WASHINGTON ACTION FOR SAFE WATER

June 8, 2010

Washington State Board of Health
Craig McLaughlin, Executive Director

PETITION TO THE WASHINGTON STATE BOARD OF HEALTH FOR RULE MAKING

OUTLINE

Subsequent sections are provided for background information.

I. PETITION TO IMPROVE AND PROTECT THE PUBLIC'S HEALTH WITH RULE MAKING ON FLUORIDATION (FLUORIDE ADDED TO PUBLIC DRINKING WATER)

This petition is made in the interest of the health and safety of the people of Washington. The addition of fluoride to public water, fluoridation, is controversial. The only intent of fluoridation is to prevent or mitigate dental caries.

An example of highly qualified scientists opposed to fluoridation is the EPA scientists at the US Environmental Protection Agency (EPA).

"In summary, we hold that fluoridation is an unreasonable risk. That is, the toxicity of fluoride is so great and the purported benefits associated with it are so small - if there are any at all – that requiring every man, woman and child in America to ingest it borders on criminal behavior on the part of governments."[1]

Many, including the Washington State Department of Health (DOH), have mistakenly relied on the EPA to regulate and determine the safety and efficacy of the addition of fluoride to public potable drinking water, fluoridation. The EPA regulates existing fluoride in water and is not authorized by the Safe Drinking Water Act to add any substance to water for the prevention of disease nor to require or authorize adding any such substance. Therefore, the EPA does not determine the safety or efficacy of the addition of fluoride to water at fluoridation concentrations.

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[1] Dr. J. William Hirzy, Senior Vice-President, Headquarters Union, US Environmental Protection Agency, March 26, 2001. This letter describes some of the harms of water fluoridation as seen by water fluoridation opponents.

The FDA (Food and Drug Administration) is responsible for substances intended to prevent disease. This petition proposes that fluoridation proceed only if fluoridation materials, label and dosage are FDA approved. This is in keeping with the EPA scientists' statement, general and specific federal and state laws.

II. PETITION FOR WAC CHANGES: SUGGESTED WORDING

The proposed WAC changes do not affect the roughly 40 chemicals which may be added to treat water contaminants, odors, turbidity, or pathogens, in other words to make water safe and potable.

The suggested WAC changes are as follows in red and italics:[2]

a. "WAC 246-290-460

(1) Purveyors shall obtain written department approval of fluoridation treatment facilities before placing them in service *and shall only use substances approved by the Food and Drug Administration Center for Drug Evaluation and Research in a New Drug Application*.

(2) Where fluoridation is practiced, purveyors shall maintain fluoride concentrations in the range *and with labeling approved by the Food and Drug Administration.* ~~0.8 through 1.3 mg/L throughout the distribution system.~~

(3) Where fluoridation is practiced, purveyors shall take the following actions to ensure that concentrations remain at *Food and Drug Administration approved* ~~optima~~l levels and that fluoridation facilities and monitoring equipment are operating properly: . . . "

(iv) If a split sample is found by the certified lab to be:

(A) Not within the range *approved by the Food and Drug Administration,* ~~of 0.8 to 1.3 mg/l~~, the purveyor's fluoridation process shall be considered out of compliance.

b. WAC 246-290-220

". . . (7) Any drug to be added to drinking water with the intent to treat, mitigate, diagnose, or prevent disease as defined in the FD&C Act, RCW 69.04.009, and/or Board of Pharmacy as a drug, shall have prior approval of the Food and Drug Administration under a New Drug Application and shall be marketed with an approved label."

If fluoridation is and has been proven safe and effective, gaining FDA approval (NDA) should not be a problem. Both opponents and proponents

[2] For full text see Appendix A

should be in favor of this rule change because the FDA has authorization and competency to evaluate substances intended to prevent disease.

III. FLUORIDATION AUTHORIZED FOR WATER DISTRICTS

"A water district by a majority vote of its board of commissioners may fluoridate the water supply system of the water district."[3]

Neither RCW 57.08.012 nor voter initiative/referendum approval of fluoridation exempts water districts from complying with the FD&C Act or general Washington statutes governing the manufacturing, marketing, dispensing, labeling, compounding, or FDA approval for drugs. RCW 57.08.005 "(3) . . . to furnish the district and inhabitants thereof . . . with an ample supply of water for all uses and purposes . . . in such a manner as is not in conflict with general law." And specifically provides for contracting of professional services.[4] An example would be the water district may have voter approval to build a building or pipeline, but all engineering and construction must be done under licensed individuals and general laws. Fluoridation is not exempt from general drug laws requiring FDA approval or the contracting with licensed health care professionals as needed.

