Appendix B

Jurisdiction

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

Fluoride "is artificially added solely for the effect it has on the individual drinking the water."[1] It is added to "control dental caries" which is a "common disease."[2] Based on the argument presented, the Kaul Court concluded "that the city is not engaged in selling drugs, practicing medicine, dentistry, or pharmacy as defined by statute."[3] Today the relevant statutes have changed. This Court should interpret current general drug laws and find that the City is engaged in manufacturing and dispensing drugs by compounding a bulk fluoride legend drug obtained in interstate commerce with its local water supply to make a new legend drug, City fluoridated water, without meeting State Board of Pharmacy and FDA requirements.[4]

Fluoridation was started in the late 1940's and is therefore not grandfathered for efficacy. This letter from the FDA is pertinent to FDA approval.

"Regarding the prescription fluoride containing products--please note there are a number of drug products on the market today that contain ingredients that have an extended marketing history. These products may contain one or more active ingredients that were first introduced into the market before 1938 or 1962, and were not covered by a New Drug Application (NDA) when first marketed. These products are presently marketed based on their manufacturers' belief that they are not subject to the drug approval provisions of the Act because they are identical to

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[1] Kaul v Chehalis 45 Wn.2d 616, 618, 277 P.2d 352 (1954)
[2] Id.
[3] Id. at 625.
[4] Per chapter 69.41 RCW.

products originally marketed before new drug applications became a requirement for marketing. Such products are sometimes referred to as 'grandfathered.'

Although there are drug products marketed without approval on the basis of marketing before enactment of the 1938 and 1962 new drug requirements, FDA believes that it is unlikely that currently marketed products are grandfathered or otherwise not subject to the new drug requirements. The new drug grandfather provisions have been construed very narrowly by the courts and drug products on the market would not be entitled to grandfather status if they differed from the previous versions in some respect, such as formulation, dosage or strength, dosage form, route of administration, indications, or intended patient population.

The FDA discussed its policy with respect to marketed unapproved drugs in the Compliance Policy Guide that issued on June 8, 2006, (http://www.fda.gov/cder/guidance/6911fnl.htm <http://www.fda.gov/cder/guidance/6911fnl.htm>), entitled Marketed Unapproved Drugs - Compliance Policy Guide, Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs. Under the guidance, FDA is encouraging companies to comply with the drug approval process and seek approval for their products, as well as safeguarding consumer access to important medicines. Those manufacturers that do not comply with drug approval requirements may be subject to enforcement action. If a firm claims that its product is grandfathered, it is that firm's burden to prove that assertion. In light of the strict standards governing exceptions to the approval process, it would be prudent for firms marketing unapproved products to carefully assess whether their products meet these standards. As stated in the guidance, any product that is being marketed illegally is subject to FDA enforcement action at any time.

Upon review of the Food and Drug Administration's (FDA) drugs@fda site (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>), it identify one approved NDA fluoride product. Therefore, all other marketed fluoride products without an application are not approved FDA drugs. These products appear to be the ones that are presently marketed on the basis of the manufacturer's belief that the products are not subject to the new drug requirements because of its marketing history. Any company marketing products on this basis should have available documentation to demonstrate the market presence of the products prior to the enactment of the new drug requirements that were established in 1938 and 1962. The FDA does not recognize these drugs or any other drugs as grandfathered.

All drugs are subject to regulation by the FDA, whether approved or not. The Federal Food, Drug, and Cosmetic Act includes provisions to insure that marketed drugs are not adulterated or misbranded. It requires that all drugs be manufactured in establishments registered with and inspected by the FDA. Drugs are required to be manufactured in conformance with the good manufacturing practice requirements. The regulations also extend to the proper labeling of drugs. Products that do not meet these requirements are subject to regulatory action by the FDA.

We hope this information is helpful to you. If you have further questions, please contact our Division of Drug Information at 1-888-463-6332 or our direct line, 301-796-3400.

Sincerely,

Division of Drug Information LL
Center for Drug Evaluation and Research
Food and Drug Administration

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."

II. WATER DISTRICT FLUORIDATION AUTHORIZED AND AG OPINION

RCW 57.08.012

Fluoridation of water authorized.

