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February 20, 2026 *Submitted electronically*

Environmental Protection Agency
Department of Health and Human Services

Re: Docket No. EPA-HQ-OW-2025-3823: Review of Science on Fluoride in Drinking Water: Preliminary Assessment Plan and Literature Survey

Dear Administrator Zeldin:

On behalf of over 11,000 members of the **American Academy of Pediatric Dentistry (AAPD)**, the following comments are provided in response to the Environmental Protection Agency (EPA) request for feedback on the **Fluoride Preliminary Assessment Plan and Literature Survey** (**Assessment Plan**) that will inform the **Fluoride Human Health Toxicity Assessment** (**Toxicity Assessment**) [Docket No. EPA-HQ-OW-2025-3823].

As pediatric dentists, we care deeply about both the oral health and the overall health of children. We appreciate the EPA's acknowledgement that, "at lower levels, fluoride has been shown to decrease the prevalence of tooth decay (dental caries/cavities), one of the most common chronic diseases among American children (CDC, 2024)." We also recognize that fluoride (F) is toxic at high doses.

Executive Summary

The AAPD urges the EPA to revise the Assessment Plan to ensure methodological rigor, policy relevance to U.S. exposures, and transparency consistent with Executive Order 14303 on Restoring Gold Standard Science.[1]

Specifically, the EPA should:

1. pre-specify adversity criteria for fluorosis and limit adverse outcomes used for reference dose derivation to moderate–severe dental fluorosis;
2. stratify neurodevelopmental evidence by exposure level and prioritize U.S. relevant exposures (≤1.5 mg/L, particularly ~0.7 mg/L);
3. update the literature search to include 2025 through early 2026 and publish a full systematic review protocol for public comment before review; and
4. clearly state that any reference dose is a threshold to avoid adverse effects and does not negate the well-documented caries-prevention benefits of fluoride at recommended levels.

These changes will reduce misinterpretation, maintain scientific integrity, and protect children's health while guiding practical, defensible policy decisions.

Children consuming fluoridated water have the benefit of frequent, low-dose fluoride exposures that act both systemically and topically to provide optimal caries prevention with maximum safety.

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In the U.S., we have been fluoridating water at low levels for this reason for 80 years. The safety profile of fluoridated water at the levels used in the United States (0.7ppm) is well established.

Conclusions drawn from the Assessment have the potential to drastically alter fluoride practices throughout the nation to the detriment of children's health. If the Assessment is not conducted responsibly and with scientific integrity, children will experience more dental pain, infection, missed school days, and lower quality of life. Parents and caregivers will experience lower productivity as they support these children and be responsible for higher health care costs to manage this chronic disease and associated systemic diseases.

Other nations and communities have experienced the harmful effects of instituting unreasonable water fluoridation policies. Canada's third largest city restored community water fluoridation after its disastrous experiment with removal resulted in a large increase in dental disease.[2] While the EPA request for comment specifically noted a disinterest in any health benefits of fluoride, it would be neglectful of us as pediatric specialists and children's health advocates to not raise this dire concern. **The Trump Administration has an opportunity to have the U.S. do better than those other countries that have made water fluoridation mistakes due to misinterpreting or ignoring the science.**

Key Revisions Requested by the AAPD

The following comments are rooted in our **collective, singular mission to uphold, promote, and protect the health and wellbeing of children**.

1. MILD FLUOROSIS IS INAPPROPRIATE FOR USE AS TOXICITY THRESHOLD

"EPA will consider the adversity of different stages of dental fluorosis when selecting appropriate benchmark response values for dose-response analysis and when identifying an overall RfD for fluoride." (Assessment Plan page 2-14)

AAPD Recommendation: Pre-specify adversity criteria for fluorosis before dose-response modeling and confine adverse outcomes for reference dose derivation to moderate–severe fluorosis. Mild fluorosis is cosmetic, typically not functional or painful, and should not be used as the toxicity threshold.

