

Amicus Curiae
submitted by
The International Academy of Oral Medicine and Toxicology
and Fluoride Action Network

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.

AMICI CURIAE BRIEF OF INTERNATIONAL ACADEMY OF ORAL MEDICINE AND
TOXICOLOGY AND FLUORIDE ACTION NETWORK IN SUPPORT OF PETITIONERS

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I. IDENTITY AND INTEREST OF AMICI CURIAE

The IAOMT Amici Curiae are International Academy of Oral Medicine and Toxicology ("IAOMT") 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" 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." Neither Initiative restricts the City from adding chemicals to treat water "PROVIDED" the fluoride level is not increased by more than 0.1 ppm. We support Petitioners' request that these Initiatives be allowed on the ballot.

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 to make water safe, palatable and aesthetically acceptable, and not on clean-up of existing contaminants in public water supplies. Rather the focus of these local Initiatives is to prohibit or limit putting drugs in local public water supplies.

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." As a matter of law, this expressed intent should be found to be the fundamental and overriding purpose of the OWOC Initiative. 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.

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

Local initiatives to prohibit or limit putting any drugs in any public water supply serving the City of Port Angeles are intrinsicly legislative. They are intrinsicly 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. 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 and by statutes giving cities the right to set local water purity standards. 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 Court to call these drugs "additives" circumventing general Washington and Federal drug laws.

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. 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. Such a practitioner in providing such health care has a "duty to secure an informed consent by a patient or his representatives." It is not practical to secure informed consent from everyone who might drink a "water and bulk drug" compound dispensed through a public water system. 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. Cities add fluoridation chemicals to their water supplies with the intent to prevent disease. This intent alone is enough to define City fluoridated water as a drug. The U.S. Environmental Protection Agency ("EPA") does not regulate drugs. The FDA regulates drugs in interstate commerce. The State Board of Pharmacy regulates drugs in intrastate commerce.

The City obtains its bulk fluoridation drug in interstate commerce and manufactures and dispenses its City fluoridated water drug in intrastate commerce. 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." 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." While the two Initiatives set more protective water standards, they are fully consistent with 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*.'" ,

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

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."

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. 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. While the AGO is not binding on this Court, it is entitled to considerable weight. 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. 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." 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.

The Opinion finds the "operation of a municipal water system" is "beyond the initiative power." 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.

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.

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. 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. The Safe Drinking Water Act also sets maximum contaminant level goals ("MCLG") based solely on health and safety regardless of the cost of removing or treating contaminants.

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. 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. This is significant because 43% of fluoridation products tested by NSF (the non-government certifying agency for fluoridation products) contain arsenic and thus cause treated water to exceed the MCLG for arsenic which is zero.

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

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."

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 - which approves drugs for marketing regardless of the method of dispensing the drug or the drug's concentration. Since 1938, every new drug has been the subject of an approved NDA ["New Drug Application"] before U.S. commercialization.

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.

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.

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. 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." However,

the City adds fluoride not as an additive to clean- 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.

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." It is added to "control dental caries" which is a "common disease." 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." 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.

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.

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.

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. But more importantly, the Initiatives only address drugs to treat people and do not address additives to meet MCLs.

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. 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 and FAN

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 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:

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

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A-32	Letter from J. William Hirzy, Ph.D., Senior Vice President of EPA Headquarters Union to Ted Crawford dated 3-26-01
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B-1 INTEREST OF AMICI CURIE