The proposed changes in this petition do not prevent the addition of fluoride to water with the intent to prevent disease. The proposed changes will bring purveyors of fluoridated drinking water into compliance with general federal and state laws and provide appropriate labels for subgroups at risk of excess fluoride exposure. This petition will protect and improve the public health.

The term "optimal" has become problematic and should be removed from the Code.

"Given the overlap among caries/fluorosis groups in mean fluoride intake and extreme variability in individual fluoride intakes, firmly recommending an "optimal" fluoride intake is problematic."[5]

FDA AND BOARD OF PHARMACY HAVE JURISDICTION OVER SUBSTANCES USED WITH THE INTENT TO PREVENT DISEASE

The FDA Has Federal Jurisdiction Over the Safety, Efficacy, Label and Dosage of Fluoridation Because It is Added With The Intent To Prevent Dental Caries.

Both the EPA (Environmental Protection Agency under the Safe Drinking Water Act) and the FDA (Food and Drug Administration under the Food, Drug and Cosmetic Act) have federal jurisdiction over fluoride in drinking water.

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[3] RCW 57.08.012

[4] RCW 57.08.005 "(14) To contract for the provision of engineering, legal, and other professional services as in the board of commissioner's discretion is necessary in carrying out their duties;"

[5] Warren J, Levy S, Froffitt B, Cavanaugh J, Kanellis M, Weber-Gasparoni K, Considerations on Optimal Fluoride Intake Using Dental Fluorosis and Dental Caries Outcomes- A Longitudinal Study, JPHD 2008

The EPA has jurisdiction over the removal of excess fluoride if it occurs naturally in drinking water, contaminated above the Maximum Contaminant Level (MCL), 4 ppm. Naturally occurring fluoride is calcium fluoride, which is less toxic than the silicofluorides or hydrogen fluoride artificially added to drinking water. The EPA is prohibited by the SDWA from adding any substance to water with the intent to prevent disease and therefore the EPA does not evaluate the safety or efficacy of fluoridation, the addition of fluoride to drinking water. No law provides the EPA with jurisdiction over the addition of substances which are used with the intent to treat, mitigate, prevent, or cure human disease.

"No national primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water."[6]

The FDA CDER (Center for Drug Evaluation and Research) under the FD&C Act has jurisdiction over fluoride if used with the intent to prevent disease.[7] See Appendix B and L,

The FD&C Act became effective in 1938 and required new drug applications demonstrating safety. Fluoridation was started about 10 years later. In 1962 the FD&C Act was amended requiring demonstration of effectiveness in addition to safety.[8] See Appendix C

The FDA and EPA entered into a Memorandum of Understanding, MOU 225-79-2001 on substances added to drinking water. Although the agreement was not ratified by Congress the agreement is reasonable for substances to control contaminants as authorized by the Safe Drinking Water Act. The MOU does not provide the EPA with authorization to approve drugs or add drugs to water. The MOU is not superior to the Safe Drinking Water Act which prohibits the EPA from adding substances to water for the prevention of disease.

B. Different State Agencies Have Jurisdiction Over Fluoride Depending on Whether it is a Contaminant or Drug.

When fluoride exists in water it is called a contaminant and regulated by agencies regulating contaminants in water such as the Board of Pharmacy[9] (as a poison), Department of Health,[10] Agriculture[11] and Board of Health. When the fluoride contaminant is added to water with the intent to prevent disease, then the Board of Health and Board of Pharmacy have primary intrastate jurisdiction.

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[6] 42 USC 300g-1(b)(11):
[7] FDA letter to Honorable Ken Calvert House of Representatives.
[8] FDA letter to Assemblyman John Kelly, 1993.
[9] RCW 69.04.730
10 RCW 69.41.010
11 RCW 69.04.006, RCW 69.04.001

This petition is in keeping with the Washington State Attorney General's opinion:

"The Washington State Board of Health should promulgate proper rules and regulations pertaining to fluoridation and should enforce such rules and regulations."[12]

" It is fair to conclude . . .that the available evidence, while supporting such hypothesis, is at the present time presumptive only. Also, that the proper various amounts of fluoride concentration are yet to be determined for different geographical locations. Also, that the amount of fluoridation may prove injurious to the public if too great an amount be used. Also, that the application of fluoride should be carefully watched so that such will not prove harmful to the various persons who apply the same. . . ."[13]

The AG raises some appropriate areas of caution and concern. However, only the FDA has competency for evaluating and approving drugs and determining a "too great an amount." Most developed countries do not fluoridate and others, such as Canada and the Province of Ontario, have lowered their fluoridation concentration to 0.6 and 0.5 ppm. The National Research Council advised the EPA that some subgroups are getting too much fluoride. This petition for rule change requiring FDA approval is consistent with the AG's opinion.

