

Washington State Department of Health Community Water Fluoridation Panel : Rebuttal & Public Comment

To: Washington State Board of Health, Governor Bob Ferguson, and Attorney General Nick Brown

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SUMMARY:

The American Dental Association requires a level of confidence of “certainty” of harm, 99+ confidence of harm.

Public Health Malpractice requires a “certainty” of harm at greater than 50/50 confidence. Malpractice does not require certainty of harm, many questions may be unanswered; however, a confidence level of 51% of harm is required for malpractice.

RCW 43.20.050(2)(a) requires the Board to “assure” safe water, in other words to have less than 1% confidence of harm.

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Recommended Actions for the Board of Health on Fluoridation

The Board of Health should suspend endorsement of community water fluoridation until safety and efficacy are affirmatively established through rigorous, modern scientific evidence. Specifically:

- **Require Safety Assurance** – Do not approve or promote systemic fluoride exposure without comprehensive toxicological and clinical safety studies, including protection for vulnerable groups such as infants, pregnant women, and those with renal or genetic susceptibilities.
- **Apply Adequate Margins of Safety** – Ensure regulations account for intraspecific variability in water consumption, cumulative fluoride exposure from multiple sources, and genetic and health-related differences in sensitivity.
- **Clarify Jurisdiction** – Acknowledge that systemic fluoride use for disease prevention constitutes drug administration and should be subject to FDA CDER standards for safety, efficacy, dosing, and labeling.
- **Adopt Precautionary Policy** – Until safety is affirmatively demonstrated, the Board should follow the precautionary principle and protect the public by not exposing entire populations to an unapproved drug through drinking water.



Pictures above are of severe skeletal and dental fluorosis. The purpose of these pictures is not to demonstrate what is happening but to demonstrate EPA's "safe" dose of fluoride. Fluoride is not considered harmful by the EPA until this type of damage is observed. Harm happens at much lower doses; however, certainty of harm decreases and the EPA requires certainty of harm. In contrast, the FDA CDER and RCW require determining safety. The EPA (and to a large extent the Fluoridation Panel) assume fluoride is safe until certainty of harm based on the EPA standard of severe dental or/and skeletal fluorosis is proven.

Introduction

I have petitioned the Washington State Board of Health and the Governor for over 15 years to protect the public from excessive fluoride exposure. The Board has failed to protect the public, failed to follow the law or science, and rather than silence in the face of harm has actively promoted community water fluoridation (CWF), claiming without quality scientific evidence or Federal regulatory approval, that CWF is safe and effective.

Rather than science, the Board has relied on endorsements. Rather than Congress and the Washington State Legislature, the Board has relied on endorsements and unauthorized agencies. Such actions undermine the credibility of public health when coercive police powers are supported by endorsements instead of legally required scientific evidence, laws and agencies. The public has and is being harmed. This is your chance to protect our most vulnerable.

Rebuttal to the Fluoridation Panel's Recommendations

(And for additional limitations, see page 10)

1. Failure to Assure Safety by Retaining Current Fluoride Levels

The Panel recommends maintaining the current “optimal” concentration of fluoride without providing a single modern, high-quality safety study demonstrating that this concentration in water along with 30%-70% more fluoride from other sources is safe for all members of the population, including the most vulnerable (pregnant women, fetuses, infants, the elderly, and individuals with renal impairment). Statutory duty under RCW 43.20.050(2)(a) requires the Board to affirmatively **assure safety**, not to balance unproven benefits against unresolved risks (Washington State Legislature, 2024). In the absence of randomized controlled trials or rigorous toxicological studies, the continuation of fluoridation policy rests on assumption rather than scientific certainty (Ihezor-Ejiofor et al., 2024; U.S. FDA, 2023).

The charge to the Fluoridation Panel was noble, to review the science. However, the Panel failed to review over 90% of the available science.

The Panel members were “cherry picked” with mostly Department of Health and government employees who have promoted fluoridation for decades and receive funding from fluoridation sources. Their bias did not permit most members to have a paradigm shift. The composition of the panel did not include published science researchers, pharmacists, ethicists, neurophysiologists, endocrinologists, or other necessary experts competent to evaluate science.

Most public health professionals have not been trained to evaluate research. In my public health master's degree program, we were firmly instructed that we were not competent to evaluate the science and we were to obey authority.

