WASHINGTON ACTION FOR SAFE WATER

September 13, 2010

Governor Chris Gregoire
Office of the Governor
PO Box 40002,
Olympia, WA 98504-0002
Sent by e-mail to: info@chrisgregoire.com; marty.lovinger@gov.wa.gov

RE: Appeal from Washington State Board of Health June 14, 2010 Denial for Rule Change Requiring Food and Drug Administration Center for Drug Evaluation and Research Approval for Fluoride Drugs Added to Public Water.

See the digital version of this letter at:
http://washingtonsafewater.com/bd-of-health/appeal-to-governor-9-13-10/

To download a Word version of this letter go to:
http://washingtonsafewater.com/wp-content/uploads/appeal-to-governor-9-13-10-doc

Dear Governor Gregoire,

Our appeal[1] under RCW 34.05.330(3) of the BOH (Board of Health) denial of rule change[2,3] is being filed late in part due to questions

[1] Appendix 1 WASW Appeal to the BOH includes lettered appendixes.
- June 8, 2010 Petition for Rule Making
- Appendix A: Requested Rule Change: Suggested Wording
- Appendix B: Jurisdiction
- Appendix C: 1993 FDA Letter
- Appendix D: Additional Laws, Court Cases and Ethics
- Appendix E: Major Health Issues
- Appendix F: *National* Sanitation Foundation
- Appendix G: How Much Fluoride Do We Need?
- Appendix H: Total Fluoride Exposure/Dosage
- Appendix I: Adverse Effect Report
- Appendix J: Fluoridation's Lack of Effectiveness
- Appendix K: National Sanitation Foundation
- Appendix L: Fluoride Regulated by the FDA
- Appendix M: Letter from Kathleen M. Thiessen, PhD

[2] Appendix 2, BOH June 9, 2010, meeting handout, Please note that appendixes for this appeal are numbered and our appeal to the Board of Health has lettered appendixes.
[3] June 14, 2010 BOH Formal Denial , http://washingtonsafewater.com/wp-content/uploads/board-of-health-denial-letter-6-14-10.pdf.

presented to the EPA[4] (Environmental Protection Agency), FDA[5] (Food and Drug Administration), CDC[6] (Centers for Disease Control), Board of Health,[7] and the lack of thoroughness in those responses, or in the case of the CDC, no response at all. We request a waiver of the 30 day deadline for this appeal so that resubmission to the Board of Health of our petition and then repetition of this appeal will not be necessary.

We respectfully ask that the Governor either overturn the Board of Health's denial and/or forward our petition to the Washington State Attorney General, requesting an opinion from that office on whether those public water systems[8] practicing fluoridation,[9] allegedly permitted by RCW 57.08.012, are none the less required in addition to make application and gain FDA CDER (Center for Drug Evaluation and Research) New Drug Approval (NDA) as required by the FD&C Act (Food Drug and Cosmetic Act) for drug manufacturers prior to marketing,[10] whether fluoridation is permitted under the Safe Drinking Water Act, and whether public water systems are required to register as drug manufacturers with the Board of Pharmacy.[11]

The Board of Health voted to deny our petition for rule making before hearing oral arguments from WASW or the public. This creates at minimum an appearance of impropriety.

Background: Incidence of dental caries has dropped around 85% reduced over the last few decades both in fluoridated and non-fluoridated areas.[12] Incidence is still common especially for those in lower socioeconomic groups. However, the general public should not be subjected to a public health intervention which is intended for a

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[4] June 14, 2010, FOIA to EPA, http://washingtonsafewater.com/wp-content/uploads/foia-to-epa-6-14-101.pdf; July 6, 2010, EPA Response, http://washingtonsafewater.com/wp-content/uploads/EPA-response-to-foia-request-7-6-101.pdf.

[5] June 14, 2010, FOIA to FDA, http://washingtonsafewater.com/wp-content/uploads/osmunson-foia-request-to-fda-6-101.doc; June 30, 2010, FDA Response to FOIA, http://washingtonsafewater.com/wp-content/uploads/FDA-response-to-foia-request-6-30-101.pdf.

