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Washington Action for Safe Water
Bill Osmunson DDS MPH

Dear Washington State Board of Health (Board) and Department of Health (Department),

RE: PETITION FOR RULE MAKING: WATER FLUORIDATION,

and FORUM ON FLUORIDATION

"Silence in the face of evil is itself evil: God will not hold us guiltless.
Not to speak is to speak.
Not to act is to act."

— Dietrich Bonhoeffer

Fluoridated water is NOT SAFE

The harm is IATROGENIC

Summary

Fluoride is a legend drug when intent of use is to prevent disease. Neither the Board nor Department have experts, procedures, funding, or authorization to determine the highly complex issue of the efficacy, dosage, label or hazard risk of drugs, such as the ingestion of fluoride, the responsibility of the FDA CDER[1]. The Board and Department are charged by the Legislature to write rules to assure safe drinking water, positively and confidently dispelling any doubt that fluoridation is safe. The Board contacted the FDA CDER charged by Congress to determine efficacy of drugs and was informed, requiring FDA CDER approval *"would effectively ban fluoridation.*" The FDA CDER has not, and would not, approve fluoridation due to a lack of one or all of the following: efficacy, dosage, safety, label, GMP[2], pharmaceutical ingredients, doctor's prescription, or patient consent. The Board is in violation of RCW 43.20.050 and other laws, to assure safe drinking water. This petition is focused on a minimum label to protect the development of the most vulnerable, i.e. fetus, infant, and child. However, this petition will not assure the safety of fluoridated public water, but will start to educate the public for their safety.

[1] Food and Drug Administration Center for Drug Evaluation and Research.
[2] Good Manufacturing Practices

The Board's duty is to adopt rules **to assure safety**. The brief summary of evidence presented in this petition will demonstrate the Board cannot assure safety of fluoridation, because fluoridation is:

- **Contributing to over exposure, overdose.**
- **Not Safe due to lack of safety research.**
- **A highly toxic poison, and not being regulated under drug laws.**
- **A legend drug, an illegal drug, because fluoridation lacks:**
    - **FDA CDER NDA approval**
    - **A doctor's prescription**
    - **Individual Patient Consent**
    - **Good Drug Manufacturing Practices**
    - **FDA Manufacturing Oversight and Licensing**
    - **Pharmaceutical grade purity of ingredients**
    - **Dosage control**
    - **Legend of patient instructions and warnings.**
- **A developmental neurotoxin as measured by:**
    - **Lower IQ**
    - **And pilot evidence of ADHD, Miscarriage, Premature Birth, Infant Mortality**
    - **Causes Tooth Damage**
    - **Contributes to Rheumatoid and Osteoarthritic-like Pain**
    - **Contributes to Cancer**
    - **Contributes to Bone Fractures**

- **Contributes to Thyroid Reduction, Diabetes, Obesity**
- **Contributes to Kidney damage**
- **Contributes to Reproductive problems**
- **Contributes to Allergies (overactive immune system)**
- **Contributes to Gastrointestinal disorders**

Alternatives to fluoridation are available for those who want to ingest fluoride, such as:

- **A doctor's prescription for fluoride supplement**
- **Bottled water with fluoride**
- **Avoid careful rinsing of toothpaste**
- **Avoid organic foods**
- **Drink more tea**
- **Drink more wine**
- **Eat more mechanically deboned meat**

The siloed purpose of fluoridation is to give people more fluoride because the Board does not trust people to make the decision for themselves, to take away freedom of choice.

The laws do not charge or permit the Board to approve drugs, nor determine safety to a confidence level of absolute certainty of harm.

The evidence presented does not permit the Board to assure, or be able to **"tell each person in Washington**

state, fluoridation is safe, positively and confidently, dispelling any doubts they may have."

The evidence presented here need only rise to the level of "doubt" in the Board's mind, not absolute confidence of harm. If the Board doubts fluoridation safety, the law requires the Board to at least stop endorsing fluoridation.

The Board should also consider we are not evaluating an and EPA industrial chemical or water purification chemical. This is an unapproved legend drug administered without consent, as a concentration rather than dosage, with known undisputed harm.

"RCW 43.20.050 Powers and duties of state board of health—Rule making—Delegation of authority—Enforcement of rules.

(1) The state board of health shall provide a forum for the development of public health. . ."

(2) In order to protect public health, the state board of health shall: ***(a) Adopt rules . . . to assure safe and reliable public drinking water*** *and to protect the public health."*

The question the Board should focus on in this petition is, **"Can the Board assure the public that fluoridation is safe?"** It is not the Board's charge to determine whether fluoride CAUSES an adverse effect. Confidence of a causality is a higher level of confidence than to **assure safety**.

Nor does **RCW 43.20.050** charge the Board with "weighing the evidence of benefit." The Board's sole charge is to assure safety. In 1975 the FDA CDER determined the evidence of efficacy was incomplete and has not changed their determination. In contrast, the Board claims on their web site fluoridation is effective and is safe, without reservation.

In 2010 we petitioned the Board 19 times to assure safe water and protect the public health. The lack of safety is not new, the evidence of harm is more robust.

However, we agree with the past Board and Department that they must rely on the FDA CDER to determine **efficacy, dosage, safety and label** of substances marketed with INTENT to prevent disease. The complex pharmacology, toxicology, epidemiology and benefit assessor is not in the lap of the Board, but the Board has attempted to assume the role of benefit (efficacy). Without accepting the FDA CDER's advice, the Board cannot assure fluoridation is safe.

The FDA CDER indicated to the Board in 2010, that should the Board accept our 2010 original petition for rule change, in effect requiring FDA CDER approval, would effectively ban fluoridation. The Board at that time, ignored the FDA and the Board did the exact opposite, more confidently promoting and endorsing fluoridation. Examples include the Board's web page and the Department's survey of public opinion on fluoridation.

The fluoridation lobby will push back against this petition. Throughout this petition, their concerns will be briefly addressed at each issue.

The Board needs to carefully review the evidence and assure themselves and the public that fluoridation is positively and confidently, dispelling any doubts they may have that fluoridation is anything but safe for everyone.

In this case the Legislature is reasonably consistent with:

"The Precautionary Principle says that if some course of action carries even a remote chance of irreparable damage to the ecology, then you shouldn't do it, no matter how great the possible advantages of the action may be. You are not allowed to balance costs against benefits when deciding what to do.

The fluoridation lobby will correctly state that the USA has not accepted the PP (Precautionary Principle) as Europe has done; however, the legislature in this case is consistent and raises the standard from PP's "remote chance" of damage, to the Legislature's increased confidence from damage to assure, positively and confidently, dispelling any doubts fluoridation is safe. And further, the PP uses "irreparable" damage rather than the Legislatures more cautious concern of "safe," which would include repairable damage or "aesthetic concern."

The Fluoridation lobby wants proof of harm, the Board is to be positive, confident, dispelling any doubts fluoridation is safe.

CONCLUSION: Some evidence is stronger than other evidence. However, when all streams of the scientific and legal evidence are assembled together and weighed, no reasonable person could assure their child or pregnant daughter that ingesting fluoridated water is safe.

To prove something is harmful, requires a different frame of reference, a different set of facts, different judgment than to assure something is safe. The Legislature has charged the Board to assure safety. For example, we do not demand to see a child's blood, broken bones or death before we determine a playground is unsafe.

More research is always desired, but no excuse for action. We have enough to know fluoridation is not safe.

OUR PETITION FOR RULE CHANGE

Consistent with health and safety issues in Title 246, Title 173, Title 296, WAC 173-340, and WAC 296-62-07521; this petition is made in compliance with RCW 34.05.330 and WAC Chapter 82-05.

This petition is for amendment to WAC 246-290-220

(8) For the safety of the developing fetus, infant, and child, the board no longer endorses the addition of fluoride to public water and recommends reducing fluoride exposure for pregnant mothers, infants and children under 6 years of age.

(a) Pregnant mothers and women planning to become pregnant (within 10 years) should limit fluoride ingestion by usually drinking water and liquids with less than 0.2 mg/L of fluoride, and do not swallow toothpaste;

(b) Care givers of infants should use water as low in fluoride as practical, less than 0.2 mg/L, for making infant formula, juice and drinking, and do not use fluoridated toothpaste.

(c) Carefully supervise children when they are using fluoridated dental products, such as toothpaste, to assure they are not swallowing the toothpaste and are able to spit, rinse and spit, and again rinse and spit without first swallowing. Read and follow the toothpaste label.

Our Point:[3] The intent of this rule change petition[4] is to start protecting the fetus, infants and children from the most significant risks and harm of fluoride exposure.

This petition will begin to protect the fetus, infant, and children from the worst known harm.

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[3] In 2010, we submitted our first rule change, which was denied. The Board mentioned:

"the EH Committee considers much of the discussion in our petitions to make points that go beyond the requested rule changes and are not pertinent to its decision." See Attachment #G We will try to explain the pertinence of each point.

[4] This petition concept is based in principle on the Safe Drinking Water Act which prohibits

-the addition of anything to water to prevent disease in humans, and

-warnings by the FDA CFSAN (Center for Food Safety and Nutrition).

BACKGROUND

We first asked the Board what was the "intent" of adding fluoride to tap water. Even though the Board had hundreds, actually thousands,[5] of documents on the intent of adding fluoride to public tap water, the Board responded that they had no records.

Our point: the intent of use determines jurisdiction.

In 2010, our first petition attempted to turn the very complex task of evaluation and judgment on the many streams of legal, ethical and scientific evidence, over to the authority charged by Congress in the FD&C Act to determine and regulate substances marketed with the intent to . . . "prevent disease."

We then filed our first petition which was denied. The Board misunderstood our petition and ignored the FDA's implied advice.

Relying on unauthorized agencies to do what they are prohibited from doing (EPA in the SDWA) does not "assure safety." The difficult complex task of determining the **efficacy** of

[5] Based on FOI documents responding with over 25,000 pages.

fluoridation,[6] and the **dosage** for that efficacy inclusive of background exposure, along with the vital determination of **safety** at that total exposure which would have efficacy, and a **label** with warnings and caution for intraspecies variations and alternatives is still the responsibility of the Board, in order to assure safety, dispelling doubt of harm.

This petition starts a label to assure the safety for our most vulnerable, but still falls short of assuring safety. As implied by the FDA, to assure safety, to remove doubt, would prohibit fluoridation.

The Board has become clear on intent of use of fluoridation is to prevent (mitigate) dental caries a disease in humans. We agree.

Petitioners are mostly not lawyers, toxicologists, epidemiologists, neurologists, endocrinologists, statisticians, physicians, pharmacists, hazard assessment experts, or risk assessors. We are voters, in effect, your "patients," and we are being harmed. I am a dentist with public health master's degree.

[6] The term fluoridation here will be used to refer to the addition of fluoride to public water with the intent to prevent dental caries (cavities) a disease.

The Board's first denial (Attachment #G) of our request for the Board or water purveyors to apply for FDA CDER (New Drug Application) would have taken the thorny, complex job of determining the safety, dosage, label, GDMP (Good Drug Manufacturing Practices), product purity, and the legal, ethical, and science off the Board's shoulders and placed the task in the lap of the authorized authority, the FDA CDER.

The Board at the time was correct in contacting the FDA, although the dental devices Division was not appropriate. Fluoride is not a dental device used by a dentist. Fluoride is a legend drug. However, the FDA did not advise the Board that FDA approval was not necessary. The FDA *"said if the Board accepted the language proposed in the petition, it effectively would ban public water fluoridation in Washington."*

Our point: The FDA would not approve fluoridation. Without FDA CDER approval, safety cannot assured.

JUDGMENT: REQUIRES EVALUATING ALL "STREAMS OF EVIDENCE"

To assure safety, the Board must consider and weigh multiple streams of evidence, concepts, studies, and disciplines, omitting none.

We always desire more studies. We always want numerous studies exactly the same so they can be precisely compared to increase confidence. We have enough evidence to be confident, fluoridation is not safe for many, most, or anyone.

LEGAL –A BRIEF SUMMATION:

All streams of legal evidence and jurisdiction, must be weighed, including, but not limited to the following questions:

1. What does Congress say about jurisdiction of substances marketed with intent to prevent disease? Congress clearly designates the jurisdiction to the FDA.
2. What has the FDA determined regarding fluoride ingestion with intent to prevent dental caries? Fluoride is a drug.
3. Has the Washington State Board of Pharmacy (Pharmacy Quality Assurance Commission, "PQAC" or "Pharmacy, or Board of Pharmacy) determined fluoride to be a legend drug? Yes. (Idaho Board of Pharmacy also determined fluoride to be a drug.) The PQAC is consistent with the FDA CDER, but neither the Board nor Department are consistent with the FDA or PQAC.
4. Does the Board or Department have the authority to determine the benefit, efficacy, of any substance with intent or claim to treat human disease i.e. drug approval? I have not found any Washington State law or provision where the Board or Department has authority to approve

drugs, regardless of dilution in tap water. Nor have I found the definitions, policies, experts, procedures, rules, or guidance recommendations the Board and Department must set up for the complex drug approval process. Nor have I seen laws exempting FDA CDER NDA from drug approval.

5. Does the Board and or Department have authority over assuring the safety of water? Yes.
6. Who has jurisdiction over the addition of drugs to tap water according to the EPA's (Environmental Protection Administration) water law office? FDA.
7. What jurisdiction does the CDC (Centers for Disease Control) have over approval of fluoridation's efficacy, safety, dosage or label? None.
8. What is a safe dose of fluoride exposure for everyone? The same as lead.
9. What have other Countries determined regarding fluoridation? Most developed countries have rejected fluoridation.

10. What does Washington RCW provide for guidance?

    Fluoride is undisputed as a highly toxic poison, exempt when regulated under drug laws.

    See more details and references below.

EFFICACY OF FLUORIDATION: examples

11. What is the intent of fluoridation, the addition of fluoride to public water, well known to the public and claimed by the Board of Health? Intent is to mitigate dental caries.
12. How effective is swallowing, ingesting, fluoride? Between none and half a cavity per person.
13. Is fluoridation cost effective when including real world costs estimated benefits, costs to fluoridate, and costs of known harm? No. Fluoridation is not cost effective.
14. Is fluoride a nutrient? Fluoride is not an essential nutrient and no disease is caused by a lack of fluoride ingestion.
15. What happens to caries when fluoridation stops?

    Research is mixed, probably no change.

DOSAGE OF FLUORIDE: examples

16. How much fluoride (mg/kg/day) is required to prevent dental caries? FDA says the evidence is incomplete.
17. How much fluoride (mg/kg/day) are people ingesting from all sources? Dosage is highly variable. The fetus, infants and children are most at risk of excess exposure.
18. What are the sources of fluoride for each individual and an individual's past exposure to fluoride? Highly variable.
19. Is the assumption that everyone needs more fluoride (supplementation) reasonable? No.
20. How much fluoride is an individual exposed to from toothpaste? Children often swallow half their toothpaste.
21. How much fluoride is the individual exposed to from the osteoclastic activity, turnover of bone? Bone contains between 1,000 and 8,000 ppm fluoride. Almost 100% of bone is remodeled in the first year of life and about 10% a year in adults.
22. How much fluoride is the individual exposed to from medical products? General anesthesia and medications can have fluoride and dosage is variable.

23. How much fluoride is the individual exposed to from foods such as mechanically deboned meat, pesticides such as cryolite and post-harvest fumigants, air such as freon and soil? Estimates vary.

SAFETY OF FLUORIDE INGESTION: examples

24. What is the purity, assay results, of the fluoride product used for fluoridation? Product is not pharmaceutical grade.
25. Is fluoride safe, lacking aesthetic or functional harm, for the teeth? Dental fluorosis, a biomarker of excess fluoride exposure, is arguable the most common disease of childhood.
26. Is fluoride safe, lacking neurotoxicity, for the developing brain? No.
27. Is fluoride safe for the fetus due to the transfer of fluoride from the mother? No.
28. Is fluoride safe for the endocrine system and thyroid? No
29. Is fluoride safe for the bones, the largest storage of fluoride in the body? Fluoride is 400% higher in those with bone cancer than normal patients for the same age.

30. What are synergistic effects, such as lead, mercury, or from other toxins? Still to be determined.

LABEL: Every approved substance with intent to prevent disease has a label for:

31. intent of use,
32. approved dosage,
33. approved label with warnings/cautions.

    Fluoridation has no label

TARGET POPULATION:

34. What percent of the population is to be protected from harm, 90%, 95% or 100%? How many thousands of people is the Board willing to put at risk? About 3.3 million in Washington State on fluoridated water. If the Board accepts 10%, that is 330,000 people ignored by the Board.
35. What margin of error, intraspecies variability, uncertainty factor is prudent? EPA uses 1:1 (no) margin of error or intraspecies variability and only accepts severe skeletal fluorosis or severe dental fluorosis as a risk.

Judging the “weight” or “power” from each of the more than 3 dozen streams of evidence is not intuitive to either researchers or lawyers. Most attempt to narrow the streams of judgment to one or two variables rather than be inclusive of all evidence.

The fluoridation lobby mistakenly claims safety by dividing the streams of risk, and each stream into drops of misty fog to obscure harm.

A “global” view, or totality of the evidence, a summation of weight is required to fully appreciate the extent of the harm and lack of safety.

“Proof” of efficacy requires randomized controlled trials (RCTs), prospective, double blinded, etc. An RCT would give subjects either the test substance or a placebo to consenting subjects and measure possible benefit and should look for harm and have blinded researchers. Intent to do good is valid research. FDA has determined evidence of efficacy is complete. Indeed, no RCTs exist on fluoridation.

“Proof” of safety is far more complex. In contrast, we cannot do randomized controlled trials giving people a poison and finding out when they are harmed or die. Harm must be determined

based on lower quality studies, such as correlation or ecological studies. Without RCTs, safety has been over-looked. No money is made on looking for harm and not selling the product. Safety is an orphan concept in a for profit culture.

Our point: Judgment requires adding the weight from each stream of evidence. A monumental task which the 2010 Board trusted to unauthorized agencies.

UNCERTAINTY FACTOR: Judgment requires the Board to select an uncertainty factor or margin of error and/or intraspecies variability? Not all humans respond the same due to genetics, health conditions, life stage, etc. Not everyone is average, drinking the average amount of water, average age, average health, etc. We all do not wear the same size shoe. The concept of "average" is important to grasp a concept, but an uncertainty factor, intraspecies variability, must be added to protect subpopulations.

This petition will not protect all the public; however, it could reduce, but not eliminate, harm to the most vulnerable.

LAWS

Washington Legislature, **RCW 43.20.05** designates authority for health and safety rules onto the Board of Health.

"RCW 43.20.050 Powers and duties of state board of health—Rule making—Delegation of authority—Enforcement of rules.

(1) The state board of health shall provide a forum for the development of public health policy in Washington state. ."

Since our petitions, 14 years ago and to our knowledge, the Board has not held a forum on fluoride exposure and fluoridation where both sides present laws and science. The Legislature did not give exemptions for difficulty, busy schedule, controversial topics, or cherry-picking participants, etc.

"RCW 43.20.050 continues:

(2) In order to protect public health, the state board of health shall:

*(a) Adopt rules for group A public water systems, as defined in RCW **70A.125.010**, necessary to assure safe and reliable public drinking water and to protect the public health."*

The Board has failed to assure safe public drinking water.

The Department's survey of public opinion on fluoridation demonstrates many, if not most of the public, do not trust the Boards opinion that fluoridation is safe. The Department should have spent the time and limited resources and surveyed "science" rather than public opinions.

Our first petition 14 years ago requested the Board advise or recommend water purveyors to apply to the FDA CDER for an NDA (New Drug Application) because fluoride was determined by the Board of Pharmacy to be a legend drug. The Board denied our petition, in part, on the grounds the rule change would *"essentially, prohibit all tap water fluoridation in Washington."*

The Board appears to have in part misunderstood the FDA. True, the FDA does not regulate contaminants in public water. However, the FDA regulates the fluoride when a health claim is made for the product, regardless of diluting the drug in tap water.

In other words, a "snake oil salesman" cannot simply take their elixir and dilute it in tap water and evade FDA oversight. EPA regulates water, FDA regulates drugs.

An important early step to assure the safety of public water when fluoride is added, was communicating with the FDA and EPA. Thank you, we agree this was a correct step.

The FDA confirmed and supported the Washington Board of Pharmacy and our petition that adopting our 2010 petition would effectively ban public water fluoridation in Washington.

It appears the Board of Pharmacy and certainly we assumed the Board would come to the logical conclusion, “if it can’t be approved, it isn’t safe.” However, the Board appears to have doubled down and promoted fluoridation for everyone, without assuring safety.

What about fluoridation would prove difficult to gain FDA approval? Lack of efficacy? Lack of controlled dosage? Lack of safety at that dosage? Lack of label? Lack of the patient’s doctor’s oversight? Lack of patient consent? Lack of chemical purity? Or, all of those? The Board cannot assure safety.

The Board does not determine **efficacy**. The U.S. Food and Drug Administration Center for Drug Evaluate and Research (FDA CDER) has jurisdiction over substances marketed with intent to prevent disease in humans.

In 1975 the FDA said the evidence of efficacy was incomplete.

The second step is to determine how much does it take to be effective, dosage.

The third step is to determine the risks and harm, i.e. safety, at that dosage. Without knowing any one of those steps, safety cannot be assured.

WAC 246-290-220 permits the Department to continue the use of non-certified chemicals (which would encompass fluoride chemicals), provided:

"(b)There exists no substantial evidence that the use of the chemical or material has caused consumers to register complaints about aesthetic issues, or health related concerns, that could be associated with leachable residues from the material;"

We are once again registering a complaint of dental fluorosis aesthetic and functional harm and other health concerns is made to the Board and Department of Health.

The Legislature appears to have concern for aesthetic issues which is part of dental fluorosis and health related concerns which is also part of dental fluorosis.

This petition for rule change is focused on the Board, but addressed to both the board and Department because both share responsibility to assure safety to the public, especially the fetus, infants and children. The Board and Department have for more than 14 years been fully aware, fluoridation is not safe.

FORUM REQUEST

A 2 or 3 minute public comment at Board meetings is not a "forum" where *"ideas, questions, and views on a particular issue can be exchanged."*[7]

For the health of the public, we have requested a forum as provided in RCW 43.20.050 where ideas, questions, views, science and laws can be exchanged on fluoridation.

"RCW 43.20.050 does not authorize the Board to dilute drugs in the water with the intent to treat humans rather than treat

[7] Oxford Languages Dictionary

water, nor does it permit the Board to reduce the safety of the water or determine efficacy of treating human disease.

RCW 43.20.050 does not appear ambiguous or uncertain. The Board is the authority in Washington State and SHALL assure the water is safe.

Assuring the water safe from unknowns is one problem; however, actually intentionally causing the unsafe water is iatrogenic harm.

When a doctor makes a mistake, the patient can be harmed. When the Board makes a mistake, millions can be harmed.

POISON DEFINED: fluoride is a highly toxic substance, a hazard, and must not be taken lightly or casually dismissed.

There is no physiologic process which requires fluoride, no "minimum daily requirement."

Fluoride is not a nutrient. No disease is caused by the absence of fluoride ingestion.

Fluoride is one of the most powerful elements known.

***"RCW 69.38.010 "Poison" defined**. As used in this chapter "poison" means:*

(1) Arsenic and its preparations;

(2) Cyanide and its preparations, including hydrocyanic acid;

(3) Strychnine; and

(4) Any other substance designated by the state board of pharmacy which, when introduced into the human body in quantities of sixty grains or less, causes violent sickness or death."

60 grains =3,888 mg.

The probable violent sickness or death of fluoride is estimated at 5 mg/Kg body weight. Although it might take 50 mg to cause violent sickness or death in an adult, an estimated 20 mg NaF could cause violent sickness or death in an infant. The probable fetus lethal dosage is unknown.

I summarized to **the Board of Pharmacy** that their job in the most simple terms was to determine whether 20 mg was less than 3,888 mg, (obviously) and if so, fluoride is defined by RCW 69.38.010 as a **"POISON."** and exempt when regulated under pesticide or drug laws, RCW 69.38.010.

Without dispute, fluoride is an extremely toxic substance, poison, more lethal than lead or gasoline.[8]

RCW 69.40.030 ". . . *and every person who willfully poisons any spring, well, or reservoir of water, is guilty of a class B felony and shall be punished by imprisonment in a state correctional facility for not less than five years or by a fine of not less than one thousand dollars."*

Do not mess around with poisons.

When evaluating fluoride, the Board must put on their "poison" hat and think serious caution with a highly dangerous toxic poison. Fluoride is not a play toy, nutrient, or food. Also keep in mind the only potential benefit of fluoride ingestion is an alleged reduction in dental caries which is a theory which lacks quality research and is disputed, unapproved by the FDA CDER in tablets or diluted in liquid.

The Board is attempting to mitigate dental caries, a very common disease, which can be seriously painful, life altering; however, not considered highly lethal or contagious.

[8] Estimate of lethal dose is by Wolford. For comparison, 1.5 to 2 mg/k for a 70 kg is considered lethal and 0.6mg/kg for arsenic. 450 mg/kg of lead is also considered lethal. 2,000 to 5,000 mg/kg of gasoline can be fatal.

RCW 69.38.010 Exempts poisons from poison laws when regulated under drug or pesticide laws.

The Board of Pharmacy exempted fluoride from poison laws and determined fluoride to be a legend drug.

Our point: Fluoride is highly toxic and unless regulated as a drug, under drug laws, fluoride remains under poison laws and for the safety of the public must be regulated as a poison, or drug.

DRUGS DEFINED

See also attachment #A

Drugs are defined as: *"articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease"* [FD&C Act, sec. 201(g)(1)].

The Board of Health responded in 2010, to my question of the intent of fluoride ingestion, responding:

This agency, therefore, is not in possession of any records related to the Board s purpose and intent for supporting the addition of fluoride to public drinking water."[9]

Seriously, the Board . . . had NOTHING to back up why they recommended adding fluoride to public water. However, FOI

[9] July 22, 2010 letter to Bill Osmunson regarding public information disclosure request.

evidence with thousands of pages clearly disagreed with the Board's claim of "no records" were available at the time on the intent of fluoridation. The public knew, and knows, why fluoride is added to public water. But not the Board?

