Fluoridation defenders might say that this is only a small amount of lead and that it can be disregarded. But where is the science that says that a small amount of lead consumed daily for life from conception to death is harmless? There is no such science. Fluoridation is reckless if for no other reason than that fluorosilicic acid comes with lead.

But our consideration of lead is not over. Fluorosilicic acid not only contains lead, it leaches lead from plumbing.

In 1992 Tacoma was fluoridating city water with fluorosilicic acid. The percentage of homes in Tacoma exceeding the action level for fluoride - then 50 ppb – was 9.8%. Because Tacoma was experiencing equipment problems and a drought, Tacoma Public Utilities stopped fluoridating temporarily. When fluoridation stopped, 90th percentile lead levels dropped from 32 ppb to 17 ppb. The 90th percentile test means that 10% of randomly selected homes had lead coming from their taps at 32 ppb and then 17 ppb.

Also in 1992 Thurmont, Maryland, stopped fluoridating. Lead levels in Thurmont dropped 78%. Thurmont turned off the fluoridation equipment permanently. Tacoma soon returned to fluoridating. The horse ran back into the burning barn.

Why would there be more lead in drinking water when water is fluoridated? The first reason is that there is lead in fluorosilicic acid. There is lead in the raw phosphate ore used to make super phosphate fertilizer, and so there is lead in fluorosilicic acid scrubber liquor. But this alone cannot account the relatively small lead levels in the water out in the water mains compared to the lead levels at the tap. The second reason is that there is lead in plumbing in most homes, and fluorosilicic acid leaches lead from plumbing.

LEAD LEACHING

Fluorosilicic acid, when dissolved in water down to 1.0 ppm fluoride or now down to .7 ppm fluoride, breaks down into fluoride ion, hydrogen fluoride, and silicic acid, H_4SiO_4, as confirmed in the 2006 National Research Council study on fluoride at page 53.

Even though there is relatively little lead in water in the water mains, even including the lead which came along with the fluorosilicic acid, lead levels at the tap can be much higher. It is the silicic acid which dissolves lead in plumbing.

Coplan, Masters, Maas, and Sawan showed that that there is much more lead in tap water fluoridated with fluorosilicic acid than with sodium fluoride. However, they do not explain the mechanism by which fluorosilicic acid dissolves lead.

Silicofluoride, more so than sodium fluoride, leaches lead out of pipes and brass fittings.

Silicic acid is classed as a weak acid and is often dismissed as relatively harmless. Unfortunately for our health, it is able to dissolve – slowly but surely – the lead in lead based pipes and fittings and lead-brass faucets. The dissociation constant of silicic acid in water is very low, 2×10^{-10}. This means that the amount of sodium carbonate, Na_2CO_3, also known as soda ash, added to neutralize the fluoride ion and hydrogen fluoride is not sufficient to neutralize the silicic acid. Although silicic acid is classed as a weak acid, it is also hard to neutralize and therefore persists and dissolves lead in plumbing.

See Dr. Richard Sauerheber explanation of the process whereby fluorosilicic acid breaks down into silicic acid and then leaches lead.

Silicic acid has another name. Supporters of fluoridation avoid calling it "acid" and instead call it silicate ion in water. When it is written as $Si(OH)_4$, there is the implication that it is not an acid. When it is written as H_4SiO_4, there is the implication that it is an acid. Beginning the chemical formula with "H" would indicate that it is an acid. See a diagram which illustrates the issue. The 2012 NSF Fluoride Fact Sheet does not even mention silicic acid. It refers only to "silicate ions in water". $Si(OH)_4$ and H_4SiO_4 have exactly the same number of atoms of silicon, oxygen, and hydrogen.

NSF then makes the inaccurate and inappropriate statement that

> "sodium, fluoride, and silicates all have toxicological studies, fluoride has an MCL regulatory level, and silicate has an NSF maximum usage assessment. Fluorosilicates do not need a toxicological assessment specifically for the fluorosilicate ion, because it does not exist in potable water at the fluoride concentrations and pH levels of public drinking water".

Yes, there is very little fluorosilicic acid after dilution, but there is a lot of silicic acid, a point which NSF glides over. Silicic acid needs a toxicological assessment, but NSF does not provide for it.

Lead leaching can be extreme. In 2004 Seattle papers reported lead at 1,600 ppb (parts per billion) in old Seattle schools, far above the 15 ppb EPA action level and the zero ppb goal. New brass pipes and faucets contain around 8% lead and older pipes contain as much as 30% lead. Old schools, homes, apartments, hospitals, office buildings, and factories have pipes containing lead, which silicic acid will leach. When water districts stop fluoridating, lead levels in water and in blood drop, as happened in Tacoma in 1992. Seattle commissioned reports on the lead in schools, but had a blind spot to the possibility that silicic acid was a factor. It is a political sin to blaspheme the fluoridation deity. Seattle replace lead pipes in schools at great cost, which was a good thing. It should also have terminated fluoridation.

And let's not forget that even if we replace all the lead pipes in schools we will have solved only a small part of the problem. We will solve the lead problem in schools, but the lead problem will remain in other structures. We cannot build our way out of the lead leaching problem. We must stop fluoridating.

Sodium fluoride, used to fluoridate around 8% of water users does not break down to form silicic acid, and therefore does not leach as much lead as does fluorosilicic acid, however, that does not mean that fluoridating with sodium fluoride is acceptable. Sodium fluoride breaks down into fluoride ion, which at acidic pH, such as in the stomach, forms hydrogen fluoride, which is a very tiny, neutral molecule, which is able to penetrate the fatty lipid layer of the stomach and enter the blood stream.

Dr. Roger Masters and Myron Coplan have worked jointly for years researching and publishing extensively regarding the effects of fluoride, specifically fluorosilicic acid and sodium silicofluoride, on violent and other abnormal behavior. The silicofluorides leach more lead and are more harmful than sodium fluoride. See the following articles written by these two authorities:

Roger Masters on Toxins, Health, and Behavior

> Toxins like lead are associated with higher rates of violent crime, learning disabilities, and substance abuse.

Roger Masters – The Harmful Side-Effects of Water Treated with Silicofluorides

> When either of these silicofluorides (SiF) is added to a water supply, published research has identified biological effects of the "residue" of partially dissociated silicofluoride molecules. These effects increase both immediate "uptake" of environmental lead to

> blood and long term "absorption" of lead in body organs. Resulting changes in brain chemistry influence social behavior and call into question the policy of using these chemicals in treating public water supplies in the U.S.

Roger Masters and Myron Coplan, Neurotoxicity and Violent Crime

> Lead, for example, lowers intelligence and learning ability, as Ben Franklin learned from British printers. More recently, neurotoxicologists have shown an association between lead uptake and poor impulse control, learning disabilities, and violence.

Roger Masters – Publications Relating to Fluorosilicic Acid

LEAD DISCLOSURE LAW IGNORED

Federal law at 42 U.S. Code § 300g–6 says:

> Each owner or operator of a public water system … shall identify and provide notice to persons that may be affected by lead contamination of their drinking water where such contamination results from … lead content in the construction materials of the public water distribution system [or] corrosivity of the water supply sufficient to cause leaching of lead. … Notice under this paragraph shall be provided notwithstanding the absence of a violation of any national drinking water standard. [emphasis added].

Washington utilities are disregarding federal laws which require reporting of lead concentrations in drinking water.

WAC 246-290-220(5) contains the following language regarding leaching:

> (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; and
> (c) The chemical or material has undergone testing through a protocol acceptable to the department and has been found to not contribute leachable compounds into drinking water at levels that would be of public health concern.

The Washington Board of Health ignores this regulation.

CLEAN WATER ACT - FEDERAL WATER POLLUTION CONTROL ACT

We drink and cook with maybe one percent of the water that flows through our homes. The other 99 percent goes down the shower, sink, and commode or out of the washing machine and then to the treatment facility. The treatment facility is unable to filter out the tiny fluoride ion, and so fluoride flows into our rivers. Four cities dump their fluoridated sewer water into the Snohomish River, Monroe, Snohomish, Everett, and Marysville. The fluoride content of sewer effluent is high enough to repel salmon and cause salmon runs to crash, as has happened in the Snohomish, Columbia and Sacramento Rivers.

The Clean Water Act of 1972 states:

> SEC. 101. (a) The objective of this Act is to restore and maintain the chemical, physical, and biological integrity of the Nation's waters. In order to achieve this objective it is hereby declared that, consistent with the provisions of this Act— (1) it is the national goal that the discharge of pollutants into the navigable waters be eliminated by 1985: … (3) it is the national policy that the discharge of toxic pollutants in toxic amounts be prohibited.…"

Fluoride is a pollutant and should not be discharged into our rivers.

Fluoridation violates the Clean Water Act and thus violates NSF Rule 60 and WAC 246-290-220, which build on the Clean Water Act.

SAFE DRINKING WATER ACT

The EPA MCLs and MCLGs mentioned in NFS 60 come from the SDWA, which is found in Title 42 of the US Code, and so the SDWA is an implied part of WAC 246-290-220. Relevant provisions of the SDWA are quoted here:

> When proposing any national primary drinking water regulation that includes a maximum contaminant level, … the Administrator shall … use … an analysis of … [t]he effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.

> Each maximum contaminant level goal established under this subsection shall be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.

Fetuses are highly sensitive to fluoride and its co-contaminants because their cells are rapidly dividing. Fluoride and its co-contaminants pass the placental barrier and lower IQ. The FDA banned prenatal supplements containing fluoride. Babies too are highly sensitive. Their cells too are still dividing, and they drink four times as much fluids per their body weight as do adults. Babies' kidneys are not mature and excrete only 20% of fluoride consumed. CDC, ADA, AMA, and the surgeon general have advised that if formula is mixed using fluoridated water fluorosis will result, an admission that other harms are being done.

Fluoride builds up in kidneys, reducing ability to excrete. Water used for dialysis must be fluoride free. After drinking fluoridated water for years, bone will contain 3,000 to 12,000 ppm fluoride, depending on water hardness and diet. At 3,000 ppm bones weaken and become brittle. Fractured pelvises are twice as common in fluoridated areas. All fluorides affects bones, joints, and tendons and exacerbate arthritis.

Fluoridated water fails to protect these sensitive populations and thus violates the SDWA and NSF Rule 60.

NSF SHOULD NOT BE APPROVING FLUORIDATION MATERIALS

Now that I have completed my analysis of fluoridation and NSF 60, I should add that EPA should never have privatized the regulation of fluoridation by passing its own responsibility off to a trade association where the industries regulated by NSF sit on the NSF board. And the FDA should be enraged that NSF has usurped is role by approving a drug to be safe for human consumption when only the FDA is authorized to do that.

Nevertheless, Washington has chosen to convert NSF 60 into some kind of regulation and to consider it binding. So it should be applied, and if it is applied, fluoridation will have to stop.

I should also add that there is a core part of NSF 60 which has validity, and that is the list of toxicological studies which must be done. It is my theory that this list was prepared by the FDA back in 1979 when it transferred authority over fluoridation to the EPA. Toxicological studies should be done on

fluoridation materials, and if they were done, the results would be so horrifying that fluoridation would end immediately.

CDC ADMITS THAT FLUORIDATION MAKES NO SENSE

Why should you believe me instead of guys in white coats? Because I quote from the white coats. Consider three important admissions which come from the CDC web site itself:

a) that fluoridation reduces caries only 18% to 25% (Other evidence says it does not reduces caries at all);

b) that 41% of adolescents suffer from some degree of dental fluorosis, with around 12% of adolescents suffering from mild, moderate, and severe fluorosis, which is noticeable, embarrassing and ugly; and

c) that "fluoride prevents dental caries predominately after eruption of the tooth into the mouth, and its actions primarily are topical for both adults and children".

Thus, according to CDC's own admission, fluoridation would not seem to be a good bargain.

Add to this the studies which indicate that there are much more effective ways to reduce and even eliminate tooth decay than fluoridation, and the issue becomes even clearer. The fixation on fluoridation distracts the dental profession from teaching methods which really do reduce caries and do so without any harm.

If we have sound teeth it is in spite of fluoridation not because of it.

CONCLUSION

You have probably heard all your life that fluoridation is a good thing. But fluoridation supporters including medical, dental, and public health advisers have been deceived by a big lie and are trapped and lost in a fluoridation maze. Fluoridation is a maze of half-truths and lies, and for some people it is hard to find the exit.

There is a tendency for people to say "I'll just take the word of the doctors and dentists" when it comes to such scientific subjects. However, if you did well in high school math, chemistry, and physics, you should easily understand the

health, safety, and effectiveness issues. As a lawyer, you should be able to understand how fluoridation violates numerous laws.

I hope you will honestly study this issue and do the right thing. As you study, bear in mind what Mark Twain said: It is a lot easier to defraud a man than it is to convince him he has been defrauded.

The right thing for you to do would be to put a halt to fluoridation and initiate a state class action suit against NSF and Simplot. The suit would be first for the money which rate payers have paid for unnecessary and harmful fluoridation chemicals and next for physical harm incurred.

MORE INFORMATION

I suggest you study this subject by reading the following documents. These will give you a general introduction to the folly of fluoridation. See:

For a general orientation to this subject, read the Safewater flier first: www.fluoride-class-action.com/safewater.

Read "National Sanitation Foundation – Sham FDA – Fraudulent Certifier of Fluoridation Materials", posted online at www.fluoride-class-action.com/sham

Read: "What Is In It?" a quantification of the contaminants contributed to drinking water through fluoridation. http://www.fluoride-class-action.com/what-is-in-it

Read about why there are much better ways to prevent tooth decay than fluoridation posted online.

Read "How Does Fluorosilicic Acid Leach Lead?" http://www.fluoride-class-action.com/silicic-acid-2

Read about the illegality of fluoridation and the coming class action against NSF, suppliers of fluoridation materials, the water districts which fluoridate, and the state which authorizes it.

Read my Fluoride Report Card For HHS and EPA.

Read my 2011 letter to HHS and EPA regarding lead in fluoridation materials.

Read the Clean Water Act of 1972.

Read the Safe Drinking Water Act of 1974.

Read about the mechanism of mass propaganda as engineered by Edward Bernays, double nephew of Sigmund Freud to manipulate women to take up cigarette smoking, and to promote the toxic use tetraethyl lead in gasoline and the fluoridation of our drinking water.

Read about how to an exit from the fluoridation maze.

EPA MCL and MCLG list.

NSF 60 Standard, 1988 version.

NSF 60 Standard, 2009, version:

NSF 60 Standard 2013.

2000 NSF letter.

2008 NSF Fact Sheet on Fluoridation.

2012 NSF Fact Sheet on Fluoridation.

Sincerely,

James Robert Deal, Attorney
WSBA Number 8103

From:	James Robert Deal
To:	Phillips, Theresa (DOH)
Subject:	Proposed Changes to Fluoridation of Drinking Water - Revised
Date:	Tuesday, February 23, 2016 4:43:41 PM
Attachments:	Deal-to-Board-of-Health-2-23-2016.pdf

Sincerely,

James Robert Deal , Attorney & Broker
James@JamesDeal.com
PO Box 2276 Lynnwood WA 98036
Direct Telephone Line: 425-771-1110
Fax: 425-776-8081
Madison Partners Real Estate
www.WashingtonAttorneyBroker.com
www.Fluoride-Class-Action.com
www.JamesRobertDeal.org

From:	Ayesha
To:	Phillips, Theresa (DOH)
Subject:	Proposed Changes to Fluoridation of Drinking Water
Date:	Tuesday, February 02, 2016 10:13:37 PM

Dear Theresa,

It is my wish that the state of Washington will take all of the fluoride out of every water system that exists in this state. It is a great contributor to osteoporosis, as well as a toxin to the human body.

All the very best,
Ayesha Rognlie
Edmonds, WA 98026

From: Katrina Brooke
To: Phillips, Theresa (DOH)
Subject: Proposed Changes to Fluoridation of Drinking Water
Date: Thursday, January 28, 2016 11:51:07 AM

As a parent I am in favor of Fluoridation in Drinking Water. I know as a kid I did not have fluoridation in my Drinking water and I had many cavities by the age of 5!! My children brush and floss but they are kids and the cavities still happen. I have had discussion with dentists and they feel just the little bit in the drinking water does not pose a risk to health but helps prevent dental decay. Dental decay can have a big effect of a persons health.

Have a wonderful day!

Katrina Brooke
Woodinville, WA 98072

February 23, 2016

Washington State Board of Health

Subject: Proposed changes to WAC 246-290-460, Fluoridation of drinking water

Dear Board,

While I cannot argue the benefits of lowering the fluoride concentration in public water from the previous 1.0ppm down to 0.7ppm, as the petition proposes, I must continue to urge that NO fluoride should be added because 0.7ppm is not safe for many water consumers who will be forced to drink it. I have previously given you testimony of my own family's great harm from fluoride chemicals in tap water, but I continue to be most concerned for those families who have NOT discovered what I have---that fluoride harms children and adults alike, even those who are not known to be hypersensitive as my son Kyle is, and that the claimed benefit does NOT justify the risk.

I have attached a letter from pediatrician, Dr. Yolanda Whyte, MD, who has mathematically shown that formula fed infants receiving fluoridated water at 0.7ppm are receiving toxic doses of fluoride, far above the EPA's Reference Dose for safety (0.114mg/kg/d). This calculation of toxic overdosing of infants must be taken into consideration especially for low income families who cannot afford effective fluoride filtration systems or reverse osmosis bottled water for their babies.

Further, the lifelong negative impacts of fluoride overdosing of formula fed infants affects black (and Hispanic) babies more than white babies, permanently harming low income black infants the most. See my second attachment or http://fluoridealert.org/studies/dental_fluorosis02/ for studies of greater harm to blacks, as evidenced by significantly more dental fluorosis and more severe cases of fluorosis than white children. The only cause of dental fluorosis is, of course, too much fluoride.

As you well know, cities and water purveyors in Washington rely specifically on the Washington State Board of Health for assurances of safety of their fluoridation programs. By passing this new proposed rule, the BOH is maintaining that 0.7ppm is safe for all citizens, including infants, and no risks have been disclosed by BOH to those water purveyors. This rule change, if passed, solidifies the BOH's claims and assurances to water purveyors that the benefits outweigh any risks of fluoride and perpetuates the assumption that no overdosing will occur once the fluoride levels are reduced to 0.7ppm. However, there is not one shred of scientific evidence that supports this presumption for infants who face a lifetime of potential harm by the negligence of public health authorities to warn water purveyors and the public of infant overdosing by fluoride.

Fluoridation chemicals added to tap water at 0.7ppm ***are not safe*** for 100% of the consuming public, as is claimed, and the failure of the Board of Health to disclose risks of fluoride infant overdosing is a gross negligence of the board's responsibilities to Washington citizens who rely on you.

Sincerely,

Audrey Adams
Washington Action for Safe Water
10939 SE 183rd Ct
Renton, WA 98055

Yolanda Whyte, M.D.
Dr. Yolanda Whyte Pediatrics, P.C.
P.O. Box 500457 Atlanta, GA 31150
(678) 395-6693
www.yolandawhytemd.com yolanda@yolandawhytemd.com

May 20th, 2013

Jill Jennings-McElheney
Micahsmission@aol.com

Toxic dose of fluoride for infants on Athens-Clarke County tap water

Dear Ms. Jennings-McElheney,

As a Georgia pediatrician, I am responding to your request regarding health concerns for your infant granddaughter who lives in Athens-Clarke County (ACC) and is drinking formula reconstituted with ACC tap water. Your infant granddaughter and other infants who consume ACC tap water, fluoridated at the current concentration 0.7 ppm, are at high risk for fluoride toxicity.

