



Complaint Form

Today's Date: October 30, 2008

1. Your Information

Name: Bill Osmunson DDS, MPH
Address: 1418 – 112th Ave NE Suite 200
City: Bellevue State: WA Zip: 98004
Phone: Work (425.455.2424) – Home (425.466.0100)

2. Information about the Facility or Health Care Professional

Type of facility or profession:

There are 163 water systems in Washington State prescribing, dispensing, selling, possessing and/or administering fluoridation substances, such as hexafluorosilicic acid, hydrofluosilicic acid, silicofluoride, or sodium fluoride, in public water systems without a health care practitioner's license (Appendix A).

Address: Appendix A

3. Resident/Guest/Patient Information

Full name (if different from above)
All Residents, Guests, and Patients in Washington State
Date of incident:
Started 1978 and continues

4. Please describe your complaint in the space below. Include the name, title and phone number of other patients, witnesses or staff members involved in the incident.

COMPLAINT TO THE WASHINGTON STATE BOARD OF PHARMACY

COMPLAINT. The Washington State Board of Pharmacy (Board) has not designated, as stipulated by law, highly toxic fluoride substances as poisons. As poisons, the Board may exempt fluoridation substances as FDA-approved legend drugs. If the Board determines fluoridation substances are legend drugs, the Board must limit the prescribing, selling, possessing, dispensing and administering of fluoridation legend

drugs to licensed practitioners. If the fluoridation substances are determined to be unapproved drugs and/or not legend drugs, the Board must clarify the matter and recommend within its authority that poisoning public water cease.

REQUEST #1. This complaint requests that the Board of Pharmacy (under **RCW 69.38.010 (4)**) designate fluoride and fluoridation substances as poisons and determine possible exemption under (**RCW 69.38.020 and 69.41**) as legend drugs.

REQUEST #2. This complaint is also submitted under (**RCW 18.130.190**) "Practice without license"¹ against those public water systems listed in Appendix A and their individual board members who are prescribing, dispensing, selling, possessing, and/or administering fluoridation substances, such as hexafluorosilicic acid, hydrofluosilicic acid, silicofluoride, or sodium fluoride, in public water systems without a health care practitioner's license and requests the Board to require fluoridation substances be FDA approved and dispensed only as legend drugs.

IMMEDIATE AND IMMINENT HARM TO THE PUBLIC HEALTH

The addition of fluoride substances to water no longer appears to prevent dental decay (Appendix B), and total exposure, (dosage) is too high and increasing (Appendix C). Furthermore, it is causing and contributing to immediate and imminent harm, including but not limited to: moderate dental fluorosis, stage I skeletal fluorosis (arthritis with joint pain and stiffness), decreased thyroid function, and detrimental effects on the brain with especially high risk for infants and individuals with chemical sensitivities (Appendix D). For the protection of public health, this complaint requests immediate action by the Washington State Board of Pharmacy to ensure and enforce that the prescribing, formulating, dispensing, and administering of fluoridation substances be FDA approved and done only by licensed practitioners (**RCW 69.38.020**).

The theory of fluoridation is to add a fluoride substance to public water systems with the sole intent of mitigating dental decay. However, current studies show no benefit from fluoridation. The reality is that fluoridation substances are of immediate and imminent harm to public health. Fluoridation substances are defined by law as poisons (**RCW 69.38.010**). If the Board exempts fluoridation substances as FDA-approved legend drugs (**RCW 69.38.020**), then they must be prescribed, dispensed, and administered by a licensed practitioner. At present, the law is being violated by prescribing, dispensing, and administering:

- an unapproved drug with police powers
- without informed consent
- without recipients being patients of record
- without consideration of the dosage and current increased exposure
- without a licensed practitioner's order or prescription and supervision
- without a scientific or ethical review process by stakeholders
- without current evidence of effectiveness for dental decay reduction
- without regard for the known and undisputed dental and medical harms and risks of harm or empirical evidence of safety

- without consideration for sensitive individuals and subsets of the population, such as infants
- without the right of individual freedom to choose not to participate
- by unlicensed agencies rather than licensed practitioners
- as a contaminated industrial waste product
- as an unapproved drug
- without scientific monitoring of dosage and safety.

