FLUORIDE

Quarterly reports

United States of America lawsuit on community water fluoridation under the Toxic Substances Control Act (TSCA)

Bruce SPITTLE[1],

[1]Editor-in-Chief, *Fluoride*, Dunedin, New Zealand

***Corresponding author:**
Bruce Spittle
Editor-in-Chief, Fluoride
727 Brighton Road
Ocean View
Dunedin, 9035
New Zealand
Phone: (+64) 0274732097
and (+64)034811418
E-mail: spittle727@gmail.com

Accepted: 2024 May 22
Published: 2024 May 29

ABSTRACT

At the time of writing this editorial, 22 May 2024, the judgement is awaited of Judge Edward M Chen, United States District Court, California Northern District (San Francisco), who has been considering the allegation, under the Toxic Substances Control Act (TSCA), that community water fluoridation, at the levels occurring throughout the USA of 0.7 mg/L, presents an unreasonable risk of injury to health. The plaintiffs are Food & Water Watch, Inc. et al. and the defendants the Environmental Protection Agency (EPA) et al. Some of the points made in the trial are considered. Although trial verdicts may be appealed in a higher court, the decision of Judge Chen is likely to receive widespread attention and have significant consequences.

Key-words: *Community water fluoridation; Fluoride-induced neurotoxicity; TSCA; Toxic Substances Control Act; Trial in United States District Court; United States lawsuit.*

Unique digital address (Digital object identifier [DOI] equivalent):
https://www.fluorideresearch.online/epub/files/272.pdf

INTRODUCTION

Disclaimer: The views expressed in this editorial are personal ones and do not represent those of the International Society for Fluoride Research which does not take a position on issues, such as community water fluoridation, but instead encourages the development of knowledge by publishing peer-reviewed research and hosting conferences where issues can be discussed.

At the time of writing this editorial, 22 May 2024, the judgement is awaited of Judge Edward M Chen who has been considering the allegation that community water fluoridation, at the levels occurring throughout the USA of 0.7 mg/L, presents an unreasonable risk of injury to health. The case, Food & Water Watch, Inc. et al. v. Environmental Protection Agency (EPA), et al. (Civil Docket §: 3:17-cv-02162-EMC) was filed in the United States District Court, California Northern District (San Francisco), on 18 April 2017, and assigned to Judge Chen.[1]

The plaintiffs initially submitted a Citizens Petition under Section 21 of the under the Toxic Substances Control Act (TSCA) in November 2016 requesting a ban on the addition of fluoridation

chemicals to water. When the EPA denied their petition, they filed suit in the Federal court.[2]

The plaintiffs allege that fluoridation at levels occurring throughout the USA presents an unreasonable risk of injury to health under the TSCA, 15 U.S.C. §2620(b)(4)(B). A bench trial took place in this matter in June 2020 and, after the case was held in abeyance for a period, while the publication of a National Toxicology Program report on fluoride was awaited, the trial resumed for a second phase from 31 January 2024 to 13 February 2024. Closing arguments were presented by Zoom on 20 February 2024.

The expert witnesses for the plaintiffs, with curriculum vitae links where available on the District Court website, were Stanley Barone Jr,[3] Brian Berridge, Philippe Grandjean,[4] Howard Hu,[5] Bruce Perrin Lanphear,[6] and Kathleen Thiessen.[7] Those called by the defendants, the EPA et al., were Stanley Barone Jr,[3] David A Savitz,[8] and Jesus Ibarluzea.[9]

The plaintiffs drew attention to the lengthy and extensive history of studies on fluoride-induced neurotoxicity in the witness declarations by Grandjean,[10] Hu,[11] Lanphrear,[12] and Thiessen[13], filed on May 20, 2020,

Grandjean summarized his opinions as:

(i) The weight of epidemiological evidence leaves no reasonable doubt that developmental neurotoxicity is a serious human health risk associated with elevated fluoride exposure, including those occurring at the levels added to drinking water in fluoridated areas. The IQ losses associated with community water fluoridation are substantial and of significant public health concern.
(ii) Application of the Benchmark Dose (BMD) methodology to the recent prospective birth cohort data shows that the level of fluoride added to water in fluoridation programs greatly exceeds the science-based limit needed to protect against developmental neurotoxicity.
(iii) The systematic review conducted by Dr. Ellen Chang, when corrected for its biases and errors in judgment, further supports my opinions on the neurotoxic risks posed by elevated fluoride exposure.

