

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.

ANSWER OF RESPONDENT WASHINGTON DENTAL SERVICE
FOUNDATION, LLC, AND AMICI CURIAE WASHINGTON STATE
DENTAL ASSOCIATION, AND WATER FLUORIDATION SCIENCE
COMMITTEE:

TO

AMICI CURIAE BRIEF OF INTERNATIONAL ACADEMY OF ORAL
MEDICINE AND TOXICOLOGY; OREGON CITIZENS NETWORK FOR
SAFE DRINKING WATER; FLUORIDE ACTION NETWORK;
WASHINGTON ACTION FOR SAFE WATER; WHIDBEY
ENVIRONMENTAL ACTION NETWORK; AUDREY ADAMS; LINDA
MARTIN; BILL OSMUNSON DDS, MPH;
GERALD H. SMITH MD; AND FLUORIDE CLASS ACTION

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TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	IDENTITY AND INTEREST OF WDSF AND AMICI CURIAE	1
III.	ISSUES ADDRESSED	3
IV.	BRIEF STATEMENT OF THE CASE	4
V.	LEGAL ARGUMENT	5
A.	Opponents’ Argument That Community Water Fluoridation is an Unapproved Drug and Without Merit	5
1.	Fluoride as Used in Community Water Fluoridation Is a Water Additive	5
2.	Fluoridation Is Not Unconstitutional “Medical Treatment”	7
B.	Community Water Fluoridation is not a Drug, and General Laws Concerning Prescriptions and Licensing are not at Issue	9
C.	Opponents Misapprehend Judicial Notice and Misinterpret or Misrepresent Scientific Facts.....	10
1.	National Research Council Report on Fluoride in Drinking Water:.....	10
2.	The Overwhelming Weight of Scientific Evidence Supports Water Fluoridation	12
D.	Opponents Misinterpret Sound Data	14
1.	Opponents Continue to Foster Conspiracy Theories.....	15
E.	Opponents’ Claims of Harm are Without Legitimate Medical or Scientific Support and Contrary to the Weight of Scientific, Medical, Dental and Public Health Authority	16
1.	Environmental Claims	16
2.	Unsupported Medical Claims	19
VI.	CONCLUSION	21

TABLE OF AUTHORITIES

Cases

<i>Baer v. City of Bend</i> , 206 Or. 221, 292 P.2d 134 (1956)	7
<i>Beck v. City Council of Beverly Hills</i> , 30 Cal. App.3d 112, 106 Cal. Rptr. 163 (1973)	7
<i>City of Port Angeles v. Our Water-Our Choice</i> , 145 Wn. App. 869, 188 P.3d 533 (2008).....	1, 10
<i>Clallam County Citizens for Safe Drinking Water v. City of Port Angeles</i> , 137 Wash.App. 214, 151 P.3d 1079, Wash.App. Div. 2, February 06, 2007.....	5, 9
<i>Coshow v. City of Escondido</i> , 132 Cal. App.4th 687, 34 Cal. Rptr.3d 19 (2005)	7
<i>Kaul v. Chehalis</i> , 45 Wn.2d 616, 277 P.2d 352 (1954)	8
<i>Kraus v. City of Cleveland</i> , 163 Ohio St. 559, 127 N.E.2d 609 (1955).....	8
<i>Long v. Odell</i> , 60 Wn.2d 151, 372 P.2d 548 (1962)	4
<i>Mains Farm Homeowners Association v. Worthington</i> , 121 Wn.2d 810, 854 P.2d 1072 (1993)	3
<i>Quiles v. City of Boynton Beach</i> , 802 So.2d 397 (2001)	8
<i>Readey v. St. Louis County Water Co.</i> , 352 S.W.2d 622 (Mo. 1962).....	7
<i>Young v. Bd. of Health of Somerville</i> , 61 N.J. 76, 293 A.2d 164 (1972).....	9

Statutes

42 U.S.C. § 300g-1	5
RCW 70.119.050	8
RCW 70.142.010	6
WAC Ch. 246-290.....	6

WAC 246-290-4606

WAC Ch. 246-2916

Rules

RAP 10.33

RAP 10.63

I. INTRODUCTION

Respondent Washington Dental Service Foundation, LLC (“WDSF”), and Amici Curiae Washington State Dental Association, and Water Fluoridation Science Committee (“Science Committee”) submit this Answer To Amici Curiae Brief of International Academy of Oral Medicine and Toxicology; Oregon Citizens For Safe Drinking Water; Fluoride Action Network; Washington Action for Safe Water; Whidbey Environmental Action Network; Audrey Adams; Linda Martin; Bill Osmunson DDS MPH; Gerald H. Smith MD; and Fluoride Class Action (“Opponents”).

This case concerns two initiative petitions submitted to the City of Port Angeles (“City”). Respondents WDSF and Amici Curiae Washington State Dental Association and Water Fluoridation Science Committee request that this Court affirm the decision of the Court of Appeals in *City of Port Angeles v. Our Water-Our Choice*, 145 Wn. App. 869, 188 P.3d 533 (2008).

II. IDENTITY AND INTEREST OF WDSF AND AMICI CURIAE

The mission of WDSF is to eliminate oral disease in order to improve overall health for all. WDSF works to promote the oral health of the public by innovating and sponsoring programs for the advancement of oral health. WDSF has assisted with community water fluoridation programs because of its support by the overwhelming weight of scientific authority and the organizations noted in Appendix A.

The Washington State Dental Association (“WSDA”) is a voluntary membership association of Washington licensed dentists. The WSDA supports drinking water fluoridation as an effective means of promoting oral health and limiting dental disease and decay. WSDA considers it essential that communities have the ability to fluoridate drinking water on a practical, low cost basis.

WDSF and WSDA have been joined in this brief by the Science Committee to help respond to the scientific claims which were not issues in this case, but which have been raised by Opponents. The interest of the Science Committee is to assist the Court with information concerning water fluoridation that is supported by overwhelming scientific authority. The members are:

Dr. Joel H. Berg, DDS, MS
Professor and Lloyd and Kay Chapman Chair for Oral Health, University of Washington
Director, Department of Dentistry Seattle Children’s Hospital
Associate Dean for Hospital Affairs
Chair, Department of Pediatric Dentistry
University of Washington School of Dentistry
Trustee, American Academy of Pediatric Dentistry
His current research interests include the development of dental caries prevention programs using risk assessment models and early childhood oral health.

Dr. Hal Clure, MD. Retired Physician
Past President, Washington Medical Association

Dr. Tom Locke, MD, MPH, Health Officer Clallam and Jefferson counties
Past Chair, Washington State Board of Health

Dr. Russell Maier MD, Family Practice Physician - Yakima, Washington
Associate Director, Central Washington Family Medicine
Clinical Professor, Department of Family Medicine, University of
Washington

Dr. Howard Pollick, BDS, MPH
Health Sciences Clinical Professor
Dept. of Preventive & Restorative Dental Sciences School of Dentistry
University of California San Francisco

III. ISSUES ADDRESSED

The decision of the City of Port Angeles to provide community water fluoridation is not before the Court in this case, which concerns local initiative powers. Nonetheless, Opponents are attempting to inject that issue into the litigation with erroneous, misleading and exaggerated claims concerning community water fluoridation which are not supported by scientific, medical, dental, and public health authority. The safety, effectiveness, and any potential harm from community water fluoridation were not addressed by the trial court. Not only were there no findings of fact on these issues, none were proposed.