Recognizing the above violations to the ethical practice of medicine, the Board must take immediate action.

Email completed form to the Customer Service Center at HSQAComplaintIntake@doh.wa.gov, or fax to 360.236.4818, or mail to:
 Washington State Department of Health
 Health Systems Quality Assurance
 Complaint Intake
 P.O. Box 47857
 Olympia WA 98504-7857

Email Form Print Form
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For Department of Health use only

Reviewed for multiple authority applications: Date _____

Name _____

Routed to: Multi-authority coordinator: _____

date _____

Office _____

date _____

Office _____

date _____

Office _____

date _____

Please attach any supporting documentation and additional sheets if necessary.

I. FLUORIDE INGESTION FOR MITIGATION OF DENTAL DECAY IS A LEGEND DRUG.

A. Poison Defined:

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 fluoride is considered by some lethal for children² and 5 mg/Kg is considered lethal for adults. Unless the Board disputes these numbers and finds fluoride safe, fluoride would be considered by **RCW 69.38.010 (4)** a poison.

Based on my phone call to the Board’s Director, no substance has been designated by the Board as a poison (other than currently listed in law: arsenic, cyanide, strychnine,

and their preparations). The Legislature and Governor placed the authority on the Board of Pharmacy, and I am requesting the Board, as defined by law, to designate fluoridation substances as poisons because they will cause violent sickness or death in quantities far less than 60 grains.

B. Exemption:

*“RCW 69.38.020 Exemptions from chapter:
All substances regulated under chapters 15.58, (Agriculture) 17.21, (Pesticide) 69.04 (Intrastate commerce), 69.41, (Legend Drug) and 69.50 (Controlled Substances) RCW, and chapter 69.45 (Drug Samples) RCW are exempt from the provisions of this chapter.”*

Note: When used to mitigate dental decay, fluoride substances (such as hydrofluosilicic acid) are poisons, perhaps exempt as legend drugs when used for human consumption, 69.41. The Drug Enforcement Administration (DEA) confirmed by phone that fluoride substances for fluoridation were not controlled substances (not habit forming like morphine), but fluoridation substances are regulated by individual states.

C. Placing Poisons into Water:

“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.”

Fluoridation is the willful placement of a known poison into an edible substance. If fluoridation substances are not exempt as FDA-approved legend drugs, then they are poisons.

D. Other Authorities:

RCW is consistent with other authorities (Congressional Hearings, EPA, FDA, Canadian National Association of Pharmacy, and International Agencies, etc.) defining fluoride as a poison and substances approved by the FDA dispensed as legend drugs.³

D. Supervision by a Licensed Practitioner:

Supervision is even more important when government agencies take away individual freedom with the use of police powers to medicate without consent and against the individual's recorded objections at the voting booth.

Without the supervision of any licensed practitioner, there is no accountability or responsibility to:

1. consider and determine total individual exposure of fluoride from all sources
2. evaluate current efficacy
3. evaluate risks, especially for infants and those individuals with sensitivities, side effects, compromised health, or complications
4. review synergistic reactions with other chemicals
5. review and report ethical concerns.

II. LEGAL GROUNDS FOR COMPLAINT

A. Use of Police Powers to Dispense an Unapproved Drug:

AGO 2008 No. 5 - March 27, 2008 The Attorney General's opinion held that "a local health district has the authority under RCW 70.05.060(3) to require a PUD to fluoridate its water supply to prevent dental decay."⁴

The AGO's opinion should be considered in context with *Doe v Rumsfeld*⁵ where the Court ruled even under emergency conditions of war the Government cannot force an individual to be medicated with a substance which has not been specifically approved for the purpose and manner it is intended. Fluoridation products are unapproved drugs.

No drug regulatory agency in the world, including the FDA, has approved any fluoridation substances for use in public water. The Washington State Board of Pharmacy Newsletter (July 2008) stated, "*Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.*" The only mass medicated drugs dispensed without prescription and administered under police powers by unapproved water districts are unapproved fluoride substances. According to the Board's Newsletter, this is illegal.