I came to this conclusion based on the following pediatric vulnerabilities that I am hoping you will take into consideration:

1. **Children receive a greater dose per body weight than adults.** For example, an average 2 week old newborn, weighing 6lbs 11 oz, and drinking formula reconstituted with ACC tap water, at a rate of 2-3 oz every 2-3 hrs (approximately 24 oz/d) is receiving toxic doses of fluoride, as shown in the following calculations.

Exhibit 1. Generic Exposure Dose Equation

$$D = C \times IR \times AF \times EF / BW$$

where,

D	=	exposure dose
C	=	contaminant concentration
IR	=	intake rate of contaminated medium
AF	=	bioavailability factor[1]
EF	=	exposure factor
BW	=	body weight

Fluoride exposure dose (**D**) = 0.7 ppm or 1mg/L (**C**) x 24oz/d* (**IR**) x 1 (**AF**) x subjective loss of value caused by a risk (EF) / 6lbs 11oz** (**BW**)

*24 oz = 0.7L
**6lbs 11oz = 3.033 kg

Fluoride exposure dose (**D**) = $\frac{0.7\text{mg/L (C)} \times 0.7\text{L/d (IR)} \times \text{subjective \% (EF)}}{3.033\text{kg}}$

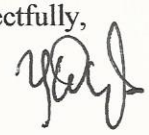
Fluoride exposure dose = 0.161 mg/kg/d

This dose is toxic, being considerably greater than the U.S. Environmental Protection Agency's (EPA) Reference Dose for safety, set at 0.114mg/kg/d. Oral consumption fluoride is not recommended or she will be at risk for conditions like dental and skeletal fluorosis, neurodevelopmental problems, IQ deficits, hypothyroidism and other conditions. She should only consume purified water via reverse osmosis, distillation or de-ionization.

2. **In pediatric toxicology, it is the early timing that determines the poison**. Children experience more severe health effects when exposed to a toxin while their organs have not completed development. For example,
    - The kidneys are less able to detoxify and excrete fluoride as efficiently as adults
    - The immune system is less able to defend itself
    - Babies/skin is more permeable to skin absorption of fluoride when bathing
    - Newborn skeleton absorbs 90% of fluoride, significantly more than an adult
    - Fluoride is able to cross the blood brain barrier and damage the brain and nervous system
    - Fluoride can also cross the placenta and affect the unborn child

Please consider requesting that ACC provide a safe alternative water source for your granddaughter, other infants and people in other high-risk groups, such as pregnant women, seniors, those with kidney, bone, thyroid, brain or nervous system conditions. The medical profession has not established any safe dose fluoride consumption for infants. Therefore, you should consider urging the Georgia General Assembly to discontinue this outdated statewide mandated practice of water fluoridation that can result in toxic doses of fluoride in infants. Feel free to contact me with any additional questions about these health hazards.

Respectfully,



Yolanda Whyte, M.D.

Racial Disparities in Dental Fluorosis

In 2005, the Centers for Disease Control published the results of a national survey of dental fluorosis conducted between 1999 and 2002. According to the CDC, black children in the United States have significantly higher rates of dental fluorosis than either white or Hispanic children. As the CDC noted, this was not the first time that black children were found to suffer higher rates of dental fluorosis. Indeed, as documented below, at least five other studies — dating as far back as the 1960s — have found black children in the United States are disproportionately impacted by dental fluorosis.

Not only do black children have higher rates of fluorosis, they have more severe forms of the condition. A 2010 study from fluoridated Indianapolis found that over 12% of surveyed black children, but none of the surveyed white children, had pitting ("a definite physical defect" of the enamel) as a result of too much fluoride exposure. (Martinez-Mier 2010). Similarly, a 1990 study from Georgia found that over 16% of black children (versus 9% of white children) had moderate or severe fluorosis, involving either "light to very dark brown" staining, pitting; and/or "large areas" of "missing" enamel with "dark-brown stain" and "altered" tooth structure. (Williams & Zermer 1990).

It is not yet known why blacks suffer higher rates of dental fluorosis. According to the CDC, it may be a result of " biologic susceptibility or greater fluoride intake." (CDC 2005). Whatever the explanation, it is clear that the black community is being disproportionately harmed by current fluoride policies in the United States.

martinez-mier (2010) — fluorosis survey in Indianapolis, Indiana:

A fluorosis survey was conducted among 83 black children and 102 white children in Indianapolis, Indiana (a fluoridated community). As noted by the authors, "the prevalence [of dental fluorosis] in African American children (80.1 percent) was significantly higher than in Whites (62.5 percent)." Not only was the fluorosis rate higher in the black community, but the severity of the fluorosis was significantly greater ($P < 0.001$). Whereas the maximum fluorosis score in the white community registered as a two on the TSIF Scale, the maximum fluorosis score in the black community registered as a five. A TSIF score of two refers to teeth with white staining covering "at least one-third of the visible surface, but less than two-thirds." A TSIF score of five refers to pitting of the enamel, which is defined as "a definite physical defect in the enamel surface" which "is usually stained or differs in color from the surrounding enamel." As the following table shows, none of the white children had a fluorosis score of five, but 12.7% of the surveyed black children did.

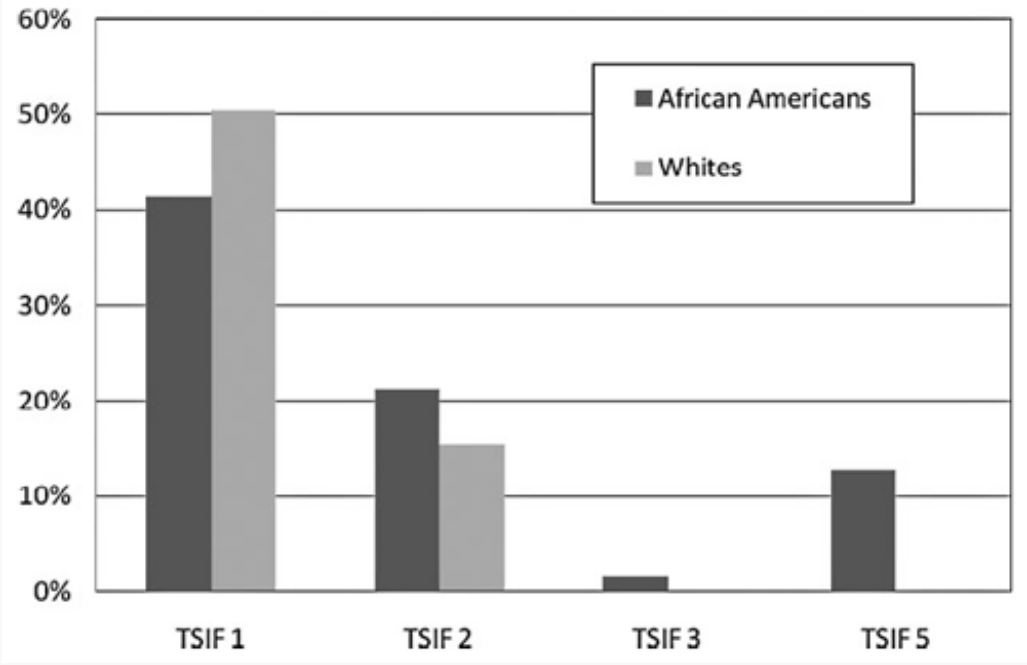


FIGURE 1: Martinez-Mier EA, Soto-Rojas AE. (2010). Differences in exposure and biological markers of fluoride among White and African American children. Journal of Public Health Dentistry 70:234-40.

Centers for disease control — national survey of dental fluorosis (1999-2002):

This study by the CDC provides national fluorosis data from the 1999-2002 NHANES survey. As noted by the CDC:

“Non-Hispanic blacks had higher proportions of very mild and mild fluorosis than did non-Hispanic white participants (Figure 19). . . . No clear explanation exists why fluorosis was more severe among non-Hispanic black children than among non-Hispanic white or Mexican-American children. This observation has been reported elsewhere, and different hypotheses have been proposed, including biologic susceptibility or greater fluoride intake.”
SOURCE: Beltran-Aguilar ED et al. (2005). Surveillance for dental caries, dental sealants, tooth retention, edentulism, and enamel fluorosis — United States, 1988–1994 and 1999—2002. MMWR Surveillance Summaries 54(3): 1-44.

The following chart provides the fluorosis rates for each racial group. As can be seen, the rate of moderate/severe dental fluorosis in the black community is almost twice as high as the rate in the white community (3.43% vs. 1.92%) and the rate of mild fluorosis is more than twice as high (8.24% vs. 3.87%). It is important to bear in mind when viewing this data that these figures are the national average, and thus include fluoridated *and unfluoridated* communities. Were the data limited to fluoridated communities, the fluorosis rates for all racial groups would be higher. The rates would also be higher if the chart excluded adults. For, as the chart shows, children and adolescents have higher fluorosis rates than the adults (due to the increase in fluoride exposure amongst the younger generation). Thus, the percentage of children and adolescents in fluoridated communities is almost certainly higher than the rates displayed in this table.

Characteristic	Unaffected		Very mild		Mild		Moderate/Severe	
	%†	SE§	%	SE	%	SE	%	SE
Age group (yrs)								
6–11	59.81	4.07	19.85	2.12	5.83	0.73	2.71	0.59
12–15	51.46	3.51	25.33	1.98	7.68	0.93	3.56	0.59
16–19	58.32	3.30	20.79	1.78	6.65	0.67	4.03	0.77
20–39	74.86	2.28	11.15	1.22	3.34	0.58	1.81	0.39
Sex								
Male	67.65	2.63	15.65	1.52	4.58	0.54	2.12	0.39
Female	66.97	2.84	15.58	1.36	4.84	0.61	2.78	0.49
Race/Ethnicity¶								
White, non-Hispanic	69.69	3.13	14.09	1.56	3.87	0.60	1.92	0.48
Black, non-Hispanic	56.72	3.30	21.21	2.16	8.24	0.82	3.43	0.54
Mexican-American	65.25	3.89	15.93	2.24	5.05	0.72	4.82**	1.81
Poverty status††								
<100% FPL	68.02	3.21	14.28	1.73	4.07	0.69	2.97	0.66
100%–199% FPL	66.92	2.91	16.11	1.46	5.21	0.78	2.65	0.56
≥200% FPL	66.88	2.75	15.56	1.56	4.83	0.50	2.00	0.37
Total	**67.40**	**2.65**	**15.55**	**1.37**	**4.69**	**0.49**	**2.45**	**0.40**

TABLE 23: Enamel fluorosis among persons aged 6–39 years, by selected characteristics — United States, National Health and Nutrition Examination Survey, 1999–2002.

Kumar (1999, 2000) — fluorosis Survey in Newburgh & kingston New york:

These two studies report the results of a fluorosis survey of children in a fluoridated (Newburgh) and unfluoridated (Kingston) town in New York. In both the fluoridated and unfluoridated communities, black children were found to have higher rates of dental fluorosis. Specifically, being black doubled the odds of getting very mild to severe dental fluorosis (odds ratio = 2.3). According to the authors:

“African-American children studied in 1995 were at higher risk for dental fluorosis than children of other racial groups. . . . The higher risk for dental fluorosis observed among African-American children is consistent with several other studies. Russell noted that dental fluorosis was twice as prevalent among African-American children than white children in the Grand Rapids fluoridation study. Because this study was conducted in an era when other sources of fluoride products were not available, this finding suggests either that fluorosis is more likely to occur in African-American children due to biologic susceptibility, or that their fluoride intake was greater.”
SOURCE: Kumar JV, Swango PA. (1999). Fluoride exposure and dental fluorosis in Newburgh and Kingston, New York: policy implications. Community Dentistry & Oral Epidemiology 27:171-80.

After finding higher rates of fluorosis in the black community, the authors attempted to determine if the rate could be explained by low-birth weight. In their follow-up analysis in 2000, the authors again found higher rates of fluorosis among black children. The higher rate, however, was not explained by low birth weight. According to the authors:

“The results support our earlier findings that African-American children were at higher risk for dental fluorosis in the fluoridated area. Even in the nonfluoridated area, there was a suggestion that African-American children were at higher risk. Whether this higher risk for African-American children is the result of their lower threshold for fluoride or due to other unknown sources of fluoride is not known. It has been reported that African-American children in the United States drink more water and less milk compared to white children. In Newburgh, this difference in the fluid consumption may have resulted in a higher prevalence of fluorosis in African-American children. . . . Because a race fluorosis association could have important policy implications, a large-scale study in a representative sample should be conducted to test specifically the hypothesis that African-American children are at higher risk for fluorosis.”
SOURCE: Kumar JV, Swango PA. 2000. Low birth weight and dental fluorosis: is there an association? Journal of Public Health Dentistry 60(3):167-71.

Williams & Zermer (1990) — Fluorosis Survey in Georgia:

In this study, the authors examined the rate of fluorosis in 374 children with lifelong residence in two fluoridated areas of Georgia: Augusta (0.9 to 1.2 mg/l) and Richmond County (0.2 to 0.9 mg/l). The authors found a very high

fluorosis rate (81%) among the children in fluoridated Augusta, with 14% of the children having moderate or severe fluorosis. The fluorosis rate in Richmond County (54%) was also high. The authors attributed the high fluorosis rate to inappropriate fluoride supplementation by local pediatricians and dentists, as well as an increase in overall fluoride exposure from other sources. As the following table shows, black children were found to have higher rates of moderate/severe fluorosis (TSIF score of 4 to 7) in both communities. A TSIF score of 4 refers to teeth with "light to very dark brown" staining, a TSIF score of 5 refers to teeth with a "definite physical defect" (pitting); and a TSIF score of 7 refers to teeth where "large areas of enamel may be missing and the anatomy of the tooth may be altered. Dark-brown stain is usually present." As the table shows, 16.7% of black children in Augusta had moderates/severe fluorosis versus 9.1% of white children. In Richmond County, the respective rates were 3.3% vs 0%.

Dental Fluorosis Rates in Augusta & Richmond County, Georgia

Residence/Race	**No Fluorosis** (TSIF Score = 0)	**Very Mild/Mild Fluorosis** (TSIF Score = 1 – 3)	**Moderate/Severe Fluorosis** (TSIF Score = 4 – 7)
City/**Black**	19.6%	63.7%	**16.7%**
City/White	18.2%	72.7%	9.1%
County/**Black**	47.8%	48.9%	**3.3%**
County/White	44.9%	55.1%	0%

SOURCE: Williams JE, Zwemer JD. (1990). Community water fluoride levels, preschool dietary patterns, and the occurrence of fluoride enamel opacities. *Journal of Public Health Dentistry* 50:276-81.

Butler (1985) — Fluorosis Survey in 16 Texas Communities:

"The severity of dental mottling in 2,592 school-aged, lifetime residents of 16 Texas communities was investigated in 1980-81 to identify factors associated with mottling and to construct a prediction model for the prevalence of mottling. The communities were selected to obtain a wide range of levels of fluoride in the drinking water. The children within each of the communities were contacted through their schools and received a dental examination to assess the severity of mottling. Information on demographic, dental health practice, and other candidate predictor variables was obtained from a questionnaire completed by a parent. A number of water quality measurements were also recorded for each community. White and Spanish-surname children had about the same prevalence of mottling while Blacks had a higher prevalence, odds ratio (OR) = 2.3, 95% confidence interval = 1.4, 3.7."
SOURCE: Butler WJ, et al. (1985). Prevalence of dental mottling in school-aged lifetime residents of 16 Texas communities. American Journal of Public Health 75:1408-1412.

Russell (1962): Fluorosis survey in grand rapids, michigan:

"Russell (1962), in the Grand Rapids fluoridation study, noted that fluorosis was twice as prevalent among African-American children than white children."
SOURCE: National Research Council. (1993). Health effects of ingested fluoride. National Academy Press, Washington DC. p. 44.

From:	Audrey Adams
To:	Phillips, Theresa (DOH)
Subject:	Proposed Changes to Fluoridation of Drinking Water
Date:	Tuesday, February 23, 2016 1:06:12 PM
Attachments:	Comment to BOH Petition re Fluoride Rule Change 2-23-16.pdf Dr Yolanda Whyte Fluoridation & Infant Toxicity letter 5-20-13.pdf Racial Disparities in Dental Fluorosis.pdf

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Theresa,

Please find my attached comment, plus two accompanying attachments, for the proposed rule change to **WAC 246-290-460** regarding the concentration of fluoridation chemicals in drinking water. Please let me know if there is any trouble opening these PDF attachments.

Thank you!

Audrey

From:	Phillips, Theresa (DOH)
To:	James Robert Deal
Subject:	RE: comment on new .7 ppm fluoridation rule
Date:	Tuesday, February 23, 2016 1:51:00 PM

I have received your email commenting on the fluoridation of drinking water rulemaking.

Theresa Phillips
Department of Health, Division of Environmental Public Health
PO Box 47820, Olympia, WA 98504-7820
☎ **360.236.3147**
Public Health – Always Working for a Safer and Healthier Washington

From: James Robert Deal [mailto:james@jamesdeal.com]
Sent: Tuesday, February 23, 2016 11:58 AM
To: Phillips, Theresa (DOH)
Cc: Audrey Adams; Scott Shock; Alli Larkin; Julie Simms; Pam Pollock; Jeff Woiton; Jeanne Gleason; Olemara Peters; Brian Richard
Subject: comment on new .7 ppm fluoridation rule

Comment on
Fluoridation of Drinking Water, WAC 246-290-460

Please acknowledge receipt.

Sincerely,

James Robert Deal , Attorney & Broker
James@JamesDeal.com
PO Box 2276 Lynnwood WA 98036
Direct Telephone Line: 425-771-1110
Fax: 425-776-8081
Madison Partners Real Estate
www.WashingtonAttorneyBroker.com
www.Fluoride-Class-Action.com
www.JamesRobertDeal.org

From:	Phillips, Theresa (DOH)
To:	Gerald Steel
Subject:	RE: Please confirm receipt today of seven emailed comments on proposed WAC 246-290-460 from Gerald Steel
Date:	Tuesday, February 23, 2016 1:19:00 PM

Yes, I have received seven separate emails from you concerning the fluoridation of drinking water rulemaking.

Theresa Phillips
Department of Health, Division of Environmental Public Health
PO Box 47820, Olympia, WA 98504-7820
☎ 360.236.3147
Public Health – Always Working for a Safer and Healthier Washington

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From: Gerald Steel [mailto:geraldsteel@yahoo.com]
Sent: Tuesday, February 23, 2016 1:18 PM
To: Phillips, Theresa (DOH)
Subject: Please confirm receipt today of seven emailed comments on proposed WAC 246-290-460 from Gerald Steel

Theresa,

Please confirm receipt today of seven emailed comments on proposed WAC 246-290-460 from Gerald Steel (not including this current request).

Gerald Steel PE
Attorney at Law
7303 Young Rd. NW
Olympia WA 98502
360.867.1166

From: James Robert Deal
To: Phillips, Theresa (DOH)
Subject: RE: Proposed Changes to Fluoridation of Drinking Water - Revised
Date: Wednesday, February 24, 2016 11:48:59 AM

The only change was on the first page in this paragraph:

> There are many grounds for opposing fluoridation, but I will focus primarily on two, the fact that it is illegal and that it leaches lead. I will also touch on the fact that it is ineffectual and that it has harmful side effects.