[6] June 14, 2010, FOIA Request to CDC, http://washingtonsafewater.com/wp-content/uploads/osmunson-foia-request-to-cdc-6-14-2010.doc; The CDC has not responded. The status is still "Pending Final Approval", http://www2a.cdc.gov/od/foiastatus/result.asp?select1=10&idnum=00870.

[7] July 15, 2010, Request for Information to Board of Health, http://washingtonsafewater.com/wp-content/uploads/osmunson-request-for-information-request-to-board-of-health-7-15-2010.doc; July 22, 2010,Response from Board of Health, http://washingtonsafewater.com/wp-content/uploads/board-of-health-response-to-public-disclosure-request-7-22-2010.pdf.

[8] 40 CFR 142.2 defines a "public water system thus:" "Public water system or PWS means a system for the provision to the public of water for human consumption through pipes or, after August 5, 1998, other constructed conveyances, if such system has at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year."

[9] Fluoridation is a term used here strictly when fluoride chemicals are added to public water systems.

[10] http://www.fda.gov/AboutFDA/CentersOffices/CDER/default.htm.

[11] "RCW 18.64.005(1) and (11)" See also AGO 1987 No 2.

[12] Appendix J: Fluoridation's Lack of Effectiveness

subpopulation, no longer appears to be effective or demonstrates measurable positive outcomes,[13, 14] causes and contributes to harm,[15] is expensive,[16] and to which we are overexposed.[17] Fluoridation chemicals are usually the contaminated waste product scrubbings of phosphate fertilizer manufacturing.[18] Fluoride is added to water with the intent to prevent dental disease,[19] dental caries, and is without any other medical or dental purpose and is not added with the intent to kill pathogens in water or treat water. Fluoride is highly toxic, more toxic than lead and less toxic than arsenic,[20] and exempt from poison laws when dispensed as a drug.[21]

The FD&C Act[22] and RCW 69.41.010(9)[23] define a substance when used with the intent to prevent disease, a drug. The Washington Board of Pharmacy agreed[24] that fluoride is a legend, prescription drug. RCW 69.41.040[25] legalizes the possession of a prescription drug when the prescription is issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs. Who is prescribing everyone fluoridated water? Is it legitimate?

Purchasing fluoride at a pharmacy for ingestion requires a prescription, and the approved FDA fluoridated toothpaste label in over-

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[13] RCW 43.70.512 Public health — Required measurable outcomes.
[14] See Appendix J, graphs and citations on decay trends.
[15] See Appendix I, Adverse Effect Report
[16] See Appendix J, lack of effectiveness.
[17] See Appendix H, Exposure
[18] See Appendix F, National Sanitation foundation
[19] http://www.cdc.gov/mmwr/preview/mmwrhtml/00039178.htm Available 9/6/10 CDC MMWR 9/29/1995/44(RR-13); 1-40, "Further studies were conducted that confirmed the cause-and-effect relation between fluoridation and the reduction of dental caries (1,3,6,38,39)."
[20] Clinical Toxicology of Commercial Products, 1984, http://washingtonsafewater.com/wp-content/uploads/clinical-toxicology-of-commercial-products-LD50-data-1984-how-toxic-is-fluoride-compared-to-arsenic-and-lead.pdf.
[21] RCW 69.38.010 "Poison" Defined. 5 mg/Kg BW can be lethal. 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."
[22] 21 USC 321 (g)(1)(B).
[23] RCW 69.41.010(9)
[24] See Petition to BOH. 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] RCW 69.41.040 Prescription requirements -- Penalty_(1) A prescription, in order to be effective in legalizing the possession of legend drugs, must be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs. An order purporting to be a prescription issued to a drug abuser or habitual user of legend drugs, not in the course of professional treatment, is not a prescription within the meaning and intent of this section; and the person who knows or should know that he or she is filling such an order, as well as the person issuing it, may be charged with violation of this chapter. A legitimate medical purpose shall include use in the course of a bona fide research program in conjunction with a hospital or university._ (2) A violation of this section is a **class B felon**y punishable according to chapter 9A.20 RCW.