Opponents have attempted to raise new issues on appeal, in violation of RAP 10.3 and 10.6 and case law.¹ They attempt through their appendices to introduce hearsay documents, two books and several articles which do not meet the criteria for learned treatises or judicial notice, excerpts taken out of context, Wikipedia articles, and a “rough transcript” of a deposition that was not certified

¹ Supreme Court does not consider issues raised first and only by amicus. *Mains Farm Homeowners Association v. Worthington*, 121 Wn.2d 810, 854 P.2d 1072 (1993); *see also Long v. Odell*, 60 Wn.2d 151, 372 P.2d 548 (1962).

by the court reporter or signed by the deponent. They even urge this Court to make a phone call for further evidence.²

Even though the issues that Opponents attempt to inject are not before the Court and a Motion to Strike has been filed, such misinformation should not go into the Supreme Court record unchallenged. More than 180 million people on public water systems in the United States enjoy the benefits of having their water adjusted to the optimal level (0.7–1.2 mg/L, or 0.7–1.2 parts per million) of fluoride for preventing tooth decay.³ This brief discusses the overwhelming weight of authority that supports community water fluoridation as safe and effective.

IV. BRIEF STATEMENT OF THE CASE

The issues actually decided by the trial court and Court of Appeals concerning local initiative powers have been addressed in the parties' briefs in the case and in the Amicus Brief of the Washington Association of Cities and the City of Forks. Those issues will not be reproduced herein.

The decision of the City to fluoridate is not an issue in this case. In another appeal, fluoride opponents unsuccessfully challenged the authority of the

² Opponents' brief p. 19.

³ Center for Disease Control (CDC) Statement on the 2006 National Research Council (NRC) Report on Fluoride in Drinking Water (Last Reviewed 2009)
http://www.cdc.gov/FLUORIDATION/safety/nrc_report.htm

City to provide community water fluoridation.⁴ No petition for review was filed in that matter and the issue is not before this Court.

V. LEGAL ARGUMENT

A. Opponents' Argument That Community Water Fluoridation is an Unapproved Drug and Without Merit

1. Fluoride as Used in Community Water Fluoridation Is a Water Additive

Although fluoride tablets, drops or varnishes are available only by prescription and are regulated by the Food and Drug Administration (FDA), this is not the case with community water fluoridation. At the low levels of concentration in community water, fluoride is a water additive, not a drug. There are over 40 different chemicals that are used to treat water and make it safe, palatable and aesthetically acceptable.⁵ The FDA does not regulate water fluoridation; rather the Environmental Protection Agency (EPA) and the Washington State Department of Health (“DOH”) specify the regulations for water quality and water additives including fluoridation.⁶

Congress has set the framework for additive concentrations in the Safe Drinking Water Act. Congress has required the EPA to set drinking water regulations for all public water systems in the country. 42 U.S.C. § 300g-1.

⁴ *Clallam County Citizens for Safe Drinking Water v. City of Port Angeles*, 137 Wash.App. 214, 151 P.3d 1079, Wash.App. Div. 2, February 06, 2007.

⁵ Declaration of Stephen P. Sperr, P. E., Engineering Manager, City of Port Angeles. Respondents' Clerk's Papers (“RPC”) at 209-213.

⁶ Declaration of Thomas Locke, Clallam County Health Officer since 1987; RPC at 206-208.

The Washington State Legislature has required drinking water standards to be established by DOH. RCW 70.142.010 requires the State Board of Health (“BOH”) to establish allowable concentrations for all chemicals in drinking water consistent with federal laws and regulations. The BOH is required to consider best available scientific information when establishing standards. These regulations for all public drinking water systems in Washington are set forth in Ch. 246-290 WAC and Ch. 246-291 WAC. Detailed monitoring is required of all public water systems to assure fluoride levels in the range of 0.8 and 1.3 mg/L throughout the distribution system. WAC 246-290-460.

2. Fluoridation Is Not Unconstitutional “Medical Treatment”

Courts throughout the United States have uniformly held that fluoridation of water is a reasonable and proper exercise of the police power in the interest of public health. *Beck v. City Council of Beverly Hills*, 30 Cal. App.3d 112, 115, 106 Cal. Rptr. 163, 166 (1973). This matter is no longer an open question. *Coshov v. City of Escondido*, 132 Cal. App.4th 687, 705, 34 Cal. Rptr.3d 19, 27 (2005).

Courts have likewise agreed that fluoridation is not medication: [F]luoridation is not mass medication but is, in effect, prevention rather than treatment; that chlorine is added to water to cut down bacterial contamination in order to reduce the occurrence of infectious disease . . . and fluoride is added to prevent or deter the progress of a widespread dental disorder and thereby preserve the dental health of the people who consume the fluoridated water.

Readey v. St. Louis County Water Co., 352 S.W.2d 622, 627 (Mo. 1962).

We see no difference from a constitutional standpoint between introducing chlorine into a water supply to remove impurities and thereby safeguard the public health, and introducing fluorides to reduce the incidence of dental decay among children and thereby promote the public health and general welfare.

Baer v. City of Bend, 206 Or. 221, 235, 292 P.2d 134, 140 (1956).

The Ohio Supreme Court expressly rejected the argument that fluoridation is mass medication:

Plaintiff's argument that fluoridation constitutes mass medication, the unlawful practice of medicine and adulteration may be answered as a whole. Clearly, the addition of fluorides to the water supply does not violate such principles any more than the chlorination of water, which has been held valid many times.

Kraus v. City of Cleveland, 163 Ohio St. 559, 566, 127 N.E.2d 609 (1955).

The Florida District Court of Appeal articulated why fluoridation is not an infringement on individual rights:

[T]he city's fluoridation of its water stops with Quiles's water faucet. The city is not compelling him to drink it. He is free to filter it, boil it, distill it, mix it with purifying spirits, or purchase bottled drinking water. His freedom to choose not to ingest fluoride remains intact.

Quiles v. City of Boynton Beach, 802 So.2d 397, 399 (2001).

State courts have upheld the fluoridation of drinking water as a valid public health measure for decades. *Kaul v. Chehalis*, 45 Wn.2d 616, 277 P.2d 352 (1954). The United States Supreme Court has regularly declined to review

these decisions. *Young v. Bd. of Health of Somerville*, 61 N.J. 76, 78-79, 293 A.2d 164, 165-66 (1972).

Opponents have no published authority for their claim that community water fluoridation constitutes “medication,” because such authority does not exist.