The specific jurisdiction of each agency must not be confused. DOH should not rely on an agency, such as the CDC or EPA,[14] to do something which the laws prohibit them from doing. The intent of use determines the agency with jurisdiction. Because fluoride is a legend drug, the FDA has federal jurisdiction over fluoride. The proposed rule changes herein are in keeping with federal and state laws.

FLUORIDE WHEN USED WITH THE INTENT TO PREVENT DISEASE IS DEFINED AS A DRUG.

Both the FD&C Act and RCW[15] define a substance, such as fluoride, used with the intent to prevent disease, such as dental caries, as a drug.

Under Washington and Federal law it is unlawful to manufacture, market, formulate, prescribe, dispense, possess or administer a legend (prescription) drug without a license and without compliance with relevant drug laws.[16] There is consensus that fluoride is

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12 See Appendix D for more details
13 http://www.atg.wa.gov/opinion.aspx?section=topic&id=13894
14 Neither the CDC nor the EPA assess the science regarding the use of fluoride. The CDC states, ". . . it is not CDC's responsibility to determine what levels of fluoride in water are safe. . . " CDC website Fluoridation Safety
See last page of Appendix B for DOH comment relying on CDC and EPA.
15 RCW 69.41.010(9)
16 Chapter 69.41 RCW; U.S.C. 21, Chapter 9 ("Federal Food, Drug, and Cosmetic Act" abbreviated herein as "FD&C Act").

added solely to water with the intent to prevent or mitigate dental caries. This intent alone is enough to define fluoridated water as a drug.[17] The EPA (Environmental Protection Agency) does not regulate drugs.[18] The FDA (Food and Drug Administration) regulates drugs in interstate commerce.[19] The State Board of Pharmacy (BOP) regulates drugs in intrastate commerce.[20] BOH should promulgate proper rules and regulations pertaining to fluoridation and should enforce such rules and regulations.[21] Public water systems obtain the bulk fluoridation drug[22] in interstate commerce and do the final manufacturing, formulating, compounding, buffering and dispensing of the fluoridated water drug in intrastate commerce.[23] Thus both Federal and Washington drug laws apply.

B. The Washington State Board of Pharmacy (BOP) has issued its interpretive opinion that fluoride, when used to prevent, mitigate or treat disease is a legend drug:

"Fluoride is a legend drug regulated under chapter 69.41 RCW. RCW 69.41.010 defines a 'legend drug' as drugs 'which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only.' In WAC 246-883-020(2), the Board specified that 'legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2002 edition of the *Drug Topics Red Book*.'"[24,25]

C. Fluoridation substances are unapproved drugs.

Fluoridated water suppliers are the final drug manufacturers. They compound the drug by mixing water and silicofluoride, hydrofluorosilicic acid, or rarely sodium fluoride with buffers to a specific concentration. The intent of use to prevent human disease defines the substance as a drug and without FDA approval it is an unapproved drug and thus misbranded drug and therefore an illegal legend drug.[26] In response to an email request, the FDA confirmed fluoride is not approved:

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[17] Federal and Washington laws define a drug as a substance or article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. sec. 321(g)(1)(B) RCW 69.41.010(9)(b)
[18] Under the Safe Drinking Water Act, the EPA regulates clean-up of contaminants and regulates additives to treat water to clean-up contaminants.
[19] 21 U.S.C. sec. 355(a).
[20] RCW 18.64.005.
[21] AG Opinion IBID
[22] A bulk drug is a substance that becomes an active ingredient of a drug. 21 C.F.R. sec. 207.3(a)(4).
[23] RCW 69.04.004.
[24] State of Washington Department of Health Board of Pharmacy June 4, 2009 letter to Bill Osmunson DDS; RCW 69.41.010(12) defines legend drugs; WAC 246-883-020(2) states legend drugs are listed in 2002 *Drug Topics Red Book*.
[25] The above-referenced Board letter continues, "While RCW 69.41.010 restricts the dispensing of prescription drugs to practitioners, the legislature has authorized water districts to fluoridate their water supplies in RCW 57.08.012." RCW .
[26] The Board can confirm that fluoridated water with these active ingredients is not an approved drug product by going to www.fda.gov and searching for Drugs@FDA, and then in that FDA approved drug database searching for these active ingredients, and can confirm in the Electronic Orange Book that water with fluoride added using any of these active ingredients is not approved for ingestion for the prevention or mitigation of dental decay by going to http://www.accessdata.fda.gov/scripts/cder/ob/docs/queryai.cfm

> "A search of the Drugs@FDA database . . . of approved drug products and the Electronic Orange Book . . . does not indicate that sodium fluoride, silicofluoride, or hydrofluorosilicic acid has been approved under a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) for ingestion for the prevention or mitigation of dental decay. . . . At the present time, the FDA is deferring any regulatory action on sodium fluoride products. . . ."[27]

Deferring regulatory action does not legalize fluoridation. For example, just because the police do not give a speeding citation to a motorist for exceeding the speed limit does not make speeding legal.

