WSBH Appeal #21. October 1, 2024

Washington State Board of Health

PO Box 47990, Olympia, WA 98504-7990 wsboh@doh.wa.gov

Petitioners: Washington Action for Safe Water and Bill Osmunson DDS MPH

Dear Washington State Board of Health

RE: PETITION FOR RULEMAKING: WATER FLUORIDATION; IN KEEPING WITH THE NATIONAL RESEARCH COUNCIL; THE WASHINGTON STATE BOARD OF PHARMACY; THE U.S. FOOD AND DRUG ADMINISTRATION; THE ENVIRONMENTAL PROTECTION AGENCY SCIENTISTS; THE U.S. SURGEON GENERAL, THE U.S. CONGRESS IN THE SAFE DRINKING WATER ACT; THE U.S. CENTERS FOR DISEASE CONTROL; MOST DEVELOPED NATIONS; THE NATIONAL TOXICOLOGY PROGRAM; AND THE UNITED STATES DISTRICT COURT OF THE NORTHERN DISTRICT OF CALIFORNIA,

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

Suggested wording:

(8) The Board of Health does not recommend adding fluoridation chemicals to water with the intent to treat humans or animals.

Alternate wording:

(**8) In keeping with the Federal Safe Drinking Water Standards, the Board of Health does not recommend chemicals, including fluoride compounds, be added to the water with the intent to treat or prevent disease in humans or animals.**

When questioned about the scientific evidence for the alleged benefit 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)

1. The CDC Oral Health Division does not assess science on drugs and has no scientific papers, label, or dosage on the safety and efficacy of fluoridation. CDC Oral Health Division relies primarily the fluoridation lobby.
2. The EPA has not determined the safety or alleged efficacy of adding fluoride to public water. The EPA regulates fluoride as a protected contaminant. The EPA did not provide their scientists to the court for their defense in the Toxic Substance Control Act. EPA scientists are competent, they simply disagree with fluoridation and superiors are protecting the practice. The Safe Drinking Water Act prohibits the EPA from adding anything to public water for the treatment of humans.

The Department said they relied on known National entities and we list National, state and international entities here which the Department and Board have ignored.

I. **U.S. District Court is a National Authority and under the Toxic Substance Control Act (TSCA) ruled fluoridation is an unreasonable risk. The ruling in *Food & Water Watch, Inc. v. United States Envtl. Prot. Agency*, 17-cv-02162-EMC (N.D. Cal. Sep. 24, 2024)** Based on 7 years, 4 weeks of two trials, several experts on both sides, and hundreds of thousands of dollars in costs, the court concluded:

"IV. CONCLUSIONS OF LAW

"121. Plaintiffs have proven, by a preponderance of the evidence, that water fluoridation at the level of 0.7 mg/L – the prescribed optimal level of fluoridation in the United States – presents an "unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation under the conditions of use."

122. The Court thus orders the Administrator to initiate rulemaking pursuant to Subsection 6(a) of TSCA. . . ."

The Board would be foolish and negligent not to immediately stop promoting the addition of what RCW defines as a poison and the Board of Pharmacy exempted from poisons when regulated as a legend drug.

The Court ruling Page 5.

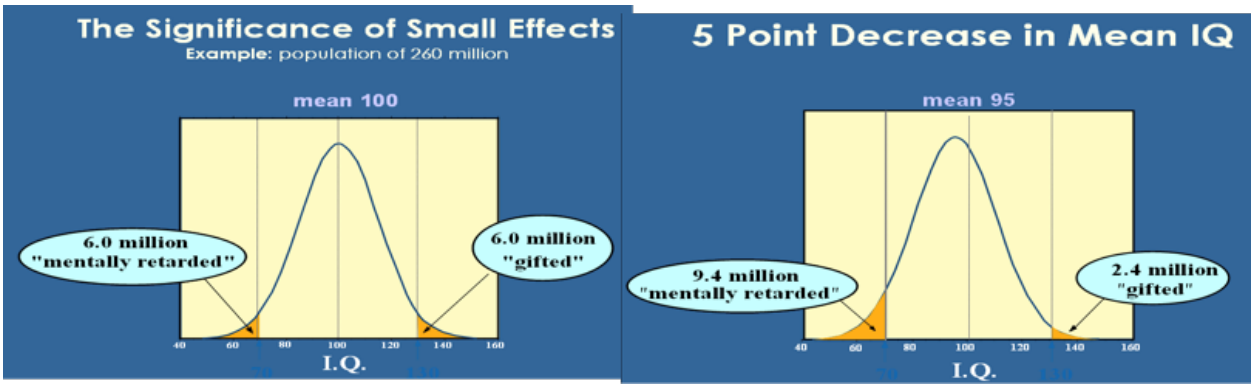
*"The pooled benchmark dose analysis concluded that **a 1-point drop in IQ of a child is to be expected for each 0.28 mg/L of fluoride in a pregnant mother's urine**. This is highly concerning, because maternal urinary fluoride levels for pregnant mothers in the United States range from **0.8 mg/L** at the median and 1.89 mg/L depending upon the degree of exposure. Not only is there an insufficient margin between the hazard level and*

these exposure levels, for many, the exposure levels exceed the hazard level of ***0.28 mg/L.”*** (Court supplied emphasis)

Based on data and analysis presented at trial, the Court at page 75 states, "*fluoride presents a risk of a decrease in IQ [for such offspring] ranging from 2.86 to 6.75 points.*" The lower number is the expected median loss and the upper number is the 95th percentile loss applicable to offspring of 1 in 20 mothers who drink the most fluoridated water.

However, we must not ignore the 5% of mothers who drink the most water, fail to fully rinse their mouths out after brushing with fluoride toothpaste and swallow some toothpaste, fail to eat organic foods, or ingest medications high in fluoride and have the highest urine fluoride concentration. About 250,000 babies are born in Washington State each year, 5% is about 12,500 babies and about 46% in Washington State on fluoridated water. Thus, **about 5,750 babies are estimated to have greater than 6.76 IQ point loss** and the Board must not ignore any babies.

Consider the charts below from the website of Physicians for Social Responsibility. When a population has 5 IQ loss, the mentally handicapped increase by 60% and we have data on those. We do not have data on the more than 60% decline in gifted or what you and I in the middle could have accomplished with 5 more IQ points.



Not all kidneys function to their optimal level and not all mothers have the same intake of other toxins which have a synergistic effect on the development of the brain of their fetus and infant, such as lead and arsenic.

The fluoridation lobby argues like the tobacco lobby, "but we do not have proof." When the Judge asked the expert witness in court, "what would it take for you to change your mind?" The expert responded, "one or two more studies." Many more have been published and the fluoridation lobby still responds, "one or two more studies are needed" and they will always want one or two more and require 100% proof of harm.

The Court Ruling understood the need for a margin of error: P6.

"The EPA's default margin of error requires a factor of 10 between the hazard level and exposure level due to variability in human sensitivities. Put differently, only an exposure that is below 1/10th of the hazard level would be deemed safe under Amended TSCA, given the margin of error required."

P 6. "In all, there is substantial and scientifically credible evidence establishing that fluoride poses a risk to human health; it is associated with a reduction in the IQ of children

and is hazardous at dosages that are far too close to fluoride levels in the drinking water of the United States. And this risk is unreasonable under Amended TSCA. Reduced IQ poses serious harm. Studies have linked IQ decrements of even one or two points to e.g., reduced educational attainment, employment status, productivity, and earned wages. Indeed, the EPA recognizes that reduction of IQ poses a serious community health issue."

Lower IQ is well-know, to result in increased Special Education rates, High School Drop-out rates, lower income, less job stability, less productivity, increased crime, increased homelessness, increased incarceration, increased divorce, decreased self-worth, increased public assistance, increased illicit drug addiction, and decrease gifted and brilliant members of our community. We are all harmed.

II. **National Research Council 2006:** The Board and Department refused to follow the advice of the **National Research Council 2006** authoritative report to the EPA nor the Dose-Response Analysis or Relative Source Contribution of the EPA 2010 or the scientists at the EPA who have said fluoridation is no longer effective and boarders on a criminal act of governments.