Grandjean concluded:

(i) Recent research has shown that the most vulnerable life stage for many toxicants, particularly those that adversely affect the brain, is during intrauterine and early postnatal development.
(ii) Fluoride fits into this paradigm, and efforts to control human fluoride exposures must therefore focus on pregnant women and small children.
(iii) Research on fluoride-exposed workers and laboratory animals suggest that elevated fluoride exposure is toxic to the brain and nerve cells. Epidemiological studies have identified links to learning, memory, and intelligence deficits, though most of the past studies focused on populations with fluoride exposures higher than those typically provided by U.S. water supplies.
(iv) Epidemiology studies of birth cohorts from the most recent years document that adverse effects on brain development happen at elevated exposure levels that occur widely in North America, in particular in communities with fluoridated drinking water. These new prospective studies are of very high quality and show very similar results, thus leaving little doubt that developmental neurotoxicity is a serious risk associated with elevated fluoride exposure. This evidence shows that community water fluoridation is associated with IQ losses that are substantial and of economic and societal concern.
(v) Applying methods for standards setting routinely used by the EPA (i.e., Benchmark Dose analysis), the recent studies on IQ deficits in children allow the estimation of a recommended limit that would protect against neurotoxicity. Such calculations show that current allowable limits for fluoride in drinking water and the levels of fluoride added in community water fluoridation programs both greatly exceed a science-based limit that would protect against developmental neurotoxicity.

(vi) The evidence on fluoride neurotoxicity in the general population is fairly recent and unlikely to represent the full toxicological perspective, including adverse effects that may occur at longer delays. As has been seen on numerous occasions, the evidence available today may well underestimate the true extent of the fluoride toxicity. With a reasonable degree of scientific certainty, I therefore consider the elevated levels of fluoride exposure in the U.S. population as a serious public health concern

Hu summarized his opinions as:

(i) The Early Life Exposures in Mexico to Environmental Toxicants (ELEMENT) prospective cohort studies of fluoride's neurodevelopmental effects are methodologically rigorous studies that provide scientifically reliable and robust results.
(ii) The results of the ELEMENT prospective cohort studies are consistent with and support the conclusion that fluoride is a developmental neurotoxicant at levels of exposure seen in the general population in water-fluoridated communities.

Lanphear summarized his opinions as:

(i) Our study of prenatal fluoride and IQ in the Maternal-Infant Research on Environmental Chemicals (MIREC) cohort (Green 2019)[14] further enhances the quality of data related to the neurotoxicity of fluoride. As with the ELEMENT cohort, we employed a prospective cohort design, had extensive control for potential confounders, and had multiple measures of fluoride exposure during pregnancy, including three types of urinary fluoride measurements for each trimester of pregnancy.
(ii) The maternal urinary fluoride levels in the MIREC cohort were significantly associated with lower intellectual abilities in 3–4-year-old children. These associations remain large and significant when controlling for relevant covariates.
(iii) Converging results from the MIREC and ELEMENT cohorts indicate that exposure to "optimal" levels of fluoride during fetal development is associated with diminished intelligence in childhood.
(iv) In the MIREC cohort, exposure to fluoridated water in infancy, particularly among formula-fed infants, was also associated with diminished intelligence (Till 2020).[15] This association remains significant after controlling for fetal fluoride exposure and other relevant covariates, suggesting that susceptibility to fluoride's adverse neurological effects may extend into infancy

Lanphear concluded:

(i) The collective evidence from prospective cohort studies supports the conclusion that fluoride exposure during early brain development diminishes the intellectual abilities in young children, including at the purportedly "optimal" levels of exposure for caries prevention.

Thiessen summarized her opinions as:

(i) Under EPA's Guidelines for Neurotoxicity Risk Assessment, there is sufficient evidence to conclude that neurotoxicity is a hazard of fluoride exposure.
(ii) The animal data on fluoride neurotoxicity are consistent with the epidemiological data in showing a risk of cognitive deficits at doses of fluoride ingested from fluoridated water.
(iii) Fluoridation chemicals present an "unreasonable risk" of neurotoxic effects, including IQ loss, if assessed under the same risk characterization and risk determination framework that EPA uses in its evaluations of other chemicals under TSCA.

A key recent high quality study, introduced into the second phase of the trial, was by Grandjean et al.[16] and merged new data from a prospective Danish Odense Child Cohort (OCC) with results from two previous birth cohort studies from Mexico and Canada to characterize the dose–effect relationship in greater detail. The OCC contributed 837 mother–child pairs to the total of >1500. The authors measured creatinine-adjusted

urine-fluoride concentrations in maternal urine samples obtained during late pregnancy. Child IQ was determined at age 7 years using an abbreviated version of the Wechsler Intelligence Scales for Children. Findings from the three cohorts were used to calculate the joint benchmark concentration (BMC) and the lower confidence limit (BMCL) after adjustment for covariables.

In the OCC, urine-fluoride concentrations varied between 0.08 and 3.04 mg/L (median 0.52 mg/L) but were not significantly associated with full-scale IQ at age 7 years (β = 0.08; 95% confidence interval −1.14 to 1.30 for a doubling in exposure). No difference was apparent between boys and girls. In the OCC, the BMC was 0.92 mg/L, with a BMCL of 0.30 mg/L. The joint analysis of all three cohorts showed a statistically significant association between urine-fluoride and IQ, with a BMC of 0.45 mg/L (BMCL, 0.28 mg/L), slightly higher than the BMC previously reported for the two North American cohorts alone. The pooling of the results from the three prospective cohorts conducted in areas with wide ranges of overlapping exposure levels offers strong evidence of prenatal neurotoxicity, and these findings should inspire a revision of water-fluoride recommendations aimed at protecting pregnant women and young children. For example, the World Health Organization's recommendation of 1.5 mg/L as an upper limit for fluoride in drinking water does not consider developmental neurotoxicity.[17] The authors' conclusion was that, as the BMCL reflects an approximate threshold for developmental neurotoxicity, the results suggest that pregnant women and children may need protection against fluoride toxicity.