The Board's claim of "no records" was simply an attempt to mislead, an egregious attempt to protect policy rather than the safety of the public, especially, the fetus, infants and children.

Once again, the Board denial in our 2010 petition, wrote:

"if the Board accepted the language proposed in the petition, (for FDA CDER approval) it effectively would ban public water fluoridation in Washington."

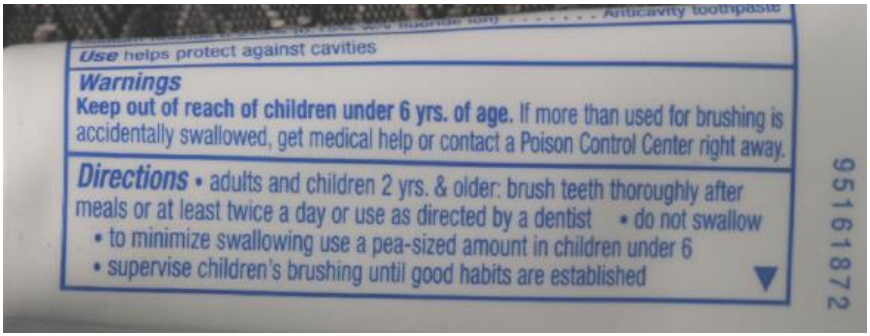
Our point exactly. The Board did not assure the safety of the public. If fluoridation cannot be approved, continuing the practice does not assure safety.

For the safety of the public, the Board must understand, either fluoride is a poison because it is highly dangerous, or it is exempt when approved under drug laws but not exempt when not approved by the FDA. Fluoride ingestion with intent to prevent dental caries is not approved for ingestion in pills, liquids, or diluted in public water.

FDA WARNING: DO NOT SWALLOW

The FDA has approved fluoridated toothpaste as an over-the-counter drug, not requiring a doctor's prescription.

The first step I took in evaluating fluoride was to read the toothpaste label. "Drug Facts." Fluoride is without dispute a drug.



The intent is clear, "helps protect against cavities."

The FDA continues:

"Keep out of reach of children under 6 years of age." "if accidentally swallowed, get medical help or contact a Poison Control Center right away."

*"Directions * adults and children 2 years. & older: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist * do not swallow * to minimize swallowing use a pea-sized amount in children under 6 * supervise children's brushing until good habits are established"*

In my pilot study, I then took a toothpaste tube and squeezed out what I thought were "pea size amounts" for the entire tube and calculated the number and the "dosage" of fluoride in each pea size amount, and took the pictures above. Then I looked up the data and realized my pea size amount as shown in the picture above on the tooth brush was twice the size as recommended by the FDA CDER, which should contain only 0.25 mg of fluoride. The picture above with the amount of toothpaste was a "large pea size" amount containing 0.5 mg of fluoride.

Consider for a moment, the Board recommends everyone be required without consent and regardless of safety, to swallow in each glass of water the same amount of fluoride (0.25 mg) as the FDA "Warnings" tell us "Do Not Swallow" and to "contact a Poison Control Center right away."

Seriously, who do you trust more? The FDA or Board?

Assuring safety is not possible if there were no other evidence.

The Department did a survey of voters to determine their opinion on fluoridation, in effect, the public was asked do they trust the messaging of the Board and Departments of Health regarding fluoridation. Many, and in some places most, do not trust the Board or Department on fluoridation. Now, who would have thought the public knows more than the Board of Health?

The FDA does not mince words, is precise, “Do Not Swallow.” The Board should have the same warning for fluoridated tap water.

The Board must think the implications through. If the Board cannot be trusted on fluoridation, can they be trusted for vaccinations, prevention of disease, sanitation, or any other public health recommendation?

Remember, the toothpaste label was approved by the FDA over a quarter of a Century ago, not fluoridation.

FLUORIDE IS A LEGEND DRUG: the Board has been fully aware for more than a decade that fluoride is a legend drug and the Board and Department have failed to assure the public water is safe.

In contrast, to the Washington State Board of Health the Washington State Board of Pharmacy (PQAC) determined*:*

"Fluoride is a legend drug regulated under chapter 69.41 RCW. RCW 69.41.010 defines a 'legend drug' as drugs 'which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only."[10]

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[10] State of Washington Department of Health Board of Pharmacy June 4, 2009 letter to Bill Osmunson DDS; RCW 69.41.010(12) (#13 in 2024) defines legend drugs; WAC 246-883-020(2) states legend drugs are listed in 2002 *Drug Topics Red Book* (relevant *Red Book* pages including page 342 that lists "Fluoride" are attached to the above-referenced Board letter.

The current online red book 2023 edition for fluoritab lists
Adverse Reactions
Severe
exfoliative dermatitis / Delayed / Incidence not known
GI bleeding / Delayed / Incidence not known
hematemesis / Delayed / Incidence not known
Moderate
stomatitis / Delayed / Incidence not known
atopic dermatitis / Delayed / Incidence not known
anemia / Delayed / Incidence not known
dental fluorosis / Delayed / Incidence not known
synovitis / Delayed / Incidence not known
Mild

Note: The Board of Pharmacy referenced the “Red Book,” not the list of approved drugs in the FDA “Orange book.”

The WSBP (PQAC) references the 2002 Drug Topics Red Book which is industry, not published by the FDA CDER but rather the Physician’s Desk Reference. As a doctor, I use the PDR, a good book for doctors. Approval of substances intended to prevent disease in humans is the FDA responsibility, that’s the FDA Orange Book.

RCW 69.41.010 (13) *"Legend drugs" means any drugs which are required by state law or regulation of the pharmacy quality assurance commission to be dispensed on prescription only or are restricted to use by practitioners only.*

When reading the laws, “think fluoridation.” Think, “how does this law apply to fluoridation? Who is the practitioner dispensing the fluoridated legend drug?

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urticaria / Rapid / Incidence not known
weight loss / Delayed / Incidence not known
asthenia / Delayed / Incidence not known
abdominal pain / Early / Incidence not known
vomiting / Early / Incidence not known
hypersalivation / Early / Incidence not known
nausea / Early / Incidence not known

For Drug Interactions: The list is long and should be read. Some interactions include: Magnesium, Aspirin, Calcium, Vit D, etc.

WAC 246-945-*010* *Prescription and chart order—Minimum requirements.*
(3) A prescription for a noncontrolled legend drug must include, but is not limited to, the following:
(a) Prescriber's name;
(b) Name of patient, authorized entity, or animal name and species;
(c) Date of issuance;
(d) Drug name, strength, and quantity;
(e) Directions for use;
(f) Number of refills (if any);
(g) Instruction on whether or not a therapeutically equivalent

Who is keeping track of the chart order for each fluoridated patient? No one.

WAC 246-945-*005* *Commission inspections and investigations.*
§ 69.41.020. Prohibited acts -- Information not privileged communication

Legend drugs shall not be sold, delivered, dispensed or administered except in accordance with this chapter.

(1) No person shall obtain or attempt to obtain a legend drug, or procure or attempt to procure the administration of a legend drug:

(a) By fraud, deceit, misrepresentation, or subterfuge; or

(b) By the forgery or alteration of a prescription or of any written order; or

(c) By the concealment of a material fact; or

(d) By the use of a false name or the giving of a false address.

Let's think this through. Has the Board misrepresented the legend drug? Yes. Fluoridation, fluoride ingestion, requires a doctor's prescription for each patient.

Has the Board concealed a material fact? Indeed, the Board or fluoridation purveyors are indeed concealing material facts on hazard, jurisdiction, safety, label, FDA CDER approval, etc. Promoting an unapproved illegal drug as without risk, without need for prescription, by false name of the EPA rather than FDA CDER are violations of **WAC 246-945-*005***.

WAC 246-945-*005 continues:*

(2) Information communicated to a practitioner in an effort unlawfully to procure a legend drug, or unlawfully to procure the administration of any such drug, shall not be deemed a privileged communication.

(3) No person shall willfully make a false statement in any prescription, order, report, or record, required by this chapter.

(4) No person shall, for the purpose of obtaining a legend drug, falsely assume the title of, or represent himself or herself to be, a manufacturer, wholesaler, or any practitioner.

(5) No person shall make or utter any false or forged prescription or other written order for legend drugs.

(6) No person shall affix any false or forged label to a package or

receptacle containing legend drugs.

Not much in **WAC 246-945-*005*** that does not directly apply to fluoridation.

The Board must also consider. ***"WAC 246-945-030 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) Those drugs determined by the FDA to require a prescription under federal law should be classified as legend drugs under state law because their toxicity, potential for harmful effect, methods of use, or collateral measures necessary to their use indicate they are only safe for use under the supervision of a practitioner.***

(2) The commission finds that under state law, legend drugs are those drugs designated as legend drugs under federal law, as of the date of adoption of this rule, and listed in at least one of the following publications:

(a) The 39th Edition, including supplements, of the Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book" (available at https://www.fda.gov/drugs/drug-approvals-and-databases/ approved-drug-products-therapeutic-equivalence-evaluations-orange- book).

(Emphasis supplied)

I asked the whether fluoride was a drug. The FDA responded:

"A search of the Drugs@FDA database . . . of approved drug products and the Electronic Orange Book. . . does not indicate that sodium fluoride, silicofluoride, or hydrofluorosilicic acid has been approved under a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) for ingestion for the prevention or mitigation of dental decay. . . . At the present time, the FDA is deferring any regulatory action on sodium fluoride products. . ."[1] Email from the FDA (7-22-09).

Our Point: “Deferring regulatory action” does not provide assurance fluoridation is safe. Fluoride is highly toxic, a poison, exempt from poison laws when dispensed as a legend drug. Fluoride is not an approved legend drug.

Are there ways to evade protecting the public? Silence is one. Relying on an unauthorized government agency is another.

Changing the law may protect policy but does not change science, empirical evidence or protect the public health, and does not assure safety.

For 14 years the Board of Health has not answered the obvious question, “who is the practitioner under who’s license the dispensing of the fluoridation drug is dispensed to everyone without their consent?”

Or, can anyone make a drug and sell it without FDA, RCW, or WAC regulatory oversight as a “snake oil salesman” simply by diluting it in tap water? No.

A person cannot, for example, mix vodka and cherry juice with some tap water and claim it to be a miracle drug to cure all

diseases and evade all drug regulatory authority. That is precisely why Congress passed the FD&C act, to stop hucksters selling fake products like fluoridation. (Remember, I promoted fluoridation for 25 years out of dental school. That "huckster" comment hits me squarely in the face.)

The Board mentions in the letter (Attachment #G) some points in our 2010 petition go beyond the rule change request. No, the Board misunderstood. Every point in that and this petition directly relates to the petition and to assure safe tap water.

Our point: **"Fluoride is toxic and to be safe must be regulated as a prescription (legend) drug and if fluoridation cannot be assured safe, fluoridation should not be endorsed by the Board."**

An FDA and Board of Pharmacy newsletter, stated:

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 Board of Pharmacy 7/2008 Newsletter

Those promoting, advising, the mass administration of a highly toxic substance, unapproved, illegal prescription drug are certainly complicit in the harm caused to the public.

RCW 43.20.050 does not authorize the Board to simply trust endorsements, the dental lobby, or any other agency, least of all an unauthorized agency. Ignoring an authorized agency does not assure safety. The Board's job is to assure safety.

RCW 57.08.012 Fluoridation of water is authorized.

"A water district by a majority vote of its board of commissioners may fluoridate the water supply system of the water district. The commissioners may cause the proposition of fluoridation of the water supply to be submitted to the electors of the water district at any general election or special election to be called for the purpose of voting on the proposition. The proposition must be approved by a majority of the electors voting on the proposition to become effective."

RCW 57.08.012 permits fluoridation but does not exempt the Board from ensuring the water is safe and correctly approved by the authorized regulatory agency.

Pause for a moment and critically evaluate **RCW 57.08.012**. Did the legislature expect each voter to spend the hundreds/thousands of hours to carefully review the many

streams of legal and scientific evidence in detail and make judgment on the legality, jurisdiction, efficacy, safety, current dosage, desired dosage, ethics with all streams of evidence of ingesting more fluoride for their neighbors? That expectation is not real world.

For example, just because RCW permits an individual to get a driver's license, does not mean they can ignore the laws of the road or the highway and can ignore safety standards.

In the denial of our 2010 first petition, the Board, in effect agreed their authority includes determining the "safety" of fluoridation by mistakenly relying on the CDC and EPA to assure the issue of safety. We agree the Board has jurisdiction over the laws and science relating to **RCW 57.08.01**. Science is dynamic. In the last 4 decades since **RCW 57.08.012** was passed, we have more evidence to consider.

Voting on an issue often relies on those with the largest marketing budget. And public relations authority will gain many voter's approval, rather than factual evidence. The dental lobby has convinced the Board to do the marketing for them.

The Board must take endorsements for fluoridation off the internet.

Our point: The Board must not rely on each voter, the EPA nor CDC nor NTP to determine the complex science on fluoridation efficacy, dosage, safety and label.

The Board appears in violation of WAC 246-290-220

"(5) The department may accept continued use of, and proposals involving, certain noncertified chemicals or materials on a case-by-case basis, if all of the following criteria are met:

(b)There exists no substantial evidence that the use of the chemical or material has caused consumers to register complaints about aesthetic issues, or health related concerns, that could be associated with leachable residues from the material;"

The law only rises the level of " no substantial evidence." I spent over 4 decades treating aesthetic and functional dental fluorosis, a known adverse effect of excess fluoride ingestion. NHANES reports a substantial 2 out of 3 children with dental fluorosis. That is a biomarker of excess fluoride exposure.

The evidence provided here is substantial evidence of both aesthetic issues and health related concerns, risks and harm.

CONTAMINATED ADULTERATED MISBRANDED PRODUCT

There are no shortages of laws regarding unapproved illegal drugs and manufacturing, requiring pharmaceutical quality ingredients. Although fluoride is not a narcotic, good manufacturing practices apply and purity of the product applies as set forth by the U.S. Pharmacopeia.

Examples: Chapter 69.50, RCW RCW 69.40.030, Chapter 18.64 RCW, RCW 18.64.005 (7) RCW 69.50.401, RCW 43.71C.060,

The chemicals added to public water for fluoridation are contaminated waste products of manufacturing, often foreign manufactured, misbranded, often without NSF[11] assay, not pharmaceutical grade, adulterated, contaminated, not manufactured under Good Drug Manufacturing Practices (GDMP), and neither approved before marketing or inspected by the FDA CDER during manufacturing and distribution.

The substance added to public water is NOT pharmaceutical grade which is assumed in the PDR and Pharmacopeia that the

[11] National Sanitation Foundation, a private company which seldom releases purity evidence to the public.

Board of Pharmacy relied on, but rather industrial grade products such as hydrofluorosilicic acid or industrial grade sodium fluoride, both are contaminated products, often containing:

Arsenic – 90 percent of the arsenic contributed by drinking water treatment chemicals is attributable to hydrofluorosilicic acid. Source: Wang C, Smith DB, Huntly GM. Treatment Chemicals contribute to Arsenic Levels. Opflow (AWWA), October 2000. EPA's MCLG is "0" "Ingestion of inorganic arsenic in drinking water has been linked to skin, lung, bladder, kidney, prostate, and liver cancers." Oregon Dept. Human Services. Drinking Water and Environmental Exposure, 2007

Lead – EPA's MCLG is "0" Ionescu Neuro Endocrinol Lett 2006, $15B to remove - awwa

Beryllium – Increase in cancer. Taylor-McCabe, Poteomics 2006

Vanadium – Mixed results

Cadmium – Increase in breast cancer McElroy J Natl Cancer Inst. June 2006

Mercury – Cancer Increase and Neurological Disorders Ionescu Neuro Endocrinol Lett 2006

Radium – Cancer Increase Lloyd Radiat Res. 2005

Radionuclides – Cancer Increase Sevan'kaev Raiats Biol Radioecol 2006

Silicon – Probably safe

Bauxite – Mixed opinions

It is important to note that not all batches have all of these contaminants, and contaminant concentrations are usually unknown. The fluoride chemical purity is assumed by the National Sanitation Foundation (NSF), a private company who refuses to

provide assay data to the public, and at times have said they do not test each batch.

When I asked NSF how the NSF permits fluoride to be added to the water at 1 ppm, when their standards do not permit more than 10% of the EPA's MCL's 4 ppm? 10% of 4 is 0.4 ppm. The NSF told me that fluoride is the product and not a contaminant in the product. The NSF response makes no sense. I commented, if the fluoride were called any other name, would NSF permit fluoride to be intentionally added to water? The choice of a name does not change the toxicity of a product. The NSF representative on the phone went silent.

And, further, China prohibits fluoride being added to their public water. Research from China on developmental neurotoxicity was some of the earliest and motivated researchers in the USA to question claims of fluoride's developmental neurotoxicity safety and start serious research.

China has excess fluoride and their toxic fluoride waste by-product of manufacturing is shipped to the USA, which the Board of Health recommends for all of us to drink, regardless of purity or dosage, an individual's health status or choice. The Board blindly

trusts China's quality of industrial product to be safe, which China does not permit in their water.

Tell the public China's industrial waste product is being disposed of in our tap water and see if the public thinks that assures them the water is safe.

THE SAFE DRINKING WATER ACT DOES NOT PERMIT FLUORIDATION.

The Board appears in violation of the **Safe Drinking Water Act** as detailed below and Attachment #F.

Our point: The SDW Act prohibits the addition of anything to tap water to treat humans. No assurance of safety from the SDWA.

THE FOOD DRUG AND COSMETIC ACT CHARGES THE FDA TO APPROVE DRUGS.

The Board also appears in violation of the **FD&C Act** as detailed below and in Attachment #A. (Eight points below)

1. RCW 18.64.011 (14) and **[FD&C Act, sec. 201(g)(1)].**

"Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;
(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;
(c) Substances (other than food) intended to affect the structure or any function of the body of human beings or other animals; or. . . "

Fluoride is in the US Pharmacopoeia.

The intent of fluoride ingestion is not in dispute and well known to the public, to allegedly prevent dental cavities.

Neither the PHS (U.S. Public Health Service) CDC (U.S. Centers for Disease Control), nor EPA (U.S Environmental Protection Agency), have authority from Congress to approve any substance with intent to prevent, mitigate or cure disease in humans.

Our point: Congress, in the FD&C Act United States Code, Title 21, has charged the FDA with approval of substances marketed with intent to prevent disease.

The purpose of drug approval is to protect the public from harmful substances such as fluoride.

As presented above, **RCW 57.08.012** authorizes a water district board of commissioners or public to vote on fluoridation, but does not address the toxicity, efficacy or safety of fluoridation. Nor does **RCW 57.08.012** designate the agency which has jurisdictional oversight to determine the efficacy, dosage, safety and label. Nor does the **RCW 57.08.012** designate who the prescribing practitioner, who the legal intermediary must be for fluoridation.

RCW 57.08.012 does not remove the requirement for the Board to assure the public that fluoridation is safe.

Nor does **RCW 57.08.012** authorize the Board or Department to be the marketing, promotional or the advertising arm for fluoridation lobby.

Our point here is although RCW 57.08.012 permits fluoridation, determining oversight jurisdiction, science on efficacy, dosage, safety, and label was never removed from the Board's responsibility to assure safe water.

2. The FDA in 2000 responded to the Honorable Ken Calvert, House of Representatives, (See letter at Supplement #D attached) to his question #1:

"If health claims are made for fluoride-containing products. . . do such claims mandate that the fluoride-containing product be considered a drug, and thus subject the product to applicable regulatory controls?"

FDA's response:

"Fluoride, when used in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals is a drug that is subject to Food and Drug Administration (FDA) regulation . . . ."

Question #2:

"Are there any New Drug Applications (NDA) on file, that have been approved, or that have been rejected, that involve a fluoride-containing product (including fluoride-containing vitamin products). . . . "

FDA's response:

"NO NDA's have been approved or rejected for fluoride drugs meant for ingestion.. . . "

Question #3:

"Does FDA consider dental fluorosis a sign of over exposure to fluoride?"

FDA Response:

“Dental fluorosis is indicative of greater than optimal ingestion of fluoride. In 1988, the U.S. Surgeon General reported that dental fluorosis, while not a desirable condition, should be considered a cosmetic effect rather than an adverse health effect. Surgeon General M. Joycelyn Elders reaffirmed this position in 1994.”

Question #4:

“Does FDA have any action-level or other regulatory restriction or policy statement on fluoride exposure aimed at minimizing chronic toxicity in adults or children?

FDA Response:

“The monograph for OTC anticaries drug products sets acceptable concentrations for fluoride dentifrices, gels and rinses (all for topical use only). This monograph also describes the acceptable dosing regimens and labeling including warnings and directions for use. FDA's principal safety concern regarding fluoride in OTC drugs is the incidence of fluorosis in children. Children under two years of age do not have control of their swallowing reflex and do not have the skills to expectorate toothpaste properly. Young children are most susceptible to mild fluorosis as a result of improper use and swallowing of a fluoride toothpaste. These concerns are addressed in the monograph by mandating maximum concentrations, labeling that specifies directions for use and age restrictions, and package size limits.”

3. Also see attached FDA letter, Supplement #C and note that accepted fluoride containing dentifrices contain the warning “do not swallow.”

4. Children may swallow half the fluoride toothpaste they use which contains 1,000 to 1,500 ppm fluoride.

I watched my 11-year-old daughter brush her teeth one night. She objected saying she knew how to brush her teeth and didn't need her daddy dentist to watch. I said I wanted to watch to be sure she did not swallow before rinsing. She leaned over the sink and I saw her little "Eve's apple" bob up and down and she then spit. The reflex of swallowing first at 11 was still strong. Children swallow toothpaste, estimated in research as often half the toothpaste they use.

5. The fluoridation lobby will object to the suggestion for FDA CDER NDA, in part, on the grounds that fluoridated bottled water is approved at 0.7 mg/L by the FDA.

Not so fast. We can learn about safety from bottled water. There are two main sections to the FDA: CFSAN (Center for Food Safety and Applied Nutrition) (Food), and CDER (Center for Drug Evaluation and Research) (Drug).

[See Supplement #B attached (stamped Exhibit 4) which is a 2006 letter from CFSAN the "Food" side of the FDA, not the Drug side.]

Supplement manufacturers would like to make health claims and the FDA CDER had stopped them. The supplement lobby went to Congress and was able to get a law to state in part:

"a manufacturer may submit to the . . . FDA a notification of health claim based on an authoritative statement from an appropriate scientific body of the United States Government or the National Academy of Sciences or any of its subdivisions."

The law firm Covington and Burling NOTIFIED the FDA that a health claim would be made for fluoridated bottled water and a claim of reduced risk of dental caries. It is important that the Board of Health understand that bottled water with fluoride did not gain FDA CDER approval. Rather the "food section of the FDA" was "NOTIFIED."

No science was provided to the FDA on efficacy, dosage, total exposure, label or safety. And no empirical evidence, facts, were provided on risk factors, margin of error or safety. Zero science, just "notification." The only evidence was endorsements by the CDC (2001), Surgeon General (2000) who heads the Public Health Service and the Public Health Service (1991).

Neither the Surgeon General, nor the Public Health Service, nor the Centers for Disease Control, nor the FDA's Center for

Food Safety and Applied Nutrition (CFSAN) nor does the Washington State Board of Health have drug approval authority.

Our Point: Writing new laws does not change the empirical factual scientific evidence and does not assure the safety of the poison/legend drug.

The FDA Warning letter (See Attachment #B) has a concentration range of 0.6 to 1.0 mg/L which in 2022 FDA food section lowered to 0.7 mg/L. The letter states,

*"The language is: "Drinking fluoridated water **may** reduce the risk of [dental caries or tooth decay]."* [emphasis provided]

The FDA language says, "MAY." Until the FDA CDER provides more confidence, "may" is a reasonable word. Of course, fluoride ingestion may not reduce dental caries. The FDA had, in 1975, determined the evidence of efficacy of fluoride ingestion was incomplete.

In contrast, the Board of Health is certain and confident that fluoridation reduces an amazing 25% of tooth decay, the Board states: ***Water fluoridation reduces tooth decay by about 25 percent over a person's lifetime."***

The FDA warning letter (See Attachment #B) continues:

"In addition, the health claim is not intended for use on bottled water products specifically marketed for use by infants."

This Petition to the Board of Health is in keeping with the Food section of the FDA, to protect infants.

The second FDA WARNING LETTER in #B, in part states,

"your product label has serious violations. . . Your product is misbranded. . . bears an unauthorized health claim in its labeling." "Health claims may not be made for food products, including bottled water, for which the label represents or purports that the food is for infants or toddlers less than two years of age. . . ."[12]

The FDA continues: *"In addition, we have the following comments:*

The serving size of your Nursery Purified Water product is based on 8 fluid ounces. While the FDA has not established a reference amount customarily consumed (RACC) for water by infants and toddlers, we recommend that you use the infant and toddler RACC for juices, which is 4 fl oz."

[12] Supplement #B attached has a second **"WARNING LETTER"** stamped as Exhibit 5 dated 2009, from the FDA PHS to CEO's at DS Waters of America, LP regarding "NURSERY Purified Water with added fluoride."

Even though the FDA was “notified,” and had no authority to refuse, the FDA cautiously added in effect the beginning of a label and a reduction in dosage, 4 fl oz. Did industry comply. . . no.

Our Point: At a minimum the Board should start a label of caution and warning which our petition intends.

6. In June, 1975, Drug Therapy reported the FDA had rejected 35 new drug applications for fluoride/vitamin combinations because*: **“There is NO substantial evidence of drug effectiveness as prescribed, recommended, or suggested in labeling.”***

The FDA CDER is still correct. Almost 80 years of fluoridation, only one randomized controlled trial on fluoride ingestion has been published. And that was on pregnant mothers, reporting no statistical benefit for their infants. None published using fluoridated water.

I applied and received FDA approval for a dental device which is less stringent than for a drug. The FDA was fair, strict, strong, scientific and raised my confidence in their efforts to protect the public. They have my respect. The Board would begin to assure safety by following the FDA CDER’s advice and label.

