

Public Comment Addendum on Institutional Conflict of Interest and the Ethics of Self-Review in Community Water Fluoridation

Prepared by:

Bill Osmunson, DDS, MPH

10300 181st Ave SE

Issaquah, WA 98027

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Executive Summary

This addendum supplements Petitions #23 and #24 and is submitted as a formal public comment to the Washington State Board of Health. It addresses a critical issue of **institutional conflict of interest and ethical self-review** within the Department of Health's fluoridation oversight process.

An ethical evaluation conducted by the same agency and individuals who have promoted, implemented, or defended fluoridation lacks the independence necessary to meet federal and professional ethical standards. Those who could not, or would not, meet the statutory and ethical requirement to assure safety without doubt are not in a position to evaluate the ethics of their own performance, their review, or the recommendations of their employers. Requesting employees to judge the ethics of their employers or their own professional conduct presents an inherent conflict of interest and renders the review process itself unethical. True ethical review requires independence from institutional hierarchy and prior policy advocacy.

This comment requests that the Board:

1. Commission an **independent, external ethics review** of community water fluoridation (CWF).
 2. Assure that the review explicitly evaluates **scientific certainty of safety and benefit**.
 3. Suspend policy promotion or endorsement of CWF until such independent findings are completed.
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1. Introduction

The Department's Fluoridation Panel has demonstrated its inability to evaluate evidence with impartiality. It failed to acknowledge that **certainty of safety** is not established for fetuses, infants, children, or adults exposed to uncontrolled and highly variable fluoride dosages in public water. When a health program continues without clear evidence of safety, its ethical foundations are compromised.

An ethics review conducted by those who implemented or defended the program constitutes an **inherent conflict of interest**. Asking employees to judge the ethics of their own conduct—or that of their superiors—is ethically untenable, analogous to asking the accused to serve as both judge and jury. Credible review requires **independent oversight** free from institutional influence, employment dependency, or prior advocacy.

2. Principles of Independent Ethical Oversight

The **Belmont Report** (1978) established that credible ethical oversight must be independent of those administering a program. Similarly, the **World Health Organization** (2011) and the **American Public Health Association** (2019) emphasize that ethics evaluations must be conducted by individuals “independent of the interests, command structure, or financial incentives of the agencies being reviewed.”

Organizational loyalty, employment dependency, and professional identity all compromise the ability of employees to critique their agency's actions objectively. As **Kunda** (1990) and **Tenbrunsel & Messick** (2004) demonstrated, institutional affiliation fosters motivated reasoning—the unconscious filtering of information to support prior beliefs and preserve social standing. Under these conditions, any internal review of fluoridation ethics would predictably reproduce the same rationalizations that led to the initial failure to assure safety.

Liberty (freedom from oppressive authoritarian restrictions) is not a luxury of public health; it is its foundation. Without autonomy for none highly contagious or lethal diseases -- such as dental caries-- becomes a public health police powers kingly act. The rediscovery of public health liberty begins with honesty — the willingness to tell patients the whole truth even when it contradicts official policy, industry profits, or a patient's bad choice.

Fluoridation is not just a loss of patient liberty, it is unethical. By attempting to create better health through chemistry rather than patient education and incentives, focuses on one disease

rather than overall health. For example, dental caries is an early symptom of poor health. A reduction in refined sugar and oral hygiene will improve several diseases such as periodontal disease, diabetes, obesity, etc.

The true harm to public health in our war over fluoridation is the time, money and resources spent on one “symptom” rather than overall good health. It is past time we focus on good health rather than just one symptom of poor health.

Public-health ethics is grounded not only in beneficence but in **respect for autonomy**. Liberty—freedom from coercive state intervention—is not a luxury but the foundation of legitimate public health. Compulsory exposure to a pharmacologically active substance to address a non-contagious condition, without informed consent or individualized risk assessment, exceeds ethical limits on state power. True ethics begins with truth-telling and shared decision-making, not coercion. Every act of informed consent is an act of civilization; every act of compulsion erodes it.

3. Regulatory and Professional Parallels

The principle of independence is codified throughout law and ethics:

- **Institutional Review Boards (IRBs)** are prohibited (45 C.F.R. §46.107[e]) from reviewing research in which members have conflicts of interest.
- **Judicial ethics** (Canon 3C, *Code of Conduct for U.S. Judges*) require recusal when prior advocacy or relationships may affect impartiality. Most of the fluoridation panel members should have recused themselves.
- **Federal ethics regulations** (5 C.F.R. §2635.101[b][14]) require employees to avoid even the appearance of partiality.

By these standards, any fluoridation ethics panel composed of Department or Board employees—especially those with prior promotional roles—cannot meet the threshold of independence or public trust.