> *"A water district by a majority vote of its board of commissioners may fluoridate the water supply system of the water district. The commissioners may cause the proposition of fluoridation of the water supply to be submitted to the electors of the water district at any general election or special election to be called for the purpose of voting on the proposition. The proposition must be approved by a majority of the electors voting on the proposition to become effective."*

I. The Washington State Attorney General has responded to two sets of questions regarding fluoridation.

"1. What is the responsibility of the Department of Health as to fluoridation of a public water supply in a specific community?

2. What action should be taken by the Washington State Board of Health when it receives information that the fluoridation of the water is being carried on or contemplated by a person, persons, firm, corporation, municipality or public utility operating a public water supply system?

The conclusions reached may be summarized as follows:

1. *Where a local public water supply system adopts or intends to adopt the fluoridation method of treating water, the Department of Health is responsible that the methods employed are not dangerous to the users of the water.*

2. The Washington State Board of Health should promulgate proper rules and regulations pertaining to fluoridation and should enforce such rules and regulations.

ANALYSIS

Section 1, chapter 116, Laws of 1901 [6001 Rem. Rev. Stat.] gives the Washington State Board of Health broad powers and duties as to the "preservation of the life and health of the people of the state."

Sections 290 and 291, chapter 249, Laws of 1909 [2542 and 2543 Rem. Rev. Stat.] and chapter 70, Laws of 1899 [9473, 9475, 9476 and 9477 Rem. Rev. Stat.] contain numerous provisions, both penal and otherwise, designed to insure the purity of water supplies.

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

The AGO places responsible to ensure fluoridation was/is not dangerous for users on the Washington State Department of Health.

When asked, “Under who’s DEA (Drug Enforcement Administration) license does the WSDH dispense fluoride compounds in water?” DOH responded February 2007**,**

”Our Environmental Health Division provided me with the following: 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.” And responded further, *“DOH will rely on known national entities like the CDC and EPA to assess the science regarding the use of fluoride in preventing tooth decay while limiting enamel fluorosis, and will modify its recommendations as warranted.”* [ii]

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

[ii] 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

III. THE SAFE DRINKING WATER ACT FORBIDS ENACTING REGULATIONS WHICH REQUIRE ADDING MEDICATION TO DRINKING WATER AND THIS RESTRICTION MAY FLOW DOWN TO THE STATES AND MUNICIPALITIES

The Centers for Disease Control (CDC) is the biggest proponent of drinking water fluoridation in the United States. See http://www.cdc.gov/fluoridation. The current surgeon general and many before him supported fluoridation. However, neither the CDC nor the Surgeon General has any jurisdiction over water fluoridation.

The Safe Water Drinking Act (SDWA) is administered by the EPA. Note that the SDWA specifically 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 only substances which the SDWA may require that states and municipalities add to their drinking water are those which remove contaminants. Substances for preventive health care may not be added. That would include drugs, medicine, and … fluoride.

It comes as a surprise to those studying this area of the law to learn that the SDWA, regulates only the removal of contaminants which naturally appear in water or which have been added through pollution. It does authorize adding chemicals but only those which remove contaminants.

Many think that because the SDWA has a 4 ppm maximum contaminant level (MCL) for fluoride, that the SDWA authorizes the insertion of fluoride up to a 4 ppm maximum. This is not so. The SDWA only requires removal of fluoride if it exceeds 4 ppm. The 2006 NRC Report at page 1, seen at Appendix D-35, clarifies this:

> In 1986, EPA established an MCLG and MCL for fluoride at a concentration of 4 milligrams per liter (mg/L) and an SMCL of 2 mg/L. These guidelines are restrictions on the total amount of fluoride allowed in drinking water. … EPA's drinking-water guidelines are not recommendations about adding fluoride to drinking water to protect the public from dental caries. … Instead, EPA's guidelines are maximum allowable concentrations in drinking water intended to prevent toxic or other adverse effects that could result from exposure to fluoride.

In each state there is a lead agency which is empowered to administer the SDWA, and in Washington that agency is the Department of Health. RCW 70.119A.080, RCW 43.21A.445. See Appendix D-36. As noted by the Court of Appeals in its Opinion at 7 (Petition for Review at A-7), the EPA has granted primacy to the state of Washington to implement the SDWA. 40 C.F.R. 42.10. In RCW 43.21A.445 several Washington agencies led by the Department of Health are "… authorized to participate fully in and are empowered to administer …" the SDWA.