B. Community Water Fluoridation is not a Drug, and General Laws Concerning Prescriptions and Licensing are not at Issue

No evidence, findings of fact or conclusions of law were requested or made by the trial court that community water fluoridation constitutes a drug, or that the administration of the City’s fluoridation program constitutes the practice of pharmacy, medicine, or dentistry as contended by Opponents.⁷ As the Court of Appeals stated in this case:

As we previously held in *Clallam County Citizens*, the City’s initial proposal to fluoridate its water was an action under a program administered by the Department of Health.” 137 Wash.App. at 220, 151 P.3d 1079.. The Department of Health has authority under RCW 70.119.050 to adopt rules and regulations relating to public water systems. 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. WAC 246-290.[Citation omitted] Here, the City itself lacks the authority to add additional legal restrictions; thus, any decisions regarding the purity of public water systems are administrative in nature.”⁸

⁷ Brief of Opponents at p. 24.

⁸ *City of Port Angeles v. Our Water-Our Choice*, 145 Wash. App. 869, 878; 188 P. 3d 533.

C. Opponents Misapprehend Judicial Notice and Misinterpret or Misrepresent Scientific Facts.

This court should not take judicial notice of disputed scientific matters as requested by Opponents. Adjudicative facts may be judicially noticed under ER 201(b) but only where those facts “not subject to reasonable dispute.” Rather, Opponents are asking this court to take judicial notice of facts “listed in this section.”⁹ that *are* highly disputed.

1. National Research Council Report on Fluoride in Drinking Water:

Opponents claim that most of the scientific facts they cite come from Fluoride in the Drinking Water: A Scientific Review of EPA’s Standards, a 2006 report prepared by the National Research Council (NRC Report). Their citations to the findings of the NRC Report are distorted and misleading by taking them out of context¹⁰ and making citations that are inapplicable to community water fluoridation from the 400-page NRC Report.¹¹ The NRC Report addresses concerns about *naturally occurring* fluoride levels between two and four parts per million in water supplies.

⁹ Opponents’ Brief at 5-9.

¹⁰ For example Opponents’ Exhibit D-31 is a chart interwoven within materials taken from the NRC Report and made to appear as though it is from that report. However, that material is nowhere in the NRC Report. Furthermore, it does not correspond to the World Health Organization data it cites as the source: <http://www.whocollab.od.mah.se/euro.html>

¹¹ Although the selective attachments to Opponents’ briefs from the National Research Council objected to are subject to a motion to strike, Amicus WDSF submits the entire document as a CD Rom for the convenience of the Court. *See* Appendix D.

In 1986, the U.S. Environmental Protection Agency (EPA) established a maximum-contaminant-level goal (MCLG) of 4 milligrams per liter (mg/L) and a secondary maximum contaminant level (SMCL) of 2 mg/L for fluoride in drinking water. These exposure values are not recommendations for the artificial fluoridation of drinking water, but are guidelines for areas in the United States that are contaminated or have high concentrations of naturally occurring fluoride.¹²

Four parts per million is two to four times the maximum level allowed by law for community water fluoridation (the optimal level of fluoride in drinking water is between 0.7 and 1.2 ppm).¹³ The report does not address community water fluoridation as practiced in Washington state and throughout the United States.¹⁴ The NRC Report did not recommend any changes in procedures currently used by communities to protect residents from preventable tooth decay.¹⁵

The NRC Report recommended that the maximum allowable level for fluoride in drinking water be re-evaluated, but this would only pertain to areas

¹² NRC Report p. xiii: http://books.nap.edu/openbook.php?record_id=11571&page=R13. A complete copy of the NRC Report has been furnished as Appendix D to this brief.

¹³ Centers for Disease Control and Prevention MMWR (2008) 57 (27); 737-741 <http://cdc.gov/mmwr/preview/mmwrhtml/mm5727a1.htm>

¹⁴ NRC Report p. 2 “Addressing questions of artificial fluoridation, economics, risk-benefit assessment, and water-treatment technology was not part of the committee’s charge.” http://books.nap.edu/openbook.php?record_id=11571&page=2

¹⁵ NRC Report p. 1 “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.” http://books.nap.edu/openbook.php?record_id=11571&page=1

that have naturally-occurring levels of fluoride that are at least four times greater than optimal levels. This affects approximately 200,000 individuals, none in Washington state.

2. The Overwhelming Weight of Scientific Evidence Supports Water Fluoridation

Contrary to the claims of Opponents, community water fluoridation has been heralded as one of the top most significant public health accomplishments of the 20th Century by the Centers for Disease Control and Prevention, the lead federal agency for protecting the health and safety of people.¹⁶ Port Angeles is not unique in recently providing the benefits of community water fluoridation to its residents. In November 2007 the Metropolitan Water District a consortium of 26 cities and water districts serving nearly 19 million customers in Southern California including San Diego and Los Angeles began a community water fluoridation program.¹⁷

¹⁶ Ten Great Public Health Achievements – United States, 1900-1999 CDC, MMWR Weekly April 02, 1999 48 (12); 241-243; <http://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm>

Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, CDC (1999). “Achievements in public health, 1900–1999: Fluoridation of drinking water to prevent dental caries”. *MMWR Morb Mortal Wkly Rep* 48 (41): 933–40. <http://cdc.gov/mmwr/preview/mmwrhtml/mm4841a1.htm>; http://www.nhc.gov.com/AgnAndDpt/HLTH/Documents/Ten%20Great_Public_Health_Achievements.pdf

¹⁷ Metropolitan completed construction of its fluoridation facilities and commenced drinking water fluoridation sequentially at all five treatment plants in 2007 The Metropolitan Water District of Southern California Annual Report 2008: <http://www.mwdh2o.com/mwdh2o/pages/about/AR/AR08/Chapter3.pdf>

The Centers for Disease Control and Prevention, as lead federal agency for protecting the health and safety of people, regularly monitors and contributes to scientific studies concerning water fluoridation.¹⁸

Scientific studies conducted by other countries also support the efficacy of water fluoridation. In Europe the NHS Centre for Reviews and Dissemination, University of York, Dental Public Health Unit, The Dental School, University of Wales, and Cardiff University of Leicester, Department of Epidemiology and Public Health conducted a critical examination of all significant studies of public water fluoridation (including criteria for their scientific rigor) in all languages in 2000. The systematic review found that water fluoridation was statistically associated with a decreased proportion of children with cavities (the median of mean decreases was 14.6%, the range -5 to 64%), and with a decrease in decayed, missing, and filled primary teeth (the median of mean decreases was 2.25 teeth, the range 0.5–4.4 teeth),¹⁹ which is roughly equivalent to preventing 40% of cavities.²⁰

¹⁸ Significant peer reviewed Journal Articles on community water fluoridation may be found at http://www.cdc.gov/oralhealth/publications/journal_articles.htm#cwf

¹⁹ McDonagh M, Whiting P, Bradley M et al. (2000). "A systematic review of public water fluoridation" (PDF). http://www.york.ac.uk/inst/crd/CRD_Reports/crdreport18.pdf

²⁰ Worthington H, Clarkson J (2003). "The Evidence Base for Topical Fluorides". *Community Dent Health* 20, 74-76.

