

BEFORE THE WASHINGTON STATE BOARD OF HEALTH

PETITION FOR RULEMAKING UNDER RCW 34.05.330

Petition #24 – Assurance of Safety Communications for Fluoride Additives in Public Drinking Water

Bill Osmunson DDS MPH and Washington Action for Safe Water. October 15, 2025

“When fluoride is added to the public water, the Board is unable to assure safety of the water.”

I. Parties and Standing

Petitioners: Washington Action for Safe Water and Bill Osmunson, DDS, MPH (Washington residents/organizations affected by Board rules governing drinking-water safety).

II. Authority for Petition

This petition is submitted pursuant to **RCW 34.05.330** (Petitions for adoption, amendment, or repeal of rules). The Board’s duties arise under **RCW 43.20.050(2)(a)** to “adopt rules as necessary to assure safe and reliable public drinking water,” implemented through **WAC 246-290** (Group A public water supplies).

III. Statement of Issue

When fluorides are added to the water, the Washington State Board of Health is not able to assure the public the water is safe.

Petitioners respectfully request the Board to acknowledge, by rule, that when fluoride compounds are intentionally added to adjust fluoride concentration in public drinking water for caries-prevention purposes, the Board has not established an assurance-of-safety determination for all consumers—including fetuses, infants, children, pregnant persons, and other susceptible subpopulations—because total ingestion of water and total fluoride exposure from all sources vary widely. No individualized dosing, labeling, or FDA-determined safe dosage exists for this use of fluoridation or all sources (see Appendices below).

No agency has conducted or approved comprehensive safety studies of fluoride ingestion across all life stages or total exposures. The Board is to “assure safety,” which means population-wide assurance under foreseeable exposures (safe for 99 %+ of the public).

The words “assure” and “ensure” have significantly different meanings.

The word “assure” is to remove doubt and build confidence, communicate.

The word “ensure” is to make sure something happens or exists, to guarantee an outcome.

The legislature requires the Board to communicate that the water is safe or not safe.

The Board’s requirement of certainty of safety is in diametric contrast to the American Dental Association (ADA) Fluoride Facts claim the water is safe until certainty of harm is proven.

Neither the Food and Drug Administration Center for Drug Evaluation and Research (FDA CDER), Court, National Toxicology Program, or depositions of the FDA, CDC, EPA, nor National Sanitation Foundation, have assured the public the fluoridated water is safe; therefore, neither can the Board assure the water is safe.

My public health profession is under significant stress and opposition, in part because agencies such as the Board of Health fail to protect the public from harm by staying current with the science and communicating safety advice. Don’t blame others for the lack of public trust in public health.

IV. Action Requested (Relief)

At a minimum, Petitioners request a simple statement by Board action to remove endorsements and marketing of CWF and a statement such as:

“When fluoride is added to the public water, the Board is unable to assure safety of the water.”

The Board does not add or mandate CWF. However, when authorities recommend an action, the public assumes the recommendation is backed by laws, science and ethics. For example, the President of the USA encouraged the public to march on the Capital in Washington DC on January 6, alleged by some as an insurrection.

The Board’s recommendation to add fluoride to public water is arguably similar and ethically more concerning because the policy removes individual consent. “Words matter” and words of recommendation by authorities borders on law in the publics’ eyes. Rebuilding trust is difficult.

Credibility of our public health profession has and is under attack. Policy and practice based on industry marketing without objective, reasoned good judgment of the scientific support for safety has caught up to our professions and squeaky-clean unexaggerated honest communication is essential.

Open rulemaking and amend **WAC 246-290-220** by adding new subsections (8) and (9) as follows.

V. Proposed Rule Text

WAC 246-290-220(8) *Assurance of safety communications for fluoride additives.*

(a) *Finding.* Due to variability in total fluoride exposure (including water, formula preparation, diet, medications, post-harvest fumigants, toothpaste ingestion, etc.) and the absence of individualized dosing and FDA-labeled conditions of use, the Board has not established an assurance-of-safety determination for all consumers when fluoride is intentionally added to public water supplies.

(b) *Communications.* Neither the Board nor the Department shall state or imply that public drinking water to which fluoride has been intentionally added is “safe” for all consumers. Public communications addressing fluoridated water shall use the standardized advisory in subsection (d).

(c) *Consumer Confidence Reports (CCR).* Group A water systems that add fluoride must include the advisory in subsection (d) in their annual CCR and on the utility website.

(d) *Advisory language.*

“When fluorides are added to the water, the Washington State Board of Health has not determined assurance of safety for all consumers, including fetuses, infants, children, pregnant persons, and other susceptible subpopulations. Caregivers preparing infant formula may consider using non-fluoridated water or consulting their health-care provider.”