Our point: The efficacy of fluoride ingestion is still incomplete.

7. At first, “lack of efficacy” stuck in my throat in disbelief. For me, the paradigm shift was extremely difficult. I was confident I could see benefit in my patients. But the science convinced me, I had been wrong. For example, my rich patients had better oral health. Socioeconomics is a confounder. I had given fluoridation credit for the rich having better health.

8. A Board member mentioned they are not supposed to have to review the science.

For drugs, well said, I agree. Drug approval is not part of the Board’s job, but ensuring the drug has been properly approved is part of the Board’s job, and the Board must assure safety.

THE BOARD’S DENIAL OF OUR 2010 PETITION

The Board of Health letter June 9, 20010, denying our petition to protect the public health, see attachment #G WA-board-of-health-memo-6-9-10, stated: (Letter quotes in brown)

“Motion: The Board denies the petition for rule making from Dr. William (sic) Osmunson dated May 11, 2010 because the US Food and Drug Administration has a memorandum of

understanding with the U.S. Environmental Protection Agency clarifying that the latter agency has authority for regulating tap water."

1. EPA & FDA MOU (Memorandum of understanding)

The Board was misdirected or misunderstood, believing the EPA had jurisdiction over drug approval ensuring fluoridation was: effective, correct dosage, with a protective label**.** See Attachment #F, February 14, 2013, EPA Letter

Steven M. Neugeborn, Associate General Counsel, Water Law Office, U.S. Environmental Protection Agency, regarding the status of an MOU between EPA and FDA states [highlight supplied] in part:

"Your first question is whether, from the viewpoint of EPA, the purpose of a 1979 Memorandum of Understanding (MOU) between EPA and the Federal Drug Administration (FDA) was 'to take away from FDA, and give to EPA, responsibility for regulating public drinking water additives intended for preventative health care purposes and unrelated to contamination of public drinking water?' Your second question is whether, if that was the purpose of the 1979 MOU, the MOU was terminated through a subsequent Federal Register notice.

"The answer to your first question is no, so there is no need to address your second question. The purpose of the MOU was not to shift any responsibilities between the Agencies. Rather, it was to help facilitate effective coordination of our respective legal authorities. . . . EPA does not have responsibility for substances added to water solely for preventative health care purposes, such as fluoride, other than to limit the addition of such

substances to protect public health or to prevent such substances from interfering with the effectiveness of any required treatment techniques. . . . The Department of Health and Human Services (HHS), acting through the FDA, remains responsible for regulating the addition of drugs to water supplies for health care purposes.

"The 1979 MOU was intended to address contamination of drinking water supplies as a result of direct or indirect additives to drinking water, not to address the addition of substances solely for preventative health purposes. . . ."

The basis for the Board's motion to deny our petition in 2010 is, in part, jurisdictionally incorrect. The FDA, not the CDC or EPA has jurisdiction over substances used with intent to prevent disease.

2. The Board's Denial of our petition to gain FDA CDER approval also includes:

"The Board has authority . . . to adopt rules for Group A public water supplies 'necessary to assure safe and reliable public drinking water and to protect public health.. . ."

"RCW 57.08.012 gives each water district the authority to decide whether to ask the electors of the water district to vote on adding fluoride to its tap water. The Board does not appear to have authority to adopt rules related to a water district deciding whether to fluoridate. The Board's authority is to regulate allowable concentration levels and method of approval of water additives.

The Board appears to accept jurisdiction to adopt rules for Group A public water supplies, and we agree.

However, *"the state board of health shall:*

*(a) Adopt rules for group A public water systems, as defined in RCW **70A.125.010**, necessary to assure safe and reliable public drinking water and to protect the public health."*

We will demonstrate below, fluoridation is not safe.

3. The Board's letter continues:

"The Board has adopted under WAC 246-290-460 an allowable concentration range for artificial fluoridation of public tap water. This range is 0.8-1.3 ppm and is based on the Centers for Disease Control and Prevention (CDC) "optimal" recommended levels to help prevent tooth decay."

The Board of Health has accepted concentration but not dosage. Concentration is not dosage because some drink little or no water, others 10 times the mean and not everyone is the same size or health, intraspecies variation. Determination of safety cannot be based on concentration.

The Board is mistaken when relying on the CDC to determine the "optimal" range or dosage of any drug with intent to prevent disease. CDC has no authority to recommend any unapproved drugs.

The letter goes on in detail on why fluoridation is set at a target of "0.7-1.2 ppm to help prevent cavities" and the Board's standard at 0.8-1.3 ppm in WAC 246-290-460. Clearly, the "intent

of use" defines fluoride as a drug which is unapproved and unapproved drugs are illegal and regulated by the FDA CDER, NOT the CDC or EPA..

Even if fluoridation were effective at 1 ppm, what evidence does the Board have that fluoridation is effective at 0.7 ppm? The Board claims a historical 25% reduction in dental caries at 1 ppm fluoride in water. What evidence does the Board have the same effect happens at 0.7 ppm?

The letter of denial continues, listing endorsements from the CDC, surgeon general, and dental lobby Ned Therien and William Bailey.

As you watch Fluoride On Trial: The Censored Science on Fluoride and Your Health | Childrens Health Defense

note the Dental director of the CDC when under oath was unable to cite research demonstrating efficacy of fluoridation. No evidence of efficacy? He was prudent and correct.

Neither efficacy, dosage, safety or label is the job of the CDC and has not been approved by the FDA. The director ended the questions before he was taken down a rabbit hole of problems

on the lack of evidence of fluoride ingestion's efficacy. The Director saved the CDC's "bacon" by not suggesting he had evidence to support fluoridation. He does not have good evidence.

Our point: The Board would be wise to no longer reference the CDC or EPA for efficacy of fluoride ingestion.

4. The Board's letter of denial continues with the 1979, EPA, FDA MOU as discussed above and supported by our attachment #F. The Board talked to Ned Therien EPA and John Kelsey DDS at the FDA. Both confirmed EPA regulates water. (silence on drugs)

The Board did not appear to push John Kelsey and specifically ask whether diluting a drug in tap water removes FDA CDER jurisdiction and places the jurisdiction with the EPA. Indeed, EPA regulates tap water, FDA CDER regulates drugs.

When the tap water is used to make a drug, the FDA CDER still has jurisdiction over the drug. See our attachment #F EPA letter.

5. The Board's letter of denial continues with support for the mass medication of everyone without consent based on **endorsements** from the dental lobby and those profiting from

fluoride sales. What science on efficacy, dosage, safety and label does the Board provide? The Board is silent.

6. The Board's letter (#G) of denial continues:

- *"EPA is lead federal agency for regulating maximum levels of contaminants and additives in tap water under the Safe Drinking Water Act."*

Yes, for maximum levels of the fluoride contaminant, but not to determine the efficacy of the drug or for drug manufacturing oversight. Simply diluting a drug in tap water does not change jurisdiction to the EPA.

The Safe Drinking Water Act states*:*

"No national primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water."

I wrote to the EPA to ask for their understanding of that section of the SDWA, and the EPA responded:

"The Safe Drinking Water Act prohibits the deliberate addition of any substance to drinking water for health-related purposes other than disinfection of the water." HQ-FOI-01418-10

Our point here in simple terms: **"The Board must not promote what the SDWA prohibits."**

8. The Board's denial letter continues:

- *"FDA has relinquished any authority it might have for regulating fluoride levels in tap water under the memorandum of understanding with the EPA"*

See our attachment #F EPA water law office: . . . . *The Department of Health and Human Services (HHS), acting through the FDA, remains responsible for regulating the addition of drugs to water supplies for health care purposes."*

The Board assumes the FD&C Act permits the FDA CDER to delegate authority for drug approval and regulation to any agency, let alone an unauthorized agency.

9. The Board's Denial states:

- ***"The Board cannot direct a federal agency to take action."***

Our petitions have never petitioned the Board to direct a federal agency to take any action. A "New Drug Application" is not "direction" and this petition should, but as a compromise does not request the Board to make NDA or require the water purveyors who are the final drug manufacturers to gain NDA. This petition focuses on assuring safety.

10 The Board's Denial states:

- *"The State Board of Pharmacy has stated it cannot regulate tap water fluoridation under its authority."*

Our petitions have not asked the Board of Pharmacy to regulate tap water but to designate fluoride as a poison as provided by RCW. The Board of Pharmacy did not play games with us. The Board of Pharmacy was professional and went directly to the focal intent of our request. Fluoride is a legend drug.

11. The NRC 2006 report:

- *"An NRC committee evaluated the scientific evidence of the health effects of fluoride in drinking water and published a report in 2006 that concluded fluoride levels in drinking water below 2 ppm are safe for health."*

The Board does not provide a correct understanding of the NRC 2006 report. Dr. Robert J. Carton, PhD, with over 30 years writing regulations for the federal government and worked for 20 years at the EPA wrote the first regulations on asbestos. His review of the NRC 2006 report is the most concise and clear review.

"The committee apparently believed that it was their mission to identify only health effects known with total certainty. . .
Dental fluorosis: *the committee agreed it is a "dose-related mottling of enamel, which is permanent once a child's teeth are formed. It is described as a toxic effect. . . . taking moderate dental fluorosis into account, the MCLG would be lower than 0.7 mg/L "*

Bone Fractures: *Hip fractures above 1.5 mg/L. "What is not discussed is the magnitude of the safety factors necessary to insure protection from anticipated adverse health effects."*

Skeletal Fluorosis*: EPA used Stage III severe fluorosis as a baseline, the NRC 2006 committee included Stage II as an adverse health effect. "Thus we have a possibility of Stage I and Stage II occurring with a daily dose over a lifetime of 1.42 mg and 2.86 mg, respectively. These are both within the range of current fluoride exposures from all sources documented in the NRC report."*

Endocrine Effects: *Decreased thyroid function, impaired glucose tolerance (Type II diabetes), and earlier sexual maturity. The Executive Summary of the report merely states that these effects are achievable with fluoride concentrations in drinking water of 4 mg/L or less.. . .*

NRC report summary at the end of the chapter, "In humans effects on thyroid function were associated with fluoride exposures. . . 0.01-0.03 mg/kg/day when iodine was inadequate."

Mean intake of water is1 liter of water a day at 0.7 mg/kg is 0.7 mg. However, pregnant mothers do and should drink more, often 3 liters/day and some drink 10 liters/day. The additional fluoride hits the fetus exactly at a most vulnerable time for the developing brain.

Assuming half the total fluoride intake is from water and half from other sources, intake would be 1.4 mg/day for the mean and almost 3 mg/day for a pregnant mom. A 70 kg person would ingest between 0.2 – 0.4 mg/kg/day, well within the effects of fluoride intake for many if not most people. What about the 90th

percentile drinking 2L/day or those drinking 10L/day? And what about those ingesting more toothpaste or having a general anesthesia? All of those are far outside the statistical mean. And no margin of error or safety factor is included.

The dental lobby had and has not seriously researched safety for most health risks. An authoritarian claim of "safe and effective" had everyone trusting each other and no one researched to be sure.

Carton continues:

"Thus, there exists a lowest observed effect level of 0.06 mg/L of fluoride to develop an MCLG using the preventative approach of the Safe Drinking Water Act. . . An appropriate safety factor does not have to be mentioned to see clearly that fluoridation at 1 mg/L cannot be considered acceptable for an MCLG."

Carton ends his conclusion: *"Using the preventive public health intent of the law, the Maximum Contaminant Level Goal for fluoride in drinking water should be zero."*

Our point: to protect the public from harm, the Board of Health should recommend the cessation of fluoridation.

12. Back to the Board of Health's denial of our petition:

- ***"EPA announced completion of a review of MCLs . . . that concluded it did not have evidence to revise the MCL for fluoride."***

That is politically true, but not based on their scientific evidence.

Instead of protecting the public, EPA did the opposite of the NRC 2006 recommendation and protected fluoride by changing the definition of "safe" and eliminating many high-risk individuals. Even then, their data does not demonstrate safety.

The Board fell into the trap of political jargon, lacking empirical evidence.

13. The denial letter continues:

- *EPA will be conducting additional reviews regarding fluoride levels in drinking water.*
- *EPA recognizes NSF/ANSI Standard 60 as appropriate for the approval of drinking water additives*
- *The range of 0.8 ppm to 1.3 ppm fluoride in WAC . . . .*

The current TSCA court trial and the NTP report have brought out additional political pressure from the dental/industry lobby, blocking the protection of the public health. The video we asked you to watch covers some of the political influence.
NTP report on developmental neurotoxic effect is covered below.

14. The Board's denial letter concludes:

The Committee further recommends the next time the Department undertakes a major review of chapter 246-290 WAC, it consider proposing the word "optimal" in section 460(3) be changed to a phrase such as "generally regarded as safe." The Committee further recommends the Board continue to review legal points raised in the petition concerning state law and Attorney General opinions.

Those recommendations do not appear to have been followed.

The letter and Board's web page now clearly states the intent of administering fluoride is to reduce dental caries, claiming fluoridation reduces dental caries by 25%. The health claim confirms intent and intent confirms jurisdiction is with the FDA CDER.

The Board relies on the fluoridation lobby and does not provide empirical evidence to support their claim of health benefit. However, the preventive health claim confirms the Board knows fluoride, because of intended use, Board of Pharmacy, FDA CDER, and listed in the U.S. Pharmacopeia, is a drug, legend drug. See: Washington State Board of Pharmacy, RCW 18.64.011(14) and 21 U.S. Code § 321 and FDA

THE ETHICS OF VOTING TO MEDICATE OUR NEIGHBORS

What does the Legislature mean to “assure safety?”

The Oxford Dictionary defines assure:

“tell someone something positively or <u>confidently</u> to <u>dispel</u> any <u>doubts</u> they may have.”

The Legislature did not require absolute proof of harm or even mention efficacy (benefit).

The Legislature charged the Board to be confident the water is safe and, in effect, be able to assure the public without doubt the water is safe.

Board members need to be able to publicly say, “I have reviewed all streams of evidence and can assure the public fluoridation is safe for everyone. And if the Board members are not confident that they can dispel all doubts in their own minds that the water is safe for everyone, then the Board must take steps to assure safety of the water. That is your ethical job, your mandate. We the public are relying on your confidence, that you have reviewed laws and science. The job is not to be delegated, that is your job to assure the public the water is safe.

We have covered parts of ethics in each section. Voters rely on water commissioners, the Board, and Department to dig into the evidence with due diligence to assure safety.

THE BOARD OF HEALTH'S EXISTING RULES DO NOT ASSURE SAFETY

Health must be built on science.

The Board of Health has no caution, warning, label, dosage, or safety evidence. Safety for all is not assured.

The product is misbranded, adulterated, and contaminated. This petition takes the first step to protect some in the public with a simple label. This petition is a compromise.

The Board of Health would be correct to advise the manufacturers of fluoridated water, purveyors, such as Seattle, to at a minimum place a label on the product (billing, etc.)

If Seattle applied to the FDA, and the fluoridated drug approved, Seattle could then patent the product and make enough money to house the homeless and pay for their dentistry and

more. Circumventing the law is costly to the public's health and finances.

Our point: The Board must first assure safety in their own minds for their own family and then assure safety for everyone else. Remove your endorsement of fluoridation off your website.

*"According to the **U.S. Food and Drug Administration (FDA)**, unapproved prescription drugs pose significant risks to patients because they have not been reviewed by FDA for safety, effectiveness or quality. Without FDA review, there is no way to know if these drugs are safe and effective for their intended use, whether they are manufactured in a way that ensures consistent drug quality or whether their label is complete and accurate[1].*

If your doctor prescribed a non-FDA approved drug, it is important to discuss the risks and benefits of the drug with your doctor. You may also want to ask your doctor if there are any FDA-approved drugs that could be used to treat your condition. If you have suffered serious side effects from a non-FDA approved drug, you may have a claim against your physician and the drug manufacturer[2].
Please note that the FDA permits some unapproved prescription drugs to be marketed if they are relied on by health care professionals to treat serious medical conditions when there is no FDA-approved drug to treat the condition or there is insufficient supply of FDA-approved drugs[1]." Reference 1 is fda.gov, 2 is liljegrenlaw.com[13]

[13] This quote appears to be a Bing AI generated report to my question regarding the prescribing of unapproved drugs. A correct statement, but not generated by me.

SCIENCE:

DENTAL CARIES ARE NOT HIGHLY LETHAL OR CONTAGIOUS.

Dental caries is very common, can become very painful, disfiguring, disabling, but are not considered highly lethal nor contagious and treatment is usually considered elective.

Fluoride is not considered an essential nutrient and has no physiologic or minimum daily requirement.

Public Health Authorities have police powers to prevent highly contagious and lethal diseases from harming and spreading throughout the public. As we have seen with the COVID vaccinations, the public has serious reservations when asked to blindly trust my public health profession, even with approved drugs for highly lethal contagious diseases.

Our point: Dental caries is not considered highly contagious or lethal, I was taught dental treatment is almost always elective.

A. Recommended Dosage

Without FDA approval for efficacy, dosage is speculation and unknown.

"The recommended optimal fluoride intake for children to maximize caries prevention and minimize the occurrence of dental fluorosis is often stated as being 0.05-0.07 mg/kg/day." (Levy 1994; Heller et al. 1999, 2000).

Burt (1992) attempted to track down the origin of the estimate of 0.05-0.07 mg/kg/day as an optimum intake of fluoride but was unable to find it." National Research Council 2006 p 68. See a Review by Carton a former EPA scientist.

"Hodge (1950) studied children consuming fluoride in their drinking water. Fluoride levels of 0-14 ppm were investigated. Dental mottling was the parameter of interest. Fluoride levels of 2-10 ppm produced a linear dose- response curve (increasing mottling with increasing dose). Fluoride levels of 0.1-1.0 ppm produced no observable effect. An assumption of 20 kg bw and 1 L/day water consumption for children was used, since the children studied were 12-14 years old. It is further assumed that a 20-kg child consumes 0.01 mg of fluoride/kg bw/day in the diet (50 FR 20164). Thus, a total intake would be approximately 0.06 mg/kg/day. " http://www.epa.gov/IRISsubst/0053.htm#oralrfd

B. As a side note, the EPA has used 0.06 mg/kg/day as their reference dose for the fluoride contaminant in water until about 2010. The NRC 2006 report on fluoride in water (covered in more detail below) told the EPA their MCL was not protective. Instead of protecting the public, the EPA changed their definition of safe, "RfD" or safe dose to 0.08 mg/kg//day, the opposite recommended by the EPA.

Changing the definition, doing the opposite of the NRC 2006 recommendation, did not change the science or assure safety.

C. The fetus, infants, and those drinking more than the 90th percentile were ignored. The only possible risk considered publicly in 1950 was severe dental fluorosis. But they knew much more as evidenced by the release of classified documents from the time. Watch: the Fluoride On Trial: The Censored Science on Fluoride and Your Health | Childrens Health Defense and the NTP 2023 report on fluoride. Ignoring 10% of the population does not assure safety.

D. HHS ASTDR in 2003 suggested infants AI (Adequate intake) be 0.01 mg/day or 0.0014 mg/kg/day, the same as recommended in 1950. (See IOM's Table 2-1)

Mean concentration of mother's milk has been reported at 0.004 mg/L for samples where fluoride was detected, reasonably consistent for infants as suggested by HHS ASTDR.

How much fluoridated water is 0.0014mg/kg/day for a 3 kg (6.6 pound) new born exclusively on formula 3 kg X 0.0014 mg = 0.0042 mg. 0.7 mg/L fluoride in water divided by 0.0042 is 0.006 L of water or about 2.9 teaspoons of food made with fluoridated water per day for the infant.

Our point: An infant needs more than 2.9 teaspoons of food a day. Note: The Institute of Medicine's AI is "Adequate

Table 2-1. Adequate Intake Levels for Fluoride[a]

Age range	Adequate intake level (mg/day)	Adequate intake level (mg/kg/day)[b]
0–6 months	0.01	0.0014
6–12 months	0.5	0.056
1–3 years	0.7	0.054
4–8 years	1	0.045
9–13 years (males and females)	2	0.05
14–18 years (males)	3	0.046
14–18 years (females)	3	0.053
>18 years (males)	4	0.052
>18 years (females)	3	0.049

[a]Source: IOM 1997
[b]mg/kg/day doses were calculated by using reference body weights reported by IOM (1997)

Intake" and does not reflect a safe dosage and the AI was their best guess/estimate assuming fluoride was effective.

E. Mother's milk provides about 150 to 250 times **less** fluoride than formula made with water at "optimum" fluoride concentrations. In other words, infants bottle fed formula made from fluoridated water have the greatest risk of being overdosed with fluoride.

F. What about the fetus? Although the mother's body protects their milk and infant from significant fluoride, in contrast, fluoride passes through the placenta to the fetus and has been measured in fetal brain. Although the Board claims fluoridation safety has many studies, in reality, not much research is available on the effect of fluoride to every cell, tissue, organ and system of adults, let alone the fetus.

The fetus has another source of fluoride. Human bone retains fluoride and the concentration increases with age. Ranges I've seen are 1,000 ppm (similar to toothpaste at 1,500 ppm) to 8,000 ppm reported in cancer patients.

The bone resorbs (osteoclasts) and builds up (osteoblasts) throughout life. The half-life of fluoride in bone is about 20 years. In other words, if a person stopped all fluoride intake for 20 years, the fluoride concentration in the bone would be about half.

The fetus during the final trimester of life needs lots of calcium and in a deficient intake of calcium, the mother's bones resorb to provide the calcium. As the bone is broken, fluoride is released and increases the burden of fluoride on the fetus at the same time the fetal brain is developing.

The fetal brain goes through essential stages of development. If the stages are interrupted, the brain may never recover and fully develop.

For optimal development of the brain, the mother should start out with a low fluoride bone concentration.

Our petition takes this source of fluoride into consideration and we recommend the mother have low fluoride exposure starting at least 20 years prior to pregnancy.

More on this below

G. **Too many are ingesting too much fluoride,** as evidenced by 2 out of 3 children showing a biomarker of having ingested too much fluoride, dental fluorosis,[14] and the EPA's Dose Response Analysis for Non Cancer Effects and Fluoride Exposure Relative Source Contribution of 2010. EPA Figure 8-1 below is

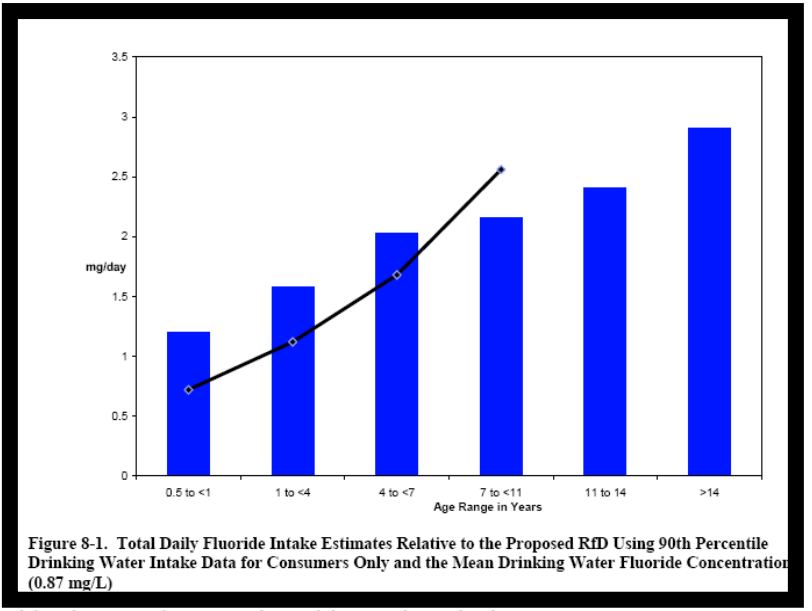


Figure 8-1. Total Daily Fluoride Intake Estimates Relative to the Proposed RfD Using 90th Percentile Drinking Water Intake Data for Consumers Only and the Mean Drinking Water Fluoride Concentration (0.87 mg/L)

critical to understand and keep in mind.

[14] Neurath C, Limeback H, Osmunson B, Connett M, Kanter V, Wells CR. Dental Fluorosis Trends in US Oral Health Surveys: 1986 to 2012. JDR Clin Trans Res. 2019 Oct;4(4):298-308. doi: 10.1177/2380084419830957. Epub 2019 Mar 6. PMID: 30931722.

The proposed mean intake/dosage is shown in mg/day represented by the blue lines for each age group. The black line is the proposed (which was adopted) RfD (maximum safe dose) for each age.

#1. Note: about a third of infants 0.5 to <1 year of age are ingesting too much fluoride. The EPA's estimate indicates about 20,000 infants at this age are ingesting too much fluoride in Washington State.

#2. Note**: Infants, birth to six months of age are omitted, ignored, unprotected.** All under six months on formula made with fluoridated water would exceed the RfD.

RCW does not exempt infants under six months of age from Board protection. New parents are busy and should not be expected to do rigorous research on the toxicology of fluoride.

#3. Note: 10% of the public drinking the most water are not included, about 330,000 directly on fluoridated water and the "halo" effect reaches many more. EPA only includes up to the 90th percentile of the public in their calculations. The EPA/Board

is totally ignoring 10% of the 3.3 million drinking the most water. RCW does not exempt the Board from protecting thee people.

#4. The fetus is ignored. That is all of us. . . at one time. The most vulnerable infants are ignored by the EPA, unprotected. No wonder research demonstrates breast feeding is superior, lack of fluoride maybe one contributing factor.