Stanley Barone Jr, a risk assessor for the EPA and the agency's key expert on fluoride's neurotoxicity, who appeared as an expert witness for both the plaintiffs and the defendants, admitted under cross examination that fluoride is neurotoxic at relatively low levels.[18] Barone conceded that the "hazard ID," the level at which a toxin causes effects, for fluoride is approximately 2 mg/L (2 ppm). He also agreed that it was generally true for toxic chemicals under TSCA that there should be a "benchmark margin of uncertainty" of 10, which meant that the allowable human exposure level should be at least 10 times lower than the hazard level. This implied that for fluoride, with a hazard level of 2 mg/L, the highest allowable fluoride in drinking water would be 0.2 mg/L. The water fluoridation levels in the U.S. are currently 0.7 mg/L (ppm), well above the allowable level if they were regulated through TSCA's norms.[18]

Barone said that there was simply not enough data available for EPA to implement its risk assessment process for fluoride. He said that the necessary physiologically-based pharmacokinetic modeling that predicts how a chemical will be absorbed and metabolized by the body, had not yet been done.[18]

Barone also conceded that the National Toxicology Program (NTP)'s Draft State of the Science Monograph and the Draft Meta-Analysis Manuscript on Fluoride 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.[18,19]

Barone 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, but said the weight of the evidence was key. Barone personally agreed that the EPA should "use health protective assumptions" when data is lacking. Judge 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. The judge said, "I mean here we have a phenomenon where I think everybody agrees, as you put it, something's going on 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 also conceded the EPA does often use the LOEL in risk assessment.[18]

When Barone was asked by Plaintiff attorney Michael Connett "Do you feel comfortable as a risk assessor 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 Judge Chen overruled. Barone sat in silence for several seconds before responding, "Again, putting this in context, my comfort level I don't think is germane.[18]

Attorneys deposed Jesús Ibarluzea, Ph.D., lead author of the Spanish INMA cohort study,[20] a key piece of EPA's evidence, in November 2023. However, he withdrew from further participation in the trial, including not making himself available to testify via Zoom.[21] Instead, attorneys from both sides edited key parts of his deposition for the court and scheduled the video for public screening during the trial. EPA attorneys moved for the judge to watch it privately, in the interest of speeding along the trial process.[18]

During his deposition, Ibarluzea told Attorney Connett that no studies exist showing a chemical could increase IQ by 15 points or more. Yet, his study of prenatal fluoride exposure and IQ among a birth cohort in the Basque region of Spain, which found no negative association between fluoride exposure and children's IQ, found that fluoride exposure can increase IQ in boys from 15 to 28 points. Ibarluzea told the court the improvement identified is improbably large and "not biologically possible." He said, however, that what mattered was that they found an increase in IQ associated with fluoride exposure and he stood by that finding.[18]

Ibarluzea said that other researchers like Xu et al., also found a positive association between fluoride and IQ, although he then conceded that the paper had been retracted.[18,22,23] The editor of BMC Public Health retracted the article after publication because concerns were raised regarding the data analysis and conclusions in the paper. The authors provided raw data, and a post-publication review found inconsistencies in methodology and a major misinterpretation of the primary result. None of the authors agreed to this retraction.[18,23]

EPA expert witness David Savitz told the court that he thought Ibarluzea's data were important because if the findings are aggregated with the other cohort studies, it markedly shifts the cumulative evidence such that there would be no association found between maternal fluoride exposure and child IQ, which would support the EPA's case. Judge Chen asked Savitz if, in making such calculations, he corrected for the "implausible" increase in IQ points. Savitz said he did not. Ibarluzea also told Connett he had "no interest whatsoever" in pursuing an explanation for certain unlikely numbers in his study that he deemed irrelevant to the overall findings. That included the question of how a standard practice of adjusting for creatinine to account for issues with urinary dilution dramatically changed the fluoride association outcomes, transforming what had been a negative relationship between fluoride exposure and IQ into a highly positive one. However, he admitted there has never been any study "that's ever been done in human history where adjustment for creatinine has had such a dramatic effect on the association between a chemical and health." He also said that he did not investigate whether the laboratory may have made an error.[18]

Connett asked Ibarluzea to explain several possible problems with the study that may have influenced the results. Connett said that according to the Basque government website, consulted at the time of the deposition, the cities in the region stopped fluoridating their water sometime over the last several years. He asked if Ibarluzea was aware of that fact. He said he was. Connett noted it was true for every town in the Basque region and asked Ibarluzea when that change was made. Ibarluzea responded with, "At this point, I am not a representative of the Basque government here in this deposition so I'm not going to give more explanation about this, OK, because it could be very difficult for me personally."[18]