the-counter sales clearly says "Drug Facts" "Do Not Swallow."[26] This warning is for the same amount of fluoride as found in one glass of fluoridated water. Public water systems, with the blessings of governmental regulatory oversight agencies, are forcing us to swallow in each glass of water the same amount of fluoride as another governmental agency, the FDA, warn us not to swallow. Even the possession of a legend drug without prescription, such as fluoridated water, is a class B felony.[27]

Manufacturers of drugs are required to gain FDA CDER approval for their drugs before marketing.[28] Public water systems adding fluoride to water are the final drug manufacturers, marketers and dispensers of the fluoridated water drug and as such are required by the FD&C Act to gain FDA CDER approval before marketing their drug with New Drug Approval and be licensed by the Washington Board of Pharmacy as drug manufacturers.

Washington Action for Safe Water petitioned the Washington State Board of Health (Board) for a rule change requiring FDA CDER approval for fluoridated water.[29] The Board denied the rule change by misbranding the fluoride drug and calling it an additive (substance to treat pathogens in water) which the FDA does not regulate.[30] The Board further claims that requiring FDA CDER approval would effectively rule out fluoridation and the Board cannot countermand state statutes. Washington Action for Safe Water disagrees with the Board of Health denial and is making this appeal.[31]

"FDA New Drug Approval." The FDA does not generally go looking for violators. The FD&C Act puts the burden on drug manufacturers to gain approval with the FDA.[32] Early on it was determined that the FDA could not police the drug manufacturing industry by doing research to prove all the drugs on the market were safe

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[26] http://washingtonsafewater.com/wp-content/uploads/CrestWarning.jpg
[27] *RCW 69.41.030 and 69.41.0.40*
[28] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm
[29] See Petition to the Board of Health
[30] See June 14, 2010, Board of Health denial letter, http://washingtonsafewater.com/wp-content/uploads/board-of-health-denial-letter-6-14-10.pdf.
[31] Ibid.
[32] "It is the responsibility of the company seeking to market a drug to submit evidence that it is safe and effective." http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm119447.htm

and effective. Thus the FD&C act was written to put the burden on the manufacturer and not the FDA.[33]

I. FOR THE PROTECTION OF THE PUBLIC HEALTH, THE GOVERNOR IS REQUESTED TO REVERSE THE BOARD OF HEALTH'S DENIAL OF OUR PETITION AND/OR REQUEST AN OPINION OF THE ATTORNEY GENERAL.

Without FDA CDER approval, the health and safety of the public is at risk of harm because no other agency as effectively evaluates the safety and efficacy of substances used for the prevention of disease.[34] Until approved by the FDA CDER, mass medicating everyone without their consent, with an unapproved drug, is probably the most extensive public health care fraud executed by governments. It is the duty of the Governor and Attorney General to reduce health care fraud especially when perpetuated by government agencies.

This appeal requests the Governor to ask the Attorney General for opinion on three specific questions and one request for response.

Question A: Does RCW 57.08.012, or any other statute purporting to authorize fluoridation, exempt water districts (suppliers) from the FD&C Act and/or RCW statutes which regulate the manufacturing, licensing, labeling, dispensing or administering of drugs? In other words, is there legal authority granting exemption to water suppliers who fluoridate water with intent to prevent disease from FDA CDER New Drug or Investigational Drug Approval?

Question B. If RCW 57.08.012 or any other statute purporting to authorize fluoridation exempt water suppliers from FDA CDER approval, then what state or national agency is responsible for determining both the safety and efficacy of the fluoridated water drug dispensed under police powers with the intent to prevent dental disease?

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[33] " ***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." http://www.doh.wa.gov/hsqa/professions/Pharmacy/documents/July2008.pdf.