B. Judicial Finding of Fact has Determined Fluoridation Harmful:

The Board and Attorney General's office need to further consider *Jacobson v Massachusetts*, 197, US 11 (1905) p. 39, where the Supreme Court ruled the statute to require a smallpox vaccination could never be interpreted to compel a vaccination whenever it could be shown "with reasonable certainty" (fair preponderance of evidence or balance of probabilities) that application to any objecting citizen "*would seriously impair his health or probably cause his death*"⁶ In the case of fluoridation, there is reasonable certainty fluoridation is seriously impairing health and contributing to the death of some. The scientific evidence of harm from fluoridation has reached beyond the purely speculative state required by the Court.⁷

Hon. John Flaherty⁸ concluded from extensive expert testimony that there was a significant increase in cancer mortality in the fluoridated cities, and Judge Farris found upon a fair preponderance of the evidence that fluoridation "may cause or may contribute to the cause of cancer, genetic damage, intolerant reactions, and chronic toxicity." Since 1978 additional animal studies and epidemiological studies⁹ further support the risk of disease, harm, and lack of benefit from fluoridation (Appendix B).

- C. Prescribing, Dispensing, Administering, Selling, Delivering, and Possession of Unapproved Legend Drugs by Unlicensed Persons is Unlawful:

RCW 69.41.030 “(1) It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician” (osteopath, dentist, veterinarian, etc.).

For example, voters may approve the financing of a bridge, but the construction contractors must be appropriately licensed and qualified to build it. The voters expect the same lawful protection from any drugs, legend or not, by licensed individuals, doctors.

- D. Public Water Districts, Public Water Associations and Water Systems do NOT have Prescribing Authority:

In the case of fluoridation substances, if the courts were to reverse *Doe v Rumsfeld* and permit forced medication with unapproved drugs, the Board would still need to provide prescribing and supervision authority for public utility districts, water associations, and/or water systems.

- E. Federal Law:

The Attorney General and Board should also consider federal laws, such as unapproved new drugs (21 U.S.C. § 355), correct labels (21 U.S.C. §§ 352, 353), dispensing without a valid prescription (21 U.S.C. § 353(b)(1)), labeling requirements, dispensing requirements 21 U.S.C. §§ 331(d) and/or (a) that may be enjoined or prosecuted. See also 21 U.S.C. §332(a), 333(a).

- E. Aiding and Abetting Crimes:

The Washington Department of Health was asked under whose drug license the DOH dispenses fluoride compounds in water. The response was, “*The Washington State Department of Health (DOH) does not dispense fluoride. Rather, the DOH regulates water systems that choose to add fluoride to water.*”¹⁰ Clearly, no one at DOH wants to put their license on the line for the prescribing, dispensing, or administering such a hazardous substance. Advising or allowing someone to continue such criminal activity is unlawful.

IN SUMMARY:

Due to the imminent and immediate harm to public health and safety, the Board is requested to designate fluoridation substances as poisons, as required and defined by law. It is further requested that the Board recommend that FDA-approved fluoride legend drugs be administered only by licensed health care providers. Because fluoridation products are not FDA approved, the Board is responsible for stopping the unapproved prescribing, dispensing, and/or administering of fluoridation substances.

¹ "RCW 18.130.190

Practice without license — Investigation of complaints — Cease and desist orders — Injunctions — Penalties.