In addition, the Australian National Health and Medical Research Council undertook a Systematic Review of the Efficacy and Safety of Fluoridation, which was completed in 2007. The recommendation from that review concludes that:

Fluoridation of drinking water remains the most effective and socially equitable means of achieving community-wide exposure to the caries prevention effects of fluoride. It is recommended that water be fluoridated in the target range of 0.6 to 1.1 mg/L, depending on climate, to balance reduction of dental caries and occurrence of dental fluorosis.²¹

D. Opponents Misinterpret Sound Data

Another example of the ways in which Opponents have misinterpreted sound data is found in Opponents' Brief at 6-7. We agree that the JADA cover article they cite by John D. B. Featherstone is scholarly and reliable.²² However, through selectivity they have totally misused his conclusions. In footnote 3 at page 6 they cite one paragraph of the article without the following paragraph which is necessary to fully understand his conclusions. Rather than saying that "drinking fluoride to prevent decay is ineffectual" as Opponents claim at page 7, Featherstone stresses the need for continual bathing of the teeth with fluoridated water. Just two paragraphs after the one quoted by Opponents Featherstone makes it clear that fluoridated water is needed throughout life.

²¹ Australian Government National Health and Medical Research Council, Systematic Review of the Efficacy and Safety of Fluoridation (2007) <http://www.nhmrc.gov.au/publications/synopses/eh41syn.htm>; NHMRC Public Statement (2007) www.nhmrc.gov.au/publications/synopses/eh41syn.htm

²² Opponents' Brief at 6 n. 3.

In summary, fluoride present in the water phase at low levels among the enamel or dentin crystals adsorbs to these crystal surfaces and can markedly inhibit dissolution of tooth mineral by acid. [internal citations omitted]. Fluoride that acts in this way comes from the plaque fluid via topical sources such as drinking water and fluoride products. Fluoride incorporated during tooth development is insufficient to play a significant role in caries protection. *Fluoride is needed regularly throughout life to protect teeth against caries.* [emphasis added]

Further, Featherstone *is* saying that fluoride is incorporated during tooth development,²³ (and not *merely* topical as Opponents claim); however, the developmental incorporation is insufficient for a life-time of caries protection. Far from supporting Opponents' claims, this article fully supports water fluoridation. It also says that there are certain high-risk populations who need additional focused attention because, by age 17 years, 40 percent of the population accounted for 80 percent of the caries.

1. Opponents Continue to Foster Conspiracy Theories

Opponents reference conspiracy theories, citing to a book "The Fluoride Deception," by journalist Christopher Bryson (2004).²⁴ His theories include claims that fluoridation was promoted by scientists at the Manhattan Project as a "cold war human experiment, serving the interests of the nuclear industrial state." (The Fluoride Deception at 78). Opponents claim community water fluoridation

²³ For further scholarly research on the importance of fluoride in tooth development, see Effects of Water Fluoride Exposure at Crown Completion and Maturation on Caries of Permanent First Molars, Singh, K.A. , Spencer, A.J., Brennan, D.S. Caries Res. 2007;41:34-42 This research postdates and supplements the Featherstone article referenced in ff 24.

²⁴ Opponents' Brief at 25-29.

is a conspiracy of the aluminum and fertilizer industries with help from government “cover-ups” and collusion from dental schools.²⁵

Opponents also claim the FDA and EPA conspired in an “illegal treaty” that effectively deregulated the addition of fluoride to drinking water and in a “sham law” they off-loaded authority to write regulations to a “trade association” NSF International (NSF), which it claims cooperates with the manufacturers, resulting in a “shell game” and “bogus regulations.”²⁶ Such conspiracy theories do not merit response.

E. Opponents’ Claims of Harm are Without Legitimate Medical or Scientific Support and Contrary to the Weight of Scientific, Medical, Dental and Public Health Authority

1. Environmental Claims

Opponents make exaggerated and misleading statements claiming that community water fluoridation is poisoning the public with arsenic in our water supply. Their statements are supposedly based on the NSF Fact Sheet. However, the very Fact Sheet they provide does not support their claim. Arsenic is at a detectable level in only 43% of the products tested, and only then when products are tested at 10 times their maximum use level in order to detect trace contaminants, and even in those cases the contamination is below the U.S. EPA Maximum Contaminant Level of 10 parts per billion. Further, water utilities

²⁵ *Id.*

²⁶ Opponents’ brief pps 15-22.

abide by a stricter standard, the ANSI/NSF Standard 60, which is much more cautious than the EPA regulation and allows only one tenth of the EPA Maximum Contaminant Level in order to certify a product – that is 1 part per billion for arsenic. The highest concentration measured when NSF tested at 10 times the maximum use level was .6 parts per billion – under the 1 part per billion Standard 60 single product allowable concentration. If the samples had been tested at the actual maximum use levels, the arsenic concentration measured would have been below the 1 part per billion reporting level for 100% of the samples measured.²⁷ While it is true that the EPA has an aspirational Maximum Contaminant Level Goal (MCLG) for arsenic of zero, EPA recognizes this goal is unobtainable in the real world therefore the MCLG is unenforceable.

Today [January 22, 2001] EPA is establishing a health-based, non-enforceable Maximum Contaminant Level Goal (MCLG) for arsenic of zero and an enforceable Maximum Contaminant Level of 0.01 mg/L....²⁸

The MCL of 0.01 mg/L is equal to 10 parts per billion. The *measurable* amount of lead is even less. Even measured at 10 times the allowable maximum use level in order to find trace elements, only two percent (2%) of products tested show such trace amounts.

²⁷ Opponents' Brief, Attachment at D-59-66 NSF Fact Sheet.

²⁸ Federal Register: January 22, 2001, Volume 66, Number 14. pps 6975- 7066 available at U. S. EPA: <http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-22/w1668.htm> [emphasis added]

Opponents similarly distort the facts concerning the relative toxicity of fluoride, lead and arsenic in Appendix D-73. These charts illustrate two fundamentally different toxicological concepts. Juxtaposed to each other, these charts reflect a misunderstanding of the difference between the toxicological basis for an LD50 (Chart 1) which is a measure of short-term (or acute) and an EPA MCLs (Chart 2) which is a measure of long-term (or chronic) toxicity. This is an apples to oranges comparison and not appropriate. Chart 1 illustrates toxicity classes for arsenic, lead, and fluoride, assigned based on LD50s. LD stands for “Lethal Dose.” An LD50 is the amount of a material, given all at once, which causes the death of 50% (one half) of a group of test animals.²⁹ The response to the chemical illustrated here is immediate, and occurs following a very high dose. For a given element, such as arsenic, lead, or fluoride, LD50s vary widely depending on animal species tested, method by which the chemical was administered, and exact type of chemical species tested, and that information has not been provided for this chart.

MCLs (Chart 2) are acceptable exposure levels determined from studies that evaluate toxicological effects following long-term (chronic) exposure. The relationship between a dose that causes acute toxicity and the dose that causes chronic toxicity can vary widely between chemicals, because modes of toxic

²⁹ Accurate reference material may be found at The Canadian Centre for Occupational Health and Safety (CCOHS), a Canadian federal government agency based in Hamilton, Ontario, which serves to support the vision of eliminating all Canadian work-related illness and injuries: <http://www.ccohs.ca/oshanswers/chemicals/ld50.html>

action and how an organism absorbs and metabolizes a chemical, can differ between low and high dose exposures. As a result, chronic toxicity cannot be readily predicted from LD50 information.

