is for public health.
Sincerely,
Bill Osmunson DDS MPH
Washington Action for Safe Water

From: bill teachingsmiles.com
Sent: 10/8/2024 4:22:00 PM
To: DOH WSBOH
Cc:
Subject: Request and Forum

External Email

Please forward to the Board of Health Members

Dear Board of Health, October 8, 2024
RE: Request for participation and Forum.
After public comment today, Tao mentioned the Department was planning on doing a review of fluoridation. In speaking with him during the break, he did not have specifics on time or contact person, but promised to get me an email address.
RCW instructs the Board, not the Department, to have a forum RCW 43.20.050 <https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fapp.leg.wa.gov%2FRCW%2Fdefaul
. I have significant reservations with the Department reviewing science and laws which they have denied and been biased with the evidence since the dawn of fluoridation. The Department has a significant investment of employee, advice, tradition, and money into fluoridation. The job is for the Board, not the Department to have a forum.
Fluoridation is controversial and a review must be transparent and balanced. Cherry picking evaluators will not result in protecting the public from harm.
The WA AGO in 1992 No. 17, "2. The Legislature has authorized the Board of Health to establish, and the Department of Health to enforce, a comprehensive regulatory scheme for public water systems."
RCW 43.20.50 (2) "In order to protect public health, the state board of health shall: (a) Adopt rules for group A public water systems. . . necessary to assure safe and reliable public drinking water and to protect the public health."
The Board's job is to adopt rules, the Department's job to enforce the rules. Turning the job of evaluating fluoridation's risk and lack of efficacy over to the "enforcer" to make a rule is unlikely to protect the public. The Department has for decades and is currently invested in promoting fluoridation. We have submitted 20 petitions to protect the public, rejected to a large extent on the advice of the Department.
Turning over the judgment of fluoridation research and laws to the Department would be similar to asking the fossil fuel industry to evaluate global worming or the tobacco industry to evaluate the risks of smoking tobacco. Explicit, implicit, hidden, unconscious bias is powerful and the Department has all 4.
Members of any review must be from both sides of the controversy or results will not be accepted by many in the community. This is a paradigm shift which requires education on the science. A forum would be valuable in educating the public. . . especially dentists and physicians engrained in the myth of fluoridation's huge benefit without any risk.
My request is for the Department of Health to provide a forum as the law requires and that I be permitted to participate with any evaluation of fluoridation done by the Board and/or Department of Health.
Sincerely,
Bill Osmunson DDS MPH

See also RCW 70.05.060 <https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fapp.leg.wa.gov%2FRCW%2Fdefaul

From: Testify Online Survey
Sent: 11/5/2024 8:58:19 AM
To: DOH WSBOH
Cc:
Subject: Survey Response: Testify Online *

The following survey response is submitted:

1.

State Board of Health Meeting Date:

November 13th 2024

2.

Agenda Item or Issue:

Metachromatic Leukodystrophy (MLD) NBS in WA

3.

Your Name:

_____

Emilia I Wilburn

4.

Do you have a professional title?

1. Yes

_____

MPD

5.

Are you representing an organization?

1. Yes

_____

Orchard Therapeutics

6.

Address:

_____

101 Seaport Boulevard, 7th Floor Boston, MA 02210 United States

7.

Email:

_____

emilia.wilburn@orchard-tx.com

8.

Phone Number (Include Area Code):

_____

5208342922

9.

Do you have any special expertise relevant to this topic?

2. No

10.

Are you testifying on a specific proposal under consideration by the board?

2. No

11.

Are you Pro or Con on the proposal?

1. Pro

Not testifying on a specific proposal under consideration by the board.