E. This petition will ensure that fluoridation will have an approved FDA label.

"To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date. . . ." RCW 69.41.050(1).

A legend (prescription) drug which is not approved by the FDA is misbranded in conflict with RCW 69.04.470 if there is not prominent labeling; in conflict with RCW 69.04.490 if active and certain inactive ingredients are not listed; in conflict with RCW 69.04.500 if there are not adequate warnings of possible dangerous use; in conflict with RCW 69.04.520 if it can be dangerous to health; and in conflict with RCW 69.04.540 if a legend drug is dispensed at retail without a written prescription.

F. Unapproved Drugs are Illegal Drugs.

The Washington State Board of Pharmacy news letter of July 2008 says in part:

> "FDA's Effort to Remove Unapproved Drugs From the Market
> Pharmacists are often not aware of the unapproved status of some drugs and have continued to unknowingly dispense unapproved drugs because the labeling does not disclose that they lack FDA approval. FDA estimates that there are several thousand unapproved drugs illegally marketed in the United States. FDA is stepping up its efforts to remove unapproved drugs from the market. . . .
>
> "FDA has serious concerns that drugs marketed without FDA approval may not meet modern standards for safety, effectiveness, manufacturing quality, labeling, and post-market surveillance. For example, FDA-approved drugs must demonstrate that their manufacturing processes can

[27] Email from the FDA (7-22-09) .

reliably produce drug products of expected identity, strength, quality, and purity. . . .

"Enforcement Priorities
Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.
Most recently, in June 2006, FDA issued a guidance entitled "Marketed Unapproved Drugs – Compliance Policy Guide" (CPG) outlining its enforcement policies aimed at bringing all such drugs into the approval process. (www.fda.gov/cder/guidance/6911fnl.pdf)" [28]

G. Fluoride is highly toxic and defined as a poison and exempt from poison laws as a legend drug.[29]

A 5-4 majority in 1953 Kaul v Chehalis decision[30] stated that fluoride was not a drug. Nevertheless, fluoride fits into the definition of poison and regulated under RCW 69.38 and 40.[31] Selling or distributing poisons is unlawful.[32] Selling repackaged poison without labeling is unlawful.[33]

RCW 69.38.010 (4). "Any other substance designated by the state board of pharmacy which, when introduced into the human body in quantities of sixty grains or less, causes violent sickness or death."

Note: 60 grains is 3,889 mg. 15 mg of silicofluoride or hydrogen fluoride (but not calcium fluoride which is less toxic) is considered by some to be lethal for children[34] and 5 mg/Kg is considered lethal for adults. Certainly 15 mg, which could be lethal for an infant, is well within the 3,889mg of the law. If silicofluoride or hydrogen fluoride is not exempt as a drug, then it is a poison.

"RCW 69.40.030 Placing poison or other harmful object or substance in food, drinks, medicine, or water — Penalty.

(1) Every person who willfully mingles poison . . . in any food, drink, medicine, . . . and every person who willfully poisons any spring, well, or reservoir of water, is guilty of a class B felony and shall be punished by imprisonment in a state correctional facility for not less than five years or by a fine of not less than one thousand dollars."

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[28] http://www.doh.wa.gov/hsqa/professions/Pharmacy/documents/July2008.pdf
[29] RCW 69.38.020 and RCW 69.41
[30] See Appendix F
[31] RCW 69.38.020
[32] RCW 69.40.010
[33] RCW 69.40.055
[34] "It may be concluded that if a child ingests a fluoride dose in excess of 15 mg F/kg, then death is likely to occur. A dose as low as 5 mg F/kg may be fatal for some children. Therefore, the probably toxic dose (PTD), defined as the threshold dose that could cause serious or life-threatening systemic signs and symptoms and that should trigger immediate emergency treatment and hospitalization, is 5 mg F/kg." SOURCE: Whitford G. (1996). Fluoride Toxicology and Health Effects. In: Fejerskov O, Ekstrand J, Burt B, Eds. Fluoride in Dentistry, 2nd Edition. Munksgaard, Denmark. p 171."

VI. THIS PETITION, REQUIRING FDA APPROVAL FOR FLUORIDATION, IS CONSISTENT WITH GENERAL FEDERAL AND STATE LAWS AND IS PROTECTIVE OF THE PUBLIC.

At this point please read Appendix D and E for further legal comments.

At one time the Washington Department of Health indicated it would support a committee or task force to evaluate fluoridation. A letter from one of the NRC 2006 members to Mr. Coleman[35] at the Department of Health provides further background information. The Department of Health later declined to have an open review of the evidence on fluoridation.

