No. 25-384

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

FOOD AND WATER WATCH, *et al.*,

Plaintiff-Appellees,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Defendant-Appellants.

On Appeal from the United States District Court
for the Northern District of California
No. 3:17-cv-02162
Hon. Edward M. Chen

BRIEF OF AMICUS CURIAE AMERICAN DENTAL ASSOCIATION IN SUPPORT OF APPELLANTS AND REVERSAL

C. Michael Kendall
Senior Associate General Counsel
AMERICAN DENTAL ASSOCIATION
401 N. Michigan Avenue, Suite 3300
Chicago, IL 60611
kendallc@ada.org
Telephone: (312) 440-2810

Jane C. Luxton
LEWIS BRISBOIS BISGAARD & SMITH PLLC
2112 Pennsylvania Avenue NW
Suite 500
Washington, DC 20037
Jane.Luxton@lewisbrisbois.com
Telephone: (202) 558-0659

Attorneys for *Amicus Curiae*

CORPORATE DISCLOSURE STATEMENT

The undersigned counsel certifies that *amicus curiae*, the American Dental Association, is a nonprofit corporation existing under the laws of the State of Illinois with its principal place of business in Chicago, Illinois. It has no parent corporation or stockholders.

Date: July 25, 2025

By: /s/Jane C. Luxton

Jane C. Luxton
LEWIS BRISBOIS BISGAARD & SMITH
2112 Pennsylvania Ave., N.W.
Suite 500
Washington, DC 20037
Jane.Luxton@lewisbrisbois.com
Telephone (202) 558-0659

Attorneys for *Amicus Curiae*

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STATEMENT OF INTEREST

Amicus Curiae represents the largest organization of dental professionals and acts as the premier source of oral health information in the United States. One of the ADA's primary purposes is to advance the overall oral health of Americans. It is this role that motivates the ADA to educate dentists and their patients about the safety and positive health effects of water fluoridation. The ADA submits this *amicus* brief to supply the Court with additional information on the safety of water fluoridation given that no party has provided the Court with such information.

ARGUMENT

I. COMMUNITY WATER FLUORIDATION IS A RECOGNIZED PUBLIC HEALTH RISK REDUCTION MEASURE THAT IS PROPERLY CONSIDERED IN MAKING AN UNREASONABLE RISK DETERMINATION UNDER AMENDED TSCA.

In its May 15, 2024, "Scientific Statement on Community Water Fluoridation," the U.S. Centers for Disease Control and Prevention ("CDC") quoted "the seminal report, Oral Health in America: A Report of the Surgeon General, [in which] Surgeon General David Satcher observed a 'silent epidemic' of dental and oral diseases […] with those suffering the most found among the poor of all ages." U.S. Ctrs. for Disease Control and Prevention, *Scientific Statement on Community Water Fluoridation* (2024) (omitted language in original) (quoting National Institute of Dental and Craniofacial Research, National Institutes of Health, Oral Health in America: Advances and Challenges (2000)), https://www.cdc.gov/fluoridation/media/pdfs/2024/09/Scientific-Statement-on-Community-Water-Fluoridation.pdf. Continuing, the CDC Scientific Statement declared that "[b]ecause of its contribution to the decline in tooth decay, CDC named community water fluoridation 1 of 10 great public health achievements of the 20th century." *Id. See also Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries*, 48 CDC MMWR 933 (Oct. 22, 1999) (omitted references in original), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4841a1.htm (discussing

nationwide decline in dental caries following adoption of water fluoridation throughout U.S.).

The CDC is hardly alone in recognizing these conclusions as to the health risk reduction achievements of community water fluoridation. As the Statement goes on to note:

> The U.S. Public Health Service; the United Kingdom's National Institute for Health Research, Centre for Reviews and Dissemination, at the University of York; and the National Health and Medical Research Council, Australia have all conducted scientific reviews by expert panels and concluded that community water fluoridation is a safe and effective way to promote good oral health and prevent decay.[] The U.S. Community Preventive Services Task Force, on the basis of systematic reviews of scientific literature, issued a strong recommendation in 2001 and again in 2013, for community water fluoridation for the prevention and control of tooth decay.