4. Independent Alternatives for Ethical Review

A credible ethics review should be conducted by institutions with no administrative or political ties to Washington's fluoridation program. Viable options include:

Academic Institutional Review Boards (IRBs):

- *University of Washington IRB* — expertise in human-exposure ethics and population research.
- *Gonzaga University IRB* — Jesuit moral-philosophy foundation emphasizing justice and autonomy.
- *Eastern Washington University IRB* — independent faculty with public-health and psychological ethics background.
- *Washington State University IRB* — toxicology and environmental-health competence relevant to systemic exposures.

Independent and Cross-Institutional Ethics Bodies:

- *Northwest Association for Biomedical Research (NWABR)* — capable of convening neutral ad hoc ethics panels.
- *National Center for Ethics in Health Care (U.S. VA)* — long experience in applied clinical ethics.
- *Reagan-Udall Foundation for the FDA* — recently led an independent ethical and scientific review of unapproved fluoride supplements for FDA CDER (June 2025).
- *National Academy of Medicine (Ethics Division)* — suitable if conflict-screened and independently chartered.

5. Fluoridation as Unconsented Human Research

Some argue CWF is not research, but under **45 C.F.R. §46.102(I)** and the **Belmont Report**, research is “a systematic investigation designed to develop or contribute to generalizable knowledge.” Fluoridation meets this definition:

- **Intent:** To prevent a medical condition (dental caries) via systemic ingestion of a pharmacologically active ion.
- **Design:** Population-wide exposure without dosage control, labeling, or informed consent.

- **Outcome:** Ongoing data collection and publication of exposure-effect findings—constituting continuous human experimentation.

Under **21 U.S.C. §321(g)(1)(B)**, fluoride intended to prevent disease is a **drug**. Administering it without FDA New Drug Application (NDA) or Investigational New Drug (IND) authorization constitutes **unapproved human experimentation**.

However, no authority has accepted responsibility for the unapproved human research and few are even evaluating the success, risks, harm, or safety of fluoridation.

The **Belmont Report**, **Nuremberg Code**, and **Helsinki Declaration** require voluntary informed consent for any exposure of uncertain safety. Because fluoridation's safety has never been confirmed by randomized controlled ingestion trials, it remains **unconsented population research**. Furthermore, the exemption in **45 C.F.R. §46.101(b)(5)** applies only to programs lawfully authorized and approved by a department head—conditions unmet here. As **Hans Jonas (1969)** warned, population-wide interventions of unknown outcome constitute de facto human experimentation.

6. Ethical Evaluation Requires Evidence of Benefit and Certainty of Safety

Ethical judgment depends on credible scientific evidence. As **Kass (2001)** and **Royo-Bordonada (2015)** observe, beneficence cannot justify interventions lacking proven safety.

- **Certainty of Benefit:** The **Cochrane (2024)** update found low-certainty evidence of caries reduction under current exposure conditions.
- **Certainty of Safety:** The **NTP (2024)** report, **Grandjean (2024)**, and **NRC (2006)** review indicate potential developmental neurotoxicity within common exposure ranges, particularly for fetuses and infants.
- **Certainty of Harm:** The threshold for known adverse effects (e.g., IQ loss) overlaps existing exposure levels, eliminating any meaningful safety margin.

RCW does not mandate the Board or Department to weigh or judge the balance of efficacy vs safety. Benefit is the jurisdiction of the FDA. RCW is focused on certainty of safety.

Where safety is unassured and efficacy uncertain, ethical justification collapses. The **Nuffield Council on Bioethics (2007)** held that population measures overriding autonomy require robust evidence of benefit and minimal risk. The **Public Health Agency of Canada (2018)** and **CADTH (2019)** similarly concluded that fluoridation ethics cannot rest on unverified assumptions of safety or efficacy.

7. Ethical Imperative for External Review

An internal ethics panel within a conflicted hierarchy cannot restore public trust. The Board's statutory duty under **RCW 43.20.050(2)(a)**—to assure the safety of public drinking water—requires evidence beyond reasonable doubt before exposure. Self-affirming reviews fail that standard.

Ethical legitimacy requires an **independent, multidisciplinary external review** empowered to evaluate both scientific and moral claims without institutional constraint or predetermined outcome.

8. Request to the Washington State Board of Health

In accordance with state and federal ethical standards, I respectfully request that the Board:

1. **Establish an Independent Ethics Review Panel** — composed of qualified experts external to the Department of Health, free from conflicts of interest, and including representation from ethics, toxicology, pediatrics, and public-health law.
 2. **Charge the Panel** — to evaluate the scientific evidence of benefit, the assurance of safety for vulnerable populations, and the ethical legitimacy of unconsented systemic exposure.
 3. **Suspend policy advocacy or endorsement** of community water fluoridation until that independent review issues a public report and recommendations.
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References

(Expanded and harmonized for citation consistency)

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- Relevant statutes: 21 U.S.C. §321(g)(1)(B); 45 C.F.R. §46.101(b)(5); 45 C.F.R. §46.102(l); 5 C.F.R. §2635.101(b)(14); RCW 43.20.050(2)(a); *Code of Conduct for United States Judges* (2023).