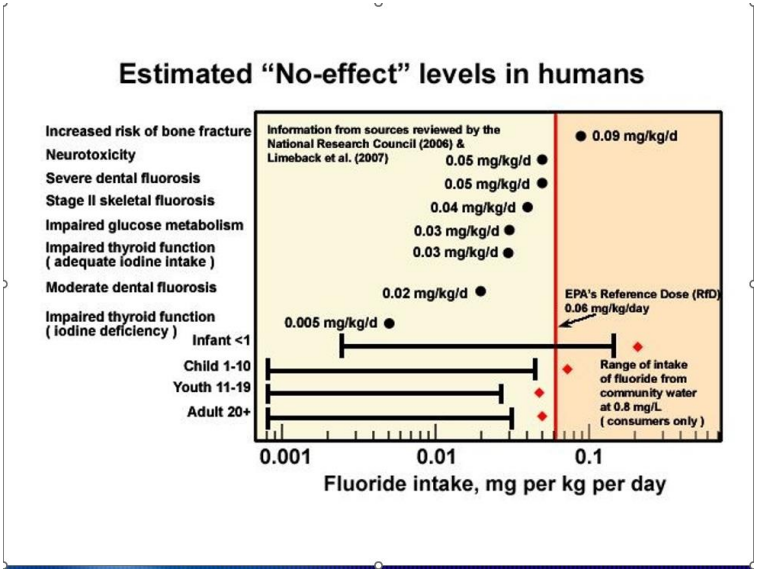
#5. Note: the "Proposed RfD" is a third higher. EPA was proposing a "safe" dosage from 0.06 mg/kg/day to 0.08 mg/kg/day and the new higher RfD, opposite the NRC 2006 recommendation, was adopted.

#6. And also remember, for Fluoride, the EPA's margin of error, uncertainty factor, intraspecies variation, is "0". The EPA is certain all humans fit in the "mean" or "average."

Our point: NRC (2006) said MCL is not safe. Instead of protecting the public, the EPA protected the contaminant and changed the definition to protect policy rather than the fetus, infants, and children. The EPA did the opposite of the NRC 2006 recommendation.

Parents give children 6 to 7 times more fluoride toothpaste than the recommended “pea size,” and 40% don’t know about the recommended amount of toothpaste.[15]

The NRC 2006 report estimated a “no-effect” level for humans about two decades ago with the following summarized evidence:



[15] Sudradjat, H., Meyer, F., Fandrich, P. *et al.* Doses of fluoride toothpaste for children up to 24 months. *BDJ Open* **10**, 7 (2024). https://doi.org/10.1038/s41405-024-00187-7

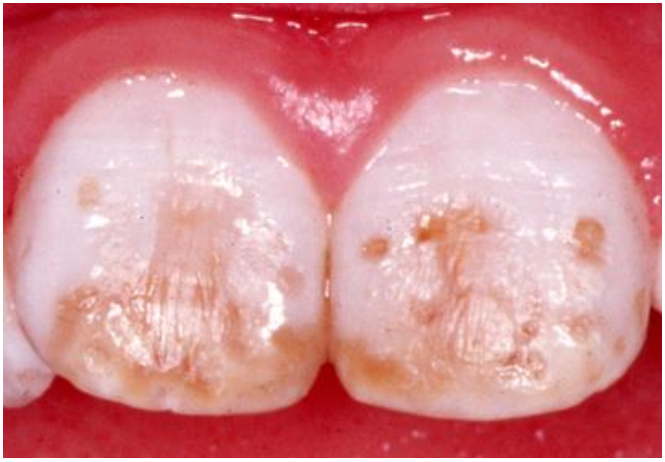
In 2006, we had fair evidence fluoridation was harming many with bone fractures, neurotoxicity, dental and skeletal fluorosis, impaired glucose metabolism, impaired thyroid function, moderate dental fluorosis and impaired thyroid function with iodine deficiency all within the range of fluoride exposure.

We brought these risks to the Board's attention in 2010 and the Board failed to protect the public. No wonder the EPA scientists said, through their union, fluoridation borders on a criminal act of governments.

EPA's THRESHOLD OF HARM

The EPA uses crippling skeletal fluorosis, like these people

Or pitting of teeth like this picture as the threshold of harm from fluoride ingestion.



Harm for the EPA does not start till severe structural damage has occurred.

Obviously, the EPA threshold of harm and the Board's, assuring safety, are not the same the same level of confidence.

The question the EPA fails to answer and the Board must answer,

"is there any harm detected before crippling skeletal fluorosis and severe dental fluorosis?"

The answer is a resounding "YES."

The fluoridation lobby dismisses the harm as "cosmetic blemish."

The EPA appears to refuse to consider any other risks from excess fluoride exposure even though they have paid researchers to provide the evidence.

Our point: The EPA must not be trusted to assure safety.

RCW instructs the Department to have aesthetic concerns as a threshold and in contrast the EPA has severe harm as a

threshold for concern. And RCW puts the threshold of harm at assuring without doubt fluoridation is safe.

Both aesthetic and health harm is reported from fluoride

The EPA in 2011 provided "Questions and Answers on Fluoride." None of the questions and answers deal with the effectiveness or effectiveness dosage of fluoride. Silence.

EPA does not weigh the benefit/risk of fluoridation. They simply protect the contaminant so those choosing may.

HOW MUCH FLUORIDE DOES A PERSON INGEST AND HOW MUCH WATER DO THEY DRINK?

Although the concentration of fluoride in water is well controlled, the amount of water ingested is highly variable and thus the dosage is highly variable.

In effect, the Board must NOT use the "statistical mean" or the EPA's RfD or the IOM's AI as a reasonable dosage of fluoride to protect everyone.

Foods can contain a significant amount of fluoride, especially some teas and foods such as mechanically deboned meat.[16]

The EPA and NRC (2006) reports the median intake of water is about 1 L/day. 90th percentile at about 2 L/day. Some drink over 10 liters/day. The NRC (2006) also reported **2-4 yr. olds ingest 0.125-0.3 mg fluoride per brushing, 2 times as much as from food and water combined and 75% more fluoride ingested for**

[16] Fluoride Content of Foods Made with Mechanically Separated Chicken | Journal of Agricultural and Food Chemistry (acs.org)
finalfluoridedatabase.pdf (tees.ac.uk)
Fluoride concentrations of infant foods - University of Iowa (uiowa.edu)

those who do not rinse. No wonder dental fluorosis, a biomarker of excess fluoride exposure has gone up to 70% of children.[17], [18]

This petition is to start protecting our most vulnerable.

Although water is most often the largest amount of individual fluoride exposure and toothpaste usually comes in second (or 1st), many other sources of fluoride affect individual exposure.

PROFUME: Ellen Connett has a brief history of a new fluoride product, Profume. Note: if a pesticide or drug has the letter "f" or letters "fu" in the name, it probably contains fluoride. The residue of fluoride on food when "Profume" is applied can be very high, although not all foods are treated. Her report includes:

[17] Neurath C, Limeback H, Osmunson B, Connett M, Kanter V, Wells CR. Dental Fluorosis Trends in US Oral Health Surveys: 1986 to 2012. JDR Clin Trans Res. 2019 Oct;4(4):298-308. doi: 10.1177/2380084419830957. Epub 2019 Mar 6. PMID: 30931722.

[18] Dong H, Yang X, Zhang S, Wang X, Guo C, Zhang X, Ma J, Niu P, Chen T. Associations of low level of fluoride exposure with dental fluorosis among U.S. children and adolescents, NHANES 2015-2016. Ecotoxicol Environ Saf. 2021 Sep 15;221:112439. doi: 10.1016/j.ecoenv.2021.112439. Epub 2021 Jun 22. PMID: 34166938.

“. . . EPA approved two “tolerances” (permitted levels in or on food): one for Fluoride levels and the other for Sulfuryl Fluoride levels. See the tolerances approved for food by US EPA as of July 15, 2005.

. . . FAN submitted comments and formal Objections and then in 2004 and 2005 EPA approved its use with high fluoride levels on all processed food, beans, grains, flour -and much more, including a fluoride residue of 900 ppm on dried eggs!

Incredibly, after many years of hard work, in January 2011, EPA concluded that it agreed with all but one of our objections and published their proposal to phase-out sulfuryl fluoride. According to protocol, EPA simultaneously solicited public comments on the phase-out. That was when the Dow Chemical Company, the proprietary owner of Sulfuryl Fluoride, did everything a powerful corporation can do to dissuade EPA from enacting the phase-out. They successfully lobbied Congress to add a few short sentences to the Farm Bill of 2014 that nullified the phase-out. . . .”

There are many sources of fluoride, water and dental products provide the most for many people. However, fluoride in foods such as mechanically deboned meat, tea, wine and medications, may provide significant dosages of fluoride to sub-populations.

GENERAL ANESTHESIA: especially for infants and children:

Characteristics of Anesthetic Agents Used for Induction and Maintenance of General Anesthesia
". . . desflurane (halogenated solely with fluorine halogenation increases potency and is essential to ensure nonflammability), halothane (halogenated with fluorine, chlorine, and bromine), isoflurane (halogenated with fluorine and chlorine), and sevoflurane (halogenated solely with fluorine). Halothane was the first fluorinated inhaled anesthetic that was wildly successful, rapidly displacing all other potent inhaled anesthetics. Efforts to develop other halogenated anesthetics with more of the characteristics of the ideal inhaled anesthetic agent than halothane led to the introduction of isoflurane, desflurane, and sevoflurane." Edgar

Our point: There are many sources of fluoride and each person is exposed to an unknown dosage.

LACK OF AN UNCERTAINTY FACTOR, MARGIN OF ERROR, AND/OR INTRASPECIES VARIATION

Some individuals are more at risk than others. For example:

Diet, such as a low iodine intake or calcium intake.
Kidney dysfunction, inability to excrete as fluoride
High water intake: athletes, diabetics, pregnancy
Socioeconomics
People of color
Age, fetus, infant, child, senior
Genetic Polymorphism, etc.

In contrast, the EPA/NIH and Board claim or imply fluoridation is so safe for everyone that a margin of error, uncertainty factor, intraspecies factor has been set at "1:1," in effect no margin of error or uncertainty factor or intraspecies variability. About 1.3% of the 3.3 million in Washington State are infants on formula and ¾ of them on formula made with water, or about 20,000 infants on formula made with fluoridated water.

"One size shoe" does not fit everyone, all munas are not at the "mean" or "average."

Condition of use is important for determining hazards and risk. Duration of fluoride is from conception (or before), frequency is several times a day and for the fetus constantly. The “halo” effect of fluoridated water shipped outside fluoridated communities must also be considered for those not on fluoridated water.

The exposure level and the hazard level is almost the same with no safety for at risk individuals.

To protect the public, an uncertainty factor of 10 and margin of error should be included, but has not. Not everyone in the public fits in the statistical mean. (NRC 2006) At a minimum, the EPA MCL should be 10% of their 4 ppm and on that item alone, fluoridation should not exceed 0.4 ppm.

The Board should not be surprised that the EPA scientists ethically spoke up with their concerns:

> *"In summary, **we hold that fluoridation is an unreasonable risk**. That is, the toxicity of fluoride is so great and the purported benefits associated with it are so small - if there are any at all – **that requiring every man, woman and child in America to ingest it borders on criminal behavior on the part of governments."***
>
> - ***Dr. J. William Hirzy, Senior Vice-President, Headquarters Union,***
> - ***US Environmental Protection Agency, March 26, 2001***

WAC 246-290-220 requires the Board of Health to have a more protective threshold of aesthetic issues, rather than the EPA's skeletal or dental disability. The Board must protect the public from aesthetic concerns which are long before severe harm occurs such as structural damage to teeth and crippling of the bones. EPA does not protect the public from harm or aesthetic concerns.

RCW 43.20.50 (1) instructs the board to "protect public health" with "safe and reliable public drinking water" but does not provide excuse for the board to recommend or promote the use of water, or to dispense an illegal drug, a prescription drug (Board of Pharmacy), or an "additive" with known aesthetic harm and without duly authorized designated oversight. Aesthetic harm is harm. If someone scratches your car, it may only be an aesthetic scratch, but it is still harm.

Our point: To assure safety, the statistical mean is not protective of many or most people. An uncertainty factor and margin of error of at least 10 should be used.

BENEFIT OF FLUORIDE INGESTION

Fluoridation is claimed to be one of public health's greatest achievements or blunders of the 20th Century, depending on whether profit or safety are considered.

A <u>recent study</u> reported a 2-3% reduction in dental caries over 20 years was just released in the UK involving millions of subjects.

Systemic Fluoride has theoretical benefit while the enamel is developing. NRC 2006 & HHS HTSDR 2003 p 9

". . . fluoride prevents dental caries predominately after eruption of the tooth into the mouth, and its actions primarily are topical for both adults and children…"[19] CDC

Keep in mind, about 60-70% of the population show signs (biomarker) of excess fluoride, dental fluorosis, which is caused from ingestion of fluoride prior to eruption of the tooth. CDC says

[19] CDC (1999). Achievements in Public Health, 1900-1999: Fluoridation of

Drinking Water to Prevent Dental Caries. MMWR, 48(41); 933-940, October 22.

benefit is primarily topical after tooth eruption. FDA has approved topical but not ingestion.

Dental saliva has about 0.019 ppm of fluoride and contact time is minimal, so it would not have much if any benefit. Studies report toothpaste below about 1,000 ppm does not show benefit. Swishing with fluoridated water is unlikely to provide significant therapeutic value.

LACK OF KNOWN MECHANISM OF ACTION

The tooth is highly resistant to the migration of fluoride. Fluoride does not flow from the pulp through the tooth to the outside of the enamel where the caries are developing. No rational mechanism for systemic fluoride benefit has been suggested. See more below.

The FDA's determination the evidence for fluoride's efficacy is incomplete has been supported with other studies.[20] [End note]

- [20] **"** Fluorosis prevalence increased significantly with higher water fluoride levels; however, caries prevalence did not decline significantly."

Hong L, Levy S, Warren J, Broffit B. (2006). Dental caries and fluorosis in relation to water fluoride levels. *ADEA/AADR/CADR* 2006.

- **"**No fluoride, socioeconomic status or beverage variables were significantly associated with lesion progression.

Warren JJ, Levy SM, et al (2006). Longitudinal study of non-cavitated carious lesion progression in the primary dentition. *JPHD* 66(2):83-7.

- **"**In the present study, fluoridated water did not seem to have a positive effect on dental health**. . .** *Community Dentistry Oral Epi* 34:63-70
- "The WHO data do not support fluoridation as being a reason for the decline in dental decay in 12 year olds that has been occurring in recent decades."

Neurath C. (2005). Tooth decay trends for 12 year olds in nonfluoridated and fluoridated countries. ***Fluoride*** 38:324-325

- **"**Our analysis shows no convincing effect of fluoride-intake on caries development." Komarek A, et al. (2005). ***Biostatistics*** 6:145-55.
- **"**Levels in fluoridated and non-fluoridated areas were similar. " Harding MA, et al. (2003). ***Community Dental Health*** 20(3):165-70.
- **"**There was no statistically significant difference between DMFT in municipalities of the same size, regardless of the presence or absence of fluoride

in the water supply..." Sales-Peres SH, Bastos JR. (2002). [An epidemiological profile of dental caries in 12-year-old

- Water fluoridation status of the children's area of residence did not have a significant effect on Early Childhood Caries (ECC)**."** Shiboski, et al. (2003).
- "[E]ven a longitudinal approach did not reveal a lower caries occurrence in the fluoridated than in the low-fluoride reference community." Seppa (2002).

- The magnitude of [fluoridation's] effect is not large in absolute terms, is often not statistically significant and may not be of clinical significance." Locker.

(1999). Benefits and Risks of Water Fluoridation. An Update of the 1996 Federal-Provincial Sub-committee Report. ***Ontario Ministry of Health***

- "[R]esults of recent large-scale studies in at least three countries show that, when similar communities are compared and the traditional DMFT index

of dental caries is used, there is no detectable difference in caries prevalence. **This has been demonstrated for school children in the major cities of New Zealand, Australia, the US and elsewhere."** Diesendorf, M. et al. (1997). New Evidence on Fluoridation. ***Australian and New Zealand Journal of Public Health***. 21: 187-190

- **Higher fluoride proportions appeared to be associated with lower dfs + DFS, with an estimated difference between fluoridated and non-fluoridated groups of 0.65 decayed or filled surfaces per child, but this** association was not statistically significant. The

effects of fluoridation on the other outcomes were small and not statistically significant." Domoto P, et al. (1996). ***JDR*** 75:1947-56

- **"**Children attending centers showed no significant differences (in baby bottle tooth decay) based on fluoride status. ***Public Health Reports*** 107: 167-73
- **The fluoride incorporated developmentally – that is, systemically into the normal tooth mineral – is insufficient to have a measurable effect on acid solubility." Featherstone JDB, M.Sc., Ph.D. , Cover Story; *J American Dental Association*, Vol. 131, July 2000, p. 890.**
- **Centers for Disease Control; *MMWR Weekly Report.* 1999;48:933-940. "laboratory and epidemiologic research suggests that fluoride prevents dental caries predominately after eruption of the tooth into the mouth, and its actions primarily are topical for both adults and children."**

3 FALSE CLAIMS ON THE Board's website

#1. The Board claims: "For water systems serving 20,000 people or more, every $1 invested in fluoridation saves $38 in dental treatment costs." No reference provided.

Cost of **HARM** is not included.

The Board's claim does not include the real-world costs of fluoridation, supplies, equipment, wages, and all manufacturing costs and avoids any costs to treat harm.

DENTAL FLUOROSIS:

I have treated dental fluorosis for more than 4 decades and made hundreds of thousands of dollars off of fluoride. I assumed the good outweighed the bad. I was wrong. If there were no other risk than dental fluorosis, the Board should at a minimum accept our petition for rule change.

COMPLAINT NOTICE: This petition is notice and registering a complaint of dental fluorosis harm.

WAC 246-290-220 "(5) The department may accept continued use of, and proposals involving, certain noncertified chemicals or materials on a case-by-case basis, if all of the following criteria are met:

(b)There exists no substantial evidence that the use of the chemical or material has caused consumers to register complaints about aesthetic issues, or health related concerns, that could be associated with leachable residues from the material;"

There is no dispute, fluoride causes dental fluorosis and fluoridation increases dental fluorosis. There is no dispute fluoridation increases "**aesthetic issues,"** long before severe skeletal fluorosis. NHANES survey reported about 2 out of 3 children with dental fluorosis.

FLUORIDATION IS NOT COST EFFECTIVE: The cost of treating dental fluorosis harm is almost never included in a cost benefit analysis.

As a treating clinician, having made many hundreds of thousands of dollars treating dental fluorosis both aesthetic and functional, I do not understand how those in ivory towers have failed to include the cost of harm from just dental fluorosis when considering the cost effectiveness of fluoridation.

Perhaps they assume fluoride only comes from fluoridation. And they assume no risk or harm except slight tooth blemishes. Another possible reason is dentists, blocked by the American Dental Association, is the only health care profession not obligated to document any diagnosis. Even if we had to document a diagnosis, we sometimes do not reasonably consider the etiology of the pathology.

Dental fluorosis is a biomarker of excess fluoride exposure.

A US Environmental Protection Agency (EPA) study[21] (1987)., funded by the EPA with fluoride concentrations between

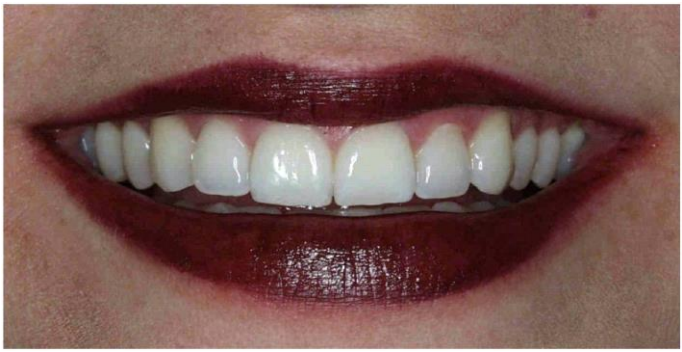
[21] Collins, E., V. Segreto, H. Martin, AND H. Dickson. ANALYSIS OF COSTS FOR THE TREATMENT OF DENTAL FLUOROSIS. U.S. Environmental Protection Agency, Washington, D.C.,

1.0-4.0 mg/L evaluated the cost of treating dental fluorosis, finding:

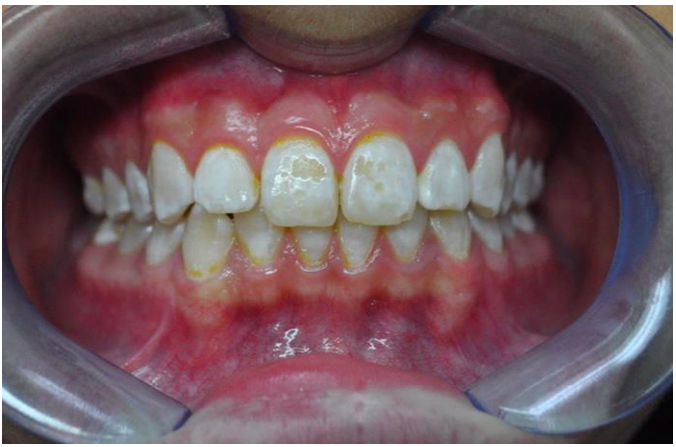
"A mean cost for all consultants shows that the estimated costs for restoring function exceeds the cosmetic costs in all categories except the minimum later costs. This represents a new finding and raises an issue that has been overlooked or ignored by previous investigators and the profession. i.e. that repair of the cosmetic discoloration was the only cost involved; or that repair of dysfunction was never considered to be a problem."

Functional harm, pits, fractures, chips, are one reason we do fillings and crowns, which may cost more than the cosmetic damage. However, as a dentist when I was young, I would see teeth with pitting or fractures and not blame my fluoride, I would blame the patient for not proper diet and cleaning, chewing ice, biting rocks, anything but fluoride.

Here is an example of teeth without fluorosis.



Here is an example of severe dental fluorosis.



His mom was certain he only had fluoridated bottled water and no fluoride toothpaste when he was young.

Dentists placing black mercury fillings are not always on the same page as our patients when it comes to aesthetics. In one study[22] of 12 year-old adolescents, 52% reported dental fluorosis at 0.7 ppm fluoride in water. Of those, 95% wished to

[22] Moimaz SA, Saliba O, Marques LB, Garbin CA, Saliba NA. Dental fluorosis and its influence on children's life. Braz Oral Res. 2015;29:S1806-83242015000100214. doi: 10.1590/1807-3107BOR-2015.vol29.0014. Epub 2015 Jan 13. PMID: 25590503. [PubMed]

remove the spots. In contrast only 14.5% had professionally diagnosed dental fluorosis.

Suppose someone took a key and scratched a line on your car. The car would drive fine, but the scratch is damage and you should be compensated.

The Department should not endorse and recommend fluoridation which is known, without dispute, to cause aesthetic damage to teeth. The Board must assure safety and dental fluorosis is damage.

If dental fluorosis, a known risk of excess fluoride, were the only risk, and if the Board wanted to assure safety of fluoridation, the Board would recommend tap water not have fluoride added.

ESTIMATED Cost to fluoridate water $3-$10 PPPY (Per Person Per Year) Ko and Thiessen

Averted caries (money saved)	$6.08 PPPY
Dental fluorosis Treatment[23]	$3.24-$153 PPPY

[23]Previously, I provided the basis for these estimates to the Board. If you would like the references and math, let me know.

Fluoridation is not cost effective if only damge from dental fluorosis is included.

Consider the study by Maupome, HMO's over 90,000 cohorts,

"Community water fluoridation was associated with reduced total and restorative costs among members with one or more visits, but the magnitude and direction of the effect varied with locale and age and the effects were generally small. In two locales, the cost of restorations was higher in nonfluoridated areas in young people (<age 18) and older adults (>age 58). In younger adults, the opposite effect was observed. The impact of fluoridation may be attenuated by higher use of preventive procedures, in particular supplemental fluorides, in the nonfluoridated areas."

Maupome squeaked out as much positive as possible and reported the cost savings was negated if only part of the costs of fluoridated materials and equipment repairs were included. No costs for treatment of functional or aesthetic harm, brain damage, thyroid damage or any other risk was included. Looking at his data and children in the non-fluoridated had lower dental costs.

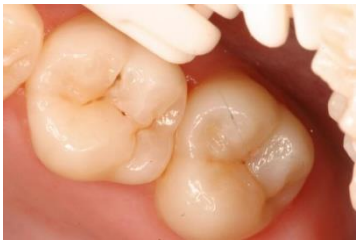
"Harm is the cost, not the treatment."

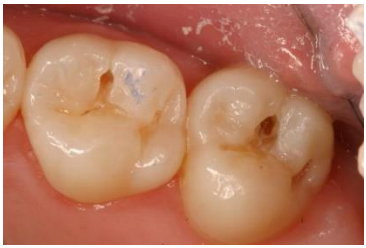
Ko 2014 *The U.S. Government states that $1 spent on CWF saves $38 in dental treatment costs. . . . Recent economic evaluations of CWF contain defective estimations of both costs and benefits. Incorrect handling of dental treatment costs and flawed estimates of effectiveness lead to overestimated benefits. The real-world costs to water treatment plants and communities are not reflected. . . .* ***Conclusions :*** *Minimal correction reduced the savings to $3 per person per year (PPPY) for a best-case*

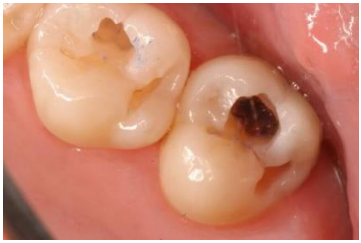
scenario, but this savings is eliminated by the estimated cost of treating dental fluorosis."

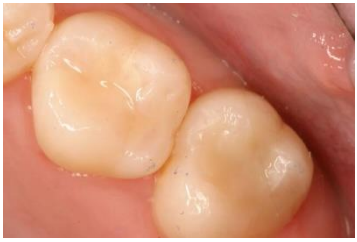
For example, the Board accepts labor costs between $7 and $9/hour while real world labor is closer to $100/hour. And no risk or harm or cost of treating harm is factored in for the Board'a claim of cost effective.

Below is a patient of mine with early functional dental fluorosis. The teeth look great, nice shiny hard enamel, just a touch of early caries. If the patient had not had fluoride, the enamel might not have been so hard and would have probably broken away sooner and pathology diagnosed sooner, and thus with less depth of caries. We call this the "fluoride bomb."