The Assessment Plan should pre-specify criteria to determine adverse levels of fluorosis before conducting dose-response analyses. The plan acknowledges a "lack of consensus" on how to characterize the adversity of fluorosis but defers this critical decision to later in the process. However, this choice is critical for determining which studies are selected for dose-response modeling, whether dental fluorosis or neurotoxicity becomes the critical effect, and ultimately the final reference dose (RfD) value.[3] This decision should be made transparent in the systematic review protocol, justified based on explicit criteria rather than post-hoc, and subject to public comment before implementation. If adversity criteria are not pre-specified, there is risk that this decision will be made in a manner that appears driven by desired regulatory outcomes instead of scientific principles. At the current

reference dose of 0.06mg/kg/day, there is no evidence in human or animal studies of toxic or adverse effects.

The current EPA RfD for fluorine states that classifying even severe levels of fluorosis as an adverse outcome is controversial. The AAPD agrees with that assessment, and most certainly objects to mild fluorosis being considered an adverse outcome.[4] Fluorosis – of any severity – is not considered a disease. As stated by the CDC, "In the U.S., dental fluorosis is mostly mild and cosmetic, meaning it does not affect tooth function and is not painful. Moderate and severe forms of dental fluorosis are rare."[5] Mild fluorosis has no deleterious or pathologic qualities, making it ill-suited for use as a threshold from which to determine toxicity. The prevalence of very mild and mild fluorosis tends to be similar in fluoridated and sub-optimally fluoridated communities.[6] The prevalence of very mild and mild fluorosis is also similar in countries that do not fluoridate their water with prevalence in the U.S.[7] Data indicates that mild dental fluorosis is beneficial as it reduces caries and can be associated with an improved oral health-related quality of life.[8] Combining all fluorosis severity levels conflates cosmetic effects with true structural or functional impairment and will lead to an inappropriately conservative toxicity value that does not reflect clinical reality.

2. INCOMPLETE RISK-BENEFIT CONTEXT

"The potential health benefits of oral fluoride exposure (e.g., decreased dental caries) are not within the scope of this toxicity assessment." (Assessment Plan page 2-9)

AAPD Recommendation: Clarify in the protocol that any derived RfD is a benchmark to avoid adverse effects—not a recommendation against exposure at levels where benefits are established (e.g., 0.7 mg/L).

The final Toxicity Assessment should include a section explicitly acknowledging the established caries prevention benefits at the recommended 0.7 mg/L level. This context is essential to prevent misinterpretation or misapplication of the RfD by decision-makers at the state and local levels. The Assessment should clarify that any derived RfD represents a threshold for avoiding adverse effects, not a recommendation against exposure at lower levels where benefits are well-documented.

A recently published systematic review and meta-analysis included 74 observational studies in qualitative analysis and 32 studies in meta-analysis. They reported standardized mean difference (SMD) of -0.32 for DMFT (decayed, missing, and filled permanent teeth) and -0.30 for dmft (decayed, missing, and filled primary teeth), favoring fluoridated communities. Caries prevalence was lower in fluoridated areas (OR = 0.52 permanent teeth; OR = 0.60 primary teeth).[9]

It would be irresponsible for the Toxicity Assessment alone to inform revisions to the Safe Drinking Water Act. Benefits to water fluoridation at specified low dose levels must be considered, as well as the risks of not including fluoride in the drinking water. We urge the

EPA to weight the Toxicity Assessment fairly amongst an overall risk-benefit analysis and benefit-cost analysis.

3. DOSE-RESPONSE CONSIDERATIONS LACKING

"For dose-response analysis of developmental neurotoxicity, EPA will critically evaluate the NTP meta-analysis of cognitive effects in children (Taylor et al., 2025) for possible use or adaptation in toxicity value derivation." (Assessment Plan page 2-11)

AAPD Recommendation: The protocol should stratify studies by exposure level (e.g., ≤0.7, 0.7–1.5, >1.5 mg/L) and context (source of fluoride, co-exposures, nutrition) and prioritize evidence generalizable to U.S. community water fluoridation. Meta-analyses indicating inverse associations at high concentrations (>1.5 mg/L) should not be extrapolated to recommended levels. U.S.-relevant studies at or below 1.5 mg/L, including recent longitudinal analyses, should receive greater weight when determining hazard identification and the point of departure for dose–response modeling.

