No. 82225-5

SUPREME COURT OF THE STATE OF WASHINGTON

CITY OF PORT ANGELES, Respondent, v. OUR WATER-OUR CHOICE and PROTECT OUR WATERS Petitioners, v. WASHINGTON DENTAL SERVICE FOUNDATION, LLC, Respondent.	CORRECTED MOTION TO FILE IAOMT, OSCDW, FAN AMICI CURIAE BRIEF

A. IDENTITY AND INTEREST OF AMICI CURIAE

The Amici Curiae are International Academy of Oral Medicine and Toxicology ("IMOMT"), Oregon Citizens for Safe Drinking Water ("OCSDW"), and Fluoride Action Network ("FAN"). The interests of each group are as follows:

JAMES ROBERT DEAL II
4130 166th Pl SW
Lynnwood, WA 98037-9027
Phone: (425) 771-1110
Fax: (425) 776-8081

International Academy of Oral Medicine and Toxicology

The fundamental mission of the International Academy of Oral Medicine and Toxicology is to promote the health of the public at large. We support the effort to inform consumers about health risks from amalgam mercury and water fluoridation, and support efforts toward eliminating these risks. The scientific activities of the IAOMT are overseen by an advisory committee composed of world leaders in biochemistry, toxicology and environmental medicine. The ideals and goals of the IAOMT are shared by dentists and physicians around the world, who have joined our efforts to promote science – based biological dentistry in their home countries. At present, there are fourteen independent chapters worldwide.

Oregon Citizens for Safe Drinking Water

Oregon Citizens for Safe Drinking Water (OCSDW) is a non-profit, all volunteer organization dedicated to protecting our drinking water through education and advocacy. Specifically, it works to keep fluoride compounds and other toxic chemicals and medications out of the public drinking water supply.

It is a coalition of individuals and organizations that includes doctors, lawyers, dentists, scientists, public health advocates, environmentalists, parents, legislators and concerned citizens. Together, it works to educate the public and policy makers about the concerns and complexities surrounding water fluoridation.

Over the past several years, it has worked with other local groups that have opposed fluoridation: Sierra Club, Oregon Chapter, Columbia Riverkeeper and other

JAMES ROBERT DEAL II
4130 166th Pl SW
Lynnwood, WA 98037-9027
Phone: (425) 771-1110
Fax: (425) 776-8081

local Riverkeeper Chapters, Oregon Conservation Network, Northwest Environmental Defense Center, Pacific Environmental Advocacy Council, Oregon Toxics Alliance, Oregon Center for Environmental Health, Oregon Trout, Native Fish Society, Oregon Health Freedom Coalition, and the Oregon League of Cities, among others.

It also works in conjunction with national groups that oppose fluoridation: EPA Unions, Environmental Working Group, Organic Consumers Association, the Fluoride Action Network (FAN), and many of the other individuals and organizations mentioned in FAN's statement of interest in this case.

For over a decade, OCSDW has worked to fight mandatory statewide fluoridation bills that have been introduced in the Oregon state legislature. It has also worked to oppose mandatory fluoridation efforts at the local level, and have offered assistance to communities whose citizens have expressed a desire to stop the intentional addition of fluoride compounds to their drinking water.

In addition, it has introduced legislation in the Oregon state legislature which would require that manufacturers selling substances to be added to drinking water for the purpose of *treating humans* (as opposed to *treating water* for safety and potability) show proof that their product: (1) has been FDA-approved for safety and effectiveness for its stated purpose; and (2) will not contribute contaminants to the finished water above EPA-established Maximum Contaminant Level Goals.

OCSDW has taken the position that local communities should be allowed to vote on this issue. However, it also acknowledge that allowing local communities to

JAMES ROBERT DEAL II
4130 166th Pl SW
Lynnwood, WA 98037-9027
Phone: (425) 771-1110
Fax: (425) 776-8081

vote on this issue in favor of adding drugs to water is problematic at best given accepted legal principals of informed consent. A fundamental ethical and constitutional question is whether legislators, states, counties, cities, water districts or any other entity should be allowed to medicate entire populations with drugs via their water supply.

Fluoride Action Network

The Fluoride Action Network ("FAN") is an international coalition seeking to broaden public awareness about the toxicity of fluoride compounds and the health impacts of current fluoride exposures.

Along with providing comprehensive and up-to-date information on fluoride issues to citizens, scientists, and policymakers alike, FAN remains vigilant in monitoring government agency actions that may impact the public's exposure to fluoride. FAN's work has been cited by national media outlets including Wall Street Journal, TIME Magazine, National Public Radio, Chicago Tribune, Prevention Magazine, and Scientific American, among others.

In May of 2004, FAN became an official project of the American Environmental Health Studies Project (AEHSP) - a registered non-profit 501(c)(3) organization.

As of January 2010, over 2700 Professionals have signed FAN's statement calling for an end to fluoridation. These include:

Arvid Carlsson, Nobel Laureate for Medicine, 2000; Magda Aelvoet, MD, Former Minister of Public Health, Belgium; Doug Everingham, former Federal Health Minister (1972-75), Australia; three members of the National Research

JAMES ROBERT DEAL II
4130 166th Pl SW
Lynnwood, WA 98037-9027
Phone: (425) 771-1110
Fax: (425) 776-8081

Council committee who wrote the 2006 report (Hardy Limeback, PhD, DDS; Robert L. Isaacson, PhD; Kathleen M. Thiessen, PhD); William Hirzy, PhD and Robert Carton, PhD, former risk assessment specialists at the EPA; William Marcus, PhD, former chief toxicologist of the EPA Water Division; Vyvyan Howard, MD, PhD, Past President, International Society of Doctors for the Environment (ISDE); Andy Harris, MD, former president, Physicians for Social Responsibility (PSR); Theo Colborn, PhD, co-author, Our Stolen Future; Lynn Margulis, PhD, a recipient of the National Medal of Science; Ken Cook, President and Executive Director, Environmental Working Group (EWG); Ron Cummins, Director, Organic Consumers Association; Peter Montague, PhD, Director of Environmental Health Foundation; Ted Schettler, MD, Science Director, Science and Environmental Health Network; Lois Gibbs, Executive Director, Center for Health, Environment, and Justice, Falls Church, VA; Jay Feldman, Executive Director, Beyond Pesticides; Sandra Duffy, Board President, Consumers for Dental Choice and environmental health leaders from over 30 countries.

B. APPLICANTS' FAMILIARITY WITH THE ISSUES AND ARGUMENT PRESENTED BY THE PARTIES

An advisor to the Applicants has been following this case since the time it was filed in superior court and has read all of the briefs filed in Superior Court, the Court of Appeals Division II, and the Supreme Court. Therefore the Applicants are well familiar with the issues and arguments presented by the parties.

JAMES ROBERT DEAL II
4130 166th Pl SW
Lynnwood, WA 98037-9027
Phone: (425) 771-1110
Fax: (425) 776-8081

C. ISSUES TO WHICH THE AMICI CURIAE BRIEF WILL BE DIRECTED

The Amici Curiae Brief addresses Issues 1 to 5 presented in the Petition for Review at 1-2.

D. APPLICANTS' REASON FOR BELIEVING THAT ADDITIONAL ARGUMENT IS NECESSARY

The decision made by the Court of Appeals Division II in the instant case is of substantial interest to the many citizens in the City of Port Angeles who will only have an opportunity to vote on local initiatives that would regulate putting drugs in their public water systems if this Court reverses the Court of Appeals Opinion. The Applicants, however, bring a national and international perspective to this case.

If the Court of Appeals Division II ruling stands, there will be no local jurisdiction in this state where citizens will be allowed to use the local initiative and referendum powers to decide whether or not to fluoridate or whether or not to allow other now unregulated drugs to be added to their public water supplies if a local legislative body with a Legislative grant to operate utilities has a municipal water supply. This ruling will effectively disenfranchise local voters around the State from having the opportunity to vote on these issues. Other states and other nations will follow the lead of Washington State and this could lead to their citizens being disenfranchised as well.

Fluoridation and adding other now unregulated drugs to public water systems is controversial. There is great public interest around this state, around this nation and in the world in allowing these matters to be decided by local initiatives and referendums. The Applicants bring this perspective to this case.

JAMES ROBERT DEAL II
4130 166th Pl SW
Lynnwood, WA 98037-9027
Phone: (425) 771-1110
Fax: (425) 776-8081

The IAOMT Amici Curiae Brief focuses on Issues 1-5 from the perspective that the Initiatives do not just regulate additives or contaminants in local public water supplies but rather that they prohibit or limit putting drugs in local public water supplies.

The Amici Curiae Brief addresses some of the reasons why it is impractical to meet legend drug laws when manufacturing and dispensing legend drugs in public water supplies. It then discusses some of the legend drug laws now being violated by the City when it serves the legend drug City Fluoridated Water through its municipal water supply with the intent to treat dental decay.

For more than fifty years, local voters in this state, this nation, and around the world have used local initiatives and referendums to vote on local public health regulations to not have fluoridated water. The Opinion should not be allowed to end local voters' right to continue to exercise police power to have local initiatives and referendums to prohibit fluoridation and local voters should be allowed to prohibit or limit other drugs as well.

Dated this 22nd day of January, 2010.

Respectfully submitted,

JAMES ROBERT DEAL PLLC

By: _____

James Robert Deal
WSBA No. 8103
Attorneys for Amici IAOMT, OCSDW, and FAN

JAMES ROBERT DEAL II
4130 166th Pl SW
Lynnwood, WA 98037-9027
Phone: (425) 771-1110
Fax: (425) 776-8081

CERTIFICATE OF SERVICE

I hereby certify that on the 22nd day of January, 2010, I personally served a true and correct copy of this certificate and the Corrected Motion to File IAOMT Amici Curiae Brief on the following:

Counsel for Washington Dental Service Foundation, LLC:

Roger Pearce/P. Steven DiJulio
Foster Pepper PLLC
1111 Third Ave., Ste. 3400
Seattle, WA 98101-3299
Email: Roger Pearce <pearr@foster.com>

Counsel for the City of Port Angeles:

William Bloor
Port Angeles City Attorney
321 East 5th Street
Port Angeles, WA 98362
Email: William Bloor wbloor@cityofpa.us

Counsel for Petitioners:

Gerald Steel
Gerald Steel PE
7303 Young Rd. NW
Olympia WA 98502
Email: Gerald Steel geraldsteel@yahoo.com

Dated this 22nd day of January, 2010 at Lynnwood, Washington.

James Robert Deal

JAMES ROBERT DEAL II
4130 166th Pl SW
Lynnwood, WA 98037-9027
Phone: (425) 771-1110
Fax: (425) 776-8081

No. 82225-5

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CITY OF PORT ANGELES, Respondent,

v.

OUR WATER-OUR CHOICE, and PROTECT OUR WATERS,
Petitioners,

v.

WASHINGTON DENTAL SERVICE FOUNDATION, LLC,
Respondent.

AMICI CURIAE BRIEF OF INTERNATIONAL ACADEMY OF ORAL MEDICINE AND TOXICOLOGY, OREGON CITIZENS FOR SAFE DRINKING WATER, AND FLUORIDE ACTION NETWORK IN SUPPORT OF PETITIONERS

James Robert Deal
James Robert Deal Attorney PLLC
Attorney for International Academy of Oral Medicine and Toxicology Oregon Citizens for Safe Drinking Water, and Fluoride Action Network as Amici Curiae.

James Robert Deal Attorney PLLC
4130 166th Place SW
Lynnwood WA 98037
Attorney Phone: 425-771-1110
Attorney Fax: 425-776-8081
Attorney email: James@JamesRobertDeal.com
WSBA # 8103

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I. IDENTITY AND INTEREST OF AMICI CURIAE

The IAOMT Amici Curiae are International Academy of Oral Medicine and Toxicology ("IAOMT"), Oregon Citizens for Safe Drinking Water ("OCSDW"), and Fluoride Action Network ("FAN"). The interests of each group are set forth in Appendix B hereto.

II. ISSUES ADDRESSED

This IAOMT Amici Curiae Brief addresses Issues 1 to 5 presented in the Petition for Review at 1-2.

III. BRIEF STATEMENT OF THE CASE

The Our Water - Our Choice ("OWOC") local initiative proposes to "prohibit medication of people through public drinking water supplies"[1] and the Protect Our Waters ("POW") local initiative proposes "safety standards for any substance intended to act on the mind or body of people and added to public drinking water. FDA [Food and Drug Administration] approval is required."[2] Neither Initiative restricts the City from adding chemicals to treat water "PROVIDED" the fluoride level is not increased by more than 0.1 ppm.[3] We support Petitioners'[4] request that these Initiatives be allowed on the ballot.

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[1] Petition for Review (9-25-08) ("Petition") at A-18.
[2] Petition at A-16 and A-17 ("This ordinance requires that any substances which are added with the intention of treating people, not the water, must meet [safety standards].")
[3] Petition at A-17 (Sec. 3) and A-19 (Sec. 3).
[4] Petitioners are also referred to as the Committees.

IV. THE LOCAL INITIATIVES ADDRESS DRUGS TO TREAT PEOPLE AND NOT ADDITIVES TO TREAT WATER AND THEY ARE INTRINSICALLY LEGISLATIVE

The IAOMT Amici Curiae Brief is to assist this Court in resolving an issue which has an effect on the constitutional right to life and liberty for individuals, especially those most vulnerable, who are chemically sensitive, infants, or those who drink excessive amounts of local public water, such as diabetics, those with kidney disease, those who work in the heat, and athletes.

The opinion ("Opinion") of the Division II Court of Appeals ("appellate court") fails to consider adequately that the Initiatives address the dispensing of drugs piped into people's homes by public water systems. The Opinion of the appellate court has left the public, especially those most vulnerable, at risk of harm.

A fundamental flaw in the Opinion of the appellate court is its failure to consider and apply the laws and regulations related to the dispensing of drugs when it considers whether the Initiatives are within the scope of the local initiative power.

The Initiatives focus is not on water additives[5] to make water safe, palatable and aesthetically acceptable, and not on clean-up of existing

[5] The Opinion (Petition at A-8) states that "both the Washington Legislature and the Washington Board of Health are powers superior to the City and their comprehensive regulations constitute a plan regulating **additives** to public drinking water." (Emphasis supplied).

contaminants in public water supplies.[6] Rather the focus of these local Initiatives is to prohibit or limit putting drugs in local public water supplies.[7]

A. The OWOC Initiative's Intent "Is To Prohibit Medication Of People Through Public Drinking Water Supplies While Allowing Necessary Treatment Of Water To Make It Safe To Drink"

The intent of the OWOC Initiative, as expressly stated on the OWOC Initiative Petition, is "to prohibit medication of people through public drinking water supplies while allowing necessary treatment of water to make it safe to drink."[8] As a matter of law, this expressed intent should be found to be the fundamental and overriding purpose of the OWOC Initiative.[9] This Court should make clear that in pre-election review of other than procedural matters, lower courts are to determine, as a matter of law, the "fundamental and overriding purpose" of both statewide and local initiatives and limit their review to considering the application of the "legislative" and "power to enact" tests to this purpose.[10]

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[6] The Opinion (Petition at A-7) states that the Department of Health is to administrate the Safe Drinking Water Act (42 U.S.C. sec. 300f et seq.) but this Act only deals with clean up of existing contaminants in public water supplies and does not address dispensing drugs through public water supplies.

[7] Supra, this brief at 1, including Notes 1 and 2.

[8] This intent is expressly stated on the face of the OWOC initiative petition. Petition at A-18. The intent of the POW Initiative is explicitly provided in Section 1 of that Initiative and, fundamentally, it is to limit drugs that are allowed to be dispensed in local public water supplies. Petition at A-17.

[9] The full text of the OWOC Initiative Ordinance is provided in the Petition at A-19 and this text is consistent with a conclusion as a matter of law that the intent expressed "to prohibit medication of people through public drinking water supplies while allowing necessary treatment of water to make it safe to drink" is the fundamental and overriding purpose of the OWOC initiative.

[10] See Issue 3 in the Petition at 2. See also Supplemental Brief of Petitioners at 15-17.

B. Local Initiatives That Prohibit Or Limit Putting Drugs In Local Public Water Supplies Are Intrinsically Legislative

Local initiatives to prohibit or limit putting any drugs in any public water supply serving the City of Port Angeles are intrinsically legislative.[11] They are intrinsically legislative because any decision to, or not to, medicate people en masse is a decision that requires the use of legislative discretion to balance benefits and harms.[12] We request that this Court take judicial notice that medical drugs can benefit people but they can also harm people with their side effects.

Such local legislative decisions by the corporate city to prohibit or limit putting any drugs in any local public water supply serving the City are permitted by police powers to prevent such harms[13] and by statutes giving cities the right to set local water purity standards.[14] Such local initiatives are not in conflict with any state or federal law. The lower courts err by not having a clear understanding that the substances to be regulated are medicines intended to treat people and are not just additives to control contaminants. Respondents err when inviting the

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[11] Relevant to Issues 1-5, Petition at 1-2.
[12] See Supplemental Brief of Petitioners Our Water-Our Choice and Protect Our Waters at 14, Note 44.
[13] Const. XI, sec. 11 allows corporate cities to use police power reasonably connected to the public peace, health, safety, morals and welfare. Seattle v. Hill, 72 Wn.2d 786, 797, 435 P.2d 692 (1967). The initiatives seek to protect the public from harm caused by medicines dispensed through public water supplies without informed consent.
[14] RCW 35A.70.070(6) and Chapter 35.88 RCW.

Court to call these drugs "additives" circumventing general Washington and Federal drug laws.[15]

C. The Appellate Court Should Have Applied Laws Regulating Manufacturing, Marketing, Formulating, Prescribing, Dispensing, Possessing, and Administering Drugs – The Initiatives Are Within The Corporate City's Power To Enact

Under Washington and Federal law it is unlawful to manufacture, market, formulate, prescribe, dispense, possess or administer a legend (prescription) drug without a license and without compliance with relevant drug laws.[16] The Initiatives recognize that it is impractical to comply with Washington drug laws when manufacturing and dispensing "water and bulk drug" compounds through public water systems.

Washington drug laws require a qualified and licensed practitioner to prescribe and dispense legend drugs.[17] Such a practitioner in providing such health care has a "duty to secure an informed consent by a patient or his representatives."[18] It is not practical to secure informed consent from everyone who might drink a "water and bulk drug" compound dispensed through a public

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[15] 21 U.S.C. sec. 321(g)(1)(B) (Appendix A-1 hereto); RCW 69.41.010(9)(b) (Appendix A-2 hereto); See Supplemental Brief of Respondents at 3 Sec. 2.2.
[16] Chapter 69.41 RCW; U.S.C. 21, Chapter 9 ("Federal Food, Drug, and Cosmetic Act" abbreviated herein as "FD&C Act").
[17] "Legend drugs" means any 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. RCW 69.41.010(12).
[18] RCW 7.70.050(1).

water system.[19] The Initiative Ordinances prohibit or limit water purveyors such as the City from putting drugs in public water supplies serving the City and prohibit or limit other persons from doing the same. These Ordinances are not in conflict with any Federal or State Law and are within the corporate city's power to enact.

V. THE RESPONDENTS OPPOSE THE INITIATIVES BECAUSE THE CITY IS CURRENTLY MANUFACTURING AND DISPENSING THE DRUG "CITY FLUORIDATED WATER" IN VIOLATION OF WASHINGTON AND FEDERAL DRUG LAWS

The City began to fluoridate its municipal public water supply in 2006.[20] Cities add fluoridation chemicals to their water supplies with the intent to prevent disease.[21] This intent alone is enough to define City fluoridated water as a drug.[22] The U.S. Environmental Protection Agency ("EPA") does not regulate drugs.[23] The FDA regulates drugs in interstate commerce.[24] The State Board of Pharmacy regulates drugs in intrastate commerce.[25]

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[19] Appendix A-41 to A-47 hereto are true and correct copies of petitions with 105 signatures of people who declare under penalty of perjury that they drink City fluoridated water but have not consented to be medicated through the municipal water supply.
[20] Petition at A-24.
[21] We request that this Court take judicial notice that fluoridated water is supplied to mitigate and prevent dental decay, a common disease of mankind in 1954. Kaul v. Chehalis, 45 Wn.2d 616, 620, 277 P.2d 352 (1954); Respondent's Clerks Papers at 132 et seq.
[22] Federal and Washington laws define a drug as a substance or article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. sec. 321(g)(1)(B) (Appendix A-1 hereto); RCW 69.41.010(9)(b) (Appendix A-2 hereto).
[23] Under the Safe Drinking Water Act, the EPA regulates clean-up of contaminants and regulates additives to treat water to clean-up contaminants. See Supplemental Brief of Petitioners at 6, including Note 24.
[24] 21 U.S.C. sec. 355(a).
[25] RCW 18.64.005.