Use the second revised version. It makes more sense.

Sincerely,

James Robert Deal , Attorney & Broker
James@JamesDeal.com
PO Box 2276 Lynnwood WA 98036
Direct Telephone Line: 425-771-1110
Fax: 425-776-8081
Madison Partners Real Estate
www.WashingtonAttorneyBroker.com
www.Fluoride-Class-Action.com
www.JamesRobertDeal.org

From: Phillips, Theresa (DOH) [mailto:Theresa.Phillips@DOH.WA.GOV]
Sent: Wednesday, February 24, 2016 7:59 AM
To: James Robert Deal
Subject: RE: Proposed Changes to Fluoridation of Drinking Water - Revised

Mr. Deal:

Can you help me understand the difference between the two letters? Please point me to the pages that are different from the previous letter.

Theresa Phillips
Department of Health, Division of Environmental Public Health
PO Box 47820, Olympia, WA 98504-7820
☎ **360.236.3147**
Public Health – Always Working for a Safer and Healthier Washington

---

From: James Robert Deal [mailto:james@jamesdeal.com]
Sent: Tuesday, February 23, 2016 4:44 PM
To: Phillips, Theresa (DOH)
Subject: Proposed Changes to Fluoridation of Drinking Water - Revised

Sincerely,

James Robert Deal , Attorney & Broker
James@JamesDeal.com
PO Box 2276 Lynnwood WA 98036
Direct Telephone Line: 425-771-1110
Fax: 425-776-8081
Madison Partners Real Estate
www.WashingtonAttorneyBroker.com
www.Fluoride-Class-Action.com
www.JamesRobertDeal.org

From:	Ronda Kirk
To:	Phillips, Theresa (DOH)
Subject:	Response to the fluoridation of drinking water
Date:	Wednesday, February 10, 2016 11:14:26 PM

The "fluoride" being added to public drinking water is not genuine fluoride. It is industrial waste. Aluminum. Known to cause Alzheimers, to interfere with the proper growth rate of children's growing brains, and to interfere with mental functioning. I personally believe in using nature wisely. I do not believe in renaming industrial poisonous waste material, "fluoride" and making questional claims that it is beneficial--or at best, that the benefits outweigh the harm. Cancer is on the rise and the public is becoming more and more informed. My son is within the Autism spectrum and I have been so very concerned about what is being added to the drinking water, that I use bottled water for cooking and drinking. Unfortunately, it is still coming out of the bath fixtures. Some parents, including me, are concerned that the flouride (and chlorine) is absorbed into the skin while bathing/showering and is having adverse affects on these sensitive individuals. It is time to follow Portland, Oregon's lead and quit adding "fluoride" to the public water system.

Sincerely,
Ronda Kirk
Renton, WA 98055

Rule Comments

Documents and Comments

Document Title	File Name	Document Description	WSR#	Author	Author Organization	Author Phone	Deadline Date
Chapter 246-296 WAC Drinking Water State Revolving Fund Loan Program							
0 Comments	1603057drinkingwaterstaterevolvingfund102final.pdf	Proposal sets specific requirements for awarding infrastructure loans to eligible water systems due to an emergency event.	16-03-084	Theresa M Phillips	EPH - ASSISTANT SECRETARY	360-236-3147	02/23/2016
0 Comments	drinkingwaterprelimarySA.pdf	Significant Legislative Analysis	16-03-084	Theresa M Phillips	EPH - ASSISTANT SECRETARY	360-236-3147	02/23/2016
WAC 246-290-460 Fluoridation of Drinking Water							
15 Comments	1603084sbohflouridation102finalcombined.pdf	Adds the new U.S. Department of Health and Human Services (HHS)	16-03-084	Theresa M Phillips	EPH - ASSISTANT SECRETARY	360-236-3147	02/23/2016

		recommendation for an optimal fluoride level of 0.7 milligrams per liter (mg/L) for Group A Public Water Systems that choose to fluoridate.		
Oppose (10)	**Commenter**	**Commenter Phone**	**Commenter Email**	**Commenter Address**
Oppose	**Bill Osmunson**	**425.466.0100**	**bill@teachingsmiles.com**	**12617 75th Place SE, Newcastle, WA 98056**

Section 2: A Significant Analysis is required for this rule.

The public is not protected with the current rule changes and a scientific analysis is required. What is the range of fluoride ingested without fluoridation of water? What is the dosage range with fluoridated water? What is the blood serum fluoride concentration of people? What is the optimal fluoride concentration for the enamel and dentin to prevent dental caries? What dosage or blood fluoride concentration is reported in children and is their IQ affected? Does IQ drop with increased severity of dental fluorosis? What dosage of fluoride increases cancer? What dosage of fluoride decreases thyroid function? What dosage of fluoride causes enzymatic, cellular, mitochondrial, and DNA harm?

CDC reports 41% of adolescents now have dental fluorosis, a biomarker of excess fluoride exposure. the board must do an analysis of a range of total fluoride exposure with and without fluoridation of public water. How much fluoride are people getting without fluoridated water? Clearly, 41% are receiving a toxic overdose of fluoride. EPA agrees with their dose response analysis that about a third of children will receive too much fluoride and virtually all infants. We now have 49

human studies reporting harm the the brain such as lower IQ from fluoride exposure. This rule will lower the IQ of many children in Washington State. The board must do an analysis to determine what percentage of the population will be harmed. The National Toxicology Program has started a review of the developmental neurotoxicity of fluoride and put it on a high priority. Fluoride is more toxic than lead and forced into people without their consent and without label on products with the fluoride. The board is required to do an analysis of this rule.

Oppose Bill Osmunson 425.466.0100 bill@teachingsmiles.com 12617 75th Place SE, Newcastle, WA 98056

Section 3. General Goals and specific objectives. RCW 43.20.050(2)(a) provides clear guidance for the board to write rules which assure the public has safe water and the public health is protected. The rule change as proposed fails to provide safe water quality standards. The board or water systems must get a chemical analysis from the manufacturer of purity of the chemicals and provide the board with a copy of purity.

RULE CHANGE FOR (3)(B)(iv) “Submit to the department the fluoride manufacturers chemical assay analysis for each batch of fluoride chemicals purchased.”

The fluoride chemicals added to the water frequently contain lead, arsenic and other contaminants. The amount of those contaminants should be understood, measured and reported to the department. NSF is not requiring confirmation of this data from the manufacturers. The lead problems in Flint, MI, are a reminder that governments must not operate on blind faith and assumptions.

And further, the rule change does not make the water safe for everyone. Those with chemical sensitivities are not considered. Those drinking more than the average (1 liter of water a day) are not protected or considered. Governments make no sense when they assume everyone drinks the same amount of water. Some drink more than 10 times the “average” amount of water. To be safe, the rule should require water systems and municipalities to caution the public not to consume more than 2 liters of the fluoridated water a day. Of most concern are infants and their developing brain and thyroids. Broadbent is the only significant study not finding an IQ loss from low levels of fluoride. However, Broadbent predominantly compared subjects on fluoridated water with subjects on fluoride pills. Comparing two different sources of fluoride did not properly evaluate fluoride itself. The majority research is reasonably consistent, low levels of fluoride, similar to what many are getting in Washington State, is causing children harm. When pharmaceutical companies want to test a new cancer drug, they sometimes give rats fluoride to cause cancer and then test the new cancer treatment drug on the rats with cancer. There is no dispute, fluoride can cause cancer.

If fluoridation is practice, informed consent must be clear and simple.

(Unfortunately, the formate for presenting comments does not permit paragraphs or underlining. Therefore, the paragraphs are run on which makes comments hard to read.)

Oppose	**Bill Osmunson**	**425.466.0100**	**bill@teachingsmiles.com**	**12617 75th Place SE, Newcastle, WA 98056**

Section 4: The board is correct lowering the fluoride concentration in water. The board is requested to include public comments over the last 10 years requesting changes to the rule and requesting lowering of the fluoride concentration in public water for the protection of the public. It has taken 10 years since the National Research Council's report to the EPA that their Maximum Contaminant Level Goal was not protective and many petitions for rule change for the department and board to slowly grind to this minimal change. This minor change will only have a slight protection of the public. In the near future, fluoridation will be stopped because good scientists and politicians choose to protect the public and provide individual freedom of choice. For the board to suggest "there are no feasible alternatives" to this rule is seriously flawed. The rule could protect the public with education on the concerns of excess fluoride exposure. At a minimum, the 0.7 mg/L of fluoride should be a maximum concentration and the marketing term "optimal" should be deleted. Rules are not the place to market highly toxic substances. The goals and objectives for public safety are not met with this rule change. What about the FDA warning manufacturers against marketing the unapproved fluoride could not be incorporated into this rule change? Simply include in the rule change that the FDA has not approved the ingestion of fluoride for the prevention of dental caries and does not find it safe or effective. See comment at Section 1.

Oppose	**Bill Osmunson**	**425.466.0100**	**bill@teachingsmiles.com**	**12617 75th Place SE, Newcastle, WA 98056**

Section 5 part B. Negative Economic Impact. 3.6% of 12 to 15 year olds being harmed with moderate to severe dental fluorosis is not rare and is costly to their health and society. The board has been presented with numerous studies reporting harm at low levels of fluoride exposure. The National Toxicology Program Office of Health Assessment and Translation has put the evaluation of fluoride's developmental neurotoxicity on a high priority. The 49 human studies reporting neurological harm suggest about 7 IQ point loss with dental fluorosis, increased fluoride serum concentrations. Each IQ point lower represents close to $1,000

annual lower economic income. If those 36,000 children have only 1 IQ point loss from fluoridation, the negative economic impact represents about $36,000,000/year/million people. Multiply that by 7 IQ points and about 5 million Washington residents on fluoridated water and we start to have material costs. . . each year. And that is only brain damage and does not include cancer or thyroid harm.

Oppose	**Bill Osmunson**	**425.466.0100**	**bill@teachingsmiles.com**	**12617 75th Place SE, Newcastle, WA 98056**

Section 5 part C. Cost Savings. A careful review of the cost benefits, cost savings from fluoridation result in several problems. Most research is based on estimates and assumptions or estimates of assumptions rather than measured evidence. Measured evidence usually takes small cherry picked clinics and do not control for significant variables. For example, studies will assume benefit and then estimate costs. Money is one thing we keep better track of than anything else. It is not difficult for insurance companies to compare costs between fluoride free and fluoridated communities. When they do, the results do not support fluoridation. (see Maupome) And research benefits have failed to include confounding factors such as

A. Not one Study corrects for Unknown Confounding Factors
B. Not one Prospective Randomized Controlled Trial
C. Socioeconomic status usually not controlled
D. Inadequate size
E. Difficulty in diagnosing decay
F. Delay in tooth eruption not controlled
G. Diet: Vitamin D, calcium, strontium, sugar, fresh and frozen year around vegetables and fruit consumption not controlled.
H. Total exposure of Fluoride not determined
I. Oral hygiene not determined
J. Not evaluating Life time benefit
K. Estimating or assuming subject actually drinks the fluoridated water.
L. Dental treatment expenses not considered
M. Breast feeding and infant formula excluded
N. Fraud, gross errors, and bias not corrected.
O. Genetics not considered

Cost savings from fluoridation is still unknown and best case savings is $3 per person. http://www.ncbi.nlm.nih.gov/pubmed/25471729

Oppose	**Bill Osmunson**	**425.466.0100**	**bill@teachingsmiles.com**	**12617 75th Place SE, Newcastle, WA 98056**

Section 5 Part D. A 30% reduction in water fluoride concentration will only have a minimal impact on the 3.6% of the population being harmed with moderate to severe dental fluorosis. . . excess fluoride exposure. To have a significant impact on the health and safety of the public, the rule should stop fluoridation. At a minimum, infants should be protected with a warning, those with kidney function protected, and a warning not to drink more than 1 liter of the fluoridated water a day.

Oppose	**Bill Osmunson**	**425.466.0100**	**bill@teachingsmiles.com**	**12617 75th Place SE, Newcastle, WA 98056**

Section 5.(Part A) Explain Costs. The department assumes benefit because they have cherry picked the evidence, used historic incomplete studies and used incomplete judgment. Fluoridation is not treating water. Fluoridation of public water is treating people. That concept appears to have alluded the rule makers. Think people, person, individual, dosage to individual patients. How much fluoride is each individual patient getting? We must think individual patient and the public at large. What percentage of the population are getting too much? Is that OK? What percentage of the population being harmed is acceptable to the department and board? And what harm is acceptable? Fluoride concentration in water is not a human dosage because some drink very little water and some drink a great deal of water; the range is from 0.5 liters to 11 liters per day. Looking only at the mean or average, fails to protect all. Because people drink a different amount of water, dosage cannot be controlled. And the amount of fluoride toothpaste they swallow is highly variable. The amount of fluoride pesticides and fluoride post harvest fumigants is highly variable. The amount of fluoride medications is variable. Dosage can get complex, but it is really quite simple. First ask the question, what is the optimal fluoride tooth concentration? In other words, what do we want for the teeth? Answer that question and then move to the optimal serum fluoride concentration in order to achieve the optimal tooth fluoride concentration. From there, move to the optimal total fluoride exposure the individual is getting so we achieve the optimal serum and tooth concentrations. And if the total fluoride without fluoridation is incomplete, then treat the patient with more fluoride. . . which could be in the form of fluoridated water. But how much is the question. Unfortunately, none of those questions have been answered. Teeth with dental caries and without dental caries have the same range of fluoride concentration (except outer microns from fluoride toothpaste and varnish). Therefore, we don't know how much fluoride is optimal for teeth, serum, ingestion, water, etc. The word "optimal" in the rule is marketing, advertising, promotional, emotional terms without scientific merit.

Section 5 references an historic study by Heller (1997), prior to fluoride post-harvest fumigants and prior to the CDC's report of 40% unaffected and about 60%. HHS suggests moderate to severe fluorosis is rare, about 3.6% of 12 to 15 year olds NHANES, 1999-2004. http://www.cdc.gov/nchs/data/databriefs/db53.pdf HHS and WSDH and WSBOH may think harming 3.6% is insignificantly rare, some of us disagree. 3.6% represents 36,000 children with moderate to severe fluorosis for every million. That is not "rare."

Oppose	**Bill Osmunson**	**425.466.0100**	**bill@teachingsmiles.com**	**12617 75th Place SE, Newcastle, WA 98056**

Section 6. Helping the water districts have “least burdensome” rules has some validity. However, keeping the focus on individual health and safety is far more important. 0.7 mg/L is a maximum compromise made by HHS. If an 0.2 mg/L range is chosen, 0.5 mg/L plus or minus 0.2 mg/L would be more protective of the public. We have too many other sources of fluoride which need to be included. The department has used historic studies to suggest benefit. To protect the public the department/board must recommend 0.0 mg/L of fluoride. At this time, there does not appear to be a lower limit of fluoride which does not cause harm. Instead of the board parroting the marketing of fluoridationists, the board and department must make it clear in the rules they do not determine the safety or efficacy of fluoridation and the local water districts and municipalities must make those scientific determinations. The board and department support and encourage fluoridation and like Flint, MI, the governments complicity in pollution is not a solution. Fluoridation is the addition of a contaminant to public water and soon will be considered one of public health’s greatest blunders of the 20th century.

Oppose	**Bill Osmunson**	**425.466.0100**	**bill@teachingsmiles.com**	**12617 75th Place SE, Newcastle, WA 98056**

Section 9 and 10. The proposed rule evades the FD&C Act and Washington State drug laws which require NDA for all substances marketed with the intent to prevent disease. If the WSBH or WSDH think they are immune or outside FDA and drug laws, then they should get a letter or statement from the FDA to such an effect. Until that time, the WSBH and WSDH are outside federal law, promoting the dispensing of an unapproved and therefore illegal, misbranded and contaminated drug. Most developed countries have stopped fluoridation. 97% of Europe is fluoridation free. China, Israel, and Japan do not fluoridate. About half of Canada which was fluoridated has stopped. Most of British Columbia stopped and dental decay rates did not go up. When East and West Germany united, the West turned off the fluoridation pumps and dental caries decreased.

Austria REJECTED: "toxic fluorides" NOT added
Belgium REJECTED: encourages self-determination – those who want fluoride should get it themselves.
Finland STOPPED: "...do not favor or recommend fluoridation of drinking water. There are better ways of providing the fluoride our teeth need." A recent study found ..."no indication of an increasing trend of caries....“
Germany STOPPED: A recent study found no evidence of an increasing trend of caries

Denmark REJECTED: "...toxic fluorides have never been added to the public water supplies in Denmark.“
Norway REJECTED: "...drinking water should not be fluoridated“
Sweden BANNED: "not allowed". No safety data available!
Netherlands REJECTED: Inevitably, whenever there is a court decision against fluoridation, the dental lobby pushes to have the judgment overturned on a technicality or they try to get the laws changed to legalize it. Their tactics didn't work in the vast majority of Europe.
Hungary STOPPED: for technical reasons in the '60s. However, despite technological advances, Hungary remains unfluoridated.
Japan REJECTED: "...may cause health problems...." The 0.8 -1.5 mg regulated level is for calcium-fluoride, not the hazardous waste by-product which is added with artificial fluoridation.
Israel SUSPENDED mandatory fluoridation until the issue is reexamined from all aspects.: June 21, 2006 “The labor, welfare and health Knesset committee”
China BANNED: "not allowed“
France Was 50% now 30% fluoridated Salt
Ireland 74% Fluoridated
UK 9% Fluoridated

Oppose **Bill Osmunson** **425.466.0100** **bill@teachingsmiles.com** **12617 75th Place SE, Newcastle, WA 98056**

The Preliminary Significant Rule Analysis is seriously and materially flawed which is and will harm the public.

Section #1. The Rule lacks precisely stating jurisdiction for weighing the evidence and determining both safety and efficacy of fluoride dosage, exposure and ethics.

RECOMENDATION: As of 2016, local water districts and municipalities should be specifically and clearly informed in the rule that no federal or state agency(s) accept jurisdiction to determine the scientific evidence of (a) total individual fluoride dosage with and without fluoridated water; (b.) optimal individual dosage of fluoride exposure to prevent dental caries; (c) safety of fluoride ingestion at the optimal dosage for all systems and tissues of the body including teeth, developmental neurotoxicity, effects on the endocrine system, cancer, enzymatic systems, synergistic effects, diet variations, water volume consumption variations AND age variations especially for infants.

NECESSARY RULE CHANGE: WAC 246-290-460 (1) Purveyors shall obtain written department approval of fluoridation treatment facilities before placing them in service, shall acknowledge that they have jurisdiction over determining the scientific evidence of both safety and efficacy, shall notify customers monthly that infant formula should be made with fluoride free water, and shall notify the department before discontinuing fluoridation.

Local water systems rely on the WSBH (board). However, the board does not accept jurisdiction to evaluate the toxicology, dosage, exposure, benefit, risk of fluoride ingestion. Rather the board relies on "federal agencies." However, no federal agency accepts jurisdiction for fluoridation. The Environmental Protection Agency's (EPA) legal counsel clearly states that the EPA is prohibited from regulating the addition of fluoride to public water with the intent to treat people and the Food and Drug Administration (FDA) has jurisdiction. The board does not mention the FDA. In turn, the FDA claims the EPA has jurisdiction over fluoridation.