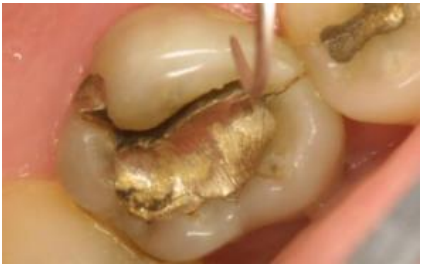


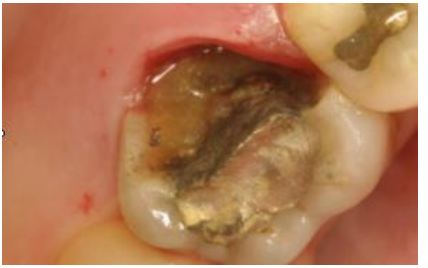






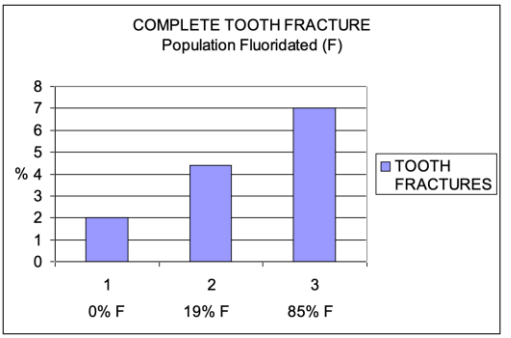
The fluoride hardens the teeth and like bones they become more brittle, like this:





Both systemic and topical fluoride excess may increase harm which has not been included in most cost benefit analysis of fluoridation.

I found a couple authors reporting “complete cusp fractures” and more than 300% increase in fractures in the 85% fluoridated community vs the community lacking fluoridation. See graph below.



Increased fluoride exposure can also increase dental caries.[24] If there is a "sweet spot" of fluoride dosage exposure to prevent caries, the spot is not hard to detect.

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[24] Awadia AK, et al. (2002). Caries experience and caries predictors - a study of Tanzanian children consuming drinking water with different fluoride concentrations. *Clinical Oral Investigations* (2002) 6:98-103. (See abstract)
Binbin W, et al. (2005). Dental caries in fluorine exposure areas in China. *Environmental Geochemistry and Health* 27:285-8. (See abstract)
Budipramana ES, et al. (2002). Dental fluorosis and caries prevalence in the fluorosis endemic area of Asembagus, Indonesia. *International Journal of Paediatric Dentistry* 12(6):415-22. (See abstract)
Ekanayake L, Van Der Hoek W. (2002). Dental caries and developmental defects of enamel in relation to fluoride levels in drinking water in an arid area of sri lanka. *Caries Research* 36(6):398-404. (See abstract)
Grobleri SR, et al. (2001). Dental fluorosis and caries experience in relation to three different drinking water fluoride levels in South Africa. *International Journal of Paediatric Dentistry* 11(5):372-9. (See abstract)
Grobler SR, van Wyk CW, Kotze D. (1986). Relationship between enamel fluoride levels, degree of fluorosis and caries experience in communities with a nearly optimal and a high fluoride level in the drinking water. *Caries Research* 20:284-8.
Mann J,et al. (1990). Fluorosis and dental caries in 6-8-year-old children in a 5 ppm fluoride area. *Community Dentistry and Oral Epidemiology* 18(2):77-9. (See abstract)
Mann J, et al. (1987). Fluorosis and caries prevalence in a community drinking above-optimal fluoridated water. *Community Dentistry and Oral Epidemiology* 15(5):293-5. (See abstract)
Olsson B. (1979). Dental findings in high-fluoride areas in Ethiopia. *Community Dentistry and Oral Epidemiology* 7(1):51-6. (See abstract)
Ramseyer WF, et al. (1957). Effect of Sodium Fluoride Administration on Body Changes in Old Rats. *Journal of Gerontology* 12: 14-19. (See excerpt)
Retief DH, et al. (1979). Relationships among fluoride concentration in enamel, degree of fluorosis and caries incidence in a community residing in a high fluoride area. *Journal of Oral Pathology* 8: 224-36. (See abstract)
Roholm K. (1937). Fluoride intoxication: a clinical-hygienic study with a review of the literature and some experimental investigations. H.K. Lewis Ltd, London. (See excerpts)
Smith MC, Smith HV. (1940). Observations on the durability of mottled teeth. *American Journal of Public Health* 30: 1050-1052.

` The most recent publication on dental fluorosis 2024, is an "Expert Panel Meeting on Health Effects of Fluoride in Drinking Water" The Panel was chosen by Canadian Health, the strongest promoter of fluoridation in Canada. A single study from1942 by Dean was the key endpoint used by the committee to determine harm, a study more than 80 years old with significant limitations. Seriously, I've been listening to 8 days of court presentations by experts. EPA experts reject the dozens of studies reporting harm as inadequate, yet accept a single study from 8 decades ago as point of departure. The fluoridation lobby make no sense.

The panel Summarized:

"Selection of a point of departure is a critical step in the development of a health-based value. The point of departure for neurocognitive effects (i.e., IQ reduction) is not yet well defined because of uncertainties, including the shape of the exposure-response curve at low concentrations of fluoride in drinking water.

Teotia SPS, Teotia M. (1994). Dental caries: a disorder of high fluoride and low dietary calcium interactions (30 years of personal research). *Fluoride* 27: 59-66. (See abstract | See study)

Wondwossen F, et al. (2004). The relationship between dental caries and dental fluorosis in areas with moderate- and high-fluoride drinking water in Ethiopia. *Community Dentistry and Oral Epidemiology* 32: 337-44. (See abstract)

Ziegelbecker R, Ziegelbecker RC. (1993). WHO data on dental caries and natural fluoride levels. *Fluoride* 26: 263-266. (See excerpt)

See also:

Steelink C. (1992). Fluoridation Controversy. (Letter). *Chemical Engineering News* July 27: 2-3.

Therefore, moderate dental fluorosis was selected as the key endpoint of concern with a point of departure of 1.56 mg F/L in drinking water.

"The tolerable daily intake is normally calculated by dividing daily intake on a µg/kg/day basis by an uncertainty factor. Since the point of departure in this case is already a measurement in drinking water, this step (and calculation of the health-based value) can be simplified by applying an uncertainty factor directly to the point of departure to account for the database deficiencies about the potential occurrence of neurotoxicity from exposure to fluoride at low doses.

"Therefore, the drinking water concentration (DWC) is calculated by dividing the point of departure (POD) by the uncertainty factor (UF).

DWC = POD/ UF

A health-based value (HBV) for fluoride in drinking water would be calculated by multiplying this DWC by an allocation factor (AF) to account for exposure to fluoride from other sources.
HBV = DWC × AF

Focusing on just **dental fluorosis** at this point and their use of 1.56 mgF/L: A safe drinking water concentration would be 1.56 mgF/L divided by the uncertainty factor (to be determined by Health Canada) or intraspecies variability. Most would agree, not all humans are the same age, health, drink the same amount of water, have the same health, in other words not all humans wear the same size shoe. The NRC 2006 and EPA reported the average person drinks about 1 liter of water a day and some drink

over 10 liters of water a day. To assure safety, an intraspecies consumption of just water, ignoring all other differences in humans, an uncertainty factor of 10 would need to be used. The committee used the formula:

DWC = POD/ UF (DWC = Desired Water Concentration) (POD = Point of Departure) (UF = Uncertainty factor)

DWC= (POD) 1.56 mgF/L X (UF) 10 = 0.156 mgF/L in public water. The Board recommends 0.7 mgF/L.

0.7 is greater than 0.156.

To assure safety, the Board would need to select 0.156 mgF/L (same as ppm) fluoride concentration in water instead of current 0.7 ppm. 0.156 ppm would be an estimated safe water fluoride concentration to prevent moderate dental fluorosis.

However, the panel also noted an “allocation factor” (how much total fluoride comes from fluoridation) of 0.5, which is a good rule of thumb, but varies more typically from 1/3 to 2/3rds and can be over 90% for some.

Assuming allocation is 0.5, total exposure reduction would go down by half if fluoride in water were 0 mg/L. Even eliminating fluoridation, some will ingest too much from other sources.

There is so much more to understand when considering the cost of fluoridation. We must add developmental neurotoxicity, more below.

If we assume just 3 lower IQ points lost and and assume about $500/person/IQ lower income, my estimates based on research and adjusted for 2021dollars IQ loss would be about$1,500/year/ person. Including dental fluorosis harm wiped out benefit. Including IQ loss gets us even further in a loss. But I have not included the other risks below.

Fluoridation is very costly.

A cost estimate resulting in savings requires the dental lobby to only use some costs to fluoridate, ignore harm, and exaggerate cost savings.

#2. The Board claims: *Water fluoridation reduces tooth decay by about 25 percent over a person's lifetime."*

No current research is provided because none is available. A public health intervention should be measured in the public at large and the Board fails to provide the evidence for their claim. The Board's claim of benefit is consistent with the CDC Oral Health Division which is virtually in lock step with the American Dental Association and CDC is part of the fluoridation lobby. The fluoridation lobby is profiting from the disposal of fluoride in public water rather than having to pay thousands of dollars a ton to dispose of the toxic waste.

When fluoridation started a 65% reduction in dental caries was claimed, based on lower quality studies, and then shown not to be true. Later, a 25% reduction was claimed and now shown not to be true. Higher quality research, more careful review of the research does not support significant benefit.

If such a robust reduction in caries were in fact true (25%), we would see significant decrease in treatment and dental costs in fluoridated communities along with lower insurance payment for

dental treatment. But costs are not lower in fluoridated communities and dentist/patient ratio is not lower in fluoridated communities.

FDA CDER REQUIRES RANDOMIZED CONTROLLED TRIALS (RCT) FOR EFFICACY.

The Board appears to disagree with the FDA CDER which has not approved ingestion of fluoride reporting: *. . . there is no substantial evidence of drug effectiveness. . . ."* Drug Therapy 1975.

And in 2010 the FDA indicated application for NDA would effectively ban fluoridation. The Board cannot assure safety if the only drug authorized regulatory agency would not approve fluoridation.

When the FDA CDER evaluates the quality of research on drug "**efficacy**," the FDA CDER requires RCTs. Note[25]

[25] "Randomized controlled trials (RCT) are prospective studies that measure the effectiveness of a new intervention or treatment. Although no study is likely on its own to prove causality, randomization reduces bias and provides a rigorous tool to examine cause-effect relationships between an intervention and outcome. This

In contrast, evaluation of **"safety"** is more complex because we cannot intentionally give a person enough of the substance to find out when they get sick or die. The FDA CDER requires monitoring for side effects, risks in the RCT studies. Absent RCT studies, as is the case with fluoride exposure, safety must be determined with lower quality ecological studies, comparing peoples or populations are the option. But those studies do not look for safety and the Board cannot assure safety without safety studies.

The fluoridation lobby will claim that ecological studies of harm are not reliable. If we disallow ecological studies, we would also throw out the studies we have on benefit.

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is because the act of randomization balances participant characteristics (both observed and unobserved) between the groups allowing attribution of any differences in outcome to the study intervention. This is not possible with any other study design. In designing an RCT, researchers must carefully select the population, the interventions to be compared and the outcomes of interest. Once these are defined, the number of participants needed to reliably determine if such a relationship exists is calculated (power calculation). Participants are then recruited and randomly assigned to either the intervention or the comparator group.[1] It is important to ensure that at the time of recruitment there is no knowledge of which group the participant will be allocated to; this is known as concealment. This is often ensured by using automated randomization systems (e.g. computer generated). RCTs are often blinded so that participants and doctors, nurses or researchers do not know what treatment each participant is receiving, further minimizing bias."

When comparing populations, the Board must keep in mind, to estimate total fluoride exposure we need to take the 0.7 mg/L from water and at least double that to include background exposure. In other words, the Board needs to actually look at 1.5 mg/L in studies on safety to even consider the mean exposure.

Comparing high and low fluoride populations does not compare the absence of fluoride with 1.5 mg/L but a lower concentration with a higher concentration.

And 1.5 mg/L does not account for those drinking more than the mean amount of water, frequently pregnant moms.

If ingesting fluoride had benefit, the Board and/or industry (dentists) could simply get FDA CDER approval and make a profit from selling the fluoride license/patent.

In fact, the Board contacted the FDA and was told requiring FDA approval would effectively ban fluoridation. And I tried to get FDA approval. Not because I thought fluoride safe or effective, but because an application might force the FDA to more closely evaluate fluoride's lack of benefit and risks, and take regulatory

action. The FDA denied my application because I'm not a water district.

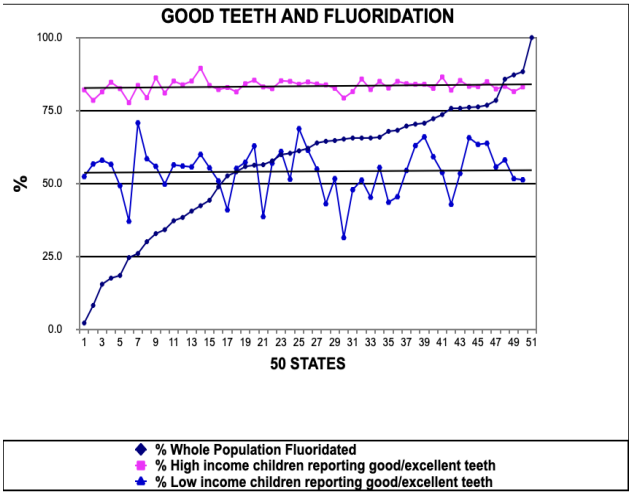
The FDA CDER have the highest standards, are highly qualified pharmacologists, toxicologists, experts and have the most respect for drug approval of all federal and state agencies.

The Board should consider that their intent to protect vulnerable populations from some dental caries is not supported by quality science and plenty of science reports additional harm to those subpopulations (low socioeconomics, increased lead exposure in fluoridated communities, etc.)

The following correlation graph was generated when I ranked the USA states on the percentage of their whole population fluoridated and reported good to excellent teeth.[26] A 25%

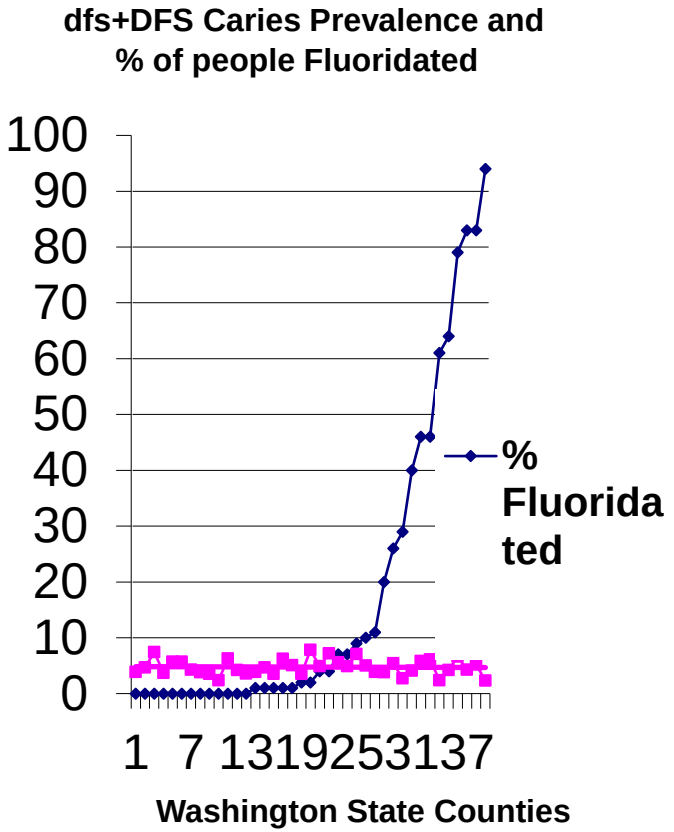
[26] http://mchb.hrsa.gov/oralhealth/portrait/1cct.htm National Survey of Children's Health.
U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau.
The National Survey of Children's Health 2003. Rockville, Maryland: U.S. Department of Health and Human Services, 2005
http://www.cdc.gov/oralhealth/waterfluoridation/fact_sheets/states_stats2002.htm
http://pubs.usgs.gov/circ/2004/circ1268/htdocs/table05.html

reduction, or any reduction, is not evident when similar SES groups are ranked.

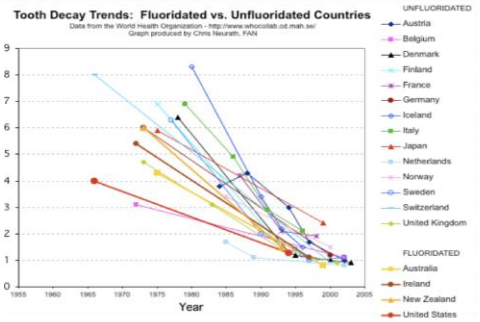


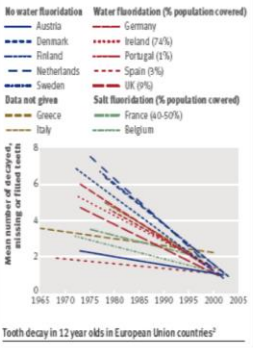
Socioeconomics is highly significant for caries prevalence, but fluoridation has no “common cause” or correlation. For 20 years as a dentist, I promoted fluoridation and thought I could see proof of benefit from fluoridation in my patients. However, after reading the research it was clear I had been comparing socioeconomics rather than fluoridation.

I also ranked Washington State Counties on the percentage of their population fluoridated and dental caries. No reduction in dental caries is supported by the population at large in Washington State, caries is about the same regardless of fluoridation.



Two published studies[27] ranking WHO data on caries over about 3 decades does not report lower caries in fluoridated countries or those who use fluoride salt, graphs below.

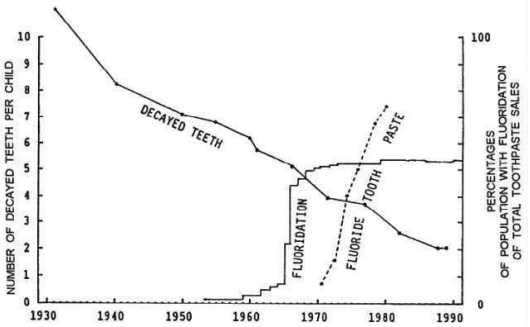




All developed countries have reduced dental caries to low levels, regardless of fluoridation or fluoride salts. Giving fluoride credit for a reduction of caries in non-fluoridated countries prior to fluoridation is not reasonable.

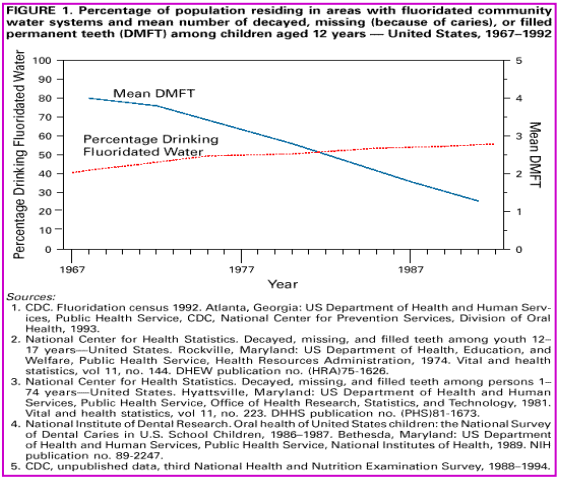
[27] Neurath http://www.fluoridealert.org/health/teeth/caries/who-dmft.html and Chen et al, BMJ 5 October 2007

To the right is a graph of caries over a longer period of time.[28] What caused the decline in dental caries,



more than half before the beginning of fluoridation? No one knows. No research on fluoridation has taken into account the huge unknown(s). We cannot give fluoridation credit for caries reduction prior to fluoridation. And any research must be suspect if it does not correct for those unknowns after fluoridation started, and no research corrects for those unknowns because they are unknown.

However, on the CDC website, a 1999 graph (right) is



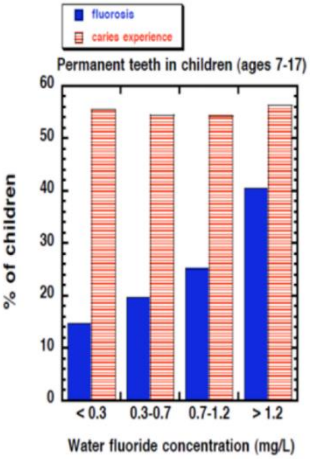
[28] In 1998, Colquhoun graphed the trend of dental caries in the USA, see graph below (ISFR 1998)

presented which at first glance looks impressive. Indeed, caries declined and fluoridation rates increased, but the graph is misleading by only looking at a few years. And it is not plausible that an increase of perhaps 10% of the public “randomly” fluoridated resulted in a decline from 4 DMFT (adult decayed, missing, filled teeth) to just over 1 for everyone. Simply not plausible. Even if the fluoride were dispensed to only the high-risk children individually, that would not have produced about a 70% decrease in DMFT. Fluoridation is not targeted, and started in some cities, not just for high-risk individuals.

The Journal of the American Dental Association published the following data which was graphed by Thiessen.

The red lines represent caries experience. Any difference in caries experience (red lines), at any concentration, is hard to detect and certainly not 25% as alleged by the Board. All red lines are at a similar height, although perhaps 2% lower at about 0.7 mg/L.

Iida, H., and Kumar, J.V. 2009. The association between enamel fluorosis and dental caries in U.S. schoolchildren. JADA 140:855-862.



The blue lines represent reported dental fluorosis. As expected, an increase in fluoride concentration in water increases the damage from excess fluoride, dental fluorosis, more than double. Dental fluorosis occurs while the tooth is developing under the skin, mostly before age 6. The developing brain and other organs are developing during the same time, and would not be spared from the excess fluoride. The teeth are not the only

tissues harmed, but they are the easiest to diagnose. (The NTP 2023 report and the Fluoride On Trial: The Censored Science on Fluoride and Your Health | Childrens Health Defense must be reviewed.)

Mechanism of Fluoride's Action (continued from above): Topical fluoride at high concentrations (over 1,000 ppm) has been shown to be effective (toothpaste) and is FDA CDER approved and listed in the Orange Book of approved drugs, but not fluoride ingestion.

On the other hand, to be effective, ingested fluoride must go from the pulp chamber through the calcium rich dentin and enamel to the surface of the tooth where the dental caries are forming.

Topical fluoride (like toothpaste) can get to the dental caries, ingested fluoride cannot. The tooth is highly resistant to the migration of fluoride. In the graph below, there is an increase in fluoride concentration near the pulp and at the surface of the tooth from topical fluoride, but in the middle the concentration is

low. Saliva has a low concentration of fluoride and cannot have much benefit.

Think of fluoride like suntan lotion. Put it on the outside and “do not swallow.”

The graph (right) shows the fluoride concentrations in the tooth.

A few of the limitations on fluoridation research often Include:

- A. Not one Study corrects for Unknown Confounding Factors. Think of the graph above reporting significant decline prior to fluoridation. That huge massive crushing dental caries prior to fluoridation is unknown and not controlled for in any study because no one knows what it is. Did it stop when fluoridation started? No, other countries prove it did not. Therefore, the most logical cause of caries reduction is the unknown(s), not fluoridation.
- B. Not one Prospective Randomized Controlled Trial (one on supplements reported no statistical benefit) And without RCT’s, no meta-analysis of RCT’s can be done.

- C. Socioeconomic status usually not controlled
- D. Inadequate size
- E. Difficulty in diagnosing decay
- F. Delay in tooth eruption not controlled
- G. Diet: Vitamin D, calcium, strontium, sugar, fresh and frozen year-round vegetables and fruit consumption not controlled.
- H. Total exposure of Fluoride not determined
- I. Oral hygiene not determined
- J. Not evaluating Life-time benefit
- K. Estimating or assuming subject actually drinks the water.
- L. Dental treatment expenses not considered
- M. Mother's fluoride exposure, Breast feeding and infant formula excluded
- N. Fraud, gross errors, and bias not corrected.
- O. Genetics not considered
- P. Studies reporting benefit were done at 1.0 ppm, we are now fluoridating at 0.7 ppm. Does the lower dose provide benefit? We don't know.

CDC: **“Ingestion of fluoride is not likely to reduce tooth decay.”**[29]

“The results show that the reviewed original studies on economic evaluation of caries prevention do not provide support for the economic value of caries prevention.”[30]

Former Director of the National Toxicology Program (NTP) and Office of Health Assessment and Translation (OHAT) at (NIEHS) (NIH) Linda Birnbaum, Ph.D., D.A.B.T., A.T.S. is a microbiologist and board-certified toxicologist. (See endnote 1.) Her sworn testimony is critical for evaluation by the Board. VIDEO: Former NTP Director’s Statement on Fluoride Neurotoxicity — Fluoride Action Network (fluoridealert.org)

Even if fluoridation at 1.0 ppm were effective, that does not prove 0.7 ppm fluoride in water is equally effective. . . if at all.

[29] Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries. MMWR, 48(41); 933-940, October 22, 199

[30] Källestål C et al. Acta Odontol Scand. 2003 Dec;61(6):341-6. Economic evaluation of dental caries prevention: a systematic review.

In 1975 my fluoride professor suggested the possible delay in tooth eruption with fluoride ingestion was adequate proof of fluoridation's benefit. Or could be simply a delay in diagnosis.

If the tooth is protected under the skin from food and harm for just a few months, researchers evaluating caries by a child's age, will be comparing different amount of time the teeth have been exposed to the environment. Of course, the concern that a delay in tooth eruption could cause a delay or premature development of other systems and organs must be considered. But we dentists only look at structures of the mouth.