Chart 2 shows MCLs for lead (15 ppb) fluoride (4000 ppb, more commonly stated as 4 ppm), and arsenic (10 ppb).³⁰ EPA has set these acceptable exposure limits for long-term drinking water exposure. ANSI/NSF standard 60 adds an additional layer of caution by considering the potential contribution to concentrations of these metals from other sources in the drinking water system (e.g., pipes, natural levels, etc.). Washington DOH requires levels no greater than 1.3 ppm from all sources in community water fluoridation systems. WAC 246-290-460(2).

A comprehensive review of water fluoridation and the environment³¹ (attached as Appendix C), which specifically considered studies in Clallam and Pierce counties, address many of these claims in more detail

2. Unsupported Medical Claims

In briefing or attachments, Opponents have claimed a relationship between fluoridated water supplies and cancer in animals or people; elevated blood levels in children; neurotoxicity and permanent hyperactivity in test animals; IQ deficits

³⁰ Accurate reference materials may be found at the U. S. Environmental Protection Agency Drinking Water Contaminants site:
<http://www.epa.gov/safewater/contaminants/index.html#inorganic>

³¹ Pollick, Howard International Journal of Occupational Environmental Health 2004; 10:343–350 <http://www.cdc.gov/fluoridation/pdf/pollick.pdf>

in children; skeletal fluorosis; bone fractures; reproductive effects in animals and humans; chronic fatigue, and kidney disease.

No credible evidence of an association between community water fluoridation and cancer exists.

A number of studies regarding water fluoridation and osteosarcoma have been published in the past. At this time, the weight of the scientific evidence, as assessed by independent committees of experts, comprehensive systematic reviews, and review of the findings of individual studies does not support an association between water fluoridated at levels optimal for oral health and the risk for cancer, including osteosarcoma.”³²

In a report issued in 1993 by the National Research Council, the Subcommittee on Health Effects of Ingested Fluoride stated that the threshold dose of fluoride in drinking water that causes kidney effects in animals is approximately 50 ppm – more than 12 times the maximum level allowed by the EPA, and 50 times greater than those used for community water fluoridation. Therefore they concluded, “ingestion of fluoride at currently recommended concentrations is not likely to produce kidney toxicity in humans.”³³

³² CDC Statement on Water Fluoridation and Osteosarcoma, (2009)
<http://www.cdc.gov/FLUORIDATION/SAFETY/OSTEOSARCOMA.HTM>; See also Queensland Australia Department of Human Services’ Public Health Branch in collaboration with The Cancer Council Victoria Information Bulletin “Osteosarcoma and Fluoride Information Bulletin July 2006
<http://www.health.qld.gov.au/oralhealth/documents/31294.pdf>

³³ Health Effects of Ingested Fluoride (1993) p. 7-8.
<http://www.nap.edu/openbook.php?isbn=030904975X&page=8>

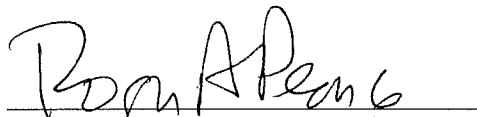
VI. CONCLUSION

This case concerns two initiative petitions filed by political action committees to the City of Port Angeles and whether they were beyond the scope of the local initiative power. The Court of Appeals decision is solidly founded on controlling Washington Supreme Court precedent and should be affirmed.

The amici brief of Opponents raises matters which are not issues in this case and for which no findings were sought or made in the trial court. This answer has been submitted in order to balance the record before this Court, but all those new issues raised by amici should be dismissed and not considered by the Court.

RESPECTFULLY SUBMITTED this 10th day of February 2010.

FOSTER PEPPER PLLC



P. Stephen DiJulio, WSBA #7139
Roger A. Pearce WSBA #21113

Attorneys for Respondent Washington Dental
Service Foundation and Amici Curiae Washington
State Dental Association, Water Fluoridation
Science Committee

APPENDIX A

Statements Supporting Water Fluoridation

American Academy of Family Physicians (2007)

“Fluoridation of public water supplies is a safe, economical, and effective measure to prevent dental caries. Dietary fluoride supplements should be considered for children from ages 6 months through 16 years when drinking water levels are suboptimal.”

<http://www.aafp.org/x1585.xml>

American Academy of Pediatric Dentistry (2007)

“The AAPD endorses and encourages the adjustment of fluoride content of domestic community water supplies where feasible.”

http://www.aapd.org/members/referencemanual/pdfs/02-03/P_FluorideUse.pdf

American Academy of Pediatrics (2007)

“Dental caries is the most common chronic disease affecting children in the United States. It is 5 times more common than asthma and 7 times more common than hay fever. Despite advances in oral health, dental and oral diseases continue to plague children. Factors contributing to an oral health decline include lack of access to care, inadequate availability of preventive measures such as water fluoridation and dental sealants, and lack of knowledge of the importance of oral health.”

<http://www.aap.org/healthtopics/oralhealth.cfm>

The American Council on Science and Health (2005)

The American Council on Science and Health (ACSH) is a consumer education consortium concerned with issues related to food, nutrition, chemicals, pharmaceuticals, lifestyle, the environment, and health. ACSH is an independent, nonprofit, tax-exempt organization. The nucleus of ACSH is a board of 350 physicians, scientists, and policy advisors - experts in a wide variety of fields - who review the Council's reports and participate in ACSH seminars, press conferences, media communications, and other educational activities. In 2005, the ACSH published, “The facts are clear: fluoride, one of Earth's most abundant elements, is a mineral found naturally in many water supplies. Low dosages of ingested fluoride will cause developing teeth to greatly increase their resistance to decay. Fluoridation of community water supplies is the most extensively investigated public health measure in history. Entire populations have been studied, and there is not a shred of bona fide evidence that anyone has been harmed by proper fluoridation of community water supplies. Fluoridation is widely considered one of the century's great public health achievements.”

http://www.acsh.org/factsfears/newsID.657/news_detail.asp

American Dietetic Association (2005)

“Fluoride is an important element in the mineralization of bone and teeth. The proper use of topical and systemic fluoride has resulted in major reductions in dental caries (tooth decay) and its associated disability. The Centers for Disease Control and Prevention have named fluoridation of water as one of the 10 most important public health measures of the 20th century. Nearly 100 national and international organizations recognize the public

health benefits of community water fluoridation for preventing dental caries. However, by the year 2000, over one third of the U.S. population (over 100 million people) was still without this critical public health measure.”

http://www.eatright.org/cps/rde/xchg/ada/hs.xsl/advocacy_adap1000_ENU_HTML.htm

American Medical Association (AMA) (1996)

“The AMA urges state health departments to consider the value of requiring statewide fluoridation (preferably a comprehensive program of fluoridation of all public water supplies, where these are fluoride deficient), and to initiate such action as deemed appropriate.” (1996) (Sub. Res. 9, I-86; Reaffirmed: Sunset Report, I-96)”

<http://www.ama-assn.org/ama/pub/physician-resources/clinical-practice-improvement/clinical-quality/accreditation-collaboration/ada-council.shtml>

American Public Health Association (2003)

“We believe that the single most important thing that a community can do for the oral health of its citizens is to fluoridate its drinking water.”

http://www.healthyteeth.us/Statements_from_Health_Communi/documents/FluoridationSurgeonGeneral2004.pdf

American School Health Association (2007)

The ASHA recommends that communities “make fluoridation available to all people ...in water supplies”...

http://www.ashaweb.org/files/public/Resolutions/Dental_Health_Education.pdf

Centers for Disease Control and Prevention (2007)

“Extensive research conducted over the past 50 years has demonstrated that fluoridation of public water supplies is a safe and effective way to reduce the incidence of dental caries for all community residents. A comprehensive review of the benefits and potential risks of fluoridation confirmed its safety and value.”

