Dear Sirs,

Please add my comments here and four attachments to your review of fluoride in drinking water . Please note, many of the laws in the attached "Ethics" opinions are not referenced for Canada; however, similar laws exist in Canada. For example, some of the ethical codes, guidelines, bioethics and regulations applicable to Canada for human subject research are included here below and found at http://www.circare.org/CAindex.htm

Sincerely,

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17720 Jean Way #200
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Appendix A: Fluoride Ethics and the Law
Appendix B: Lack of Benefit
Appendix C: Exposure
Appendix D: Harm

Appendix A

FLUORIDATION CHEMICALS: ETHICS AND THE LAW

The right and obligation of public water systems to treat water to make water "safe, palatable and aesthetically acceptable"[1] is not disputed.[2]

A fundamental flaw in the opinion of proponents of fluoridation is the failure to recognize the difference between "additives" and "drugs." Without having a clear understanding of the intended use of the substances regulated, a house of cards has been built.

C. Artificially-Fluoridated Water Is An Illegal, Unapproved, Prescription Drug When Used To Prevent, Mitigate, Or Treat Dental Disease

Federal and state laws define a drug as a substance or article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease."[3]

1. A "legend" drug is commonly known as a prescription drug. 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*.'"[4,5]

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[1] This is part of an Amicus to the Supreme Court of Washington and references sometimes refer to the legal documents of this case. Brief of Respondents (8-20-07) at 7.

[2] See Supplemental Brief of Petitioners (6-1-09) at 6, Note 24.

[3] 21 U.S.C. 321(g)(1)(B) (Appendix **CITE** A-1 hereto) and RCW 69.41.010(9)(b) (Appendix **CITE A-2** hereto).

[4] State of Washington Department of Health Board of Pharmacy June 4, 2009 letter to Bill Osmunson DDS (Appendix **CITE** A-4 to A-8 hereto) at A-4; RCW 69.41.010(12) (Appendix **CITE** A-2 hereto) defines legend drugs; WAC 246-883-020(2) (Appendix **CITE** A-9 hereto) states legend drugs are listed in 2002 *Drug Topics Red Book* (relevant *Red Book* pages including page 342 that lists "Fluoride" are attached to the above-referenced Board letter (Appendix **CITE** A-5 to A-7 hereto). We request that this Court take judicial notice that fluoride is a legend drug.

[5] The above-referenced Board letter (Appendix **CITE** A-4 hereto) 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." This Court should note, the City is not a water district (Appellants' Clerk's Papers ("ACP") at 30, Para. 3.15) and may not fluoridate under RCW 57.08.012.

2. Fluoridated water, a mixture of water and silicofluoride, hydrofluorosilicic acid, or rarely sodium fluoride is an unapproved prescription drug.[6] In response to an email request, the FDA sent this response to Bill Osmunson:

> "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. . . ."[7]

3. The FDA has rejected applications for the ingestion of fluoride supplement on the basis that "there is no substantial evidence of drug effectiveness as prescribed, recommended, or suggested in labeling."[8] Health Canada states:

4. The Washington State Board of Pharmacy warn,

> "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." [9]

5. A prescription drug not approved by the FDA as safe and effective for its intended use (pursuant to 21 U.S.C. 355(d)) is generally improperly provided unless there

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[6] We request that this Court take judicial notice that fluoridated water is supplied to mitigate and prevent dental decay. Kaul v. Chehalis, 45 Wn.2d 616, 620, 277 P.2d 352 (1954); Respondent's Clerks Papers at 132 et seq. We request that this Court also take judicial notice that sodium fluoride, sodium fluorosilicate, and fluorosilicic acid (this latter substance is used by the City of Port Angeles) are the commonly used active ingredients in water fluoridation. (Appendix **CITE** A-16 hereto). This Court 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. This Court 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 We request that this Court take judicial notice that water fluoridated by addition of any of these active ingredients is not an "approved" drug for ingestion for the prevention or mitigation of dental decay.