Not all studies agree there is a delay in tooth eruption with fluoridation; however, the evidence should be considered, see

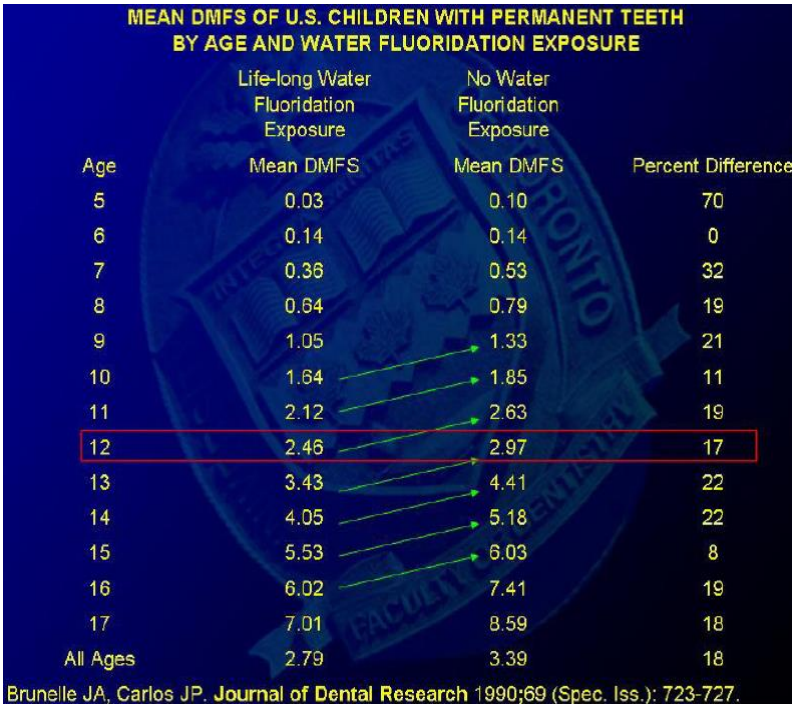
data below, the first from 1957, the second from 1990.

CAClinch © 2010

Newark, Delaware

	Decayed-Missing-Filled Teeth		Percent Caries-Free Children	
Age	After Fluoridation	Before Fluoridation	After Fluoridation	Before Fluoridation
6	0.2	1.1	88.8	54.8
7	1.1	2.3	44.9	22.7
8	1.7	2.9	31.5	8.6
9	2.8	3.7	11.3	4.8
10	3.4	4.9	6.4	7.5

Reference: Journal American Dental Assoc. Vol. 54, June 1957
Note: 1-year DELAY in DMF per child. At age 10 FEWER caries-free children AFTER fluoridation than BEFORE.



REPUTABLE AGENCIES OPPOSED TO FLUORIDATION:

The fluoridation lobby has claimed there are no “reputable” health agencies which oppose fluoridation, yet their definition of “reputable” limits their search to those agencies which promote fluoridation.

Austria REJECTED: “toxic fluorides” NOT added

Belgium REJECTED: encourages self-determination – those who want fluoride should get it themselves.

Finland STOPPED: “...do not favor or recommend fluoridation of drinking water. There are better ways of providing the fluoride our teeth need.” A recent study found ...”no indication of an increasing trend of caries....“

Germany STOPPED: A recent study found no evidence of an increasing trend of caries

Denmark REJECTED: “...toxic fluorides have never been added to the public water supplies in Denmark.“

Norway REJECTED: “...drinking water should not be fluoridated“

Sweden BANNED: “not allowed”. No safety data available!

Netherlands REJECTED: Inevitably, whenever there is a court decision against fluoridation, the dental lobby pushes to have the judgment overturned on a technicality or they try to get the laws changed to legalize it. Their tactics didn't work in the vast majority of Europe.

Hungary STOPPED: for technical reasons in the '60s. However, despite technological advances, Hungary remains unfluoridated.

Japan REJECTED: "...may cause health problems...."

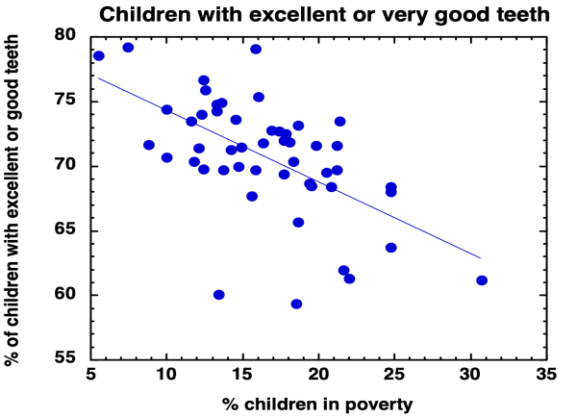
Israel SUSPENDED mandatory fluoridation until the issue is reexamined from all aspects.: June 21, 2006 "The labor, welfare and health Knesset committee"

China BANNED: "not allowed" Some of the earliest studies raising concern on developmental toxicity were done in China. China should be given credit for starting to wake the USA up to fluoride's developmental neurotoxic risks.

When the 50 states are ranked based on their whole population fluoridated, we do see a slight decline in the states with

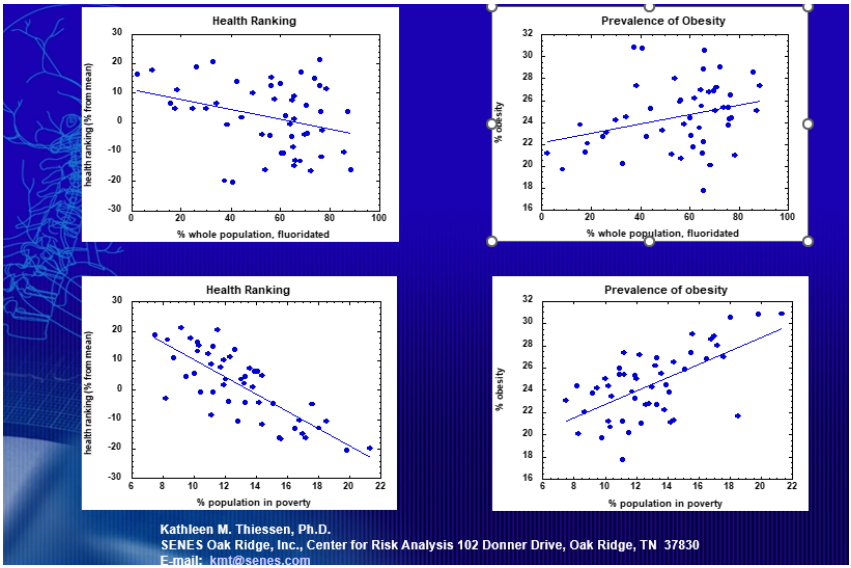
more of their population fluoridated.[31] Based on this data we see about a 7% caries reduction for third graders.

Dr. Thiessen ranked the states on socioeconomics. The wealthier appear to have better dental health.



Additional graphs by Thiessen below. Health ranking appears to decline with fluoridation and significant decline for those states with a higher percentage of poor. Obesity increases and obesity is affected by the thyroid and fluoride harms the thyroid, more seriously for the poor. Fluoridation harms the poor the most.

[31] Kathleen Thiessen PhD kmt@senes.com *SENES Oak Ridge Inc.* Center for Risk Analysis



ADA awarded Kentucky with "50 Year Award" for (100%) fluoridation in 2003 at the same time 42% were edentulous, #1 in USA (2002 Mortality Weekly Report) Connecticut, Detroit, and Boston all reported a crisis of dental caries and all have had fluoridation for decades.[32]

32

http://www.fortwayne.com/mld/newssentinel/7521679.htm?template=contentModules/printstory.jsp
http://www.enquirer.com/editions/2002/10/06/loc_special_report.html
http://www.fluoridealert.org/f-boston.htm

When questioned about the scientific evidence for benefits and safety of fluoridation, the Washington Department of Health responded: “DOH will rely on known national entities like the CDC and EPA to assess the science. . . .” (Letter from DOH)

See Fluoride On Trial: The Censored Science on Fluoride and Your Health | Childrens Health Defense for the CDC’s response. See attached letter from EPA for EPA’s response.

Even when the CDC reported the CDC does not determine the safety of fluoridation and the CDC along with the ADA warned infants should NOT have fluoridated water for formula and drinking, the Washington Department of Health responded in disagreement, reporting: *“Parents and health providers should weigh the balance.”* Seriously? Does the Department of health expect parents to review the literature when the Department doesn’t have the experts or money to review the evidence?

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http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=13678102&query_hl=1
http://www.nhregister.com/site/news.cfm?newsid=14472801&BRD=1281&PAG=461&dept_id=517515&rfi=8&xb=kasan

And the Board expects parents and health providers to do what the Board and Department fail to do. I doubt the legislature expected the public to weigh the complex scientific data.

Our point: The Board should not assume a 25% reduction in dental caries exists.

In 2003, the EPA asked the NRC to review EPA's Maximum Contaminant Level Goal (MCLG) for fluoride. The NRC unanimous agreement was that EPA's MCL for fluoride was too high. For 18 years the EPA has not changed the MCL or MCLG for fluoride. The NRC 2006 report based their decisions on concerns for:

- **Tooth Damage**
- **Rheumatoid and Osteoarthritic-like Pain**
- **Bone Cancer**
- **Bone Fractures**
- **Thyroid Reduction**
- **Diabetes**
- **Obesity**
- **Kidney damage**

- **Reproductive problems**
- **Lower IQ and increased Mental Retardation**
- **Allergies (overactive immune system)**
- **Gastrointestinal disorders**

#3. The Washington Board of Health also claims:

Community water fluoridation is safe. After 65 years in service and hundreds of studies it continues show its safety."

"*Over the past 75 years, health authorities have declared that community water fluoridation-a practice that reaches over 400 million worldwide-is safe. Yet, studies conducted in North America examining the safety of fluoride exposure in pregnancy were nonexistent. . . .*

The tendency to ignore new evidence that does not conform to widespread beliefs impedes the response to early warnings about fluoride as a potential developmental neurotoxin. Evolving evidence should inspire scientists and health authorities to re-evaluate claims about the safety of fluoride, especially for the fetus and infant for whom there is no benefit."[33]

[33] Till C, Green R. Controversy: The evolving science of fluoride: when new evidence doesn't conform with existing beliefs. Pediatr Res. 2021

Scientists have avoided the controversies of fluoride exposure. Publishing controversial research is a career killer. As one of my mentors would say, tongue in cheek: *"Never let a rational thought interfere with a lucrative procedure."*

If fluoridation were the only source of fluoride, fluoridation would not be safe.

If teeth were the only tissues of the body, fluoridation would not be safe. Fluoride ingestion may or may not have benefit, but fluoride without dispute harms teeth both aesthetically and functionally. The dental lobby only considers benefit to teeth and discounts harm as only aesthetic.

Endorsements of benefit, are not science, empirical evidence, facts or evidence of safety.

The Board is assuming endorsements by unauthorized agencies, industry, claiming or "declaring" benefit and safety are factual evidence. "The absence of safety evidence is not proof of safety."

Nov;90(5):1093-1095. doi: 10.1038/s41390-020-0973-8. Epub 2020 May 22. PMID: 32443137; PMCID: PMC9922476.

THE FETUS: (See attachment H.)

I have found no safety studies determining the safety of fluoride exposure for the developing fetus. The Board cannot assure safety for the fetus without safety studies.

Here are the two most vulnerable cells starting the dividing and growing process of life, the mother is probably not even aware. Fluoride passes from the mother through the placenta to those cells.

As the fetus grows, there is no developed blood brain barrier to protect the fetus's developing brain from toxins. In time, the fetus drinks the amniotic fluid, the developing kidneys excrete some of the fluoride and we assume half stays in the fetus, mostly the developing bones. The fetus drinks the fluoride fluid laced urine, concentrating the fluoride mostly in the bones, but also potentially affecting every cell, system, organ of their body, anatomy and physiology.

Excess fluoride is "recycled.". Yet the Board, without research, blindly assumes the fetus is not affected and safe.

Challenged on safety, dentists often claim everything outside of the mouth is not their purview.

DEVELOPMENTAL NEUROTOXICITY (Fluoride's toxic effect to the developing brain):

"Fluoride is most definitely a developmental neurotoxicant."[34]

A large volume(s) could be written on just fluoride's effect on the brain, especially for the fetus, infant and child, who are receiving the highest dose of fluoride.

Our point: The consistency and number of studies reporting lower IQ for children in a linear relationship as dose of fluoride increases is reasonable. The more fluoride, the more brain damage.

The brain is the most precious gift of life. The brain goes through stages of development and if harmed at a stage, may never recover.

Knowingly harming the brain is inexcusable and no Board recommendation and policy should steel the essence of the highest quality of life a person can have.

[34] Dr. Grandjean February 1, 2024 in sworn testimony in the TSCA EPA trial.

Over a decade ago, the Board of Health refused our petitions to protect the health of the developing brain, fetus, infant, and children. Instead, the Department and Board trusted the EPA and CDC who have no jurisdiction over the efficacy, dosage, safety or label of fluoride. (See attached #F, letter from the EPA)

I, and others, turned to the U.S. National Toxicology Program (NTP), the highest scientific authority in the USA to review the toxicity, safety, of fluoride exposure. Due to cost, time, and the need to evaluate thousands of other toxins, the NTP agreed to review just one aspect of fluoride's toxicity, developmental neurotoxicity i.e. as measured with lower IQ. This link is to the 700+ page draft which includes reviewers' comments and NTPs responses. The NTP Board of Counselors voted unanimous approval. NTP's review of just one harm does not imply brain damage is the only harm from fluoride exposure.

Again, links to the Draft NTP Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects: A Systematic Review. and Table of Contents.

The dental lobby will dismiss applicability of the NTP Monograph to fluoridation, in part, because the NTP was politically prevented from evaluating fluoridation. However, the science clearly shows fluoride exposure to be a developmental neurotoxicant at dosages common to many. In court, we learned some of the reviewers have strong ties to vested fluoride interests.

In October and December of 2022, evidence in a TSCA (Toxic Substance Control Act) legal action against the EPA for failure to protect the public, reported political pressures from HHS's Rachael Levine, prevented release of the NTP monograph. It took a Court order for release of the science.

I must digress. Withholding of medical research is research misconduct. The World Health Organization reported it is an ethical imperative to support full disclosure of all clinical trial research. Lack of full disclosure puts the public at risk of ineffective and harmful medical products*. "In short, disclosing clinical trial results leads to better-informed science and saves lives."*

WHO states further, *"Withholding clinical trial results defeats the purpose of medical research."*[35]

A great deal of tax payer money, thousands of hours of researchers' time and cohort time went into research provided to the NTP and their 6 years of research and review. Any attempt to cover up, hide, withhold the research is unethical, an insult to the researchers and subjects. Levine and collaborators should be disciplined for withholding the NTP monograph.

The Department of Justice had attempted to block testimony from the NTP, but the court ruled he could testify. Withholding evidence tarnishes the credibility of the person and agency.

Back to the TSCA trial. The Judge said the report would be considered final and would be given "a fair amount of weight." Like the Court, the Board of Health should also give the report a fair amount of weight.

[35] Vasee Moorthy, a technical officer with the WHO, in email to CMAJ. And Dr. Ben Goldacre author of the books Bad Science and Bad Pharma

May 4, 2023, the Board of Scientific Counselors approved the NTP report. HHS has still not officially published the monograph, and the Director reported the monograph may never be published. Political pressure is blocking good science.

The NTP monograph included 72 human fluoride IQ studies of which 64 found a relationship between fluoride and lower IQ. 19 of the studies were considered high quality and 18 reported IQ loss, the vast majority.

Of the vast majority of human studies accepted by the NTP evaluating developmental neurotoxicity, 95% report harm. The consistency is remarkable and is a growing data base.

Fluoride has met the standard of EPA hazard causation.

Due to political pressure, the report was divided into two sections. The first is called the State of the Science and the second is the Meta-analysis. The State of the Science appears to be more influenced by the dental lobby. The meta-analysis appears to have more empirical, factual, evidence.

A few NTP quotes:

"Our meta-analysis confirms results of previous meta-analyses and extends them by including newer, more precise studies with individual-level exposure measures. The data support

a consistent inverse association between fluoride exposure and children's IQ."

When an unnamed government fluoridation proponent claimed:

"The data do not support the assertion of an effect below 1.5 mg/L…all conclusory statements in this document should be explicit that any findings from the included studies only apply to water fluoride concentrations above 1.5 mg/L."

The NTP responded:

*"**We do not agree with this comment**…our assessment considers fluoride exposures from all sources, not just water…because fluoride is also found in certain foods, dental products, some pharmaceuticals, and other sources… Even in the optimally fluoridated cities…individual exposure levels…suggest widely varying total exposures from water combined with fluoride from other sources."*

"Discussion

The results of this meta-analysis support a statistically significant association between higher fluoride exposure and lower children's IQ. The direction of the association was robust to stratification by risk of bias, sex, age group, timing of exposure, study location, outcome assessment type, and exposure assessment type. There is also evidence of a dose-response relationship. Although the estimated decreases in IQ may seem small, research on other neurotoxicants has shown that subtle shifts in IQ at the population level can have a profound impact on the number of people who fall within the high and low ranges of the population's IQ distribution [50-54] For example, a 5-point decrease in a population's IQ would nearly double the number of people classified as intellectually disabled [55]."

The NTP's meta-analysis raises confidence that fluoride is indeed harming the developing brain. And as with the early reports of lead's harm, further more precise, focused study on lead confirmed rather than disputed the earlier studies.

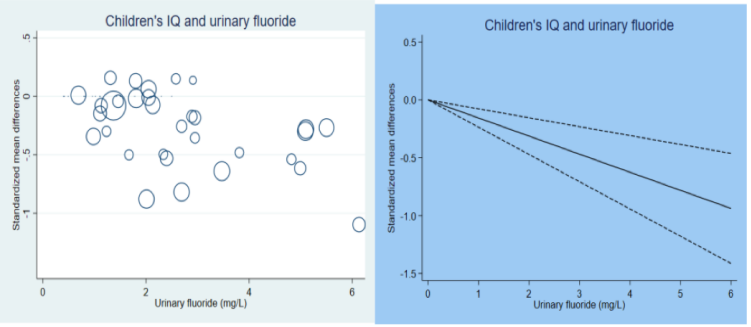
Note: One standard deviation is 15 IQ points.

The NTP charts below, for example, show a mother with 1 mg/L of fluoride in her urine would have a child with about 0.1 standard deviation loss of IQ. At 2mg/L about 0.3 SD loss and 3 mg/L fluoride urine concentration, common for women in the third trimester of pregnancy, about half a SD IQ loss.

Half a standard IQ loss would be about 7-8 IQ points lost. Under oath the EPA's expert conceded that fluoride is a neurotoxicant.

The NTP graphs below should be reviewed. For reasonable estimates, urine fluoride concentration approximates total fluoride exposure because about half the fluoride stays in the body, mostly, but not all, in the bones.

Urinary Fluoride Exposure



eFigure 18. Pooled Dose-Response Association Between Fluoride in Urine and Standardized Mean Differences in Children's IQ

Left panel: Circles indicate standardized weighted mean differences in individual studies; size of bubbles is proportional to precision (inverse of variance) of the standardized mean differences. Right panel: Urinary fluoride levels were modeled with a linear random-effects model (solid line). Dashed lines represent the 95 % confidence intervals for the linear model. Please see **eTable 2** for characteristics of the studies included in the *dose-response meta-analysis* (studies with urinary fluoride exposure and at least two exposure levels).

Urine fluoride concentration of 3 mg/L representing about half a standard deviation would expect to have a child with about 7 IQ less. A mom drinking 3 liters per day at 0.7 mg/L would ingest about 2.1 mg of fluoride just from water, more than the NTP hazard level. Additional fluoride from other sources could easily push the mom over 3 mg fluoride per day.

Figure 2 of the NTP meta-analysis, page 19 presented below:

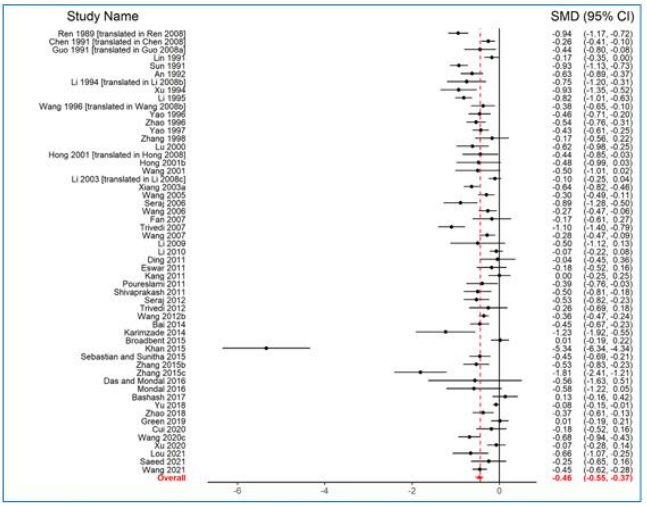


Figure 2. Association Between Fluoride Exposure and IQ Scores in Children

Forest plot for random-effects meta-analysis of the association between fluoride exposure and child's IQ scores. Effect size is expressed as the standardized weighted mean difference for heteroscedastic population variances (SMD). The random-effects pooled SMD is shown as a solid triangle. Horizontal lines represent 95% CIs for the study specific SMDs.

Research seems to mostly be around -0.46 mean overall standard deviation which represents about 7 IQ point loss. (1 SMD is 15 IQ points)

Performance IQ is reported at 8.8 IQ loss, full scale 4.4 IQ loss[36] with an increase of 0.5 mg/L fluoride in water.

36 Till C, Green R, Flora D, Hornung R, Martinez-Mier EA, Blazer M, Farmus L, Ayotte P, Muckle G, Lanphear B. Fluoride exposure from infant formula and child IQ in a Canadian birth cohort. Environ Int. 2020 Jan;134:105315. doi: 10.1016/j.envint.2019.105315. Epub 2019 Nov 16. PMID: 31743803; PMCID: PMC6913880. [PubMed]

Two studies in Australia, evaluating the same area did not find IQ loss. One did not control for fluoride supplements in the non-fluoridated cohorts. Low exposure levels are more difficult to see.

One study[37] not reporting IQ loss is promoted by the fluoridation lobby and is impossible, an outlier. The samples need to be sent to a different laboratory for testing.

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[37] A study by Dr. Jesus Ibarluzea, at low fluoride concentrations not only does fluoride NOT lower IQ, but it can transform an average-IQ boy living in a non-fluoridated area, that is correct, a NON-fluoridate area with some fluoride into a genius with low levels of fluoride exposure, for example raising IQs for boys by 28 points. . . but not girls. When asked if he would be looking into why such a large increase, he said he had no interest in finding the problem. This study is an outlier from other studies.

In fact, the 15 IQ and 28 IQ point increase for boys as reported, is based on using 1 mg/g. In fluoride neurotoxicity epi studies, a common exposure increase is 1 mg/L of urine. The difference is about 30%. This correction increases the implausibility of a 15 or 28 IQ point increase for boys to an impossible 20 to 37 IQ increase for boys.

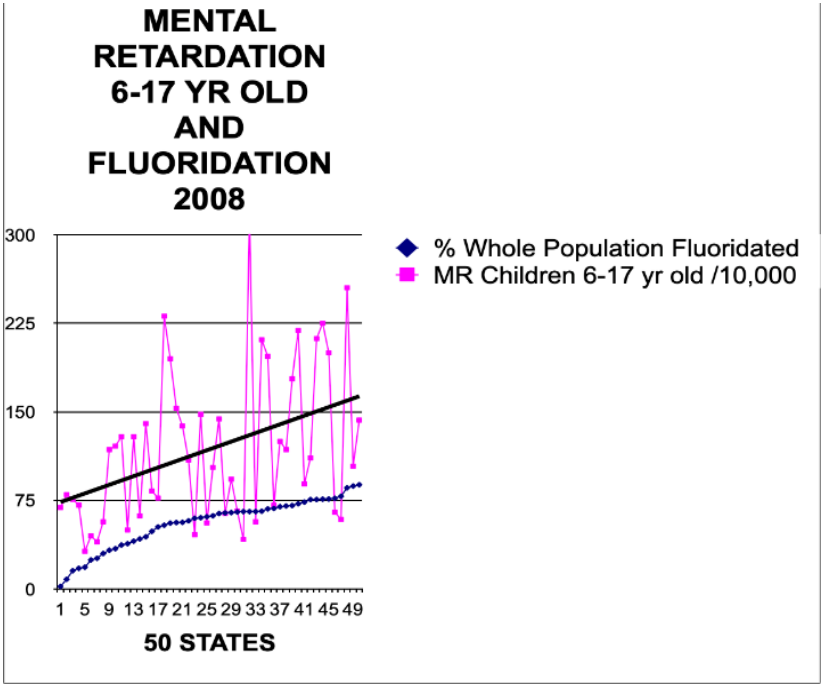
During his deposition as a witness in the TSCA trial, Dr. Ibarluzea was asked whether he ever asked anyone to delete information about his fluoride study, to which he responded, “Never, never, never, ever.” According to a FOIA document, however, Dr. Ibarluzea sent the CDC’s Division of Oral Health an email about his study, which ended with the words “Please delete this message.” The contents of the message remain unknown because CDC redacted the entire email with the exception of the “Please delete this message” instruction.

Dr. Ibarluzea then withdrew from any further participation in TSCA legal case. Another study promoted by the dental lobby, a meta-analysis, relied heavily on Dr. Ibarluzea’s study to report no harm from fluoride exposure.

Dr. Grandjean who has published over 500 studies on toxic substances, is a risk assessment expert, testified in court under oath, said he had never seen or could imagine such an outlier as accurate. He said the authors should immediately send samples back to the lab, or a different lab, for verification.

Future studies evaluating will likely report with further clarity more serious harm for individuals at various socioeconomic levels, various races, ages, and gender (males), more sensitive to fluoride various types of IQ loss and greater harm.

After the 2006 NRC report suggesting possible brain damage from fluoride, I wanted to personally see if I could confirm the NRC 2006 report. I ranked the 50 states and plotted their



reported mental retardation (intellectual disability) and percent of the whole population fluoridated, a correlation study. The trend, more than doubling of "mentally retarded," about 7-8 IQ loss, (half

a standard deviation) raised concerns and is supported with more recent published studies including the NTP meta-analysis.

Nearly doubling the number of “mentally retarded ” would represent close to 7 IQ point loss. The EPA uses just one IQ loss as their threshold of harm. Equally of concern is the serious reduction in gifted and of course the rest of us in the middle are harmed.