The EPA Assessment Plan relies on Taylor et al. (2025) for dose-response modeling which uses exposure levels and populations not relevant to U.S. policy.[10] That publication—which found inverse associations between fluoride and IQ—examined exposure levels far exceeding those experienced by Americans. They had "moderate confidence" in their finding of fluoride exposure above 1.5 mg/L being associated with lower IQ in children. Most of the areas with higher levels of fluoride were due to high naturally occurring fluoride in groundwater and was not a result of community water fluoridation. Only 4.5% of the U.S. population is exposed to fluoride levels at or above 1.5 mg/L,[11] and Taylor et al.'s findings for concentrations below this threshold were null. The document does not adequately address the fundamental limitation that none of the studies underlying this conclusion were conducted in the United States or at exposure levels relevant to U.S. community water fluoridation policy.

The RfD derivation for a population must be based on evidence from populations with exposure characteristics, co-exposures, nutritional status, and modifying factors reasonably like the target population. The studies included in Taylor et al. (2025) were predominantly conducted in China, India, Iran, and Mexico with substantially higher exposures (often >3 mg/L), different exposure sources, distinct socio-economic indicators, and confounding patterns compared to U.S. community water fluoridation at 0.7 mg/L. We strongly recommend the EPA prioritize evidence from generalizable contexts. Using data from populations with considerably higher exposures can violate fundamental principles of external validity in this assessment.

The recent high-quality U.S.-based evidence (Warren et al 2025) found that children exposed to recommended levels of fluoride in drinking water exhibit modestly better cognition in secondary school, and this study is not adequately reflected in the document.[12] The EPA's assessment should also give substantial weight to the Kumar et al. (2023) meta-

analysis, which specifically examined studies conducted in areas with fluoride exposure at or below 1.5 mg/L—the range relevant to U.S. policy.[13] Their conclusion states: "fluoride exposure relevant to community water fluoridation is not associated with lower IQ scores in children."

The systematic review protocol should include a clear stratification of neurodevelopmental studies by exposure level, with explicit recognition that studies examining populations exposed to >1.5 mg/L fluoride have limited applicability to U.S. policy decisions regarding community water fluoridation at 0.7 mg/L. The Warren et al. (2025) study should be prioritized given its unique strengths: nationally representative U.S. sample, policy-relevant exposure levels, longitudinal design, and robust confounding adjustment.

4. MISREPRESENTED HUMAN HEALTH HAZARDS

"Two children's health outcomes, tooth weakening (dental fluorosis) and developmental neurotoxicity (e.g., decreased intelligence quotient (IQ)), were identified as well-established and sensitive health effects associated with fluoride exposure."(Assessment Plan page 1-2)

Neurobehavioral effects of fluoride have been studied extensively over the past decade using a variety of models. Numerous human studies addressing this issue, including multiple systematic reviews,[13,14] are available yet absent from the search results dashboard. The National Toxicology Program report—on which this Assessment Plan relies heavily—concluded there was no association between fluoride exposure below 1.5 mg/L in drinking water (more than twice the currently recommended community water recommendation in the U.S.) and outcomes such as IQ related to neurodevelopment of children.[15]

Studies in Australia and New Zealand show no effect on community water fluoridation and IQ.[16,17] Other systematic reviews on this topic support no association between IQ and fluoride exposure, while others show negative associations at fluoride levels higher than 1.5.[13,16] A long-term study evaluating IQ and fluoride supplement use prior to age 5 years showed no change in IQ throughout childhood and up to age 38 years.[17]

The evidence from human studies strongly supports the conclusion that there are not negative cognitive or neurobehavioral outcomes from children consuming fluoridated water at the U.S.-recommended levels.[14] **It is not appropriate for the EPA to conclude that neurocognitive development has been categorized as a "well-established" health hazard *before* a literature review is conducted. Jumping to this conclusion – when the NTP report specifically states that their conclusions are only for levels above 1.5 mg/L – is not in line with the science and will be detrimental to human health. The AAPD urges the EPA to not limit its data review to biased and limited studies and to consider the extensive scientific studies and literature available.**

5. HIGHLY PROBLEMATIC METHODOLOGICAL SHORTCOMINGS

The Assessment Plan is replete with concerning elements suggesting rushed development and prematurely drawn conclusions, as described below. Additional review and engagement with scientists, practitioners and other stakeholders is urged.