(e) *Guidance.* The Department shall publish guidance addressing aggregate exposure, susceptible subpopulations, and measures caregivers can take to manage exposure.

WAC 246-290-220(9) *Therapeutic-intent additives and federal jurisdiction.*

(a) Where a substance is intentionally added to public drinking water to prevent disease in humans, the addition constitutes a therapeutic intended use under 21 U.S.C. § 321(g)(1)(B). In such cases, determinations of drug safety, efficacy, labeling, and conditions of use fall within the jurisdiction of the U.S. Food and Drug Administration (FDA/CDER).

(b) Nothing in this section alters the EPA's authority under the Safe Drinking Water Act to set national primary drinking-water regulations for contaminants, including fluoride, or a water system's obligations to comply with such standards.

(c) The Department shall refrain from communications implying that SDWA compliance alone constitutes an FDA-style assurance of safety for therapeutic ingestion, and shall instead refer the public to the advisory in subsection (8) unless and until FDA has made applicable determinations.

VI. Factual and Legal Basis (Summary)

A. Board Duty to Assure Safety. RCW 43.20.050(2)(a) obligates the Board to adopt rules that assure safe and reliable public drinking water. "Assure" entails an affirmative demonstration of safety for foreseeable exposures, including for susceptible subpopulations. The word assure is often defined as to "positively, confidently, without doubt, certainty" affirm the water is safe.

This is in contrast to the fluoridation lobby such as the American Dental Association (ADA) that assumes safety until absolute certainty of harm. Even then, when harm to the teeth of dental fluorosis is caused from excess fluoride exposure (seen in 2 out of 3 children), the ADA downgrades the cosmetic and functional harm as simply a "side effect." Requiring certainty of harm is similar to the tobacco lobby, industry profits and reputation have clouded the judgment of the fluoridation lobby with bias.

The Board is to assure safety, not assume safety.

EPA's contaminant model seeks to prevent harm; FDA/CDER's drug model requires affirmative assurance of safety and benefit.

B. Ethics in Public Service. RCW 42.52 requires decisions in the public interest, free from undue influence, and communicated truthfully and transparently. Ethics support standardized, balanced advisories when assurance of safety has not been established for all consumers. (See Appendix B, Ethics of CWF)

C. Federal Jurisdiction for Therapeutic Intent. Where substances are added to prevent disease, intended use aligns with the FD&C Act's definition of a drug (21 U.S.C. § 321(g)(1)(B)). Only FDA/CDER can determine drug safety/efficacy and labeled conditions; Board/Department communications must avoid categorical safety assurances in the absence of such determinations. (See Appendix A)

Note on Board Authority and FDA Application

The Board has rejected our previous twenty-three petitions to protect public health, asserting that it cannot “order” a federal agency to grant approval. That position is correct in a narrow sense; however, it overlooks the Board’s legitimate authority to **apply** for approval.

An application is not an order. It is a formal request for evaluation within the federal framework that governs substances intended for disease prevention. Years ago, the Board contacted the FDA and later informed me in our early petition that the FDA would likely prohibit fluoridation if such an application were filed. This acknowledgment underscores the central issue: **no FDA Center for Drug Evaluation and Research (CDER) approval exists for any ingested fluoride product**—whether delivered through community water systems, tablets, or liquid supplements. Why is there no approval? The FDA has consistently held that the evidence of fluoride ingestion is incomplete for safety or efficacy.

To restate plainly: the scientific evidence on the efficacy and safety of ingested fluoride is insufficient to meet FDA CDER standards for drug approval, and the Board does not have Legislative authority to approve a drug with lower standards than the FDA CDER. The National Pharmacy Compliance News, Washington State, July 2008, “Manufacturers of **unapproved drugs are usually fully aware that their drugs are marketed illegally**, yet they continue to circumvent the law and put consumers’ health at risk.” [Washington State Department of Health](#)

In numerous FDA warning letters, phrases like “it is illegal to market unapproved drugs” are used. FDA estimates “several thousand drug products are marketed illegally (without required approval).” [radars.org](#)

The Department’s presentation to the Board in rejection of our petition #23, stated: “The Board cannot give authority within its rules to a federal agency that is not granted that authority,” and “fluorides in public water are not drugs.” However, the Department’s claims are not supported by state or Federal law, science, or common sense, see Appendices below.