Because the SDWA prohibits requiring "the addition of any substance for preventive health care purposes" and because the SDWA requires that state "… drinking water regulations" be "no less stringent than the national primary drinking water regulations," Washington regulations likewise must be so limited. Therefore, the Department and Board of Health may not authorize or require municipalities to add fluoride or any other medication intended for "preventive health care purposes."

This limitation on "the addition of any substance for preventive health care purposes" flows down to the states, but does it flow down further to municipalities? 40 C.F.R. 142.3 provides:

> "… [T]his part [40 C.F.R.. Part 142—National Primary Drinking Water Regulations Implementation] applies to each public water system in each State.

40 C.F.R. 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.

Using the wording of this federal regulation, it would appear that the Port Angeles city council enacted a "drinking water regulation" which requires "the addition of" a "substance for preventive health care purposes unrelated to contamination of drinking water," namely fluoride. If the limitations imposed by the SDWA do flow down to the City, then the City's decision to fluoridate was ultra vires, and for that reason too the electorate should have the right to vote on the two Initiatives in question – to reverse an ultra vires decision – which would make this issue legislative and not administrative.

On its face WAC 246-290-460 does not regulate the decision to fluoridate but only sets out procedures to follow if a municipality decides to fluoridate. Thus state regulations have not occupied the fluoridation field and, as well, say nothing about adding other medicines to public water supplies.

The US Food and Drug Administration (FDA) should have jurisdiction over fluoride added to drinking water, simply because fluoridated water meets the definition of a drug. The Food, Drug, and Cosmetics Act (FDCA) defines a drug as an article "… intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal. 21 U.S.C. 321 (g)(1)(B). Dental caries is a disease, and fluoride is added to water to prevent caries.

However, the FDA has chosen not to assert jurisdiction over fluoride scrubber liquor in its raw state nor over the fluoride-tap water mixture called fluoridated water. The FDA has asserted jurisdiction over toothpaste and mouthwash, which are not to be swallowed, and has asserted limited jurisdiction over fluoridated bottled water. But the FDA has not asserted jurisdiction over the fluoride tap water drug.

It was in 1974 that 42 USC 300g-1(b)(11) was added to the SDWA. See page 10 above. Recall that it specifically forbad the EPA from requiring "the addition to drinking water of any substance for preventive health care purposes unrelated to contamination of drinking water."

However, in 1979 the FDA and the EPA entered into an inter-agency treaty, a Memorandum of Understanding, numbered MOU 225-79-2001, in which the agencies agreed that the FDA would

> … control bottled drinking water and water, and substances in water, used in food and for food processing….

On the other hand, the EPA would

> "… take appropriate measures, under the SDWA and/or TSCA [Toxic Substances Control Act], and FIFRA [Federal Insecticide, Fungicide, and Rodenticide Act], to control direct additives to drinking water (which encompass <u>any substances purposely added to the water</u>), and indirect additives (which encompass any substance which might leach from paints, coatings or other materials as an incidental result of drinking water contact), and other substances. [emphasis added]

There were two problems with this deal. First, only Congress can change a federal statute. Agencies cannot cede their authority to each other. Second, the FDA was ceding to the EPA all its authority "to control direct additives to drinking water." However, the EPA had been prohibited in 1974 from creating any regulations which require adding any "substance for preventive health care purposes unrelated to contamination of drinking water." The FDA might theoretically have had the power to regulate medication of water, but it could not assign such power to the EPA. It was a role the EPA was barred from filling.

The net result was that the FDA was unwilling to regulate and the EPA was legally barred from regulating the addition of fluoride to drinking water, although the illegal treaty made it appear that the EPA could do so.

In 1985 the EPA assigned to a trade association known as NSC the EPA's authority to write regulations governing the addition of fluoride to drinking water. The EPA did not own the powers it assigned.

Who or what is NSF? A July 7, 2000, letter from Stan Hazan, then NSF general manager, to Rep. Ken Calvert:

> NSF involvement in the evaluation of drinking water chemicals, including fluoride-based chemicals, began in 1985, when the U.S. EPA granted an NSF-led consortium of stakeholders the responsibility to develop consensus, health-based, quality specifications for drinking water treatment chemicals and drinking water system components. [emphasis added]

NSF proceeded to construct the NSF Standard 60 rule. The "NSF 60" logo is stamped on every fluoride shipment bill of lading. The Hazen letter continues:

> "NSF 60 Drinking Water Treatment Chemicals – Health Effects" was initially adopted in December 1987, and was last revised in May 2000. The standard was developed using a consensus standards development process with representation of the major stakeholder interests, including product manufacturers [emphasis added]…. Id., Appendix D-47.