1. The National Research Council 2006 (NRC) unanimous decision that EPA's MCLG was not protective of harm, included numerous risks. Other risks raised by the NRC in 2006 and scientifically more fully confirmed during the last 18 years include:
    a. **Tooth damage**
    b. **Rheumatoid and osteoarthritic-like pain**
    c. **Bone cancer**
    d. **Bone fractures**

e. **Thyroid reduction**

f. **Diabetes**

g. **Obesity**

h. **Kidney damage**

i. **Reproductive problems**

j. **Lower IQ --developmental neurotoxicity**

k. **Allergies (overactive immune system)**

l. **Gastrointestinal disorders.**

If too much of a highly toxic substance causes spots on the hard tissue teeth, we would be seriously presumptive to rule out "spots" on the soft tissues or other hard tissues. My professions of dentistry and public health have been negligent in not researching the **safety** of fluoride ingestion. Without FDA approval, the study of safety has been mostly absent and risks ignored.

III. **Washington State Board of Pharmac**y: The Board of Pharmacy was the highest authority on toxic substances and drugs in Washington State, until disbanded. The Department of Health and the Board of Health have disagreed with the **Washington State Board of Pharmac**y which determined fluoride to be a legend drug, i.e. requires the patient's doctor's prescription and patient consent rather than poison. See **RCW 69.38.010.** Unfortunately, the Board of Pharmacy's reward for honesty was to be disbanded and placed under the heel of the Department of Health. The only legal option under RCW is for fluoride to be regulated as a poison because fluoride is highly toxic and poison laws are very strict and exempt when regulated as a legend drug needing FDA CDER approval with the patient's approval under the

supervision of a licensed health care provider. Based on science, laws and ethics, the Board of Pharmacy was indeed correct.

A. U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is a National Authority: The Board of Health has put itself as a higher authority and expert disagreeing with the **Food and Drug Administration (FDA).** The Department of Health has not relied on the authorized national authority.

a. The FDA warns, “Do Not Swallow” on the toothpaste label, referring to 0.25 mg of fluoride. The same dosage as one 11 oz glass of fluoridated water.

b. In a warning to drug manufacturers, the FDA was clear and correct, that the evidence of fluoride’s effectiveness was incomplete. Only one randomized controlled trial of fluoride ingestion has been published and it reported no statistical evidence of fewer dental caries, i.e. benefit. Yet the Board of Health claims benefit in disagreement with the FDA CDER.

c. The Board’s first denial of our request for the Board or water purveyors to apply for FDA CDER NDA (Food and Drug Administration, Center for Drug Evaluation and Research, 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 authorities, the FDA CDER.

d. In fact, the Board did call the FDA and the FDA specifically warned the Board that if the Board tried to gain FDA approval, fluoridation would be banned. What about “Do Not Swallow”, “incomplete evidence” and “banned” does the Board not understand and can dismiss as not relevant?

B. **National Toxicology Program (NTP) is most certainly a National Authority:** In 2015, I nominated cancer, thyroid harm and developmental neurotoxicity to the **National Toxicology Program (NTP)** for review. The NTP accepted the developmental neurotoxicity of fluoride for review and told me in a phone call the review usually takes about 2 years, inclusive of animal testing.

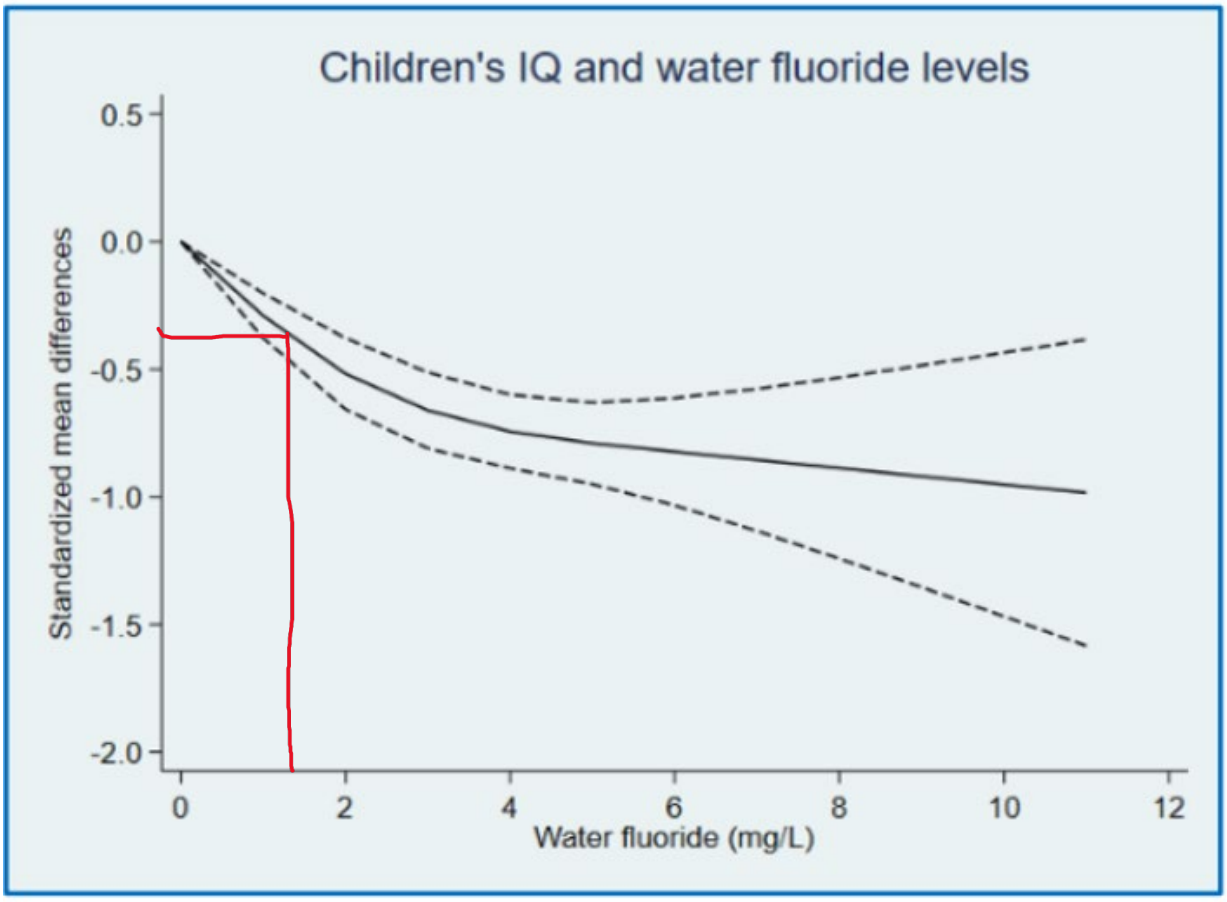
The 700-page draft had repeated peer reviews, (more than one is highly unusual) both internal and external of HHS, including the fluoridation lobby, and was blocked by HHS from release until the Court ordered the draft released. Eight years and eight months after nomination, the first section was published and the meta-analysis which has the strongest conclusions is supposed to be published later this year. The draft reported a presumed developmental neurotoxicant and the published reports moderate confidence. The NTP report did not suggest a "safe" concentration. Below 1.5 mg/L the meta-analysis shows there is no threshold of safety and at 0.7 mg/L fluoride in water has about 3 IQ loss.

A few considerations must be made on the NTP graph eFigure 17. Pooled Dose-Response Association Between Fluoride in water and Standardized Mean Differences in Children's IQ pasted below.

a. About half of fluoride ingested is from water and half from other sources, the NTP listed risk from water and the Board must consider total fluoride exposure. We have added two orange lines at the 1.5 mg/L fluoride concentration in water and the second going over to the standardized mean difference of about 0.4.
b. Water fluoride concentration of 0.7 mg/L is about half (30-70%) the total fluoride exposure. Thus 1.5 mg/L in water is approximately the total fluoride exposure of individuals. The fluoridation lobby and EPA have tried to separate the water from total fluoride exposure. Real-world exposure is total fluoride and the two cannot

and should not be separated. Thus, 1.5 mg/L is used here and the orange lines demonstrate the approximate 0.4 standardized mean difference (SMD).

c. The fluoridation lobby will discount 0.4 SMD as not significant, and they would be correct if SMD were the same as IQ. However, 1 SMD is 15 IQ points and 0.4 is 6 IQ point loss.



Now consider the 5% ingesting 10 times the mean quantity of water who would have babies with 10 to 15 IQ point loss.