- (1) The secretary shall investigate complaints concerning practice by unlicensed persons of a profession or business for which a license is required by the chapters specified in RCW 18.130.040. In the investigation of the complaints, the secretary shall have the same authority as provided the secretary under RCW 18.130.050.
- (2) The secretary may issue a notice of intention to issue a cease and desist order to any person whom the secretary has reason to believe is engaged in the unlicensed practice of a profession or business for which a license is required by the chapters specified in RCW 18.130.040. The person to whom such notice is issued may request an adjudicative proceeding to contest the charges. The request for hearing must be filed within twenty days after service of the notice of intention to issue a cease and desist order. The failure to request a hearing constitutes a default, whereupon the secretary may enter a permanent cease and desist order, which may include a civil fine. All proceedings shall be conducted in accordance with chapter 34.05 RCW.
- (3) If the secretary makes a final determination that a person has engaged or is engaging in unlicensed practice, the secretary may issue a cease and desist order. In addition, the secretary may impose a civil fine in an amount not exceeding one thousand dollars for each day upon which the person engaged in unlicensed practice of a business or profession for which a license is required by one or more of the chapters specified in RCW 18.130.040. The proceeds of such fines shall be deposited to the health professions account.
- (4) If the secretary makes a written finding of fact that the public interest will be irreparably harmed by delay in issuing an order, the secretary may issue a temporary cease and desist order. The person receiving a temporary cease and desist order shall be provided an opportunity for a prompt hearing. The temporary cease and desist order shall remain in effect until further order of the secretary. The failure to request a prompt or regularly scheduled hearing constitutes a default, whereupon the secretary may enter a permanent cease and desist order, which may include a civil fine.
- (5) Neither the issuance of a cease and desist order nor payment of a civil fine shall relieve the person so practicing or operating a business without a license from criminal prosecution therefor, but the remedy of a cease and desist order or civil fine shall be in addition to any criminal liability. The cease and desist order is conclusive proof of unlicensed practice and may be enforced under RCW 7.21.060. This method of enforcement of the cease and desist order or civil fine may be used in addition to, or as an alternative to, any provisions for enforcement of agency orders set out in chapter 34.05 RCW.
- (6) The attorney general, a county prosecuting attorney, the secretary, a board, or any person may in accordance with the laws of this state governing injunctions, maintain an action in the name of this state to enjoin any person practicing a profession or business for which a license is required by the chapters specified in RCW 18.130.040 without a license from engaging in such practice or operating such business until the required license is secured. However, the injunction shall not relieve the person so practicing or operating a business without a license from criminal prosecution therefor, but the remedy by injunction shall be in addition to any criminal liability.
- (7)(a) Unlicensed practice of a profession or operating a business for which a license is required by the chapters specified in RCW 18.130.040, unless otherwise exempted by law, constitutes a gross misdemeanor for a single violation.
- (b) Each subsequent violation, whether alleged in the same or in subsequent prosecutions, is a class C felony punishable according to chapter 9A.20 RCW.
- (8) All fees, fines, forfeitures, and penalties collected or assessed by a court because of a violation of this section shall be remitted to the health professions account.

² "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."

³ 1. "Fluoride, when used in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal, is a drug that is subject to Food and Drug Administration (FDA) regulation." SOURCE: United States Food and Drug Administration letter Dec, 2000, to Congressman Kenneth Calvert, Chairman, Subcommittee on Energy and Environment, Committee on Science, Washington, D.C.

However, under the Safe Drinking Water Act, the FDA and EPA agreed the EPA would regulate public water, not the FDA. The Safe Drinking Water Act prohibits the EPA from adding chemicals to water for the treatment of humans. Neither the EPA nor FDA are responsible for adding fluoride to water, but the EPA is responsible for the maximum contaminant of fluoride in water.

2. Fluoride for ingestion is not sold over the counter and a prescription is required.
3. Labels on all fluoridated toothpastes have the words, "Drug Facts," "do not swallow" and non-fluoridated toothpastes do not have the words or warnings. Over the counter fluoride has warnings not to swallow.
4. Fluoride is not a nutrient. The absence of fluoride does not cause any disease. The absence of a nutrient results in a disease.

5. The (Canadian) National Association of Pharmacy Regulatory Authorities (www.napra.org) states that "fluoride and its salts" are considered a drug:

- Schedule I drug at doses greater than 1 mg requires a prescription.
- Schedule III drug at doses at or less than 1 mg per dose can only be bought at pharmacies.