The City obtains its bulk fluoridation drug[26] in interstate commerce and manufactures and dispenses its City fluoridated water drug in intrastate commerce.[27] Thus both Federal and Washington drug laws apply to the City's manufacturing and dispensing of City fluoridated water.

The Initiatives will stop the City from violating Washington and Federal drug laws and will stop the City from manufacturing, formulating, marketing, prescribing, and administering unapproved drugs in the form of City fluoridated water to City residents without their consent, each action being an unlawful function.

The Opinion 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."[28] However, there is no general 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 Opinion states: "a local initiative can only create new law that is not inconsistent with or inapposite to state and federal law."[29] While the two Initiatives set more protective water standards, they are fully consistent with

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[26] A bulk drug is a substance that becomes an active ingredient of a drug. 21 C.F.R. sec. 207.3(a)(4). We request that this Court take judicial notice that the bulk fluoridation drug used by the City to fluoridate its water is manufactured out-of-state and therefore subject to FDA regulation when it is used as an active ingredient of City fluoridated water.
[27] RCW 69.04.004.
[28] Petition at A-8.
[29] Id. at A-9.

Federal and Washington drug laws. The 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 public water system from Washington and Federal drug laws and does not exempt a city public water system from public health ordinances adopted by the corporate city under Const. art. XI, sec. 11 or under RCW 35A.70.070(6) and Chapter 35.88 RCW.

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

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.*'"[30,31]

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[30] State of Washington Department of Health Board of Pharmacy June 4, 2009 letter to Bill Osmunson DDS (Appendix A-4 to A-8 hereto) at A-4; RCW 69.41.010(12) (Appendix A-2 hereto) defines legend drugs; WAC 246-883-020(2) (Appendix 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 A-5 to A-7 hereto). We request that this Court take judicial notice that fluoride is a legend drug.

[31] The above-referenced Board letter (Appendix 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.

Fluoridated water, a mixture of water and silicofluoride, hydrofluorosilicic acid, or rarely sodium fluoride is an unapproved legend drug.[32] 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. . . ."[33]

The FDA has withdrawn approval of a new drug application for the ingestion of fluoride supplements on the basis that "there is no substantial evidence of drug effectiveness as prescribed, recommended, or suggested in labeling."[34]

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[32] 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, also called hydrofluorosilicic acid, is used by the City of Port Angeles) are the commonly used active ingredients in water fluoridation. (Appendix 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 a FDA Drug Division or Washington state "approved" over-the-counter or legend drug for ingestion for the prevention, mitigation or treatment of dental decay.

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

[34] Drug Therapy June 1975 (Appendix A-11 hereto).

B. There Is No Authority To Manufacture And Dispense Artificially-Fluoridated Water With Intent To Prevent Disease Without Compliance General Drug Laws

Water districts, public utility districts, and cities all have authority to operate Class A public water systems. Water districts may medicate people with fluoride by authority of statute.[35] However, this 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 add any drug other than fluoride to their public water system.

The Attorney General has issued an opinion that public utility districts ("PUDs") do not have authority to medicate people with any drug put in their public water supplies.[36] While the AGO is not binding on this Court, it is entitled to considerable weight.[37] PUDs have authority under Chapter 54.04 RCW to operate water systems. 2008 AGO No. 5 concludes that this grant of authority to operate a water system does not give PUDs authority to medicate people through their water system.

There is, and never has been, a specific statute which authorizes a city to fluoridate its municipal water supply or otherwise authorizes medicating people through the city's water system. So the Supreme Court in Kaul at 621, relied on police power pursuant to Const. art. XI, sec. 11 to justify fluoridation by a city.

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[35] RCW 57.08.012.
[36] 2008 AGO No. 5.
[37] Washington Mutual v. Dep't of Revenue, 77 Wn. App. 669, 676, 893 P.2d 654 (1995).

Const. art. XI, sec. 11 allows the city to "enforce within its limits all such local police, sanitary and other regulations as are not in conflict with general laws." Local initiatives that either 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 Washington or Federal drug laws and are not in conflict with any statutory authority to the City's legislative body to operate a water system.

1. The Opinion errs when it relies on the City legislative body's statutory authority to "operate water utilities" to give the City authority to fluoridate its water supply or otherwise medicate people

In Section E of the Opinion, the appellate court finds that the Initiatives fail to meet the "power to enact" test because they interfere with the statutory authority of the City's legislative body to "operate water utilities."[38] 2008 AGO No. 5 concludes that a grant of power to operate water utilities "does not delegate public health police powers" and "does not provide authority regarding decisions to fluoridate water." Because the City legislative body's statutory authority to "operate water utilities" does not provide authority regarding decisions to fluoridate and otherwise medicate people through its water supply, the Opinion errs when it finds that the Initiatives interfere with such an authority granted to the City's legislative body.

[38] Petition at A-10 to A-13.

The Opinion finds the "operation of a municipal water system" is "beyond the initiative power."[39] And while this is correct, this Court should find that City's authority regarding decisions to fluoridate and otherwise medicate through municipal water supplies does not derive from the City legislative body's authority to "operate water utilities." Instead, this Court should find that authority regarding decisions to fluoridate and otherwise medicate through municipal water supplies derives from police power granted by Const. art. XI, sec. 11 and from RCW 35A.70.070(6) and Chapter 35.88 RCW and these powers belong to the corporate city and not just to the legislative body. [40]

VI. FLUORIDATION: IN CONFLICT WITH GENERAL LAWS

The Initiatives using the corporate City's police power authority to prohibit or limit putting drugs including fluoride into any public water supply serving the City do not violate any general law. However, the putting of fluoride or other legend drugs into public water supplies with intent to prevent and/or treat disease does violate Washington and Federal general drug laws unless the drug and water compound is manufactured and dispensed in accord with these general laws.

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[39] Petition at A-11.
[40] Supra, this brief at 4, Notes 13 and 14.

A. General Legend (Prescription) Drug Statutes Apply To City Water Fluoridation And To The Dispensing Of Any Legend Drugs Through Public Water Supplies

> "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).

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.

For the City to manufacture, prescribe, dispense, or administer legend drugs, including City fluoridated water, without appropriate licenses and without informed consent of its patients is in conflict with the legend drug statutes and is *ultra vires*.

The City has failed to label the legend (prescription) drug "City 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 any public water system serving the City be prohibited or prohibited unless they are dispensed as approved by the FDA and meet certain other requirements.

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

A. 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.[41] It sets a maximum contaminant level ("MCL") for common contaminants based on the health risk reduction to be achieved tempered by a realistic assessment of the cost of removing or treating that contaminant.[42] The Safe Drinking Water Act also sets maximum contaminant level goals ("MCLG") based solely on

[41] 42 U.S.C. sec. 300g-1
[42] 42 U.S.C. sec. 300g-1(b)(3)(C).

health and safety regardless of the cost of removing or treating contaminants.[43]

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.[44] To protect public health, certainly contaminants should not be added to public water supplies if doing so would cause the MCLG (the EPA health and safety standard) to be exceeded such that health would be threatened. Adhering to the MCLG is the intent of Section 3(B) of the POW Initiative.[45] This is significant because 43% of fluoridation products tested by NSF (the non-government certifying agency for fluoridation products) contain arsenic[46] and thus cause treated water to exceed the MCLG for arsenic which is zero.[47]

The appellate court erred when relied on the Safe Drinking Water Act and its implementation by the Washington Legislature and the Washington Board of Health when the Initiatives do not address treatment

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[43] 42 U.S.C. sec. 300g-1(b)(4)(A).
[44] Fluoride in Drinking Water, National Research Council (2006) (Appendix A-26 hereto).
[45] Petition at A-17.
[46] http://www.nsf.org/business/water_distribution/pdf/NSF_Fact_Sheet.pdf (Appendix A-18 and A-19 hereto). The contaminant levels reported "represent contaminant levels that would be expected" in treated water. Id.
[47] http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-22/w1668.htm (Appendix A-24 hereto); WAC 173-200-020(16) (Petition at A-48) gives the definition of MCLG; WAC 246-290-72012 (Petition at A-49 to A-53) shows MCLG for arsenic and lead is zero. According to NSF, 43% of fluoridation products contain arsenic and 2% of fluoridation products contain lead (Appendix A-18 to A-21 hereto).

of existing contamination but rather address adding of any drugs, including fluoride, to any public drinking water supply serving the City.[48]

B. EPA Union Scientists Oppose Fluoridation

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."[49]

VIII. 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

When the intent is to prevent human disease, it is the FDA – not the EPA[50] – which approves drugs for marketing regardless of the method of dispensing the drug or the drug's concentration.[51] Since 1938, every new drug has been the subject of an approved NDA ["New Drug Application"] before U.S. commercialization.[52]

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[48] See Petition at A-6 to A-8.
[49] Dr. J. William Hirzy, Senior Vice-President, Headquarters Union, US Environmental Protection Agency, March 26, 2001 (Appendix A-32 hereto). This letter describes some of the harms of water fluoridation as seen by water fluoridation opponents.
[50] 42 U.S.C. sec. 300g-1(b)(11)
[51] FDA response to Honorable Ken Calvert, Chairman Subcommittee on Energy and Environment Committee on Science, House of Representatives, Dec 21, 2000 at 1 (Appendix A-34 hereto).
[52] FDA New Drug Application, Introduction (Appendix A-37 hereto). We request that this Court take judicial notice that community water fluoridation began in the 1940's after regulations requiring NDAs were in place.

> 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.[53]

According to the FDA,

> Fluoride products in the form of liquid and tablets meant for ingestion were in use prior to enactment of the Kefauver-Harris Amendments (Drug Amendments of 1962) to the Food, Drug, and Cosmetic Act in which efficacy became a requirement.[54]

The effectiveness of ingested fluoride to prevent dental disease was not demonstrated to the FDA and so no NDAs are approved for fluoride drugs meant for ingestion.[55] Despite the lack of approval of bulk fluoridation drugs by the FDA, such products are shipped in interstate commerce to the City and a legend drug we call City fluoridated water is manufactured and dispensed in violation of Washington and Federal general drug laws.

The City is correct when it says that "the FDA does not regulate additives to drinking water."[56] However, the City adds fluoride not as an additive to clean-

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[53] FDA New Drug Application, Introduction (Appendix A-37 hereto).
[54] FDA response to Honorable Ken Calvert, Chairman Subcommittee on Energy and Environment Committee on Science, House of Representatives, Dec 21, 2000 at 2 (Appendix A-35 hereto); See Drug Therapy June 1975 (Appendix A-11 hereto).
[55] Id. (Appendix A-35 and A-11 hereto).
[56] Brief of Respondent at 10, Note 15.

up contaminants, but as a legend drug for "preventive health care purposes." This is subject to the jurisdiction of the FDA and State Board of Pharmacy.[57]

IX. THE CITY IS ENGAGED IN THE PRACTICE OF PHARMACY WITHOUT A LICENSE AND IS MANUFACTURING AND SELLING DRUGS WITHOUT A LICENSE WHEN IT PUTS FLUORIDE OR ANY DRUG IN THE CITY PUBLIC WATER SUPPLY

Fluoride "is artificially added solely for the effect it has on the individual drinking the water."[58] It is added to "control dental caries" which is a "common disease."[59] 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."[60] 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.[61]

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[57] Appendix A-34 hereto.
[58] Kaul v Chehalis 45 Wn.2d 616, 618, 277 P.2d 352 (1954)
[59] Id.
[60] Id. at 625.
[61] Per chapter 69.41 RCW.

X. THE APPELLATE COURT OPINION, IF NOT REVERSED, COULD PREVENT FUTURE LOCAL INITIATIVES AND REFERENDUMS ON FLUORIDATION IN THIS STATE AND IN THIS NATION

Amici are very concerned that the appellate court opinion, if not reversed could prevent future local initiatives and referendums on fluoridation in this state and in this nation. The appellate court opinion rests on two erroneous conclusions. The first is that because the Safe Drinking Water Act and implementation of this Act by the State sets drinking water standards,

> Decisions by local water companies about which chemicals to add to public water systems are administrative in nature because those decisions merely implement plans already adopted and supervised by the Health Department.[62]

The second is that because a local legislative body has statutory authority to operate water utilities, there is not "power to enact" a local initiative or referendum because it would interfere with that statutory authority.[63]

The first conclusion is erroneous because the Safe Drinking Water Act and State implementation only set statewide Maximum Contaminant Levels ("MCLs") that trigger clean-up and only govern additives related to treating water to meet these MCLs. Local ordinances are allowed that set more strict local water purity standards.[64] But more importantly, the Initiatives only address drugs to treat people and do not address additives to meet MCLs.

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[62] Petition at A-8.
[63] Petition at A-10 to A-13.
[64] RCW 70.142.010(2).

The second conclusion is erroneous because statutory authority to "operate water utilities" does not grant a statutory right to adopt public health regulations related to putting drugs in public water systems. For more than fifty years, local voters in this state and this nation have used local initiatives and referendums to vote on local public health regulations to not have fluoridated water.[65] The Opinion should not be allowed to end local voters' right to continue to exercise police power to have local initiatives and referendums to prohibit fluoridation.

XI. CONCLUSION

This Court should find that the two Initiatives meet the "legislative" test and the "power to enact" test such that they should be allowed on the ballot. This Court should not allow the Opinion to prohibit future local government initiatives and referendums that would prohibit fluoridation locally. Amici request that this Court reverse the Opinion and issue an order pursuant to RCW 35.17.290 to place both Initiatives on the ballot.

Dated this 19th day of January, 2010.

Respectfully submitted,

James Robert Deal Attorney PLLC

By: _____
James Robert Deal WSBA No. 8103
Attorney for Amici IAOMT, OCSDW, and FAN

[65] The dissent in Kaul at 640-41 mentions eleven such referendums held in 1954 alone.

CERTIFICATE OF SERVICE

I certify that on the 19th day of January, 2010, I caused a true and correct copy of this certificate and the Amici Curiae Brief of International Academy of Oral Medicine and Toxicology, Oregon Citizens for Safe Drinking Water and Fluoride Action Network In Support of Petitioners and Motion to File IAOMT Amici Curiae Brief to be served on the following by first class mail with proper postage:

Counsel for Washington Dental Service Foundation, LLC:

Roger Pearce/P. Steven DiJulio
Foster Pepper PLLC
1111 Third Ave., Ste. 3400
Seattle, WA 98101-3299
Email: Roger Pearce <pearr@foster.com>

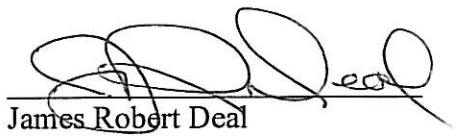
Counsel for the City of Port Angeles:

William Bloor
Port Angeles City Attorney
P.O. Box 1150
Port Angeles, WA 98362
Email: William Bloor wbloor@cityofpa.us

Counsel for Petitioners:

Gerald Steel
Gerald Steel PE
7303 Young Rd. NW
Olympia WA 98502
Email: Gerald Steel geraldsteel@yahoo.com

Dated this 19th day of January, 2010 at Lynnwood, Washington.



James Robert Deal

APPENDIX INDEX

APPENDIX INDEX (CONTINUED)

21 U.S.C. § 321 : US Code - Section 321: Definitions; generally

For the purposes of this chapter -

(a)(1) The term "State", except as used in the last sentence of section 372(a) of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

RCW 69.41.010: Definitions.

RCW 69.41.010
Definitions.

As used in this chapter, the following terms have the meanings indicated unless the context clearly requires otherwise:

(1) "Administer" means the direct application of a legend drug whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(a) A practitioner; or

(b) The patient or research subject at the direction of the practitioner.

(2) "Community-based care settings" include: Community residential programs for the developmentally disabled, certified by the department of social and health services under chapter 71A.12 RCW; adult family homes licensed under chapter 70.128 RCW; and boarding homes licensed under chapter 18.20 RCW. Community-based care settings do not include acute care or skilled nursing facilities.

(3) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a legend drug, whether or not there is an agency relationship.

(4) "Department" means the department of health.

(5) "Dispense" means the interpretation of a prescription or order for a legend drug and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

(6) "Dispenser" means a practitioner who dispenses.

(7) "Distribute" means to deliver other than by administering or dispensing a legend drug.

(8) "Distributor" means a person who distributes.

(9) "Drug" means:

(a) Substances recognized as drugs in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals;

(c) Substances (other than food, minerals or vitamins) intended to affect the structure or any function of the body of human beings or animals; and

(d) Substances intended for use as a component of any article specified in (a), (b), or (c) of this subsection. It does not include devices or their components, parts, or accessories.

(10) "Electronic communication of prescription information" means the communication of prescription information by computer, or the transmission of an exact visual image of a prescription by facsimile, or other electronic means for original prescription information or prescription refill information for a legend drug between an authorized practitioner and a pharmacy or the transfer of prescription information for a legend drug from one pharmacy to another pharmacy.

(11) "In-home care settings" include an individual's place of temporary and permanent residence, but does not include acute care or skilled nursing facilities, and does not include community-based care settings.

(12) "Legend drugs" means any 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.

(13) "Legible prescription" means a prescription or medication order issued by a practitioner that is capable of being read and understood by the pharmacist filling the prescription or the nurse or other practitioner implementing the medication order. A prescription must be hand-printed, typewritten, or electronically generated.

(14) "Medication assistance" means assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or in-home care setting to facilitate the individual's self-administration of a legend drug or controlled substance. It includes reminding or coaching the individual, handing the medication container to the individual, opening the individual's medication container, using an enabler, or placing the medication in the individual's hand, and such other means of medication assistance as defined by rule adopted by the department. A nonpractitioner may help in the preparation of legend drugs or controlled substances for self-administration where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate. Medication assistance shall not include assistance with intravenous medications or injectable medications, except prefilled insulin syringes.

(15) "Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(16) "Practitioner" means:

(a) A physician under chapter 18.71 RCW, an osteopathic physician or an osteopathic physician and surgeon under chapter 18.57 RCW, a dentist under chapter 18.32 RCW, a podiatric physician and surgeon under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a registered nurse, advanced registered nurse practitioner, or licensed practical nurse under chapter 18.79 RCW, an optometrist under

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chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010, an osteopathic physician assistant under chapter 18.57A RCW, a physician assistant under chapter 18.71A RCW, a naturopath licensed under chapter 18.36A RCW, a pharmacist under chapter 18.64 RCW, or, when acting under the required supervision of a dentist licensed under chapter 18.32 RCW, a dental hygienist licensed under chapter 18.29 RCW;

(b) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a legend drug in the course of professional practice or research in this state; and

(c) A physician licensed to practice medicine and surgery or a physician licensed to practice osteopathic medicine and surgery in any state, or province of Canada, which shares a common border with the state of Washington.

(17) "Secretary" means the secretary of health or the secretary's designee.

[2009 c 549 § 1024; 2006 c 8 § 115. Prior: 2003 c 257 § 2; 2003 c 140 § 11; 2000 c 8 § 2; prior: 1998 c 222 § 1; 1998 c 70 § 2; 1996 c 178 § 16; 1994 sp.s. c 9 § 736; prior: 1989 1st ex.s. c 9 § 426; 1989 c 38 § 3; 1984 c 153 § 17; 1980 c 71 § 1; 1979 ex.s. c 139 § 1; 1973 1st ex.s. c 186 § 1.]

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STATE OF WASHINGTON
DEPARTMENT OF HEALTH

June 4, 2009

Bill Osmunson DDS, MPH
Aesthetic Dentistry of Bellevue
1418 112th Avenue NE, Suite 200
Bellevue, Washington 98004

Dear Dr. Osmunson:

This letter is in response to your request at the May 7, 2009 meeting of the Washington Board of Pharmacy for a response to your question about designating fluoride as a poison under chapter 69.38 RCW. RCW 69.38.020 states that "[a]ll substances regulated under chapters 15.58, 17.21, 69.04, and 69.50, and chapter 69.45 RCW are exempt from the provisions [of chapter 69.38 RCW]. 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*." Enclosed are copies of pages 169, 342, and 690 of the 2002 edition of the *Drug Topics Red Book*. Page 169 is the key to the products requiring prescription (legend drugs) and page 342 contains the fluoride products. Page 690 contains the listing of over-the-counter fluoride products, primarily toothpaste containing fluoride.