C. **The U.S. District Court** September 2024, ruling supported the NTP and determined that fluoridation at 0.7 mg/L in water is an **unreasonable risk** and not only referred to a published Benchmark Dose Analysis but in effect did one.

*"The pooled benchmark dose analysis concluded that **a 1-point drop in IQ of a child is to be expected for each 0.28 mg/L of fluoride in a pregnant mother's urine**. This is highly concerning, because maternal urinary fluoride levels for pregnant mothers in the United States range from **0.8 mg/L** at the median and 1.89 mg/L depending upon the degree of exposure. Not only is there an insufficient margin between the hazard level and these exposure levels, for many, the exposure levels exceed the hazard level of **0.28 mg/L**."* (Court supplied emphasis)

a. It should be understood that the median urine fluoride concentration of 0.8 mg/L and 1.89 mg/L is not exactly the same as the concentration of fluoride in water, 0.7 mg/L accounting for various quantities of water consumed and other sources of fluoride. About half the fluoride is retained in the body (depending on kidney function etc.) and about half is excreted. And about half the total exposure of fluoride is from water and about half (estimated 30-70%) from other sources. Thus, the Court's 0.8 mg/L fluoride in urine is similar to 0.7 mg/L fluoride in water. For ball park estimations, urine and water concentrations are reasonably comparable. And 1.89 mg/L represents a reasonable variation in water consumption for up to the 95th percentile of mothers. On page 75 of the Court's findings the 95th percentile of mothers drinking 2-3 liters of water a day with children having 6.75 points IQ loss is reasonable.
b. As stated earlier, the Board cannot call fluoridation safe for a mother drinking the average of 1 liter per day of fluoridated water. Mothers drinking 2 to 3 liters of water are at the 95th percentile and their children would probably have 6.75 IQ loss. Even worse are the 5% of mothers who drink more than 2 to 3 times times

the mean/media. A few mothers drinking for example 4 liters of water a day would expect closer to a 10 IQ point loss for their child.

D. Based on FOI documents, **the U.S. Surgeon General** quietly stopped endorsing fluoridation.

E. **The U.S. Environmental Protection Agency scientists** through their union: *"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

F. **The Centers for Disease Control:** CDC: "Ingestion of fluoride is not likely to reduce tooth decay." Drinking Water to Prevent Dental Caries. MMWR, 48(41); 933-940, October 22, 1999 Achievements in Public Health, 1900-1999:

The Oral Health Division of the CDC is in the pocket of the American Dental Association and seldom in statements even alters the words enough to avoid plagiarism.

The CDC does not approve drugs, the FDA CDER has drug approval authority. The CDC does provide free drugs for investigational purposes, fluoride is not one.

G. **International authorities opposed to fluoridation. 97% of Europe** is fluoridation free. Most developed countries do not fluoridate public water.

H. Austria REJECTED: "toxic fluorides" NOT added

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

J. 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...."

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

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

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

N. Sweden BANNED: "not allowed". No safety data available!

O. 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.

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

Q. Japan REJECTED: "...may cause health problems...." The 0.8 -1.5 mg regulated level is for calcium-fluoride, not the hazardous waste by-product which is added with artificial fluoridation.

R. Israel SUSPENDED mandatory fluoridation until the issue is reexamined from all aspects.: June 21, 2006 “The labor, welfare and health Knesset committee” As of 2024 still suspended.

S. China BANNED: "not allowed“

T. International Academy of Oral Medicine and Toxicology is opposed to fluoridation. Position paper

U. American Academy of Environmental Medicine “Fluoridation has been called one the ten great public health achievements of the 20th century by the Centers of Disease Control in the US. As research continues to unfold the truth about the use of this supposed ‘healthy mineral’ has become clear. Fluoridation is more

likely one of the ten most dangerous public health practices in this country and in the world. The American Academy of Environmental Medicine's position is that there is absolutely no benefit to public health that Fluoride should be recommended or utilized."

V. **The Nuffield Council, Bioethics on fluoridation:** "public health policy involving the water supply should be considered in relation to:

a. the balance of risks and benefits [brains are more important than teeth]

b the potential for alternatives that rank lower on the intervention to achieve the same outcome. [oral hygiene and diet]

c. the role of consent where there are potential harms"[1] [fluoridation lacks consent and has known harm, more than potential harms.

The US Department of Bioethics has not yet responded and I will inform the Board when they respond.

FLUORIDATION LOBBY: For about the first 25 years of practice I promoted fluoridation and was part of the fluoridation lobby. After reading the science and all streams of evidence, I became opposed to fluoridation. With further study I realized I, like most dentists, had made millions of dollars selling fluoride topical in my office and

[1] Ethics Consultation Report Ethical Considerations in Community Water Fluoridation, by the Public Health Agency of Canada's Public Health Ethics Consultative Group, December 18, 2018 p.2. https://www.caphd.ca/sites/default/files/Ethical%20Considerations%20for%20Community%20Water%20Fluoridation.pdf

treating both cosmetic and functional dental fluorosis with fillings, crowns, root canals, extractions, bridges, implants and more.

a. The fluoridation lobby, those employed to promote fluoridation, those with memberships supporting fluoridation, the fluoride manufacturers, dental product manufacturers using fluoride, those selling fluoride in their offices, are biased because of money. For example, a dentist with 1,000 patients (many have more) charges about $30 for fluoride treatments 2x a year or $60 per person per year X 1,000 patients is $60,000. My office with 4,000 patients generated close to half a million dollars a year with almost no doctor time and very little materials costs. Functional harm can exceed cosmetic harm easily costing thousands of dollars per patient.
b. The fluoridation lobby discounts the Court ruling due to misunderstanding and bias. The fluoridation lobby often fails to understand the difference between concentration and dosage. Concentration of fluoride in water is held reasonably constant but dosage is not controlled because not everyone drinks the same amount of water, some 10 times more than the mean. (NRC 2006)
c. The pushback from the fluoridation lobby/salesmen is reminiscent of the tobacco defense of tobacco, which for decades delayed public health action. Simply delay, delay, delay and raise doubt.
d. The fluoridation lobby attempts to separate out just the fluoride from water from all the other fluoride and when talking is referring to just the fluoride contributed by the fluoridation. In the real world to determine hazard, total fluoride exposure needs to be considered.

e. The fluoridation lobby fails to consider the chemicals added to the water are industrial grade rather than pharmaceutical grade.

f. The fluoridation lobby fails to include individual consent.

g. Dentists are prohibited from diagnosing general health diseases such as developmental neurotoxicity and without evidence have claimed fluoridation is safe. . . meaning for teeth, not the entire body. However, fluoridation harms teeth, dentists think they are doing good and forget the harm.

h. The fluoridation lobby has been so intent on protecting fluoridation they have failed to provide quality research and gain FDA CDER approval.

i. The fluoridation lobby usually only considers up to the 90th percentile who drink twice the average of 1L of water/day, about 330,000 of the 3.3 million people in Washington State.

j. The fluoridation lobby does not include a margin of error or intraspecific variability which should be 10x for each, 100 X the hazard benchmark.

k. The fluoridation lobby accepts observational studies for proof of efficacy; however, they reject observational studies of risk and harm as inadequate quality.

l. The fluoridation lobby has failed to gain FDA CDER approval.

m. The Fluoridation lobby has failed to follow RCW such as provide a forum. 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 . . . ."

(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."*

n. We are unable to find in Washington State or Federal Laws where the Board or Department of Health is specifically authorized to determine the **efficacy** of a substance added to public water intended to treat humans.

However, WAC 246-290-220 permits the Department to continue 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;''

o. We again register our complaint of dental fluorosis aesthetic and functional harm and other health concerns is made to the Department of Health.

For the health of the public, we have requested a forum as provided in RCW 43.20.050 where experts can provide the Board with evidence and we can hear concerns, objections, and questions.

p. **"RCW 43.20.050** does not authorize the Board to dilute drugs in the water with the intent to treat humans rather than treat water, nor does it permit the Board to reduce the safety of the water.

q. **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. Fluoridation is NOT safe.

r. **FLURODIE IS HIGHLY TOXIC:** 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, however, preliminary studies indicates a higher rate of miscarriage in fluoridated communities. Without dispute, fluoride is an extremely toxic substance, poison, more lethal than lead or gasoline.

s. FLUORIDATION IS AN UNAPPROVED ILLEGAL DRUG

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."*

Seriously, the Board . . . had NOTHING to back up why they recommended adding fluoride to public water. However, FOI 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 Board's claim of "no records" was simply a "white lie."