<http://www.cdc.gov/fluoridation/>

Head Start Bureau (2007)

“Fluoride, which is found in water, rocks, and soil, prevents tooth decay. Fluoride is safe and benefits everyone in the community by saving money on costly dental treatments. Health managers and program administrators may use this information to demonstrate the benefits of drinking fluoridated water.”

<http://eclkc.ohs.acf.hhs.gov/hslc/ecdh/Health/Oral%20Health/Oral%20Health%20Program%20Staff/NaturesWaytoP.htm>

The International Association for Dental Research (1999)

“Considering that dental caries (tooth decay) ranks among the most prevalent chronic diseases worldwide; and recognizing that the consequences of tooth decay include pain, suffering, infection, tooth loss, and the subsequent need for costly restorative treatment; and taking into account that over 50 years of research have clearly demonstrated its efficacy and safety; and noting that numerous national and international health-related

organizations endorse fluoridation of water supplies; fully endorses and strongly recommends the practice of water fluoridation for improving the oral health of nations.
<http://www.iadr.org/i4a/pages/index.cfm?pageid=3566>
(Scroll down to “Fluoridation of Water Supplies.)

National Academy of Sciences (2002)

“Claims about nutrient-disease relationships are more easily made than scientifically supported. Because the implications for public health are so important, caution is urged prior to accepting such claims without supportive evidence from appropriately designed, typically large, clinical trials.” “Research provides conclusive evidence that fluoridation of the water supply or supplemental fluoride reduces dental caries, and of all dietary components exhibiting a protective effect against caries, the most effective is fluoride.” “The earlier children are exposed to fluoridated water or dietary fluoride supplements, the greater the reduction in dental caries in both the primary and permanent teeth.”
<http://books.nap.edu/openbook.php?isbn=0309083087&page=19>

Office of the Surgeon General (2001)

“Water fluoridation has helped improve the quality of life in the United States through reduced pain and suffering related to tooth decay, reduced time lost from school and work, and less money spent to restore, remove, or replace decayed teeth. Fluoridation is the single most effective public health measure to prevent tooth decay and improve oral health over a lifetime, for both children and adults.”
<http://www.cdc.gov/fluoridation/>

Office of the Surgeon General (2004)

“Fluoridation is the single most effective public health measure to prevent tooth decay and improve oral health over a lifetime, for both children and adults.”
http://www.cdc.gov/fluoridation/fact_sheets/sg04.htm

State of Utah (2004), (recently increased the availability of fluoridated water to 50% of their population (up from 2%)

“The nationwide goal to prevent cavities through community water fluoridation is similar to previous public health efforts to prevent other common health Problems. These include adding iodide to salt to prevent thyroid problems, adding iron to infant formula to prevent anemia, adding Vitamin D to milk to prevent rickets, adding niacin to flour and other foods to prevent pellagra, and adding folic acid to cereal grain, products to prevent birth defects. Each of these public health efforts represent situations where a nutritional additive is provided to everyone or to large target populations since it is impossible to individually identify and effectively treat the significant number of people who are at risk. As a result of these programs thousands of cases of illness, disability, and death are prevented each year with no harm to the rest of the population.”
<http://www.health.utah.gov/oralhealth/pdf/Fluoridation07.pdf>

World Health Organization (2001)

“Many communities worldwide lack sufficient natural fluoride in their drinking water to prevent caries. Fluoridation of water supplies, where possible, is the most effective public health measure for the prevention of dental decay. Community water fluoridation is effective in preventing dental caries in both children and adults. Water fluoridation benefits all residents served by community water supplies regardless of their social or economic status.”

http://www.who.int/water_sanitation_health/oralhealth/en/index2.html

Ten Great Public Health Achievements -- United States, 1900-1999

“Fluoridation of drinking water began in 1945 and in 1999 reaches an estimated 144 million persons in the United States. Fluoridation safely and inexpensively benefits both children and adults by effectively preventing tooth decay, regardless of socioeconomic status or access to care. Fluoridation has played an important role in the reductions in tooth decay (40%-70% in children) and of tooth loss in adults (40%-60%).”

<http://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm>

Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries

“Although other fluoride-containing products are available, water fluoridation remains the most equitable and cost-effective method of delivering fluoride to all members of most communities, regardless of age, educational attainment, or income level.”

http://www.healthyteeth.us/Statements_from_Health_Communi/statements_from_health_communi.html

APPENDIX B

Australian Government
National Health and
Medical Research Council
N H M R C
www.nhmrc.gov.au

NHMRC Public Statement

The Efficacy and Safety of Fluoridation 2007

<p>The existing body of evidence strongly suggests that fluoridation is beneficial for reducing dental caries (NHMRC 2007).</p>	<p>The aim of a recent NHMRC systematic review of fluoride and health was to synthesise high level evidence in relation to the efficacy and safety of different forms of fluoridation, with emphasis on those able to be delivered as a widespread public health initiative. Methods of fluoride delivery reviewed were water, milk, salt and topical agents such as toothpaste and gels, though the evidence for water fluoridation is the most extensive.</p> <h3>Water Fluoridation</h3> <p>The aim of water fluoridation is the adjustment of the natural fluoride concentration in fluoride-deficient water to that recommended for optimal dental health. The figure below shows the dates of introduction of water fluoridation to Australian capital cities, target fluoride levels and percentage of the population who have access to fluoridated water.</p>
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[Map deleted]

NHMRC Recommendation

Fluoridation of drinking water remains the most effective and socially equitable means of achieving community-wide exposure to the caries prevention effects of fluoride. It is recommended that water be fluoridated in the target range of 0.6 to 1.1 mg/L, depending on climate, to balance reduction of dental caries and occurrence of dental fluorosis.

Additional information

Infant Formulae

Recent Australian research does not show an association between use of infant formulae and dental fluorosis. The critical period for development of dental fluorosis is after

the first twelve months of life, by which time the majority of Australian children have ceased exclusive formula consumption.

Measurements were made of 49 samples of formula available at supermarkets, finding that the fluoride concentrations have fallen considerably to allow reconstitution with fluoridated water.