With confusion and denial of jurisdiction at the federal level, the board relies on EPA/HHS/NSF. However, Congress did not give EPA/HHS/NSF authority to determine the safety or efficacy of any substance. Congress specifically gave the FDA in the Food Drug and Cosmetic Act jurisdiction over substances used with the intent to prevent disease. HHS can give opinions, but has no scientific qualifications, policies, procedures, jurisdiction or authority to determine the dosage, toxicity, epidemiology, or ethics of any substance used with the intent to prevent disease.

Fluoridation does not meet NSF safety standards. The board does not have monitoring results of fluoride purity as tested by NSF because NSF does not have those tests. NSF does not permit any contaminant in chemicals which would increase the contaminant level in water above 10% of the EPA's MCL. EPA's MCL for fluoride is currently 4 ppm. 10% of 4ppm is 0.4ppm. To keep within NSF safety standards, the board must select a maximum of 0.4 ppm as the so called optimal concentration for fluoride.

The board perpetuates the mythology and public health marketing of fluoridation as a "major factor responsible for the decline in prevalence and severity of dental caries." However, the board does not provide a scientific randomized controlled trials or primary studies for their assumption. The fact remains, dental caries has declined just as much in non-fluoridated communities and countries as fluoridated. Public health benefit of fluoridation is not currently detectible in the public at large.

The FDA have policies, procedures and experts to determine whether the scientific evidence rises to the level of confidence for any substance intended to prevent disease. The board must take note of the FDA's repeated notices to fluoride supplement manufacturers in their letter below. The FDA has shut down the

manufacturing of even 0.25 mg of ingested fluoride, the same amount as delivered without consent in a 11 oz glass of fluoridated water.

The public loses confidence in governments when one branch shuts down marketing of the same amount as another branch forces everyone to ingest. Government's make no sense.

Jurisdiction must be clearly stated in the Rule so the public can hold that agency responsible.

http://www.fda.gov/iceci/enforcementactions/warningletters/2016/ucm483224.htm

Kirkman Laboratories, Inc. 1/13/16

Department of Health and Human Services
Public Health Service
Food and Drug Administration

Seattle District
Pacific Region
22215 26th Avenue SE, Suite 210
Bothell, WA 98021

Telephone: 425-302-0340
FAX: 425-302-0402

January 13, 2016

OVERNIGHT DELIVERY
SIGNATURE REQUIRED

In reply refer to Warning Letter SEA 16-07

David K. Humphrey
Chief Executive Officer and President
Kirkman Laboratories, Inc.
10639 Professional Circle
Reno, Nevada 89521

WARNING LETTER

Dear Mr. Humphrey:

The United States Food and Drug Administration (FDA) conducted an inspection of your drug manufacturing facility, Kirkman Laboratories, Inc., located at 6400 Rosewood St., Lake Oswego, Oregon on June 3, 2015, through June 24, 2015. This inspection revealed that your firm is marketing the following unapproved new drugs: Kirkman Laboratories, Inc. Flura-Drops ® Sodium Fluoride drops, 2.21 mg; Perry Medical Fluorabon Drops USP; Kirkman Laboratories, Inc. 1.1 mg Cherry Dye-Free Sodium Fluoride Tablets; and Kirkman Laboratories, Inc. 2.21 mg Cherry Dye-Free Sodium Fluoride Tablets, in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 355(a)]. Additionally, FDA has determined that these products are misbranded drugs in violation of section 502 and 503 of the Act [21 U.S.C. §§ 352 and 353], as detailed below.

A. Unapproved New Drug Violations

Based on the information collected during the recent inspection, you manufacture and/or distribute unapproved new drugs in violation of sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)].

The unapproved new drugs include, but are not limited to:

• Kirkman Laboratories, Inc. Flura-Drops® Sodium Fluoride Drops, 2.21 mg (NDC 58223-517), which is labeled “for once daily, self-administered, systemic use as a dental caries preventive in pediatric patients”;
• Perry Medical Fluorabon Drops USP, 0.25mg (NDC 11763-524), which is labeled “as an aid in the prevention of dental caries”;
• Kirkman Laboratories, Inc. 1.1 mg Cherry Dye-Free Sodium Fluoride Tablets (NDC 58223-678), which is labeled “as an aid in the prevention of dental caries”; and
• Kirkman Laboratories, Inc. 2.21 mg Cherry Dye-Free Sodium Fluoride Tablets (NDC 58223-679), which is labeled “as an aid in the prevention of dental caries.”

The above products are drugs within the meaning of section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)], because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans. Further, as labeled, these drugs are “new drugs” within the meaning of section 201(p) of the Act [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective under the conditions prescribed, recommended, or suggested in their labeling. Under sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or (j) of the Act [21 U.S.C. § 355(b) or (j)] is in effect for the drug. There are no FDA-approved applications on file for the drugs listed above. The marketing of these drugs, or other new drugs, without an approved application constitutes a violation of the Act.[1]

B. Misbranding Violations

The above products also are “prescription drugs” as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], because, in light of their toxicity or potential for harmful effects, or the method of their use, or the collateral measures necessary for their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer them.1

Because these prescription drug products are intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written for them so that a layman can use them safely for their intended uses. Consequently, the labeling of your firm’s unapproved prescription drug products fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(l) of the Act [21 U.S.C. § 352(f)(1)]. Because your drugs lack required approved applications, they are not exempt under 21 CFR 201.115 from the requirements of section 502(f)(1) of the Act. The above products also are misbranded under section 503(b)(4)(A) of the Act [21 U.S.C. § 353(b)(4)(A)], because the labels fail to bear the symbol “Rx Only.” The introduction or delivery for introduction into interstate commerce of these drugs therefore violates sections 301(a) of the Act [21 U.S.C. § 331(a)].

C. Conclusions

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence and the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal actions without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts. You should discontinue marketing all of the unapproved prescription drugs manufactured at your facility immediately. Additionally, FDA may withhold approval of requests for export certificates or approval of pending new drug applications listing your facility as a manufacturer until the above violations are corrected. A re-inspection may be necessary to verify corrective actions have been completed.

FDA requests that you contact CDER's Drug Shortages Staff immediately at drugshortages@fda.hhs.gov so that we can work with you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture, as required under 21 U.S.C. § 356c(a), and to allow FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

Please notify this office in writing within fifteen (15) working days of receiving this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If the corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the timeframe within which the corrections will be completed. Please include copies of any documentation demonstrating that corrections have been made. If you no longer manufacture or market your fluoride products, your response should indicate, including the reasons that, and the date on which, you ceased production.

Your reply should be sent to the following address: U.S. Food and Drug Administration, 22215 26th Avenue SE, Suite 210, Bothell, Washington 98021 to the attention of Maria P. Kelly-Doggett, Compliance Officer. If you have any questions regarding any issues in this letter, please contact Compliance Officer Maria Kelly-Doggett by telephone at 425-302-0427.

Sincerely,
/S/
Miriam R. Burbach
District Director

cc: Lawrence A. Newman
Chief Operating Officer Technical & Regulatory Affairs
Kirkman Laboratories, Inc.
6400 Rosewood St.
Lake Oswego, Oregon 97035

1 Over-the-Counter (OTC) fluoride dentifrice drug products are subject to the final rule for Anticaries Drug Products for OTC Human use found in 21 CFR 355. As described in 21 CFR 355.60, the professional labeling allows for anticaries fluoride treatment rinses that are specifically formulated so they may be swallowed (fluoride supplements) and are provided to health professionals (but not to the general public) to contain additional dosage information. This additional information cannot be directed to consumers and the product must be in accordance with 21 CFR 355.60. The Flura-Drops® Sodium Fluoride Drops, 2.21 mg (NDC 58223-517), Fluorabon Drops USP, 0.25mg (NDC 11763-524), 1.1 mg Cherry Dye-Free Sodium Fluoride Tablets (NDC 58223-678), and 2.21 mg Cherry Dye-Free Sodium Fluoride Tablets (NDC 58223-679) labels and labeling do feature additional dosage information (i.e., professional labeling information) and as such, the information is inappropriately directed to consumers. Additionally, 21 CFR 355.60 only allows additional dosage information for children 3 to under 14 years of age. These products all indicate for use down to age 6 months. Furthermore, a fluoride tablet is not a dosage form permissible under the final rule.

http://www.fda.gov/iceci/enforcementactions/warningletters/2016/ucm483224.htm

Support (5)	Commenter	Commenter	Commenter Email	Commenter Address

Rule Comments

Documents and Comments

	Phone		
Russell Maier	**5095746126**	**russell.maier@chcw.org**	**1806 W lincoln**

Fluoridation is one of the top ten public health interventions of the last century. Like any health intervention, better science, better access, changes in the prevalence of the disease create the need for modifications.

This is good science.
This is a great public health intervention.

I am fully in support of a rule changes that supports the adjustment of fluoride in drinking water to be in compliance with the HHS recommendations @ 0.7ppm.

Leona M Groesbeck	**3607391938**	**flossyrdh@gmail.com**	**1357 Olivia Ct.**

I support this rule change fully. It is based on valid scientific evaluation of health benefits of optimal public water fluoridation, which the Surgeon General confirms as one of the best ways to improve the oral health of the public.

Max	**(201)677-3157**	**max3133@gmail.com**	**www.spiritsuniverse.com**

This book give much information for my research. Thanks alot

			Moeggih

This is supported by significant evidence-based, scientific research. The statistics of the anti-fluoridationists have been proven false or at the minimum, misleading. They are the same claims used for over four decades. Caries is not just a disease of children; adults, and in particular, institutionalized and geriatrics are at high risk. This maintains the preventive aspect, but also reduces risk of fluorosis.

			Moeggih@gmail.com

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Rule Comments

Documents and Comments

1 Comments	**Preliminary Significant Analysisfloruide.pdf**	**Preliminary Significant Legislative Analysis**	**16-03-084**	**Theresa M Phillips**	**EPH - ASSISTANT SECRETARY**	**360-236-3147**	**02/23/2016**
Oppose (1)	**Commenter**	**Commenter Phone**	**Commenter Email**		**Commenter Address**		
Oppose	**Bruce Guthrie**	**4255827588**	**spdsk8@aol.com**		**6406 135th pl SW, Edmonds, WA 98026**		

Please reduce or eliminate added fluoride to our water supply.
1) The dosage can not be controlled. People drink different amounts of water. Some will get too much fluoride.
2) Water drains to streams. We do not know the effect of this runoff on ecosystems.
3) Fluoride is intended to treat teeth. But ingesting it, systemically, instead of applying it topically to teeth, is wasteful and may be harmful.
4) Government should not have the power to medicate us via the water supply. It sets a very dangerous precedent. There is no consent.
5) Fluoridation is expensive and hazardous to the workers who must handle it. Municipalities are exposing themselves to liability risk for future worker injury claims.
6) It erodes pipes, and causes unnecessary expense at a time when budgets are tight.
7) We get fluoride in our toothpaste and at the Dentist's office. We don't need it in the water supply.
8) Some studies show higher fluoride levels are associated with lower child IQ.
It is not worth the risk and the expense. It sets a dangerous precedent.

Please reduce or eliminate added fluoride in the water supply.
Thank you for your consideration.

50 REASONS TO STOP FLUORIDATION

Fluoridation Is A Bad Medical Practice

1. Fluoride is the only chemical added to water for the purpose of medical treatment.
2. Fluoridation is unethical.
3. The dose cannot be controlled.
4. The fluoride goes to everyone regardless of age, health, or vulnerability.
5. People now receive fluoride from many other sources besides water.
6. Fluoride is not an essential nutrient.
7. The fluoride level in mothers' milk is very low.
8. Fluoride accumulates in the body.
9. No health agency in fluoridated countries is monitoring fluoride exposure or side effects.
10. There is not any randomized clinical trial to show fluoridation's effectiveness or safety.

Swallowing Fluoride Provides No (Or Very Little) Benefit

11. Benefit is topical (from application to the tooth surface) not systemic (from swallowing).
12. Fluoridation is not necessary. ***See*** **ATTACHED FIGURE 1.**
13. Fluoridation's role in the decline of tooth decay is in serious doubt.
14. NIH-funded study on individual's fluoride ingestion and tooth decay found no correlation.
15. Tooth decay is high in low-income communities that have been fluoridated for years.
16. Tooth decay does not go up when fluoridation is stopped.
17. Tooth decay was coming down before fluoridation started. ***See*** **ATTACHED FIGURE 2.**
18. The studies that launched fluoridation were methodologically flawed.

Children Are Being Over-Exposed To Fluoride

19. Children are being over-exposed to Fluoride.
20. The highest doses of fluoride are going to bottle-fed babies.

Evidence Of Harm To Other Tissues

21. Dental fluorosis (in 41% of 12-15 year olds) may be an indicator of wider systemic damage.
22. Drinking fluoridated water may damage the brain.
23. Drinking fluoridated water may lower IQ.
24. Drinking fluoridated water may cause non-IQ neurotoxic effects.
25. Drinking fluoridated water affects the pineal gland.
26. Drinking fluoridated water affects thyroid function.
27. Drinking fluoridated water causes arthritic symptoms.
28. Drinking fluoridated water damages bone.
29. Drinking fluoridated water increases hip fractures in the elderly.
30. People with impaired kidney function are particularly vulnerable to bone damage.
31. Fluoridation may cause bone cancer (osteosarcoma).
32. Drinking fluoridated water shown to increase risk of bone cancer in young boys by 600%.
33. Drinking fluoridated water may cause reproductive problems.
34. Some individuals are highly sensitive to low levels of fluoride.
35. Other subsets of population are more vulnerable to fluoride's toxicity: infants, elderly, diabetics.

(continued on next page)

50 REASONS TO STOP FLUORIDATION

No Margin Of Safety

36. There is no margin of safety for several health effects.

Environmental Justice

37. Low-income families penalized by fluoridation because unable to afford other drinking water.
38. Black and Hispanic children are more vulnerable to fluoride's toxicity.
39. Minorities are not being warned about their vulnerabilities to fluoride.
40. Tooth decay reflects low-income not low-fluoride intake.

Largely Untested Chemicals Are Used In Fluoridation Programs

41. The chemicals used to fluoridate water are not pharmaceutical grade.
42. The most commonly-used chemicals (silicon fluorides) have not been tested comprehensively.
43. These silicon fluorides may increase lead uptake into children's blood.
44. Fluoride may leach lead from pipes, brass fittings, and soldered joints.

Continued Promotion Of Fluoridation Is Unscientific

45. Key health studies have not been done.
46. Endorsements do not represent scientific evidence.
47. Review panels hand-picked to deliver a pro-fluoridation result.

More And More Independent Scientists Oppose Fluoridation

48. As of July 2011, over 3700 professionals have called for a worldwide end to water fluoridation.

Proponents Dubious Tactics

49. Proponents usually refuse to defend fluoridation in open debate.
50. Proponents use censorship and intimidation to promote fluoridation.

See http://www.fluoridealert.org/50-reasons.htm# for more information on each of the 50 reasons.

Attached hereto are three exhibits: Figures 1, 2 and 3.

This document was prepared by Protect the Peninsula's Future, P.O. Box # 2418, Sequim, WA 98382. For more information contact Eloise Kailin, MD eloisek@olympus.net, Keith Wollen, Ph.D. kfw@olypen.com , or Gerald Steel PE, Attorney at Law geraldsteel@yahoo.com .

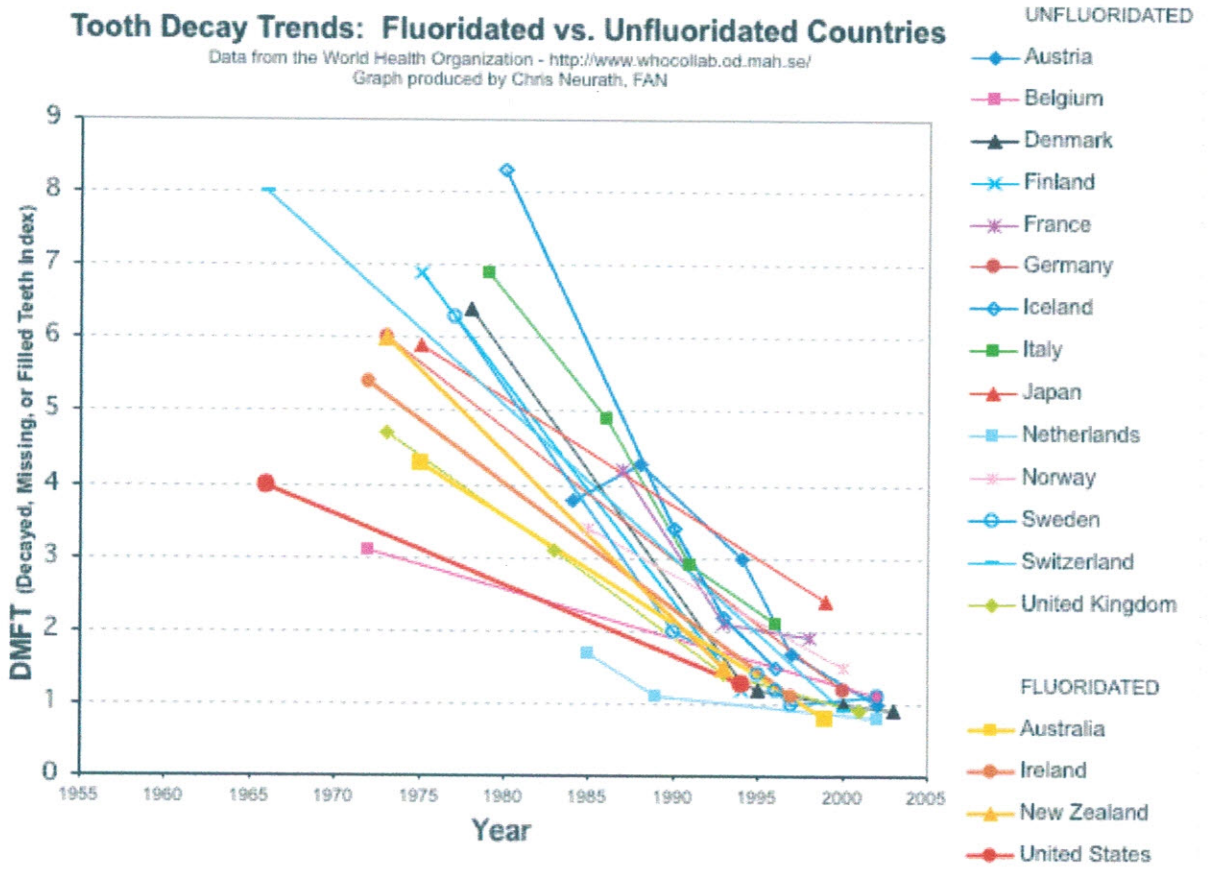

Figure 1. Water Fluoridation is an insignificant factor worldwide in reduction of tooth decay.