The Board now clearly states,

"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 think anyone could get FDA CDER approval. The Board preferred to be dishonest and claim they had no record of intent, rather than protect the public health. Intent determines jurisdiction.

t. **In contrast, to the Washington State Board of Health the Washington State Board of Pharmacy 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."

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

The WSBP 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, but the FDA rather than industry approves substances intended to prevent disease in humans.

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.*

u. For 14 years the Board of Health has not answered the obvious question, "who is the practitioner under who's license the dispensing the fluoride drug is dispensed to everyone without their consent?"

v. The 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

w. 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, nor does the law state the intent to fluoridate. Our rule change petition does not conflict with RCW 57.08.012.

Pause for a moment and seriously let **RCW 57.08.012** soak in. 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? No.

For example, just because RCW permits an individual to get a drivers license, does not mean they can ignore the laws of the road or the highway jurisdiction 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 ensure the issue of safety. We agree the Board has jurisdiction over the laws and science relating to **RCW 57.08.012** are followed. In the last 4 decades since **RCW 57.08.012** was passed we have more evidence to consider.

x. The Department 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 requires "substantial evidence." I spent over 4 decades treating aesthetic and functional dental fluorosis, a known adverse effect of excess fluoride ingestion.

y. The substance added to public water is NOT pharmaceutical grade which is assumed in the PDR that the Board of Pharmacy relied on, but rather industrial grade 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.

z. THE SAFE DRINKING WATER ACT DOES NOT PERMIT FLUORIDATION.

The Board appears in violation of the **Safe Drinking Water Act** as detailed below

Our point: The SDW Act prohibits the addition of anything to tap water to treat humans.

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

The Board is also in violation of the **FD&C Act** as detailed below and in Attachment #A.

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 fluoridation is well known to the public, to prevent dental cavities.

The Board's intent to add fluoride to water is to 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.

Only the FDA CDER (U.S. Food and Drug Administration Center for Drug Evaluation and Research) has legal authority to approve substances with intent to prevent disease and they will determine efficacy, dosage for efficacy, safety at that dosage and a label of warning and caution. Other agencies have opinions and endorsements, but not legal authority to approve drugs.

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 or 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, the legal intermediary must be.

Legislators in 1988 did not have the science available to approve RCW 57.08.012, and the dental lobby deceived the Legislature.

Nor does RCW 57.08.012 authorize the Board or Department to be the marketing, promotional or advertising arm for the unapproved drug.

Neither a vote by the public, vote by commissioners, vote by the Board of Health, or vote by the Legislature changes science, empirical facts, the lethality, the poisonous hazardous nature of fluoride any more than they can vote the weather to change.

I contacted the FDA and asked if sodium fluoride was an approved drug, 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).

Lack of FDA CDER approval for fluoride ingestion should immediately turn off the fluoride pumps until approval is gained. Anything less, including this petition, will leave many harmed.

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."

"It is difficult to get a person to understand something when their salary, profit, or reputation is dependent on them not understanding it." Upton Sinclair (paraphrased)

The fluoridation lobby[2], profiting from fluoridation, has bias in favor of fluoridation. This rule change does not prohibit fluoridation but rather states the Board's recommendation and

[2] The profitable sales of fluoride and treatment of dental flurorosis, both cosmetic and functional damage which contributes to increased chipped, broken, cracked teeth, and the resulting fillings, crowns, root canals, extractions, bridges, and implants are included, the average dentist makes millions of dollars throughout their professional lives on fluoride. The American Dental Association, dentists, sponsoring manufacturers, those with salaries (public health) to promote fluoridation, the sugar industry, pesticides, pharmaceuticals, military, and chemical companies are a few of the fluoridation lobby.

begins the process of informing the public. Water purveyors may still fluoridate water; however, this rule change should encourage them to re-evaluate their practice.

The Board's words have an impact and water purveyors and the public have trusted the Board of Health and this rule change of caution will help to protect the Board's credibility. For example, the January 6 insurrection was impacted by words from an authority and many of those trusting the authority are in jail. The Board of Health's claim that fluoridation is safe and effective is harming many, especially our most vulnerable. The Board has recently placed responsibility for fluoridation on cities and water districts. However, the Board as authority must not attempt to hide from the impact of your words.

The impact on the Board of Health of this rule change will be to remove your endorsement from your web page.

This petition builds on the science of our first 20 petitions and they should be reviewed to more fully understand the science and laws supporting this petition. Although this petition has been motivated by the current "US District Court Finding" that fluoridation is an unreasonable risk, the Board must keep in mind:

2. IQ loss is only one way to measure developmental neurotoxicity and developmental neurotoxicity is just one health risk from fluoride ingestion.

The Board would be wise to take a "global" view of all risks, total fluoride exposure from all sources and not just water. And further, to consider all subpopulations such as age, synergistic effects, race, gender, ethics, individual health, and authoritative statements from regulatory authorities worldwide. It is not the duty of the patient to prove with absolute certainty that the Board of Health is harming them, that duty lies on the authorities fluoridating, i.e. the Washington State Board of Health.

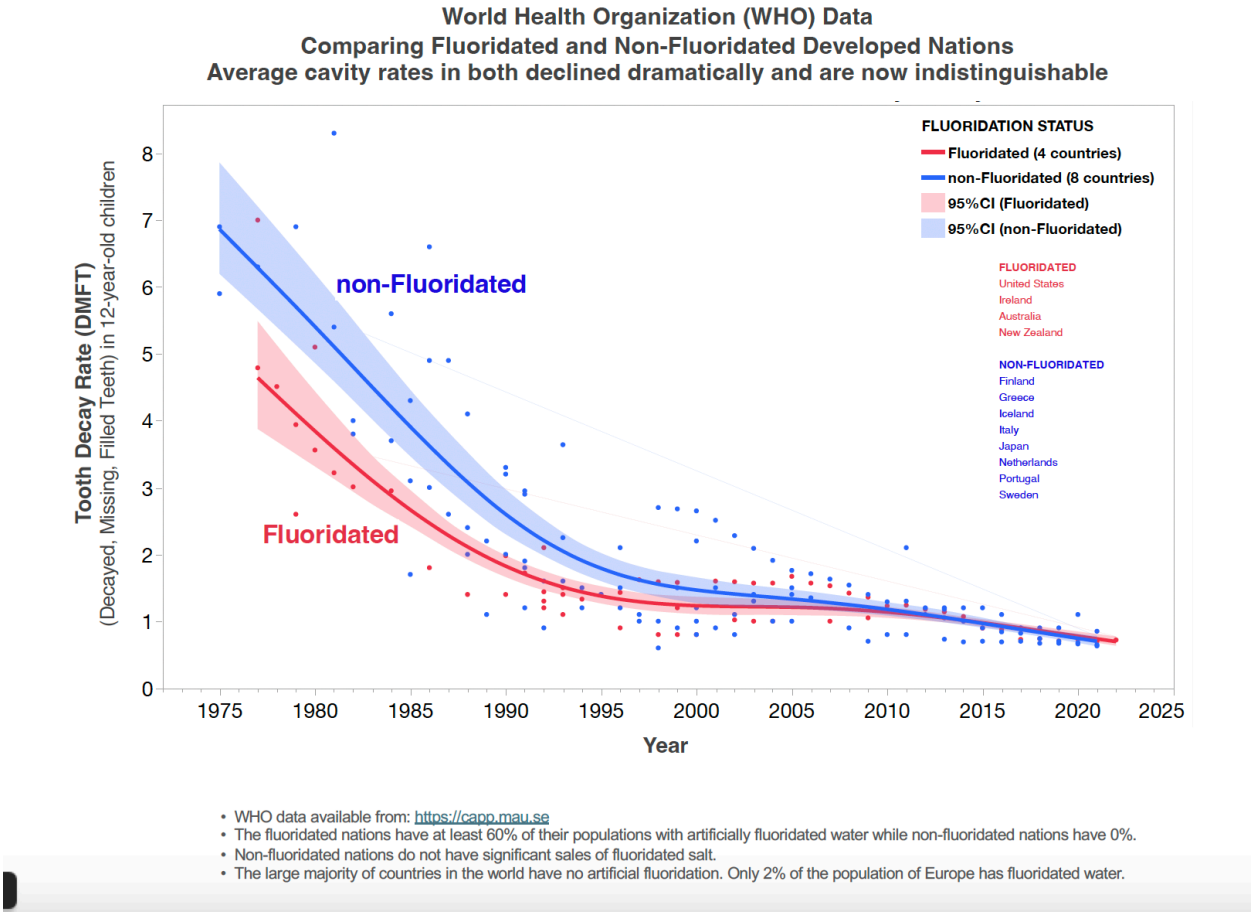
Absolute 100% proof of harm is not necessary to determine unreasonable risk of harm. Science does not operate in 100% proof. For example, we do not fully understand nor have all

the answers on how one body of matter such as the earth has an attraction, i.e. gravity. And we scientists must never anchor a belief, concept or thought in stone. Science is a moving understanding. We should always be learning. The challenge is that health care providers and authorities must make treatment decisions and policy based on the best and yet usually incomplete evidence. And we must be willing to change treatment and policy when the science changes. That is one reason professional continuing education is essential.