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 authority was recognized by the Washington Supreme Court in *Parkland Light & Water Company v. Tacoma-Pierce County Board of Health, et al.*, 151 Wn.2d 428 (2004). By adopting a specific statute on the fluoridation of water supplies, the legislature has superseded the more general statutes in the legend drug act requiring a practitioner to dispense fluoride. *Tunstall v. Bergeson*, 141 Wn.2d 201, 211 (2000).

For the above-stated reasons, the Board of Pharmacy will not be considering your request to designate fluoride as a poison under chapter 69.38 RCW.

Sincerely,

Susan Teil Boyer, MS, RPh, FASHP
Executive Director
Washington State Board of Pharmacy
PO Box 47852
Olympia WA 98504-7852

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KEY TO Rx PRODUCT LISTINGS

How to Find an Rx Product

The layout of *Red Book* product listings allows for easy identification of Rx products, manufacturer names, generic cross-references and repackagers of pharmaceutical products. It also identifies Federal Upper Limit prices for Medicaid reimbursement from the newly named Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration or HCFA. Products are listed alphabetically by their prescribing names, as explained below. (For information on how to locate and interpret OTC and non-drug product listings, refer to section 10.)

Package quantities appear in National Council for Prescription Drug Programs (NCPDP) standard billing units (e.g., ea, ml, gm). Please see Section 6, "Drug Reimbursement Information," for an explanation of the NCPDP standard. A conversion table can be found in Section 2, "Clinical Reference Guide."

Trademarked Name: Detailed product information is available under the actual brand name rather than the generic name; i.e., "Valium" product information is listed under "Valium" rather than under diazepam. However, you will find a cross-reference under Roche, the manufacturer of Valium, in the diazepam listing.

VALIUM (Roche Labs)
diazepam
Tabs, Oral, 2 mg:
100s ea, C-IV ..... 00140-0008-01 166.92 AB

Generic Name: In-depth product information on generic products can be found by locating the generic product name, under which the various manufacturers, suppliers, or distributors are listed alphabetically; i.e., diazepam features several dozen generic manufacturers. Manufacturers listed under their trademarked product names contain a cross-reference to their name.

DIAZEPAM
FDB
TAB, PO, 2 mg, 100s ea 2.09
(Abbott Hosp)
INJ, IJ (AMP)
5 mg/ml,
2 ml 10s, C-IV ..... 00074-3210-01 86.69 AP
(Roche Labs) *See VALIUM*

Single-ingredient generic names are spelled out in full. Multiingredient products (two or more) are listed in the alphabetical order of their ingredients using the standard abbreviations listed on the following pages.

Drug Class Symbols

The following descriptive symbols indicate a product's status under the Controlled Substances Act of 1970. They apply to all entries under the product name or dosage form in which they appear. Use these symbols only as a guide. Check the manufacturer's label for definitive information.

C-II — High Potential for Abuse. Prescriptions must be written as first or typewritten and signed by the practitioner. Verbal prescriptions must be confirmed in writing within 72 hours and may be given only in a genuine emergency. No refill rights.

C-III — Some Potential for Abuse. Prescriptions may be oral or written. Up to 5 refills are permitted within 6 months.

C-IV — Low Potential for Abuse. Prescriptions may be oral or written. Up to 5 refills are permitted within 6 months.

C-V — Subject to State and Local Regulation. Abuse potential is low; a prescription may not be required.

Rx — Prescription only; not a controlled substance.

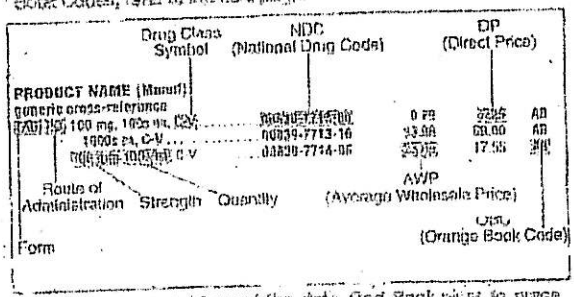
How to Read the Listings

The first line of an entry features the product or generic name. CMS Federal Upper Limit price information is provided for all applicable multi-source product categories. The [FUL] symbol can be found immediately following the generic product name. A complete listing of Federal Upper Limit prices appears in Section 6 (Drug Reimbursement Information).

Manufacturers are listed alphabetically within generic listings. Repackagers of products feature the [REPACK] symbol next to their names. For trade name listings, generic cross-references appear in lower case on the following line.

A three-letter abbreviation indicates the form of the drug; i.e., CAP indicates capsules, TAB indicates tablets, etc. For a key to additional abbreviations, refer to the table on the following page.

Route of administration, descriptive information, strength, quantity, and drug class symbol (where applicable) appear next, followed by National Drug Code (NDC) number. The Average Wholesale Price (AWP), Direct Price (DP), and the Orange Book Code (OBC) complete the entry for each product. For more information on Orange Book Codes, refer to the next page.



All prices are current as of the date *Red Book* went to press. However, actual prices paid by retailers may vary, and all prices are subject to change without notice. The prices shown here are based on data obtained from manufacturers, distributors, and other suppliers. While great care has been exercised in compiling this information, the publisher of *Red Book* does not warrant its accuracy. Information may be supplemented by subscribing to the monthly *Red Book UPDATE*, *RxReadyPrice™*, *Red Book for Windows™*, *Red Book* database services, or by obtaining prices published in catalogs or other printed materials disseminated by manufacturers or distributors.

ROUTE OF ADMINISTRATION ABBREVIATIONS

Route of Administration (ROA) refers to the intake or application method of a product. The following abbreviations are used to indicate the ROA:

BU ..... Buccal
DE ..... Dental
EP ..... Epidural
IC ..... Intracavernosal
ID ..... Intradermal
IH ..... Inhalation
IL ..... Injection
IL ..... Intralesional
IM ..... Intramuscular
IN ..... Intranasal
IP ..... Implantation
IR ..... Intraperitoneal
IS ..... Intrasternal
IT ..... Intrathecal
IV ..... Intravenous
MM ..... Mucous membrane
MR ..... Multiple routes
NA ..... Not applicable
NS ..... Nasal
OP ..... Ophthalmic
OT ..... Otic
PE ..... Intrapleural
PO ..... Oral
RT ..... Intraperitoneal
RC ..... Rectal
SC ..... Subcutaneous
SG ..... Subgingival
SL ..... Sublingual
TD ..... Transdermal
TP ..... Topical
UR ..... Intrauterine
VG ..... Vaginal

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ORANGE BOOK CODES

The Orange Book Codes supply the FDA's therapeutic equivalence rating for applicable multi-source categories. Codes beginning with "A" signify that the product is deemed therapeutically equivalent to the reference product for the category. Codes beginning with "B" indicate that bioequivalence has not been confirmed. In certain instances, a number is added to the end of the AB code to make it a three-character code (i.e., AB1, AB2, AB3, etc.). Three-character codes are assigned only in situations where more than one reference listed drug of the same strength has been designated under the same heading. "EE" is assigned by *Red Book* to products that have been evaluated by the FDA but for which an equivalence rating is not available.

Products appearing in the Orange Book have historically been limited to those manufacturers holding the original approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA). However, in recognition of the fact that generic products are available from a widespread number of sources, *Red Book* publications and database services extend Orange Book ratings to distributors and generic labelers other than the holder of the NDA or ANDA. All ratings applied to such labelers have been directly supplied to *Red Book* through written certification attesting to the accuracy of the codes supplied.

AA.....No bioequivalence problems in conventional dosage forms
AB.....Meets bioequivalence requirements
AB1.....Meets bioequivalence requirements to AB1 rated reference drug
AB2.....Meets bioequivalence requirements to AB2 rated reference drug
AN.....Solution or powder for aerosolization
AO.....Injectable oil solution
AP.....Injectable aqueous solution
AT.....Topical product
BC.....Controlled-release tablet, capsule, or injectable
BD.....Documented bioequivalence problem
BE.....Enteric-coated oral dosage form
BN.....Product in aerosol-nebulizer delivery system
BP.....Potential bioequivalence problem
BR.....Suppository or enema for systemic use
BS.....Testing standards are insufficient for determination
BT.....Topical product with bioequivalence issues
BX.....Insufficient data to confirm therapeutic equivalence
B*.....Requires further FDA investigation and review
EE.....This entry has been evaluated by the FDA, but a rating is not available for it's labeler's product

OTHER DESCRIPTIVE ABBREVIATIONS

The following abbreviations are used to provide additional descriptive information about products:

A.F.....Alcohol-free
AMP.....Ampule
D.F.....Dye-free
EXT.STR.....Extra-strength
F.F.....Fragrance-free
FR.....French
INSTIT.USE.....Institutional use
MDV.....Multidose vial
MAX.STR.....Maximum strength
P.C.....Plastic container
P.F.....Preservative-free
R.N.P.....Reversed number
S.D.....Single dose
S.D.V.....Single-dose vial
S.F.....Sugar-free
SRN.....Syringe
TAX INCL.....Federal excise tax included
U.S.P.....US Pharmacopeia

STANDARD DOSAGE FORM DESCRIPTIONS

The following three-character abbreviations are used to indicate the form in which a product is available:

ACC	Accessory
AER	Aerosol liquid
APP	Medication-filled stick
ARO	Aerosol powder
BAN	Bandage
BAR	Bar
BEA	Beads
C12	Capsule, extended release, 12-hr.
C24	Capsule, extended release, 24-hr.
CAK	Cake
CAP	Capsule
CER	Capsule, extended release
CHI	Chip
CRE	Cream
CRY	Crystal
CTB	Tablet, chewable
CTG	Cartridge
DEV	Device
DRE	Dressing
DSK	Disk
ECC	Capsule, delayed release
ECT	Tablet, enteric-coated
ELI	Elixir
EMU	Emulsion
FDS	Food, solid
FIL	Film
FLA	Flake
FOA	Foam
GAS	Gas
GEF	Powder, effervescent
GEL	Gel/jelly
GER	Granules, extended release
GFS	Gel-forming solution
GRA	Granules
GUM	Gum
ICR	Insert, extended release
IMP	Implant
INJ	Injection
KIT	Kit
LEA	Leaf
LIQ	Liquid
LOT	Lotion
LOZ	Lozenge/troche
LUM	Lump
NMA	Enema
ODT	Tablet, disintegrating
OIL	Oil
OIN	Ointment
PAD	Pad
PAK	Patient pack
PAS	Paste
PDR	Powder for suspension
PDS	Powder for solution
PEL	Pellet
PI1	Powder for suspension, 1-month
PI3	Powder for suspension, 3-month
PI4	Powder for suspension, 4-month
PIH	Powder for inhalation
PKT	Packet
POD	Pod
POW	Powder
PRO	Prophylactic
PUD	Pudding
SER	Suspension, extended release
SGL	Capsule, liquid-filled
SHA	Shampoo
SOA	Soap
SPE	Suppository, extended release
SOL	Solution
SPG	Sponge
SPR	Spray
STI	Stick
SUP	Suppository
SUS	Suspension
SWA	Swab
SYR	Syrup
T12	Tablet, extended release, 12-hr.
T24	Tablet, extended release, 24-hr.
TAB	Tablet
TAM	Tampon
TAP	Tape
TCP	Tablet, coated particles
TDM	Patch, extended release
TEF	Tablet, effervescent
TER	Tablet, extended
TES	Test
TIN	Tincture
WAF	Wafer
WAX	Wax

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PROD/MFR	NDC	AWP	DP	OBC
(Gallipot)				
POW, UA (MICRONIZED U.S.P.)				
1 gm	51662-0056-01	52.50		
5 gm	51662-0056-05	236.25		
(Ivax Pharm)				
SOL, TP, 0.05%, 60 ml	00182-5080-60	26.10		AT
(Major) *See FLUOCINONIDE*				
(Major)				
CRE, TP, 0.05%, 15 gm	00904-0770-36	7.30		AB
60 gm	00904-0770-02	15.50		AB
SOL, TP, 0.05%, 60 ml	00904-0769-03	25.45		AT
(Medicis) *See LIDEX*				
(Medicis) *See LIDEX-E*				
(Medisca)				
POW, UA (MICRONIZED U.S.P.)	38779-0018-06	63.75		
5 gm	38779-0018-03	287.50		
10 gm	38779-0018-01	502.50		
25 gm	38779-0018-04	1125.00		
(NuCare Pharm)				
CRE, TP, 0.05%, 15 gm	66267-0073-15	24.16		EE
(Pharma Pac)				
CRE, TP, 0.05%, 15 gm	52959-0098-01	25.36		EE
30 gm	52959-0098-03	30.35		EE
60 gm	52959-0098-02	48.98		EE
OIN, TP, 0.05%, 15 gm	52959-0315-01	22.15		EE
30 gm	52959-0315-03	30.50		EE
(Phys Total Care)				
CRE, TP, 0.05%, 15 gm	54868-0431-02	4.42		EE
30 gm	54868-0431-03	6.76		EE
60 gm	54868-0431-01	10.71		EE
OIN, TP, 0.05%, 30 gm	54868-3435-00	18.96		EE
60 gm	54868-3435-01	44.93		EE
SOL, TP, 0.05%, 60 ml	54868-2451-01	19.14		EE
CRE, TP, 0.05%, 30 gm	54868-3408-00	15.66		EE
60 gm	54868-3408-01	27.76		EE
(Qualitest)				
CRE, TP, 0.05%, 15 gm	00603-7769-74	7.32		AB
30 gm	00603-7769-78	9.86		AB
SOL, TP, 0.05%, 60 ml	00603-7759-93	19.95		AB
(Southwood)				
CRE, TP, 0.05%, 15 gm	58016-3121-01	23.92		EE
30 gm	58016-3121-03	24.92		EE
GEL, TP, 0.05%, 60 gm	58016-3274-01	52.65		EE
(Teva)				
CRE, TP, 0.05%, 15 gm	51672-1253-01	13.56		AB
30 gm	51672-1253-02	13.00		AB
60 gm	51672-1253-03	23.72		AB
120 gm	51672-1253-04	67.50		AB
GEL, TP, 0.05%, 15 gm	51672-1279-01	23.07		AB
30 gm	51672-1279-02	20.94		AB
60 gm	51672-1279-03	48.85		AB
OIN, TP, 0.05%, 15 gm	51672-1264-01	21.04		AB
30 gm	51672-1264-02	20.19		AB
60 gm	51672-1264-03	40.58		AB
SOL, TP, 0.05%, 20 ml	51672-1273-02	16.89		AT
60 ml	51672-1273-04	37.00		AT
CRE, TP (EMULSIFIED BASE)				
0.05%, 15 gm	51672-1254-01	19.40		AB
30 gm	51672-1254-02	25.66		AB
60 gm	51672-1254-03	45.06		AB
(Tova)				
CRE, TP, 0.05%, 15 gm	00093-0262-15	8.97		AB
30 gm	00093-0262-30	13.02		AB
60 gm	00093-0262-92	21.04		AB
GEL, TP, 0.05%, 60 gm	00093-0265-92	46.01		AB
OIN, TP, 0.05%, 15 gm	00093-0264-15	19.33		AB
30 gm	00093-0264-30	27.51		AB
60 gm	00093-0264-92	46.01		AB
SOL, TP, 0.05%, 60 ml	00093-0265-39	26.18		AT
CRE, TP (EMULSIFIED BASE)				
0.05%, 15 gm	00093-0263-15	19.90		AB
30 gm	00093-0263-30	27.50		AB
60 gm	00093-0263-92	46.00		AB
(Thames)				
CRE, TP, 0.05%, 15 gm	49156-0212-20	5.04		AB
30 gm	49156-0212-68	8.40		AB
60 gm	49156-0212-24	14.72		AB
SOL, TP, 0.05%, 20 ml	49156-0316-64	10.60		AT
60 ml	49156-0316-48	23.49		AT
0.05%, 15 gm	52544-0449-73	16.36		AB
CRE, TP, 0.05%, 15 gm	52544-0449-73	16.36		AB
SOL, TP, 0.05%, 60 ml	52544-0447-60	28.68		AB
60 gm	52544-0447-09	29.60		AT
(Watson)				

PROD/MFR	NDC	AWP	DP	OBC
FLUOCINONIDE (Major)				
CRE, TP, 0.05%, 30 gm	00904-0770-61	10.15		AB
FLUOGEN (Phys Total Care)				
REPACK				
influenze virus vaccine (subvirion)				
SOL, IM (M.D.V.,STERI-VIAL,95-00)				
45 mcg/0.5 ml				
5 ml	54868-4124-00	30.96		
FLUOR-A-DAY (Pharmascience Labs)				
sodium fluoride				
CTB, PO (S.F., RASPBERRY)				
0.25 mg, 120s ea	51817-0602-16	7.02		
0.5 mg, 120s ea	51817-0611-16	7.02		
1 mg, 120s ea	51817-0622-16	7.02		
LIQ, PO (DROPS)				
0.5 mg/0.6 ml	51817-0656-61	5.61		
LOZ, PO (S.F., MINT)				
1 mg, 100s ea	51817-0672-16	7.25		
(medvantx)				
REPACK				
CTB, PO (S.F., RASPBERRY)				
0.25 mg, 30s ea	55110-0104-30	1.03		
FLUOR-I-STRIP (Bausch&Lomb Pharm)				
fluorescein sodium				
TES, OP (STRIP)				
9 mg, 300s ea	24208-0396-63	77.00		
(Allscripts)				
REPACK				
TES, OP (STRIP)				
9 mg, 300s ea	54569-2086-00	77.50		
FLUOR-I-STRIP A.T. (Bausch&Lomb Pharm)				
fluorescein sodium				
TES, OP (STRIP)				
1 mg, 300s ea	24208-0391-63	77.50		
FLUOR-OP (Novartis Ophth)				
fluorometholone				
SUS, OP, 0.1%, 5 ml	58768-0356-05	16.03		AB
10 ml	58768-0356-10	22.56		AB
15 ml	58768-0356-15	20.16		AB
FLUORAGON (Perry Med)				
sod fl/vit a/vit c/vit d				
SOL, PO (DROPS, BASIC)				
(Perry Med)/ml, 50 ml	11763-0519-20	4.16		
sodium fluoride				
CTB, PO (ORANGE)				
1 mg, 100s ea	11763-0525-01	1.99		
(ORANGE)				
LIQ, PO (DROPS)				
1 mg, 100s ea	11763-0522-01	1.99		
50 ml	11763-0524-20	2.75		
0.25 mg/0.6 ml				
FLUORACAINE (Akorn)				
fluorescein/proparacaine				
SOL, OP (GLASS BOTTLE)				
0.25%-0.5%, 5 ml	17478-0311-10	9.15		
FLUORESCEIN (Akorn)				
10%				
(Fl)				
FLUORESCEIN SODIUM (A.T. Sodium)				
25%				
(Akorn) *See AK-FLUOR*				
(Akorn) *See D.E.T. DRY EYE TEST*				
(Akorn) *See FLUORETS*				
(Akorn) *See FUL-GLO*				
(Alcon Ophthalmic) *See FLUORESCITE*				
(Allscripts)				
SOL, OP, 4%, 1 ml UD	54569-0073-00	16.74		
(Bausch&Lomb Pharm) *See FLUOR-I-STRIP A.T.*				
(Bausch&Lomb Pharm) *See FLUOR-I-STRIP*				
(EyeSupply USA) *See ANGIOSCEIN*				
(Integra)				
POW, UA (U.S.P., REAGENT)				
100 gm	F5801020	48.90		
(WATER SOLUBLE)				
100 gm	F5805020	22.40		