If the Board refuses to apply for FDA CDER approval which would undoubtedly be denied for lack of scientific evidence of efficacy or safety, then the Board bears an independent duty to assure safety by establishing a state-level drug equivalent oversight framework—complete with qualified drug regulatory experts, evidence-based review procedures, and ongoing post-market monitoring. At present, no member of the Board or Department is trained as a drug regulatory professional. If such a competent state authority were convened, the outcome would almost certainly parallel the federal position and reject community water fluoridation as an unapproved drug use for lack of quality research on safety, benefit, dosage, exposure, and ethics. The FDA advises drug approval can take 12-15 years and cost many millions of dollars.

D. Dose Control and Consent Constraints. Public water delivery lacks individualized dosing, labeling, or informed consent, and total fluoride exposure varies (water, diet, infant formula, toothpaste ingestion), particularly for infants and pregnant persons.

E. Record Development. The EPA Water Law Office has expressly stated: "The FDA, remains responsible for regulating the addition of drugs to the water supply for health care purposes." — Steve Neugeboren, Associate General Counsel, EPA Water Law Office, Feb. 14, 2013, Response to Attorney General Steel. Petitioners request that the Board include this statement in the rulemaking file as Exhibit A and reference it in the concise explanatory statement.

F. Balanced Presentations: The Washington State Department of Health (WSDH) has not consistently provided balanced presentations or comprehensive scientific reviews.

Examples:

On October 8, 2025, the Department PPT presentation slide referenced the historical EPA webpage titled "Basic Information about Fluoride in Drinking Water" existed at water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm. The page has since been retired/migrated. And the statement places jurisdiction onto the states and local communities. (i.e. WSBH and water purveyors: the least scientifically competent to approve CWF)

On the same slide at the same presentation, the Department refers to the court in *Protect the Peninsula's Future v. City of Port Angeles* (Wash. Ct. App. Div. II, 2013), where the court explicitly declined to reach any question about federal law or agency jurisdiction. It said it would not address "the doctrine of primary jurisdiction" or "whether the Cities' fluorides are prescription drugs under federal law," because those issues weren't necessary to decide the appeal— which turned on Washington's state legend-drug statute and whether a private cause of action existed. Therefore, the court's opinion does not say whether FDA or EPA has jurisdiction over adding fluoride to public water. It resolved a state-law procedural issue and left federal-agency jurisdiction unanswered.

The Fluoridation Panel review earlier this year did not follow the charge to the committee and did not review all the science, which must, and did not include science on safety, ethics and laws.

The Department did not present the Federal Food Drug and Cosmetic Act, Federal Safe Drinking Water Act or state drug and water laws that specifically define drugs and SDWA prohibiting the EPA from adding anything to the water for treatment of human disease, other than treating water.

This petition is not an attack on staff integrity, but a request for adherence to statutory and ethical standards requiring balanced, evidence-based decision-making.

See: VII next and Appendix A for more on the FDA/CDER and EPA.

VII. Federal Jurisdiction: FDA/CDER vs EPA (Intended Use)

When a substance is added to drinking water with the intent to prevent disease in humans, that use satisfies the FDCA definition of a drug, placing primary federal authority with FDA/CDER over safety, efficacy, labeling, and conditions of use. FDA regulates anticaries drugs (21 CFR Part 355) and regulates added fluoride in bottled water (21 CFR 165.110) that is not approved for infants. EPA's distinct SDWA role is to set contaminant limits (e.g., MCLs) and does not provide FDA-style approval for therapeutic claims or dosing. The EPA Water Law Office confirmation (Exhibit A) removes jurisdictional ambiguity. The EPA does not have any experts to determine the benefit of any substance for preventing human disease other than treating water.

In effect, the FDA regulates therapeutic use in people and EPA regulates contaminants in water.

“The Department has not provided:

- i. any FDA-approved safety studies (especially for the fetus, infants and children
- ii. any high-quality RCTs of benefit;
- iii. dose-response analyses by age;
- iv. safety data for fetuses/infants;
- v. ethical evaluation;
- vi. discussion of alternatives.

VIII. Standards the Board Should Apply

- Assurance of Safety for susceptible subpopulations (fetuses, infants, children, pregnant persons).
- Aggregate Exposure (all sources) and reasonable certainty of no harm for vulnerable groups.
- Transparent, balanced risk communication and avoidance of categorical safety claims absent FDA determinations.

These standards align with federal risk-assessment best practices and ethical norms of transparency and precaution.

IX. Implementation and Compliance

- CR-101 within 30 days; final rule within 180 days.
- Standard advisory language available within 60 days of adoption.
- CCR advisory required for the first reporting cycle following adoption.
- Department guidance issued within 90 days.