My mentor in dental school reminded us that "50% of what we know is wrong. The problem is we don't know which 50%." All of us must be open to learning and correcting our flawed understanding when new science is discovered.

The Board of Health, as the authority in Washington State over fluoridation, would be wise and protective of the public health by following the Court's Finding of Fact and Conclusions of Law Case No. 17-cv-02162-EMC, US District Court, Northern District of California see attached. Although the Court's ruling was the first step against the EPA, as the Toxic Substance Control Act requires, the science and conclusions apply to the Board and all. Fluoride from fluoridation, along with other sources of fluoride, is unreasonably excessive. The EPA will either stop fluoridation or the court will come back with a stronger ruling. The Board should not continue to harm infants and babies for years witing for the EPA delays. Stop promoting fluoridation as most authoritative authorities have done.

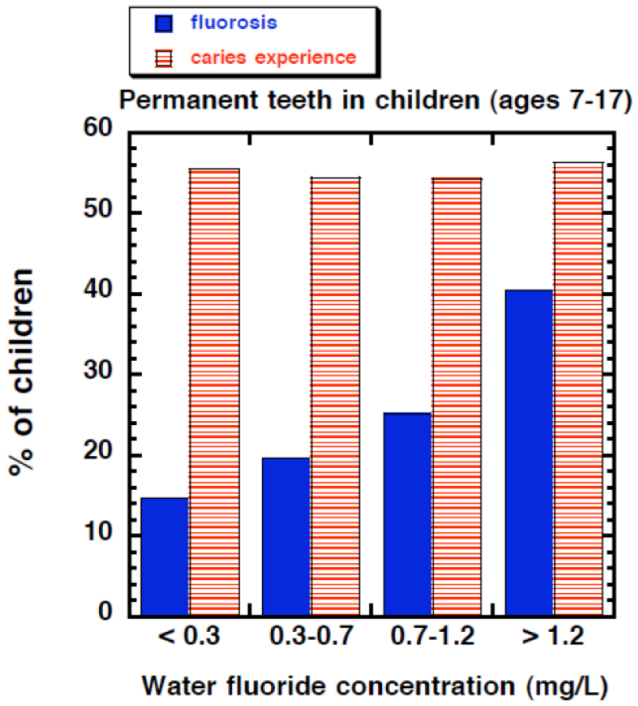
For example, see the graph below comparing cavity rates between fluoridated and non-fluoridated countries. Current evidence does not find public health benefit of fluoridation.



Then how does the fluoridation lobby come up with a 25% reduction in dental caries? As presented in previous petitions, there are several serious limitations to current research and many reasons for reduced caries. Fluoridation has been mistakenly been given credit for a reduction in dental caries.

Consider the following data published in the Journal of the American Dental Association.

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

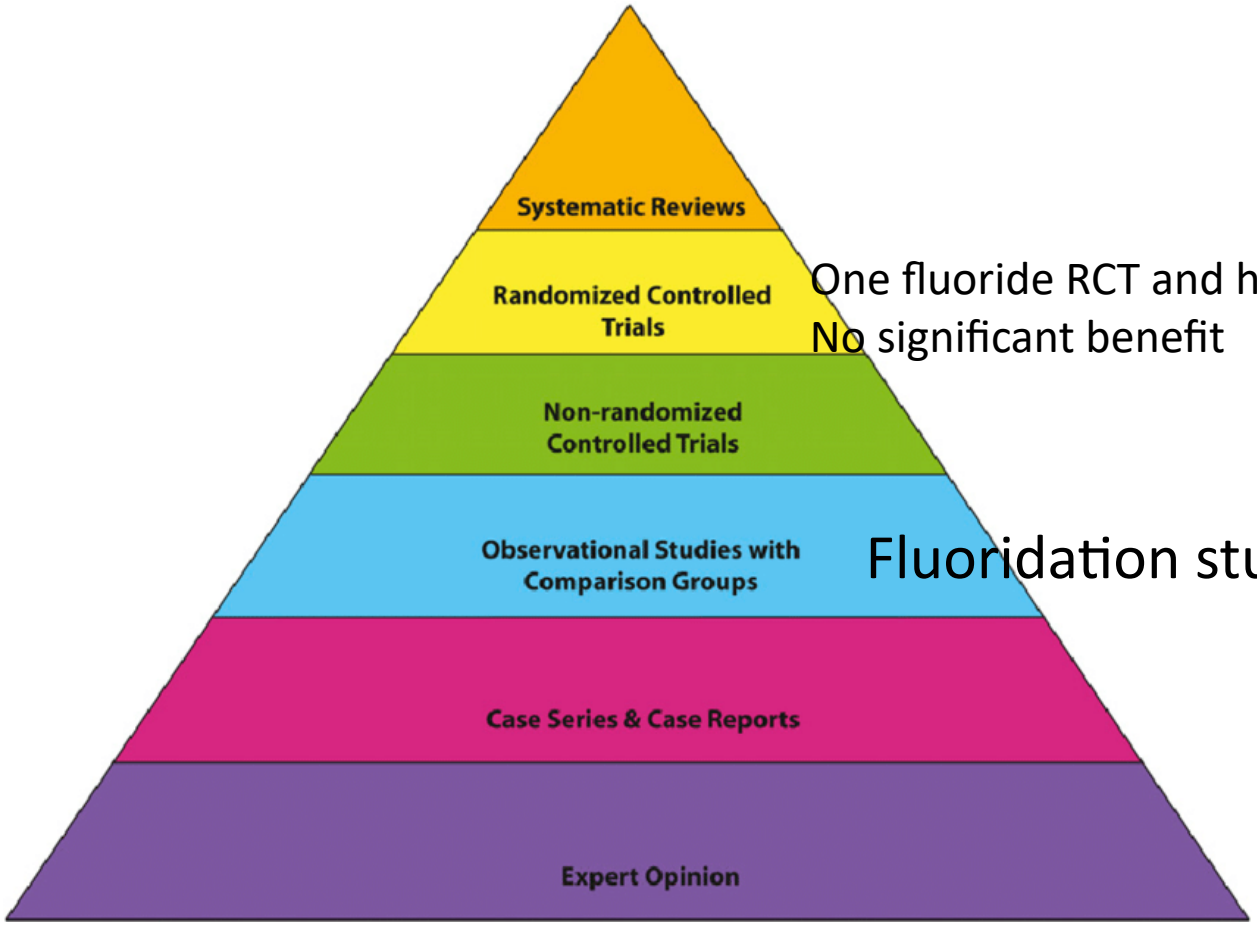


The data was published; however, this graph was produced from the published data.

When fluoride concentration goes up in the water, dental fluorosis goes up but caries has a non-significant change. Claiming a "25%" reduction in dental caries is based on historic flawed observational studies.

A short review of research quality is prudent, see the graph below. Note that the highest quality of research supporting fluoridation's benefit is "observational" which is not adequate for FDA approval. In part, evaluating risks, harm and adverse effects is not likely when only benefits with an observational study are considered. And just because two

events are observed does not mean they are related. Too many factors affect dental caries to have confidence that fluoridation is the cause for some coming into our office with fewer cavities.



By mistakenly giving credit to fluoridation for fewer cavities, public health wastes time and effort which could be spent on promoting better and safer interventions.

SCIENCE:

HOW LETHAL AND CONTAGIOUS ARE DENTAL CARIES?

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

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 are not considered highly contagious or lethal. Even ingestion of pharmaceutical grade fluoride is not FDA CDER approved to mitigate (prevent) caries.