[7] Email from the FDA (7-22-09) (Appendix **CITE** A-10 hereto).

[8] Drug Therapy June 1975 (Appendix **CITE** A-11 hereto).

[9] Compliance News, July 2008 Washington State Board of Pharmacy News Letter at 3 on line at http://www.doh.wa.gov/hsqa/professions/pharmacy/documents/July2008.pdf
(Appendix CITE A-12 to A-15 hereto at A-13 and A-14).

is informed consent.[10] In **Doe v. Rumsfeld** the US Supreme Court expressed a fundamental principle stemming from the First, Fourth, Fifth, Ninth, and Fourteenth Amendments to the Constitution, and from the common law, of the right to "**bodily integrity and the importance of complying with legal requirements**" which is the basis for requiring **informed consent**.[11] For military applications only, the requirement that there be informed consent may be avoided by Presidential waiver.[12]

> "The Court is persuaded that the right to bodily integrity and the importance of complying with legal requirements, even in the face of requirements that may potentially be inconvenient or burdensome, are among the highest public policy concerns one could articulate."[13]

Doe v. Rumsfeld involved the use of **Anthrax Vaccine Adsorbed ("AVA")** to vaccinate soldiers against inhaled anthrax.[14] The similarities and differences between AVA vaccination at the time of Doe v. Rumsfeld and fluoridated water are informative: **Both** have the intent to prevent disease. **Both** are **unapproved by the FDA for the intended use**. AVA is manufactured under FDA and state drug **Good Manufacturing Principles, laws and regulations**, while fluoridated water is not. AVA is dispensed by a pharmacy, while fluoridated water is dispensed primarily by fertilizer companies as unfiltered smokestack scrubber liquor.. AVA is **prescribed and administered by a licensed practitioner**, while fluoridated water is not. AVA has gone through strict **evaluation for safety, efficacy, pharmacokinetics, dosage, purity**, and much more, while fluoridated water has not. AVA is **approved for the treatment of specific diseases**, while fluoridated water has not been approved by the FDA for treatment of any disease.

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[10] RCW 7.70.050; McKee v. American Home Products, 113 Wn.2d 701, 711-12, 782 P.2d 1045 (1989).
[11] Id.; In re Colyer, 99 Wn.2d 114, 119-21, 660 P.2d 738 (1983).
[12] Doe v. Rumsfeld, 297 F.Supp.2d 119, 134 (D.C.C. 2003) ("Doe v. Rumsfeld").
[13] Id.
[14] Doe v. Rumsfeld at 122-24.

does not regulate drugs. **Div II failed first to determine the intent of adding fluoridation chemicals in order to determine which laws apply to the two initiatives**.[15]

3. Regarding City actions related to the City public water supply, the initiatives will stop the City from **violating Federal and Washington drug laws** and will stop the City from **manufacturing, formulating, marketing, prescribing, and administering unapproved drugs** in the form of fluoridated water to City residents **without their consent**, each action being an unlawful function.

4. The City **misbranded fluoridated water as a mere additive**, and the lower courts erred in accepting this misbranding. In misbranding the drug, the Division II Court of Appeals i**mproperly relied on the Safe Drinking Water Act for authority rather than the Food, Drug, and Cosmetics Act (FD&C Act)**. **Without the constraints of the FDA drug approval process, the City could add any drug to City water and misbrand it a mere additive**.

5. The Court of Appeals states that the standard is "whether a plan has already been adopted 'by the legislative body [of the City] itself or some power superior to it.'"[16] However, there is no plan adopted either by the City or by the state of Washington that allows or regulates the use of public water systems serving the City to deliver drugs. The two initiatives either prohibit delivery of any drug in any public water system serving the City or allow such delivery if there is FDA approval of the drug and the conditions of the initiative are met.[17]

6. The Court of Appeals states: "a local initiative can only create new law that is not inconsistent with or inapposite to state and federal law."[18] While the two initiatives set more protective water standards, they are fully consistent with Federal and Washington drug laws. The

[15] Id.
[16] Id. at A-8.
[17] Id. at A-18 to A-19 (OWOC Initiative) and at A-16 to A-17 (POW Initiative).
[18] Id. at A-9.

lawful operation of a city public water system is within the authority of the local legislative body, but RCW 35A.11.020 does not exempt a city from Washington and Federal drug laws.