2. Abdication of State Responsibility to Local Governments

The Panel's suggestion that community water fluoridation should remain a "local decision" improperly shifts responsibility for a statewide drug exposure policy onto local jurisdictions that lack the expertise, resources, or authority to evaluate drug safety. For 80 years, federal agencies including FDA CDER and EPA scientists have struggled with unresolved questions about fluoride's pharmacokinetics, toxicity thresholds, and systemic effects (NRC, 2006; National Toxicology Program [NTP], 2022). To suggest that municipal councils or water districts—entities with no toxicological or pharmacological expertise and lacking time and resources—should resolve these scientific uncertainties is an abdication of the Panel's duty. It makes no sense and is a waste of time and money to have 100+ cities and water districts go through the complex scientific regulatory process that the Fluoridation Panel has undertaken. And it would take even more time for voters to carefully review the science and laws. This approach undermines both public confidence and the principle that statewide standards exist to protect health uniformly, not variably by zip code.

3. Inadequate Margin of Safety in Adopting a 1.5 mg/L Action Level

The proposed State Action Level of 1.5 mg/L fails to protect infants and other high-exposure groups. Formula-fed infants, who consume more water per body weight than adults, would receive doses far exceeding recognized thresholds of safety (Zohoori & Maguire, 2018). The recommendation assumes that all individuals:

- drink identical amounts of water,
- metabolize fluoride uniformly,
- receive no significant additional fluoride from food, air, dental or medical products,
- have the same genetic chemical sensitivity,
- have the same total toxic chemical burden with no synergistic effects,
- and have the same health status to handle the toxic chemical effect.

Each of these assumptions is demonstrably false. Established principles of toxicology require adequate margins of safety to account for variability in water consumption, susceptibility, and cumulative exposure (EPA, 2010). The proposed action level provides no such margin and therefore cannot be regarded as protective, positively and confidently without doubt assuring safety.

4. Reliance on Messaging Rather Than Regulation

The Panel's reliance on "updated messaging" to pregnant women, fetuses, and infants acknowledges risk but fails to provide actual protection. Advisories and voluntary guidance do not meet the statutory requirement to assure safe water. Decades of similar messaging have been buried in agency documents with no measurable reduction in systemic fluoride exposure (NRC, 2006). Public health obligations cannot be met through warnings alone; enforceable regulatory limits based on rigorous safety data are required.

Rebuttal of Panel’s Conclusion

The Panel’s recommendations—retaining current fluoridation, delegating decisions to local jurisdictions, adopting an unsafe action level, and substituting messaging for regulation—do not satisfy the Board’s statutory duty to protect the public’s health. Without demonstrable proof of safety, these recommendations perpetuate risk, defer responsibility, and prioritize political expedience over scientific and ethical accountability.

The Board should instead:

- Reject continuation of fluoridation policy until safety is affirmatively established.
- Require comprehensive toxicological and clinical safety studies before endorsing fluoride ingestion at any concentration.
- Adopt a precautionary standard that ensures protection of the most vulnerable populations, rather than deferring to local political bodies.

Only by adhering to its legal and ethical duty can the Board credibly assure the people of Washington that their drinking water is safe.

References for the Rebuttal Above

Environmental Protection Agency (EPA). (2010). Fluoride: Dose-Response Analysis for Non-Cancer Effects. Washington, DC.

Iheozor-Ejiofor, Z., et al. (2024). Water fluoridation for the prevention of dental caries. Cochrane Database of Systematic Reviews, Issue 3.

National Research Council (NRC). (2006). Fluoride in Drinking Water: A Scientific Review of EPA’s Standards. National Academies Press.

National Toxicology Program (NTP). (2022). Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects. National Institute of Environmental Health Sciences.

U.S. Food and Drug Administration (FDA). (2023). Use of Orally Ingestible Unapproved Prescription Drug Products Containing Fluoride in the Pediatric Population: Public Listening Session.

Washington State Legislature. (2024). RCW 43.20.050(2)(a). Duty of the State Board of Health to assure safe and reliable public drinking water.

Zohoori, F. V., & Maguire, A. (2018). Infant formula and fluoride exposure: A systematic review. *Journal of Public Health Dentistry*, 78(1), 18–39.

Fluoride Classified as a Poison and Legend Drug

Fluoride is highly toxic and falls under RCW 69.38.010's definition of a poison, being lethal at doses below 3,889 mg (approximately 60 grains). Whitford (1996) estimated the probable toxic dose for adults at 5 mg/kg body weight. For a 70 Kg adult, 350 mg is significantly less than 3,889, a definite poison unless regulated under drug laws as a prescription drug. In 2009, the Washington State Board of Pharmacy determined that fluoride is to be regulated as a legend (prescription) drug. However, CWF is not regulated as a legend drug, and therefore reverts to the status of an unapproved, illegal drug or poison. Infants fed formula prepared with fluoridated tap water receive up to 175 times the fluoride dose of natural breast milk, a disproportionate and unsafe exposure given their vulnerability with developing brains, organs, systems and cells. Giving local water purveyors and voters the option of CWF at their discretion while the Board actively promotes CWF on their website based on endorsements is not assuring safety.