PROD/MFR	NDC	AWP	DP	OBC
(U.S.P., REAGENT)				
500 gm	F5801030	97.65		
(WATER SOLUBLE)				
500 gm	F5805030	52.15		
(Novartis Ophth) *See ANGIOSCEIN*				
(Ocumed) *See OCU-FLUR 10*				
FLUORESCEIN/PROPARACAINE				
(Akorn) *See FLUORACAINE*				
(Gensolt) *See FLUCAINE*				
FLUORESCITE (Alcon Ophthalmic)				
fluorescein sodium				
SOL, IV (AMP)				
10%, 5 ml	00065-0092-05	18.95		
(SRN, 10 ML)				
10%, 5 ml	00065-0093-05	37.20		
(AMP)				
25%, 2 ml	00065-0094-02	22.02		
FLUORETS (Akorn)				
fluorescein sodium				
TES, OP (STRIP)				
1 mg, 100s ea	17478-0400-01	13.50		
FLUORI-METHANE (Gebauer)				
dichlorotrichloromono				
SPR, TP (FINE)				
15%-85%, 103 ml	00386-0093-04	23.20		
(Allscripts)				
REPACK				
SPR, TP (FINE)				
15%-85%, 103 ml	54569-3567-00	24.69		
(Phys Total Care)				
REPACK				
SPR, TP (FINE)				
15%-85%, 103 ml	54868-4150-00	29.10		
FLUORIDE (Vintage)				
sodium fluoride				
LIQ, PO (DROPS)				
0.25 mg/drop	00254-0430-48	5.10		
FLUORINSE (Oral B Lab)				
sodium fluoride				
SOL, PO (A.F.,CINNAMON)				
0.2%, 180 ml	00041-0351-07	7.49		
(A.F.,MINT)				
FLUORO/GLY GEL (Topix)	00041-0356-07	7.49		
glycolic acid				
GEL, TP (OFFICE USE ONLY)				
30%, 120 gm	51326-0025-04	15.00		
50%, 120 gm	51326-0027-04	25.00		
70%, 120 gm	51326-0029-04	35.00		
FLUORO/GLY PADS (Topix)				
glycolic acid				
PAD, TP (OFFICE USE ONLY)				
30%, 30s ea	51326-0006-30	30.00		
50%, 30s ea	51326-0008-30	50.00		
70%, 30s ea	51326-0010-30	70.00		
FLUOROMETH/SULFACET SOD				
(Allergan Inc) *See FML-S LIQUIFILM*				
FLUOROMETHOLONE				
(FML)				
SUS, OP, 0.1%, 5 ml		8.00		
FLUOROMETHOLONE FORTE				
ROY				
(Allergan Inc) *See FML FORTE LIQUIFILM*				
(Allergan Inc) *See FML LIQUIFILM*				
(Allergan Inc) *See FML S.O.P.*				
SUS, OP, 0.1%, 5 ml	54569-4371-00	13.84		EE
(Allscripts)				
10 ml	54569-4372-00	26.18		EE
15 ml	54569-4373-00	35.20		EE
(Bausch&Lomb Pharm)				
SUS, OP, 0.1%, 5 ml	24208-0268-05	15.00		AB
15 ml	24208-0268-15	35.18		AB
10 ml	24208-0268-10	26.16		AB
(Caremark Inn.)				
SUS, OP, 0.1%, 5 ml	00339-5080-50	15.03		AB
10 ml	00339-5080-51	23.63		AB
15 ml	00339-5080-52	31.30		AB
SUS, OP, 0.1%, 5 ml	61314-0328-05	15.80		AB
(Falcon Ophthalmics)				
10 ml	61314-0328-10	26.20		AB
15 ml	61314-0328-15	35.20		AB

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FLEET PREP KIT 3 (Fleet,C.B.)
KIT,NA (W/SMALL-VOLUME ENEMA)
ea 01320-2120-10 4.87

FLEET SOF-LAX (Fleet,C.B.)
TAB,PO (GELCAPLET)
100 mg, 60s ea 01320-7516-00 5.60

FLEET SOF-LAX OVERNIGHT (Fleet,C.B.)
TAB,PO (GELCAPLET)
30 mg-100 mg,
30s ea 01320-7553-00 4.80
60s ea 01320-7550-00 8.00

FLETCHER'S CASTORIA (Medtech)
LIQ,PO, 0.5%, 75 ml 10742-0032-10 3.59

FLEXALL 454 (Chattem)
GEL,TP, 7%, 60 gm 41167-1601-15 3.24
120 gm 41167-1601-30 4.86
240 gm 41167-1601-60 7.68

FLEXALL 454 MAXIMUM STRENGTH (Chattem)
GEL,TP, 45 gm 41167-1602-10 3.24
90 gm 41167-1602-20 4.86
180 gm 41167-1602-40 7.68

FLEXALL ULTRA PLUS (Chattem)
GEL,TP (GREASELESS)
3.1%-16%-10%,
60 gm 41167-1603-10 4.86
120 gm 41167-1603-30 6.88

FLEXI-SEAL FECAL COLLECTOR (Convatec)
DEV,NA (W/TAIL CLIPS)
10s ea 00003-6500-70 78.97 92.91

FLEXI-TRAK ANCHORING (Convatec)
ACC,NA (LARGE)
50s ea 00003-0374-49 99.23 94.59

FLEXIBLE FABRIC STRIPS
(Chelo Drug Marketing)
BAN,TP (ASSORTED)
20s ea 63508-0030-10 0.99

FLEXIFIX TRANSPARENT ADHESIVE FILM
(Smith & Nephew)
TAP,TP (2"X11YD ROLL)
ea 00223-4161-30 14.84 19.78
(4"X11YD ROLL)
ea 00223-4161-40 25.98 34.64

FLEXIFLO III PUMP W/SPIKE (Hospira)
KIT,NA, ea 00005-9017-05 6.64

FLEXIFLO QUANTUM COLORMARK PUMP (Ross Hair)
KIT,NA (W/PIERC PIN & FLUSH BAG)
ea 70074-5249-00 16.54
(W/PIERCING PIN)
ea 70074-5248-00 10.04
(W/TOP-FILL & FLUSH BAGS)
ea 70074-5459-10 21.38
(W/TOP-FILL BAG)
ea 70074-5454-00 16.48

FLEXIFLO QUANTUM ENTERAL PUMP (Ross Hair)
DEV,NA, ea 70074-5050-70 1398.00
KIT,NA (40MM)
ea 70074-5080-30 7.85

FLEXIFLO QUANTUM PUMP (Ross Hair)
KIT,NA (W/PIERC PIN & FLUSH BAG)
ea 70074-5060-50 13.74
(W/PIERCING PIN)
ea 70074-5060-10 8.44

FLEXIFLO-III COLORMARK PUMP (Ross Hair)
KIT,NA (W/PIERCING PIN)
ea 70074-5248-40 9.66

FLEXIFLO-III ENTERAL NUTRITION PUMP
(Ross Hair)
DEV,NA (REFURBISHED)
ea 70074-6436-10 638.60
KIT,NA, ea 70074-0007-70 6.26
(W/PIERCING PIN)
ea 70074-0007-80 7.26

FLEXITAINER 500 CONTAINER (Ross Hair)
KIT,NA (ENTERAL NUTRITION)
ea 70074-0005-60 5.21

FLEXITAINER NUTRITION CONTAINER (Ross Hair)
ACC,NA, ea 70074-0005-90 8.38

FLEXOPLAST (Western Medical)
BAN,TP (3" ELASTIC ADHESIVE)
12s ea BL1003 102.99
(3" REVERSE ADHESIVE)
12s ea BL1003R 102.99
(4" ELASTIC ADHESIVE)
12s ea BL1004 123.31

FLEXTEND SKIN BARRIER NON-STERILE
(Hollister)
DEV,NA (6"X6" 35 ea 8001 57.59 65.01
(4"X4") 6s ea 8800 25.24 28.76

FLEXZAN (Bertek)
DRE,TP (4"X6" SHEETS)
5s ea 62704-0085-32 35.25
(6"X8" SHEETS)
5s ea 62704-0085-64 70.50
(2"X3" SHEETS)
10s ea 62704-0085-08 24.00
(4"X4" SHEETS)
10s ea 62704-0085-16 32.00

FLEXZAN EXTRA (Bertek)
DRE,TP (4"X5")
5s ea 62704-0081-32 40.00
(8"X8")
5s ea 62704-0081-64 77.00

FLINTSTONES (Bayer Cons)
CTB,PO, 60s ea 16500-0781-08 4.46
100s ea 16500-0781-40 6.52

FLINTSTONES COMPLETE (Bayer Cons)
CTB,PO, 60s ea 16500-0860-60 6.54
150s ea 16500-0871-30 10.68

FLINTSTONES PLUS CALCIUM (Bayer Cons)
CTB,PO, 60s ea 16500-0770-60 5.67

FLINTSTONES PLUS EXTRA C (Bayer Cons)
CTB,PO, 60s ea 16500-0801-60 5.67
100s ea 16500-0801-90 8.23

FLINTSTONES W/IRON (Bayer Cons)
CTB,PO, 60s ea 16500-0790-00 5.67
100s ea 16500-0790-50 7.53

FLIP-FLO INCONTINENCE VALVE (Bard Medical)
ACC,NA (18 OZ,BONUS PACK)
ea 150419 23.86 29.57
(18 OZ,W/LATEX STRAP)
ea 150319 6.42 8.02
(32 OZ,BONUS PACK)
ea 150432 23.65 29.57

FLIPPER HOLDER/RACK (Bernell Corp)
ACC,NA (HOLDS 12 FLIPPERS)
ea ..... BCFH 52.95

FLIPPER W/FOUR CELLS (Bernell Corp)
DEV,NA (EMPTY,NO LENSES)
ea BC4F 5.56

FLIPPER W/TWO PAIRS OF LENSES
(Bernell Corp)
DEV,NA (+1/+1.25-2 DIOPTERS)
ea BC1278 16.05
(+1/+1.25-4 DIOPTERS)
ea BC1270 17.95
(ANY COMBINATION)
ea BC12705 20.55

FLO-GARD PUMP W/SPIKE (Hospira)
KIT,NA, ea 00005-9000-09 6.64

FLORICAL (Morrison)
CAP,PO, 354 mg-0.3 mg,
100s ea 00394-0102-02 9.96
500s ea 00394-0102-05 46.95
TAB,PO, 354 mg-0.3 mg,
100s ea 00394-0100-02 9.12
500s ea 00394-0100-05 42.65

FLORIDA FOAM IMPROVED (Hill Derm)
LIQ,TP, 240 ml 20105-0009-00 5.31

FLOW DETECTOR (Abbott Hosp)
KIT,NA (54")
ea 00074-1907-25 163.55

FLU & COLD MEDICINE (Perrigo)
PDR,PO (LEMON, PACKET)
650 mg-4 mg-60 mg,
6s ea 58940-0113-01 2.36

FLU COLD & COUGH NIGHTTIME
(Cardinal Health)
PKT,PO (MAX. STR.,LEMON)
6s ea 57205-0331-01 3.52

(Major)
PKT,PO (MAX. STR.,A.F.,LEMON)
6s ea 00904-5461-06 3.45

FLU MULTI-SYMPTOM MAXIMUM STRENGTH (Eckerd)
TAB,PO (GELCAP,NON-DROWSY)
500 mg-15 mg-30 mg,
24s ea 19458-2676-01 4.08

FLU SOLUTION (Ortlieb)
PEL,SI, 5s ea 00724-0001-11 4.17 5.95

FLU SOLUTION PLUS (Ortlieb)
TAB,SL, 45s ea 00134-0506-41 4.17 5.95

FLU, COLD & COUGH MEDICINE
(Cardinal Health)
PDR,PO (PACKET,LEMON)
6s ea 57205-0310-01 3.19

FLU-RELIEF (Pfeiffer)
TAB,PO, 325 mg-2 mg-30 mg,
36s ea 00027-0324-03 2.94 5.29

FLU/COLD/COUGH MEDICINE (Dorsey Brunswig)
POS,PO (MAX STR, PACKET,LEMON)
6s ea 24385-0006-01 3.59 4.39
(PACKET,LEMON)
6s ea 24385-0830-01 3.19 3.99

(Perrigo)
PDR,PO (PACKET,LEMON)
6s ea 58940-0555-01 2.39

FLUORIDE TARTAR CONTROL TOOTHPASTE
(Perrigo)
GEL,TP (FRESHMINT)
0.15%, 181 gm 58940-0270-26 1.74
PAS,TP (ORIGINAL)
192 gm 58940-6233-20 1.74

FLUORIDE TOOTHPASTE (Perrigo)
PAS,TP (MINT)
192 gm 58940-0007-20 1.56
(REGULAR)
192 gm 58940-0016-20 1.56

FLUORIGARD (Colgate Oral)
SOL,PO, 0.05%, 473 ml 00126-0228-16 3.65

FO-TI (Botanical Labs.)
LIQ,PO, 30 ml 41954-0201-80 4.50 8.99

FOAM INVALID RING REPLACEMENT COVER
(Hermell)
ACC,NA (FOR IR7210,12,14)
ea IR7210/12/14 2.75
(FOR IR7211,13,15)
ea IR7211/13/15 4.00

FOAM INVALID RING W/COVER (Hermell)
DEV,NA (14 1/4"X12 3/4",PLAID)
ea IR7000 6.15
(14 1/4"X12 3/4",POLYCOT)
ea IR7070 6.60
(16 1/4"X13",PLAID)
ea IR7020 8.05
(16 1/4"X13",POLYCOT)
ea IR7070 8.25
(18 1/4"X15 1/4",PLAID)
ea IR7050 8.10
(18 1/4"X15 1/4",POLYCOT)
ea IR7040 7.40

FOAM PAD (Torbal)
ACC,NA (1/16",LARGE,BLACK)
ea 433L 1.60
(1/16",LARGE,WHITE)
ea 431L 1.30
(1/16",REGULAR,BLACK)
ea 433R 1.60
(1/16",REGULAR,WHITE)
ea 431R 1.30
(1/16",SPEC SMALL,BLACK)
ea 433S 1.60
(1/16",SPEC SMALL,WHITE)
ea 431S 1.30
(1/16",VERY LARGE,BLACK)
ea 434V 2.25
(1/16",VERY LARGE,WHITE)
ea 432V 1.85
(1/16",X-LARGE,BLACK)
ea 434G 2.25
(1/16",X-LARGE,WHITE)
ea 432G 1.40
(1/16",X-SMALL,BLACK)
ea 433E 1.60
(1/16",X-SMALL,WHITE)
ea 431E 1.30
(1/8",LARGE,WHITE)
ea 731L 1.30
(1/8",REGULAR,WHITE)
ea 731R 1.20
(1/8",SPEC SMALL,WHITE)
ea 731S 1.30
(1/8",VERY LARGE,WHITE)
ea 732V 1.35
(1/8",X-LARGE,WHITE)
ea 732G 1.40
(1/8",X-SMALL,WHITE)
ea 731E 1.30

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WAC 246-883-020

Agency filings affecting this section

Identification of legend drugs for purposes of chapter 69.41 RCW.

(1) In accordance with chapter 69.41 RCW, the board of pharmacy finds that those drugs which have been determined by the Food and Drug Administration, under the Federal Food, Drug and Cosmetic Act, to require a prescription under federal law should also be classified as legend drugs under state law because of their toxicity or potential for harmful effect, the methods of their use and the collateral safeguards necessary to their use, indicate that they are only safe for use under the supervision of a practitioner.

(2) For the purposes of chapter 69.41 RCW, 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*. Copies of the list of legend drugs as contained in the *Drug Topics Red Book* are available for public inspection at the headquarters office of the State Board of Pharmacy, 1300 Quince Street S.E., P.O. BOX 47863, Olympia, Washington 98504-7863. To obtain copies of this list, interested persons must submit a written request and payment of seventy-six dollars for each copy to the board.

(3) There may be changes in the marketing status of drugs after the publication of the above reference. Upon application of a manufacturer or distributor, the board may grant authority for the over the counter distribution of certain drugs which had been designated as legend drugs in this reference. These determinations will be made after public hearing and will be published as an amendment to this chapter.

[Statutory Authority: RCW 69.41.075 and 18.64.005(7). 02-14-049, § 246-883-020, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 69.41.075, 18.64.005. 00-06-078, § 246-883-020, filed 3/1/00, effective 4/1/00. Statutory Authority: RCW 69.41.075. 96-21-041, § 246-883-020, filed 10/11/96, effective 11/11/96. Statutory Authority: RCW 18.64.005. 92-09-070 (Order 264B), § 246-883-020, filed 4/14/92, effective 5/15/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-883-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.075]. 85-18-091 (Order 196), § 360-32-050, filed 9/4/85. Statutory Authority: RCW 18.64.005 and 69.41.075. 83-20-053 (Order 176), § 360-32-050, filed 9/29/83. Statutory Authority: RCW 69.41.075. 81-10-025 (Order 160), § 360-32-050, filed 4/28/81. Statutory Authority: 1979 1st ex. s. c 139. 79-09-138 (Order 149, Resolution No. 9/79), § 360-32-050, filed 9/5/79.]

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From: CDER DRUG INFO [mailto:DRUGINFO@fda.hhs.gov]
Sent: Wednesday, July 22, 2009 7:20 AM
To: Bill
Subject: RE: The legend drug fluoride

Dear Dr. Osmunson:

Thank you for writing the Division of Drug Information, in the FDA's Center for Drug Evaluation and Research.

A search of the Drugs@FDA database (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm) of approved drug products and the Electronic Orange Book (http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm) 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.

The FDA is aware of sodium fluoride-containing products in various dosage forms that are currently marketed. At the present time, the FDA is deferring any regulatory action on sodium fluoride products that were marketed prior to 1962 as long as the currently marketed product is identical to the pre-1962 product. Any prescription sodium fluoride-containing product coming into the marketplace after 1962 that is not identical to the pre-1962 labeling and that has drug claims, is subject to the FDA drug review process prior to marketing.

Best regards,
Drug Information SH
Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration

For up-to-date drug information, follow the FDA's Division of Drug Information on Twitter: http://twitter.com/fda_drug_info <http://twitter.com/fda_drug_info>

This communication is consistent with 21CFR10.85(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 the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: Bill [mailto:bill@teachingsmiles.com]
Sent: Saturday, July 18, 2009 2:52 PM
To: CDER DRUG INFO
Subject: The legend drug fluoride

Dear FDA,

I am writing an Amicus for the Washington State Supreme Court. In an effort to give them the best information without them having to do the research and digging on the web site, I am requesting a letter or email from the FDA stating that the FDA has not approved the ingestion of sodium fluoride or silicofluorides for the prevention of dental decay.

Specifically to my question, "Is sodium fluoride, silicofluoride or hydrofluorosilicic acid an approved drug for ingestion for the prevention or mitigation of dental decay?

Bill Osmunson DDS, MPH
25977 Canyon Creek Suite G
Wilsonville, OR 97070
425.466.0100
bill@teachingsmiles.com

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NDA withdrawn for fluoride and vitamin combinations

The FDA has addressed a "regulatory letter" to approximately 35 companies marketing combination drugs consisting of fluoride and vitamins. The letter states that these drugs are related to a product (Enziflur lozenges) for which FDA has withdrawn approval of a new drug application. The NDA for Enziflur was withdrawn because there is no substantial evidence of drug effectiveness as prescribed, recommended, or suggested in its labeling. The FDA has therefore advised manufacturers of combination fluoride and vitamin preparations that their continued marketing is in violation of the new drug provisions of the *Federal Food, Drug, and Cosmetic Act*; they have, therefore, requested that marketing of these products be discontinued.

DRUG THERAPY/JUNE 1975

July 2008

NEWS

Washington State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

Dept. of Health, PO Box 47863, Olympia, WA 98504-7863
https://fortress.wa.gov/doh/hpqa1/hps4/pharmacy/default.htm

No. 969 National Standardized Examination for Pharmacy Technician Certification

The Washington State Board of Pharmacy adopted rule changes at its public hearing on May 29, 2008. The amended rules result in new requirements for certification as a pharmacy technician. Effective January 1, 2009, all technician applicants must pass a national standardized examination. In addition, all applicants are still required to complete a Board-approved technician training program. Individuals who have obtained a pharmacy technician credential before January 1, 2009, will not be required to meet the new standards.

In the next few months, the Board will be developing the criteria for a Board-approved examination. The plan for applying the rule includes adopting examination standards and identifying which examination(s) are Board-approved. The rule changes also require updates to the basic standards for Board-approved training programs. It is expected that these activities will be further defined at the July 17, 2008, business meeting.

For updates, please visit the Board's Web page at *https://fortress.wa.gov/doh/hpqa1/hps4/Pharmacy/default.htm.* (WAC246-901-030 & 060)

No. 970 New Preceptor Certifications

If you have renewed your pharmacist license recently, you may have noticed some changes. With the implementation of the new licensing system, your preceptor certification no longer appears on your pharmacist license. A separate license is now issued to pharmacists with active preceptor certifications.