NOTE I: This petition stands on the laws regardless of which side of the fluoridation controversy a person may lean. We all want safety for our families and friends. No further evidence for this petition is necessary. Obeying the law will protect the public health. The following is to enable the Board to better understand the need for FDA approval.

NOTE II: Although the precautionary principle may not have been adopted by the Board, the concept is sound.

Proponents of fluoridation demand opponents prove harm and opponents of fluoridation demand proponents prove safety. Who is right? Should those claiming harm be required to prove the government is wrong or should the government be required to prove their public health theory is safe, effective and legal? The laws are quite clear that persons, which includes government agencies, marketing drug products, whether government agencies, private, non-profit or individuals, must gain FDA approval. It is not the obligation of the public to defend themselves from the government with absolute proof of harm. In the case of fluoridation, it is the water suppliers, usually government agencies, who must provide enough evidence of efficacy and safety to gain FDA approval.

Evaluating fluoridation science is problematic. The evidence on both sides of this controversy is incomplete and sometimes is fair or poor, depending on the perspective of the reader. There are no randomized controlled trials, so "judgment" is needed to weigh each piece of evidence. Numerous reviews claiming benefits from fluoridation are seriously flawed, grounded on estimates, assumptions, and lack of control for confounding factors. The same problem exists for those opposed to fluoridation. However, it is incumbent on those promoting fluoridation under police powers, governments, to provide the evidence for efficacy and safety. FDA approval is reasonable and legal.

Some of the scientific evidence which raises concerns with excess exposure, lack of efficacy, lack of safety, and unethical public health practice is provided below.

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[35] See Appendix M

VII. SOURCE OF FLUORIDATION CHEMICALS

The fluoridation chemicals are not pharmaceutical grade and usually consist of the scrubbings and waste products of the phosphate fertilizer manufacturing industry. Currently a shortage of fluoridation chemicals exists in the USA, one of the few developed countries fluoridating, and more of our fluoridation chemicals are coming from China. China's waste products may or may not be more contaminated. Lack of testing for purity is a concern and reports are not publicly disclosed.

FDA approval will require purity of chemicals.

VIII. THE NATIONAL SANITATION FOUNDATION

The National Sanitation Foundation (NSF) is a private non-profit corporation funded by the manufacturers it regulates. Results of testing, if done, are proprietary and not accessible to the public for verification.

NSF is supposed to test for contaminants within the fluoridation products. NSF does not test whether the addition of 1 ppm of fluoride to water is safe or effective. See Appendix F

The specific jurisdiction of each agency must not be confused and we should not rely on an agency or private company, such as the CDC, EPA,[36] or NSF to do something which the laws prohibit them from doing. The intent of use determines the agency with jurisdiction. Because fluoride is a legend drug, the FDA has federal jurisdiction over fluoride, not the NSF, EPA, or CDC. The proposed rule changes herein are in keeping with federal laws and provide disclosure of chemical testing.

IX. HOW MUCH FLUORIDE SHOULD A PERSON INGEST?

Dental caries are not a result of a lack of fluoride. Fluoride is not a required element for human function or health.

One of the best indicators for an optimal amount of fluoride for infants is mother's milk. Mother's milk is considered ideal for infants and has been essential for the survival of our species. Mother's milk contains about 250 times less fluoride than formula made with fluoridated water. In other words, the EPA's MCLG is 4.0 ppm and mother's milk contains about 0.004 ppm, 1,000 times less fluoride than the EPA's goal.

The target population for fluoridation is children up to age 8,[37] around 9% of the total population, while the enamel of the teeth is forming. In an attempt to reach children that

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[36] Neither the CDC nor the EPA assess the science regarding the use of fluoride. The CDC states, ". . . it is not CDC's responsibility to determine what levels of fluoride in water are safe. . . " CDC website Fluoridation Safety

[37] NRC 2006

age, governments medicate everyone through the water even if they don't have teeth or are opposed to fluoridation. See Appendix G

Read a fluoridated toothpaste label. The FDA warns not to swallow, use a pea size amount, and if more than used for brushing is swallowed, contact the poison control center. (Variable wording is permitted.) A pea size of toothpaste contains 0.25 mg of fluoride, the same as one glass of fluoridated water. The conflict is clear. We, the public, have the FDA warning not to swallow 0.25 mg of fluoride at the same time the City of Seattle (and all fluoridation entities) gives us no choice but to swallow that same amount in each glass of water and provides no warning. The obvious conflict between government agencies makes no sense and warrants no respect.

This petition requesting rule change requiring FDA approval, will help to reconcile the clear and undisputed conflict between the FDA and fluoridating water systems.