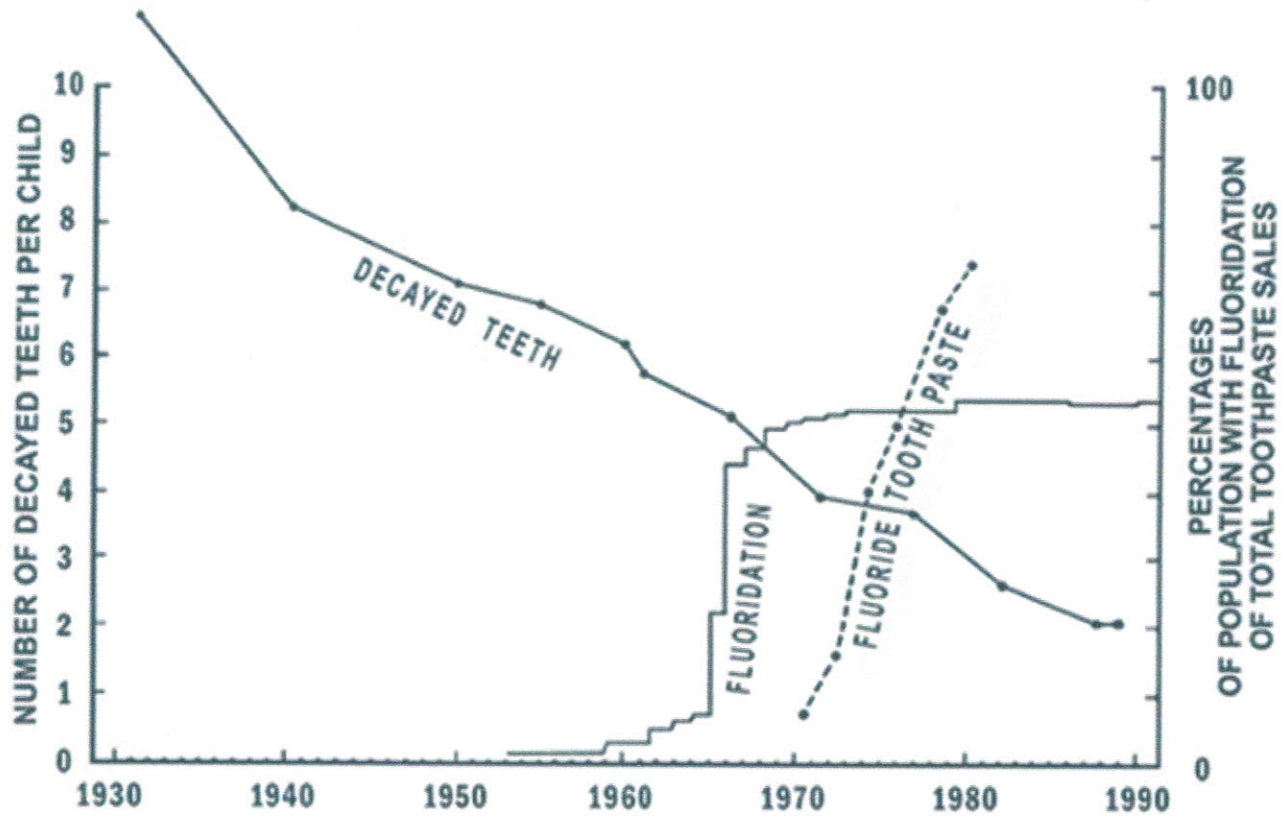

Figure 2. The steady decline in tooth decay in New Zealand 5-year olds is independent of fluoridation or fluoridated tooth paste.

PHOTOGRAPHS OF DENTAL FLUOROSIS

Keith A. Wollen, Ph.D.

Fluoride that is ingested accumulates in bones, including the teeth. Dental fluorosis results when children ingest too much fluoride, which changes the crystalline structure of teeth. Mild forms result in white spots on the teeth, which can produce embarrassment and emotional stress. Severe forms result in black or brown spots, often with pitting, chips, fractures, and decay. Severe forms are a serious medical and dental problem. Below are photographs of mild through severe fluorosis.

Mild Moderate Severe

Figure 3. Photographs of mild, moderate, and severe dental fluorosis. The US Department of Health and Human Services announced in the Federal Register on January 13, 2011 (76 FR 2385) that in 1999 to 2004, 29% of 12 to 15 year olds in the United States had very mild dental fluorosis, an additional 9% had mild dental fluorosis, and an additional 4% (one of every 25 children) had moderate or severe dental fluorosis. This is a permanent condition absent ongoing cosmetic surgery. In the state of Washington, 3.5 million people were served with fluoridated water in 2008 based on the false claim that water fluoridation prevents tooth decay. *See* http://www.cdc.gov/fluoridation/statistics/2008stats.htm

FLUORIDE IN DRINKING WATER:

A Scientific Review of EPA's Standards

Committee on Fluoride in Drinking Water

Board on Environmental Studies and Toxicology

Division on Earth and Life Studies

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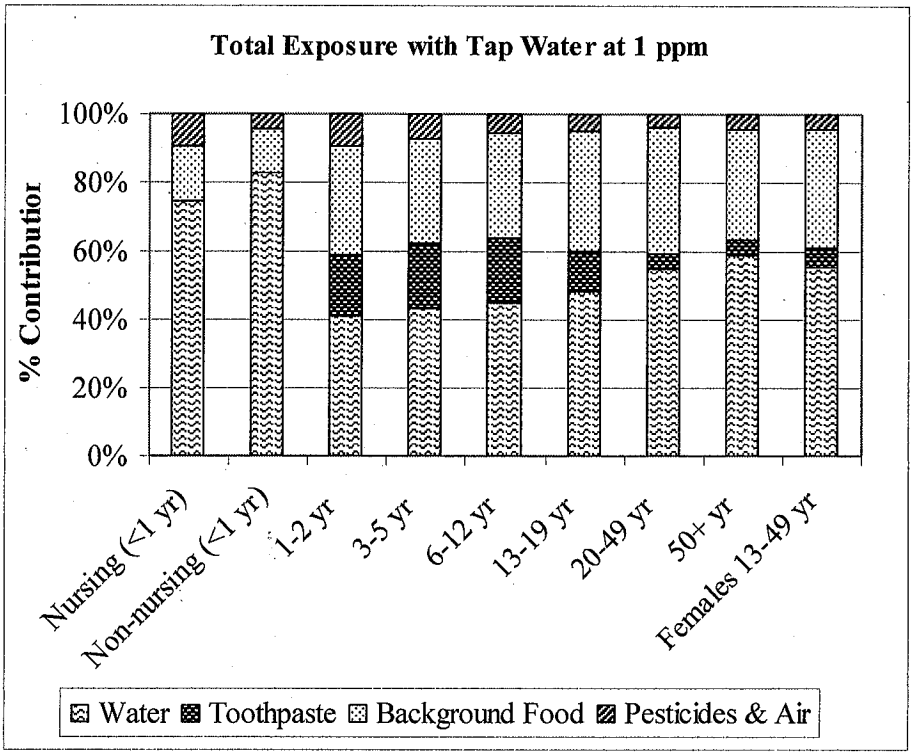

FIGURE 2-1 Source contribution to total inorganic fluoride exposure, including fluoride at 1 mg/L in tap water. The estimated chronic inorganic fluoride exposures from the various routes are presented in Tables 2-9 and 2-10. No fluoride supplement is included for any population subgroup. The total exposures as presented in Table 2-11 for the population subgroups are: 0.030 mg/kg/day (nursing infants), 0.087 mg/kg/day (non-nursing infants), 0.066 mg/kg/day (1-2 years old), 0.060 mg/kg/day (3-5 years old), 0.040 mg/kg/day (6-12 years old), 0.028 mg/kg/day (13-19 years old), and 0.031 mg/kg/day for adults (20 to 50+ years old) and women of child-bearing age (13-49 years old).

toothpaste, children inappropriately given fluoride supplements in a fluoridated area, children in an area with high fluoride concentrations in soil, and children with pica who consume large amounts of soil.

The exposure estimates presented in this chapter for non-drinking water routes are based on the potential profile of fluoride residue concentrations in the current exposure media. They likely do not reflect the concentration of past exposure scenarios, particularly for routes that show changes in time (e.g., pesticide use practices). Any new and significant source of fluoride exposure, such as commodities approved for sulfuryl fluoride fumigation application beyond April 2005, is expected to alter the percentage of drinking water contribution as presented in this chapter.

Different assumptions for the drinking water concentration alone also can result in slightly different estimates. For example, values in Table 2-11 are derived from assuming that the nontap water has a fixed fluoride concentration of 0.5 mg/L, while tap water concentration varies up to 4 mg/L. Table 2-12 provides alternative calculations of total exposure by assuming that all sources of drinking water (both tap and nontap water) contain the same specified fluoride

From:	Gerald Steel
To:	Phillips, Theresa (DOH)
Cc:	Audrey Adams; Scott Shock; Bill Osmunson
Subject:	WAC 246-290-460 Rulemaking - Fluoridation at any level makes public drinking water unsafe to many people
Date:	Tuesday, February 23, 2016 11:27:56 AM
Attachments:	NRC (2006) cover and page 49.pdf 50 Reasons to Stop Fluoridation.pdf

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I submit this comment on proposed WAC 246-290-460 on behalf of myself and King County Citizens Against Fluoridation.

Today 1-12 year olds get any necessary ingested fluoride without drinking fluoridated water. The SBOH should end its policy of promotion of fluoridation and instead promote dental hygiene and good diet. The attachment includes page 49 from NRC (2006). It shows that for 1-12 year olds, approximately 40% of ingested fluoride prior to 2006 came from fluoridated water at 1 ppm fluoride. Several points can be made based on this data.

First, this NRC (2006) data is for fluoridation at 1 ppm fluoride. If fluoridation were adjusted to 0.7 ppm fluoride using this NRC (2006) data, 32% of ingested fluoride for 1-12 year olds would come from fluoridated water. In the data on page 49 of NRC (2006) for 1-12 year olds, about 30% of ingested fluoride comes from fluoridated toothpaste and pesticides/air. From 2006 to today there has been substantial growth in use of fluoride (primarily as sulfuryl fluoride) as a pesticide and fumigant so that today about 33% of ingested fluoride for 1-12 year olds comes from fluoridated toothpaste and pesticides/fumigants/air. See e.g. <http://fluoridealert.org/researchers/pesticide/fluoride-residues-food/> http://fluoridealert.org/researchers/pesticide/fluoride-residues-food/ When the U.S. Public Health Service (PHS) recommended 0.7 ppm fluoride as the lower level for fluoridation in 1962, the contributions to ingested fluoride from toothpaste and pesticides/fumigants/air was nearly 0%. Today children 1-12 get enough ingested fluoride from toothpaste, pesticides, fumigants, and air so that they get the 1962 recommended level for ingested fluoride without drinking any fluoridated water. Any supplement to ingested fluoride from fluoridated water for 1-12 year olds causes excessive ingested fluoride and is damaging to the health of many of these children.

This explains much of the data that is being reported today. In 1934, Dr. H. Trendley Dean from the Dental Section of the U.S. Public Health Service published an article classifying dental fluorosis according to the following categories: questionable, very mild, mild, moderate, moderate to severe, and severe. (H.T. Dean, "Classification of Mottled Enamel Diagnosis." Journal of the American Dental Association 49, No. 1 (1934): 1421-26.) These definitions are still used today. Mild dental fluorosis involves an impaction of up to 50% of a tooth surface; moderate involves 100% of the tooth surface being affected, with some pitting; and severe affects 100% of the tooth surface with more pitting and brittleness. (Id.) Today these categories are applied when at least two teeth meet the

described condition. In 1952, Dean stated in his testimony before the Delaney Committee of the U.S. Congress: “We don’t want any ‘mild’ [fluorosis] when we are talking about fluoridation. We don’t want to go that high and we don’t have to go that high . . . I don’t want to recommend any fluoridation where you get any ‘mild’”. Today, with the increased ingestion of fluoride from toothpaste, pesticides, fumigants, and air, fluoridating water just creates excessive fluoride ingestion and should no longer be promoted by the SBOH. The 1999-2004 NHANES National Study found 12.2% of 12 to 15 year olds in the U.S. (or one in eight) had mild, moderate, or severe dental fluorosis. This was quoted by former HHS Secretary Sebelius in 76 FR 2383 at 2385. In the words of Dr. H.T. Dean, “We don’t want to go that high.” Fluoridation is no longer necessary to get any fluoride needed for ingestion. Fluoridation is unsafe, because it increases fluoride ingestion to unsafe levels.

As much as the SBOH members want to help decrease tooth decay, the SBOH obligation is to provide safe drinking water and today fluoridation is no longer safe. You must respect the conclusions of Dr. H.T. Dean who was the Surgeon General responsible for fluoridation. He would roll-over in his grave if he knew governments were still promoting fluoridation when one in eight children are getting mild, moderate or severe dental fluorosis. The 1999-2004 NHANES National Study found 1% of 12-15 year olds in the U.S. were getting severe dental fluorosis that everyone agrees is an adverse health effect. Is it not more important to avoid this adverse health effect of fluoridation than it is to protect the statistically insignificant alleged benefit of fluoridation? Typically, severe dental fluorosis is not confined to two teeth but affects most of the teeth in the mouth.

Attached is a file named 50 Reasons to Stop Fluoridation which I request that you review. On Figure 3 on page 4 of this file are pictures of Mild, Moderate, and Severe dental fluorosis. You can stop this from happening in Washington State if you stop fluoridation. You are no doubt familiar with the claim by CDC and others that water fluoridation is one of ten great public health achievements of the 20th century. The presumption is that the dramatic decline in tooth decay from the 1966 to 2000 was caused by fluoridation. But this is far from the truth. Fluoridation has a statistically insignificant effect on tooth decay as was demonstrated by the 1986-87 NIDR National Survey of 39,207 children from all over the United States. Figure 1 on page 3 of the "50 Reasons" file plots World Health Organization data on tooth decay (DMFT) rates in 14 unfluoridated countries and 4 fluoridated countries and I challenge you to distinguish the tooth decay trend lines for the fluoridated countries from those of the unfluoridated countries without looking at the Index. The 14 unfluoridated countries had an insignificant amount of water **or salt** fluoridation. Both fluoridated and unfluoridated countries have had the same great public health achievement in the 20th century of major reductions in tooth decay. But a statistically insignificant portion of this reduction can be fairly associated with fluoridation. You have been deceived and now you should step forward and do the right thing, the safe thing, for Washington citizens, and reduce the adverse health effects of fluoridation by calling

for a moratorium on fluoridation in Washington State.

Thank you for consideration of our comments.

Gerald Steel
Attorney at Law
7303 Young Rd. NW
Olympia WA 98502
Tel/Fax (360) 867-1166

Appendix B

LACK OF FLUORIDATION'S EFFECTIVENESS:

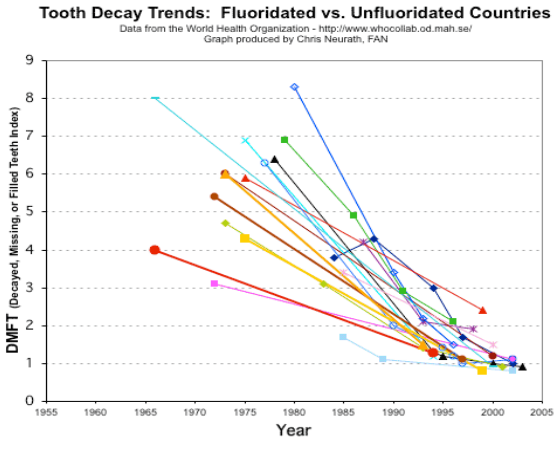
There is no government scientific department(s), or agency with oversight responsibility for the efficacy, safety, total exposure, or ethics of fluoridation. If we think the financial sector lacked government oversight and accountability, resulting in a current banking crisis, the scientific side of health care has a similar lack of oversight and is resulting in a crisis for some aspects of our health care system. Fluoridation is an unregulated aspect of healthcare, which will one day be viewed as one of the 10 greatest public health blunders of the 20th Century.

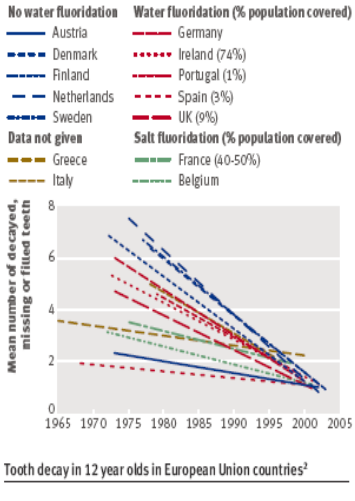
1. Current scientific literature is generally finding little or no effectiveness from fluoridation.[1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19] Studies finding benefit are frequently historical and flawed for lack of controlling confounding factors and basic statistics.[20 21 22] The NIH (National Institute of Health) and Surgeon General's report suggest efficacy estimates based on randomized controlled trials under ideal circumstances are best; however, no one disputes that in the case of fluoridation those types of studies would be difficult and have never been done. Therefore, a greater degree of caution and margin of safety must be used to protect public health than with most drugs.

In 2007 Pizzo et al reported a review of original fluoridation articles from 2001 to 2006 and found ". . . it is now accepted the primary cariostatic action of fluoride occurs after tooth eruption. Moreover, the caries reduction directly attributable to water fluoridation have declined in the last decades. . . whereas enamel fluorosis has been reported as an emerging problem in fluoridated areas. Several studies conducted in fluoridated and non-fluoridated communities suggested that this method of delivering fluoride may be unnecessary for caries prevention."[23]

2. After 60 years of fluoridation, we should be able to detect the effectiveness of fluoridation. Current effectiveness studies concur that there appears to be little or no detectable benefit from fluoridation.[24 25 26 27 28 29 30 31 32 33 34] As reflected in the two graphs below, regardless of fluoridation all developed countries have reduced dental decay to similar low levels. Therefore, suggestions that the ubiquitous halo effect benefits neighboring communities[35] are flawed.

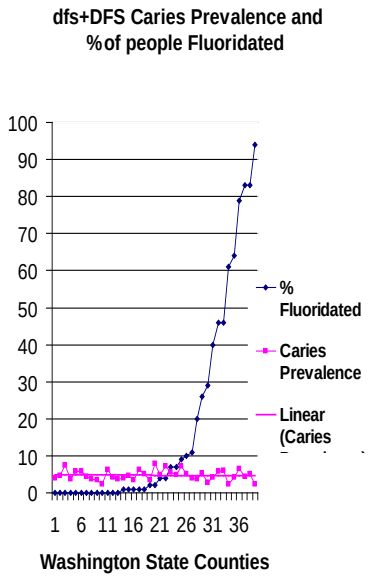
Graphs A and B[36] show the decline of decay over several decades. Regardless of whether the country has fluoridated water, fluoridated salt, or no fluoridated products, decay rates are similar. Clearly, other factors (such as socioeconomics) are more relevant than fluoridation.

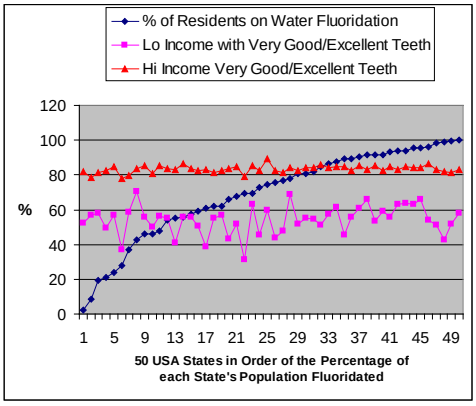




Graph A Graph B

3. Lourox in 1996[37] reported data on counties in Washington State (Graph C - was not drawn by the author). With 46% of public water users fluoridated, no significant reduction in dental decay could be detected in the fluoridated areas. In spite of the lack of fluoridation's benefit, the Department of Health and other Public Health officials aggressively promoted fluoridation. As of 2008, 59% of public water users in Washington State are fluoridated.