[34] "The mission of FDA is to enforce laws enacted by the U.S. Congress and regulations established by the Agency to protect the consumer's health, safety, and pocketbook. *The Federal Food, Drug, and Cosmetic Act* is the basic food and drug law of the U.S. With numerous amendments, it is the most extensive law of its kind in the world. The law is intended to assure the consumer that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that all labeling and packaging is truthful, informative, and not deceptive." http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm090410.htm

The Safe Drinking Water Act (SDWA) forbids the EPA from adding anything to water for the prevention of 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."[35]

> "Washington has a formal agreement with the Environmental Protection Agency (EPA) (PDF 99 KB) for meeting the requirements of the federal Safe Drinking Water Act (SDWA). . ."[36]

RCW 70.119A requires DOH to assume primary enforcement responsibilities for the SDWA, which appears to be in direct conflict with RCW 57.08.012 authorizing a substance prohibited by the SDWA. A formal agreement[37] confirms DOH's acceptance of jurisdiction in Washington for the SDWA. Federal laws preempt state statutes. RCW 70.119A appears to be in conflict with RCW 57.08.012.

Question C. In accordance with RCW 69.41.040, under whose drug license is the prescription drug fluoride being given to everyone? In other words, who is our doctor, our legal intermediary for fluoridation?

The DOH responded in 2007 that,

> "The Washington State Department of Health (DOH) does not dispense fluoride. Rather, the DOH regulates water systems that choose to add fluoride to water. Therefore, DOH does not operate under any DEA license for the dispensing of fluoride"[38]

DOH has agreed to enforce the SDWA not to add anything to water for health-related purposes, but DOH is evading their responsibility to enforce the SDWA.

Request for Response D. The Governor and the Attorney General are requested to ask the Board of Pharmacy whether fluoride, under RCW 69.38.010 is defined as a poison. For two years we have requested

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[35] 42 USC 300g-1(b)(11):
[36] http://www.doh.wa.gov/ehp/dw/our_main_pages/dwover.htm
[37] http://www.doh.wa.gov/ehp/dw/Publications/SEA-EPA-07-09.pdf is the latest copy posted on the Web.
38 http://washingtonsafewater.com/wp-content/uploads/board-of-health-response-department-of-health-does-not-dispense-fluoride-regulates-water-systems-that-choose-to-2-28-2007.doc Victor Colman, JD Senior Policy Advisor Division of Community and Family Health, Office of the Assistant Secretary, Washington State Department of Tel: 360.236.3721 Cell: 360.561.3299 Fax: 360.664.4500 PUBLIC HEALTH: Always Working For A Safer and Healthier Washington Sent: Wednesday, February 28, 2007 2:58 PM To: 'Bill Osmunson DDS MPH'

the Board of Pharmacy to designate fluoride a poison and the Board of Pharmacy said fluoride is exempt as a prescription drug, but has failed to designate fluoride or any other substance not listed in law, a poison.

> "RCW 59.38.010 "Poison" defined. . . . (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."[39]

Sixty grains = 3,889 mg whereas only 15 mg of fluoride will likely cause death in a child.[40] In simple terms the Board of Pharmacy has been asked whether 15 is less than 3,889. If yes, then the Board is requested to follow the law and designate fluoride as a poison.

Substances are exempt from poison laws when used as drugs (RCW 69.41) and the Board of Pharmacy has confirmed fluoride is exempt as a prescription drug when used with the intent to prevent dental disease.

Designation by the Board of Pharmacy will help the Board of Health and the public to better understand the toxicity of fluoride.

II. FDA: THE FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH HAS JURISDICTION OVER THE APPROVAL OF SUBSTANCES USED WITH THE INTENT TO TREAT OR PREVENT DISEASE IN HUMANS DEFINED AS DRUGS.

A drug is defined as an article or substance "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal." 21 USC 321 (g)(1)(B)

and similar wording is found in RCW 69.41.010(9)(b).

Intended use determines which government regulatory oversight agency has jurisdiction over fluoridation.

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[39] http://apps.leg.wa.gov/RCW/default.aspx?cite=69.38.010
[40] 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."

"How is a product's intended use established?