Connett also asked Ibarluzea why he did not adjust for fish consumption in his study.[24] Ibarluzea testified that people in the Basque region eat more small, oily fish with high levels of fatty acids known to be beneficial to the brain than almost anyone in the world. The plaintiffs' witnesses all testified that this was a concerning confounding factor in the study.[18,23]

In other research Ibarluzea had done on per- and polyfluoroalkyl substances (PFAS) chemicals, he wrote that when a chemical is found in seafood it can produce a spurious beneficial association between the chemical and IQ. Ibarluzea said they didn't consider fish consumption as a variable because they were already looking at a lot of variables.[18]

Because the Ibarluzea study found no association between fluoride exposure and loss of IQ in children and because it is the most recently published "high quality" cohort study, it has been a centerpiece of the EPA's evidence. Throughout the trial, plaintiffs' witnesses questioned the study's validity because of the massive increase in IQ in boys linked to fluoride exposure that all researchers, including Ibarluzea, agreed is not a plausible finding.[18] Grandjean commented during the trial that he considered the Ibarluzea paper must contain an error for the creatinine correction to have such a large effect on the IQ with an increase of 15 IQ points.

They plaintiff's witnesses also questioned why the study did not control for major factors like fish consumption. EPA witnesses pointed to the high quality of the study design and discounted the effects for fish, which they argued were accounted for in the adjustments made for mercury. The INMA fluoride study examined the relationship between fluoride exposure and IQ in children in the only region of Spain, the Basque region, that fluoridated its water, but Ibarluzea's testimony raises the question of whether the water was fluoridated throughout the duration of the study.[18]

David Savitz, who worked with the National Academies of Sciences, Engineering, and Medicines (NASEM), reviewing the National Toxicology Program's (NTP) draft report[19] linking fluoride to lower IQ in children, also downplayed the link between fluoride and IQ loss in children.[23] Savitz's testimony supported the EPA's three key arguments:[25]

(i) Data on fluoride's neurotoxic effects for children at current levels of water fluoridation are mixed or uncertain and therefore no action should be taken.
(ii) 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 mg/L.[18]
(iii) More recent studies not considered by the NTP cast doubt on the NTP's findings.

However, the plaintiffs' attorney and federal Judge Edward Chen pushed back on some of his conclusions. Plaintiff's attorney Michael Connett underscored in his cross-examination that Savitz is an expert in epidemiology, but he had no experience researching fluoride. Savitz countered that his lack of experience researching fluoride was an asset because it allowed him to examine the evidence in an unbiased manner.[25]

Savitz also was one of six expert consultants commissioned to advise Health Canada, the country's public health agency, on water fluoridation. Health Canada commissioned a new systematic review[26] which the panel wrote a report on.[27] The report was admitted into the trial evidence along with the systematic review.

The conclusions of the review were: Based on the entire body of evidence reported from human, animal, and *in vitro* streams to date, and relying predominantly on studies of high or acceptable quality, four endpoints were chosen as candidates for further assessment using the Bradford Hill considerations for causality, in addition to dental fluorosis. These endpoints included reduction of IQ levels in children, thyroid dysfunction, kidney dysfunction, and sex hormone disruptions. The evidence supports a conclusion that fluoride exposure reduces IQ levels in children at concentrations close to those seen in North American drinking water, although there is some uncertainty in the weight of evidence for causality

and considerable uncertainty in the point of departure. The evidence also moderately supports the link with thyroid dysfunction, and weakly supports the link with kidney dysfunction. Evidence was considered limited to support a link between fluoride and sex hormone disruptions. Using moderate dental fluorosis as the most appropriate endpoint, a point of departure of 1.56 mg fluoride/L may be preferred as a starting point for setting a health-based guidance value for fluoride in drinking water.[24]

Savitz testified the panel determined that the data linking 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. He said the agency did. He also told Chen he was unaware that two other members of the panel, Steven Levy, DDS, and World Health Organization report author John Fawell were known for their activist work in support of water fluoridation. Savitz said the reviewers didn't want the NTP report findings to be 'misused.'[25]

Savitz said NASEM determined the first draft of the NTP's report,[28] which classified fluoride as a neurotoxin, fell short of providing "a clear and convincing argument" that supported its assessment and that it was "tempered" and "more consistent" with what he thought they were trying to do after revisions were made.[19,28-30]

As this review process was ongoing, former NTP director Brian Berridge, DVM, Ph.D., privately expressed frustration that political pressure was put on the NTP to change its evaluations. Berridge told thought this raised issues for public health and that "Inaction is an action."[25]

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 (Odense Child Cohort and 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.[25]

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. Judge 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.[25]