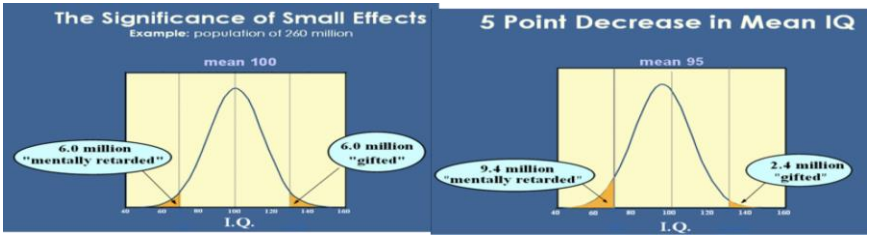
When other confounders are considered for ranking the 50 states, socioeconomics is slightly lower in the more fluoridated states. Socioeconomics and IQ are related, to a degree.

Remember the “Bell Curve.” The graphs below illustrate 5 IQ loss with over 50% increase in the number of low IQ, and a third the gifted is a concern.

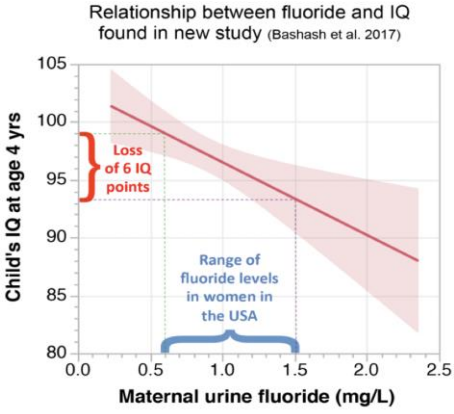
To assure the public fluoridion is safe, the Board must provide quality research to support safety.

Think of our special education classes. Think of employers, parents and those children who know they are not as “smart” as others. Low IQ tend to be incarcerated more, higher

divorce rates, homeless, etc. And a loss of more than half the gifted is serious.



Bashash in 2017, reported about 4 IQ loss at 0.7 ppm fluoride in water.



The Board's claim and recommendation that fluoridation is safe is factually, empirically unsupported, and is not based on current scientific evidence, law or logic. For almost two decades the Board has been given quality research, but not in as high a scholarly presentation as the NTP monograph. The Board's claim of efficacy and safety is wrong and harming the public.

Hearing a Board member say*, but we are not supposed to have to review science"* makes the term "Board of Health" at best a rubber stamp of industry. Either health is based on science or trust. Trust is not empirical and factual evidence. HHS Rachael Lavine's blocking of release of the evidence did not change the science or protect the public health and neither does the Board of Health promote health if they avoid and evade science.

Fluoridation at 0.7 mg/L is not reported safe. **"A Benchmark Dose Analysis for Maternal Pregnancy Urine-fluoride and IQ in children . . . 0.2 mg/L"** Grandjean 2022.

Dr. Granjean is a professor at both Harvard and the University of Southern Denmark and has published hundreds of studies on the toxicity of chemicals. You will hear from equal but

not more accomplished research scientists in the field of toxicology.

How does the fluoridation lobby respond to the evidence?

In court the defense (fluoridation lobby) agreed fluoride is a developmental neurotoxicant. The question they refuse to answer is at what dosage is the end point. . .they are uncertain but don't claim fluoridation is safe. In other words, over 70 human studies are just not quite enough to be sure, absolutely confident, fluoride harms the developing brain at any specific developmental stage, age, location, gender, race, dosage, etc. Yes, high dosages, but they won't answer what is safe.

The trick to defending toxic substances is to divide the evidence enough to remove confidence. For example, avoid studies with higher concentrations than the "mean" intake as inconclusive to confirm absolute confidence of harm. Demand the evidence show proof of harm. The lower concentrations of fluoride studies can be divided from those evaluating prenatal IQ loss from infant IQ loss. Discount studies from countries like China

(Ok to use their toxic waste in our water, but their research reporting harm is not to our standards.) Avoid total fluoride exposure, don't include those who drink the most water, avoid any other possible risks or confounders. In other words, divide the research enough times and there are not enough studies in each sub section to reach their level of confidence to establish a threshold.

The fluoridation lobby is requiring PROOF OF HARM rather than assuring the public of safety.

And the Epidemiologists and toxicologists will clearly state they are not risk analysis experts but they don't agree with the risk analysis experts, because the risk analysis experts claim fluoride at fluoridation concentrations is a developmental neurotoxicant.

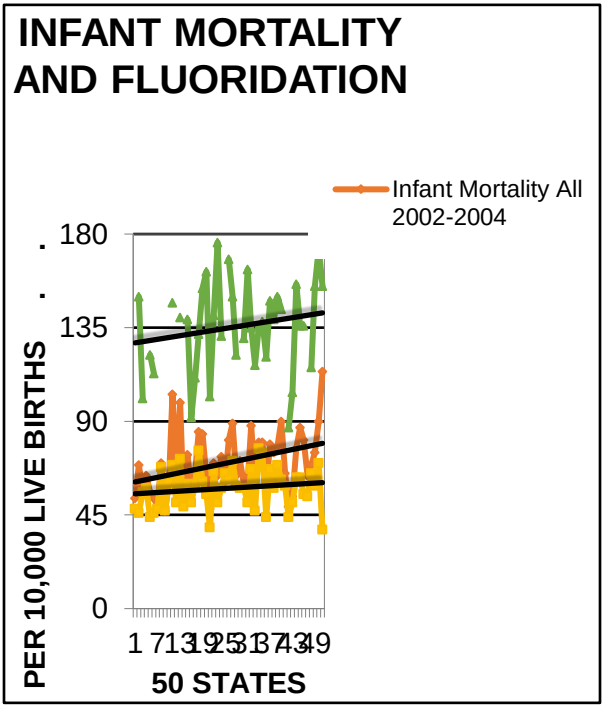
Not once do the fluoridation lobby experts answer the question "can you assure the public that fluoridation is safe?"

Not once do the fluoridation lobby experts answer, "would you recommend your pregnant daughter or grandchildren drink fluoridated water? The answers are pretty clear.

INFANT MORTALITY

It should be noted that IQ is simply one method of measuring brain damage and developmental toxicity from fluoride. I once again ranked the states on the percentage of their whole population fluoridated and plotted infant mortality per 10,000 live births, and found about 15% increase in infant mortality. See graph below.

Infant mortality is complex. The most common causes of infant mortality in the United States are birth defects, preterm birth and low birth weight, sudden infant death syndrome (SIDS), pregnancy complications,



accidents and toxins such as lead and the evidence fluoride contributes to infant mortality is growing.

Do not assume these other birth defects are not increased with fluoridation, we simply have not looked.

Data on infant mortality is readily available and the USA has a poor record compared to other countries trying to keep babies alive during their first year of life. Confounding factors need to be considered. This is a pilot study and not proof. However, the Board cannot assure the public fluoridation is safe simply because we do not have absolute proof of harm for each risk.

A pilot study using U.S. Government records reported an increase in infant mortality (perhaps 20% increase) and premature births in fluoridated communities with soft water, such as Seattle water. See Figure 3 below.

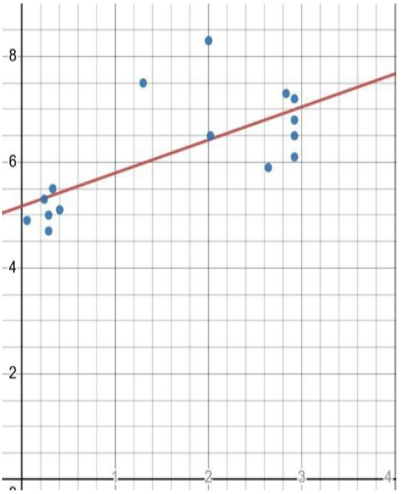


Figure 3: Infant mortality per 1,000 live births in hard water and soft water U.S. States on the vertical axis is plotted as a function of the ratio of the percent of the state population provided fluoridated water (0.7 ppm recommended) to water hardness as the calcium carbonate concentration (mg/L). Points were fitted with linear regression given by

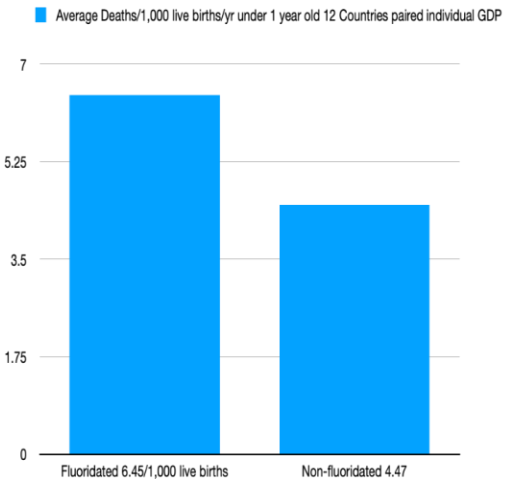
$Y = 0.627X + 5.167$ ($r = 0.694$).

In other words, add fluoride to soft Seattle water and infants have greater chance of harm and death.

Research reporting an increase in infant mortality in fluoridated communities is growing. The concern for miscarriage, and preterm birth must be considered. Although more study is always wanted, the Board must weigh the evidence with judgment.

Even if there were a decrease in dental caries from fluoridation, potential increase in infant mortality far out-weighs potential alleged benefit to teeth, which we can fix.

I recently compared six highly fluoridated countries paired economically (individual GDP) with six countries without fluoridated water or salt. Comparing these countries results in almost 30% increase in infant mortality.[38] Six countries is a small sample and fluoride is certainly not the only contributing factor for infant mortality.



The trend is serious and in keeping with the developmental neurotoxicity of fluoride.

[38] Six highly fluoridate countries were paired with six countries with no fluoridated water or salt and similar individual GDP's or area. Infant mortality rates based on CIA.gov data, GDP per Capita - Worldometer (worldometers.info), and fluoride concentrations in water

Preterm birth is defined as birth prior to 37 weeks of pregnancy. Damage to cerebral white matter is the most commonly recognized pathology of prematurity, say neuroscientists at the Dana Alliance for Brain Initiatives. "Babies born preterm face a range of potential neurological disruptions … The earlier the birth, the greater the risk that these disruptions will produce devastating and potentially life-long cognitive, behavioral, and socialization deficits."[39]

Hart reported, in 2009,

"Domestic water fluoridation was associated with an increased risk of PTB (9545 (6.34%) PTB among women exposed to domestic water fluoridation versus 25278 (5.52%) PTB among those unexposed, p < 0.0001)). This relationship was most pronounced among women in the lowest SES groups (>10% poverty) and those of non-white racial origin. Domestic water fluoridation was independently associated with an increased risk of PTB in logistic regression, after controlling for age, race/ethnicity, neighborhood poverty level, hypertension, and diabetes."

1.[39] Patoine B. The vulnerable premature brain: Rapid neural development in third trimester heightens brain risks. Dana Foundation. May 2010. Available at https://www.dana.org/media/detail.aspx?id=27882.

The fluoridation lobby demands proof of harm. One public health dentist told me he would promote fluoridation until it was proven people were falling over in the street dead from fluoridation.

These possible deaths of our babies, our future, our most vulnerable who the Board is NOT protecting must not be ignored. Harming their brains and possibly their deaths, certainly harming teeth and bones, without proof of efficacy is unforgivable. The Board members, and all of us who did and still do promote the ingestion of additional fluoride without patient consent are or have been complicit. And I too promoted fluoridation and was complicit in the harm.

The Board makes no sense to medicate everyone with a highly toxic poison, to be regulated as a drug but not, with 2 out of 3 children showing a biomarker of excess fluoride exposure, with doubtful benefit for a non-contagious, almost never lethal disease, without a doctor's supervision, of a known legend drug, and the Board expects the patient to provide absolute proof of harm and precise dosage.

The Legislature did not charge the voters to assure safety.

DENTAL FLUOROSIS was briefly covered above when discussing the Board's website. See page 109. Much more could be added.

FLUORIDE AND CANCER

It has been said, "Genes load the cancer gun, environment pulls the trigger."

One of the problems with cancer research is latency. It can take 20 to 30 years after exposure to the primary etiology.

Dean Burk PhD, head of cytochemistry, National Cancer Institute 1974, Co-discoverer of Biotin compared 10 large unfluoridated cities as controls 6.3 million people with 10 large cities which became fluoridated between 1952-1956, 11 million people.

Cancer Deaths/100,000

year	1940	1950	1970
CDRo (+F)	154.2	186.3	222.6
CDRo (- F)	153.5	183.6	188.8

Representing a 31.3/100,000 increase in deaths/yr after 15-20 years of fluoridation

When I was in Dental School, we were shown a critical review of Burk's work which suggested two significant numbers were transposed and no adverse effect had been shown.

However, we were not told that Burk had responded with evidence that the critics had transposed the numbers and he was indeed correct.

Burk's study stopped when the unfluoridated cities became fluoridated.

Although NRC (2006) committee reviewing fluoride for the EPA was charged with "non-cancer" effects of fluoride, fluoride increasing cancer is biologically plausible and a connection between fluoride and osteosarcoma, focuses on three facts:

1. Most fluoride is stored in bones, particularly during growth spirts.
2. Fluoride is a mutagen
3. Fluoride stimulates osteoblasts which “increases the risk for some of the dividing cells to become malignant.” (NRC 2006) See a timeline link.

Some history on fluoride and cancer as reported by Ellen Connett in 2014. See endnote[40]

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[40] In the 1980s the US Congress mandated the National Toxicology Program to conduct animal studies to determine if fluoride causes cancer. Battelle Columbus Laboratories were contracted to perform the studies that began in 1985 and ran for 2 years. In 1988 Battelle submitted their final report that included the finding of a dose-dependent increase of a rare liver cancer (hepatocholangiocarcinoma) in male & female mice and a small but statistically significant dose-related increase in osteosarcomas in male rats but not in the female rats. For the rare liver cancer, the first scientist to describe this cancer said that Battelle made a correct diagnosis. However, this rare liver cancer was reclassified by a government review panel as a non-cancer and one of the osteosarcomas was downgraded leading to the

classification of “equivocal evidence of cancer”. There were also increases in oral and thyroid cancers, but they were not considered statistically significant.

The politics that raged around this study.
William Marcus, the senior scientist in the Office of Drinking Water at the Environmental Protection Agency, expressed concerns about the “systematic downgrading” of cancers in the 1990 published study and requested that the EPA assemble an independent board of pathologists and others to review the data produced in the study. In the 2013 documentary *Fluoridegate: An American Tragedy*, Marcus has this to say about the study:
“… rats got cancer of the bone and they got a very unusual cancer of the liver. And that was extremely surprising. First of all to produce cancer of the bone in rodents is never seen because the time that you have between birth and death of a rodent is only 3 ½ to four years and it usually takes longer than that to produce a cancer in bone. The cancer of the liver is extremely rare … and the fact that it happened meant that it was significant. This doesn’t happen. I wrote this memo in which I claimed that I thought fluoride was a carcinogen and that we had as much evidence with the animal studies to show that it was a carcinogen as we had

with any of the other compounds [that EPA studied] and therefore should be treated as such."

Also, three out of four in-vitro tests proved fluoride to be mutagenic, which Marcus said supported "the conclusion that fluoride is a probable human carcinogen." The internal memorandum that Marcus wrote was leaked to the press. It caused embarrassment to senior EPA officials and Marcus was fired.

"An Enemy of The State"
The National Whistleblowers Association represented Marcus in his two trials against the EPA and they won both. The EPA was forced to pay Marcus' legal fees, 2 ½ years of back pay, and an undisclosed sum for damages to his reputation.

In the *Fluoridegate* documentary Stephen Kohn of the National Whistleblowers Association stated:
"… I do not know why the agency (EPA) did what it did to Dr Marcus. But I do represent whistleblowers and I can tell you they went after Dr Marcus with a vengeance, a vengeance. He was a board certified toxicologist with years of seniority, the most respected toxicologist in the agency with an international reputation. When he wrote that memo they went after him like he

was an enemy of the state. They just hammered, and hammered, and hammered, and they went way over the line by destroying evidence and obstructing justice. And even after we won the first case where he was ordered reinstated they went after him again. And even though there were 2 court rulings finding retaliation they never touched or disciplined those agency officials involved. This case marks a black mark on the EPA and raises fundamental issues about scientific freedom and about fluoride and why this agency went against one of its most respected scientists on that issue."

Robert Reich as Secretary of Labor in the Clinton administration upheld the decision of the Administrative Law Judge in 1994 who said that "the true reason for the discharge was retaliation." Reich wrote that he found particularly disturbing that the trumped-up charges against Marcus were accepted by his supervisors "in the absence of any convincing documentation."

The principal finding of NTP's study, performed by Battelle Columbus Laboratories, was a dose-dependent increase in osteosarcoma (bone cancer) among the fluoride-treated male rats.

However, despite the fact that

1) the cancer occurred in the target organ (bone) for fluoride accumulation,
2) the increase in bone cancer was statistically-significant,
3) the doses of fluoride were low for an animal cancer study, and
4) NTP acknowledged it is "biologically plausible" that fluoride could induce bone cancer,

the NTP ruled that the study only provided "equivocal evidence" that fluoride was the cause of the cancer.

The NTP did not assure the public fluoridation did not cause cancer. NTP did not have absolute proof of harm.

According to a 1990 report by Bette Hileman in *Chemical & Engineering News*: "A number of government officials who asked not to be identified also have told C&EN that they have concerns about the conclusions of the 1990 NTP study. They, too, believe that fluoride should have been placed in the "some evidence" category, in part because osteosarcoma is a very rare form of cancer in rodents."

In 2000, Dr. J William Hirzy testified before the U.S. Senate's Subcommittee on Wildlife, Fisheries and Drinking Water on behalf of the EPA's professional union, NTEU Chapter 280, requesting an independent review of NTP's cancer bioassay study.

In 2002, the World Health Organization (Fluorides: Environmental Health Criteria 227) advised scientists to take NTP's finding seriously. According to the WHO: "Such a (dose-dependent) trend associated with the occurrence of a rare tumour in the tissue in which fluoride is known to accumulate cannot be casually dismissed."

In 2005, the Environmental Working Group "asked the National Toxicology Program (NTP) of the National Institutes of Health (NIH) to list fluoride in tap water in its authoritative Report on Carcinogens, based on its ability to cause a rare form of childhood bone cancer, osteosarcoma, in boys."

In addition to increased bone cancer, the NTP study also found increases in rare liver cancers, oral cavity cancers and thyroid cancers among the fluoride-treated rats. The NTP ruled, however, that the cancers were not related to the fluoride treatment – despite reaching "statistical significance" in some of NTP's analyses.

"We observed that for males diagnosed before the age of 20 years, fluoride level in drinking water during growth was associated with an increased risk of osteosarcoma, demonstrating a peak in the odds ratios from 6 to 8 years of age. All of our models were remarkably robust in showing this effect, which coincides with the mid-childhood growth spurt. For females, no clear association between fluoride in drinking water during growth and osteosarcoma emerged." (Bassin EB, et al. 2006. Age-specific fluoride exposure in drinking water and osteosarcoma (United States). Cancer Causes & Control 17(4):421-8. May.)

Chester Dougles published a small study, 20 controls, too small for reliable conclusions, the controls were over twice the age, representing about 400% higher bone fluoride concentrations for age paired. Douglas not only used controls averaging more than double the age, but compared the osteosarcoma cases with other bone tumors as controls. Clearly, the data was collected to protect fluoride exposure. Just because the concentration of fluoride in bones of osteosarcoma patients and bone tumor patients are similar, does not mean the fluoride concentration in bone is safe. Using bone tumors as controls cooked the evidence.

As Editor of the Colgate report, Douglas received significant funding from Colgate.

Our point: Several researchers confirm, fluoride is a carcinogen. The question is the dosage for each patient.

FLUORIDE'S IMPACT ON THYROID HORMONES: THYROID, PARATHYROID, PANCREAS, PINEAL, ADRENAL, GONADS, ANTERIOR AND POSTERIOR PITUITARY, AND PLACENTA.

See Attachment #E Thyroid

Fluoride is considered an endocrine disruptor. As little as 2 to 5 mg/day can reduce most patient's thyroid activity. (Galletti & Joyet 1958)

For easy estimation, half of fluoride exposure is from fluoridated water. At 0.7 mg/L, **about six glasses of fluoridated** water along with the "average" fluoride from other sources can be expected to reduce thyroid hormones. But wait, many are ingesting more fluoride from other sources and drinking more than six glasses of water.

We in public health tell those with thyroid harm from fluoride that their obesity, diabetes, and malaise is their fault,

when in fact we are contributing to their health problems, idiopathic harm.

"We found that higher levels of fluoride in drinking water provide a useful contribution for predicting prevalence of hypothyroidism. We found that practices located in the West Midlands (a wholly fluoridated area) are nearly twice as likely to report high hypothyroidism prevalence in comparison to Greater Manchester (non-fluoridated area)." Peckham S, et al. (2015). *Journal of Community Health & Epidemiology* (see study)

The NRC 2006 review of fluoride's effect on the thyroid gland should be reviewed. See pages 224-236. *"Fluoride in Drinking Water: A Scientific Review of EPA's Standards."*

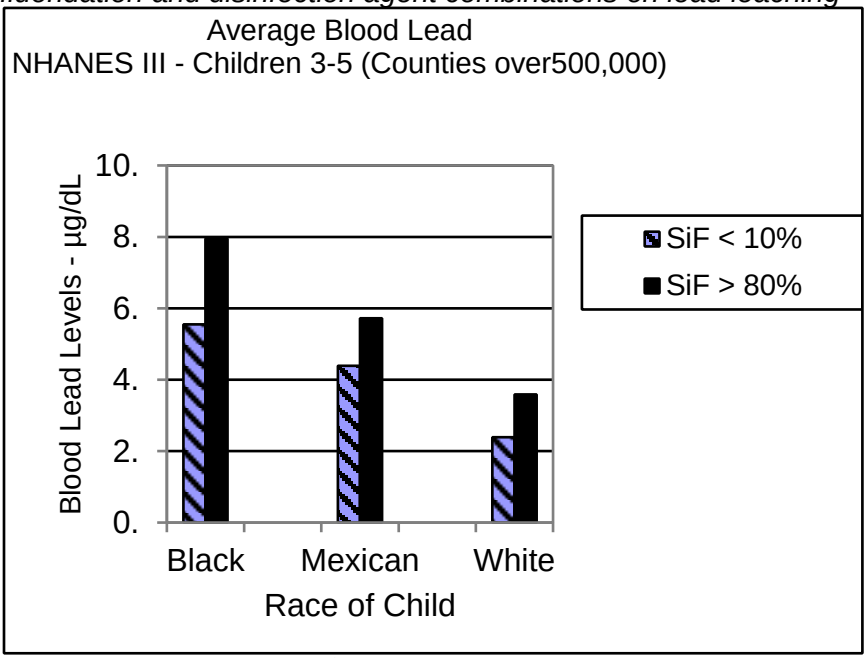
For a more referenced and scientific discussion of Fluoride's effects on the endocrine system, aggravated by iodine deficiency, effects on goiters, impact on thyroid hormones and excess iodine intake, see here and pubmed.gov.

FLUORID AND LEAD

*Blood **Lead** levels in Fluoridated areas 2X higher for Whites and 6X higher for Blacks*[41]

[41] Confirmation of and explanations for elevated blood lead and other disorders in children exposed to water disinfection and fluoridation chemicals. Coplan

Prevalence of children with elevated blood lead (PbB>10mug/dL) is about double that in non-fluoridated communities. When FSA was added "lead concentrations spiked to over 900 ppb. Effects of fluoridation and disinfection agent combinations on lead leaching



from leaded-brass parts.[42]

MJ, Patch SC, Masters RD, Bachman MS. Neurotoxicology. 2007 Sep;28(5):1032-42. Epub 2007 Mar 1.
See also: Masters RD, Coplan M. 1999 International Journal of Environmental Science 56: 435-449.
And: Masters RD, Coplan MJ, Hone BT, Dykes JF. 2000 Neurotoxicology 21(6): 1091-1100.

[42] Maas RP, Patch SC, Christian AM, Coplan MJ. Neurotoxicology. 2007 Sep;28(5):1023-31. Epub 2007 Jun 30
See also: Blood lead concentrations in children and method of water fluoridation in the United States, 1988-1994. Macek MD, Matte TD, Sinks T, Malvitz DM. Environ Health Perspect. 2006 Jan;114(1):130-4.

FLUORIDE'S IMPACT ON BONES

Skeletal fluorosis is an undisputed effect of excess fluoride. The EPA uses severe skeletal fluorosis as a threshold of concern for excess fluoride exposure. But pathology from fluoride starts much sooner than crippling skeletal fluorosis.

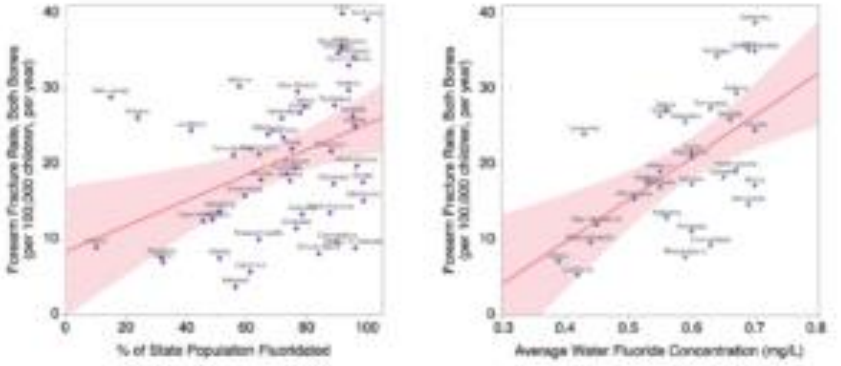
Fluoride seemed like a good idea for bones and teeth to make them harder, until studies such as Helte et al raised concerns of bone fracture and osteoarthritis, arthritic like symptoms, stiffness and pain in joints. BAO 2003 (Luo 2012; Su 2012; Bao 2003; Savas 2001; Tartatovskaya 1995; Chen 1988; Xu 1987)

A recent study in the Journal of the American Academy of Orthopaedic Surgeons by Lindsay et al. Results:

"Positive correlations were found between the percentage of state water fluoridation and fracture rates for both bone forearm fracture (BBFFx) and femur fracture. Fluoride levels had positive correlations with fracture rates for all fracture types. Increased fracture rates were found between states in the highest quartiles of percentage of state water fluoridation and fluoride water levels for supracondylar humerus fracture and BBFFx."