U.S. Ctrs. for Disease Control and Prevention, *supra* p. 1 (internal references omitted).

As a recent publication by the Congressional Research Service ("CRS") notes, *amicus curiae* ADA, along with the "CDC, the American Medical Association . . . the American Academy of Pediatric Dentistry, and other organizations recommend fluoridation of community water supplies as a way to protect dental health, particularly in low-income communities where children are less likely to receive adequate dental care." Cong. Rsch. Serv., R48539, *The Development of Federal Recommendations and Regulations for Fluoride in Drinking Water* 4 (2025) (internal references omitted), https://www.congress.gov/crs-product/R48539. The ADA's recommendation is

based on more than 80 years of scientific research demonstrating the effectiveness of community water fluoridation in reducing dental decay.

Yet, little to none of this compelling evidence of the dental and oral disease reduction attributable to community water fluoridation was allowed into evidence and considered as part of the unreasonable risk determination by the Court below. This situation resulted from the Court's first-impression interpretation of key statutory language from the Toxic Substances Control Act ("TSCA").

In 2016, Congress amended the TSCA ("Amended TSCA") to require that in seeking an injunction to compel EPA to initiate a rulemaking under section 21 of that Act, plaintiffs must establish that the "chemical substance" under consideration "presents an unreasonable risk of injury to health or the environment, without consideration of *costs or other nonrisk factors*, including an unreasonable risk to a potentially exposed or susceptible population, under the conditions of use." 15 U.S.C. § 2620(b)(4)(B)(ii) (emphasis added).

Notably, the statutory provision at issue does not define the terms "risk" or "nonrisk," and does not even use the term "benefit." 15 U.S.C. § 2620. However, proceeding without sufficiently rigorous analysis, the Court assumed that evidence of the health risk reduction in dental and oral diseases due to fluoridation of drinking water must be regarded as a "benefit" and was not appropriate for consideration in the unreasonable risk determination. 5-ER-1065-71.The Court so

held, notwithstanding EPA's arguments that such risk reduction is properly considered a human health risk-related factor under the Amended TSCA. For example, EPA noted that its final rule implementing the Amended TSCA specifically lists "effects of the chemical substance on health" as a "relevant factor" in making an unreasonable risk determination. Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,735 (July 20, 2017).

Nonetheless, stating with conclusory reasoning that because "benefit after all is a nonrisk factor," the Court excluded evidence of fluoridation's disease reduction effects to ensure it made an unreasonable risk determination "without consideration of costs or other *nonrisk* factors." 5-ER-1066 (emphasis added). At the same time, however, the Court acknowledged that Plaintiffs' experts had written "extensively about [the lack of health] benefits in their expert reports," which were considered by the Court, and allowed limited evidence on this point, but only to challenge the credibility of those expert reports. 5-ER-1073.

The Amended TSCA also explicitly requires consideration of "an unreasonable risk to a potentially exposed or susceptible population," but the Court did not consider the Surgeon General's observation that harm from this "silent epidemic" of disease falls most heavily on a susceptible population, the "poor of all ages." U.S. Ctrs. for Disease Control and Prevention, *supra* p. 1 ("'silent

epidemic' of dental and oral diseases […] with those suffering the most found among the poor of all ages."). Further, the Surgeon General emphasized that:

> [P]rofound disparities in oral health status remain for some population subgroups, such as the poor, the elderly, and many members of racial and ethnic minority groups. Tooth decay is one of the most common chronic diseases among American children with 1 of 4 children living below the federal poverty level experiencing untreated tooth decay. Untreated decay can cause pain, school absences, difficulty concentrating, and poor appearance—all contributing to decreased quality of life and ability to succeed."

Id. (footnotes omitted).

Based on its interpretations of the Amended TSCA, the Court did not take into account in reaching its unreasonable risk decision the immense weight of scientific evidence supporting the critical importance of community water fluoridation in reducing the human health risk of the "'silent epidemic' of dental and oral diseases" in America today, nor did it assess the risk-related implications for susceptible populations. This failure to consider key evidence resulted in a deficient unreasonable risk determination.