X. EXPOSURE: MANY ARE INGESTING TOO MUCH FLUORIDE.

See Appendix H

A. Increased Sources of Fluoride Exposure.

When fluoridation was first started in the early 1950's, fluoride toothpaste, fluoride dental products, fluoride pesticides, fluoride post-harvest fumigants and most fluoride medications did not exist. Adding fluoride to water at 1 ppm was not expected to show an increase in dental fluorosis. Today, with several sources of fluoride, one third of children are experiencing dental fluorosis. Dental fluorosis is a biomarker of excess fluoride ingestion.

FDA approval will require an evaluation of total exposure and FDA approved label would caution regarding excess exposure.

B. Mother's Milk has Almost No Fluoride.

The CDC, American Dental Association, and several state health departments no longer recommend fluoridated water be used for infants. The Washington Department of Health (DOH) responded to my question on their position for infants by saying they will leave the issue up to parents. I have not seen any effort by DOH to educate care givers and the public.

Without doubt, an FDA approved label would require warnings not to use fluoridated water for infant formula.

C. Concentration is Not Dosage.

Concentration of a substance must not be confused with dosage. Some people drink very little water and others drink more than 5 liters a day. Due to the wide variation in water consumption, determining safety based on "average" consumption or even the 90th percentile is not protective of everyone.

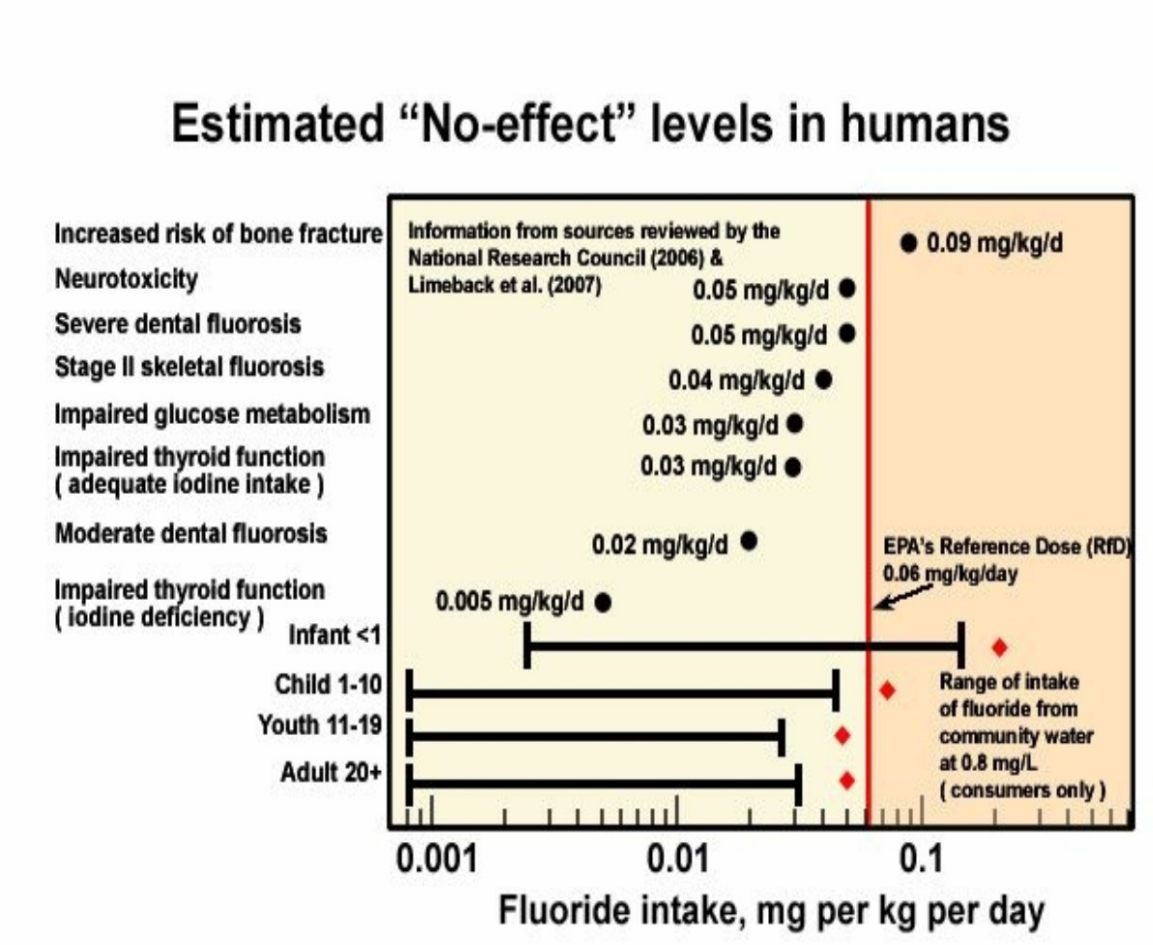
D. Risk of Harm.