Failure of Federal and Washington State Agencies to Provide Safety Evidence

RCW 43.20.050(2)(a) and the FDA CDER (FDA's Center for Drug Evaluation and Research) in the FD&C Act, are on the same page requiring the assurance of safety. The Board is wise to verify the FDA CDER's safety data but must include FDA CDER guidance for safety in any review and safety claims. The FDA CDER has made mistakes on drugs and has learned from their mistakes and will continue to learn. Ignoring the FDA CDER does not assure the public of safety or efficacy. The Fluoridation Panel failed to consider the FDA CDER guidance for safety.

In sworn testimony, Federal agencies including the FDA, CDC, EPA, and NSF admitted they had no safety studies on fluoride's effects on the developing brain and could not identify a safe dose. Furthermore, FDA CDER has never approved ingestion of fluoride in any form with intent to prevent dental caries. This absence of safety data constitutes a fundamental regulatory failure by both Federal and state Public Health Authorities.

Lacking guidance by the Board on what quality of scientific evidence to accept and lacking a single quality safety study, the Board's Fluoridation Panel relied on EPA's less protective standard of certainty of harm, rather than the more protective safety requirements of the FDA CDER assuring safety with safety studies.

The Fluoridation Panel was convened by the Department of Health consisting of public health staff. Cherry picking like minded employed believers who have been paid to promote CWF all their professional lives is an extremely high bar of bias to overcome. A balanced objective review of all the science was not possible due to bias, lack of appropriate charge to the Panel, educational background and time. Not a single member was a drug regulatory expert or has to my knowledge even gone through the NDA approval process. None of them or any of us have the judgment skills and training to judge safety of a drug better than the FDA CDER.

Requirements for a Safety Study of Community Water Fluoridation (CWF) (Not considered by Panel)

The Fluoridation Panel (p.4) did not assess total fluoride exposure. In other words, the Panel did not determine or seriously weigh how much fluoride an adult, child, infant or fetus is ingesting from all sources. Safety of adding more fluoride cannot seriously be determined without knowing how much fluoride is already being dosed or exposed from other sources. 30% to 70% of exposure is from other sources.

To lawfully assure the safety of CWF, rigorous standards must be met, including preclinical GLP toxicology, developmental neurotoxicity testing, endocrine, thyroid and all potential risks evaluated, dose-response modeling, and large-scale human prospective cohorts with biomarkers, exposure diaries, and validated neurodevelopmental endpoints. None of those were provided by or to the Fluoridation Panel for consideration. These requirements are established under FDA CDER's drug framework and EPA's environmental risk assessment guidance.

A. Regulatory Frame & Governance For Safety Study (Panel did not determine)

Regulatory pathway:

1. 1. FDA:

If CWF (fluoride added to water) is treated as a drug exposure (intent to prevent disease), human studies must meet ICH Good Clinical Practice (E6[R2]) and ICH E8(R1) quality-by-design principles, with IRB approval, informed consent, DSMB, preregistration, and a public statistical analysis plan (FDA).

OR

2. 2. EPA:

If treated as an environmental exposure such as endemic fluoride in Southwest Washington State, analyses must follow EPA risk-assessment methods (hazard ID, dose-response, exposure, risk characterization), using benchmark-dose (BMD) approaches and RfD derivation that explicitly protect sensitive subgroups. EPA is protective based on certainty of harm. For example, fluoride ingestion is safe until absolute certainty of harm with severe crippling skeletal fluorosis or severe dental fluorosis. In other words, for EPA's judgment which the Panel assumed, fluoride intake is not harmful until harm is close to this.

Judgment of absolute certainty is one reason the TSCA law (Toxic Substance Control Act) was written by Congress, to judge toxins with "presumed" harm rather than "certainty" of harm. That confidence level for judgment is still lower than the FDA CDER's requirement for safety with label and doctor's prescription.

FDA CDER and EPA pathways are significantly different and a key is intent of use (FDA CDER) and difficulty in removing the toxin (EPA endemic fluoride).

We are persuaded that the addition of fluoride to water (discussed below) is with the intent to prevent dental caries and is a drug based on toxicity, Board claims of disease prevention, public perception with intent to prevent dental caries, U.S. Pharmacopeia, FDA testimony to Congress, EPA Water Law Office, and more.

Drug Studies Also Require (Not seriously discussed by the Panel)

- Ethics & transparency: Independent DSMB; conflict-of-interest disclosures; data and code sharing; protocol/SAP preregistered.
- Reporting standards: CONSORT (for RCTs) and STROBE (for observational cohorts).