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. Judge Chen pointed out that the studies would have controlled for that issue. Savitz conceded they did. On cross-examination, Plaintiff's attorney 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 those data to consider toxic exposure levels in the US, using the same methods NTP scientists and other researchers were using with endemic fluoride data, which Savitz criticized.[25]

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."[25]

Judge Chen also asked Savitz if the gender-based differences in response to fluoride, which were identified in the studies, were meaningful,

regardless of their statistical significance. Savitz said they were simply "flukes" because there is no reason to think gender would affect outcomes. He said he wouldn't expect to see sex differences and he didn't know anyone who could explain them, so he thought it made more sense to focus on the aggregate data. On cross-examination, Connett challenged Savitz's conclusions, introducing seminal work on sex differences in response to neurotoxins, explaining how common that is.[25]

Connett also introduced the NTP's report on fluoride and neurotoxicity in animals, which identified sex-differentiated responses and called for more research into the matter. Savitz responded that he was an epidemiologist and therefore not familiar with the toxicology literature on sex differentiation.[25]

Savitz identified several recent "high-quality" studies, published after the NTP completed its review, that he said found no statistically significant relationship between fluoride and IQ loss in children: the Mexican Cantoral et al. 2021 study,[31] the Canadian Dewey et al. 2023 study,[32] and the Australian Do et al. 2023 study.[33] Savitz said these three studies contributed to the uncertainty about water fluoridation's risks. On cross-examination, Connett asked Savitz why, in his expert report to the court, he never disclosed that some of the findings in both the Cantoral[30] and the Dewey[31] studies did show statistically significant associations between fluoride and cognitive ability in children. Savitz said those pieces of data were only part of the findings, but not what he considered important as part of the overall evidence from the paper. In response, Connett walked through each paper, highlighting the statistically significant findings in the papers that Savitz had not reported. For example, Dewey found significant adverse associations between maternal fluoride exposure and executive function in girls, and the authors reported this as a key finding. Savitz said he thought the authors were simply highlighting the most "interesting" findings, and that it was bad practice. Judge Chen asked whether he found a problem in the findings he did not report. He said he didn't, but he didn't place a premium on them.[25]

Connett then moved to the Do study,[32] which Savitz correctly reported found no relationship between fluoride and IQ loss. He asked Savitz if he was aware the study was published in a dental journal, not a neurotoxicology journal, by a dentist with no prior experience studying neurotoxicology using a methodology his co-author said had validity problems. Savitz said he didn't.[25]

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.[25]

Savitz said he didn't know anything about Kaj Roholm's research in Denmark. Roholm was the world's first great fluoride researcher, and he documented the severe harm that fluoride caused in occupational exposure of workers at a cryolite plant and compared it to harm caused by fluoride in pigs, rats, and dogs. Roholm published his findings in a 364-page book, Fluorine intoxication: A clinical-hygienic study with a review of the literature and some experimental investigations, and because of Roholm's science reports most of Europe never fluoridated its water.[25,34]

Savitz also admitted he knew nothing of the work of Phyllis Mullenix, PhD, who published a landmark paper in 1995 establishing that, in her animal study, fluoride dramatically harms brain development.[35] In addition, Savitz admitted that, while he'd heard about the NRC's landmark review, Fluoride in drinking water: A scientific review of EPA's standards, he'd never read it.[25,36]

The EPA et al., the defendants in the trial, argued that the available data are too inconsistent, and leave too many questions, to allow it to conclude that there is a demonstrable hazard or any clear dose-response curve for the alleged harm by fluoride to children's brains. They considered that there were no clear hazards, so they had no ability to engage in risk assessment. With no risk assessment, EPA had no need to do anything. There was nothing for it to prove and they had no

burden of demonstrating the safety of water fluoridation. The only burden of proof was on the plaintiffs and they considered that the plaintiffs have not met their burden of proof and therefore the judge should rule against them, finding EPA blameless.[25]

EPA, however, appeared to apply a double-standard when they claimed the total weight of evidence was "unclear" or "inconsistent" for fluoride and loss of IQ, when, for every other chemical they have determined to pose an "unreasonable risk" (which is the legal standard for this lawsuit,) there has been substantially less evidence, and much greater inconsistency in the evidence. Furthermore, in virtually all the other EPA TSCA risk determinations, the studies have either been only in animals and at much higher exposures than in humans, or in a limited number of studies in humans at much higher exposures than occur in the general population. Almost all those human studies were in occupationally exposed. The evidence on community water fluoridation is stronger than that for the other chemicals evaluated by EPA under TSCA. Even the ostensibly "high dose" fluoride studies of people in China, India, and elsewhere have exposures only slightly higher than in the USA for at least some people drinking fluoridated water at 0.7 mg/L.

Corporate media coverage of the trial was limited. Derrick Broze covered the proceedings for The Last American Vagabond[37-42] and on X (Twitter).[43]

Judge Chen will now decide whether the EPA's claims of uncertainty are a smokescreen to justify its inaction on water fluoridation and whether the plaintiffs have met their burden of proof to establish that water fluoridation presents a real neurotoxic hazard to children's brains.[25] Although this editorial has focused on the material considered in the trial in January and February 2024, in reaching his decision Judge Chen will also consider the evidence presented in the bench trial in June 2020.