7. Europe: The legal definition of a medicinal product in the European Union (Codified Pharmaceutical Directive 2004/27/EC, Article 1.2) is any substance or combination of substances "presented as having properties for treating or preventing disease in human beings" or "which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action." Furthermore, in 1983 a judge ruled that fluoridated water fell within the Medicines Act 1968, "Section 130 defines 'medicinal product' and I am satisfied that fluoride in whatever form it is ultimately purchased by the respondents falls within that definition." Source: Lord Jauncey. Opinion of Lord Jauncey in *causa Mrs Catherine McColl (A.P)* against Strathclyde Regional Council. The Court of Session, Edinburgh, 1983.

"If fluoride is a medicine, evidence on its effects should be subject to the standards of proof expected of drugs, including evidence from randomised trials." "There have been no randomised trials of water fluoridation." Source: Cheng KK, Chalmer I, Sheldon TA 2007 *British Medical Journal* October 6, 335: 699-702.

DEFINITIONS ... Drug: Any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.

⁴ <http://www.atq.wa.gov/opinion.aspx?id=19452>

⁵ Case regarding AVA, a non FDA approved anthrax drug. *Doe v. Rumsfield* 2003 U.S. Dist. LEXIS 22990

⁶ www.nap.edu/catalog/11571.html; Law reviews by Douglas Balog, *Fluoridation of Public Water Systems: Valid Exercise of State Police Power or Constitutional Violation?*, 14 *Pace Env'tl. L. Rev.* 645 (Pace University 1997) and J.R. Graham and Pierre Morin, *Highlights in North American Litigation During the Twentieth Century on Artificial Fluoridation of Public Water Supplies*, 14 *Jour. Land Use & Env'tl. L.* 195 (Florida State University 1999)

⁷ *Paduano v New York*, 257 N.Y.S. 2d 531 (S. Ct. N. Y. County 1965), and

⁸ Hon. John Flaherty, later Chief Justice of the Pennsylvania Supreme Court in *Paul Aitkenhead et al. v. Borough of West View* No. GD-4585-78 and Judge Farris in *Safe Water Foundation of Texas v. City of Houston*, No 80-52271

⁹ "Over the course of five months, the court held periodic hearings, which consisted of extensive expert testimony from as far as England. At issue was the most recent time-trend study of Dr. Burk and Dr. Yiamouyiannis which compared cancer mortality in ten cities which fluoridated their water systems with ten which did not fluoridate over a period of twenty-eight years from 1940 to 1968. The study concluded that there was a significant increase in cancer mortality in the fluoridated cities. -- Opinion, November 16, 1978, page 6". "- In proceedings before Judge Farris, Dr. Burk gave extended testimony on adjustments for age, race, and sex, including reference to both direct and indirect methods. His testimony on demographic adjustments appears in the trial transcript on pages 48-105 (January 13-14, 1982). His active attention to the question of demographic adjustments is reflected in a series of articles published in two sets. The first set, representing his earlier views, was published as Dean Burk and John Yiamouyiannis, *Fluoridation of Public Water Supplies and Cancer Death Rates*, 35 *Fed. Proc. Am. Soc. Biol. Chem.* 1707 (1976), and *Fluoridation and Cancer: Age-Dependence of Cancer Mortality Related to Artificial Fluoridation*, 10 *Fluoride* 123 (1977). The second set, representing his matured views, was published as Dean Burk and J. R. Graham, *Lord Jauncey and Justice Flaherty: Opposing Views on the Fluoridation-Cancer Link*, 17 *Fluoride* 63 (1984), and Dean Burk, J. R. Graham, and Pierre Morin, *A Current Restatement and Continuing Reappraisal Concerning Demographic Variables in American Time-Trend Studies on Water Fluoridation and Human Cancer*, 61 *Proc. Pa. Acad. Sci.* 138 (1988)." Major Health Issues Chapter VIII Judicial Findings.

¹⁰ Victor Colman, JD Senior Policy Advisor, Division of Community and Family Health, Office of the Assistant Secretary Washington State Department of Health, PO Box 47830, Olympia, WA 98504-7830, Tel: 360.236.3721 Cell: 360.561.3299 Fax: 360.664.4500

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