B. Preclinical (GLP) Toxicology Package (Not considered by Panel)

- Developmental neurotoxicity (OECD TG 426). Extended one-generation reproductive toxicity (OECD TG 443).
- Repeated-dose, chronic toxicity, carcinogenicity, and genotoxicity as indicated.
- Toxicokinetics/PBPK modeling linking dose to biomarkers.
- Endocrine and thyroid endpoints integrated. BMD modeling with uncertainty factors per EPA guidance.
- Over 20 additional risks should also be included.

C. Human Evidence — Core Studies (Not carefully considered by Panel)

- Multi-site prospective pregnancy–birth cohort, with child follow-up, supplemented by stepped-wedge/natural experiments.
- Exposure assessment: water sampling, urinary fluoride, serum fluoride, and total intake accounting (formula reconstitution, tea, dental products).
- Endpoints: neurodevelopment, thyroid function, renal indices, bone, reproductive outcomes, dental fluorosis.
- Confounding and co-exposures measured (lead, arsenic, iodine, SES, etc.). Power sufficient to detect ≤ 2 IQ-point differences.

D. Chemical Product & Water-System Characterization (Not considered by Panel)

- Verification of additive identity/purity, contaminant profiles, process controls, distribution-system mapping.

E. Decision Framework & Stopping Rules (Not considered by Panel)

- A priori harm thresholds (e.g., ≥ 2 IQ-point reduction).
- Interim analyses with DSMB oversight.
- Risk assessment synthesis integrating animal and human data to derive RfDs.

F. Quality, Compliance & Documentation (Not considered by Panel)

- IRB approvals, GCP training logs, DSMB minutes, data integrity audits, version-controlled code, public dataset access.

G. Standards & Guidance to Cite (Not considered by Panel)

- ICH E6(R2); ICH E8(R1).
- OECD TG 426; OECD TG 443.
- CONSORT; STROBE; EQUATOR.
- EPA Benchmark Dose Guidance (2012).

The Fluoridation Panel does not report a single safety study, nor do they outline what a safety study would look like in their report. Neither did the Panel determine a safe dose of fluoride versus a toxic dose of fluoride. The direct charge of the Legislature to the Board in law was legally and scientifically largely ignored. The Board cannot assure the public the water is safe without a single safety study or even know what a safety study would include.

Absence of Randomized Controlled Trials and Requirements for FDA

Approval of Benefit (Not seriously considered by Panel)

Although the Board has attempted to claim that fluoridation benefits outweigh its risks, the law does not authorize the Board to evaluate drug benefits or conduct benefit–risk assessments. That authority belongs solely to the FDA CDER. No quality randomized controlled trials (RCTs) of community water fluoridation have ever been conducted. The 2024 Cochrane Review confirmed that the evidence for caries prevention is of low certainty, based on outdated and methodologically weak observational studies.

For FDA NDA approval of any drug, including systemic fluoride, the sponsor must provide: two adequate and well-controlled RCTs demonstrating statistically significant and clinically meaningful benefit. Endpoints would include reduced caries incidence measured with standardized DMFT/DMFS scores, tooth retention, and secondary measures such as fluorosis rates and quality-of-life indicators. Representative populations and control groups must be used, with long-term follow-up and strict adherence to CONSORT standards. No such trials exist for CWF.

Thus, the Board and its Fluoridation Panel have attempted to assure benefit without legal authority or adequate science. Without FDA NDA approval, fluoridation remains an unapproved drug practice that fails both safety and efficacy standards.

Limitations of the Washington State Fluoridation Panel

The Fluoridation Panel convened by the Department of public health employees over the last six months was composed of well-meaning public health servants who have supported fluoridation for their professional careers. However, none have conducted a safety study, none understand the regulatory requirements of drug safety evaluation, and none have

petitioned FDA CDER for drug approval. The Panel lacks training in drug regulation, toxicology, and RCT design. The Board cannot lawfully rely on untrained, unauthorized employees to substitute for FDA CDER experts.

1. Scope and Legal Authority Misstated and Illegal

Benefit–risk determinations for a substance intended to prevent disease are exclusively under the U.S. Food, Drug, and Cosmetic Act (FD&C Act) and FDA’s Center for Drug Evaluation and Research (CDER). A substance marketed with intent to prevent disease is a drug under 21 U.S.C. § 321(g)(1), and approval requires an NDA with “adequate and well-controlled investigations” (21 U.S.C. § 355; 21 C.F.R. § 314). State boards may regulate water system operations, but they cannot lawfully approve or substitute benefit–risk determinations in place of FDA. Washington’s Board’s statutory authority under RCW 43.20.050 is to assure safe drinking water, not to establish drug efficacy. RCW 57.08.012 allows local systems to decide whether to fluoridate but does not displace the duty to assure safety (RCW 43.20.050). The Panel chose endorsements of benefit rather than authorized regulatory authority, the FDA CDER.