AAPD Recommendation: Consistent with Executive Order 14303, EPA should release the full systematic review protocol for public comment and independent peer review before initiating its final review. The protocol should specify: databases and gray literature sources; language limits; inclusion/exclusion criteria; exposure metrics and how short-term biomarkers (e.g., urine) will be interpreted relative to chronic intake; risk-of-bias tools; plans for stratified analyses by exposure level and context; and approaches to uncertainty. EPA should update the literature search through 2025 and early 2026 and provide a rationale for any selective inclusion of 2025 studies to avoid perceived bias.

a. **Skewed Conclusions:** Conclusions raised by the EPA that state "well-established children's health effects," "tooth weakening dental fluorosis," and "neurodevelopmental effects of fluoride are a well-established hazard," are not scientifically accurate and misguided. The Assessment Plan relies heavily on the often-discredited NTP report. The NTP report had significant shortcomings that are well documented.[18] It failed peer review multiple times and was released without reflecting the necessary changes outlined by the National Academies of Sciences, Engineering, and Medicine (NASEM).[19]

   Only three of the five key studies cited by the EPA are from the U.S. Some of these reports did not explore or include content on dental fluorosis, one of the key outcomes of interest. The EPA is exclusively relying on limited reports, the majority of which are from or are based on studies from other nations with much different water composition.

b. **Indications that the Toxicity Assessment is already complete:**

   The EPA notice states, "To expedite the toxicity assessment development, EPA leveraged consensus hazard conclusions based on its critical review of the latest fluoride health science from EFSA (EFSA Scientific Committee, 2025), Health Canada (Health Canada, 2024; Taher et al., 2024), and NTP (NTP, 2024) rather than re-review the full set of literature to establish hazards for fluoride" (emphasis added).

   Based on this statement, it is not clear if the described literature search conducted by the EPA was fully used to support the EPA's findings. The AAPD requests that the EPA elaborate on the purpose of the Assessment Plan for public comment? What selection criteria pointed to the use of only the four named documents? How and why were the other 500+ scientific papers excluded from the Assessment?

This language also seems to imply that the Toxicity Assessment is complete, meaning the Assessment Plan has been conducted as described and without public input. If that is so, why are those conclusions not being provided? What are the Agency's intentions for seeking public input on the Assessment Plan at this stage?

c. **Outdated literature search:** The literature search end date parameter is currently listed as 2024. The notice notes, "EPA is developing a new fluoride toxicity assessment that considers all of the available peer-reviewed literature." The AAPD is alarmed that the EPA decided to *not* include literature published in 2025, especially since sophisticated search tools and AI capabilities were employed, and this would be simple to update. In accordance with Gold Standard Science and its principles on timeliness and comprehensiveness, the search should be updated to include peer-reviewed publications from 2025 and early 2026 prior to moving forward with the Toxicity Assessment.

d. **Flawed literature search:** "Most studies [included in the assessment] lacked sufficient data to be used for dose-response analysis (n = 436), while the remainder will be assessed further for suitability (n = 127)." The notice goes on to justify its reliance on the NTP report given the supposed paucity of data from which to assess a dose-response relationship, having not (yet) identified a single other study for inclusion. The dose response relationship between fluoride and neurodevelopmental defects is very well established.[13,20,21] The search failed to identify highly relevant scientific literature of import.

e. **Inconsistently applied time-bounds of search:** Contrary to the date parameters noted above, there is one select 2025 paper cited in the notice and used in the Assessment Plan. "Subsequent meta-analysis of epidemiological data by NTP authors (Taylor et al., 2025) provided a quantitative estimate of the decrease in children's IQ score per unit of fluoride exposure." The Agency should provide its rationale for inclusion of consideration of that 2025 paper while neglecting to include other relevant literature from 2025. Gold Standard Science demands consideration of all available evidence and appreciation of the convergence of the evidence.