Graph C Graph D

4. Ranking 50 US states based on the percentage of residents receiving fluoridation (ascending line Graph D) and plotting the low income segment of the population reporting very good/excellent teeth (lower horizontal line Graph D) and the high income segment reporting very good to excellent teeth (upper horizontal line Graph D), finds about 53% of the poor and 82% of the wealthy have very good to excellent teeth

regardless of fluoridation. A state could fluoridate zero or 100% of their population without change to decay incidence.[38] [39] [40] [41]

a. "It is remarkable... that the dramatic decline in dental caries which we have witnessed in many different parts of the world has occurred without the dental profession being fully able to explain the relative role of fluoride in this intriguing process."[42]

b. "A very marked decline in caries prevalence [in Europe] was seen in children and adolescents...The number of edentulous adults in Europe has also been declining considerably."[43] 99% of Europe is fluoridation free and limited use of fluoride salts.

c. "The caries attack rate in industrialized countries, including the United States and Canada, has decreased dramatically over the past 40 years." (regardless of fluoridation).[44]

d. "Since the 1960s and 70s, however, a continuous reduction (in tooth decay) has taken place in most 'westernized' countries, it is no longer unusual to be caries-free.. . It is difficult to get a full picture of what has happened, as the background is so complex and because so many factors may have been involved both directly and indirectly. In fact, no single experimental study has addressed the issue of the relative impact of all possible factors, and it is unlikely that such a study can ever be performed."[45]

e. "Caries prevalence data from recent studies in all European countries showed a general trend towards a further decline for children and adolescents. . . The available data on the use of toothbrushes, fluorides and other pertinent items provided few clues as to the causes of the decline in caries prevalence."[46]

5. The Centers for Disease Control promotes substances, "markets", advises, recommends, collects data, but does not determine the safety, efficacy, toxicology, exposure, dosage, or ethics of substances. The CDC promotes fluoride as a "major factor in the overall decline in recent decades in the prevalence and severity of dental caries in the United States and other economically developed countries."[47] For this alleged multinational effectiveness, the CDC repeatedly uses historical references. A repeated CDC reference is the "anecdotal" historical report of Bratthall et al. 1996, which questioned a group of experts for their opinion on "*Reasons for the caries decline: what do the experts believe?"* "A main finding of our study was that there was a very large variation in how the experts graded the impact of various possible factors. In fact, only in the evaluation of "fluoride toothpaste" was there a clear, positive agreement among experts." [48] The CDC's claim that fluoridation is one of the ten greatest public health achievements of the 20th Century is not supported by the CDC's own listed reference. In fact, a review of original studies in 2007 by Pizzo et al found fluoridation in industrialized communities unnecessary.[49] The Washington Department of Health does not determine the safety of fluoridation and relies on other agencies, none of which determine the safety and efficacy of fluoridation.

The CDC admits "there are no randomized, double-blind, controlled trials of water fluoridation." The CDC further references historical studies conducted from 1945 through the early 1980s which contained significant flaws, such as failing to control for confounding factors of delayed tooth eruption, differences in socioeconomics, race, and/or lack of statistical significance.[50] (See Section V, for Risks)

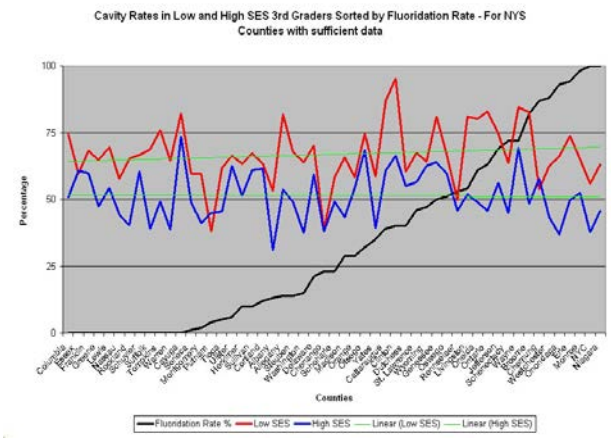
6. The International Academy of Oral Medicine and Toxicology reports "no discernible health benefit with fluoridation."[51] Many good scientists are opposed to fluoridation.[52] The Environmental Protection Agency scientists through their union have said fluoridation no longer reduces tooth decay, if it ever did.

7. Cessation of fluoridation has not been shown to usually result in an increase in dental decay.[53] The CDC claims, “When fluoridation is withdrawn and there are few other fluoride exposures, the prevalence of caries increases” however, the CDC’s own references do not accurately support the CDC’s unqualified statement. For example, the CDC reference “In spite of discontinued water fluoridation, no indication of an increasing trend of caries could be found in Kuopio”.[54]

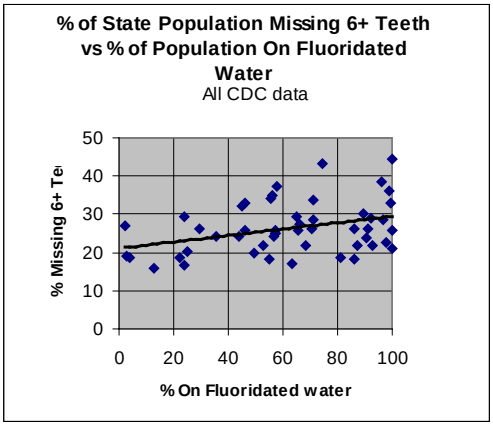
8. In some places the CDC, IOM (Institute of Medicine), and NRC (National Research Council) suggest potential benefits from fluoridation would be during the development of the tooth up to eight years of age. The level of fluoride in saliva is so minor as to have minimal effect on oral bacteria. Researchers report the potential cariostatic benefit from fluoride is “topical and not systemic.”[55] When carefully evaluated, the CDC comments are clearly conflicting and not in agreement with current published studies.

9. Current epidemiological effectiveness comparisons[56] [57] [58] between Washington State with 59% of the population receiving fluoridated water and Oregon’s 19%[59] find Oregon having similar or better dental health with a third the percentage of population fluoridated (confounding factors similar or in Washington’s favor).[60] [61]

10. Comparing counties in New York State (Graph E) finds no detectable benefit from fluoridation (blue line is low socioeconomic residents, the red line is high, and the black line is the percentage of people in each county on fluoridated water).



Graph E



Graph F

11. Ranking states on the increasing percentage of population fluoridated finds an increasing trend in the percentage of individuals with six or more teeth missing.[62] (Graph F) Certainly if fluoridation reduced tooth loss, we would expect the opposite to occur.

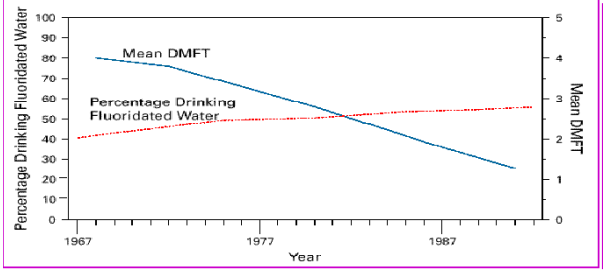
12. Proponents suggest “studies prove water fluoridation continues to be effective in reducing tooth decay by 20-40%” [63] when in fact biostatisticians find the same studies show no significant benefit.[64]

Part of the support for the alleged effectiveness from fluoridation is the graph and references below.[65] The numbers are not disputed; however, the two events are not related because:

a. Communities with or without fluoridation have decreased DMFT (decayed, missing, or filled teeth) to similar levels and show a similar decline.

b. It is statistically improbable - if not impossible - for a random 17% increase of population to be treated, resulting in a 70% drop in incidence for the entire population. To achieve those stunning results, fluoridation projects would have had to target specific high-risk individuals rather than random communities.

FIGURE 1. Percentage of population residing in areas with fluoridated community water systems and mean number of decayed, missing (because of caries), or filled permanent teeth (DMFT) among children aged 12 years — United States, 1967–1992



Sources:

1. CDC. Fluoridation census 1992. Atlanta, Georgia: US Department of Health and Human Services, Public Health Service, CDC, National Center for Prevention Services, Division of Oral Health, 1993.
2. National Center for Health Statistics. Decayed, missing, and filled teeth among youth 12–17 years—United States. Rockville, Maryland: US Department of Health, Education, and Welfare, Public Health Service, Health Resources Administration, 1974. Vital and health statistics, vol 11, no. 144. DHEW publication no. (HRA)75-1626.
3. National Center for Health Statistics. Decayed, missing, and filled teeth among persons 1–74 years—United States. Hyattsville, Maryland: US Department of Health and Human Services, Public Health Service, Office of Health Research, Statistics, and Technology, 1981. Vital and health statistics, vol 11, no. 223. DHHS publication no. (PHS)81-1673.
4. National Institute of Dental Research. Oral health of United States children: the National Survey of Dental Caries in U.S. School Children, 1986–1987. Bethesda, Maryland: US Department of Health and Human Services, Public Health Service, National Institutes of Health, 1989. NIH publication no. 89-2247.
5. CDC, unpublished data, third National Health and Nutrition Examination Survey, 1988–1994.

It is not unreasonable to consider whether two events are related, but it is unreasonable for police powers to continue after 50 years to be used to force medication without evidence for effectiveness.

13. Cost of dental treatment is not lower in fluoridated communities.[66] Certainly if fluoridation were to reduce dental decay by 15-40% as some claim, the cost for dental treatment should be lower.

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[1] http://www.slweb.org/colquhoun.html and www.ada.org

[2] " Fluorosis prevalence increased significantly with higher water fluoride levels; however, caries prevalence did not decline significantly." Hong L, Levy S, Warren J, Broffit B. (2006). Dental caries and fluorosis in relation to water fluoride levels. *ADEA/AADR/CADR Conference*, Orlando Florida, March 8-11, 2006.

[3] "No fluoride, socioeconomic status or beverage variables were significantly associated with lesion progression." Warren JJ, Levy SM, Broffitt B, Kanellis MJ. (2006). Longitudinal study of non-cavitated carious lesion progression in the primary dentition. *Journal of Public Health Dentistry* 66(2):83-7.

[4] "In the present study, fluoridated water did not seem to have a positive effect on dental health, as it might have been expected in a community with the respective caries prevalence." Meyer-Lueckel H, et al. (2006). Caries and fluorosis in 6- and 9-year-old children residing in three communities in Iran. *Community Dentistry and Oral Epidemiology* 34:63-70

[5] "The WHO data do not support fluoridation as being a reason for the decline in dental decay in 12 year olds that has been occurring in recent decades." Neurath C. (2005). Tooth decay trends for 12 year olds in nonfluoridated and fluoridated countries. *Fluoride* 38:324-325

[6] "Our analysis shows no convincing effect of fluoride-intake on caries development." Komarek A, et al. (2005). A Bayesian analysis of multivariate doubly-interval-censored dental data. *Biostatistics* 6:145-55.

[7] "Levels in fluoridated and non-fluoridated areas were similar. " Harding MA, et al. (2003). Dental erosion in 5-year-old Irish school children and associated factors: a pilot study. *Community Dental Health* 20(3):165-70.

[8] "There was no statistically significant difference between DMFT in municipalities of the same size, regardless of the presence or absence of fluoride in the water supply..." Sales-Peres SH, Bastos JR. (2002). [An epidemiological profile of dental caries in 12-year-old children residing in cities with and without fluoridated water supply in the central western area of the State of Sao Paulo, Brazil]. *Cadernos de Saude Publica* 18: 1281-8

[9] Water fluoridation status of the children's area of residence did not have a significant effect on Early Childhood Caries (ECC) at the 0.1 level of significance in the unadjusted logistic regression analysis, nor was it found to be a confounder of the effect of race/ethnicity on ECC prevalence in the multivariable model." Shiboski CH, et al. (2003). The association of early childhood caries and race/ethnicity among California preschool children. *Journal of Public Health Dentistry* 63(1):38-46

[10] "[E]ven a longitudinal approach did not reveal a lower caries occurrence in the fluoridated than in the low-fluoride reference community." Seppa L. et al. (2002). Caries occurrence in a fluoridated and a nonfluoridated town in Finland: a retrospective study using longitudinal data from public dental records. *Caries Research* 36: 308-314

[11] The magnitude of [fluoridation's] effect is not large in absolute terms, is often not statistically significant and may not be of clinical significance." Locker, D. (1999). Benefits and Risks of Water Fluoridation. An Update of the 1996 Federal-Provincial Sub-committee Report. Prepared for *Ontario Ministry of Health and Long Term Care*

[12] "[R]esults of recent large-scale studies in at least three countries show that, when similar communities are compared and the traditional DMFT index of dental caries is used, there is no detectable difference in caries prevalence. This has been demonstrated for schoolchildren

in the major cities of New Zealand, Australia, the US and elsewhere." Diesendorf, M. et al. (1997). New Evidence on Fluoridation. *Australian and New Zealand Journal of Public Health*. 21: 187-190

[13] Higher fluoride proportions appeared to be associated with lower dfs + DFS, with an estimated difference between fluoridated and non-fluoridated groups of 0.65 decayed or filled surfaces per child, but this association was not statistically significant. The effects of fluoridation on the other outcomes were small and not statistically significant." Domoto P, et al. (1996). The estimation of caries prevalence in small areas. *Journal of Dental Research* 75:1947-56

[14] "Children attending centers showed no significant differences (in baby bottle tooth decay) based on fluoride status for the total sample or other variables." Barnes GP, et al. (1992). Ethnicity, location, age, and fluoridation factors in baby bottle tooth decay and caries prevalence of head start children. *Public Health Reports* 107: 167-73

[15] The fluoride incorporated developmentally – that is, systemically into the normal tooth mineral – is insufficient to have a measurable effect on acid solubility." Featherstone JDB, M.Sc., Ph.D. , Cover Story; *J American Dental Association*, Vol. 131, July 2000, p. 890.

[16] Centers for Disease Control; *MMWR Weekly Report.* 1999;48:933-940. "Fluoride's caries-preventive properties initially were attributed to changes in enamel during tooth development because of the association between fluoride and cosmetic changes in enamel and a belief that fluoride incorporated into enamel during tooth development would result in a more acid-resistant mineral. However, laboratory and epidemiologic research suggests that fluoride prevents dental caries predominately after eruption of the tooth into the mouth, and its actions primarily are topical for both adults and children."

[17] "It is no longer acceptable to use fluoride supplements on large populations, even if the caries rate is higher than average." Limeback H. "A re-examination of the pre-eruptive and post-eruptive mechanism of the anticaries effects of fluoride: is there any anti-caries benefit from swallowing fluoride?" *Community Dentistry and Oral Epidemiology* 27: 62-71, 1999.

[18] "In 1970, during a meeting in Switzerland on fluoride research, I was astounded to hear the statement from a European cariologist of great reputation that the mechanism of action of fluoride against dental caries was entirely topical! At that time I believed, along with the majority of American caries researchers, that fluoride worked because it became incorporated into enamel – especially developing enamel – to increase its resistance to acid demineralization. We thought that where this could not be accomplished preeruptively by water fluoridation, we ought to try to achieve the same goal posteruptively by short-term regimens of very highconcentration fluoride solutions and gels. I thought that my European colleague was very poorly informed.

Now, twelve years later, I continue to be impressed by the wisdom of his assertion. Probably it was not completely correct; absolute statements about biological processes rarely are. However, each year since then the evidence has continued to accumulate to support the hypothesis that the anti-caries mechanism of fluoride is *mainly* a topical one."

12. Fejerskov O. et al. "Rational use of fluorides in caries prevention". *Acta*

[19] "As a direct consequence any method which places particular emphasis on incorporation of bound fluoride into dental enamel during formation may be of limited value. Therefore, there is limited scientific data to support the assertion that systemic fluoride treatment should be initiated from shortly after birth." Fejerskov O. et al. "Rational use of fluorides in caries prevention". *Acta Odontol. Scand*. 1981, 39:241-249.

[20] Confounding factors such as delay in tooth eruption are not included in studies. See Komarek A, et al. Biostatistics. 2005 Jan;6

[21] McDonagh, M., P. et al 2000a. A Systematic Review of Public Water Fluoridation. NHS Centre for Reviews and Dissemination, U. of NY

[22] Leroy R, et al. (2003). The effect of fluorides and caries in primary teeth on permanent tooth emergence. Community Dentistry and Oral Epidemiology31(6):463-70

[23] Pizzo G, Piscopo MR, Picco I, Giuliana G,, Community water fluoridation and caries prevention: a critical review.Clin Oral Inve. 2007 Feb.

[24] "The aim of this paper is to review publications discussing the declining prevalence of dental caries in the industrialized countries during the past decades...[T]here is a general agreement that a marked reduction in caries prevalence has occurred among children in most of the developed countries in recent decades."
SOURCE: Petersson GH, Bratthall D. (1996). The caries decline: a review of reviews. *European Journal of Oral Science* 104: 436-43"

[25] "The regular use of fluoridated toothpastes has been ascribed a major role in the observed decline in caries prevalence in industrialized countries during the last 20 to 25 years, but only indirect evidence supports this claim." Haugejorden O. (1996). Using the DMF gender difference to assess the "major" role of fluoride toothpastes in the caries decline in industrialized countries: a meta-analysis. *Community Dentistry and Oral Epidemiology* 24: 369-75

[26] "The marked caries reduction in many countries over the last two decades is thought to be mainly the result of the widespread and frequent use of fluoride-containing toothpaste... There seem to be no other factors which can explain the decline in dental caries, which has occurred worldwide during the same period, in geographic regions as far apart as the Scandinavian countries and Australia/New Zealand." Rolla G, Ekstrand J. (1996). *Fluoride in Oral Fluids and Dental Plaque*. In: Fejerskov O, Ekstrand J, Burt B, Eds. Fluoride in Dentistry, 2nd Edition. Munksgaard, Denmark. p 215

[27] "Although difficult to prove, it is reasonable to assume that a good part of the decline in dental caries over recent years in most industrialized countries, notably those Northern European countries without water fluoridation, can be explained by the widespread use of fluoride toothpastes. This reduction in caries has not been paralleled by a reduction in sugar intake..." Clarkson BH, Fejerskov O, Ekstrand J, Burt BA. (1996). *Rational Use of Fluoride in Caries Control.* In: Fejerskov O, Ekstrand J, Burt B, Eds. Fluoride in Dentistry, 2nd Edition. Munksgaard, Denmark. p 354

[28] "During the past 40 years dental caries h as been declining in the US, as well as in most other developed nations of the world... The decline in dental caries has occurred both in fluoride and in fluoride-deficient communities, lending further credence to the notion that modes other than water fluoridation, especially dentrifices, have made a major contribution." Leverett DH. (1991). Appropriate uses of systemic fluoride: considerations for the '90s. *Journal of Public Health Dentistry* 51: 42-7

[29] "In most European countries, the 12-year-old DMFT index is now relatively low as compared with figures from 1970-1974. WHO (World Health Organization) data relating to availability of fluoride in water and toothpaste appear reliable. However, these data did not explain differences between countries with respect to the DMFT index of 12-year-olds." Kalsbeek H, Verrips GH. (1990). Dental caries prevalence and the use of fluorides in different European countries. *Journal of Dental Research* 69(Spec Iss): 728-32

[30] "The most striking feature of some industrialized countries is a dramatic reduction of the prevalence of dental caries among school-aged children." Binus W, Lowinger K, Walther G. (1989). [Caries decline and changing pattern of dental therapy] [Article in German] *Stomatol DDR* 39: 322-6

[31] "The current reported decline in caries tooth decay in the US and other Western industrialized countries has been observed in both fluoridated and nonfluoridated communities, with percentage reductions in each community apparently about the same." Heifetz SB, et al. (1988). Prevalence of dental caries and dental fluorosis in areas with optimal and above-optimal water-fluoride concentrations: a 5-year follow-up survey. *Journal of the American Dental Association* 116: 490-5"

[32] "(D)uring the period 1979-81, especially in western Europe where there is little fluoridation, a number of dental examinations were made and compared with surveys carried out a decade or so before. It soon became clear that large reductions in caries had been occurring in unfluoridated areas. The magnitudes of these reductions are generally comparable with those observed in fluoridated areas over similar periods of time." Diesendorf, D. (1986). The Mystery of Declining Tooth Decay. *Nature* 322: 125-129

[33] "Even the most cursory review of the dental literature since 1978 reveals a wealth of data documenting a secular, or long term, generalized decline in dental caries throughout the Western, industrialized world. Reports indicate that this decline has occurred in both

fluoridated and fluoride-deficient areas, and in the presence and absence of organized preventive programs." Bohannan HM, et al. (1985). Effect of secular decline on the evaluation of preventive dentistry demonstrations. *Journal of Public Health Dentistry* 45: 83-89

[34] "The decline in caries prevalence in communities without fluoridated water in various countries is well documented. The cause or causes are, at this time, a matter of speculation." Leverett DH. (1982). Fluorides and the changing prevalence of dental caries. *Science* 217: 26-30

[35]http://www.cdc.gov/fluoridation/benefits.htm The Halo Effect: Quantifying the diffused benefit from water fluoridation in the United States Griffin SO, Gooch BF, Lockwood SA, Tomar SL. *Community Dent Oral Epidemiol* 2001;29:120–129.