2. Evidence Base Selectively Framed

The Cochrane Collaboration’s most recent review (Iheozor-Ejiofor et al. 2024) rated the certainty of evidence for reductions in permanent tooth decay as low because most studies were ecological, at high risk of bias, and conducted before widespread use of fluoride toothpaste. No randomized controlled trials (RCTs) of community water fluoridation (CWF) efficacy or safety exist (McDonagh et al. 2000; Iheozor-Ejiofor et al. 2024). Yet FDA requires at least two adequate and well-controlled trials to establish benefit for any NDA (21 C.F.R. § 314.126). CDC itself acknowledges that fluoride’s predominant effect is topical, not systemic (CDC 2001).

3. Risk Evidence Downplayed

The National Toxicology Program (NTP 2024) concluded with moderate confidence that increased fluoride exposure is consistently associated with lower IQ in children, even at levels overlapping U.S. drinking water concentrations. In September 2024, the U.S. District Court for the Northern District of California held under the Toxic Substances Control Act (TSCA) that fluoridation at 0.7 mg/L presents an “unreasonable risk” of neurodevelopmental harm and ordered EPA to initiate regulatory action (*Food & Water Watch v. EPA*, 2024). The panel’s suggestion to “keep the current optimal level” disregards this federal finding.

3.1 NTP did NOT Determine a Safe Dose of Fluoride

The NTP did not determine a safe water fluoride concentration. Confidence in harm increased over 1.5 mg/L, but safety was not determined at any dosage or water fluoride concentration. The Court did not report a safe water fluoride concentration. The Court correctly determined an unreasonable risk at 0.7 ppm, The Court took testimony from the best scientists money could hire and the Court did not report safety or confidently dispelling doubt, that fluoride in water at 0.7 ppm is safe.

4. “Local Decision” Argument Legally Incomplete

Saying fluoridation “should remain a local decision” omits that the Board has a non-delegable duty to assure safety under RCW 43.20.050. Delegating safety assurance to localities—especially in light of a federal “unreasonable risk” determination—does not satisfy this statutory mandate. Delegating a highly complex toxic, drug, regulatory decision to voters makes no sense and does not omit the Board’s duty and permit the Board to promote fluoridation as safe and effective.

5. State Action Level of 1.5 mg/L Inconsistent and Indefensible

The Panel’s proposed 1.5 mg/L “State Action Level” is derived from WHO’s guideline intended to prevent dental fluorosis (WHO 2017), and confidence in neurodevelopmental effects harm, not safety. It is inconsistent to set a permissive state threshold at 1.5 mg/L while the NTP and a federal court have not identified a safe dosage at 0.7 mg/L (NTP 2024; Food & Water Watch v. EPA 2024).

5.1 Safety Factors and Individual Variability

The Panel confuses individual dose with the “statistical mean,” failing to account for established toxicological principles. A margin of safety—typically a factor of 10 to 100—must be applied to protect against variability in exposure and susceptibility. Not all individuals drink the same amount of water, have the same level of exposure from other sources, or share identical genetic profiles, health status, or chemical sensitivities. For example, an individual consuming two liters of water at 0.7 ppm fluoride receives double the intake of someone consuming only one liter, even though both fall within the “average” range. Furthermore, individuals with single nucleotide polymorphisms (SNPs) or other genetic variations may be markedly more sensitive to fluoride’s effects. By failing to incorporate safety factors or address intraspecific variability, the Panel’s recommendation does not meet basic standards of public health protection.

6. Messaging to Pregnant People and Infants Inadequate

Guidance to “limit exposure” is not a substitute for source protection. Pregnant women and infants ingest more water per body weight than adults (NRC 2006). About 75% of U.S. caregivers use tap water to reconstitute infant formula, resulting in exposures during the most vulnerable developmental window (CDC 2010). In contrast, breast milk contains ~0.004 ppm fluoride (Institute of Medicine 1997). Warnings cannot replace the statutory duty to deliver safe water at the tap.

The Panel appears to expect a single parent hauling an infant and toddler with groceries and now water for the formula on public transportation is ethical and reasonable.

7. Lack of FDA Regulatory Alignment

There is no FDA approval for any ingested fluoride product to prevent caries. FDA’s OTC anticaries monograph applies only to topical products (e.g., toothpaste, rinses) (FDA 2020). Systemic ingestion through water remains unapproved. The panel’s reliance on

endorsements from health organizations cannot substitute for the FDA drug approval process.