II. THE STATUTORY STANDARD REQUIRES A SHOWING BY A PREPONDERANCE OF THE EVIDENCE THAT THE CHEMICAL SUBSTANCE PRESENTS AN UNREASONABLE RISK UNDER THE CONDITIONS OF USE, WHICH HERE IS 0.7 MILLIGRAMS PER LITER IN COMMUNITY DRINKING WATER.

As noted above, plaintiffs must establish by a preponderance of the evidence that fluoridation of drinking water "presents an unreasonable risk of injury to

health" "under the conditions of use." Here the conditions of use are addition of fluoridation chemicals to community drinking water to achieve optimal levels of 0.7 milligrams per liter ("mg/L"). 2-ER-74.

The draft National Toxicology Program Monograph ("Draft NTP Monograph") published in 2022, on which the Court below explicitly relied, concluded, "with moderate confidence, that higher [levels of] fluoride exposure[,]" such as drinking water containing more than 1.5 milligrams of fluoride per liter, are "consistently associated with lower IQ in children." 2-ER-319. However, the Draft NTP Monograph also stated "[m]ore studies are needed to fully understand the potential for lower fluoride exposure to affect children's IQ." *Id.* When the NTP finalized its Monograph in 2024, it stated in bolded text that **"[i]t is important to note that there were insufficient data to determine if the low fluoride level of 0.7 mg/L currently recommended for U.S. community water supplies has a negative effect on children's IQ.**" *Fluoride Exposure: Neurodevelopment and Cognition*, Nat'l Toxicology Program, U.S. Dep't of Health and Hum. Servs., (Emphasis in original), https://ntp.niehs.nih.gov/research/assessments/noncancer/completed/fluoride#:~:text=It%20is%20important%20to%20note%20that%20there%20were,fluoride%20exposure%20had%20adverse%20effects%20on%20adult%20cognition (referencing Nat'l Toxicology Program, U.S. Dep't of Health and Hum. Servs., *NTP*

Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopment and Cognition: A Systematic Review (2024), https://ntp.niehs.nih.gov/sites/default/files/2024-08/fluoride_final_508.pdf). The NTP further advised "**more research is needed to better understand if there are health risks associated with low fluoride exposures.**" *Id*. (Emphasis in original).

These conclusions are amply borne out by numerous other expert reviews and studies that assessed low level exposures, as opposed to higher exposure studies conducted in non-U.S. populations:

- The U.S. Public Health Service conducted an expert review and recommended community water fluoridation at an optimal 0.7 mg/L level to maintain dental caries prevention efforts. Fed. Panel on Cmty. Water Fluoridation, U.S. Dep't of Health & Hum. Servs., *U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries*, 130 Pub. Health Reps. 318, 319 (2015), https://journals.sagepub.com/doi/epdf/10.1177/003335491513000408 (USPHS Final Recommendation for Fluoride).

- Health Canada convened an Expert Panel Meeting on the Health Effects of Fluoride in Drinking Water and concluded in 2023 that the scientific evidence did not justify lowering its 1.5 mg/L guideline for

allowable levels of fluoride in drinking water, based on the consensus finding that "at this time, the evidence is not considered sufficient to use neurocognitive endpoints as the basis for deriving a point of departure" and health-based value for neurocognitive effects. Health Can., *Expert Panel Meeting on the Health Effects of Fluoride in Drinking Water: Summary Report*, Health Can. (June 8, 2023), https://www.canada.ca/content/dam/hc-sc/documents/services/environmental-workplace-health/reports-publications/water-quality/expert-panel-meeting-effects-fluoride-drinking-summary/expert-panel-meeting-effects-fluoride-drinking-summary.pdf.