E. Authority To Fluoridate: Police Power When "Not In Conflict With General Law"

At least three entities in Washington operate water systems.

1. Water districts may medicate people with fluoride by authority of statute. RCW 57.08.012, however, the statute does not exempt water districts from complying with the FD&C Act or general Washington statutes governing drugs. Statutes do not give authority to water districts to medicate people with any other [delete "other" other than what?] drug added to their public water supplies.

2. The Attorney General has issued his opinion that Public Utility Districts do not have authority to medicate people with any drug in their public water supplies.[19] Such AGO opinions are regarded as binding on state and local governments. [Is this a true statement?]

3. Nor can cities rely on any specific statute which authorizes water fluoridation. So the Supreme Court in Kaul at 621, relied on police power to justify fluoridation by a city. Article XI, Sec 11 of the Washington State Constitution allows the city to "enforce within its limits all such local police, sanitary and other regulations as are not in conflict with general laws." Initiatives to prohibit supplying any drugs in any public water systems citywide or to prohibit supplying drugs in any public water systems citywide unless there is FDA approval are not in conflict with Federal or Washington drug laws.

V. FLUORIDATION: IN CONFLICT WITH GENERAL LAWS

Fluoride is an element in nature, a substance, a contaminant, a pesticide, a post-harvest-fumigant, an over-the-counter drug, a legend (prescription) drug, a poison. It is used in

[19] AGO 2008 No. 5.

manufacturing many inorganic and organic compounds. Depending on its intended use, is regulated as a very powerful toxic substance, contaminant, toxic waste, or drug by the FDA, EPA, BOP, and other agencies.

A. Dispensing Legend (Prescription) Drugs Requires A Prescription

Fluoride and fluoridated water, like many other legend (prescription) drugs, are toxic poisons.[20] Substances that are otherwise poisons are exempt from Chapter 69.38 RCW (Poisons – sale and manufacturing) when used as legend drugs as defined in Chapter 69.41 (Legend drugs – prescription drugs).[21] Legend drugs require a prescription primarily due to their toxicity. When a court circumvents the protections provided by legend (prescription) drug laws and regulations, the public may be harmed, and the constitutional right of individuals to life and liberty may be violated.

B. General Legend (Prescription) Drug Statutes Apply To City Water Fluoridation And To The Dispensing Of Other Drugs Through The City Public Water Supply

> "Legend drugs shall not be sold, delivered, dispensed or administered except in accordance with this chapter." RCW 69.41.020 (preamble).
>
> "It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician [or other authorized provider]." RCW 69.41.030(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." RCW 69.41.040(1).
>
> "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).

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[20] http://www.ncbi.nlm.nih.gov/pubmed/8259189

[21] RCW 69.38.020.

A legend (prescription) drug 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.

A City is not licensed to prescribe drugs and for the City to manufacture, prescribe, dispense, or administer legend drugs in conflict with the legend drug statutes is *ultra vires*.

The City has failed to label the legend (prescription) drug "fluoridated water" with the name of the authorized prescriber, to provide directions for use, to give warnings of adverse reactions especially by certain vulnerable populations, to specify the patient for whom this drug is prescribed, or to specify the date range for its use or the amount to be consumed. Any other legend drug introduced into public water supplies would have to meet these same requirements. The two initiatives propose either that the addition of drugs to City water be prohibited or prohibited unless they are dispensed as approved by the FDA and meet certain other requirements.