Failure to Meet Statutory Duty

RCW 43.20.050(2)(a) mandates that the Washington State Board of Health must adopt rules necessary to assure safe drinking water. This duty requires affirmative demonstration of safety, not reliance on endorsements or assumptions. Although RCW permits local governments or voters to choose fluoridation, that option does not supersede the Board's statutory duty to assure water safety. By promoting fluoridation as safe and effective without FDA-approved safety and efficacy data, the Board is in direct violation of its statutory mandate.

Credibility of Public Health

Public health professions lose credibility on all policies and rules when unable to follow state and federal law. By promoting fluoridation as safe and effective based solely on endorsements, while ignoring FDA CDER's regulatory authority, the Board undermines public trust in health governance.

Recommended Actions for the Board of Health on Fluoridation

The Board of Health should suspend endorsement of community water fluoridation until safety and efficacy are affirmatively established through rigorous, modern scientific evidence. Specifically:

- **Require Safety Assurance** – Do not approve or promote systemic fluoride exposure without comprehensive toxicological and clinical safety studies, including protection for vulnerable groups such as infants, pregnant women, and those with renal or genetic susceptibilities.
- **Apply Adequate Margins of Safety** – Ensure regulations account for intraspecific variability in water consumption, cumulative fluoride exposure from multiple sources, and genetic and health-related differences in sensitivity.
- **Clarify Jurisdiction** – Acknowledge that systemic fluoride use for disease prevention constitutes drug administration and should be subject to FDA CDER standards for safety, efficacy, dosing, and labeling.
- **Adopt Precautionary Policy** – Until safety is affirmatively demonstrated, the Board should follow the precautionary principle and protect the public by not exposing entire populations to an unapproved drug through drinking water.

Appendices

Appendix A. Requirements for a Safety Study of Community Water Fluoridation (CWF)

To lawfully assure safety, a scientifically valid safety study must include both preclinical toxicology and human clinical investigations, consistent with FDA CDER standards for drugs and EPA guidelines for environmental exposures.

A.1 Regulatory Framework

- FDA Drug Pathway (21 U.S.C. § 355; 21 C.F.R. § 314.126): CWF is a drug (intent to prevent disease), and human trials must meet ICH Good Clinical Practice (E6[R2]) and ICH E8(R1) standards, with IRB approval, informed consent, DSMB oversight, preregistration, and a published statistical analysis plan.
- EPA Risk Assessment Pathway (EPA, 2012 Benchmark Dose Guidance): If treated as an environmental exposure, analysis must follow hazard identification, dose–response modeling, exposure assessment, and risk characterization, explicitly protecting sensitive subgroups.

A.2 Preclinical GLP Toxicology

- Developmental neurotoxicity testing (OECD TG 426).
- Extended one-generation reproductive toxicity (OECD TG 443).
- Chronic toxicity, carcinogenicity, and genotoxicity studies.
- Endocrine and thyroid endpoints.
- Toxicokinetic/PBPK modeling linking intake to biomarkers.
- Benchmark dose (BMD) modeling with safety/uncertainty factors.

A.3 Human Evidence

- Prospective multi-site pregnancy–birth cohorts, with follow-up into childhood, supplemented by stepped-wedge/natural experiments.
- Exposure assessment: water sampling, urinary/serum fluoride, diet/dental sources, and total intake accounting.
- Endpoints: neurodevelopment (IQ, cognitive tests), thyroid, renal, bone, reproductive outcomes, and dental fluorosis.
- Statistical power sufficient to detect ≤ 2 IQ-point differences, as required by FDA CDER standards.

A.4 Ethical and Reporting Standards

- Independent DSMB, conflict-of-interest disclosure, protocol preregistration.
- CONSORT (for RCTs), STROBE (for observational studies), EQUATOR network guidelines.
- Public access to datasets, code, and version-controlled statistical plans.

Appendix B. Supporting Toxicological Data

B.1 Fluoride as a Poison

RCW 69.38.010 defines a poison as “liable to be destructive to adult life in quantities of 60 grains ($\approx 3,889$ mg) or less.” Whitford (1996) estimated the probable toxic dose of fluoride at 5 mg/kg body weight. For a 70 kg adult, this is 350 mg — well below the statutory definition of a poison.

B.2 Infants and Breast Milk

Breast milk contains a mean of 0.004 ppm fluoride (Institute of Medicine, 1997). Formula prepared with fluoridated tap water (~ 0.7 ppm) delivers up to 175 \times the natural fluoride dose found in breast milk. Infants consume more water per body weight than adults, amplifying exposure during critical neurodevelopmental windows.