Fluoride supplements, including toothpastes

When using the parameter of 'fluorosis of aesthetic concern' (in contrast to 'any fluorosis'), there was no statistical significance between those using fluoride toothpaste and controls. Australia has been at the forefront of the use of a low fluoride children's toothpaste by children up to the age of six years, including giving advice on the appropriate use of toothpaste. This has been associated with significant reductions in the prevalence of any fluorosis (especially very mild and mild fluorosis) in Australian children.

Risks associated with Fluoridation

Fluorosis

There is consistent evidence that water fluoridation results in the development of dental fluorosis, however, the majority of dental fluorosis is not considered to be of 'aesthetic concern'. The prevalence of fluorosis has been significantly reduced with more appropriate use of other fluoride sources.

Skeletal effects

Water fluoridation at levels aimed at preventing dental caries has little effect on fracture risk.

Fluoridation at 0.6 to 1.1 mg/L may lower overall fracture risk compared to both no fluoridation and fluoridation at levels well above those experienced in Australia. There is currently no evidence to determine the impact of milk and salt fluoridation, or other fluorides used to prevent dental caries, upon fracture risk and osteoporosis.

Cancer

There is no clear association between water fluoridation and overall cancer incidence or mortality. The evidence shows variations on either side of the effect, however only two studies present statistically significant results, one showing an increase and one a decrease in cancer incidence.

Other

There is insufficient evidence to reach a conclusion regarding other possible negative effects of water fluoridation. There is currently no evidence available to determine the other possible negative effects of milk, salt or topical fluoride supplementation.

The report is available at:
www.nhmrc.gov.au/publications/synopses/eh41s_yn.htm

NHMRC Recommendation

Fluoridation of drinking water remains the most effective and socially equitable means of achieving community-wide exposure to the caries prevention effects of fluoride. It is recommended that water be fluoridated in the target range of 0.6 to 1.1 mg/L, depending on climate, to balance reduction of dental caries and occurrence of dental fluorosis.

WORKING TO BUILD A HEALTHY AUSTRALIA

APPENDIX C

Water Fluoridation and the Environment: Current Perspective in the United States,
Howard F. Pollick, BDS, MPH

[on following pages]

Water Fluoridation and the Environment: Current Perspective in the United States

HOWARD F. POLLICK, BDS, MPH

Evidence of water fluoridation's effects on plants, animals, and humans is considered based on reviews by scientific groups and individual communities, including Fort Collins, CO, Port Angeles, WA, and Tacoma-Pierce County, WA. The potential for corrosion of pipes and the use of fluoridation chemicals, particularly fluoro-silicic acid, are considered, as is the debate about whether fluoridation increases lead in water, with the conclusion that there is no such increase. The arguments of anti-fluoridationists and fluoridation proponents are examined with respect to the politics of the issue. *Key words:* fluoridation; environment; toxicology.

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Prior to 1945, epidemiologic and laboratory studies confirmed the association between the environment (naturally-occurring fluoride in water supplies) and the health and cosmetic appearance of teeth.¹ Where fluoride levels were low, prevalences and severity of dental caries were high among lifetime residents, yet where fluoride levels were high, the prevalences and severity of dental caries were low, but dental fluorosis occurred with high prevalence and severity. This led to the concept of creating an ideal environment for optimal dental health through adjusting the naturally occurring fluoride level to about 1 mg/L (1 part per million). In 1986, the U.S. Environmental Protection Agency (EPA) set the maximum contaminant level (MCL) for naturally-occurring fluoride in public drinking water at 4 mg/L, with a secondary standard at 2 mg/L.²

Water fluoridation, then, is the controlled adjustment of fluoride concentrations of community water systems to optimal levels to minimize the incidence of dental caries (tooth decay) and dental fluorosis (enamel mottling). From initial efforts begun as community trials in 1945, water is now fluoridated in thousands of public water systems and reaches two thirds of the U.S. population served by such systems.³ Community water fluoridation and other uses of fluorides, such

as in toothpaste, have significantly reduced the prevalence of dental caries in the United States.¹

Early investigations into the physiologic effects of fluoride in drinking water predated the first community field trials.⁴⁻⁷ Since 1950, opponents of fluoridation have claimed it increases the risks for cancer, Down's syndrome, heart disease, osteoporosis and bone fracture, acquired immunodeficiency syndrome, low intelligence, Alzheimer disease, allergic reactions, and other health conditions.⁸ The safety and effectiveness of water fluoridation have been re-evaluated frequently, and no credible evidence supports an association between fluoridation and any of these conditions.^{9,10}

The Environment

Environmental concerns have been investigated in literature reviews for the Tacoma-Pierce County Health Department, Washington (August 2002),¹¹ and the City of Port Angeles, Washington (October 2003),¹² and no negative impact of water fluoridation on the environment has been established. Issues related to discharge to water; emissions to air; production, storage, or release of toxic or hazardous substances; or production of noise have been found to be nonsignificant. Emissions of fluoride into the air are not released outside the well houses. Fluoride concentrations in rivers downstream of the discharges increase by less than 0.01 mg/L due to adding fluoride to the water supply system.

Fluoridated water losses during use, dilution of sewage by rain and groundwater infiltrate, fluoride removal during secondary sewage treatment, and diffusion dynamics at effluent outfall combine to eliminate fluoridation related environmental effects. In a literature review, Osterman found no instance of municipal water fluoridation causing recommended environmental concentrations to be exceeded, although excesses occurred in several cases of severe industrial water pollution not related to water fluoridation.¹³ Osterman found that overall river fluoride concentrations theoretically would be raised by 0.001-0.002 mg/l, a value not measurable by current analytic techniques. All resulting concentrations would be well below those recommended for environmental safety.

A study conducted in Phoenix, Arizona, to test the efficacy of soil aquifer treatment systems indicated that fluoride concentrations decline as water travels under-

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ground. This study suggests that 40–50% of the fluoride discharged to groundwater is removed as the water travels through the soil and aquifer. Thus, fluoride does not concentrate in groundwater.¹⁴

PLANTS AND ANIMALS

The concentration of fluoride in the treated water does not reach levels that could harm any plant or animal species.^{11,12} A report of the effect of industrial pollution, from an aluminum plant on salmon indicated that the usual fluoride concentration of the river was 0.1 mg/L, and when the concentration was raised experimentally to 0.5 mg/L, there was an effect on the salmon.¹⁵ Since rivers and streams are not fluoridated and the increase in the fluoride concentration of a river as a result of runoff from fluoridated water would be insufficient to raise the level to even 0.2 mg/L, fluoridation of water can have no effect on salmon.