VI. THE SAFE DRINKING WATER ACT ADDRESSES CLEAN-UP OF NATURAL CONTAMINANTS IN PUBLIC WATER SUPPLIES AND DOES NOT REGULATE UNRELATED ADDITIVES OR DRUGS

A. The Safe Drinking Water Act Prohibits EPA From Requiring Addition Of Drugs, Including Fluoride, In Drinking Water

The Safe Drinking Water Act prohibits the EPA from requiring addition of drugs to drinking water: "No national primary drinking water regulation may require the additional of any substance for preventive health care purposes."[22]

[22] 42 U.S.C. 300g-1(b)(11).

B. The Safe Drinking Water Act Sets Drinking Water Standards To Trigger Clean-Up Of Natural Contaminants In Public Water Supplies But Does Not Authorize Addition Of Drugs To Drinking Water

The Safe Drinking Water Act regulates existing levels of contaminants in public water supplies.[23] It sets a maximum contaminant level ("MCL") based on the health risk reduction to be achieved tempered by a realistic assessment of the cost of removing or treating that contaminant.[24] The Safe Drinking Water Act also sets maximum contaminant level goals ("MCLG") based solely on health and safety regardless of the cost of removing or treating contaminants.[25]

The Safe Drinking Water Act does not deal with the concept of adding contaminants to public water supplies except to treat water to make it safe.[26] One should not add a contaminant if doing so would cause the MCLG to be exceeded and would threaten health. Adhering to the MCLG is the intent of Section 3(B) of the POW Initiative.[27] This is significant because 43% of fluoridation products tested by NSF (a non-government certifying agency to which the EPA off-loaded some of its regulatory duties) contain arsenic[28] and thus cause treated water to exceed the MCLG for arsenic which is zero.[29]

D. EPA Union Scientists Oppose Fluoridation

[23] 42 U.S.C. 300g-1
[24] 42 U.S.C. 300g-1(b)(3)(C).
[25] 42 U.S.C. 300g-1(b)(4)(A).
[26] Fluoride in Drinking Water, National Research Council (2006) (Appendix **CITE** A-26 hereto).
[27] Petition at A-17.
[28] http://www.nsf.org/business/water_distribution/pdf/NSF_Fact_Sheet.pdf (Appendix **CITE** A-18 and A-19 hereto).
[29] http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-22/w1668.htm (Appendix A-24 hereto).

The EPA scientists who do the actual research, as opposed to political appointees, are firmly opposed to water fluoridation:

> "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."[30]

VII. THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) APPROVES THE MARKETING AND DISPENSING OF DRUGS AND NO NEW DRUG APPLICATION HAS BEEN APPROVED FOR THE INGESTION OF FLUORIDE TO PREVENT DISEASE

[I reordered this section] When the intent is to prevent human disease, it is the FDA – not the EPA[31] – which approves drugs for marketing regardless of the method of dispensing the drug or the drug's concentration.[32] The FDA's "New Drug Application" is extensive, protective of health, and reasonable. An NDA is not required just for "new" drugs but for all drugs in use for which an NDA has not previously been submitted

> "The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions: Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks. Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain. Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity."[33]

Fluoride for ingestion with intent to prevent disease, although unapproved by the FDA in any "New Drug Application,"[34] is sold in two places; in pharmacies as a prescription "Legend Drug"[35] [what are you referring to? Fluoride pills?] and *en masse* in fluoridated water.

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[30] Dr. J. William Hirzy, Senior Vice-President, Headquarters Union, US Environmental Protection Agency, March 26, 2001 (Appendix **CITE** A-32 hereto).
[31] 42 USC Sec. 300g-1(b)(11)
[32] FDA response to Honorable Ken Calvert, Chairman Subcommittee on Energy and Environment Committee on Science, House of Representatives, Dec 21, 2000 at 1 (Appendix **CITE** A-34 hereto).
[33] FDA New Drug Application, Introduction (Appendix **CITE** A-37 hereto).
[34] Id. at 2 (Appendix **CITE** A-35 hereto).
[35] RCW 69.41.010 (12).