Several concerns of health risk have been raised. FDA approval would evaluate and monitor these concerns. The EPA does not evaluate the addition of fluoride to water, but the EPA does determine the maximum contaminant level permitted and goals which would be better to achieve.

"Due to misdirection by EPA management, who requested the report, the NRC committee identified only health effects known with total certainty. This is contrary to the intent of the Safe Drinking Water Act (SDWA), which requires the EPA to determine "whether any adverse effects can be reasonably anticipated, even though not proved to exist." Further misdirection by EPA consisted of instructing the committee not to identify a new MCLG—in other words, not to determine a safe level of fluoride in drinking water, and not to discuss silicofluorides, phosphate fertilizer manufacturing by-products used in most cities to fluoridate their water. Despite these restrictions, the committee broke new ground . . . On the basis of this information and the proper interpretation of the SDWA, the following are all adverse health effects: moderate dental fluorosis, stage I skeletal fluorosis (arthritis with joint pain and stiffness), decreased thyroid function, and detrimental effects on the brain, especially in conjunction with aluminum. The amount of fluoride necessary to cause these effects to susceptible members of the population is at or below the dose received from current levels of fluoride recommended for water fluoridation. The recommended Maximum Contaminant Level Goal (MCLG) for fluoride in drinking water should be zero[38]

Dr. Thiessen, one of the NRC members, made a graph below for Health Canada showing the various risks, age and mg/kg/day. Even at 0.8 ppm of fluoride in water there is an increased risk of neurotoxicity, severe dental fluorosis, stage II skeletal fluorosis, impaired glucose metabolism, impaired thyroid function and moderate dental fluorosis. See **Appendix I** for addition information on Risks.

[38] Carton, R Review of the 2006 United Stat4es National Research Council Report: Fluoride in Drinking Water, Fluoride 39(3)163-172 Jul-Sep 2006. http://www.fluorideresearch.org/393/files/FJ2006_v39_n3_p163-172.pdf



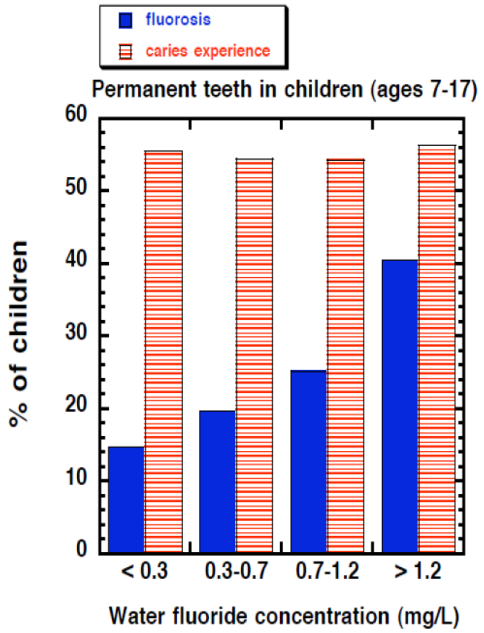
XI. FLUORIDATION NO LONGER SHOWS SIGNIFICANT BENEFIT

Without efficacy, any risk is unacceptable. The FDA will carefully evaluate the numerous published studies disputing the effectiveness of fluoridation. Appendix J

A. Caries experience is no longer reduced with fluoridation.

The graph below by Iida is one of many current examples showing a lack of dental decay reduction with fluoridation. The caries experience (tall red lines) is virtually the same regardless of the amount of fluoride in the water. However, the percent of children with fluorosis roughly doubles at fluoridation levels 0.7-1.2 mg/L. Dental fluorosis is a biomarker of excess fluoride ingestion.

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



B. No Measured Dental Treatment Cost Savings.

The evidence for a public health intervention should be measured in the community at large. If we had two communities, one where everyone had received the optimal polio vaccine and the other few if any were vaccinated, certainly we would expect the measured costs for polio treatment to be lower in the vaccinated community. The measured dental treatment costs in fluoridated communities do not show significant reductions. "What is wrong?"

After 60 years of fluoridation, there is only one published study, and it had historical data, finding a cost reduction in fluoridated communities, about half a percent savings. Perhaps enough savings to pay for equipment repairs, but not enough savings to pay for the fluoride chemicals, equipment installation or promoting fluoridation. And comparing dental costs for children in the two largest communities showed the children in the non-fluoridated community with slightly lower dental costs.

Fluoridation's effectiveness is controversial. The most competent agency to evaluate efficacy of the legend drug fluoride is the FDA.

Most developed countries of the world do not fluoridate water in part because the evidence no longer finds significant benefit.