A. How Much Fluoride is Recommended? Dosage and Dose

"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, did not change the science.

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.

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) By comparison, mean concentration of mother's milk has been reported at 0.004 mg/L for samples where fluoride was detected.

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 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, 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 critical to understand and keep in mind.

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.

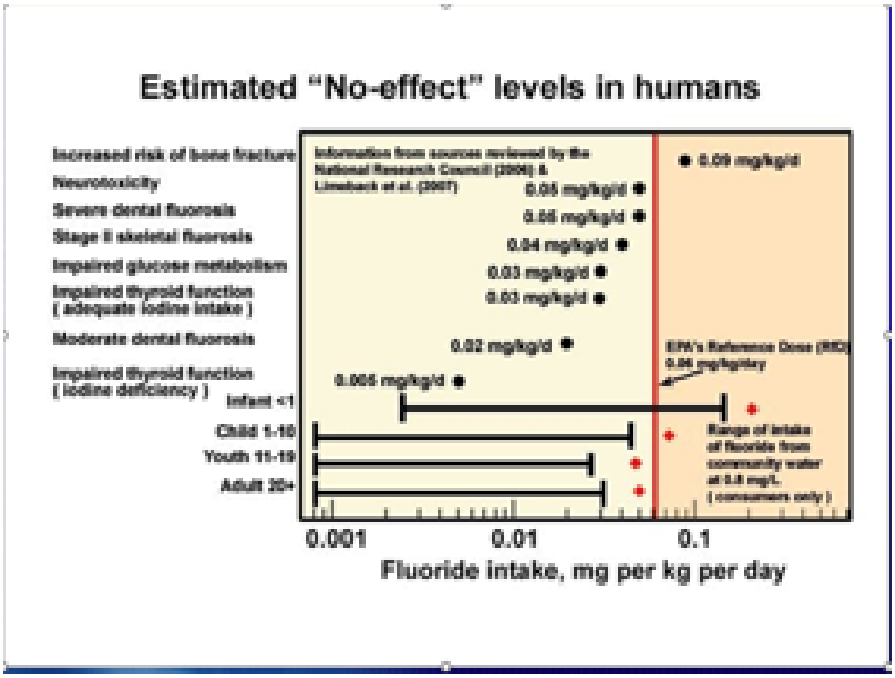
#4. The fetus is ignored. That is all of us. . . at one time. The most vulnerable infants are ignored by the EPA, unprotected. No wonder research demonstrates breast feeding is superior, lack of fluoride maybe one contributing factor.

#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.

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



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 harm is caused.

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 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 determine the efficacy, dosage, safety or label of fluoride ingestion. Congress charged the FDA CDER with that task. EPA does not assume responsibility for determining the efficacy of fluoridation.

RCW instructs the Board to have aesthetic concerns as a threshold and in contrast the EPA has severe harm as a threshold for concern. Again, even if the Board insists the EPA has authority to regulate and approve drugs when mixed with tap water, the Board and public must not trust the EPA to have oversight of fluoridation as a contaminant. While the EPA has 4 ppm MCLG, the rest of the world uses 1.5 ppm.

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.

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

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:

". . . 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, OR INTRASPECIES VARIATION**

In contrast, the EPA claims fluoridation is so safe for everyone that a margin of error or uncertainty factor has been set at "0," no margin of error or uncertainty factor for anyone regardless of how much water they drink, toothpaste they swallow, general anesthesia they undergo, post-harvest fumigated foods they eat, kidney function, other toxins they ingest, genetics, etc.

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: The statistical mean is not protective of many or most people. An uncertainty factor and margin of error must be added.

BENEFIT OF FLUORIDE INGESTION

Fluoridation is claimed to be one of public health's greatest achievements of the 20th Century. Many English speaking health associations are repeating the claim.

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…" CDC

Keep in mind, about 60-70% of the population show signs (biomarker) of excess fluoride, dental fluorosis, prior to eruption of the tooth. CDC says benefit is primarily topical after tooth eruption.

Dental saliva has about 0.019 ppm of fluoride and contact time is minimal. 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. [End note]

A closer look at **three (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 and the caries reduction is disputed.

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. 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;"

Fluoride's intent of use and the Board of Pharmacy determination places fluoride as a drug and drugs are certified and approved by the FDA CDER. Fluoride chemicals are not certified as effective.

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 and dental fluorosis for many, if not most, children.

The cost of all "health related concerns" has not been estimated. Just dental damage OR brain damage far exceeds possible caries mitigation.

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.

Add 3 lower IQ points resulting in lower income, and fluoridation becomes a cruel and unusual punishment for the public. My estimates based on research and clinical experience. PPPY is Per Person Per Year. Dollars adjusted to 2021.

ESTIMATED Cost to fluoridate water $3-$10 PPPY Ko and Thiessen

Averted caries (money saved)	$6.08 PPPY (Ko and Thiessen)
Dental fluorosis Treatment	$3.24-$153 PPPY (Osmunson estimate)
IQ loss (assume 3 IQ loss and $500/yr lower income/year	$2,156 to $2,552 PPPY (Osmunson estimate)

Cost of harm to just the teeth, overwhelms any estimate of cost benefit. A cost estimate resulting in savings requires the dental lobby to only use some costs to fluoridate, minimize harm, exaggerate cost savings, and ignore costs for damage, harm, risks.

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." Caries explodes inside before a diagnosis.

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.

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.

Increased fluoride exposure can increase dental caries. If there is a "sweet spot" of fluoride dosage exposure to prevent caries, the spot is not big.

#2. Another Board false claim: "Water fluoridation reduces tooth decay by about 25 percent over a person's lifetime."

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 and 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 and then shown not to be true. Now a 25% reduction is claimed and shown not to be true. Higher quality research, more careful review of the research does not support 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 ration is not lower in fluoridated communities.

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

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. But there is no substantial evidence of drug effectiveness. The FDA CDER have the highest standards, are highly qualified pharmacologists and toxicologists, and have the most respect for drugs of all

federal and state agencies. The Board and dental industry constantly refuse to gain FDA CDER approval, which places the public in harm.

The Cochrane reviews are generally considered some of the best scientific evidence available. They generally rely on randomized controlled trials (RCTs), which are required for drugs. As no RCTs on fluoridation have been published (one on fluoride supplements, not finding statistical benefit), the Cochrane evaluators used lower quality research. The CDC Oral Health funded a Cochrane review of fluoridation and reported some benefit with reservations.

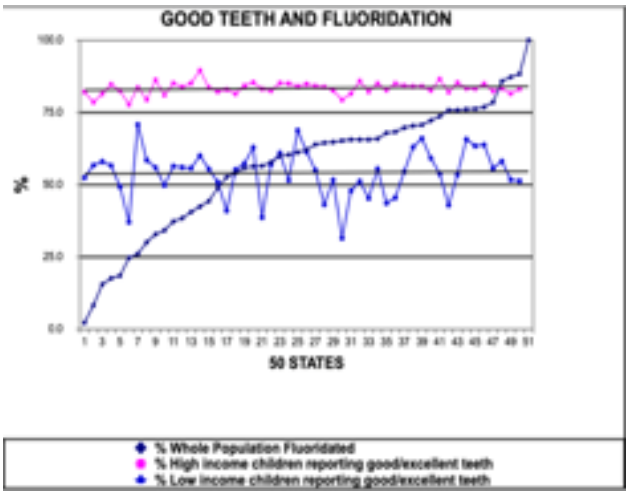
Although the Cochrane review gave cautious support for fluoridation benefit for children (at 1.0 ppm), the review did not cover ethics or risks or costs of harm or even benefit at the reduced concentration of 0.7 ppm. The Cochrane review in part, states:

"*There was insufficient information available to find out whether the introduction of a water fluoridation programme changed existing differences in tooth decay across socioeconomic groups." The Board MUST understand that their intent to protect vulnerable populations from some dental caries is not supported by science and plenty of science reports additional harm to those subpopulations (low socioeconomics, increased lead, etc)*

"*There was insufficient information available to understand the effect of stopping water fluoridation programmes on tooth decay."*

"*No studies met the review's inclusion criteria that investigated the effectiveness of water fluoridation for preventing tooth decay in adults, rather than children."*

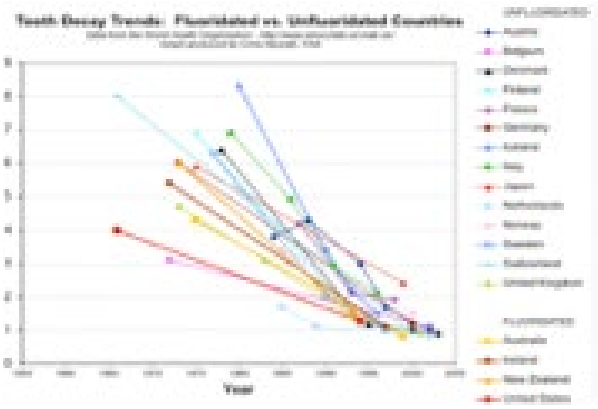
The following correlation graph was generated when I ranked the USA states on the percentage of their whole population fluoridated and reported good to excellent teeth. A 25% reduction, or any reduction, is not evident when similar SES groups are ranked.