During the implementation of the new system, we discovered that the issue and expiration date of several active preceptor certifications were not correctly transferred from the old system. We are working on correcting this matter and plan to issue replacement preceptor certifications. Please note: Board staff can access past preceptor license history for verification when a pharmacy intern submits hours while under your supervision.

A certificate of participation is mailed to all original and renewed preceptor licensees. Participation in this program will earn the licensee 0.3 continuing education credits. Preceptor certification expires on the licensee's birthday and is issued for no more than five years from the activation date.

When applying for a new or renewing a pharmacist preceptor certification, please use the new application form found on the Board's Web site.

No. 971 Frequently Asked Questions

Q. How should prescriptions from Canada be handled?

Prescriptions from a Canadian province that shares a common border with Washington can be dispensed here. Currently, British Columbia is the only province that qualifies.

Prescriptions from Canada for Food and Drug Administration-approved legend drugs can be filled if written by one of the following practitioners licensed in Canada:

- physician licensed to practice medicine and surgery;
- physician licensed to practice osteopathic medicine and surgery;
- dentist licensed to practice dentistry;
- podiatric physician and surgeon licensed to practice podiatric medicine and surgery;
- veterinarian licensed to practice veterinary medicine. (RCW 69.41.030)

In addition, all state and applicable federal requirements for prescriptions must also be met.

Prescriptions for Schedule II through V medications cannot be filled in Washington if written in Canada.

Q. Where can I find information on practitioners' prescriptive authority?

You can find information on the Board of Pharmacy's Web site under the site directory titled "Prescribing Authority." The chart lists the professions that have prescribing authority and notes any restrictions or limitations. The relevant state laws and rules are also noted.

The list includes professions that can administer medications under a prescriber's order. The section on "General Limitations" contains information on prescribing, such as not prescribing controlled substances for yourself*, and which out-of-state practitioners you can accept prescriptions from, etc. Lastly, there is a section that lists professions whose scope does not allow prescribing, administering, or dispensing of medications.

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Continued on page 4

A Community Pharmacy Technician's Role in Medication Reduction Strategies

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and Food and Drug Administration (FDA) in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Pharmacy technicians play a major role in community pharmacy practice. The pharmacist relies on the technician to provide an extra layer of safety. It is important for technicians to follow system-based processes and inform the pharmacist when these processes do not work or are unmanageable.

Prescription Drop Off

The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy information should be questioned and updated at every patient encounter. Medical condition information, such as pregnancy, communicated to the technician at drop off should be updated in the computerized profile system to help the verification pharmacist determine counseling opportunities. Knowing a person's medical conditions also helps the pharmacist determine if prescriptions are written incorrectly or for the wrong drug.

Data Entry

Medication safety is enhanced when technicians know the particular language of pharmacy when entering a prescription.

New drugs are at a particular risk because it is more likely that the technician is not aware of the new drug and a more familiar drug is selected. Pharmacists and technicians should work together to determine the best method of distributing information regarding availability of new drugs on the market.

It is important that the technician understands the safety features of the computer system and does not create work-arounds to improve efficiency at the risk of decreasing accuracy and safety. Drug alerts can be numerous, and the technician may be inclined to override the alert and not "bother" the pharmacist. A better way to resolve too many alerts would be to establish protocol between the technician and the pharmacist to determine which level and type of alert needs pharmacist intervention.

Production

Mix-ups occur primarily due to incorrectly reading the label. The problem is aggravated by what is referred to as *confirmation bias*. Often a technician chooses a medication container based on a mental picture of the item, whether it be a characteristic of the drug label, the shape and size or color of the container, or the location of the item on a shelf. Consequently the wrong product is picked. Physically separating drugs with look-alike labels and packaging helps to reduce this contributing factor.

Point of Sale

Correctly filled prescriptions sold to a patient for whom it was not intended is an error that can be avoided by consistent use of a second identifier at the point of sale. Ask the person picking up the prescription to verify the address or in the case of similar names, the date of birth, and compare the answer to the information on the prescription receipt.

Internal errors should be discussed among all staff for training purposes. In addition, it is important to read about and discuss errors and methods of prevention occurring and being employed at other pharmacies within a chain and in other pharmacies, nationwide. ISMP Medication Safety Alert! Community/Ambulatory Edition offers this information to both pharmacists and technicians.

FDA's Effort to Remove Unapproved Drugs From the Market

Pharmacists are often not aware of the unapproved status of some drugs and have continued to unknowingly dispense unapproved drugs because the labeling does not disclose that they lack FDA approval. FDA estimates that there are several thousand unapproved drugs illegally marketed in the United States. FDA is stepping up its efforts to remove unapproved drugs from the market.

Background

There are three categories of unapproved drugs that are on the market. The first category consists of those that have been approved for safety, or that are identical, related, or similar to those drugs, and either have been found not to be effective, or for which FDA has not yet determined that they are effective. Between 1938 (passage of the Federal Food, Drug, and Cosmetic Act) and 1962, manufacturers were only required to demonstrate that drugs were safe; the requirement that they also demonstrate that drugs were effective was added in 1962. Drugs that fall in this category have been part of the DESI (Drug Efficacy Study Implementation) review, which was implemented to determine whether drugs approved between 1938 and 1962, or drugs that are identical, related, or similar to such drugs, met the new effectiveness requirements. While the DESI review is mostly completed, some parts of it are still continuing. The second category of unapproved drugs consists of those drugs that were on the market prior to 1938 (passage of the Federal Food, Drug, and Cosmetic Act). The third category, new unapproved drugs, comprises unapproved drugs that were first marketed (or changed) after 1962. Some also may have already been the subject of a formal agency finding that they are new drugs.

FDA's Concerns About Unapproved Drugs

FDA has serious concerns that drugs marketed without FDA approval may not meet modern standards for safety, effectiveness, manufacturing quality, labeling, and post-market surveillance. For example, FDA-approved drugs must demonstrate that their manufacturing processes can reliably produce drug products of expected identity, strength, quality, and purity. In addition, FDA's review of the applicant's labeling ensures that health care professionals and patients have the information necessary to understand a drug product's risks and its safety and efficacy.

Sponsors that market approved products are subject to more extensive reporting requirements for adverse drug events than sponsors of unapproved drugs. Reporting of adverse events by health care professionals and patients is voluntary, and under-reporting is well documented. FDA, therefore, cannot assume that an unapproved drug is safe or effective simply because it has been marketed for some period of time without reports of serious safety or effectiveness concerns.

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Enforcement Priorities

Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.

Most recently, in June 2006, FDA issued a guidance entitled "Marketed Unapproved Drugs – Compliance Policy Guide" (CPG) outlining its enforcement policies aimed at bringing all such drugs into the approval process. (The CPG is available at *www.fda.gov/cder/guidance/6911fnl.pdf*) The agency provided industry with specific notice that anyone who markets an unapproved drug is subject to enforcement action. This CPG outlines the agency's risk-based enforcement policies aimed at bringing all such drugs into the approval process without imposing undue burdens on consumers or unnecessarily disrupting the market. For all unapproved drugs, the CPG gives highest enforcement priority to the following:

- Drugs with potential safety concerns
- Drugs that lack evidence of effectiveness
- Fraudulent drugs
- Drugs with formulation changes made as a pretext to avoid enforcement
- Unapproved drugs that directly compete with an approved drug

Table 1 lists examples of drugs or classes of drugs that, consistent with the CPG, FDA has identified as a higher priority because of safety or other concerns. For six of them, FDA has specifically announced its intention to take enforcement action against companies marketing unapproved versions of those drug products. FDA has withdrawn the approval of the seventh product.

Table 1: Examples of FDA Actions Regarding Unapproved Drugs
Extended release combination drug products containing guaifenesin (competed with approved products)
Trimethobenzamide hydrochloride suppositories (lacked evidence of effectiveness)
Ergotamine-containing drug products (labeling did not include critical warnings regarding the potential for serious, possibly fatal interactions with other drugs)
Quinine sulfate drug products (665 reports of adverse events, including 93 deaths, and the labeling lacked necessary warnings and safe dosing information)
Carbinoxamine drug products (associated with 21 infant deaths)
Colchicine injectables (50 reports of adverse events, including 23 deaths)

Importance to Pharmacists

FDA is taking steps to ensure that all marketed US drugs have met approval requirements. FDA recognizes that some unapproved drugs may provide benefits; however, since these products have not undergone FDA review for safety and efficacy, the agency recommends that pharmacists, prescribers, and patients carefully consider the medical condition being treated, the patient's previous response to a drug, and the availability of approved alternatives for treatment. FDA will proceed on a case-by-case basis and make every effort to avoid adversely affecting public health, imposing undue burdens on health care professionals and patients, and unnecessarily disrupting the drug supply. More information regarding the FDA's Unapproved Drug Initiative can be found on its Web site: *www.fda.gov/cder/drug/unapproved_drugs/*.

NABP Educates Public on Buying from Internet Pharmacies with New Section on its Web site

On May 16, 2008, the National Association of Boards of Pharmacy® (NABP®) launched the Internet Pharmacies section of its Web site, educating patients on the potential dangers of buying medicine online and empowering them to make informed choices. As of mid-June, the site listed 250 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby putting those who purchase from these sites in danger of purchasing drugs that could cause patients serious harm or even death.

NABP developed these standards for its new Internet Drug Outlet Identification program with input from its member boards of pharmacy, interested stakeholders, and regulatory agencies, including the FDA and the US Drug Enforcement Administration. Internet drug outlets operating in conflict with these criteria are listed on the NABP Web site as "not recommended." NABP has identified another 300 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the "not recommended" list. Of the hundreds of sites reviewed under this program so far, only nine have been found to be potentially legitimate, pending verification of licensure and other criteria. At this time, NABP recommends that patients buying medicine online use only Internet pharmacies accredited through the VIPPS® (Verified Internet Pharmacy Practice Sites™) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as "recommended."

These lists, along with program criteria and related patient information, are accessible in the Internet Pharmacies section of the NABP Web site.

The new program is an outgrowth of a 2007 NABP resolution, "Internet Pharmacy Public Safety Awareness," in which the Association pledges to continue collaborating with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources. As part of this initiative, NABP will provide information to assist state and federal regulators in their efforts to shut down rogue Internet drug outlets.

RxPatrol Video Helps Pharmacists Address and Prevent Pharmacy Theft

Pharmacy theft is a serious crime that is on the rise, costing pharmacies billions annually in stolen medication according to the Federal Bureau of Investigation (FBI). RxPatrol® has teamed up with Crime Stoppers and other law enforcement officials to disseminate information regarding pharmacy crime. One resource that pharmacists can use to educate themselves and their coworkers is a training video that provides tips for pharmacists to address the rising issue of pharmacy robberies. The video includes interviews with law enforcement officials from the FBI and police department about what can be done to prevent such activity. The video can be found on the RxPatrol Web site at *www.rxpatrol.com/videos.asp* and by clicking on "Pharmacy Safety – Robbery."

RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze and disseminate pharmacy theft information. RxPatrol helps protect the pharmacy environment and ensure legitimate patients' access to life-sustaining medicines.

Continued from page 1

You may also link to other professions' Web sites by selecting "Profession Links (A-Z)" for the site directory.

**On February 28, 2008, the Medical Quality Assurance Commission (MQAC) adopted a policy regarding* Self-Treatment or Treatment of Immediate Family Members. *Visit the MQAC Web site for more information at* https://fortress.wa.gov/doh/hpqa1/hps5/Medical/default.htm.

Q. When do ancillary personnel utilization plans need to be updated?

New or amended utilization plans must be submitted to the Board office for approval. The plans should be tailored specifically to the needs and practice situation of your individual pharmacy. *Sample Ancillary Personnel Utilization Plans* are available on our Web site through the "Forms/Applications" page under the "Forms" section. The pharmacy technician plan also includes a section on the requirements for approval of specialized functions. Visit *https://fortress.wa.gov/doh/hpqa1/HPS4/Pharmacy/forms.htm.*

No. 972 Treating Partners of Patients with Sexually Transmitted Diseases

Recently, the Board provided input to the MQAC on a special prescribing protocol for partners of patients with sexually transmitted chlamydia and gonorrhea. Adequate treatment of these sexually transmitted diseases has long been a difficult public health issue. A study by Dr Mathew Golden of Public Health Seattle and King County (PHSKC) demonstrated success with the use of the special prescribing protocol in treating partners. In the protocol, antibiotic treatment is provided by public health staff and pharmacies to partners through use of prepackaged "partner packs." The MQAC urges practitioners to use all reasonable efforts to ensure that appropriate information and advice is made available to the absent partner or partners. Absent partners are advised to seek a medical evaluation for sexually transmitted disease.

Contact your local Public Health clinic for more specific information on the special prescribing protocol. To view MQAC's policy, please visit its Web site at *https://fortress.wa.gov/doh/hpqa1/hps5/Medical/default.htm.*

No. 973 Are Your ADDDs Approved?

ADDDs are not extra-hyper druggists, but automated drug distribution devices. These devices may also be known as automated cabinets or automated dispensing systems. Used as drug storage devices in many health care settings, ADDDs provide access, security, and accountability in the use of medications. The use of all ADDDs must be approved by the Board and is restricted to those facilities listed in the rule. The rule also describes the responsibilities of the pharmacy and the facility. To request approval, pharmacies must send policies and procedures to the Board office for review. For more information, visit the Board's Web site at *https://fortress.wa.gov/doh/hpqa1/hps4/Pharmacy/default.htm* for the application form and applicable rules.

No. 974 Welcome New Board Member

Governor Chris Gregoire has appointed Albert Linggi to the Board of Pharmacy. Mr Linggi's four-year term began on March 10, 2008.

Mr Linggi is a graduate of the University of Washington. He has an executive masters in business administration from Fuqua School of Business at Duke University. Mr Linggi has over 30 years of experience in the pharmaceutical industry. His positions include appointments as administrative director of pharmacy for St Joseph, regional director for Franciscan Health Systems, and vice president for McKesson Corporate Business Development. We look forward to Al bringing his expertise and willingness to serve the people of Washington through his Board appointment.

No. 975 Fifty-year Certificates

We would like to acknowledge and congratulate the following pharmacists for 50 years of licensure in Washington State. The honorees were recognized at the Northwest Pharmacy Conference in June of this year. Harold E. Bennett, Seattle, WA; John A. Benson, Bellingham, WA; Elwin H. Blair, Bellevue, WA; Walter G. Davison, Port Angeles, WA; Ann C. Donnelly, Tucson, AZ; Ronald D. Gilbert, Portland, OR; Robert J. Grady, Whitefish, MT; Ralph N. Herbison, Spokane, WA; Donald L. Kelly, Wenatchee, WA; Michael D. Lyon, Prosser, WA; John S. McCluskey, Naches, WA; Laverne F. Moore, Pendleton, OR; Daniel J. Nault, Lynnwood, WA; Charles E. Nunn, Buckley, WA; Joan C. Skalabrin, Port Orchard, WA; Donald A. Stoebner, Anacortes, WA; James C. Wright, Gig Harbor, WA; Marvin L. Wheeler, Harrison, ID.

No. 976 Upcoming Board of Pharmacy Meetings

The Board of Pharmacy is encouraging all pharmacists to mark their calendars with the following meeting dates.

July 17, 2008	Tumwater
September 4, 2008	Yakima
October 30, 2008	Kent
December 11, 2008	Kent

Board meetings are open to the public and pharmacists and auxiliary staff are encouraged to attend. Pharmacists are able to earn up to three contact hours (0.3 CEUs) of continuing education credit each license renewal period for attending a Board meeting. While the meetings have a formal structure, there are often public comment periods for the agenda items. If you are interested in receiving the meeting agenda, please contact WSBOP@listserv.wa.gov. This is a great opportunity to help the profession progress.

The *Washington State Board of Pharmacy News* is published by the Washington State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Steven M. Saxe - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Larissa Doucette - Communications Manager

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February 2008

NSF Fact Sheet on Fluoridation Chemicals

Introduction

This fact sheet provides information on the fluoride containing water treatment additives that NSF has tested and certified to NSF/ANSI Standard 60: Drinking Water Chemicals - Health Effects. According to the latest Association of State Drinking Water Administrators Survey on State Adoption of NSF/ANSI Standards 60 and 61, 45 states require that chemicals used in treating potable water must meet Standard 60 requirements. If you have questions on your state's requirements, or how the NSF/ANSI Standard 60 certified products are used in your state, you should contact your state's Drinking Water Administrator.

Water fluoridation is the practice of adjusting the fluoride content of drinking water. Fluoride is added to water for the public health benefit of preventing and reducing tooth decay and improving the health of the community. The U.S. Centers for Disease Control and Prevention is a reliable source of information on this important public health intervention. For more information please visit www.cdc.gov/fluoridation/.

NSF certifies three basic products in the fluoridation category:

1. Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic Acid).
2. Sodium Fluorosilicate (aka Sodium Silicofluoride).
3. Sodium Fluoride.

NSF Standard 60

Products used for drinking water treatment are evaluated to the criteria specified in NSF/ANSI Standard 60. This standard was developed by an NSF-led consortium, including the American Water Works Association (AWWA), the American Water Works Association Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA), and the Conference of State Health and Environmental Managers (COSHEM). This group developed NSF/ANSI Standard 60, at the request of the US EPA Office of Water, in 1988. The NSF Joint Committee on Drinking Water Additives continues to review and maintain the standard annually. This committee consists of representatives from the original stakeholder groups as well as other regulatory, water utility and product manufacturer representatives.

Standard 60 was developed to establish minimum requirements for the control of potential adverse human health effects from products added directly to water during its treatment, storage and distribution. The standard requires a full formulation disclosure of each chemical ingredient in a product. It also requires a toxicology review to determine that the product is safe at its maximum use level and to evaluate potential contaminants in the product. The standard requires testing of the treatment chemical products, typically by dosing these in water at 10 times the maximum use level, so that trace levels of contaminants can be detected. A toxicology evaluation of test results is required to determine if any contaminant concentrations have the potential to cause adverse human health effects. The standard sets criteria for the establishment of single product allowable concentrations (SPAC) of each respective contaminant. For contaminants regulated by the U.S. EPA, this SPAC has a default level not to exceed ten-percent of the regulatory level to provide protection for the consumer in the unlikely event of multiple sources of the contaminant, unless a lower or higher number of sources can be specifically identified.

NSF Certification

NSF also developed a testing and certification program for these products, so that individual U.S. states and waterworks facilities would have a mechanism to determine which products were appropriate for use. The certification program requires annual unannounced inspections of production and distribution facilities to ensure that the products are properly formulated, packaged, and transported with safe guards against potential contamination. NSF also requires annual testing and toxicological evaluation of each NSF Certified product. NSF Certified products have the NSF Mark, the maximum use level, lot number or date code and production location on the product packaging or documentation shipped with the product.

The use of this standard and the associated certification program have yielded benefits in ensuring that drinking water additives meet the health objectives that provide the basis for public health protection. NSF maintains listings of companies that manufacture and distribute treatment products at www.nsf.org. These listings are updated daily and list the products at their allowable maximum use levels. In recognition of the important safeguards that NSF Standard 60 provides to public drinking water supplies, 45 U.S. States and 10 Canadian Provinces and Territories require drinking water treatment chemicals to comply with the requirements of the standard.

Treatment products that are used for fluoridation are addressed in Section 7 of NSF/ANSI Standard 60. The products are allowed to be used up to concentrations that result in a maximum use level of 1.2 mg/L fluoride ion in water. The NSF standard requires that the treatment products added to drinking water, as well as any impurities in the products, are supported by toxicological evaluation. The following text explains the rationale for the allowable levels established in the standard for 1) fluoride, 2) silicate, and 3) other potential contaminants that may be associated with fluoridation chemicals.