f. **Unclear search parameters:** Were only studies published in English included? Was gray literature included? What were the processes for identifying gray literature? What were the pre-defined eligibility criteria for inclusion? While the literature dashboard is helpful to readers, it does not clarify these foundational questions underlying the selection of included studies.

g. **Exposure measurement, metrics:** Fluoride exposure measurement is complex. A child's exposure to fluoride comes from a variety of sources, including food, beverages, and dental preventive products. Studies have suggested that a total daily fluoride intake of 0.05 to 0.07 mg F/kg body weight is protective against

developing tooth decay without safety issues or the development of dental fluorosis.[22]

Methods for fluoride exposure measurement have wide ranging utility and reliability. For instance, as noted on page 28, "Fluoride in blood or urine may be highly influenced by recent exposure rather than the typical or average exposure of an individual." At the *outset* of any review (this stage, Assessment Plan), it should be determined how the various methodologies for exposure measurement across included studies will be managed. This is alluded to on page 27: "Criteria for the consideration of exposure metrics during study evaluation will be presented in the assessment protocol." This is a key factor that could heavily influence the findings and conclusions. More should be described, decided upon, and shared for public input.

h. **Protocol absent:** "EPA will consider all public comments during the next step in the toxicity assessment process, which is the development of the Systematic Review Protocol (Protocol)." The EPA should release the full systematic review protocol for the Toxicity Assessment and open it to public comment and independent peer review before starting the review itself. This approach would better align with the Administration's guidance on Gold Standard Science, which emphasizes transparency and peer review throughout the entire research process, not solely at the end. The systematic review protocol is fundamental to the study design and decisions. The inclusion criteria, risk of bias assessment, plan for stratified analyses, and handling of uncertainty are important choices that shape what evidence gets considered and its interpretation. These are prominently lacking in this document. Making the protocol available for scrutiny early on ensures these critical decisions are transparent and can be challenged before they lock in the direction of the entire assessment. This is standard practice for assessments as significant as this and represents a relatively small additional step that could significantly enhance the rigor and legitimacy of the findings and conclusions.

   A comprehensive protocol should be available to the public before proceeding with the development of the Toxicity Assessment. It should also be submitted to a publicly accessible registry like PROSPERO, as is standard for systematic reviews, even those privately conducted.

i. **Compromised Agency Expertise:** Since the EPA Office of Research and Development and the Program on Health and Environment Risk are no longer in existence, the EPA should describe the safeguards it is putting into place to effectively evaluate health and environmental risks and benefits in an objective manner.

The AAPD is extremely concerned that the Toxicity Assessment – resulting from this Assessment Plan – will lack scientific integrity and reach conclusions based on flawed and limited information, falsely pointing to a recommendation of de-fluoridation of water supplies in the future. This conclusion by the EPA would undoubtedly lead to an increase in dental caries, days children miss school, lowered productivity among parents and caregivers as they support these children, increased health care costs, increased emergency room visits, and an overall decrease in the health and quality of life for children. These are not simply predictions; they are proven outcomes based on communities and populations that have removed fluoride from drinking water in the past.[2,21]

We urge the EPA and HHS to provide an unbiased and valid Gold Standard Scientific review by revising its Assessment Plan before moving forward with the systematic review and the development of the Toxicity Assessment. We strongly encourage the EPA to engage an independent external reviewer of this work, specifically the National Academies of Sciences, Engineering, and Medicine (NASEM), as has been proposed in the Protect Our TEETH Act.[23] Without that assurance, we fear any product will be deemed heavily politicized and not scientifically sound, a shame for any taxpayer-supported effort. The Administration has an opportunity to do better, so the U.S. does not suffer from the misguided decisions made by other nations.

Thank you for the opportunity to provide feedback. If we can be helpful in addressing any questions or offering additional input, please do not hesitate to contact the AAPD (Dr. Chelsea Fosse, Vice President, Research & Policy Center, cfosse@aapd.org). We look forward to continuing our work to promote and protect children's oral and overall health.

Sincerely,

Thomas G. Ison, DMD
President

John S. Rutkauskas, DDS, MBA, CAE
Chief Executive Officer

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