So the industries which produce fluosilicic acid are on the board which developed the standards that regulate fluosolicic acid.

Hazan's letter contains contradictory statements regarding testing of the fluoride product:

> The standard requires that the manufacturer of a product submitted for certification provide toxicological information, if available. NSF requires that manufacturers seeking certification to the standard submit this information as part of their formulation or ingredient supplier submission. … Emphasis added. Id., Appendix D-48.

Toxicological studies are to be provided by the fluoride manufacturers if such studies are available. Even if such studies are provided, the public is not allowed to read them:

> Individual test reports, as well as formulation information are protected by nondisclosure agreements with certification clients. Id., Appendix D-48.

NSF took over fluoride regulation from the EPA but NSF Standard 60 is a private document. To read it you must buy it for $325. http://www.techstreet.com/cgi-bin/results.

Most water departments do not even posses a copy the Standard 60 book. Nevertheless, WAC 246-290-220(3) requires water districts to conform to Standard 60.

The EPA lacked authority to regulate the addition of fluoride to drinking water, but the EPA set up the NSF, and NSF right away wrote Standard 60 and started regulating the addition of fluoride to drinking water.

Note that NSF follows the EPA 4 ppm Maximum Contaminant Level for fluoride:

> NSF has based its certification on the product use not exceeding the EPA's MCL [maximum contaminant level] for fluoride. …

NSF was using the EPA 4 ppm MCL for a purpose for which the EPA could not use it, that is for the addition of fluoride to drinking water. Maybe this shows that the people running NSF do not understand what the SDWA does not allow. Hazen continues:

> Contaminants in the finished drinking water are not permitted to exceed one-tenth of the EPA's regulated MCL (Maximum Contaminant Level) when the product is added to drinking water at its Maximum Use Level, unless it can be documented that a limited number of sources of the contaminant occur in drinking water. … Id., Appendix D-48.

This shows again that NSF does not follow its own rules. Instead of setting a .4 ppm MAL, maximum allowable level, which would be one-tenth of the EPA 4.0 ppm MCL, NSF sets a 1.2 ppm MAL and justifies it in this way:

> An MAL of greater than 10% of the MCL can be established by the certification body in limited cases if it can be reasonably documented that there are no other significant sources of the same contaminant, that together, would result in the finished drinking water contaminant concentration exceeding the MCL. Fluoride has an MAL of 1.2 mg / liter, which is 30% of the MCL. This is justified on the basis of the limited number of other potential sources of fluoride ion to drinking water. For example, water that naturally contains sufficient fluoride is not additionally fluoridated, and fluoride is seldom present in other additives. Id., Appendix D-52.

The justification given is that there are no other sources of fluoride that add to the 30 percent load. However, there are many other sources of fluoride besides the fluoride added to drinking water, the greatest being common fruits, grains, beverages, and toothpaste accidentally swallowed, especially by children under two. The Environmental Working Group notes, for example, that there is up to 900 ppm of fluoride in dried eggs and that one-third of all eggs are dried and then added to food products. See Appendix D-54. Grains are fumigated with sulfuryl fluoride to kill weevils, and the grain is fed to the chickens.

The February 2008 NSF Fact Sheet on Fluoridation Chemicals says:

> "The NSF Joint Committee … consists of … product manufacturing representatives. … Standard 60 … requires a toxicology review to determine that the product is safe at its maximum use level and to evaluate potential contaminations in the product. … A toxicology evaluation of test results is required to determine if any contaminant concentrations have the potential to cause adverse human health effects. … NSF also requires annual testing and toxicological evaluation …. The NSF standard requires … toxicological evaluation. …"

It is hard to prove something does not exist, but there is evidence that there are no toxicological studies. First, there are no toxicological studies of fluoride on the extensive NSF web site at www.NSF.org. Blake Stark is the person at NSF International now in charge of fielding questions regarding Standard 60. Call Blake at 734-769-5480 or email him at Stark@NSF.org and ask him if there are any toxicological studies. He will tell you there are none. A California deposition in which another NSF official, Stan Hazen, also admits that suppliers are not required to deliver toxicological studies.