The City has not provided necessary evidence for FDA approval such as bioavailability, content of chemistry, manufacturing, controls, microbiology, clinical and statistical, stability of drug and biologics, analytical data on variability, impurities, pharmacokinetics, toxicology, pharmacology, effectiveness, laws, regulations, policies and procedures.[36]

The City is correct when it says that "the FDA does not regulate additives to drinking water,"[37] however, the City adds fluoride not as an additive to make water safer but for "preventive health care purposes unrelated to contamination of drinking water."[38] This is the jurisdiction of the FDA.[39]

VIII. INDIVIDUAL CONSENT AND HUMAN SUBJECT RESEARCH

Unless outweighed by overriding state interest, a person (or his/her representative) has the right to choose one medical treatment over another or even to refuse medical treatment altogether.[40] This personal right involves both a constitutional privacy right and a common law right to be free from bodily invasion.[41]

For the City to fluoridate its water is tantamount to saying that some people's rights can be ignored because the City knows better than they what is good for them." Crucial to the case is this issue: Who defines one's own personal health requirements, the individual or the state?

Without drug approval by the FDA or any national drug regulatory authority and without one singe randomized controlled trial of fluoridation, the act of mass medicating everyone without their consent must be called an experiment, research, or study and the cohorts given the right of consent and the right to refuse participation in the experiment. And if a convincing

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[36] FDA New Drug Application, Introduction (Appendix **CITE** A-38 to A-40 hereto).
[37] Brief of Respondent at 10, Note 15.
[38] 42 U.S.C. Sec 300g-1(b)(11) Safe Drinking Water Act
[39] Appendix **CITE** A-34 hereto.
[40] In re Ingram, 102 Wn.2d 827, 836, 689 P.2d 1363 (1984).
[41] Id.

argument can be made that fluoridation is a drug, then the patient must be given the right to be treated by a licensed practitioner.

After WWII, the Nuremburg trials included what is called the "Doctor's Trial". 20 physicians and administrators were convicted for crimes. The US Public Health Service funded the infamous syphilis study of several hundred black men, observing the course of the disease for decades after a cure was found. From these and other tragedies of governments and scientists "gone mad" violating the subjects freedom of choice, human rights recommendations have been formulated, restated, and expanded in many international, national, University opinions, AMA, American Hospital Association Patient Bill of Rights, 1973, and policies of human rights and the rights of patients in experiments and observational studies. The foundation of the more than 20 such reports is the fundamental principal of the individual person's right to informed legal consent.

Regardless of whether the reader considers fluoride to be an experiment or preventive therapy, fluoridation violates the most fundamental principles of human rights.

Science is not stagnant and the practice of medicine must constantly be evaluated. Fluoridation is highly controversial. It is an experiment which would almost certainly not be approved by any research ethics board. If water were fluoridated as part of a research experiment, the City would at least keep track of the efficacy and safety of the drug added, but it does neither.

For the protection of human subjects in research, federal regulations such as 45 CFR 46.116 and Washington policies[42] require the consent of subjects:

> "Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's

[42] See e.g. University of Washington Human Subjects Manual (Appendix **CITE** A-41 hereto).

> legally authorized representative. An investigator shall seek such consent only under circumstances that 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" [43]

Thus Federal and Washington regulations provide that the voluntary consent of a subject be obtained before the subject ingests a prescription drug, that the subject should have legal capacity to consent or be legally represented, and that it is the duty of the individual who initiates the experiment to ascertain the quality of the consent. City water fluoridation is an irresponsible experiment which violates all these ethical guidelines.

X. WATER FLUORIDATION BY **THE CITY IS ULTRA VIRES**

Adding substances to make water "safe, palatable or aesthetically acceptable;"[44] is an administrative action, but dispensing legend drugs without a prescription from a licensed medical practitioner is outside the authority of the City and therefore ultra vires.

> The Human Subjects Review Committee of the University of Washington has set up good guidelines, which generally have been ignored by public health agencies and officials. However, the guidelines apply to the fluoridation experiment. *"Human subjects asked to contribute their time and effort to research should consent to do so freely. The consent should be given only after the subject understands what he or she is consenting to, and any risks that may be involved. Subjects should be assured that there will be no penalties for declining to participate, and that they are free to withdraw from the research at any time after they have given their initial consent."* See also http://www.fluoridealert.org/health/brain/#human.