Intended use may be established in a number of ways. Among them are:

- Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials. Certain claims may cause a product to be considered a drug, even if the product is marketed as if it were a cosmetic. Such claims establish the product as a drug because the intended use is to treat or prevent disease or otherwise affect the structure or functions of the human body. Some examples are claims that products will restore hair growth, reduce cellulite, treat varicose veins, or revitalize cells.
- Consumer perception, which may be established through the product's reputation. This means asking why the consumer is buying it and what the consumer expects it to do.
- Ingredients that may cause a product to be considered a drug because they have a well known (to the public and industry) therapeutic use. An example is fluoride in toothpaste."[41]

There is no dispute that the intent of fluoridation is to prevent dental disease. The FDA CDER web site also explains the role of the CDER:

"What does the Center for Drug Evaluation and Research do?
The Center is a consumer watchdog in America's healthcare system. CDER's best-known job is to evaluate new drugs before they can be sold. The Center's review of new drug applications not only prevents quackery, but it provides doctors and patients with the information they need to use medicines wisely. The Center makes sure that safe and effective drugs are available. . . .

What drugs are regulated by CDER?
From aspirin to cancer treatments, CDER ensures that the benefits of drug products outweigh any known risks. The Center has oversight responsibilities for prescription, over-the-counter and generic drugs. This responsibility includes products that many consumers usually do not associate as drugs, such as fluoride toothpaste, dandruff shampoos and sunscreens. . . .

Does the FDA test drugs?
FDA does not develop, manufacture or test drugs. Drug

[41] http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm

> manufacturers submit full reports of a drug's studies so that the Center can evaluate its data. The studies answer the question: "Does this drug work for the proposed use?" By analyzing the data, CDER reviewers assess the benefit-to-risk relationship and determine if the drug will be approved. . . .
>
> Once FDA approves a drug, does this mean that the product is perfectly safe?
>
> No drug product is "perfectly" safe. Every single drug that affects the body will have some side effects. Since the FDA considers both the benefits and risks of all medications before approval, side effects are generally not serious. For every drug FDA approves, the benefits are balanced against its risks. In addition, FDA makes sure the labeling (package insert) outlines the benefits and risks reported in the tested population. . . .
>
> What is required for a drug to be approved by CDER?
> Under current law, all new drugs need proof that they are effective and safe before they can be approved for marketing."[42]
>
> "A note on "new drugs": Despite the word "new," a "new drug" may have been in use for many years."[43]

If fluoridation is indeed effective and safe with appropriate protections for the public then the Board of Health and water suppliers should not have anything to fear from making application to the FDA CDER for approval and the Governor should approve our petition and/or forward to the Attorney General for opinion. Opposition from the Board or Department of Health is a sure sign that they do not have evidence of safety or efficacy and the protection of the public is at risk.

II. EPA: THE ENVIRONMENTAL PROTECTION AGENCY HAS JURISDICTION OVER THE APPROVAL OF ADDITIVES INTENDED TO DISINFECT AND TREAT WATER AND IS PROHIBITED FROM ADDING ANY SUBSTANCE FOR HEALTH-RELATED PURPOSES OR PREVENTION OF 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."[44]

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[42] http://www.fda.gov/AboutFDA/CentersOffices/CDER/FAQsaboutCDER/default.htm#1
[43] http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm
[44] 42 USC 300g-1(b)(11):

The Board of Health appears to have rejected or misunderstood the SDWA quote above. In its response to WASW's petition and under the Freedom of Information Act request, the EPA responded and restated the SDWA.

> "The Safe Drinking Water Act prohibits the deliberate addition of any substance to drinking water for health-related purposes other than disinfection of the water."[45]

The EPA does not regulate substances such as fluoridation when added to water for the purpose of preventing disease. The EPA regulates additives for the treatment of water and killing pathogens in the water.

> RCW 70.119A.080 requires the Department of Health to: "administer a drinking water program which includes, but is not limited to, those program elements necessary to assume primary enforcement responsibility for part B, and section 1428 of part C of the federal safe drinking water act. . . ."