[36] "Graphs of tooth decay trends for 12 year olds in 24 countries, prepared using the most recent World Health Organization data, show that the decline in dental decay in recent decades has been comparable in 16 non-fluoridated countries and 8 fluoridated countries which met the inclusion criteria of having (i) a mean annual per capita income in the year 2000 of US$10,000 or more, (ii) a population in the year 2000 of greater than 3 million, and (iii) suitable WHO caries data available. *The WHO data do not support fluoridation as being a reason for the decline in dental decay in 12 year olds that has been occurring in recent decades."* Neurath 2005. [36] (Graph A)[36] British Medical Journal published a similar graph and report in 2007. (Graph B)[36]

[37] Leroux, et al Univ. WA, J Dent Res 1996

[38] National Survey of Children's Health. http://mchb.hrsa.gov/oralhealth/portrait/1cct.htm.

[39] http://www.cdc.gov/oralhealth/waterfluoridation/fact_sheets/states_stats2002.htm

[40] The National Survey of Children's Health 2003. Rockville, Maryland: U.S. Department of Health and Human Services, 2005

[41] U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau

[42]Aoba T, Fejerskov O. (2002). Dental fluorosis: chemistry and biology. *Critical Review of Oral Biology and Medicine* 13: 155-70

[43] Reich E. (2001). Trends in caries and periodontal health epidemiology in Europe. *International Dentistry Journal* 51(6 Suppl 1):392-8

[44]Fomon SJ, Ekstrand J, Ziegler EE. (2000). Fluoride intake and prevalence of dental fluorosis: trends in fluoride intake with special attention to infants. *Journal of Public Health Dentistry* 60: 131-9"

[45] "Since the 1960s and 70s, however, a continuous reduction (in tooth decay) has taken place in most 'westernized' countries, it is no longer unusual to be caries-free... During the decades of caries decline, a number of actions have been taken to control the disease, and the literature describes numerous studies where one or several factors have been evaluated for their impact. Still, it is difficult to get a full picture of what has happened, as the background is so complex and because so many factors may have been involved both directly and indirectly. In fact, no single experimental study has addressed the issue of the relative impact of all possible factors, and it is unlikely that such a study can ever be performed." Bratthall D, Hansel-Petersson G, Sundberg H. (1996). Reasons for the caries decline: what do the experts believe?" *European Journal of Oral Science* 104:416-22

[46] "Caries prevalence data from recent studies in all European countries showed a general trend towards a further decline for children and adolescents...The available data on the use of toothbrushes, fluorides and other pertinent items provided few clues as to the causes of the decline in caries prevalence." Marthaler TM, O'Mullane DM, Vrbic V. (1996). The prevalence of dental caries in Europe 1990-1995. ORCA Saturday afternoon symposium 1995. *Caries Research* 30: 237-55

[47] http://www2.nidcr.nih.gov/sgr/sgrohweb/chap7.htm

[48] The CDC also references Horowitz and Ismail 1996, Johnston 1994, Ripa 1990, Stookey and Beiswanger 1995, however all these reviewed topical application of fluoride, not the addition of fluoride to water. http://www2.nidcr.nih.gov/sgr/sgrohweb/chap7.htm

[49] Pizzo G, et al, Community water fluoridation and caries prevention: a critical review. Clin Oral Investig. 2007 Feb 27.

[50] Not one study reporting benefits of fluoridation includes the confounding factor of delay in tooth eruption caused by fluoridation. In addition: statistics based on percentages can show huge changes when actually minor effects were actually observed. For example, a drop of one less decayed tooth surface from 128 to 127 is less than one percent, however the same drop of one surface from 2 surfaces to 1 surface is exaggerated as a 50% drop in decay. In fact both are less than one percent of possible tooth surfaces.

[51] www.IAOMT.org; Kentucky fluoridated for over 50 years has the highest tooth loss of any state. 2002 CDC MMWR; www.fortwayne.com/mld/newssentinel/7521679.htm?template=contentModules/printstory.jsp http://www.enquirer.com/editions/2002/10/06/loc_special_report.html; http://www.fluoridealert.org/f-boston.htm http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=13678102&query_hl=1 http://www.nhregister.com/site/news.cfm?newsid=14472801&BRD=1281&PAG=461&dept_id=517515&rfi=8&xb=kasan

[52] A few scientists opposed to fluoridation include: Kenji Akiniwa, DDS; Phillip Allen, MD, Harvard Medical School, '54; Vinod Barot, PhD; James Beck, MD,; W. Dexter Bellamy, PhD; Miklos Bely, PhD; Shlomi Ben-Arush; Larry Bowden DMD; Laurie Brett, DDS; John Brawner, MD; Chris Bryson (author "The Fluoride Deception"); Albert Burgstahler, PhD, Editor, Fluoride, co-author, "Fluoridation: The Great Dilemma" ; Adolf Butenandt (Nobel Laureate for Chemistry, 1939); Gladys Caldwell (deceased) (co-author of "Fluoridation and Truth Decay"); Noel Campbell; Arid Carlsson, PhD (Nobel Laureate in Medicine, 2000); Robert Carton, PhD, former risk assessment specialist at the US EPA; N. J. Chinoy, (deceased) (past Vice-President of the International Society for Fluoride Research); John Colquhoun, PhD (deceased); Michael Connett FAN; Paul Connett, PhD, Executive Director of the Fluoride Action Network; Ronnie Cummins, Executive Director of Organic Consumers Association; Stephen A. Dean; Lynn H. Ehrle; Nick Dienel, MD; Mark Diesendorf, PhD; Mike Dolan, PhD; Sam Epstein, MD (author of the "Politics of Cancer"); Hans von Euler-Chelpin (Nobel Laureate for Chemistry, 1929); Dr Doug. N. Everingham, Former Federal Health Minister, Australia; Fred B. Exner, MD (deceased) (co-author "The American Fluoridation Experiment"); Rich Fischer, DDS, Past President of the International Academy of Oral Medicine and Toxicology; Richard G. Foulkes, MD (former advisor of the Ministry of Health, British Columbia); Mike Godfrey, MD; Dorothy Goldin-Rosenberg, PhD; Edward Goldsmith, (former editor and publisher of The Ecologist); Anne-Lise Gotzsche (author "The Fluoride Question: Panacea or Poison?"); Barry Groves, PhD; Ella Haley, PhD; Joseph Hensley, MD (State senator from Tennessee); Walter Rudolf Hess (Nobel Laureate for Medicine, 1949); W. Robert Hetrick, PhD; Corneille Jean-François Heymans (Nobel Laureate for Medicine, 1938); Sir Cyril Norman Hinshelwood (Nobel Laureate for Chemistry, 1956); William Hirzy, PhD (Vice-President of the Union representing professionals at EPA Washington, DC, HQ.; C. Vyvyan Howard; Bob Isaacson, PhD; Antone G. Jacobson, PhD; Jackie Jacobson, PhD; Tushar Kant Joshi; Emily A. Kane, DNM, AK, author "Managing Menopause Naturally"; Jong-Chul Kim, Editor, Green Review, South Korea; Stephen M. Koral, DMD; David Kennedy, DDS, Past President IAOMT; Lennart Krook, PhD; Linda Langness, PhD; Todd Lawson DMD; Evie Lawson DO; John R. Lee, MD; Joshua Lederberg (Nobel Laureate for Medicine, 1958); Hardy Limeback, DDS, PhD; Lewis McKinley, PhD (co-author: "Fluoridation: the Great Dilemma."; Peter Mansfield, MD; William Marcus, PhD; Joseph Mercola, MD; Henry Micklem, PhD; Peter Montague, PhD, editor of Rachel's Environmental biweekly; Raul A. Montenegro, PhD; Deborah E. Moore, PhD; Jeffrey Morris, PhD; Phyllis Mullenix, PhD; William P. Murphy (deceased) (Nobel Laureate for Medicine, 1934); Tohru Murakami, DDS; Ralph Nader; Giulio Natta (Nobel Laureate for Chemistry, 1963); Pierce Noble; Bill Osmunson, DDS, MPH; Geoff Pain, PhD; Gilles Parent (co-author); Richard J. Perry, PhD; James Presley, PhD; Alan Price, PhD; Sir Robert Robinson (deceased) (Nobel Laureate for Chemistry, 1947); Perry Roehl, PhD; Paul Ruben, DDS,; Andrew Rynne, MD; Mageswari Sangaralingam ; Albert Schatz (deceased) PhD (co-discoverer of streptomycin); Nikolai Semenov (deceased) (Nobel Laureate for Chemistry, 1956); Richard Shames, MD, author "Feeling Fat, Fuzzy or Frazzled?"; John Shonerd, DO; Bruce Spittle; Caroline Snyder, PhD; Anna Strunecka; James B. Sumner PhD (deceased) (Nobel Laureate for Chemistry, 1946); A.K. Susheela, PhD; James Sumner PhD (deceased) (Nobel Laureate in Chemistry...); Philip Sutton, DDS (deceased) (author of "The Greatest Fraud: Fluoridation); Hugo Theorell (deceased)(Nobel Laureate for Medicine, 1955); Kathleen Thiessen, PhD; Artturi Virtanen (deceased) (Nobel Laureate for Chemistry, 1945); George Waldbott, MD (author "A Struggle with Titans;" co-author "The American Fluoridation Experiment," and co-author, "Fluoridation: The Great Dilemma"); Glen Walker, (author, "Fluoridation: Poison on Tap"); Alan Watson; Susan

Willis, PhD; Mae W. Woo, DDS; John Yiamouyiannis, PhD (deceased) (author of The Aging Factor); Philip E. Zanfagna, MD (deceased) (co-author of "Fluoridation and Truth Decay"); Rudolf Ziegelbecker; Dr.techn. Rudolf Ziegelbecker, jun.; Sam Ziff, Loty Zilberman,

[53] Komarek et al, A Bayesian analysis of multivariate doubly-interval-censored dental data, Biostat. 2005 6 pp 145-155; Armfield & Spencer, 2004 Community Dental Oral Epidemiology; See www.slweb.org

Kunzel W, Fischer T. (2000). Caries prevalence after cessation of water fluoridation in La Salud, Cuba. Caries Research 34: 20-5.

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[54] Kugel (sp) and Fischer 1997, Seppä et al. 1998 "In spite of discontinued water fluoridation, no indication of an increasing trend of caries could be found in Kuopio. The mean numbers of fluoride varnish and sealant applications decreased sharply in both towns between 1992 and 1995. In spite of that caries declined. CONCLUSIONS: These findings suggest that the decline of caries has little to do with professional preventive measures performed in dental clinics." and Stephen et al.

[55]Pizzo G, et al, Community water fluoridation and caries prevention: a critical review. Clin Oral Investig. 2007 Feb 27.

[56] http://www.doh.wa.gov/cfh/Oral_Health/Documents/SmileSurvey2005FullReport.pdf

[57]http://www.oregon.gov/DHS/ph/oralhealth/docs/databook.pdf#search='Oregon%20Decay%20experience'

[58] BRFSS 2002 http://www.dhs.state.or.us/dhs/ph/chs/brfs/02/orahea/dentvisi.shtml
http://apps.nccd.cdc.gov/brfss/display.asp?state=WA&cat=OH&yr=2004&qkey=6610&grp=0&SUBMIT4=Go Sample size OR 3509 and WA 12,926 2004 data

[59] http://www.cdc.gov/oralhealth/waterfluoridation/fact_sheets/states_stats2002.htm

[60] National Survey of Children's Health. http://mchb.hrsa.gov/oralhealth/portrait/1cct.htm
U.S. Department of Health and Human Services, http://www.fluoridationcenter.org/papers/2002/cdcmmwr022102.htm

[61] http://quickfacts.census.gov/qfd/states/41000.html

[62] "Fewer fillings had been required in the nonfluoridated part of my district than in the fluoridated part." 1997 John Colquohoun PhD, DDS http://www.slweb.org/colquhoun.html

[63] http://www.ada.org/prof/resources/positions/statements/fluoride_community_effective.asp 7/13/06

[64] Komarek, Biostatistics. 2005; NRC 2006; Spencer et al 1996; de Liefde 1998

[65] CDC MMWR, October 22, 1999

[66] Maupome JPHD, 2007. Data collected in 1995

From:	Gerald Steel
To:	Phillips, Theresa (DOH)
Cc:	Audrey Adams; Scott Shock; Bill Osmunson
Subject:	WAC 246-290-460 Rulemaking - Fluoridation benefits in Reducing Tooth Decay are Statistically Insignificant
Date:	Tuesday, February 23, 2016 11:07:02 AM
Attachments:	Lack of Fluoridation"s Effectiveness.doc

I submit the attached comments on the Lack of Fluoridation's Effectiveness prepared by Dr. Bill Osmunson. These comments are submitted on behalf of myself and King County Citizens Against Fluoridation.

Gerald Steel
Attorney at Law
7303 Young Rd. NW
Olympia WA 98502
Tel/Fax (360) 867-1166

From:	Gerald Steel
To:	Phillips, Theresa (DOH)
Cc:	Audrey Adams; Scott Shock; Bill Osmunson
Subject:	WAC 246-290-460 Rulemaking - Purveyor should take action if fluoride concentration exceeds 0.7 ppm
Date:	Tuesday, February 23, 2016 1:07:49 PM

I submit this comment on behalf of myself and King County Citizens Against Fluoridation.

In proposed WAC 246-290-460(4), there is no valid reason that a purveyor does not take action to reduce fluoride added if sampling shows fluoride levels above 0.7 mg/l. HHS took explicit action to remove all fluoride concentrations above 0.7 mg/l from its recommended levels. There is no justification in the record to show that fluoride concentrations above 0.7 mg/l are safe in the current environmental when some people are already getting unhealthy levels of fluoride in their diet without any contribution from fluoridated water.

Gerald Steel
Attorney at Law
7303 Young Rd. NW
Olympia WA 98502
Tel/Fax (360) 867-1166

SUMMARY OF KEY HARMS FROM FLUORIDATION

By Gerald Steel (geraldsteel@yahoo.com)

3-26-15

EXECUTIVE SUMMARY

The major dietary source of fluoride for most people in the United States is fluoridated drinking water. NRC (2006) at 24 (http://www.nap.edu/catalog/11571/fluoride-in-drinking-water-a-scientific-review-of-epas-standards). Currently, local politicians, generally with no medical training, decide whether or not to put fluoridation chemical additives into public drinking waters. HHS and FDA admit that these additives and fluoridated waters are intended for use to prevent tooth decay disease but they refuse to exercise responsibilities under the Food Drug and Cosmetic Act (FDCA) to regulate these articles as drugs. 21 USC 393(a) and (b); 21 USC 321(g)(1). FDA states that the Safe Drinking Water Act (SDWA) relieves it of this responsibility. HHS Dr. Wanda Jones 11-21-14 Letter to Ms. McElheney. EPA administrates the SDWA and so has agency authority for its interpretation. EPA interprets the SDWA to not relieve HHS and FDA of their responsibilities "for regulating the addition of drugs to water supplies for health care purposes." Steven Neugeboren 2-14-13 Letter to Mr. Steel. However, EPA remains responsible for regulating total fluoride in public drinking water through setting a Maximum Contaminant Level (MCL) Goal and setting and enforcing a MCL. This Goal is required by the SDWA to be "set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." 42 USC 300g-1(b)(4)(A).

In the materials below, I discuss some of the substantial evidence that connects fluoridation to "known or anticipated adverse effects on the health of persons." Generally in the United States fluoridation levels are about 1 mg/L fluoride. There is substantial evidence of harm. With a common margin of safety of 10, safe fluoride levels in drinking water can be no higher than 0.1 mg/L (and must be less because there is fluoride in the diet). There will be no dental caries reduction benefit at 0.1 mg/L fluoride. Therefore, there is no point in adding fluoride to get 0.1 mg/L fluoride. Fluoridation should end. Scientific studies of the mechanisms by which fluoride causes harms should be continued. But there is enough information to know that some subpopulations are harmed by fluoridation, and would be, even if it were reduced to 0.7 mg/L fluoride. So I believe that it is most important to educate the public by developing graphs that show harms and benefits (if any) of fluoridation in the United States. I include graphs of prevalence of Mental Retardation (MR) (Appendix A-1 hereto) and Attention Deficit Hyperactivity Disorder (ADHD) (Appendix A-2 hereto) versus percent of state population fluoridated in the fifty states. These graphs show increasing levels of developmental disabilities with increased percent of population fluoridated. We provide a graph (Appendix A-3 hereto plotted by Dr. Osmunson DDS) of prevalence of children with good/excellent teeth versus percent of state population fluoridated. This graph shows no increase in children with good/excellent teeth with increased percent of population fluoridated in the fifty states.

What science or ethics-based issues regarding fluoridation are of concern?