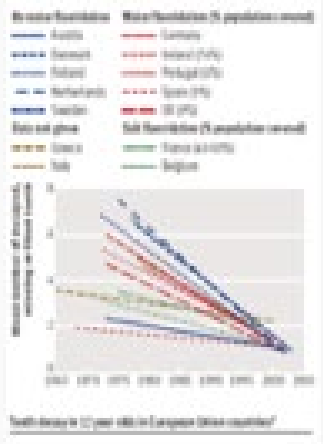


Socioeconomics is highly significant for caries prevalence, but fluoridation has no "common cause" or correlation. For 20 years as a dentist, I promoted fluoridation and thought I could see proof of benefit from fluoridation in my patients. However, after reading the research it was clear I had been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

I also ranked Washington State Counties on the percentage of their population fluoridated and dental caries. The Board claims a 25% reduction in caries, but a robust reduction in dental caries is not supported by the population at large in Washington State.

Two published studies 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 is not reasonable.

To the right is a graph of caries over a longer period of time. 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 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.

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 results show that the reviewed original studies on economic evaluation of caries prevention do not provide support for the economic value of caries prevention.”**

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)

I am unaware of any fluoridation published studies of current 0.7 ppm fluoride concentration versus 1.0 ppm fluoride concentration in water**.** 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.

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.

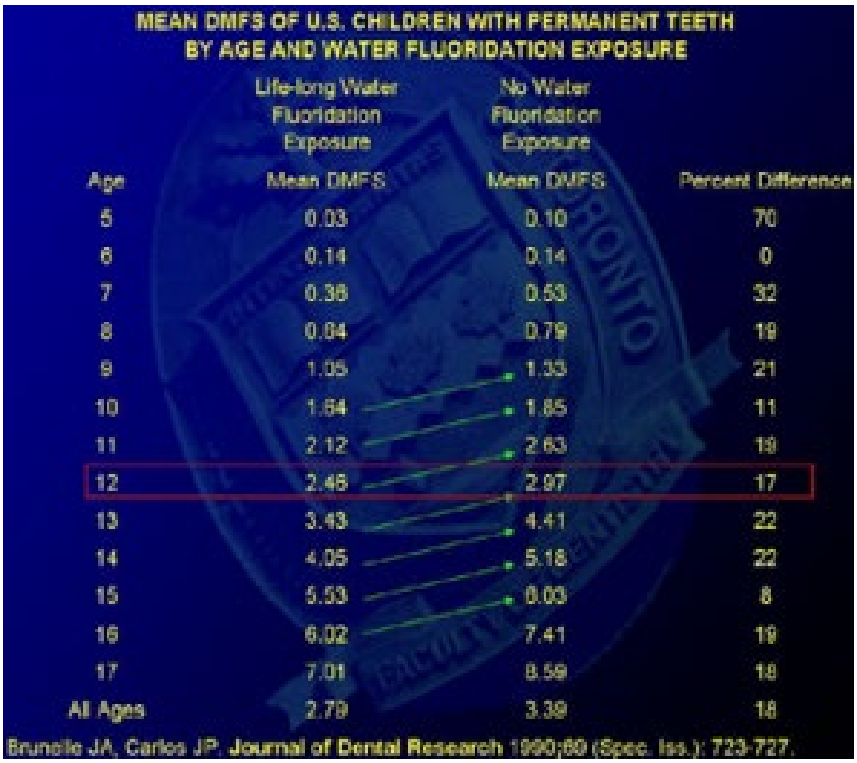
If the tooth is protected under the skin from food and harm for just a few months, researchers evaluating caries by a child’s age, will be comparing different amount of time the teeth have been exposed to the environment. Of course, the concern that a delay in tooth eruption could cause a delay or premature 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.

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.



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? The Board cannot trust the Department.

And the Board doesn't want to weigh the balance, but they expect parents and health providers to do what the Board and Department fails to do. I doubt the legislature expected the public to weigh the complex scientific data. Silence speaks.

#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.*"*

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.

No rational scientist would claim we have safety studies on the physiologic function of the cells, organs, all systems of the human body throughout all stages of life. If fluoride ingestion were in fact safe, we could make billions of dollars if we got authorized regulatory approval.

In effect, 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." However, the absence of evidence is also not proof of harm.

CAUTION: When discussing risk, the dental lobby often:

1. Avoids "total fluoride exposure." and assumes no other fluoride intake than fluoridated water.

2.. Ignores subpopulations such as the fetus, infants, children, those allergic to fluoride, those medically compromised, etc.

3. Assumes everyone fits in the statistical median.

4. Assumes everyone drinks the median amount of water.

5. Assumes fluoride ingestion actually prevents dental caries.

6. Discounts any research or experts raising questions on the safety of fluoride exposure and fluoridation.

7. Although safety may involve hundreds or thousands of variables, research attempts to narrow the variables down to 2, if possible. Any research claiming, for example, "No dose-related anomalies in internal organs were observed in fetuses," is an anatomical, not physiologic start for safety research and incomplete.

Not everyone fits in the “statistical mean” (similar to the average person). For example, perhaps the “statistical mean” shoe size is 9.5. Toddlers and children would not be comfortable in those huge shoes, most adults would find the shoe size too small or too large.

The ”statistical mean” is important for generalizations but lacks applicability for all humans at all ages.

THE FETUS:

Consider the fetus. There are no safety studies determining the safety of fluoride exposure for the developing fetus and there is no known benefit to the fetus.

Here are the two most vulnerable cells starting the dividing and growing process of life, the mother is probably not 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 bones. The fetus drinks the fluoride fluid/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.

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 at very low dosages. And as with the early reports of lead's harm, further more precise, focused study on lead confirmed rather than disputed the earlier studies.

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:

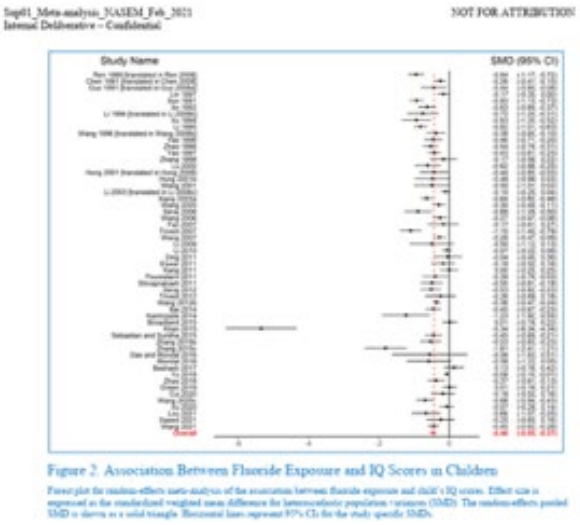


Figure 2. Association Between Fluoride Exposure and IQ Scores in Children

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 between-exposure population comparisons (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)

However, there are several methods to “measure” brain and developmental damage and several types of IQ. **Performance IQ is reported at 8.8 IQ loss, full scale 4.4 IQ loss from the amount of fluoride the Board recommends be added to our water.**

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 not reporting IQ loss is promoted by the fluoridation lobby and is implausible, an outlier.

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.