In August 1996, the EPA notified water systems:

> "In order to maintain primary enforcement responsibility for regulations promulgated under the SDWA, States must adopt regulations that are no less stringent than federal regulations within 2 years of the date of promulgation of the federal regulations." [46]

Fourteen years later neither the Board of Health nor the Department of Health have brought WAC 246-290-460(l) or WAC 246-290-220 into compliance with the Safe Drinking Water Act which "prohibits the deliberate addition of any substance to drinking water for health-related purposes." [47] The Board should not make rules attempting to legitamize illegal drug distribution by water systems or deny citizens the right to freedom not to be medicated with unapproved illegal drugs.

III. CDC: THE CENTERS FOR DISEASE CONTROL DOES NOT HAVE JURISDICTION TO APPROVE THE USE OF SUBSTANCES TO EITHER TREAT WATER OR HUMANS.

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[45] FOIA Request HQ-FOI-01418-10 http://washingtonsafewater.com/wp-content/uploads/epa-response-to-6-14-10-foia-request-from-osmunson-7-6-10.pdf.

[46] http://water.epa.gov/lawsregs/guidance/sdwa/summ.cfm#5A

[47] 42 USC 300g-1(b)(11). FOIA Request HQ-FOI-01418-10 http://washingtonsafewater.com/wp-content/uploads/epa-response-to-6-14-10-foia-request-from-osmunson-7-6-10.pdf.

The Board of Health's Environmental Health Committee (EHC) is flawed when it advised the Board of Health to deny our petition for rule change because of CDC recommendations. The EHC represented to the Board,

> "The range of 0.8 ppm to 1.3 ppm fluoride in WAC 246-290-460 is within the control range (0.1 ppm below to 0.5 ppm above) recommended by CDC for target "optimal" concentrations based on average maximum temperatures in various regions of Washington."

Although without current scientific support for efficacy or safety the CDC cheers for fluoridation, admitting that "…it is not CDC's responsibility to determine what levels of fluoride in water are safe…."[48]

IV. BOH: THE WASHINGTON STATE BOARD OF HEALTH ERRED WHEN DENYING OUR RULE CHANGE PETITION REQUIRING FDA APPROVAL FOR FLUORIDATION.

If fluoride is not exempt from RCW 69.38.010 as a drug, then by definition (although not designation by the BOP) fluoride is a poison. In effect, the BOH is regulating the concentration of a poison or drug to public water. And the DOH and BOH are advising those who do add the fluoride poison/drug to public water. It seems reasonable for the Board of Health and Department of Health to admit that fluoridation is exempt from poison laws because it is being used as a drug with the intent to prevent dental disease.

The Board's June 14, 2010 formal notice of denial provided three primary reasons for denial.

Board Denial Reasoning #1. "The FDA maintains that it does not and will not regulate additives to tap water."

The Board bases the FDA's position on a phone call by the EHC representative to the FDA (probably not the CDER) and failed to use the correct terms with the FDA or ask the questions in writing or receive the response in writing. Thus, there is no way the public can insure that the correct questions were asked or that the answers pertain to the issue at hand. The FDA is correct that it does not regulate additives, but the FDA does regulate drugs. The difference between poison and drug is "intent of use."

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[48] http://www.cdc.gov/fluoridation/safety.htm

The Board's first step should be to determine the intent of fluoridation. However, the Board has not "taken a formal position. . ." and is "not in possession of any records related to the Board's purpose and intent. . . ."[49] Without knowing why they are doing what they are doing, the Board is floundering in lack of specificity and receiving wrong answers for wrong questions and not protecting the health of the public. Did the Board actually talk to someone at the Center for Drug Evaluation and Research and explain the intent of fluoridation? There is no written record.

The Board is flawed in their understanding of the terms "additive," "drug," and "FDA New Drug Approval" and the misbranding of the drug may have resulted in an incorrect verbal comment from the FDA.

Additive: The EHC said that the EPA and not the FDA regulates additives to water. Federal law says the,

> "SDWA authorizes the United States Environmental Protection Agency (US EPA) to set national health-based standards for drinking water to protect against both naturally-occurring and man-made contaminants that may be found in drinking water. US EPA, states, and water systems then work together to make sure that these standards are met."[50]

Maximum Contaminant Level Standards (MCL) are not desirable targets for addition of contaminants, but maximum amounts of naturally occurring contaminants. The intentional addition of contaminants to water with the intent to treat humans is prohibited by the SDWA.[51]

For example, the assessment of the efficacy of a disinfectant additive to water is to test the pathogens in the water. Chlorine disinfects water and is regulated by the EPA.