X. Economic and Equity Considerations

Standardized advisories and communications impose minimal costs compared with potential societal costs of developmental harm. Equity is enhanced by clear guidance to caregivers who rely on tap water for infant formula.

Just the known and undisputed costs to treat dental fluorosis outweighs the possible marginal caries reduction. Trasande (2005), Grandjean (2020) Osmunson (2024)

XI. Alternatives Considered

- No action—fails to meet the assure-safety duty for vulnerable groups.
- A full ban may exceed current administrative authority and would bypass opportunity for informed public choice.
- Advisory only without rule—insufficiently durable; a rule ensures uniformity and accountability.

XII. Requested Process and Service

Open CR-101 within 30 days; provide written reasons per RCW 34.05.330 if declined. Serve Board, DOH, AG's Office, Governor's Policy Office, and stakeholders.

VIII. Recent Evidence on Benefit, Exposure, and Practical Alternatives

A. Magnitude of benefit today.

Contemporary systematic reviews indicate the **carries-preventive effect of community water fluoridation (CWF) appears smaller in the modern era**—after widespread use of fluoride toothpaste—than in pre-1975 studies. The 2024 Cochrane update reports that post-1975 studies show **only slight reductions** (clear for primary dentition; uncertain for permanent teeth), with overall effect sizes **smaller than historical estimates**. [Cochrane Oral Health+1](#)

These biomarker findings underscore the importance of evaluating total exposure before promoting additional systemic intake.

(For balance, modeling and advocacy sources continue to project **population-level benefits and cost savings** from maintaining CWF, including a recent JAMA Health Forum analysis projecting **worse oral health and higher costs** if CWF were removed nationally, and ADA summaries citing **~25% average** carries reduction across the lifespan. These are model-based and press-summary estimates, not randomized trials.) [ADA+3JAMA Network+3PMC+3](#)

B. Total exposure and biomarkers.

Dental fluorosis is widely used as a **biomarker of excess fluoride intake during enamel formation** (i.e., exposure exceeding optimal during early childhood). [PMC](#) Major U.S. surveys show **high prevalence** of *any* fluorosis in adolescents: for ages 12–15 years, NHANES data indicate an increase to **~65%** by 2011–2012; other analyses report **~68%** in 2015–2016 (with a spike to **~87%** in 2013–2014, likely reflecting cycle variability). Examiner-agreement studies from CDC support reliability of the fluorosis scoring in these cycles. Taken together, these findings are consistent with **roughly two-thirds of U.S. children exhibiting some degree of fluorosis**, a population-level biomarker of **excess early-life fluoride exposure**. [CDC+3SAGE Journals+3PubMed+3](#)

C. Practical, less-restrictive alternatives (multi-component prevention).

Given the modest contemporary effect sizes and the high prevalence of fluorosis as a biomarker of excess exposure, the Board can emphasize **effective, lower-intrusion measures** that do not require ingestive exposure and pose minimal risk when properly used:

- **Dietary sugar reduction** (especially free sugars) and **oral-hygiene programs** in schools/clinics.
- **A tax on soft drinks has shown a drop in consumption and the money can be used for health education. Additional taxes on sugar and highly refined foods should also improve health, not only reduced dental caries but lower the risk of diabetes and obesity.**
- **Topical fluoride** (toothpaste/varnish) delivered with dosing and labeling—well-supported by trials and existing clinical guidelines.
- **Hydroxyapatite (HAP) toothpaste:** recent systematic reviews and clinical trials indicate **HAP can be as effective as fluoride toothpaste at inhibiting caries progression**, including fluoride-free formulations—a potentially useful option for young children who swallow toothpaste. [PubMed+2ScienceDirect+2](#)
- **Nutrition support**, including adequate **vitamin D**, and caries-risk-based preventive care (sealants, recall intervals, etc).
- **WHO Oral Health Database and OECD data indicate that over 97% of Western Europe does not fluoridate, yet caries rates are comparable to the U.S.**

D. Implication for rulemaking.

The current record supports (1) **transparent communications** that avoid categorical “safe for all consumers” claims where an all-consumer assurance has not been established; (2) attention to **aggregate exposure** and **susceptible subpopulations** (fetuses/infants); and (3) prioritization of **less-restrictive alternatives** (topical agents, HAP toothpaste, sugar reduction, oral hygiene) that can achieve prevention **without** mandatory, population-wide ingestion.

See also:

Appendix A — FDA CDER Jurisdiction of CWF

Appendix B — Ethics of CWF

Appendix C — Scientific Data and Figures: Fluoride Exposure, Benefit, and Risk Context

Washington Action for Safe Water

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