[43] 45 CFR 46.116.
[44] Brief of Respondent p 7

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Appendix B

LACK OF FLUORIDATION'S EFFECTIVENESS:

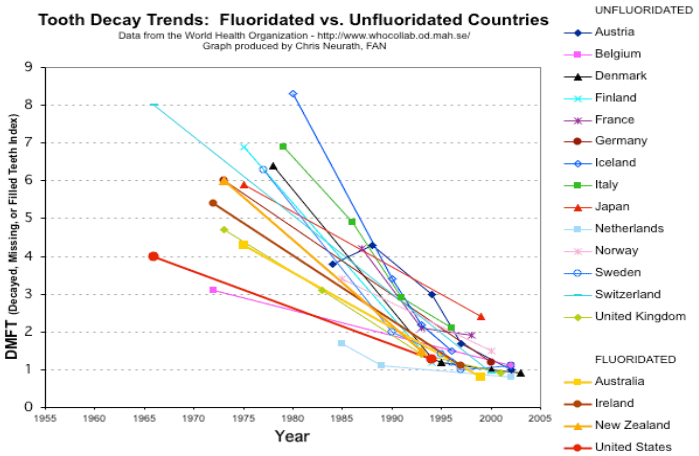
There is no government scientific department(s), or agency with oversight responsibility for the efficacy, safety, total exposure, or ethics of fluoridation. If we think the financial sector lacked government oversight and accountability, resulting in a current banking crisis, the scientific side of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

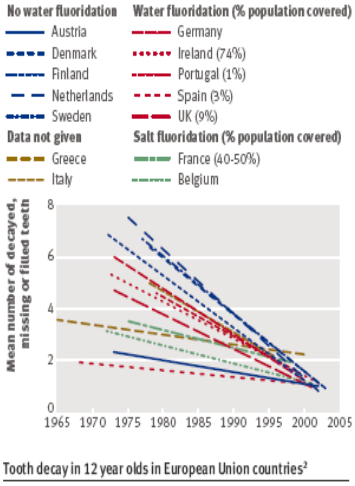
1. Current scientific literature is generally finding little or no effectiveness from fluoridation. tuie fndngbenefit are frequently historical and flawed for lack of controlling confounding factors and basic statistics. The NIH (NaioalInstitute of Health) and Surgeon General's report suggest efficacy estimates based on randomized controlled trials under ideal circumstances are best; however, no one disputes that in the case of fluoridation those types of studies would be difficult and have never been done. Therefore, a greater degree of caution and margin of safety must be used to protect public health than with most drugs.

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

2. After 60 years of fluoridation, we should be able to detect the effectiveness of fluoridation. Current effectiveness studies concur that there appears to be little or no detectable benefit from fluoridation. A rflcted in the two graphs below, regardless of fluoridation all developed countries have reduced dental decay to similar low levels. Therefore, suggestions that the ubiquitous halo effect benefits neighboring communities are flawe.