The assessment of the efficacy of a drug added to water is to test the prevalence and/or incidence of the disease in humans. The intent of fluoridation is to allegedly prevent dental disease and based on intent to prevent disease is regulated by the FDA.

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[49] See Appendix 5 WBOH Public Information Disclosure Request #1 Intent of Use.
[50] http://water.epa.gov/lawsregs/guidance/sdwa/basicinformation.cfm
[51] 42 USC 300g-1(b)(11)

Drugs: Fluoride is added with the intent to affect people, not water, and based on intent of use, fluoride is defined by laws as a drug.[52]

> RCW 69.41.010(9) "Drug" means . . . (b) Substances intended for use in the . . . prevention of disease in human beings. . ."
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> The Washington Board of Pharmacy confirmed, "Fluoride is a legend drug regulated under chapter 69.41 RCW."[53]
>
> "RCW 69.41.030 Sale, delivery, or possession of legend drug without prescription or order prohibited."
>
> "The Department of Health supports water fluoridation as a sound population-based public health measure. . . ." [54]

Simply being in possession of fluoridated water is a violation of RCW 69.41.030.

The lack of determining the intent of fluoridation prevents government regulatory agencies from protecting the health of the public by using incorrect terms and laws. Determining intent will start the process of "Who has jurisdiction over the substance?" "At what concentration is it effective and contribute to risks?"

Board Denial Reasoning #2. "Requiring water suppliers to use only FDA-approved additives and operate only within FDA-approved concentrations for fluoride would effectively rule out water fluoridation in Washington."

There is no problem with the FDA ruling out what the EPA also prohibits. The EPA and the FDA are consistent. The BOH should focus first on obeying the law and not on giving its blessing to fluoridation in spite of the law. Other, safer and more effective methods are available for reducing dental caries.

Again, the Board uses the term "additives;" however, the FDA does not regulate additives to water. Water suppliers should apply to the FDA CDER for approval of any drug added to public water systems.

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[52] http://www.fda.gov/AboutFDA/CentersOffices/CDER/default.htm
[53] 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*. http://washingtonsafewater.com/wp-content/uploads/wa-board-of-pharmacy-6-4-2009-response-to-5-7-2009-osmunson-letter-re-fluoride-as-poison.pdf.
[54] http://www.doh.wa.gov/cfh/oralhealth/docs/fluoride/cwfsupport.pdf

The reasoning by the Board of Health underscores the intent and urgency of our petition. If fluoridation as practiced is so unsafe that the FDA CDER oversight authority would not approve the practice, then the practice needs to be changed or stopped. Rather than protect the public, the Board protects the status quo.

The Board's position relying on the CDC and EPA, neither permitted by law from regulating drugs, leaves fluoridation without adequate oversight or authorized regulation. This situation is similar to the recent lack of oversight of the financial industry, BP oil spill and recent salmonella outbreaks. We do not give our consent to be fluoridated. Even in the exercise of police powers, FDA CDER approval for fluoride to be used as a drug is required.[55]

FDA approval might necessitate adjusting concentration levels and probably would require an appropriate label of warning or the FDA might find fluoridation is not effective and not safe. Rather than run the risk of having to require water systems to adjust concentration or warn patients to limit water intake, or stop a practice which the FDA determines is not safe or effective, the Board denied our petition.

For those wanting fluoride, fluoride can be ingested from many other sources such as fluoride chewing gum, toothpaste, certain foods, pesticides, post-harvest fumigants, medical and dental products, prescription at the pharmacy and soil.

Board Denial Reasoning #3. "Since the Board cannot compel a federal agency to act and it cannot adopt rules that countermand state statutes, it has no authority to consider the rule changes you have requested."