Fluoride

NSF/ANSI Standard 60 requires, when available, that the US EPA regulated maximum contaminant level (MCL) be used to determine the acceptable level for a contaminant. The EPA MCL for fluoride ion in water is 4 mg/L. The NSF Standard 60 single product allowable concentration (SPAC) for fluoride ion in drinking water from NSF Certified treatment products is 1.2 mg/L, or less than one-third of the EPA's MCL. Based on this the allowable maximum use level (MUL) for the NSF Certified fluoridation products are:

1. Fluorosilicic Acid: 6 mg/L.
2. Sodium Fluorosilicate: 2 mg/L.
3. Sodium Fluoride: 2.3 mg/L.

Silicate

There is no EPA MCL for silicate in drinking water. When an MCL does not exist for a contaminant, NSF/ANSI Standard 60 provides criteria to conduct a toxicological risk assessment of the contaminant and the development of a SPAC. NSF has established a SPAC for silicate at 16 mg/L. A fluorosilicate product, applied at its maximum use level, results in silicate drinking water levels that are substantially below the 16 mg/L SPAC established by NSF. For example, a sodium fluorosilicate product dosed at a concentration into drinking water that would provide the maximum concentration of fluoride allowed (1.2mg/L) would only contribute 0.8 mg/L of silicate – or 5 percent of the SPAC allowed by NSF 60.

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Potential Contaminants

The NSF toxicology review for a chemical product considers all chemical ingredients in the product as well as the manufacturing process, processing aids, and other factors that have an impact on the contaminants present in the finished drinking water. This formulation review identifies all the contaminants that need to be analyzed in testing the product. For example, fluosilicic acid is produced by adding sulfuric acid to phosphate ore. This is typically done during the production of phosphate additives for agricultural fertilizers. The manufacturing process is documented by an NSF inspector at an initial audit of the manufacturing site and during each annual unannounced inspection of the facility. The manufacturing process, ingredients, and potential contaminants are reviewed annually by NSF toxicologists, and the product is tested for any potential contaminants. A minimum test battery for all fluoridation products includes metals of toxicological concern and radionuclides.

Many drinking water treatment additives, including fluoridation products, are transported in bulk via tanker trucks to terminals where they are transferred to rail cars, shipped to distant locations or transferred into tanker trucks, and then delivered to the water treatment plants. These tanker trucks, transfer terminals and rail cars are potential sources of contamination. Therefore, NSF also inspects, samples, tests, and certifies products at rail transfer and storage depots. It is always important to verify that the location of the product distributor (the company that delivers the product to the water utility) matches that in the official NSF Listing for the product (available at www.nsf.org).

NSF has compiled data on the level of contaminants found in all fluoridation products that have applied for, or have been listed by, NSF. The statistical results in Table 1 (attached) include the test results for these products, as well as the annual monitoring tests from the period 2000 to 2006. This includes 245 separate samples analyzed during this time period. The concentrations reported represent contaminant levels that would be expected when the product is dosed into water at the Maximum Use Level (MUL). Lower product doses would produce proportionately lower contaminant concentrations (e.g. a 0.6 mg/L fluoride dose would produce one half the contaminant concentrations listed in Table 1.)

Table 1 documents that there is no contamination of drinking water from the fluoridation products NSF has tested and certified. NSF issued previous summaries of contaminant levels in fluoridation products for earlier reporting periods in 1999 and 2003. While some contaminant levels in those earlier periods were slightly higher than the current data for certain contaminants, there has not been a single fluoride product tested since the initiation of the program in 1988 with a contaminant concentration in excess of its corresponding SPAC. The documented reduction of impurities for this most current time period is due, at least in part, to the effectiveness of NSF/ANSI Standard 60 and the NSF certification program for drinking water treatment additives, and demonstrates the effectiveness of the program. The reduction in impurities is further attested to by an article in the Journal of the American Water Works Association entitled, "Trace Contaminants in Water Treatment Chemicals."[1]

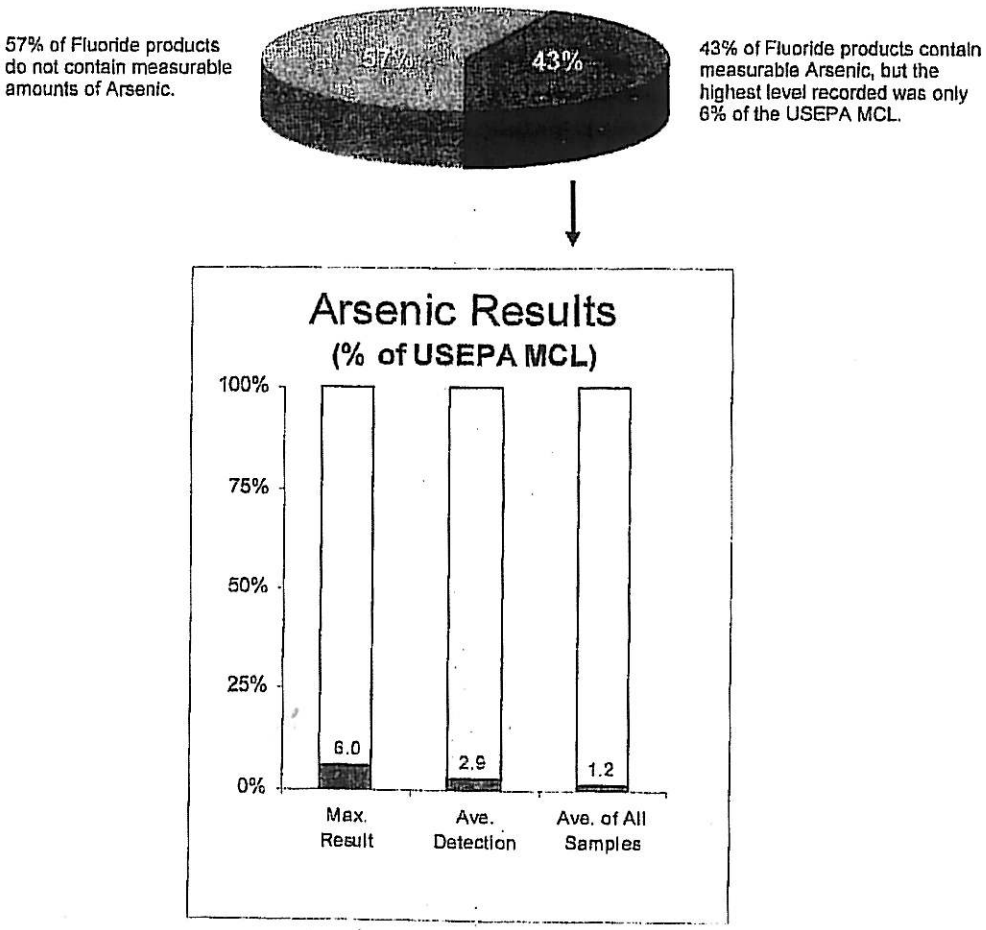
Arsenic

The results in Table 1 indicate that the most common contaminant detected in these products is arsenic, but it is detected in only 43% of the product samples. This means that levels of arsenic

[1] Brown, R., et al., "Trace Contaminants in Water Treatment Chemicals: Sources and Fate." Journal of the American Water Works Association 2004: 96:12:111.

in 57% of the samples were non-detectable, even though products are tested at 10 times their maximum use level. All detections were at levels below the Single Product Allowable Concentration, if the product is added to drinking water at (or below) its maximum use level. The SPAC, as defined in NSF/ANSI Standard 60, is one tenth of the US EPA's MCL. The current MCL for arsenic is 10 ppb, the highest detection of arsenic from a fluoridation chemical was 0.6 ppb (shown on Table 1), and the average concentration was 0.12 ppb. Even the highest concentration of 0.6 ppb was only detected because the standard requires testing the chemical at 10 times its maximum use level to detect these trace levels of contaminants. Had the dose of fluoridation additives been tested in water at the maximum use level, instead of at 10 times their maximum use levels, the arsenic concentration measured would have been below the 1 ppb reporting limit for arsenic for 100 percent of the samples measured.

Figure A



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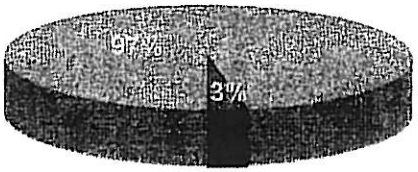
Copper

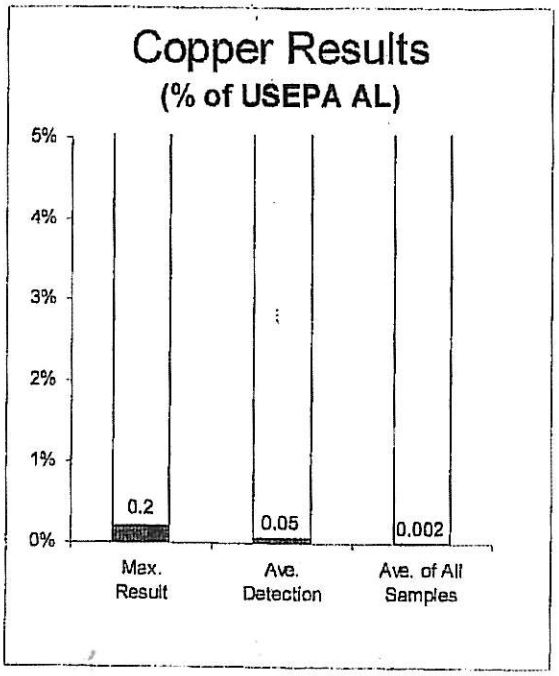
The second most common contaminant found, and on a much less frequent basis, is copper, and 97% of all samples tested had no detectable levels of copper. The average concentration of copper has been 0.02 ppb with 2.6 ppb being the highest concentration detected. This is well below the 130 ppb SPAC requirement of NSF 60.

Figure B

97% of Fluoride products do not contain measurable amounts of Copper.



3% of Fluoride products contain measurable Copper, but the highest level recorded was only 0.2% of the USEPA Action Level.



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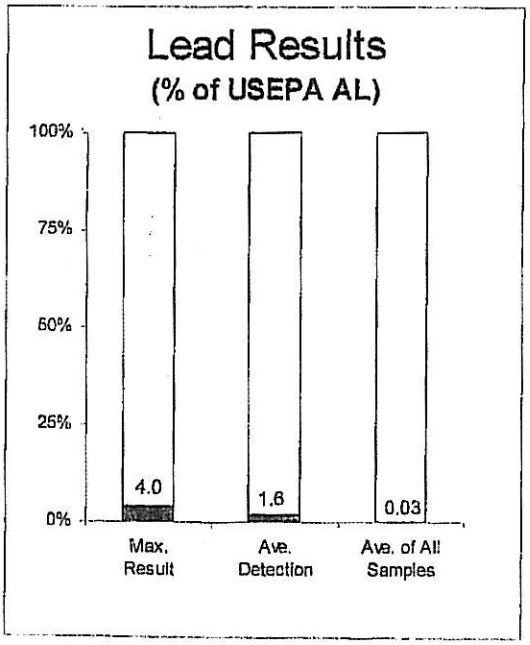
Lead

The third most common contaminant found is lead. It occurs on a much less frequent basis, and 98% of all samples tested had no detectable levels of lead. The average concentration of lead has been 0.005 ppb with 0.6 ppb being the highest concentration detected. This is well below the 1.5 ppb SPAC requirement of NSF 60.

Figure C

98% of Fluoride products do not contain measurable amounts of Lead.

2% of Fluoride products contain measurable Lead, but the highest level recorded was only 4% of the USEPA Action Level of 15ppb.



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Radionuclides
Fluoridation products are also tested for radionuclides. All samples tested have not had any detectable levels of alpha or beta radiation.

Summary
In summary, the majority of fluoridation products as a class, based on NSF test results, do not add measurable amounts of arsenic, lead, other heavy metals, or radionuclide contamination to drinking water.

Additional information on fluoridation of drinking water can be found on the following web sites:

American Water Works Association (AWWA) Fluoridation Chemical Standards
http://www.awwa.org/Bookstore/producttopicsresults.cfm?MetaDataID=121&navItemNumber=5093

American Water Works Association (AWWA) position
http://www.awwa.org/Advocacy/pressroom/fluoride.cfm

American Dental Association (ADA) http://www.ada.org/public/topics/fluoride/index.asp

U.S. Centers for Disease Control and Prevention (CDC) http://www.cdc.gov/fluoridation

Table 1

	Percentage of Samples with Detectable Levels	Mean Contaminant Concentration in all samples (ppb)	Mean Contaminant Concentration in detectable samples (ppb)	Maximum Contaminant Concentration in detectable samples (ppb)	NSF/ANSI Standard 60 Single Product Allowable Concentration	US EPA Maximum Contaminant or Action Level
Antimony	0%	ND	ND	ND	0.6	6
Arsenic	43%	0.12	0.29	0.6	1	10
Barium	<1%	0.001	0.3	0.3	200	2000
Beryllium	0%	ND	ND	ND	0.4	4
Cadmium	1%	0.001	0.08	0.12	0.5	5
Chromium	<1%	0.001	0.15	0.2	10	100
Copper	3%	0.02	0.68	2.6	130	1300
Lead	2%	0.005	0.24	0.6	1.5	15
Mercury	<1%	0.0002	0.04	0.04	0.2	2
Radionuclides – alpha pCi/L	0%	ND	ND	ND	1.5	15
Radionuclides – beta mrem/yr	0%	ND	ND	ND	0.4	4
Selenium	<1%	0.016	1.95	3.2	5	50
Thallium	<1%	0.0003	0.04	0.06	0.2	2

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Abbreviations used in this Fact Sheet

ANSI – American National Standards Institute

AWWA – American Water Works Association

AWWARF – American Water Works Association Research Foundation

ASDWA – Association of State Drinking Water Administrators

COSHEM – Conference of State Health and Environmental Managers

EPA – U.S. Environmental Protection Agency

MCL – maximum contaminant level

mrem/yr – millirems per year – measurement of radiation exposure dose

MUL – Maximum use level

NSF – NSF International (formerly the National Sanitation Foundation)

ppb – parts per billion

PCi/L – pico curies per liter – concentration of radioactivity

SPAC – Single Product Allowable Concentration

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141 and 142

[WH-FRL-6934-9]
RIN 2040-AB75

National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Today EPA is establishing a health-based, non-enforceable Maximum Contaminant Level Goal (MCLG) for arsenic of zero and an enforceable Maximum Contaminant Level (MCL) for arsenic of 0.01 mg/L (10 µg/L). This regulation will apply to non-transient non-community water systems, which are not presently subject to standards on arsenic in drinking water, and to community water systems.

In addition, EPA is publishing clarifications for monitoring and demonstration of compliance for new systems or sources of drinking water. The Agency is also clarifying compliance for State-determined monitoring after exceedances for inorganic, volatile organic, and synthetic organic contaminants. Finally, EPA is recognizing the State-specified time period and sampling frequency for new public water systems and systems using a new source of water to demonstrate compliance with drinking water regulations. The requirement for new systems and new source monitoring will be effective for inorganic, volatile organic, and synthetic organic contaminants.

DATES: This rule is effective March 23, 2001, except for the amendments to Secs. 141.23(i)(1), 141.23(i)(2), 141.24(f)(15), 141.24(h)(11), 141.24(h)(20), 142.16(e), 142.16(j), and 142.16(k) which are effective January 22, 2004.

The compliance date for requirements related to the clarification for monitoring and compliance under Secs. 141.23(i)(1), 141.23(i)(2), 141.24(f)(15), 141.24(f)(22), 141.24(h)(11), 141.24(h)(20), 142.16(e), 142.16(j), and 142.16(k) is January 22, 2004. The compliance date for requirements related to the revised arsenic standard under Secs. 141.23(i)(4), 141.23(k)(3), 141.23(k)(3)(ii), 141.51(b), 141.62(b), 141.62(b)(16), 141.62(c), 141.62(d), and 142.62(b) is January 23, 2006. For purposes of judicial review, this rule is promulgated as of January 22, 2001.

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FLUORIDE IN DRINKING WATER:

A Scientific Review of EPA's Standards

Committee on Fluoride in Drinking Water

Board on Environmental Studies and Toxicology

Division on Earth and Life Studies

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

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Summary

Under the Safe Drinking Water Act, the U.S. Environmental Protection Agency (EPA) is required to establish exposure standards for contaminants in public drinking-water systems that might cause any adverse effects on human health. These standards include the maximum contaminant level goal (MCLG), the maximum contaminant level (MCL), and the secondary maximum contaminant level (SMCL). The MCLG is a health goal set at a concentration at which no adverse health effects are expected to occur and the margins of safety are judged "adequate." The MCL is the enforceable standard that is set as close to the MCLG as possible, taking into consideration other factors, such as treatment technology and costs. For some contaminants, EPA also establishes an SMCL, which is a guideline for managing drinking water for aesthetic, cosmetic, or technical effects.

Fluoride is one of the drinking water contaminants regulated by EPA. 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. Because fluoride is well known for its use in the prevention of dental caries, it is important to make the distinction here that EPA's drinking-water guidelines are not recommendations about adding fluoride to drinking water to protect the public from dental caries. Guidelines for that purpose (0.7 to 1.2 mg/L) were established by the U.S. Public Health Service more than 40 years ago. 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 the early 1990s at the request of EPA, the National Research Council (NRC) independently reviewed the health effects of ingested fluoride and the scientific basis for EPA's MCL. It concluded that the MCL was an appropriate interim standard but that further research was needed to fill data gaps on total exposure to fluoride and its toxicity. Because new research on fluoride is now available and because the Safe Drinking Water Act requires periodic reassessment of regulations for drinking-water contaminants, EPA requested that the NRC again evaluate the adequacy of its MCLG and SMCL for fluoride to protect public health.

COMMITTEE'S TASK

In response to EPA's request, the NRC convened the Committee on Fluoride in Drinking Water, which prepared this report. The committee was charged to review toxicologic,

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epidemiologic, and clinical data on fluoride—particularly data published since the NRC's previous (1993) report—and exposure data on orally ingested fluoride from drinking water and other sources. On the basis of its review, the committee was asked to evaluate independently the scientific basis of EPA's MCLG of 4 mg/L and SMCL of 2 mg/L in drinking water and the adequacy of those guidelines to protect children and others from adverse health effects. The committee was asked to consider the relative contribution of various fluoride sources (e.g., drinking water, food, dental-hygiene products) to total exposure. The committee was also asked to identify data gaps and to make recommendations for future research relevant to setting the MCLG and SMCL for fluoride. Addressing questions of artificial fluoridation, economics, risk-benefit assessment, and water-treatment technology was not part of the committee's charge.

THE COMMITTEE'S EVALUATION

To accomplish its task, the committee reviewed a large body of research on fluoride, focusing primarily on studies generated since the early 1990s, including information on exposure; pharmacokinetics; adverse effects on various organ systems; and genotoxic and carcinogenic potential. The collective evidence from in vitro assays, animal research, human studies, and mechanistic information was used to assess whether multiple lines of evidence indicate human health risks. The committee only considered adverse effects that might result from exposure to fluoride; it did not evaluate health risk from lack of exposure to fluoride or fluoride's efficacy in preventing dental caries.

After reviewing the collective evidence, including studies conducted since the early 1990s, the committee concluded unanimously that the present MCLG of 4 mg/L for fluoride should be lowered. Exposure at the MCLG clearly puts children at risk of developing severe enamel fluorosis, a condition that is associated with enamel loss and pitting. In addition, the majority of the committee concluded that the MCLG is not likely to be protective against bone fractures. The basis for these conclusions is expanded upon below.

Exposure to Fluoride

The major sources of exposure to fluoride are drinking water, food, dental products, and pesticides. The biggest contributor to exposure for most people in the United States is drinking water. Estimates from 1992 indicate that approximately 1.4 million people in the United States had drinking water with natural fluoride concentrations of 2.0 to 3.9 mg/L, and just over 200,000 people had concentrations equal to or exceeding 4 mg/L (the presented MCL). In 2000, it was estimated that approximately 162 million people had artificially fluoridated water (0.7 to 1.2 mg/L).

Food sources contain various concentrations of fluoride and are the second largest contributor to exposure. Beverages contribute most to estimated fluoride intake, even when excluding contributions from local tap water. The greatest source of nondietary fluoride is dental products, primarily toothpastes. The public is also exposed to fluoride from background air and from certain pesticide residues. Other sources include certain pharmaceuticals and consumer products.

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Highly exposed subpopulations include individuals who have high concentrations of fluoride in drinking water, who drink unusually large volumes of water, or who are exposed to other important sources of fluoride. Some subpopulations consume much greater quantities of water than the 2 L per day that EPA assumes for adults, including outdoor workers, athletes, and people with certain medical conditions, such as diabetes insipidus. On a per-body-weight basis, infants and young children have approximately three to four times greater exposure than do adults. Dental-care products are also a special consideration for children, because many tend to use more toothpaste than is advised, their swallowing control is not as well developed as that of adults, and many children under the care of a dentist undergo fluoride treatments.