Washington law, WAC 246-290-220(3), requires that

> any treatment chemicals with the exception of commercially retailed hypochlorite compounds such as Clorox, Purex, etc., added to water intended for potable use

must comply with ANSI/NSF Standard 60.

We are coming full circle now. Municipalities rely on the NSF for certification that the fluoride it buys is not harmful. By law, municipalities must conform to a sham law. Again, the electorate should have the right to vote against enforcement of a sham law, and this by definition makes this issue legislative and not administrative.

A October 28, 2008, letter from Gregg Grunenfelder of the Department of health to Eloise Kailin, Mr. Grunenfelder says:

> [W]e rely on national certification protocols to ensure the safety of water additives. Specifically, Washington Administrative Code 246-290-220(3), requires that: "Any treatment chemicals … must comply with ANSI/NSF Standard 60…. Since the fluoridation product being used by the city of Port Angeles is certified under NSF Standard 60, the city's use of this product is in compliance with state law.

What is fluosilicic acid? The February 2008 NSF Fact Sheet on Fluoridation Chemicals, describes this chemical:

> [F]luosilicic acid is produced by adding sulfuric acid to phosphate ore. This is typically done during the production of phosphate additives for agricultural fertilizers. … The most common contaminant detected in these products is arsenic …. The current MCL for arsenic is 10 ppb, the highest detection of arsenic from a fluoridation chemical was 0.6 ppb …. The third most common contaminant found is lead … with 0.6 ppb being the highest concentration detected [emphasis added].

However, the MCLG, the maximum contaminant level goal, for arsenic and lead are both zero. See 40 CFR 141.51, Appendix D-72. These chemicals are so nasty that there is no justification for adding any of them to drinking water. Fluoride is a little more toxic than lead, a little less toxic than arsenic. However, the MCL for lead is 15 ppb; the MCL for arsenic is 10 ppb; but the MCL for fluoride is 4,000 ppb, that is 4.0 ppm. See Appendix D-73, Clin Toxicology Commer Products. The Amici ask the Court to take judicial notice of this.

If there is any doubt regarding the bogus nature of NSF Standard 60 certification, read through the NSF documents again looking for any reference to the 2006 NRC Report. There is none. NSF standards are outdated, and Port Angeles is relying on a sham law that is also outdated.

Tudor Davies, former director of the Office of Science and Technology for the EPA stated in his April 2, 1998, letter to George Glasser, the following:

> In the United States, there are no Federal safety standards which are applicable to drinking water additives, including those intended for use in fluoridating water. In the past the EPA assisted the States and public water systems through the issuance of advisory opinions on acceptability of many additive chemicals. However, the Federal advisory program was terminated on October 4, 1988, and EPA assisted in establishment of voluntary product standards at NSF International (NSF) …. NSF Standard 60 … was developed by NSF by a consortium of representatives from utilities, government, manufacturers and the public health community. [emphasis added]

So this is how the shell game works. Most people naively assume that the EPA has jurisdiction over drinking water fluoridation through the SDWA. The EPA helped start NSF and gave it legitimacy. The NSF pretends to be authoritative, and pretends to have inherited its authority over fluoride from the EPA, and so people trust it when its fact sheet mentions health, safety, inspections, and toxicology. What is going on is that the NSF is pretending to do what the EPA by law is barred from doing, to authorize and regulate the addition of fluoride to water.

Water commissioners like Grunenfelder are deceived by the shell game. This is a different kind of shell game. In the old days there was a pea under one of the walnut shells. In this case, there is no pea under any of the shells.

No federal agency is empowered to write regulations which require that fluoride be added to drinking water, so we must ask if there is a Washington agency which does so. The

Department of Health is the lead agency for enforcement of the SDWA in Washington, but it is forbidden by the SDWA from writing a regulation requiring the addition to water of "any substance for preventive health care purposes unrelated to contamination of drinking water." See the page 10 above. Further, the Department of Health does not require the addition of fluoride to water, it merely says that if a municipality fluoridates, it must follow certain fluoridation practices. WAC 246-290-460. The municipalities make the decision to fluoridate.