- Developmental Disabilities

Impact of population-wide levels of exposure to fluoride on neurodevelopment

I am aware of NIEHS Project # R01ES021446 regarding Prenatal and Childhood Exposure to Fluoride and Neurodevelopment by Howard Hu at the University of Toronto. This project is studying the impact of population-wide levels of exposure to fluoride on neurodevelopment. His pilot research of 40 mother/child pairs found increases in pregnant mother fluoride exposure resulted in lower offspring IQ. (*See* http://grantome.com/grant/NIH/R01-ES021446-04) This is an adverse effect of fluoridation on the mental health of persons. The full study is also looking at impacts of childhood fluoride exposure on neurodevelopment. This study started in June 1, 2012 and ends on Feb. 28, 2017. This study measures fluoride exposure using archived urine, fasting plasma, and toenail specimens. Results from five statistically significant IQ studies (Appendix A-4 hereto from Connett Presentation, Sydney Australia, 2-21-15 (Connett (2015) based on NIEHS publication at http://ehp.niehs.nih.gov/wp-content/uploads/2012/09/ehp.1104912.pdf references) already suggests that each increase of fluoride of 0.25 mg/L in drinking water by water fluoridation could lower child IQ by one point. Appendix A-1 hereto, plotted by Dr. Osmunson DDS, shows number of Mental Retardation Children 6-17 years old per 10,000 in the fifty states increases with increasing percentage of state population fluoridated. Appendix A-5 hereto from Connett (2015) shows average IQ reduced about 6 points even when dental fluorosis was Dean Index 1 (very mild) and Dean Index 2 (mild). So it appears that significant IQ loss from fluoridation can occur even with very mild and mild levels of dental fluorosis.

Correlation of fluoridation prevalence on ADHD in fifty states

Appendix A-2 hereto shows a correlation of fluoridation prevalence with Attention-Deficit Hyperactivity Disorder (ADHD) in fifty states. This graph is adapted from Malin (2015) by adding color. (*See* http://www.ehjournal.net/content/14/1/17/abstract) This graph shows percent of children 4-17 medically-diagnosed with ADHD increases linearly with increases in percent of state population fluoridated. Fluoridation information is from CDC. ADHD rates are from the National Survey of Children's Health. Socioeconomic status is controlled. In 2011, 8.8 percent of children in non-fluoridated states were diagnosed with ADHD. This increased to 13.9 percent for fully-fluoridated states. This is a 58% increase. Child ADHD prevalence is linearly correlated with fluoridation prevalence with relatively little scatter.

From the Office of Children's Health Protection (OCHP) of EPA, Children's Environmental Health Facts show concerns for "Developmental Disabilities." This webpage states that between 3 and 8 percent of children will have developmental disorders such as ADHD or mental retardation. The data presented above shows medically-diagnosed ADHD levels actually averaged 11 percent in 2011. This data alone should create overwhelming concern for politicians and agencies that fluoridation may be a major cause of developmental disorders. The webpage also states mental retardation is more common for children from lower income families and for certain racial and ethnic groups. These are the same children that are targeted for fluoridation.

- Endocrine Disruption

Correlation of diagnosed hypothyroidism with fluoridation levels

"Between 4% and 5% of the U.S. population may be affected by deranged thyroid function, making it among the most prevalent of endocrine diseases." NRC (2006) at 224-25 (citations omitted). NRC (2006) at 266 concludes that fluoride is an "endocrine disruptor." NRC (2006) at 263 calls it a "cause for concern" that asymptomatic hypothyroidism in pregnant mothers is inversely correlated with the IQ of the offspring. A recent study in England, found a positive correlation between fluoride levels in water and hypothyroidism. Nearly 8000 areas, with about 99% of the country's population, were studied. Areas with drinking water fluoride above 0.3 mg/L were found to be 30% more likely to have diagnosed hypothyroidism in more that 3.57 percent of the area's population. The study was controlled for sex, age, and social-economic status in the various areas but not for iodine deficiency. Hypothyroidism leads to neuropsychiatric impairments. http://www.endocrine-abstracts.org/ea/0011/ea0011s16.htm

- Bones

Correlation of hip fractures for people 65+ years old with fluoridation levels

The York Review (2000) was limited to review of human epidemiological studies of water fluoridation (around 1 ppm fluoride). Over 3,200 primary studies were identified but only 9 studies met relevance criteria and measured Relative Risk (RR) of hip fracture for people 65+ years old in fluoridated areas compared to the risk in unfluoridated areas. York Review (2000) at 10, 48, and 99.) For these 9 studies, there were only 4 analyses that produced statistically significant data (i.e. RR = 1.0 was not in the 95% Confidence Interval). Each of these statistically significant analyses show an increased risk of hip fracture for those people 65+ years old living in fluoridated areas. The studies are identified in the York Review at page 48 as:

Author (Year)	Sex	Relative Risk	95% Confidence Interval
Jacqmin-Gadda (1998)	Both	2.43	(1.1, 5.3)
Danielson (1992)	Women	1.27	(1.1, 1.5)
Jacobsen (1992)	Women	1.08	(1.06, 1.10)
Jacobsen (1992)	Men	1.17	(1.13, 1.22)

A Relative Risk of 1.27 means that there is a 27% higher risk of hip fractures when living in a fluoridated area (for the 65+ year old women in the Danielson (1992) study in Utah). This is evidence that some subpopulations will have increased risk of hip fracture when their water is fluoridated at 1 mg/L. With an adequate margin of safety of 10, the MCLG for fluoride must be set lower than 0.1 mg/L. (42 USC 300g-1(b)(4)(A).) "About 300,000 Americans are hospitalized for a hip fracture every year." (Connett (2010) at page 173.) "Fracture of the hip is a major cause of morbidity and mortality [disease and death] in persons 65 years of age and older." Irish Forum (2002) at 121.

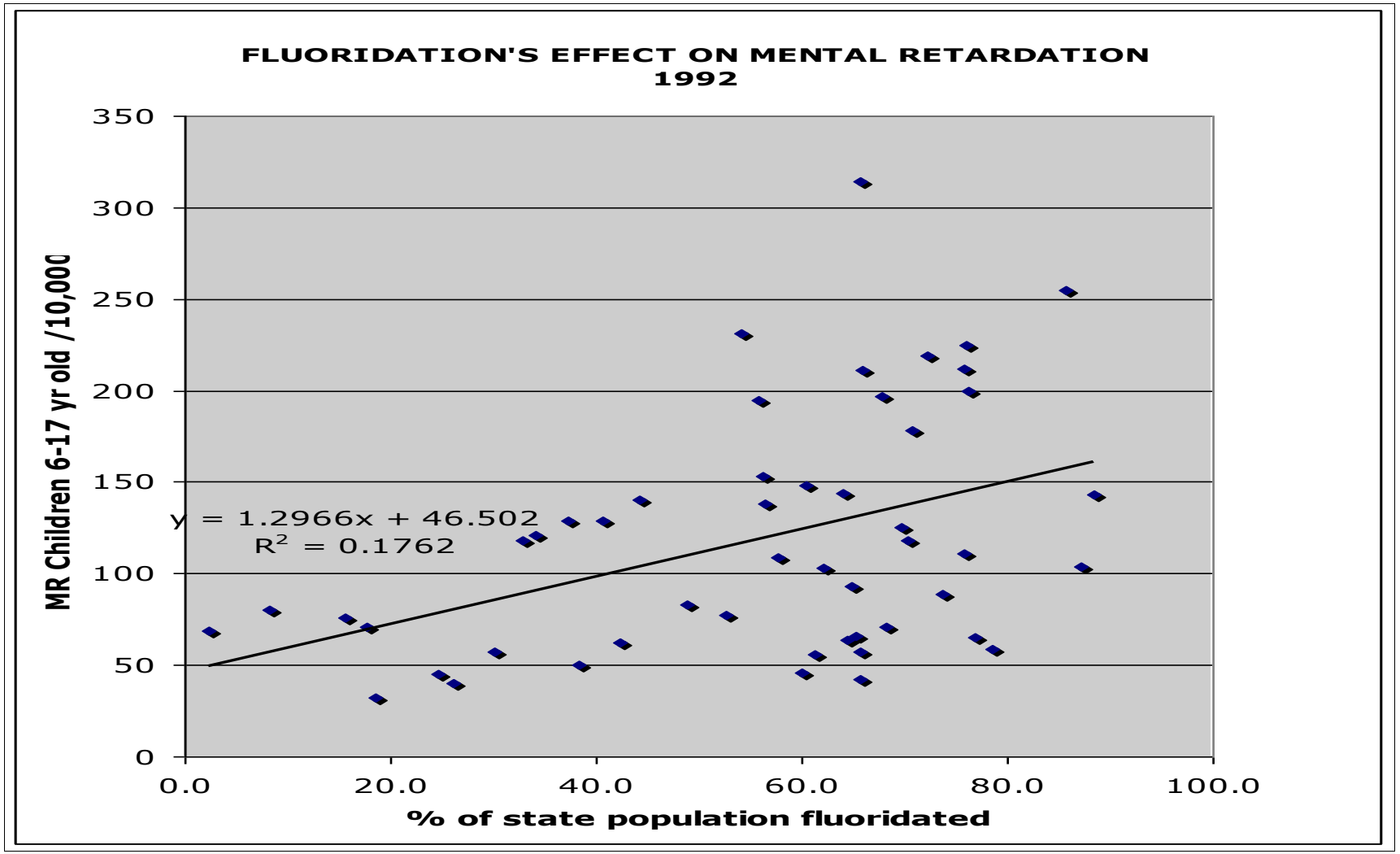
- Ethics

What ethical issues are of concern regarding fluoridation?

1. Should citizens be medicated with fluoridation without their consent?
2. Should fluoridation medicine be given to all to benefit a few?
3. Should fluoridation medicine be a choice so that vulnerable people are protected?
4. Should politicians who are not medical doctors be allowed to authorize treatment for their jurisdiction's whole population without consultation with each person?
5. Should public drinking water be used over the long term to deliver medicine to people?
6. Should infants and young children be given unsafe drinking water for a minimal possible benefit to older children?
7. Should people hypersensitive to fluoride be required to drink fluoridated water if they cannot afford fluoride-free water?
8. Should people be subjected to increased risks of side effects like lowered IQ in children, increased ADHD in children, increased hypothyroidism, increased hip fractures in people 65+, five- to sevenfold greater risk of contracting osteosarcoma (bone cancer) by the age of twenty for boys drinking fluoridated water when they are 6-8 years old, all for a statistically-insignificant reduction in tooth decay for older children?
9. Ethically, should a government be allowed to put a medical additive into drinking water for the benefit of the society?
10. Should the role of a water purveyor or government include medicating its customers or citizens without consultation with those customers and citizens?
11. Should water purveyors or governments be able to subject more than 42% of our children to permanent dental fluorosis by serving them fluoridated drinking water?
12. Should children with good/excellent teeth be required to ingest fluoridated water when it provides no benefit to them and only harmful side effects?
13. Should the precautionary principle be applied today because fluoridation raises threats of harm to human health? What precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically?
14. Should the Hippocratic writing *Epidemics* regarding treating disease be applied to first "do no harm"?

SUMMARY

Based on the evidence discussed above, it must be anticipated that fluoridation, even at 0.7 mg/L, will have adverse effects on the health of some persons.



http://apps.nccd.cdc.gov/giscvh/map.aspx
http://apps.nccd.cdc.gov/nohss/FluoridationV.asp
http://pubs.usgs.gov/circ/2004/circ1268/htdocs/table05.html
http://www.cdc.gov/mmwR/preview/mmwrhtml/00040023.htm

Plotted by Dr. Bill Osmunson DDS

Percent of children with ADHD
versus
Percent of state population fluoridated

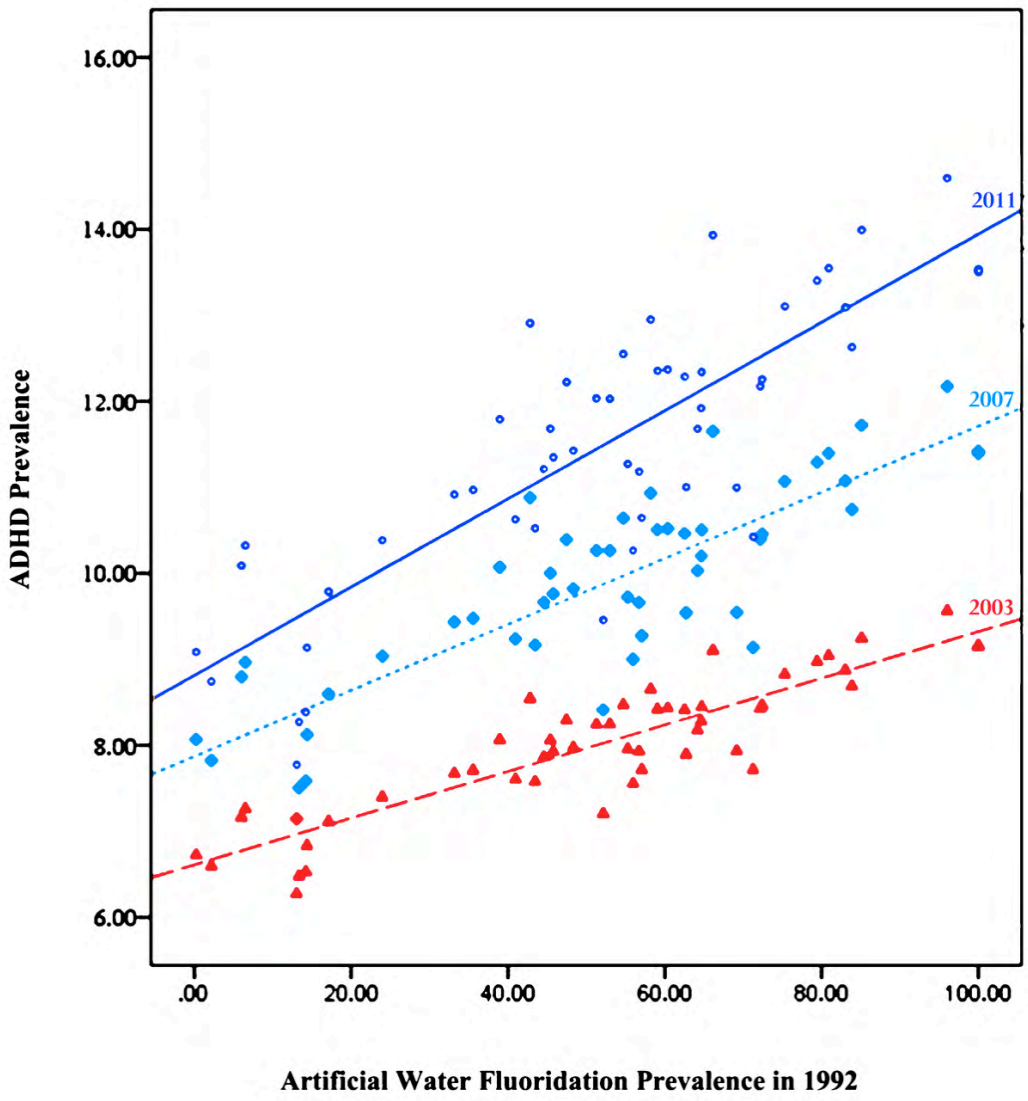
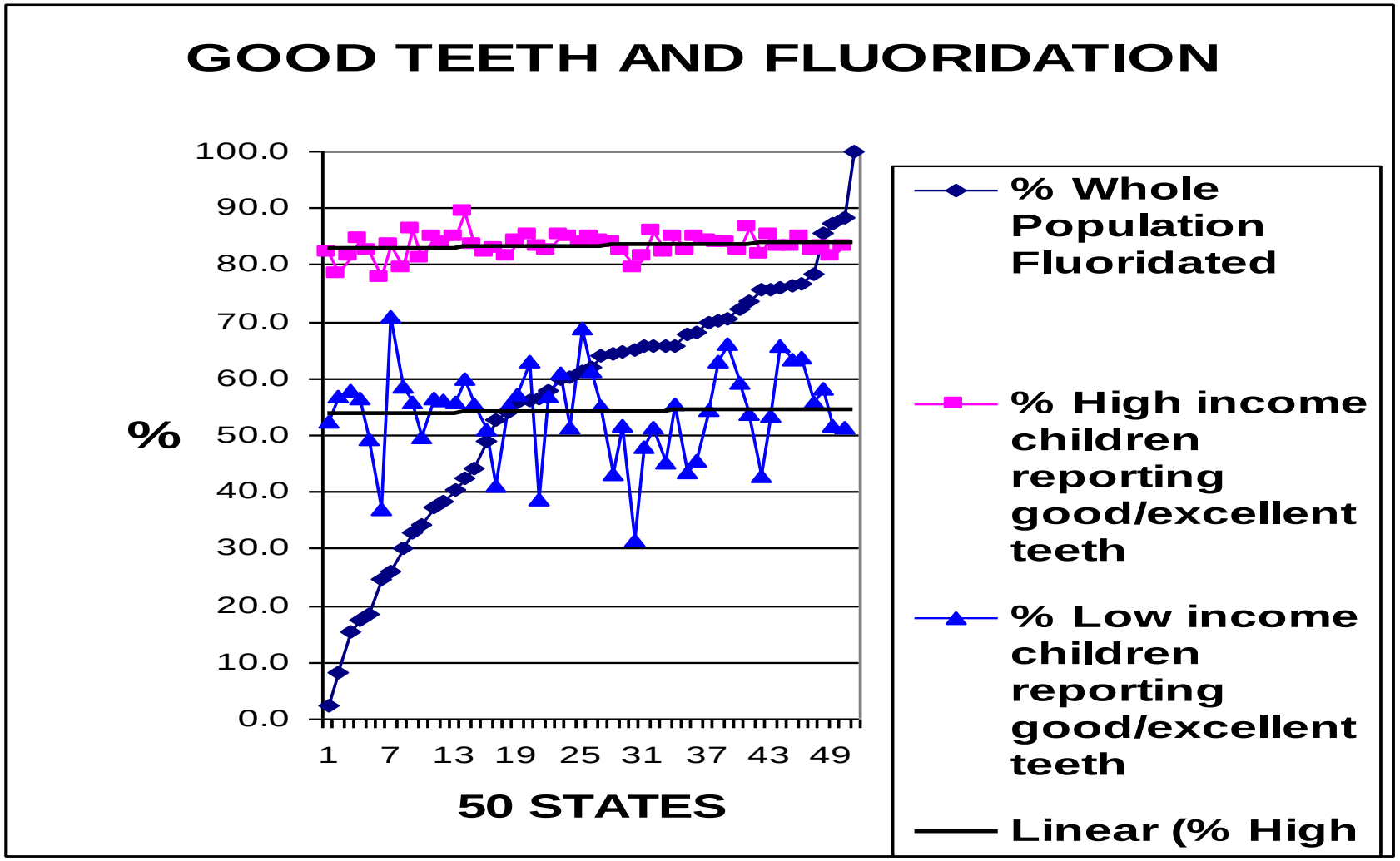


Figure 1. Artificial fluoridation prevalence predicting ADHD prevalence after adjusting for 1992 median household income, by state. Each color is for a different year of ADHD prevalence data: 2003, 2007, and 2011.

Figure and text adapted from:

Malin AJ, Till C. Exposure to fluoridated water and attention deficit hyperactivity disorder prevalence among children and adolescents in the United States: an ecological association. *Environmental Health.* 2015;14. doi:10.1186/s12940-015-0003-1.
Available at: http://www.ehjournal.net/content/14/1/17/abstract



National Survey of Children's Health. U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau, National Survey of Children's Health 2003. Rockville, Maryland: U.S. Department of Health and Human Services, 2005

Plotted by Dr. Bill Osmunson DDS

IQ studies with water F concentration below 3 mg/L in "higher F group", and with statistically significant results

Study	IQ point difference	Water F concentration "high F group" (mg/L)
Xu et al. 1994	-14.0	1.8
Yao et al. 1997	-6.5	2
Hong et al. 2001	-6.6	2.90
Seraj et al. 2006	-13.4	2.5
Poureslami et al. 2011	-6.2	2.38