In my view, the scientific evidence that fluoride at the levels used in community water fluoridation of about 0.7 mg/L, are neurotoxic to the foetus and infant has been clearly established for some time.[44-46] The case presented by the expert witnesses for the plaintiff's in the trial is supported by a new prospective cohort study by Malin et al. of 229 mother-child pairs in Los Angeles, California, which found that prenatal fluoride exposure was associated with increased neurobehavioral problems.[47] Malin et al. concluded that these findings suggest that there may be a need to establish recommendations for limiting fluoride exposure during the prenatal period.

Although trial verdict may be appealed in a higher court, the decision of Judge Chen is likely to receive widespread attention and have significant consequences.

Bruce Spittle
Editor-in-Chief, *Fluoride*, Dunedin, New Zealand

REFERENCES

[1] United States District Court Northern District of California. Food and Water Watch et al. v. United States Environmental Protection Agency et al. [cited 2024 May 14]. Available from: https://www.google.com/url?sa=t&source=web&rct=j&opi=89978449&url=https://www.cand.uscourts.gov/food-and-water-watch-v-us-epa/&ved=2ahUKEwjm7Yf8jomGAxVC3jgGHRrJBmYQFnoECAwQAQ&usg=AOvVaw2AWc6P0RMTWxqg5B5hkS9N

[2] FluorideAlert.org. Fluoride Action Network. TSCA trial. Available from: https://fluoridealert.org/issues/tsca-fluoride-trial/fact-sheet/

[3] United States District Court Northern District of California. Food and Water Watch et al. v. United States Environmental Protection Agency et al. [cited 2024 May 14]. Curriculum vitae of Stanley Barone Jr. Available from: https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20651.pdf

[4] United States District Court Northern District of California. Food and Water Watch et al. v. United States Environmental Protection Agency et al. [cited 2024 May 14]. Curriculum vitae of Philippe Grandjean. Available from: https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20062.pdf

[5] United States District Court Northern District of California. Food and Water Watch et al. v. United States Environmental Protection Agency et al. [cited 2024 May 14]. Curriculum vitae of Howard Hu. Available from:

https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20063.pdf

[6] United States District Court Northern District of California. Food and Water Watch et al. v. United States Environmental Protection Agency et al. [cited 2024 May 14]. Curriculum vitae of Bruce Perrin Lanphear. Available from:

https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20064.pdf

[7] United States District Court Northern District of California. Food and Water Watch et al. v. United States Environmental Protection Agency et al. [cited 2024 May 14]. Curriculum vitae of Kathleen M Thiessen. Available from: https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20065.pdf

[8] United States District Court Northern District of California. Food and Water Watch et al. v. United States Environmental Protection Agency et al. [cited 2024 May 14]. Curriculum vitae of David A Savitz. Available from: https://files.cand.uscourts.gov/files/17-cv-2162_Food_&_Water_Watch,_Inc._et_al._v._Environmental_Protection_Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial Ex 650.pdf

[9] United States District Court Northern District of California. Food and Water Watch et al. v. United States Environmental Protection Agency et al. [cited 2024 May 14]. Curriculum vitae of Jesus Ibarluzea Maurolagoitia. Available from: https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20652.pdf

[10] FluorideAlert.org. Fluoride Action Network. Witness declaration of Philippe Grandjean. Available from: https://fluoridealert.org/wp-content/uploads/EPA-trial-Grandjean-Declaration.pdf

[11] FluorideAlert.org. Fluoride Action Network. Witness declaration of Howard Hu. Available from: https://fluoridealert.org/wp-content/uploads/EPA-trial-Hu-Declaration.pdf

[12] FluorideAlert.org. Fluoride Action Network. Witness declaration of Bruce Perrin Lanphear. Available from: https://fluoridealert.org/wp-content/uploads/EPA-trial-Lanphear-declaration.pdf

[13] FluorideAlert.org. Fluoride Action Network. Witness declaration of Kathleen Thiessen. Available from: https://fluoridealert.org/wp-content/uploads/EPA-trial-Thiessen-Declaration.pdf

[14] Green R, Lanphear B, Hornung R, Flora D, Martinez-Mier EA, et al. Association between maternal fluoride exposure during pregnancy and IQ scores in offspring in Canada. JAMA Pediatr 2019;173:940-8. doi:10.1001/jamapediatrics.2019.1729. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6704756/

[15] Till C, Green R, Flora D, Hornung R, Martinez-Mier EA, Blazer M, et al. 2020. Fluoride exposure from infant formula and child IQ in a Canadian birth cohort. Environ Int 2020;134:4–11. doi:10.1016/j.envint.2019.105315. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6913880/

[16] Grandjean P, Meddis A, Nielsen F, Beck IH, Bilenberg N, Goodman CV, et al. Dose dependence of prenatal fluoride exposure associations with cognitive performance at school age in three prospective studies. Eur J Public Health 2024;34(1):143-9. Available from: https://doi.org/10.1093/eurpub/ckad170

[17] World Health Organization. Fluoride in Drinking-Water. London, UK: IWA Publishing, 2006.