- The New Zealand Ministry of Health concluded in 2024 that "there has been no high-quality evidence published since the 2014 and 2021 reports to suggest a causal link between fluoride exposure at the levels used in Aotearoa New Zealand for community water fluoridation and significant harm to health." The "conclusions reached regarding the health benefits and safety aspects of community water fluoridation in New Zealand" were not "alter[ed]" by the "US National Toxicology Program Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopmental and Cognition: A Systematic

Review" (August 2024), "the Cochrane review of the evidence related to the prevention of dental decay by community water fluoridation" (October 2024), and the "US District Court for the Northern District of California ruling relating to community water fluoridation" (October 2024). *Community Water Fluoridation Policy: Ministry of Health 2024 Evidence Update*, New Zealand Ministry of Health, https://www.health.govt.nz/strategies-initiatives/programmes-and-initiatives/oral-health/community-water-fluoridation-policy#toc-0-2 (last visited July 24, 2025).

- The European Union Scientific Committee on Health and Environmental Risks ("SCHER") conducted a review of human and animal studies and concluded, "SCHER agrees that there is not enough evidence to conclude that fluoride in drinking water at concentrations permitted in the EU may impair the IQ of children. SCHER also agrees that a biological plausibility for the link between fluoridated water and IQ has not been established." Sci. Comm. on Health and Env't Risks (SCHER), Eur. Comm'n, *Critical Review of Any New Evidence on the Hazard Profile, Health Effects, and Human Exposure to Fluoride and the Fluoridating Agents of Drinking Water*, at 18 (2011),

https://ec.europa.eu/health/scientific_committees/opinions_layman/fluoridation/documents/fluoridation.pdf."

- The Leibniz Research Centre, funded by the German central and regional governments, found "[t]he available epidemiological evidence does not provide sufficient arguments to raise concerns with regard to CWF [community water fluoridation] in the range of 0.7–1.0 mg/L, and to justify the conclusion that fluoride is a human developmental neurotoxicant that should be categorized as similarly problematic as lead or methylmercury at current exposure levels." Sabine Guth et al., Dep't of Toxicology, Leibniz Rsch. Ctr. for Working Env't and Hum. Factors, *Toxicity of Fluoride: Critical Evaluation of Evidence for Human Developmental Neurotoxicity in Epidemiological Studies, Animal Experiments and In Vitro Analyses* 94 Archives of Toxicology 1375, 1405 (2020), https://link.springer.com/article/10.1007/s00204-020-02725-2. "[B]ased on the totality of currently available scientific evidence, the present review does not support the presumption that fluoride should be assessed as a human developmental neurotoxicant at the current exposure levels in Europe." *Id.*, at 1375.

- The available evidence from recent publications demonstrates that fluoride exposure at concentrations used in community water fluoridation (i.e., 0.7 mg/L) "is not associated with lower IQ scores in children." Jayanth V. Kumar et al., *Association Between Low Fluoride Exposure and Children's Intelligence: A Meta-Analysis Relevant to Community Water Fluoridation* 219 Pub. Health 73, 82 (2023), https://doi.org/10.1016/j.puhe.2023.03.011. Similarly, individual studies conducted in fluoridated communities in Spain, Jesús Ibarluzea et al., *Prenatal Exposure to Fluoride and Neuropsychological Development in Early Childhood: 1-to 4 Years Old Children* 207 Env't Rsch. (2021), https://doi.org/10.1016/j.envres.2021.112181, and Australia, L.G. Do et al., *Early Childhood Exposures to Fluorides and Cognitive Neurodevelopment: A Population-Based Longitudinal Study* 104 J. of Dental Rsch. 243 (2025), further show that there is not a preponderance of the evidence that fluoride presents an unreasonable risk under the conditions of use, that is 0.7 mg/L in community drinking water.

The statutory standards requiring a showing by a preponderance of the evidence that fluoridation of community drinking water presents an unreasonable risk at the "condition of use," 0.7 mg/L, have not been met.

CONCLUSION

For the foregoing reasons, the Court should reverse the decision below.

Dated: July 25, 2025

Respectfully submitted,

/s/ Jane C. Luxton
LEWIS BRISBOIS BISGAARD & SMITH
2112 Pennsylvania Ave., N.W.
Suite 500
Washington, DC 20037
Jane.Luxton@lewisbrisbois.com
(202) 558-0659

Attorneys for *Amicus Curiae*

UNITED STATES COURT OF APPEALS
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