The study reported at 0.7 mg/L fluoride in water, rates of child forearm fractures were 2.5 times greater than in states with

the lowest average concentration, which was about 0.4 mg/L as illustrated here:



(quality of graph is also hard to read in the Journal, but the data is also printed)

AUTHORITIES

The fluoride lobby will often claim hundreds of organizations endorse fluoridation. I doubt any have reviewed the science, they simply trust others.

Here are a few with researvations:

I. The Washington State Board of Pharmacy and RCW:

The Board of Pharmacy was disbanded in part because they agreed with the law and science that fluoride ingested with intent to prevent disease is a prescription drug.

Neither the Board, voters, nor water purveyors have authority to prescribe drugs. At least the Board of Health can provide accurate information for water purveyors and the public.

Pharmacists have more training and expertise with toxins, dosage, adverse reactions and inter reactions of toxins than other licensed professions and weighing their judgment is essential.

"RCW 18.64.011

(14) "Drugs" means:
(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States; [sodium fluoride is listed]

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;" [intended use is to prevent a disease]

II. **U.S. Congress** which has authorized the Food and Drug Administration Center for Drug Evaluation and Research (FDA CDER) to evaluate substances used with intent to prevent disease and Congress prohibit the EPA from adding anything for the treatment of humans.

Again, the authority of the US Congress, designating the FDA CDER with authority over drugs.

III. **FDA CDER** has determined fluoride ingestion lacks evidence of efficacy. And the FDA has given warnings to bottled water manufacturers (not FDA CDER approved) the fluoridated water must not be marketed to those under two years of age. The FDA indicated requiring FDA approval would effectively ban fluoridation. The Board of Health is harming the public by disagreeing with authorized regulatory agencies.

IV. The Environmental Protection Agency scientists finding over two decades ago that fluoridation borders on a criminal Act because of toxicity and lack of current benefit. And the EPA Dose Response Analysis and Relative Source Contribution of 2010 reporting that most or all infants and toddlers are ingesting too much fluoride.

V. The National Research Council 2006 report for the EPA that EPA's Maximum Contaminant Level for fluoride was not protective. That's right, fluoride is a contaminant the Board recommends adding to water.

VI. The National Toxicology Program: Draft Report of 2023 report of 55 human studies, 52 reported IQ loss, a 95% consistency. And their meta-analysis reports IQ loss. Not everyone has the same sensitivity to drugs/toxins or the same health or the same ability to handle drugs/toxins. Some individuals had much more IQ loss and some were probably unaffected. The mean is not protective or representative of each

individual. The Board must protect everyone, not just the healthiest and wealthiest.

VII. Lack of quality research: Only one RCT (randomized controlled trial, the highest quality of research) of fluoride ingestion has been published and it report no statistical benefit from ingesting the fluoride. That's right. NO, NONE, ZERO quality studies reporting dental benefit of fluoride ingestion. No wonder the FDA said the evidence of efficacy is incomplete.

VIII. The lack of mechanism of action: Fluoride cannot go from the blood to the tooth pulp chamber through the calcium rich dentin and enamel to the outside of the tooth where the dental caries are forming and active. Fluoride's contact with teeth during swallowing of water is short term, and little gets to the lower teeth. The theoretical slight increase of fluoride in saliva with water at 0.7 ppm is too dilute to have an effect. Research has not reported a benefit at 700 ppm let alone 0.7 ppm.

IX. 97% of Europe does not fluoridate their water. And their dental caries are a similar rate as fluoridated communities and states not fluoridated.

X. The Court: In Doe v Rumsfeld, ruled that even under emergency conditions of war, the Government cannot force an individual to be medicated with a substance which has not been specifically approved for the purpose and manner it is intended. Fluoride ingestion is unapproved and therefore illegal, unless an authorized prescribing health care provider prescribes the fluoride for their patient of record off label. Ther is no approved label for fluoridation or fluoride tablets.

The Board appears to trust industry who profit from the sales of fluoride**.** We dentists make a ton of money off of fluoride. . . topical which has good evidence of efficacy. Raising alarms of fluoride toxicity will reduce our income, but speaking up against fluoridation harms a dentist's reputation among peers.

The Board appears to trust the CDC dental division who are in lockstep with industry and politics, not scientific facts. The CDC does not determine either the efficacy, dosage nor safety of any drugs. Congress charged the FDA CDER with that job.

The Board appears to trust the US Public Health Service, but not the NTP within the USPHS. The USPHS has no Congressional authority to approve the safety, dosage or efficacy of any drugs and fails to review the scientific evidence.

The Board appears to trust public health reviews of fluoridation from like-minded believers rather than digging deep into the science.

This request for rule change is to protect the public from harm caused by too much fluoride ingestion, in part, promoted and encouraged by the Board of Health.

You will get pushback from the dental lobby and industry profiting from the sale of fluoride. And you will get push back from those who have not evaluated both sides of the science. We can

and should agree that many are ingesting too much fluoride and the early days, months, years of life appear to have the greatest risk of harm.

The exact individual health, dosage, mechanism, age, race, diet, and synergistic chemical effects from other toxins are less certain and in time will be more thoroughly studied. Fluoridation should be stopped; however, the paradigm shift maybe too much for the Board.

We must and will, someday after many millions are harmed, simply turn off the fluoride pumps. At a minimum the Board can start to consider science and start on a label to protect the unborn, infants and young.

Much more evidence could be added. This is a brief summary of reasons the Board cannot assure the public fluoridation is safe.

This petition will start to protect the public from over exposure to fluoride and although not assure the public is safe, will be a good first step. This is not a definitive review of literature, rather a more than adequate review to determine fluoridation cannot be assured to be safe.

Note, I promoted fluoridation for a quarter of a century and am complicit in the harm which has been caused to the developing brains of the public. If you feel I have thrown a stone at you, I am passionate because the stone hit me first.

Sincerely,

Bill Osmunson DDS MPH

Washington Action for Safe Water

Washington State Board and Department of Health
PO Box 47990
Olympia, WA 98504-7990
wsboh@doh.wa.gov

February 18, 2024

Washington Action for Safe Water

Bill Osmunson DDS MPH

Dear Washington State Board of Health (Board) and Department of Health (Department),

RE: PART II: SOME REASONS FLUORIDAITON IS AN ENTRENCHED DENTAL PUBLIC HEALTH BELIEF. FURTHER TO OUR PETITION FOR RULE MAKING: WATER FLUORIDATION,

As defined and regulated by the FDA, fluoride is a drug. It is the only drug anywhere in the world allowed to be administered through public drinking water. There is absolutely no control over who gets it, how much, for how long and no warnings of its potential harmful side effects. It violates every protocol of prescribing a drug by a physician.

"The dose makes the poison." If you put this drug into the drinking water, you can't control the dose. If you can't control the dose, you can't control the poison. It defies common sense to put ANY drug into tap water.

OUTLINE

I. Failure to consider long term disease trends, morbidity

II. Failure to critically examine and confirm how the theory started

III. Failure to require quality research and Failure to research HARM/SAFETY

IV. Failure to be inclusive of those who disagree with us

V. Failure to combine all streams of evidence.

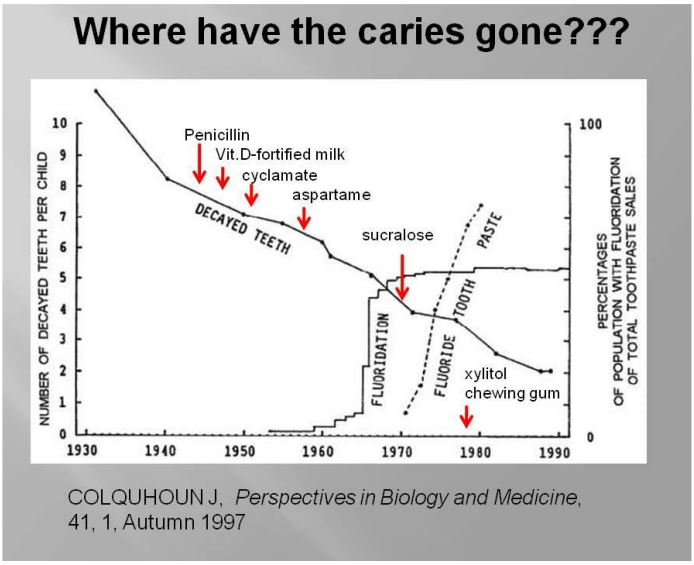
VI. How to Hide the Evidence of Harm

VII. Failure to critically question those we trust

I. Failure to consider long term disease trends, morbidity

Diseases have cycles. We know the yearly increase and decrease cycle in diseases such as influenza. However, there are long term cycles over many years. In research, controlling for the cycles can be problematic.

Once again, a graph of dental caries over 60 years. The fluoridation lobby has not answered the critical question, what caused dental cavities to decline **prior** to



fluoridation? No one knows. This graph suggests some possibilities for caries reduction. Others have speculated possibly better nutrition with fresh fruit and vegetables shipped year-round, i.e. transportation.

Certainty, the caries decline prior to fluoridation was not caused by fluoridation. Research can't knowingly and adequately control for the powerful effect of those unknowns. Critical thinking must question the confidence of later research when we don't know why caries declined before fluoridation and are unable to control for those unknowns. Just because two events happen, is not proof they are related.

II. Failure to critically examine and confirm how the theory started

An excellent easy book to read is by Christopher Bryson, “The Fluoride Deception” How a Nuclear Waste Byproduct Made Its Way Into the Nation’s Water Supply. I don’t like the title, because it sounds like a “deep state conspiracy.” However, the book is well documented, fluoridation is not “deep state conspiracy” and the book is an easy read.

To make the atomic bomb, back in the 1940’s, fluoride was and is used to refine uranium. Research was done to determine how hazardous the fluoride would be. The option was given, be safe, do the research slowly and with precautions, or build the bomb fast and some people will be harmed. World War II was in progress and many were dying. The choice was made to build the bomb fast at the risk of workers in an effort to save soldiers. The research was part of the Manhatton Project and not till years later became public. Meanwhile, the public was assured fluoride was safe.

Public Health employees were hired to promote fluoridation and early research, although flawed, became fact. Theory became fact without adequate research.

My last class in my master’s program the professor was telling us how we were to promote policy regardless of our personal opinion. I raised my hand and asked, “what if my boss tells me to promote tobacco smoking.” He paused and said, “promote tobacco smoking but not to the best of your ability.” I changed professions because I could not ethically support condoning or remaining silent when people are being harmed. Silence is not always silent.

Fluoride was alleged to prevent dental caries because people living in naturally high fluoride areas appeared to have fewer cavities, or was it the minerals? The phosphate fertilizer companies were spewing fluoride scrubbings into the environment causing serious damage. The obvious solution to the pollution was dilution.

Read Bryson’s book. I’ll send you mine if you ask. Well referenced and an easy read.

III. Failure to require quality research and Failure to research HARM/SAFETY

DO NOT CONFUSE CLAIMS OF EFFICACY WITH ASSURING SAFETY

The Board is to assure safety, not efficacy. To assure safe water requires safety studies. The fluoridation lobby will constantly move the discussion to efficacy rather than provide safety studies. Many studies "claim" safety but do not evaluate safety. The Board claims they have thousands of studies on safety, references are missing.

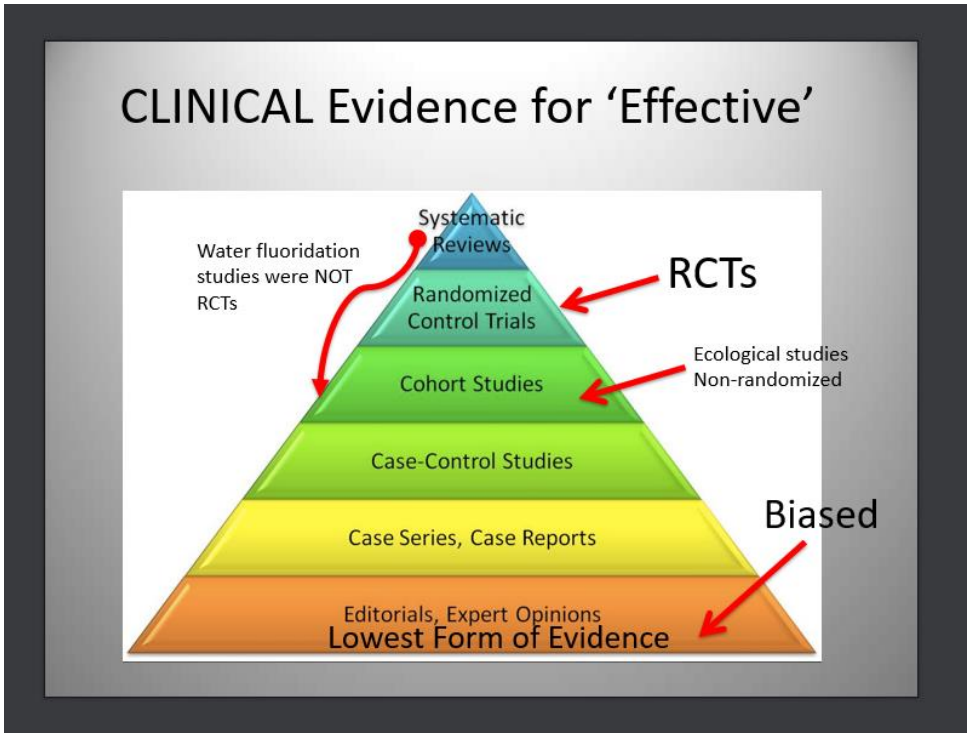
However, the Board should also understand the studies on efficacy have not risen to the quality level of FDA CDER approval. Randomized Controlled Trials (RCT) are considered the "gold standard" for research. RCTs are prospective studies, essential to determine efficacy. Researchers and subjects are both blinded, they don't know if they have the drug or a placebo. Subjects are randomly selected and the study is prospective in design. Even those are not "proof" positive of benefit and long-term risks are seldom considered.

No RCTs have been done with community water fluoridation. They could be done, but more complex because we are dealing with tap water. However, fluoride tablets could be used and one was published, but it did not show significance.

Without RCTs we are left with lower quality studies which have less confidence and safety is not readily observable.

Fluoridation efficacy studies are not RCTs and have more uncertainty. Safety studies are lacking, incomplete. For example, the NRC 2006 report highlighted inadequacies in many areas of "safety" research.

A pyramid of increasing quality of studies for efficacy is provided below.



Safety is difficult to study. Research on safety cannot have RCTs. It would be unethical to intentionally cause harm. The study of fluoridation's safety, at best, uses cohort studies, ecological studies and seldom monitors side effects other than dental fluorosis. Seldom is money put into determining risk and harm because there is no profit looking for harm. And if harm is found, liability becomes a concern.

Our recent experience with COVID should give the Board pause. Many were dying, hospitals full, an experimental vaccine came out and many of us agreed the public must get the vaccine, and most of us did. Risks were minimized. Harm may have been under reported and studies incomplete.

The same minimizing of risks, marginalizing of harm, lack of safety studies and robust support from authorities, has taken place with fluoridation over the past 80 years, except dental caries are not highly lethal nor contagious. The vaccine has RCTs, FDA CDER NDA approval, labels, dosage, doctor's oversight, and patient

consent. Fluoridation has none of those. Even choosing where we live does not avoid the water because we don't know if the drinks or processed foods contain fluoridated water. (I am not anti-vaccination. The illustration is used because I know the Board is well aware of the public's concern.)

Some research supporting fluoridation's efficacy, include the 2000 York Review, the Community Preventive Task Force of 2013, the 2017 Australian Government Review, the 2022 Brazilian Systematic Review. However, these and others were stacked with believers who confirmed their belief, and did not seriously evaluate safety. For example, if we survey Ford dealers, guess which truck comes out as the best. "Safe and Effective" has been repeated so many times, we assumed it true.

The Cochrane Review of fluoridation in 2015 was slightly different and a better quality of review. However, Cochrane Reviews require RCT studies. None exist, so Cochrane failed to require RCTs. Cochrane limited the studies reviewed to lower quality prospective studies.

When you listen to the fluoride lobby, they will almost always limit their comments to Cochrane's statements that *"fluoridation is effective at reducing levels of tooth decay among children."* And will fail to mention the Cochrane study reservations. Summarized:

1. "These results are based predominantly on old studies and may not be applicable today."
2. "we did not find any on the benefits of fluoridated water for adults."
3. "We found insufficient information about the effects of stopping water fluoridation."
4. "We found insufficient information to determine whether fluoridation reduces differences in tooth decay levels between children from poorer and more affluent backgrounds."

5. “We had concerns about the methods used, or the reporting of the results, in the vast majority (97%) of the studies.”
6. “For example, many did not take full account of all the factors that could affect children’s risk of tooth decay or dental fluorosis.”
7. “There was also substantial variation between the results of the studies, many of which took place before the introduction of fluoride toothpaste.”
8. “This makes it difficult to be confident of the size of the effects of water fluoridation on tooth decay or the numbers of people likely to have dental fluorosis at different levels of fluoride in the water.”
9. **Authors' conclusions:**

10. There is very little contemporary evidence, meeting the review's inclusion criteria, that has evaluated the effectiveness of water fluoridation for the prevention of caries.

11. The available data come predominantly from studies conducted prior to 1975, and indicate that water fluoridation is effective at reducing caries levels in both deciduous and permanent dentition in children. Our confidence in the size of the effect estimates is limited by the observational nature of the study designs, the high risk of bias within the studies and, importantly, the applicability of the evidence to current lifestyles. The decision to implement a water fluoridation programme relies upon an understanding of the population's oral health behaviour (e.g. use of fluoride toothpaste), the availability and uptake of other caries prevention strategies, their diet and consumption of tap water and the movement/migration of the population. There is insufficient evidence to determine whether water fluoridation results in a change in disparities in caries levels across SES. We did not identify any evidence, meeting the review's inclusion criteria, to determine the effectiveness of water fluoridation for preventing caries in adults.

12. There is insufficient information to determine the effect on caries levels of stopping water fluoridation programmes.

13. There is a significant association between dental fluorosis (of aesthetic concern or all levels of dental fluorosis) and fluoride level. The evidence is limited due to high risk of bias within the studies and substantial between-study variation.

The Cochrane review lacks confidence in efficacy. However, based on the limited evidence available, Cochrane reviewers reported “a significant association between dental fluorosis and fluoride level.” Safety from dental fluorosis is not assured, in fact undisputed. The Board’s job is to assure safety, not efficacy. The fluoridation lobby will claim dental fluorosis is just a slight blemish and of no concern. Patients disagree, almost half would like the spots removed. When both functional and cosmetic dental fluorosis harm is combined, dentists make

a significant amount of money selling the fluoride and treating the fluorosis caused by excess fluoride.

The absence of evidence of research safety is not proof the water is safe. In 2006, the National Research Council raised doubt fluoride was safe for:

1. Tooth Damage
2. Rheumatoid and Osteoarthritic-like Pain
3. Bone cancer
4. Bone Fractures
5. Thyroid Reduction, Obesity & Diabetes
6. Kidney damage
7. Reproductive problems
8. Lower IQ and Increased Mental Retardation
9. Allergies (overactive immune system)
10. GI disorders.

Further studies on each of those risks has supported concern of harm and has not assured us fluoridation is safe.

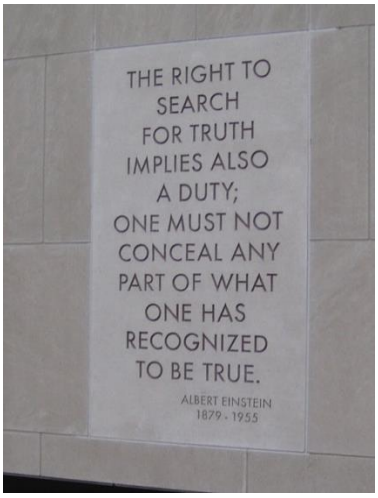
IV. Failure to be inclusive of those who disagree

The Chair of the National Research Council 2006 report on fluoride for the EPA which reported EPA's MCL was not protective, confirmed that this review was unique in that it was the first time a review committee had been formed which did not limit the members to those who supported fluoridation.

If only those who support a theory are asked to review the theory, the biased conclusion is possibly determined prior to the evaluation of the studies. Efficacy is claimed, harm is minimized and ignored.

V. Failure to combine evidence from all streams.

Our petition reviewed some streams of evidence. Keep in mind, it wasn't until the NRC 2006 committee raising concerns of fluoride's risks that some research funding started to evaluate primarily one risk, developmental neurotoxicity. The belief by authorities that fluoridation was safe, caused the few researchers evaluating safety to lose their laboratories, their funding, and some of them their jobs. Avoiding publishing their results of harm, protected future funding for their further research.



On the National Academies of Science Building, a plaque has been placed, pictured here. Failure to publish non-supporting evidence or cherry-picking evaluators or research is part of concealment.

Foreign countries started to evaluate fluoride's developmental neurotoxic effects before English speaking countries and those studies were first translated by the Fluoride Action Network. The Fluoride Action Network claimed to have a larger data base on fluoride than the Library of Congress (on developmental neurotoxicity of fluoride) due to translation of research into English.

Research started mainly on developmental neurotoxicity, brain damage while the brain is developing. Understanding the relationship between a toxin and the developing brain takes years for the child to develop and many more to understand toxic effects for adults. Measuring fluoride exposure and possible miscarriage, premature birth, infant mortality, and a host of other risks later in life, also takes time and funding. And studies must be repeated to achieve confidence.

Assuring safety is required, not proving harm beyond doubt.

VI. The Fluoridation lobby hides the harm: How to Hide Harm

1. Divide the streams of evidence and don't consider all the evidence.
2. Divide each stream of evidence enough times and raise doubt each specific aspect has absolute confidence of harm. Assuring safety is not the criteria. Proof of harm is required. And proof of harm takes many years, many studies, and a ton of money.
3. Divide each study, for example, divide subjects on natural fluoride from artificial fluoridation, divide the methods of measuring fluoride, age, gender, race, geography, health status, socioeconomics and the number of cohorts drops below significance.
4. If confusion and doubt on the harm is not achieved with those tricks, assume everyone fits in the mean. For example, assume everyone is in the mean and everyone drinks the same amount of water,
5. Assume other minerals in the water, such as calcium, have no effect.
6. Assume the comparison is only fluoridated water with zero fluoride exposure.
7. The EPA hired experts testified in court and agreed above 1.5 ppm fluoride concentration in water, the evidence is reasonably consistent fluoride is a developmental neurotoxin. However, below 1.5 ppm fluoride in water the EPA experts suggested the research is "inconsistent," less certain. Most of their doubt was based on one study which has been discredited.
8. Assume concentration is dosage. Pretend the only source of fluoride comes from water and if fluoridation is 0.7 ppm, then 1.5 ppm would be safe, assuming everyone drinks the same amount of water and no other source of fluoride.
9. Many experts suggest, for easy figuring, half the fluoride comes from water and half from other sources, although 1/3rd or 2/3rds is more realistic. In other

words, 0.7 ppm in water plus the same dosage of fluoride from other sources and would be close to an equivalent of 1.5 ppm fluoride. At that exposure level, court experts, both plaintiffs and defense, agreed with the NTP that fluoride was reasonably considered a developmental neurotoxin.

10. Although both a review by Canada Health experts and EPA's hired risk assessor in court refused to suggest an intraspecies uncertainty factor, even a 1:1 puts many in harm because not everyone is average. Most toxins have a 10:1 or 100:1 safety factor, or at least a 3:1 which would put many at risk of harm. If a 10:1 is used, water fluoridation should not exceed 0.15 ppm and a 3:1 would not exceed a 0.5 ppm concentration of fluoride in water. Fluoridated water at 0.7 cannot be assured safe. Even a 0.5 ppm concentration would still be much higher than mother's milk which has about 0.004 ppm fluoride concentration.
11. The third trimester of pregnancy is critical for fetal brain development and the average mom to be ingests 3.1L of water.
12. More research is always desired, but not necessary for us to be confident the Board cannot assure fluoridation is safe. For example, modeling or physiologically-based pharmacokinetic modeling that predicts how a chemical will be absorbed and metabolized by the body, hasn't yet been done for developmental neurotoxicity. . . or even after almost 80 years for fluoride ingestion, i.e. fluoridation.

The fluoridation lobby fails to take their criticisms of incomplete lack of proof of harm, safety research, and apply those criteria to their claim of efficacy.

VII. Failure to critically question those we trust

I trusted my professors on many issues and that was wise and essential, because that was the best they knew. However, one of my mentors reminded me that half of what they taught was wrong and they didn't know which half. In other words, we must be humble and not camp on any theory. We don't know it all and never will. The more of an expert in an area we become, the less dogmatic we become.

I was a school board trustee in a rural red neck community. The Chair wisely handled the public comments, "I've never learned anything from those who agree with me."

One of the reviewers of the NTP report on developmental neurotoxins, was also an expert witness in court defending the EPA's 4 MCL. The expert has, reportedly, been testifying for 34 years as an "Epidemiology Consultant," mostly lawsuits for defense of pesticides such as for Paraquat, manufacturers such as Syngenta and Chevron. Most countries have banned Paraquat which reportedly increases Parkinsons and is an acute poison. Another issue he has apparently been defense expert for is the cell phone companies and the research the electromagnetic fields from power lines and cell phones contribute to cancer. He does not say they are safe, simply raises enough doubt to stop regulation.

The Board's job is not to determine a confidence level of "proof of harm" but to assure without doubt the water is safe.

Our petition provides education for those evaluating fluoridation and the public. It is a start, although it will not stop fluoridation.

Washington Action for Safe Water