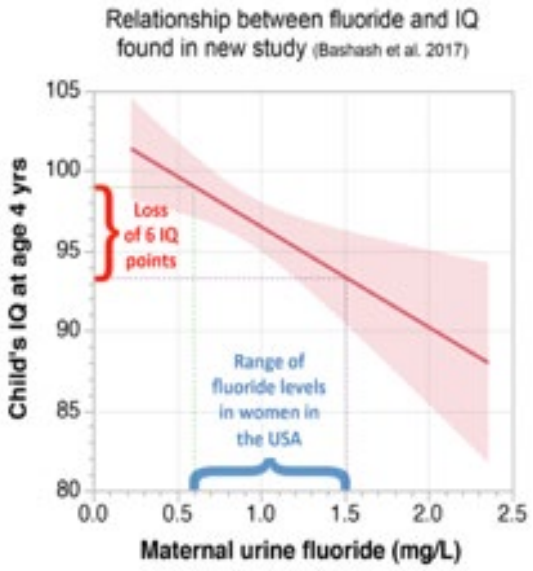
After the 2006 NRC report suggesting possible brain damage from fluoride, I wanted to personally see if I could confirm the NRC 2006 report. I ranked the 50 states and plotted their reported mental retardation (intellectual disability) and percent of the whole population

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.

A doubling of the reported “développemental disability ” would represent close to 7 IQ point loss. The EPA uses just one IQ loss as their threshold, but not for fluoride exposure.

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.

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.

INFANT MORTALITY

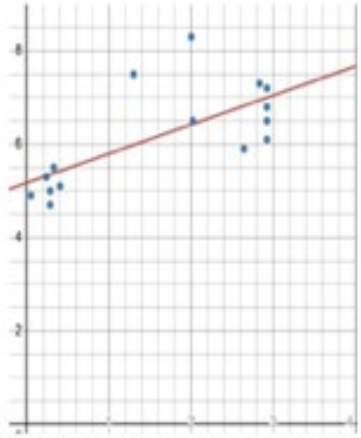
It should be noted that IQ is simply one method of measuring brain damage and developmental toxicity from fluoride. I once again ranked the states on the percentage of their whole population fluoridated and plotted infant mortality per 10,000 live births, about 15% increase in infant death. See graph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

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.



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, a potential increase in infant mortality far out-weighs potential alleged benefit to teeth.

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. 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.

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.”

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.”

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. Harming their brains and possibly their deaths, certainly harming teeth and bones, without proof of efficacy. 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 to 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 any dosage.

DENTAL FLUOROSIS:

What is the most common disease in children? Frequently the answer is dental caries. Actually, dental fluorosis caused in part by the Board of Health's promotion of fluoridation is the most common disease in children.

Among children aged **6 to 8 years, over half (52%)** have had a cavity in their primary (baby) teeth. Children from low-income families are twice as likely to have untreated cavities as higher-income children. Among adolescents aged **12 to 19, more than half (57%)** have had a cavity in their permanent teeth. However, NHANES (National Health and Nutrition Examination Survey) 2015-2016 data reported about 70% of children and adolescents have dental fluorosis, a biomarker of excess fluoride ingestion prior to age 8. Although some have suggested that is not plausible, no refuting data has been presented.

A US Environmental Protection Agency (EPA) study+ (1987)., funded by the EPA with fluoride concentrations between 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."*

Not every case of dental fluorosis will be repaired, but "Damage is the cost, not the repair."

Patient #1 (below) has a normal ideal smile with healthy teeth, no fluorosis detected, and was raised predominantly on mother's milk and no formula was made with CWF.

For comparison, Patient #2, (below) diagnosed with Dean's Fluorosis Index of 4, " discrete or confluent pitting," moderate to severe dental fluorosis and has functional damage with chipped, pitted and warn teeth.

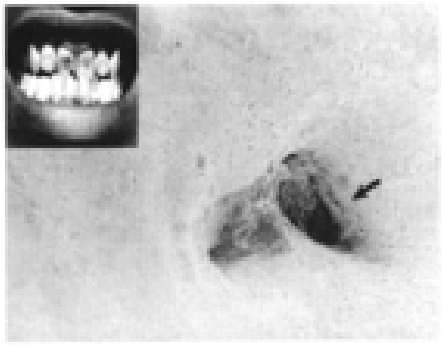
Patient #2 was raised mostly on formula made with fluoridated water. Mom was confident fluoridated toothpaste was not swallowed and no fluoride supplements ingested. In this case, 24 teeth had cosmetic and functional dental fluorosis damage.

A study of adolescents at 12 years of age reported 52% at a fluoride concentration in water of 0.7 mg/L (CWF concentration) had dental fluorosis. Of the subjects, 95% wished to remove the spots. In contrast to the subjects reported concern, only 14.5% had professionally diagnosed mild, moderate or severe dental fluorosis. The contribution of fluoridation to total exposure is authority administered iatrogenic harm. Beauty is in the eye of the beholder rather than the eye of the diagnostician.

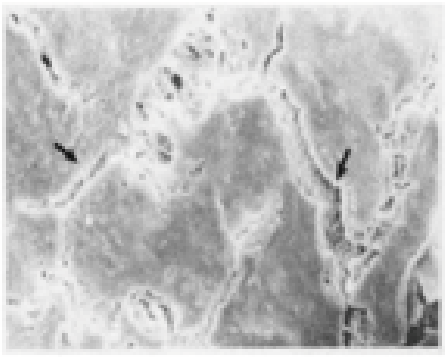
Stopping fluoridation is the simplest, easiest, quickest method to reduce total individual fluoride excess exposure. Sources from pesticides, post-harvest fumigants, medications and swallowing toothpaste are not as easy for the Board to influence.

The cosmetic effects and functional effects of dental fluorosis along with the lack of cost benefit when the cost of harm is included, has been presented here previously.

Dental Fluorosis Viewed by Scanning Electron Microscope



Pits in enamel



Cracks and Fissures in enamel

The Board must not dismiss aesthetic concerns as “lacking harm.” All potential harm must be included in judgment of any benefit/risk from fluoride ingestion.

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 and focuses on three facts:

1. Most fluoride is stored in bones, particularly during growth spirts.

Fluoride is a mutagen

1. 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

Osteosarcoma: A timeline by Ellen Connett.

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.

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 older (average 41 years and cases averaged 18 years) and fluoride concentration of cases were about 300% higher than average fluoride concentrations for normal bone at 18 years of age. Douglas reported no association between fluoride and osteosarcoma.

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.

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*

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.

FLUORIDE'S IMPACT ON BONES

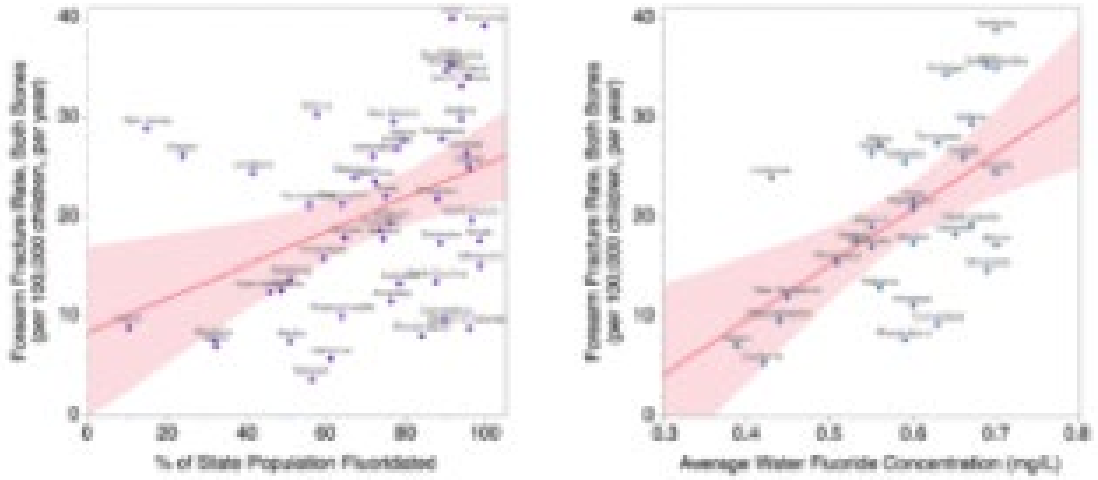
Skeletal fluorosis is an undisputed effect of excess fluoride. The EPA uses severe skeletal fluorosis as a threshold of concern for excess fluoride exposure. But pathology from fluoride starts much sooner than crippling skeletal fluorosis.

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)

Based on the preponderance of the evidence, fluoridation is not safe and effective.

Sincerely,

Bill Osmunson DDS MPH