Our petition for rule making does not ask the Board to direct or compel the FDA or any other federal agency to take any unauthorized action. Our petition simply asks the BOH to require manufacturers of fluoridated water to make application for FDA CDER approval for their drug, just as all drug manufactures are required to do. Regulatory compliance does protect the public.

For example, a city passing an ordinance to build a new city hall does not thereby nullify building codes requiring contractors, engineers, and architects be licensed or approved materials be used. Building codes

[55] John Doe #1, et al, Plaintiffs, v. Donald H. Rumsfeld, et al Defendants. Civil Action No. 03-707 (EGS) US District Court for DC. 2003 US Dist. Lexis 22990 Decided December 2003.

requiring approved materials and requirements that professionals be licensed do protect the public.

The use of police powers to administer drugs does not exempt water district drug manufacturers from obeying other general drug approval or administering laws.[56]

V. ADDITIONAL BOARD REASONS FOR DENIAL

There are additional reasons for denial which were not stated in the formal notice but which appear in the Environmental Health Committee (EHC) report. Perhaps the Board understood that these additional reasons are flawed and lack factual support and therefore did not include them in the formal notice. However, the Board's vote followed the EHC's presentation and was based on the EHC's recommendations, with almost no discussion among Board members implying complete acceptance, while a rebuttal of the facts from the public in attendance was not allowed.

EHC Additional Denial Reasoning #1. The State Board of Pharmacy has stated it cannot regulate tap water fluoridation under its authority.

Our petition did not ask the Board of Pharmacy for approval or rule change. The significance of the Washington State Board of Pharmacy (BOP) letter to our petition is that the BOP confirmed that fluoride when used to prevent caries is a legend (prescription) drug. A legend drug is a substance which has greater risk for abuse or toxicity and requires a legal intermediary, a doctor.

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

This is an incorrect statement.[57] Washington Action for Safe Water issued a Public Information Disclosure Request to the Board of Health (Exhibit 5 Question 5), asking the Board to point out any statement from the 2006 NRC report which concluded that "fluoride levels in drinking water below 2 ppm are safe for health." The Board failed to provide any such statement because the more than 500 page NRC report did not make such a statement of safety.

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[56] Ibid.
[57] See Appendix M

The NRC committee found pathology and risk of damage at levels below 1 ppm. The NRC Committee was unanimous that 4 ppm was not protective—in other words, did not provide a margin of safety for everyone—but was not allowed to make a determination of safety. The NRC Committee was forbidden to evaluate the addition of fluoride to water, a concept consistent with the SDWA which prohibits such action.

EHC Additional Denial Reasoning #3. EPA announced completion of a review of MCLs in the Federal Register in March 2010 that concluded it did not have evidence to revise the MCL for fluoride.

EPA will be conducting additional reviews regarding fluoride levels in drinking water.

Again, the Board of Health is relying on erroneous information. The SDWA, which regulates the EPA and limits what it can do, states at 42 USC 300g-1(b)(11):

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

The EPA is planning to conduct reviews of naturally occurring calcium fluoride which would look into whether it should be removing naturally occurring fluoride from drinking water if it exceeds 4 ppm or whether EPA should lower this threshold. However, the EPA will not be conducting any reviews regarding adding fluoride to water for health care purposes because, by law, the EPA is not allowed to do so. The Board is expecting the EPA to do what the EPA is prohibited from doing.

Adding fluoride to water, formulating the fluoridated water drug, with the intent to prevent disease, falls under the jurisdiction of the FDA as a drug and prohibited by the SDWA. The Board of Health is flawed in its belief that the EPA has jurisdiction which it is forbidden to.

EHC Additional Denial Reasoning #4.

> "EPA recognizes NSF/ANSI Standard 60 as appropriate for the approval of drinking water additives."

NSF/ANSI does not evaluate the safety or efficacy of products added to water. NSF/ANSI evaluates the concentration of contaminants within the product and not the product itself.[58]

The Board is flawed in relying on NSF/ANSI, a private company, to regulate or determine something they do not regulate or determine.

Thank you for taking the time to seriously consider our petition. We would appreciate your referring this matter to the Attorney General for his interpretation of the relevant law.

Sincerely,

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[58] See Appendix F