[18] FluorideAlert.org. Fluoride Action Network. EPA's final witnesses concede fluoride's harm, admit to flaws in key study as trial closes. [cited 2024 May 14]. Available from: https://fluoridealert.org/news/epas-final-witnesses-concede-fluorides-harm-admit-to-flaws-in-key-study-as-trial-closes/

[19] NTNTP. National Toxicology Program. US Department of Health and Human Services. NTP Board of Scientific Counselors Working Group Report on the Draft State of the Science Monograph and the Draft Meta-Analysis Manuscript on Fluoride. Final Report: Approved by the NTP Board of Scientific Counselors on May 16, 2023. Available from: https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20069.pdf

[20] Ibarluzea J, Gallastegi M, Santa-Marina L, Zabala AJ, Arranz E, Molinuevo A, Lopez-Espinosa M-J, et al. Prenatal exposure to fluoride and neuropsychological development in early childhood: 1-to 4 years old children. Environmental Research 2022;207:112181. Available from: https://www.sciencedirect.com/science/article/pii/S0013935121014821?via%3Dihub

[21] United States District Court Northern District of California. Food and Water Watch et al. v. United States Environmental Protection Agency et al. [cited 2024 May 14]. Correspondence about the participation in the trial of Jesus Ibarluzea Maurolagoitia. Available from: https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20135.pdf

[22] Xu KH, An N, Huang H, Duan LZ, Ma J, Ding JH, et al. Fluoride exposure and intelligence in school-age children: evidence from different windows of exposure susceptibility. BMC Public Health 2022; 22:2044. Published online 2022 Nov

8. doi: 10.1186/s12889-022-14470-5. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7640398/

[23] Retraction note for: Xu KH, An N, Huang H, Duan LZ, Ma J, Ding JH, et al. Fluoride exposure and intelligence in school-age children: evidence from different windows of exposure susceptibility. BMC Public Health 2022; 22: 2044. Published online 2022 Nov 8. doi: 10.1186/s12889-022-14470-5. This retracts the article "Fluoride exposure and intelligence in school-age children: evidence from different windows of exposure susceptibility" in volume 20, 1657.] Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9644480/

[24] Julvezd J, Mendez M, Fernandez-Barres S, Romaguera D, Vioque J, Llop S, et al. Maternal consumption of seafood in pregnancy and child neuropsychological development: A longitudinal study based on a population with high consumption levels. Am J Epidemiol 2016;183(3):169-82. Available from: https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20105.pdf

[25] FluorideAlert.org. Fluoride Action Network. TSCA trial. EPA paid expert witness $137,000 to testify in landmark fluoride trial. Available from: https://fluoridealert.org/news/epa-paid-expert-witness-137000-to-testify-in-landmark-fluoride-trial/

[26] Taher MK, Momoli F, Go J, Hagiwara S, Ramoju S, Hu XF, et al. Systematic review of epidemiological and toxicological evidence on health effects of fluoride in drinking water Critical Reviews in Toxicology 2024. Available from: https://doi.org/10.1080/10408444.2023.2295338 and https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20129.pdf

[27] Bellinger D, Fawell J, Haber L, Levy S, Savitz D, Schoeny R. Expert Panel Meeting on the Health Effects of Fluoride in Drinking Water: Summary report June 8-9, 2023. Ottawa, ON, Canada: Health Canada; 2023. Available from: https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20128.pdf

[28] NTP. National Toxicology Program. Monograph on the systematic review of fluoride exposure and neurodevelopmental and cognitive health effects. September 6, 2019. Office of Health Assessment and Translation, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, US Department of Health and Human Services. Available from:

https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20125.pdf

[29] NTP. National Toxicology Program. Draft NTP monograph on the systematic review of fluoride exposure and neurodevelopmental and cognitive health effects. Revised September 16, 2020. [*The September 6, 2019 draft monograph was peer reviewed by a committee convened by the National Academy of Sciences, Engineering, and Medicine (NASEM). This current draft incorporates changes in response to that review and is being submitted to the same NASEM committee for an additional round of peer review.] Office of Health Assessment and Translation, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, US Department of Health and Human Services. Available from: https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20126.pdf

[30] NTP. National Toxicology Program. NTP monograph on the state of science concerning fluoride exposure and neurodevelopmental and cognitive health effects. A systematic review. NTP Monograph. May 2022. National Toxicology Program, Public Health Service, US Department of Health and Human Services. Available from:

https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20067.pdf

[31] Cantoral A, Tellez-Rojo MM, Malin AJ, Schnaas L, Osorio-Valencia E, Mercado A, et al. Dietary fluoride intake during pregnancy and neurodevelopment in toddlers: A prospective study in the progress cohort. Neurotoxicology 2021;87:86-93. Available from: https://fluoridealert.org/wp-content/uploads/cantoral-2021.final .pdf