Overall, the committee found that the contribution to total fluoride exposure from fluoride in drinking water in the average person, depending on age, is 57% to 90% at 2 mg/L and 72% to 94% at 4 mg/L. For high-water-intake individuals, the drinking-water contribution is 86% to 96% at 2 mg/L and 92% to 98% at 4 mg/L. Among individuals with an average water-intake rate, infants and children have the greatest total exposure to fluoride, ranging from 0.079 to 0.258 mg/kg/day at 4 mg/L and 0.046 to 0.144 mg/kg/day at 2 mg/L in drinking water. For high-water-intake individuals exposed to fluoride at 4 mg/L, total exposure ranges from 0.294 mg/kg/day for adults to 0.634 mg/kg/day for children. The corresponding intake range at 2 mg/L is 0.154 to 0.334 mg/kg/day for adults and children, respectively.

Dental Effects

Enamel fluorosis is a dose-related mottling of enamel that can range from mild discoloration of the tooth surface to severe staining and pitting. The condition is permanent after it develops in children during tooth formation, a period ranging from birth until about the age of 8. Whether to consider enamel fluorosis, particularly the moderate to severe forms, to be an adverse health effect or a cosmetic effect has been the subject of debate for decades. In previous assessments, all forms of enamel fluorosis, including the severest form, have been judged to be aesthetically displeasing but not adverse to health. This view has been based largely on the absence of direct evidence that severe enamel fluorosis results in tooth loss; loss of tooth function; or psychological, behavioral, or social problems.

Severe enamel fluorosis is characterized by dark yellow to brown staining and discrete and confluent pitting, which constitutes enamel loss. The committee finds the rationale for considering severe enamel fluorosis only a cosmetic effect to be much weaker for discrete and confluent pitting than for staining. One of the functions of tooth enamel is to protect the dentin and, ultimately, the pulp from decay and infection. Severe enamel fluorosis compromises that health-protective function by causing structural damage to the tooth. The damage to teeth caused by severe enamel fluorosis is a toxic effect that is consistent with prevailing risk assessment definitions of adverse health effects. This view is supported by the clinical practice of filling enamel pits in patients with severe enamel fluorosis and restoring the affected teeth. Moreover, the plausible hypothesis concerning elevated frequency of caries in persons with severe enamel fluorosis has been accepted by some authorities, and the available evidence is mixed but generally supportive.

Severe enamel fluorosis occurs at an appreciable frequency, approximately 10% on average, among children in U.S. communities with water fluoride concentrations at or near the current MCLG of 4 mg/L. Thus, the MCLG is not adequately protective against this condition.

Two of the 12 members of the committee did not agree that severe enamel fluorosis should now be considered an adverse health effect. They agreed that it is an adverse dental effect but found that no new evidence has emerged to suggest a link between severe enamel fluorosis, as experienced in the United States, and a person's ability to function. They judged that demonstration of enamel defects alone from fluorosis is not sufficient to change the prevailing opinion that severe enamel fluorosis is an adverse cosmetic effect. Despite their disagreement on characterization of the condition, these two members concurred with the committee's conclusion that the MCLG should prevent the occurrence of this unwanted condition.

Enamel fluorosis is also of concern from an aesthetic standpoint because it discolors or results in staining of teeth. No data indicate that staining alone affects tooth function or susceptibility to caries, but a few studies have shown that tooth mottling affects aesthetic perception of facial attractiveness. It is difficult to draw conclusions from these studies, largely because perception of the condition and facial attractiveness are subjective and culturally influenced. The committee finds that it is reasonable to assume that some individuals will find *moderate* enamel fluorosis on front teeth to be detrimental to their appearance and that it could affect their overall sense of well-being. However, the available data are not adequate to categorize moderate enamel fluorosis as an adverse health effect on the basis of structural or psychological effects.

Since 1993, there have been no new studies of enamel fluorosis in U.S. communities with fluoride at 2 mg/L in drinking water. Earlier studies indicated that the prevalence of moderate enamel fluorosis at that concentration could be as high as 15%. Because enamel fluorosis has different distribution patterns among teeth, depending on when exposure occurred during tooth development and on enamel thickness, and because current indexes for categorizing enamel fluorosis do not differentiate between mottling of anterior and posterior teeth, the committee was not able to determine what percentage of moderate cases might be of cosmetic concern.

Musculoskeletal Effects

Concerns about fluoride's effects on the musculoskeletal system historically have been and continue to be focused on skeletal fluorosis and bone fracture. Fluoride is readily incorporated into the crystalline structure of bone and will accumulate over time. Since the previous 1993 NRC review of fluoride, two pharmacokinetic models were developed to predict bone concentrations from chronic exposure to fluoride. Predictions based on these models were used in the committee's assessments below.

Skeletal Fluorosis

Skeletal fluorosis is a bone and joint condition associated with prolonged exposure to high concentrations of fluoride. Fluoride increases bone density and appears to exacerbate the growth of osteophytes present in the bone and joints, resulting in joint stiffness and pain. The condition is categorized into one of four stages: a preclinical stage and three clinical stages that increase in severity. The most severe stage (clinical stage III) historically has been referred to as the "crippling" stage. At stage II, mobility is not significantly affected, but it is characterized by

sporadic pain, stiffness of joints, and osteosclerosis of the pelvis and spine. Whether EPA's MCLG of 4 mg/L protects against these precursors to more serious mobility problems is unclear.

Few clinical cases of skeletal fluorosis in healthy U.S. populations have been reported in recent decades, and the committee did not find any recent studies to evaluate the prevalence of the condition in populations exposed to fluoride at the MCLG. Thus, to answer the question of whether EPA's MCLG protects the general public from stage II and stage III skeletal fluorosis, the committee compared pharmacokinetic model predictions of bone fluoride concentrations and historical data on iliac-crest bone fluoride concentrations associated with the different stages of skeletal fluorosis. The models estimated that bone fluoride concentrations resulting from lifetime exposure to fluoride in drinking water at 2 mg/L (4,000 to 5,000 mg/kg ash) or 4 mg/L (10,000 to 12,000 mg/kg ash) fall within or exceed the ranges historically associated with stage II and stage III skeletal fluorosis (4,300 to 9,200 mg/kg ash and 4,200 to 12,700 mg/kg ash, respectively). However, this comparison alone is insufficient for determining whether stage II or III skeletal fluorosis is a risk for populations exposed to fluoride at 4 mg/L, because bone fluoride concentrations and the levels at which skeletal fluorosis occurs vary widely. On the basis of the existing epidemiologic literature, stage III skeletal fluorosis appears to be a rare condition in the United Sates; furthermore, the committee could not determine whether stage II skeletal fluorosis is occurring in U.S. residents who drink water with fluoride at 4 mg/L. Thus, more research is needed to clarify the relationship between fluoride ingestion, fluoride concentrations in bone, and stage of skeletal fluorosis before any conclusions can be drawn.

Bone Fractures

Several epidemiologic studies of fluoride and bone fractures have been published since the 1993 NRC review. The committee focused its review on observational studies of populations exposed to drinking water containing fluoride at 2 to 4 mg/L or greater and on clinical trials of fluoride (20-34 mg/day) as a treatment for osteoporosis. Several strong observational studies indicated an increased risk of bone fracture in populations exposed to fluoride at 4 mg/L, and the results of other studies were qualitatively consistent with that finding. The one study using serum fluoride concentrations found no appreciable relationship to fractures. Because serum fluoride concentrations may not be a good measure of bone fluoride concentrations or long-term exposure, the ability to show an association might have been diminished in that study. A meta-analysis of randomized clinical trials reported an elevated risk of new nonvertebral fractures and a slightly decreased risk of vertebral fractures after 4 years of fluoride treatment. An increased risk of bone fracture was found among a subset of the trials that the committee found most informative for assessing long-term exposure. Although the duration and concentrations of exposure to fluoride differed between the observational studies and the clinical trials, bone fluoride content was similar (6,200 to more than 11,000 mg/kg ash in observational studies and 5,400 to 12,000 mg/kg ash in clinical trials).

Fracture risk and bone strength have been studied in animal models. The weight of evidence indicates that, although fluoride might increase bone volume, there is less strength per unit volume. Studies of rats indicate that bone strength begins to decline when fluoride in bone ash reaches 6,000 to 7,000 mg/kg. However, more research is needed to address uncertainties associated with extrapolating data on bone strength and fractures from animals to humans. Important species differences in fluoride uptake, bone remodeling, and growth must be

considered. Biochemical and physiological data indicate a biologically plausible mechanism by which fluoride could weaken bone. In this case, the physiological effect of fluoride on bone quality and risk of fracture observed in animal studies is consistent with the human evidence.

Overall, there was consensus among the committee that there is scientific evidence that under certain conditions fluoride can weaken bone and increase the risk of fractures. The majority of the committee concluded that lifetime exposure to fluoride at drinking-water concentrations of 4 mg/L or higher is likely to increase fracture rates in the population, compared with exposure to 1 mg/L, particularly in some demographic subgroups that are prone to accumulate fluoride into their bones (e.g., people with renal disease). However, three of the 12 members judged that the evidence only supports a conclusion that the MCLG *might not* be protective against bone fracture. Those members judged that more evidence is needed to conclude that bone fractures occur at an appreciable frequency in human populations exposed to fluoride at 4 mg/L and that the MCLG is not *likely* to be protective.

There were few studies to assess fracture risk in populations exposed to fluoride at 2 mg/L in drinking water. The best available study, from Finland, suggested an increased rate of hip fracture in populations exposed to fluoride at concentrations above 1.5 mg/L. However, this study alone is not sufficient to judge fracture risk for people exposed to fluoride at 2 mg/L. Thus, no conclusions could be drawn about fracture risk or safety at 2 mg/L.

Reproductive and Developmental Effects

A large number of reproductive and developmental studies in animals have been conducted and published since the 1993 NRC report, and the overall quality of that database has improved significantly. Those studies indicated that adverse reproductive and developmental outcomes occur only at very high concentrations that are unlikely to be encountered by U.S. populations. A few human studies suggested that high concentrations of fluoride exposure might be associated with alterations in reproductive hormones, effects on fertility, and developmental outcomes, but design limitations make those studies insufficient for risk evaluation.

Neurotoxicity and Neurobehavioral Effects

Animal studies designed to test motor coordination, performance of species-typical behaviors, and some forms of learning and memory have reported deficits in performance related to fluoride exposure. A few epidemiologic studies of Chinese populations have reported IQ deficits in children exposed to fluoride at 2.5 to 4 mg/L in drinking water. Although the studies lacked sufficient detail for the committee to fully assess their quality and relevance to U.S. populations, the consistency of the results appears significant enough to warrant additional research on the effects of fluoride on intelligence.

A few animal studies have reported alterations in the behavior of rodents after treatment with fluoride, but the committee did not find the changes to be substantial in magnitude. More compelling were studies on molecular, cellular, and anatomical changes in the nervous system found after fluoride exposure, suggesting that functional changes could occur. These changes might be subtle or seen only under certain physiological or environmental conditions. More research is needed to clarify the effect of fluoride on brain chemistry and function.

EPA Union: "We hold that Fluoridation is an Unreasonable Risk"

The following is a letter from Dr. J. William Hirzy, Senior Vice President of the EPA's Headquarters Union (NTEU Chapter 280) in Washington D.C. The letter is addressed to Ted Crawford, of the Bennington Citizens Against Fluoridated Water. To read Dr. Hirzy's recent testimony to the US Senate, where he announced the Union's request for a "national moratorium on fluoridation" (June 29, 2000) visit: www.fluoridealert.org/testimony.htm

March 26, 2001

Dear Ted,

I understand that you have a meeting coming up at which you want to report on our union's position with respect to water fluoridation. Here is the latest word from us.

Our union comprises and represents the toxicologists, chemists, biologists, engineers and other professional employees at the Headquarters location of the U.S. Environmental Protection Agency in Washington, D.C. The Agency's position on fluoride may not corrspond to the one that we professionals have taken. We have done our own homework on this matter and have reached our own conclusions.

As you know, our union first voted in 1997 on legislation relating to fluoridation, when we endorsed a Citizens For Safe Drinking Water initiative in California to prohibit the addition of fluoride to that State's water supplies. Our opposition to fluoridation has grown stronger in the three years since that first action because of the accumulation of research reports that ever more clearly show: 1) that fluoridation of drinking water does not reduce dental caries rates; and 2) the hazards associated with ingestion of fluoride, especially fluoride derived from hydrofluosilicic acid or its sodium salt (a.k.a. silicofluorides, SiF).

There are two specific and compelling concerns related to the use of SiF. First, use of SiF in fluoridation systems in the United States has been identified as a factor related to increased risk of elevated blood-lead levels in children (1,2). Second, SiF contributes significant amounts of arsenic to the water supplies to which it is added. The importance of this is that the U.S. Environmental Protection Agency (EPA) has established a (non-enforceable) Maximum Contaminant Level Goal for arsenic of zero, meaning that as a health protection measure, drinking water ought not to contain any arsenic whatsoever. Recently, EPA reported (3) that the National Academy of Sciences recommended that EPA should lower its enforceable Maximum Contaminant Level (MCL) for arsenic from 50 parts per billion (ppb) to possibly as low as 3 ppb as a cancer preventative measure; EPA then proposed an MCL of 5 ppb, finally setting it at 10 ppb for political reasons. Recent action by Administrator Whitman has suspended that proposal.

SiF may add ca. 0.5 ppb arsenic to water. Arsenic is known to cause cancer in humans.

The alternative to SiF as a fluoridating agent, sodium fluoride, has been shown to cause changes in the brain structure of test animals at the level used in fluoridation, i.e. at 1 part per million fluoride ion (4). Two other studies (5,6) demonstrate the neurotoxicity of sodium fluoride, including the induction of permanent hyperactivity in test animals exposed to fluoride before birth.

While promoters of fluoridation continue to cite decades-old studies purporting to show huge benefits of fluoridation, e.g. (7), they pointedly ignore the more recent and better conducted work that indicates little or no benefit derives from ingestion of fluoride, e.g. (8,9). Even the Centers for Disease Control, long an avid fluoridation promoting agency of the federal government, now admits that any benefits from fluoride are primarily topical.

While the factors I cite above are important ones, our opposition to fluoridation is based on other aspects of the practice as well, and these are summarized in our position paper of May 1, 1999. This paper can be accessed on the union website at www.nteu280.org .

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.

Please feel free to use this message as you see fit to help your government officials better understand this important public health issue.

J. William Hirzy, Ph.D.
Senior Vice-President
NTEU Chapter 280

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 21 2000

The Honorable Ken Calvert
Chairman
Subcommittee on Energy and Environment
Committee on Science
House of Representatives
Washington, D.C. 20515-6301

Dear Mr. Chairman:

Thank you for the letter of May 8, 2000, to Dr. Jane E. Henney, Commissioner of Food and Drugs, regarding the use of fluoride in drinking water and drug products. We apologize for the delay in responding to you.

We have restated each of your questions, followed by our response.

1. **If health claims are made for fluoride-containing products (e.g. that they reduce dental caries incidence or reduce pathology from osteoporosis), do such claims mandate that the fluoride-containing product be considered a drug, and thus subject the product to applicable regulatory controls?**

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. FDA published a final rule on October 6, 1995, for anticaries drug products for over-the-counter (OTC) human use (copy enclosed). This rule establishes the conditions under which OTC anticaries drug products are generally recognized as safe and effective and not misbranded. The rule has provisions for active ingredients, packaging conditions, labeling, and testing procedures that are required by manufacturers in order to market anticaries products. A new drug application (NDA) may be filed for a product containing fluoride that does not meet the provisions stated in the final rule. As you know, the Environmental Protection Agency regulates fluoride in the water supply.

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2. **Are there any New Drug Applications (NDA) on file, that have been approved, or that have been rejected, that involve a fluoride-containing product (including fluoride-containing vitamin products) intended for ingestion with the stated aim of reducing dental caries? If any such NDA's have been rejected, on what grounds were they rejected? If any such NDA have been approved, please provide the data on safety and efficacy that FDA found persuasive.**

No NDAs have been approved or rejected for fluoride drugs meant for ingestion. Several NDAs have been approved for fluoride topical products such as dentifrices and gels. Fluoride products in the form of liquid and tablets meant for ingestion were in use prior to enactment of the Kefauver-Harris Amendments (Drug Amendments of 1962) to the Food, Drug, and Cosmetic Act in which efficacy became a requirement, in addition to safety, for drugs marketed in the United States (U.S.). Drugs in use prior to 1962 are being reviewed under a process known as the drug efficacy study implementation (DESI). The DESI review of fluoride-containing products has not been completed.

3. **Does FDA consider dental fluorosis a sign of over exposure to fluoride?**

Dental fluorosis is indicative of greater than optimal ingestion of fluoride. In 1988, the U.S. Surgeon General reported that dental fluorosis, while not a desirable condition, should be considered a cosmetic effect rather than an adverse health effect. Surgeon General M. Joycelyn Elders reaffirmed this position in 1994.

4. **Does FDA have any action-level or other regulatory restriction or policy statement on fluoride exposure aimed at minimizing chronic toxicity in adults or children?**

The monograph for OTC anticaries drug products sets acceptable concentrations for fluoride dentifrices, gels and rinses (all for topical use only). This monograph also describes the acceptable dosing regimens and labeling including warnings and directions for use. FDA's principal safety concern regarding fluoride in OTC drugs is the incidence of fluorosis in

children. Children under two years of age do not have control of their swallowing reflex and do not have the skills to expectorate toothpaste properly. Young children are most susceptible to mild fluorosis as a result of improper use and swallowing of a fluoride toothpaste. These concerns are addressed in the monograph by mandating maximum concentrations, labeling that specifies directions for use and age restrictions, and package size limits.

Thanks again for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure
"Final Rule/Federal Register - October 6, 1995
Over-the-Counter Anticaries Drug Products"

Web site administrator's note:
To perform query to access this document
Enter: http://www.access.gpo.gov/su_docs/aces/aces140.html
Enter: checkmark for 1995 Volume 60
Enter: On: 10/06/95
Enter: Search terms: anticaries

Drugs

New Drug Application (NDA)

Introduction

For decades, the regulation and control of new drugs in the United States has been based on the New Drug Application (NDA). Since 1938, every new drug has been the subject of an approved NDA before U.S. commercialization. The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA.

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.

The documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged. The following resources provide summaries on NDA content, format, and classification, plus the NDA review process:

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Resources for NDA Submissions

The following resources have been gathered to provide you with the legal requirements of a new drug application, assistance from CDER to help you meet those requirements, and internal NDA review principles, policies and procedures.

Guidance Documents for NDAs

Guidance documents represent the Agency's current thinking on a particular subject. These documents are prepared for FDA review staff and applicants/sponsors to provide guidelines to the processing, content, and evaluation/approval of applications and also to the design, production, manufacturing, and testing of regulated products. They also establish policies intended to achieve consistency in the Agency's regulatory approach and establish inspection and enforcement procedures. Because guidances are not regulations or laws, they are not enforceable, either through administrative actions or through the courts. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. For information on a specific guidance document, please contact the originating office.

For the complete list of CDER guidances, please see the Guidance Index. For information on a specific guidance document, please contact the originating office.

Guidance documents to help prepare NDAs include:

- Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations (Issued 10/2000, Posted 10/27/2000). This guidance should be useful for applicants planning to conduct bioavailability (BA) and bioequivalence (BE) studies during the IND period for an NDA, BE studies intended for submission in an ANDA, and BE studies conducted in the postapproval period for certain changes in both NDAs and ANDAs.

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- Changes to an Approved NDA or ANDA [HTML] or [PDF] (Issued 11/1999, Posted 11/19/1999)
  - Changes to an Approved NDA or ANDA: Questions and Answers [HTML] or [PDF] (Issued 1/2001, Posted 1/22/2001)
- Container Closure Systems for Packaging Human Drugs and Biologics. (Issued 5/1999, Posted 7/6/1999)
- Format and Content of the Chemistry, Manufacturing and Controls Section of an Application. (Withdrawn as per FR notice, 6/1/2006)
- Format and Content of the Microbiology Section of an Application.
- Format and Content of the Clinical and Statistical Sections of an Application. (Issued 7/1988, Posted 5/21/1997)
- Format and Content of the Summary for New Drug and Antibiotic Applications. (Issued 2/1987, Posted 3/2/1998)
- Formatting, Assembling and Submitting New Drug and Antibiotic Applications. (Issued 2/1987, Posted 3/2/1998)
- Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances.
- Submitting Documentation for the Stability of Human Drugs and Biologics. (Issued 2/1987, Posted 3/2/1998)
- Submitting Samples and Analytical Data for Methods Validation.
- Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Products.
- NDAs: Impurities in Drug Substances (Issued 2/2000, Posted 2/24/2000)
- Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application. (Issued 2/1987, Posted 3/2/1998)
- Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application. (Posted 3/2/1998)
- Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products. Describes the quantity of evidence, and the documentation

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of the quality of evidence necessary to support a claim of drug effectiveness.