This petition recommends deleting the term "optimal" from WAC 246-290-460(3) which is in keeping with current good scientific evidence.

"These findings suggest that achieving a caries-free status may have relatively little to do with fluoride intake, while fluorosis is clearly more dependent on fluoride intake. . .

"Thus, given that the present study found considerable overlap among caries/fluorosis groups in terms of mean fluoride intake and extreme variability in individual fluoride intakes for those with no fluorosis or caries history (Figure 2), firmly recommending an "optimal" fluoride intake is problematic, and as stated by Burt and Eklund, perhaps it is time that "the term optimal fluoride intake be dropped from common usage"(1)."[39]

XII. ETHICS OF FLUORIDATION

The FDA may evaluate the ethics of fluoridation to ensure the label appropriately protects each member of the public.

A. Fluoridation is a Hypothesis and Experimental Research.

The Washington Attorney General suggests fluoridation is a "hypothesis,"[40] a term sometimes considered a provisional idea worth further study or the prediction of an experiment. Experimental research includes the collection and evaluation of measured data.

To suggest fluoridation is "experimental research," would indicate someone is collecting data on the benefits and risks experienced by cohorts. However, seldom is data collected on fluoridation and almost never analyzed. Thus, fluoridation does not even reach the level of "experimental research." However, other terms are even less appealing.

Fluoridation needs FDA drug approval so proper research can be done if the FDA determines such is needed.

B. Human Subjects Research

The ethics of Title 45 of the Federal Code states, ". . . provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."

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[39] Warren J, Levy S, Broffitt B, et al Considerations on Optimal Fluoride Intake Using Dental Fluorosis and Dental Caries Outcomes – A Longitudinal Study, Journal of Public HealthDentistry Published Online 24 Nov 2008.

[40] http://www.atg.wa.gov/opinion.aspx?section=topic&id=13894

The University of Washington has guidelines for human research, ". . . no informed consent . . . may include any exculpatory language through which the subject . . . is made to waive or appear to waive any of the subject's legal rights. . . the sponsor, the institution or its agents from liability for negligence." http://www.washington.edu/research/hsd/hsdman4.html

The Nurenberg Nazi Medical War Crimes Trials, Nuremberg Doctors' Trial, United Nations Declaration of Human Rights, Federal Policy on protection of Human subjects, Willowbrook Study, Declaration of Helsinki, Syphilis study at Tuskegee, are just a few examples of declarations for human subject research.

For example, declarations of medical ethics were laid down in 1947 after the Nurenberg trials.

"1. The subject must give his or her voluntary consent, knowing the nature, direction, purpose, inconveniences, and hazards of the experiment".

Fluoridation does not provide for voluntary consent of subjects. The majority cannot vote to remove human subject research consent of the individual.

"2. The experiment should be necessary both in yielding fruitful results for the good of society and in the sense that the information cannot be gained without experiment."

Fluoridation in Washington State has not had the results evaluated, based on an email from the DOH. And preliminary results indicate fluoridation is not yielding fruitful results either with a reduction of dental decay or reduced dental expenses.

"3. The anticipated results justify doing the experiment."

Results are controversial.

"4. All unnecessary physical and mental suffering must be avoided."

The FDA is the most competent agency to determine how much physical and mental suffering is being caused.

"5. There should be no prior reason to believe that death or injury will occur."

Current evidence gives plenty of reason to "believe" that death or injury is occurring with chronic use. Absolute proof is not required. The level of confidence is to the level of "belief."

"6. The degree of risk shall not exceed the humanitarian importance of the problem."

Fluoridation no longer shows a reduction in tooth decay and therefore any risk is excessive.

"7. Preparations should be made and adequate facilities provided against the remote possibility of adverse effects."

This code of ethics is concerned about the "remote possibility of adverse effects" not simply violent sickness or death. There is undisputed evidence adverse effects of dental fluorosis is higher in fluoridated communities and plenty of evidence many are harmed with other diseases.

"8. Those who conduct the experiment shall exercise the highest degree of skill and care and be scientifically qualified."

Fluoridation, a drug, is prescibed by water district board members who are not physicians and is compounded and dispensed by water district employees who are not pharmacists. These board members and their employees—as well as the majority of voters—have little or no scientific or medical training and are unqualified to run a complex scientific experiment on human subjects.

"9. The subject must always be free to bring the experiment to an end."

As the subject of this experiment, we are requesting FDA approval for the substance.

"10. The investigator must terminate the experiment if its continuation may be detrimental to the patient."

CASE HISTORIES

See Appendix K

XIII. CONCLUSION

The intent of this petition is to protect the public health by requiring FDA approval for fluoridation. This petition is consistent with general federal and state laws, constitutions as well as international "laws" and ethics.

Sincerely,

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cc: Washington State AG
US FDA