[32] Dewey D, England-Mason G, Ntanda H, Deane AJ, Jain M, Barnieh N, et al. Fluoride exposure during pregnancy from a community water supply is associated with executive function in preschool children: A prospective ecological cohort study. Science of the Total Environment 2023;891:164322. Available from: https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20117.pdf

[33] Do LG, Spencer AJ, Sawyer A, Jones A, Leary S, Roberts R, Ha DH. Clinical early childhood exposures to fluorides and child behavioral development and executive function: A population-based longitudinal study. International Association for Dental Research and American Association for Dental, Oral, and Craniofacial Research 2022. DOI: 10.1 177/002203452211 19431. journals.sagepub.com/home/jdr. Available from: https://files.cand.uscourts.gov/files/17-cv-2162%20Food%20&%20Water%20Watch,%20Inc.%20et%20al.%20v.%20Environmental%20Protection%20Agency/17-cv-02162_Food_&_Water_Watch_Inc_v_Environmental_Protection_Agency/Trial%20Ex%20113.pdf

[34] Roholm K. Fluorine intoxication: A clinical-hygienic study with a review of the literature and some experimental investigations. Copenhagen and London: NYT Nordisk Forlag and HK Lewis & Co Ltd; 1937. Available from: http://fluoridealert.org/wp-content/uploads/Roholm-19371.pdf

[35] Mullenix PJ, Denbesten PK, Schunior A, Kernan WJ. Neurotoxicity of sodium fluoride in rats. Neurotoxicology and Teratology 1995;17(2):169-77. Available from: https://www.fluoridealert.org/wp-content/uploads/mullenix-1995.pdf

[36] Committee on Fluoride in Drinking Water, Board on Environmental Studies and Toxicology, Division on Earth and Life Studies, National Research Council of the National Academies. Fluoride in Drinking Water: A Scientific Review of EPA's Standards. Washington, DC, USA: The National Academies Press, National Academies of Sciences, Engineering, and Medicine; 2006. Available from: https://nap.nationalacademies.org/catalog/11571/fluoride-in-drinking-water-a-scientific-review-of-epas-standards

[37] Broze D. The fluoride lawsuit comes to an end: Federal judge to decide the future of water fluoridation. The Last American Vagabond. 2024 May 16. Available from: https://www.thelastamericanvagabond.com/fluoride-lawsuit-comes-to-an-end/

[38} Broze. D. Everything You Need To Know About Week 1 Of The 2nd Phase Of The #FluorideLawsuit. The Last American Vagabond. 2024 May 18. Available from: https://www.thelastamericanvagabond.com/week1-fluoride-lawsuit/

[39] Broze D. Fact checking The Fact Checkers: Experts say fluoridated water not safe to drink. The Last American Vagabond. 2024 May 18. Available from: https://www.thelastamericanvagabond.com/fact-checking-fact-checkers-fluoridated-water/

[40] Broze D. Derrick Broze interview – narrative shift: EPA experts admit fluoride is neurotoxic & can lower IQ. The Last American Vagabond. 2024 May 19. Available from: https://www.thelastamericanvagabond.com/derrick-broze-interview-2-17-24/

[41] Broze D. Week 2 of the #FluorideLawsuit: EPA rests their case, admits harm related to fluoride exposure. The Last American Vagabond. 2024 May 20. Available from: https://www.thelastamericanvagabond.com/week-2-fluoridelawsuit/

[42] Broze D. Michael Connett interview – Leading the charge in the fight against water fluoridation. The Last American Vagabond. 2024 May 21. Available from: https://www.thelastamericanvagabond.com/michael-connett-interview-2-5-24/

[43] Broze D. The conscious resistance network. X (Twitter). Available from: https://x.com/DBrozeLiveFree

[44] Spittle B. Neurotoxic effects of fluoride [editorial]. Fluoride 2011;44(3):117-124. Available from: https://www.fluorideresearch.org/443/files/FJ2011_v44_n3_p117-124_sfs.pdf

[45] Spittle B. The importance of timing in fluoride-induced developmental neurotoxicity [editorial]. Fluoride 2019;52(40:483-8. Available from: https://www.fluorideresearch.online/524/files/FJ2019_v52_n4_p483-488_pq.pdf

[46] Spittle. B. Revisiting the importance of timing in fluoride-induced developmental neurotoxicity [editorial]. Fluoride 2023;56(2):99-100. Available from: https://www.fluorideresearch.online/562/files/FJ2023_v56_n2_p099-100_pq.pdf

[47] Malin AJ, Eckel SP, Hu H, Martinez-Mier EA, Hernandez-Castro I, Yang TY, et al. Maternal urinary fluoride and child neurobehavior at age 36 months. JAMA Netw Open. 2024;7(5):e2411987. doi:10.1001/jamanetworkopen.2024.11987. Available from: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2818858