- Drug Master Files. A Drug Master File (DMF) is a submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.
- Required Specifications for FDA's IND, NDA, and ANDA Drug Master File Binders
- Qualifying for Pediatric Exclusivity. Certain applications may be able to obtain an additional six months of patent exclusivity.

- PET Drug Applications - Content and Format for NDAs and ANDAs [HTML] or [PDF] (Issued 3/7/2000, Posted 3/7/2000)

- Refusal to File. (Issued 7/12/1993, Posted 11/26/99) Clarifies CDER's decisions to refuse to file an incomplete application.

Laws, Regulations, Policies and Procedures

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

Code of Federal Regulations (CFR)

Code Of Federal Regulations (CFR) The final regulations published in the *Federal Register* (daily published record of proposed rules, final rules, meeting notices, etc.) are collected in the *CFR*. The *CFR* is divided into 50 titles which represent broad areas subject to Federal regulations. The FDA's

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Declaration of Nonconsent

Drinking water supplied by the City of Port Angeles contains a fluoride compound added with advertised intent to reduce dental decay, thus meeting the definition of a medication. This medication is supplied, unlabeled, as drinking water not only to residences, but to public facilities such as restaurants, work places, schools, County Courthouse, City Hall, library, hospital, motels and an international ferry.

By signing below, I declare and certify under penalty of perjury that to the best of my knowledge after June 1, 2006 at some time I consumed City of Port Angeles municipal water but **I have not consented to being medicated through this municipal water supply.** I declare that I signed this Declaration in Port Angeles, I am over the age of 18, and I am competent to be a witness before a court of law.

	Printed Name	Signature	Date	Address (Street, City, Zip)
1	JANET KAILIN	Janet Kailin	12/4/09	2902 S. Regent St., Port Angeles, WA 98362
2	John W Hughes	JOHN W HUGHES	04 DEC 09	2902 S. REGENT ST. PORT ANGELES WA 98362
3	CURT CROSTEN	Curt Crosten	12/5/09	207 Alderwood Cir Port Angeles 98362
4	Kay S Crosten	Kay S Crosten	12-5-09	207 Alderwood Circle Port Angeles WA 98362
5	Toni K Thompson	Toni K Thompson	12/5/09	2914 S. Regent St. Port Angeles WA 98362
6	Gail L Miller	Gail L Miller	12/5/09	121 E. Park Ave Port Angeles, WA 98362
7	Frank L. Thompson	Frank L Thompson	12-5-09	2914 S Regent St, Port Angeles, WA 98362
8	Carla L. Baker	Carla L Baker	12.5.09	3121 S. Regent St. Port Angeles, WA 98362
9	Ellen K. Gage	Ellen K Gage	12.5.09	203 W. 10th St. Port Angeles, WA 98362
10	DeeRenee Ericks	DeeRenee Ericks	12.5.09	622 S. Francis St. Port Angeles, WA 98362
11	Nancy O'Gorman	Nancy O'Gorman	12/05/09	2901 S. Regent St. Port Angeles WA 98362
12	KERMIT COKENKR	Kermit Cokenkr	12-5-09	2906 REGENT PORT ANGELES, WA 98362
13	Dolores Guenkel	DOLORES GUENKEL	12-05-09	2906 Regent Port Angeles, Wa. 98362
14	ARLENE LAMOUREUX	Arlene Lamoureux	12-05-09	602 Whidby, Port Angeles, Wa. 98362
15	PAUL LAMOUREUX	P R Lamoureux	12/5/09	602 WHIDBY PORT ANGELES WA 98362

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Declaration of Nonconsent

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	Printed Name	Signature	Date	Address (Street, City, Zip)
1	Gay C Hunter	Gay C Hunter	12/1/2009	3324 Upland Lane, Port Angeles, WA 98362
2	Herb Gaul LABIAN	Herb Gaul	12/1/2009	212 E. 11th st Port Angeles, 98362
3	Gerald Esthers	Gerald Esthers	12/2/09	1022 S Cherry St, Port Angeles 98362
4	DIANA L. ESTBERG	Diana L. Estberg	12/2/09	1022 S CHERRY ST., PORT ANGELES, WA 98362
5	SHARON M OLSEN	Sharon M Olsen	12/2/09	624 E 7th St Port Angeles WA 98362
6	Frances L. Stiggall	Frances L. Stiggall	12/2/09	1022 S Cherry St. Port Angeles, WA 98362
7	SHIRLEY E PETERS	Shirley E Peters	12/2/09	916 E 10 ST. PORT ANGELES WA 98362
8	DAVID NASSÉ	David Nassé	12/2/09	192 N. Solmar Dr. Sequim. 98382
9	Rosemary Moorhead	Rosemary Moorhead	12/2/09	4124 Old Mill Rd Pt Angeles, WA 98382
10	Sandy Schultz	Sandy Schultz	12/2/09	15 N. Orchard Ln Pt. Angeles, 98362
11	REX CARLSON		12-2-09	1646 OLSON SEQUIM 98382
12	Kayla Dyment	Kayla Dyment	12-2-09	47733 Hwy 112 Joyce, WA 98343
13	WAYNE A PETERS	Wayne A Peters	12-3-09	916 E 10TH PORT ANGELES, WA 98362
14	Corinne Winters	Corinne Winters	12/3/09	2842 Finn Hall Road Pt. Angeles, WA 98362
15	Robert L. Pluete	Robert L. Pluete	12/3/09	309 W 11th Port Angeles, WA 98362

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Declaration of Nonconsent

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	Printed Name	Signature	Date	Address (Street, City, Zip) 98362
1	RICHARD T. SMITH	Richard T. Smith	11-30-09	82 Island View Road Port Angeles WA
2	WALTER H. BARBER	Walter H. Barber	4-DEC-09	431 AMERICA BLVD, SEQUIM, WA 98382
3	ELINOR CLAUSEN	Elinor M. Clausen	4-Dec-09	154 Fulta Lane, Sequim, WA 98382
4	Derrick Dickinson	[illegible]	4-Dec-09	258612 HWY 101 Sequim WA 98382
5	Kristen Lawrence	Kristen Lawrence	12-4-09	2354 E. 3rd Ave, PA WA 98362
6	Jon Blank	CARISSA BLANK	12-4-09	152 CHICKEN COOP RD. SEQUIM WA 98382
7	KELLY STEED	Kelly Steed	12-4-09	605 THISTLE ST. PORT ANGELES, WA 98362
8	TERRY RANDALL	Terry L. Randall	12-4-09	731 no. 4th PORT ANGELES WA 98362
9	[illegible]	JOHN E NAPLES	12-4-09	231 W 4TH PORT ANGELES WA 98362
10	M. C. Riolo	MARC RIOLO	12-4-09	2442 E. Hwy 101 #30 PORT ANGELES WA 98362
11	[illegible]	JAMES REYNOLDS	12-4-09	1012 W 7th ST PORT ANGELES WA 98363
12	ROBERT MOORE	[illegible]	12-4-09	922 S CHASE ST PORT Angeles Wa. 98362
13	JOHN STRETCH	[illegible]	12/4/09	123 W 11TH PORT ANGELES, WA. 98362
14	Rikki D. Mack	[illegible]	12/4/09	316 Vashon Ave. Port Angeles, WA 98362
15	Dawn Roberts	Dawn G. Roberts	12/4/09	2412 E. Kyle Drive ~ Port Angeles, WA 98362

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Declaration of Nonconsent

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	Printed Name	Signature	Date	Address (Street, City, Zip)
1	SUSAN H. DANIELSON	Susan H Danielson	12/2	121 Uphill Dr Port Angeles 98362
2	Crystal Traxler	Crystal Traxler	12/3	2222 Taylor Cutoff Sequim 98382
3	Glenda ~~Fleming~~ Rubens	Glenda Rubens	12/3	317 E 6th St. PA WA 98362
4	Taylor Allyra		12/3	Power 2989 PA WA 98362
5	MARJORIE HARTJE	Marjorie Hartje	12/3	302 E. Arnette Rd P.A. 98362
6	STEVE PARTY		12-3	301 SOUTH DIAMOND SPORT your SLOVEN WA 98382
7	Dalia S. Perez	Dalia S. Perez	12-3	1017 1/2 E 6th ST, Pa. WA 98362
8	Robyn Schoep	Robyn Schoep	12-3	1231 Campbell Apt 3c. PA, WA, 98362
9	Noah Smith		12-3	605 W 11th St P.A. WA, 98362
10	MARGARET JAROS	Margaret Jaros	12-3	1435 PARK VIEW LANE P.A. WA 98363
11	Karen Swarm	Karen Swarm	12/3	710 South 'A' St. P.A. WA 98363
12	Robert J. Flake	ROBERT J. FLAKE	12/3	3752 Hill Circle P.A. WA. 98362
13	Veronica Flake	Veronica E. Flake	12/3	3752 Hill Circle PA WA 98362
14	HAZEL E MEIER	Hazel E. Meier	12/3	3736 Hill Circle PA WA 98362
15	DeLong		12/3	3770 Hill CR PA WA 98362

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Declaration of Nonconsent

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	Printed Name	Signature	Date	Address (Street, City, Zip)
1	ANN W MATHEWSON		12/2/09	1923 W 6th ST PORT Angeles, WA 98363-1609
2	PATRICIA FLOOD, MSLac		12/2/09	1124 E 4th St. Port Angeles, WA 98362
3	Jesse C. Wilson	Jesse C. Wilson	04 Dec 09	1025 West 11th St Port Angeles, WA 98363
4	Kambra Reader	Kambra Reader	12/4/09	PO Box 1696 Port Angeles, WA 98362
5	Stephanie Balducci	Stephanie Balducci	12-4-09	1080 Fairmount Ave PA 98363
6	CHAD CRUMLEY		12/4/09	Newell Rd Apartments Apt C-1 Port Angeles WA 98363
7	[illegible]		12/4/09	1016 W 7th St PA WA 98363
8	Lynnea R. Tucker	Lynnea R. Tucker	12/4/09	1120 W. 7th St PA WA 98363
9	Jeannette Graf	Jeannette Graf	12/4/09	707½ W 5th St P.A 98363
10	Erin Shield	Erin Shield	12/4/09	525 W. 4th St, Port Angeles, WA 98362
11	COLLEEN CUNNINGHAM	Colleen Cunningham	12/4/09	537 W. 7th St. Port Angeles, WA 98362
12	MARGARET H, BER	[illegible]	12/4/09	204 W 4th St Port Angeles 98362
13	Janet Rose Marschall	Janet Rose Marschall	12/4/09	194 S. Barr Rd Port Angeles 98362
14	Richard A. Marschall	Richard A. Marschall	12-4-09	162 S. Barr Rd PA WA 98362
15	Alfredo Quinta	[illegible]	12-4-09	4872 Deer Park Rd. PA WA 98362

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Declaration of Nonconsent

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	Printed Name	Signature	Date	Address (Street, City, Zip)
1	Bert Grable	Bert Grable	12/2/09	1117 S Peabody St, Port Angeles, Wa 98362
2	Jessica R. Grable	Jessica R. Grable	12/2/09	1117 S Peabody St. Port Angeles WA 98362
3	Connie L. McManis	Connie L. McManis	12/2/09	305 Webb Rd. Sequim WA 98382
4	KAREN ANN ANDERSON	Karen A. Anderson	12/3/09	428 S. 2nd Sequim WA 98382
5	Janice E Reid	Janice E Reid	12/3	503 W 4th Port Angeles
6	[illegible]	Jim R. Armstrong	12/4	820½ S C" ST Port Angeles 98362
7	Fernlie Osterberg	Fernli Osterberg	12/4	33 N Hemlock Cir. Port Angeles 98362
8	CAROL THOMASSON	Carol Thomasson	12/5	1107 S Peabody Port Angeles WA 98362
9	Jerry Filbeck	Jerry Filbeck	12/5	528 W Lauridsen Blvd Port Angeles, Wa. 98362
10	Connie L. Zentz	Connie L Zentz	12/5	528 W. Lauridsen Blvd #215 Port Angeles WA 98362
11	Lillian Pelkey	Lillian Pelkey	12/5	528 W. Lauridsen Blvd 111 Pt Angeles Wa 98362
12	SUSAN PANSINE	Susan Pansine	12/5	528 W. Lauridsen Blvd 112 Pt Angeles, WA 98362
13	MARY GALYEAN	Mary Galyean	12/5	528 W. Lauridsen Blvd 110 Port Angeles WA. 98362
14	Christopher Standley	Christopher Standley	12/5	528 W. Lauridsen #108 Port Angeles WA 98362
15	Mary James	528 West Lauridsen Mary James	12-5-09	528 W. Lauridsen #203 Pt Angeles Wa 98362

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Declaration of Nonconsent

Drinking water supplied by the City of Port Angeles contains a fluoride compound added with advertised intent to reduce dental decay, thus meeting the definition of a medication. This medication is supplied, unlabeled, as drinking water not only to residences, but to public facilities such as restaurants, work places, schools, County Courthouse, City Hall, library, hospital, motels and an international ferry.

By signing below, I declare and certify under penalty of perjury that to the best of my knowledge after June 1, 2006 at some time I consumed City of Port Angeles municipal water but **I have not consented to being medicated through this municipal water supply.** I declare that I signed this Declaration in Port Angeles, I am over the age of 18, and I am competent to be a witness before a court of law.

	Printed Name	Signature	Date	Address (Street, City, Zip)
1	Rudolph Meyer	Rudolph Meyer	12/4	1703 Lambert PA 98362
2	Shelley Dorfmann Schostak	Shelley Dorfmann Schostak	12/4	6575 S. Mt Angeles PA 98362
3	[illegible]	[illegible]	12/4	124 Mt [illegible] Port Ang - PA 98362
4	Raena Young	[illegible]	12/5	173 Walker Valley Rd Port Angeles, WA 98362
5	Paul PAUL REANDEAU	[illegible]	12/5	111 E. SEVENTH Port Angeles 98362
6	Colleen Miller	[illegible]	12/5	805 E 5th St Apt Port Angeles, WA 98362
7	Ruth Ryswyk	[illegible]	12/5	604 S. B St PA 98363
8	Cynthia Spawn	Cynthia Spawn	12/5	918 E 9th PA 98362
9	Shirley Edelman	Shirley Edelman	12/5	145 Viewcrest Ave. PA 98362
10	Delaney Ranish	Delaney Ranish	12/5	1622 west 14th Street Port Angeles, WA 98363
11	Mary Norris	[illegible]	12/5	2913 S. Peabody St. Port Angeles, WA 98362
12	Kia Armstrong	Kia Armstrong	12/5	4661 Seguim-Dungeness Way, SQ 98382
13	Abby Hare	Abby Hare	12/5	4091 Blue Mt Rd Port Angeles, WA
14	David Applbaum	[illegible]	12/5	585 Wasankari Rd, PA., 98363
15	Russell Lawser	[illegible]	12/5	" "

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APPENDIX B

INTERESTS OF AMICI CURIAE

International Academy of Oral Medicine and Toxicology

The fundamental mission of the International Academy of Oral Medicine and Toxicology is to promote the health of the public at large. We support the effort to inform consumers about health risks from amalgam mercury and water fluoridation, and support efforts toward eliminating these risks. The scientific activities of the IAOMT are overseen by an advisory committee composed of world leaders in biochemistry, toxicology and environmental medicine. The ideals and goals of the IAOMT are shared by dentists and physicians around the world, who have joined our efforts to promote science – based biological dentistry in their home countries. At present, there are fourteen independent chapters worldwide.

Oregon Citizens for Safe Drinking Water

Oregon Citizens for Safe Drinking Water (OCSDW) is a non-profit, all volunteer organization dedicated to protecting our drinking water through education and advocacy. Specifically, we work to keep fluoride compounds and other toxic chemicals and medications out of the public drinking water supply.

We are a coalition of individuals and organizations that includes doctors, lawyers, dentists, scientists, public health advocates, environmentalists, parents, legislators and concerned citizens. Together, we work to educate the public and policy makers about the concerns and complexities surrounding water fluoridation.

Over the past several years, we have worked with other local groups that have opposed fluoridation: Sierra Club, Oregon Chapter, Columbia Riverkeeper and other local Riverkeeper Chapters, Oregon Conservation Network, Northwest Environmental Defense Center, Pacific Environmental Advocacy Council, Oregon Toxics Alliance, Oregon Center for Environmental Health, Oregon Trout, Native Fish Society, Oregon Health Freedom Coalition, and the Oregon League of Cities, among others.

We also work in conjunction with national groups that oppose fluoridation: EPA Unions, Environmental Working Group, Organic

Consumers Association, the Fluoride Action Network (FAN), and many of the other individuals and organizations mentioned in FAN's statement of interest in this case.

For over a decade, OCSDW has worked to fight mandatory statewide fluoridation bills that have been introduced in the Oregon state legislature. We have also worked to oppose mandatory fluoridation efforts at the local level, and have offered assistance to communities whose citizens have expressed a desire to stop the intentional addition of fluoride compounds to their drinking water.

In addition, we have introduced legislation in the Oregon state legislature which would require that manufacturers selling substances to be added to drinking water for the purpose of *treating humans* (as opposed to *treating water* for safety and potability) show proof that their product: (1) has been FDA-approved for safety and effectiveness for its stated purpose; and (2) will not contribute contaminants to the finished water above EPA-established Maximum Contaminant Level Goals.

OCSDW has taken the position that local communities should be allowed to vote on this issue. However, we also acknowledge that allowing local communities to vote on this issue in favor of adding drugs to water is problematic at best given accepted legal principals of informed consent. A fundamental ethical and constitutional question is whether legislators, states, counties, cities, water districts or any other entity should be allowed to medicate entire populations with drugs via their water supply.

Fluoride Action Network

The Fluoride Action Network ("FAN") is an international coalition seeking to broaden public awareness about the toxicity of fluoride compounds and the health impacts of current fluoride exposures.

Along with providing comprehensive and up-to-date information on fluoride issues to citizens, scientists, and policymakers alike, FAN remains vigilant in monitoring government agency actions that may impact the public's exposure to fluoride. FAN's work has been cited by national media outlets including Wall Street Journal, TIME Magazine, National Public Radio, Chicago Tribune, Prevention Magazine, and Scientific American, among others.

In May of 2004, FAN became an official project of the American Environmental Health Studies Project (AEHSP) - a registered non-profit 501(c)(3) organization.

As of January 2010, over 2700 Professionals have signed FAN's statement calling for an end to fluoridation. These include:

Arvid Carlsson, Nobel Laureate for Medicine, 2000; Magda Aelvoet, MD, Former Minister of Public Health, Belgium; Doug Everingham, former Federal Health Minister (1972-75), Australia; three members of the National Research Council committee who wrote the 2006 report (Hardy Limeback, PhD, DDS; Robert L. Isaacson, PhD; Kathleen M. Thiessen, PhD); William Hirzy, PhD and Robert Carton, PhD, former risk assessment specialists at the EPA; William Marcus, PhD, former chief toxicologist of the EPA Water Division; Vyvyan Howard, MD, PhD, Past President, International Society of Doctors for the Environment (ISDE); Andy Harris, MD, former president, Physicians for Social Responsibility (PSR); Theo Colborn, PhD, co-author, Our Stolen Future; Lynn Margulis, PhD, a recipient of the National Medal of Science; Ken Cook, President and Executive Director, Environmental Working Group (EWG); Ron Cummins, Director, Organic Consumers Association; Peter Montague, PhD, Director of Environmental Health Foundation; Ted Schettler, MD, Science Director, Science and Environmental Health Network; Lois Gibbs, Executive Director, Center for Health, Environment, and Justice, Falls Church, VA; Jay Feldman, Executive Director, Beyond Pesticides; Sandra Duffy, Board President, Consumers for Dental Choice and environmental health leaders from over 30 countries.