B.3 Systemic Accumulation

Fluoride accumulates in bones, teeth, and soft tissues, interacting with cells, enzymes, and endocrine pathways (NRC, 2006). The National Toxicology Program (2024) found consistent associations between higher fluoride exposure and reduced IQ in children, even at levels overlapping U.S. water concentrations.

Appendix C. Legal and Regulatory Framework

C.1 FDA Jurisdiction

Under 21 U.S.C. § 321(g)(1), any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease is a drug. Adding fluoride to water with the stated purpose of preventing dental caries constitutes drug administration. FDA CDER requires two adequate and well-controlled clinical trials to demonstrate efficacy (21 U.S.C. § 355; 21 C.F.R. § 314.126). FDA’s OTC anticaries monograph (21 C.F.R. pt. 355) applies only to topical fluoride products (e.g., toothpaste, rinses), not systemic ingestion.

C.2 EPA Jurisdiction

EPA regulates contaminants under the Safe Drinking Water Act. EPA’s approach is based on certainty of harm (e.g., skeletal fluorosis) rather than assurance of safety. In *Food & Water Watch v. EPA* (2024), the U.S. District Court held that fluoridation at 0.7 ppm posed an “unreasonable risk” under TSCA, reinforcing EPA’s inability to assure safety.

C.3 Washington State Law

RCW 43.20.050(2)(a): The Board of Health must adopt rules necessary to assure safe and reliable drinking water. RCW 57.08.012: Water districts may choose to fluoridate, but this does not relieve the Board of its duty to assure safety. RCW 69.38.010: Fluoride meets the legal definition of a poison unless regulated as a prescription drug.

References

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Washington State RCW 69.38.010. Definition of poison.

Addendum: Expanded Critique of the Panel’s Recommendations and Process

A. “Recommendations in Conflict” — Additional Grounds

- A1. The Panel assessed CWF concentration rather than total fluoride dose

The report repeatedly reasons from the water concentration of fluoride (0.7 mg/L) as if it were the exposure of interest. Risk, however, turns on dose (mg/kg-day) and aggregate exposure from *all* sources (tap water, beverages/foods, tea, formula reconstituted with tap water, dental products, workplace exposures). This is not a trivial distinction; the TSCA court specifically faulted EPA for ignoring additive exposure when judging risk. A lawful, protective assessment must start from total fluoride intake across pathways and life stages—especially pregnancy and infancy—then apply conservative uncertainty factors to protect sensitive subgroups. The Panel did neither.

- Implication: Keeping 0.7 mg/L “for now” is scientifically indefensible without an aggregate-exposure analysis that includes biomonitoring (e.g., urinary/serum fluoride), dietary diaries, and infant formula practices, followed by margins of safety (10–100×) for interindividual variability.
- A2. Misapplied regulatory standard: EPA’s “certainty of harm” vs FDA/CDER’s “assurance of safety” (and RCW’s parallel duty)
- The Panel’s posture mirrors EPA contaminant logic—seeking certainty of harm—instead of FDA/CDER’s drug standard to affirmatively assure safety before population exposure. Washington’s RCW 43.20.050(2)(a) likewise charges the Board to *assure safe* drinking water, not to presume safety until definitive harm is proven.
- Recommending continuation of systemic exposure absent FDA-quality evidence inverts these standards: it treats fluoridation like a contaminant question (wait for proof of harm) rather than a drug question (require proof of safety and benefit first).
- Implication: As long as CWF is justified by intent to prevent disease, the legally relevant benchmark is FDA/CDER’s *certainty of safety and efficacy*, not EPA’s *certainty of harm*. The Panel applied the wrong standard.
- A3. “Begin rulemaking to consider a 1.5 mg/L State Action Level” is less protective than current practice

- At 1.5 mg/L, the proposed SAL is $\sim 2.14\times$ the current CWF target of 0.7 mg/L. Positioning 1.5 mg/L as “actionable” implicitly normalizes exposures substantially higher than present targets, and does so without a demonstrated margin of safety for fetuses and infants. The Panel itself cites neurodevelopmental findings converging around, at, or below this neighborhood. Raising the ceiling while conceding uncertainty for the most vulnerable is a retrograde risk posture.
 - Implication: If anything, any interim action should move toward lower ceilings pending FDA-quality safety data, not toward a permissive action level that exceeds today’s dosing by more than twofold.
 - A4. Messaging is not protection—and it has failed for decades
 - Telling the public (particularly new parents) to “limit exposure” or avoid using fluoridated tap water to mix infant formula does not satisfy a duty to provide safe water at the tap. Practical barriers (cost, time, logistics, awareness, literacy, and trust) ensure uneven compliance, disproportionately burdening low-income families. History shows warnings do not meaningfully reduce systemic exposure when the source remains the drinking water itself.
 - Implication: Source control (policy and engineering) is the public-health solution; messaging is at best a stopgap and at worst a shifting of responsibility onto those least able to bear it.
 - A5. “Optimal” is asserted without a safety dossier
 - The report labels 0.7 mg/L “optimal” but provides no modern safety dossier demonstrating protection for pregnancy, infancy, renal impairment, or genetically susceptible groups. “Optimal” is an evidentiary conclusion, not a branding term—it requires preclinical toxicology, human biomonitoring, exposure accounting, dose–response analysis, and uncertainty factors sufficient to cover vulnerable subpopulations. Those elements are absent.
 - Implication: Dropping the word “optimal” from policy and communications is appropriate until a defensible, FDA-grade safety package exists.
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B. Process Defects: Panel Charge, Membership, and Presupposition of Benefit