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

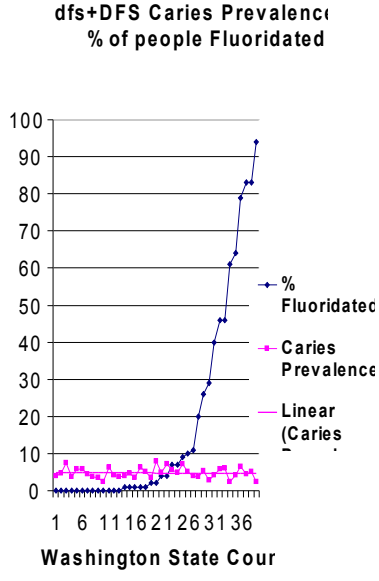


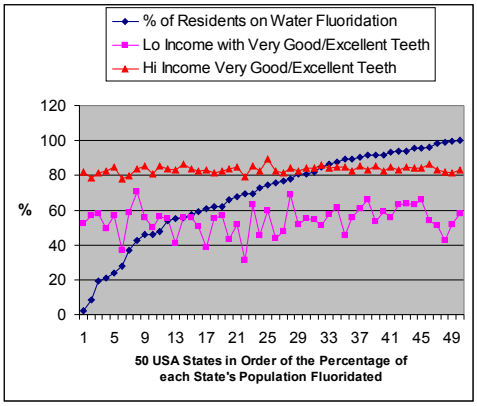


Graph A

Graph B

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





Graph C Graph D

4. Ranking 50 US states based on the percentage of residents receiving fluoridation (ascending line Graph D) and plotting the low income segment of the population reporting very good/excellent teeth (lower horizontal line Graph D) and the high income segment reporting very good to excellent teeth (upper horizontal line Graph D), finds about 53% of the poor and 82% of the wealthy have very good to excellent teeth regardless of fluoridation. A state could fluoridate zero or 100% of their population without change to decay incidence.

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

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

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

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

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

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

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

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

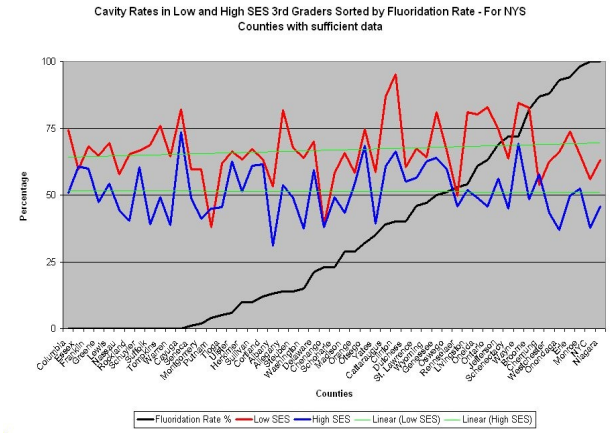
if it ever did.

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

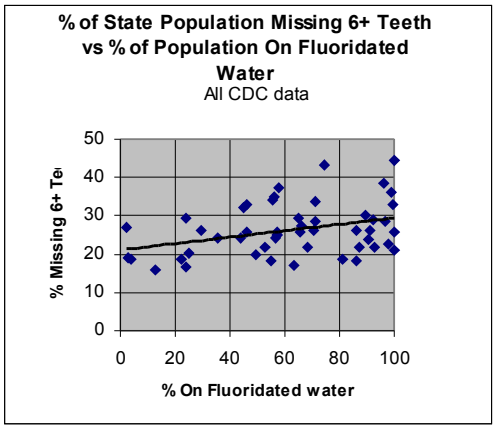
8. In some places the CDC, IOM (Institute of Medicine), and NRC (National Research Council) suggest potential benefits from fluoridation would be during the development of the tooth up to eight years of age. The level of fluoride in saliva is so minor as to have minimal effect on oral bacteria. Researchers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

9. Current epidemiological effectiveness comparisons etween Washington State with 59% of the population receiving fluoridated water and Oregon’s 19% ind Oregon having similar or better dental health with a third the percentage of population fluoridated (confounding factors similar or in Washington’s favor).

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



Graph E



Graph F

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

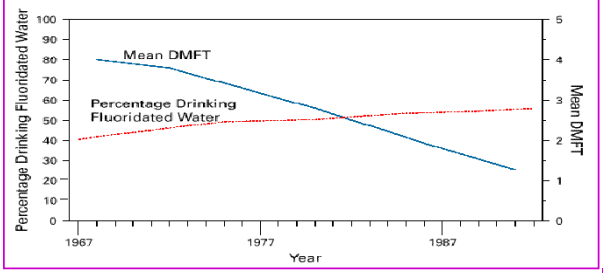
12. Proponents suggest “studies prove water fluoridation continues to be effective in reducing tooth decay by 20-40%” when in fact biostatisticians find the same studies show no significant benefit.

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

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

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

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



Sources:

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

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

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