- B1. Charge failed to require high-quality evidence
- The Department did not appropriately charge the Panel to require FDA-grade evidence (adequate and well-controlled trials for efficacy; GLP preclinical plus robust human evidence for safety). Instead, the charge asked the Panel to “interpret the science” around CWF—framed as a risk-benefit question—without first demanding the threshold question: *Has safety and efficacy been affirmatively established?* That omission all but guaranteed a status-quo conclusion.
- B2. Predetermined composition and expertise gap
- Staffing the Panel with public-health employees who have promoted CWF for much of their careers predictably narrowed the range of evaluation and increased the risk of confirmation bias. The Panel lacked drug regulatory, risk-assessment, clinical trials, Pharmacology and biostatistics experts necessary to evaluate what a lawful safety dossier must contain. Unsurprisingly, the process “found” a way to maintain CWF—indicating the Panel did not learn much beyond its starting assumptions.
- B3. Presupposition of benefit guided the deliberations
- The report admits the Panel “centered around how best to get the benefits of community water fluoridation while minimizing risks to fetuses and infants.” That sentence assumes benefit at the outset and narrows the inquiry to harm minimization—without the FDA-required proving of benefit via modern trials and without a safety margin for the most vulnerable. Methodologically, this is risk management after the fact, not pre-market assurance of safety and efficacy.
- B4. No safety studies reviewed—because none exist at required quality
- By the Panel’s own scope and citations, there are no randomized controlled trials of systemic CWF for benefit or safety; high-quality developmental neurotoxicity testing and comprehensive human cohort evidence with biomarkers and exposure accounting were not provided. The Panel then implicitly reversed the burden of proof—treating CWF as safe until proven unsafe with certainty—contrary to FDA/CDER standards and RCW’s duty to assure safety.

C. Specific Omissions by the Panel that Undermine the Recommendations

1. Aggregate Exposure Accounting. No comprehensive assessment of total daily fluoride intake across sources and life stages; no scenario analysis for high-end consumers (e.g., high water intake, tea consumption, formula-fed infants).
2. Biomonitoring. No plan for population-level urinary or serum fluoride monitoring to verify dose assumptions or identify overexposed groups.
3. Uncertainty/Safety Factors. No application of 10–100× factors for interindividual variability (age, renal status, iodine status, SNPs affecting susceptibility).
4. Sensitive Subgroups First. No protective limit derived from the most sensitive group (fetuses/infants), then back-translated to a water concentration.
5. Stopping Rules. No pre-specified thresholds (e.g., IQ decrement, thyroid perturbations) that would trigger immediate reduction/suspension.
6. Alternatives and Substitution. No appraisal of topical-only strategies (toothpaste/varnish) that deliver the cited benefit without systemic dosing.
7. Regulatory Alignment. No path to reconcile CWF’s disease-prevention intent with FDA/CDER jurisdiction, despite relying on “benefit” claims.

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D. Corrective Policy Direction (to replace the Panel’s three recommendations)

1. Suspend endorsements of systemic CWF pending FDA-grade safety and efficacy evidence, with policy aligned to RCW’s duty to assure safety.
2. Adopt a protective interim ceiling derived from fetuses/infants using aggregate exposure, biomonitoring, and conservative safety factors—not a permissive 1.5 mg/L action level.
3. Replace messaging with source control: If the water is not demonstrably safe for formula reconstitution, change the water policy rather than tasking parents with workarounds.
4. Commission an independent scientific review with experts in drug regulation (FDA/CDER), developmental toxicology, epidemiology/biostatistics, exposure science, and risk assessment; require a written protocol, transparent data, and a pre-registered analysis plan.
5. Evaluate topical-only fluoride strategies as the default alternative that preserves any local dental benefit without systemic dosing.