There is no evidence that fluoridated water has any effect on gardens, lawns, or plants. Although silver fluoride is not used in water fluoridation, silver fluoride at 1 mg/L used as a disinfectant had no effect on growth of wheat.¹⁶ There is evidence that very high concentrations of fluoride have no toxic effect on plants in ponds:

The fate of fluoride in a simulated accidental release into an experimental pond was observed for 30 days in Grenoble, France. The components investigated were water, sediments, plants, algae, molluscs, and fish. Twenty-four hours after the release, most (99.8%) of the fluoride was distributed in the physical components (water and sediments), and the biological agents contained only 0.2% of the fluoride released. Despite an exposure to hot spots of 5,000 ppm at the beginning of the accidental release, no visible toxic effects were observed on the biological components such as plants, algae, molluscs, and fish.¹⁷

There is evidence that ladyfinger (okra) can withstand up to 120 mg/L fluoride. The consumption by people of this plant grown with fluoridated water at 1 mg/L would be 0.2 mg per kg:

Because of suggestions that food is a rich source of fluoride to humans and the absence of permissible and upper limits of fluoride for irrigation water, plant uptake studies were conducted using fluoride-rich irrigation water. Ladyfinger was grown in sand and soil cultures for 18 wk and the accumulation of fluoride in various plant parts was studied. The potential for ingestion of fluoride by humans through this route was also considered. The percentage uptake was greater in sand-cultured plants than in soil-cultured plants. The root accumulates most of the fluoride supplied through irrigation water and the fruit accumulates the least. Up to 120 mg/L fluoride of irrigation water did not harm the plants. The ingestion of fluoride by humans from plants irrigated with water containing 10 mg/L fluoride would be 0.20 mg per 100 g ladyfinger.¹⁸

HUMANS

The Institute of Medicine, Food and Nutrition Board has estimated that the tolerable upper limit for human daily intake of fluoride is 10 mg per day for adults and children over 8 years of age.¹⁹ Ten independent U.S. and Canadian studies published from 1958 to 1987 showed that dietary fluoride intakes by adults ranged from 1.4 to 3.4 mg/day in areas where the water fluoride concentration was 1.0 mg/L. Where the water concentration was less than 0.3 mg/L, daily intakes ranged from 0.3 to 1.0 mg/day.¹⁹

Several municipal or territorial reviews of the water fluoride issue have concluded that available information indicates that there is no significant adverse health impact associated with water fluoridation. The Fort Collins review²⁰ included reviews from other communities, including Brisbane, Australia (1997),²¹ Natick, Massachusetts (1997),²² Calgary, Alberta, Canada (1998),²³ Ontario, Canada (1999),²⁴ and Escambia County Utilities Authority, Florida (2000).²⁵ Additionally, the Fort Collins review considered several “Tier One” reviews, including reviews by or for the Centers for Disease Control and Prevention,¹ the Institute of Medicine (1999),¹⁹ the World Health Organization (1994),²⁶ the National Research Council (1993),⁹ the U.S. Public Health Service (1991),²⁷ the International Programme on Chemical Safety (1984),²⁸ the Medical Research Council, UK (2002),²⁹ the Agency for Toxic Substances and Disease Registry, U.S. Public Health Service (2001 draft and 1993),³⁰ and York, U.K. (2000).³¹

The Fort Collins report found that:

- The weight of the evidence suggests that there is caries (cavities) reduction in populations exposed to water fluoridation at or near an optimal level
- Likely total exposure values for children older than six months living in communities with water fluoridated at up to 1.2 mg/L (ppm) do not exceed the upper limit set to be protective of moderate dental fluorosis by the Institute of Medicine. Total dietary exposures of fluoride can exceed this threshold amount (0.7mg/day) in infants fed formula reconstituted with optimally fluoridated water.
- There is no consistent evidence from human or animal studies that exposure to optimally fluoridated drinking water and other sources causes any form of cancer in humans, including bone and joint cancer
- The FTSG agrees with the conclusion of the Medical Research Council of Great Britain that states, “The possibility of an effect on the risk of hip fracture is the most important in public health terms. The available evidence on this suggests no effect, but cannot rule out the possibility of a small percentage change (either an increase or a decrease) in hip fractures.” [Medical Research Council 2002, page 3]

- At the concentrations of fluoride provided in Fort Collins water including exposures from all sources over a lifetime, skeletal fluorosis caused by drinking water exposure is not likely to be a health issue.
- At the concentrations of fluoride provided in Fort Collins water, in combination with other sources of fluoride, as many as one in four children under age 8 may develop very mild to mild dental fluorosis. This degree of fluorosis may or may not be detectable by the layperson. With oral health as the goal, this degree of dental fluorosis is considered an acceptable adverse effect given the benefits of caries prevention.
- In the literature reviewed, doses appropriate for caries reduction were not shown to negatively impact thyroid function. Studies in which humans received doses significantly higher than the optimum fluoride intake for long periods of time showed no negative impact on thyroid function.
- Overall, evidence is lacking that exposure to fluoride through drinking water causes any problems to the human immune system.²⁰

In general, there is no credible evidence indicating a cause-and-effect relationship between water fluoridation and increased health risks.

CORROSION

According to the U.S. Environmental Protection Agency and the National Association of Corrosion Engineers, corrosion is not related to fluoride.³² Corrosion by potable water is primarily caused by dissolved oxygen, pH, water temperature, alkalinity, hardness, salt, hydrogen sulfide, and certain bacteria. Fluoride, at concentrations found in potable water, does not cause corrosion. A small increase in the corrosivity of potable water that is already corrosive may occur after treatment with alum, chlorine, fluorosilicic acid, or sodium silicofluoride, which decreases pH. This may occur in some potable water sources with little buffering capacity; it can easily be resolved by adjusting the pH upward.^{11,12,33}

CHEMICALS USED FOR FLUORIDATION

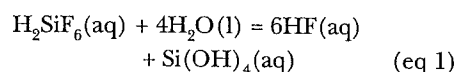
Fluorosilicates

Urbansky reviewed available information on fluorosilicates, with three objectives:

- (1) to enumerate unresolved chemical issues germane to understanding fluoridation and ascertaining the fate of fluoride and fluorospecies, (2) to critically review what is known or reported, and (3) to assemble a knowledge base to provide a starting point for future study.³⁴

Urbansky states:

Since [1962], toxicity and adverse health impacts have tested fluoride rather than fluosilicates. As a recent example, in 2001, the FDA reported that Americans' exposure to fluoride had increased from dentifrices, and it demonstrated that any increases did not produce observable health effects in rats. Fluoride salts were continually tested instead of fluorosilicates because the complete and fast dissociation-hydrolysis (eq 1) of fluorosilicates to fluoride and (hydr)oxosilicates was generally accepted as a chemical fact. Accordingly, no reason was apparent to test fluorosilicates separately.



all the rate data suggest that equilibrium should have been achieved by the time the water reaches the consumer's tap if not by the time it leaves the waterworks plant. . . . The most common fluoridating agents used by American waterworks are sodium fluoride (NaF), fluorosilicic acid (H_2SiF_6), and sodium fluorosilicate (Na_2SiF_6) (see table below).

TABLE³⁴

	Sodium <u>Fluoride</u>	Sodium <u>Fluorosilicate</u>	Fluorosilicic <u>Acid</u>
(a) Number of Utilities	2491	1635	5876
(b) People served	11,700,000	36,100,000	80,000,000

*Data for the United States from the CDC's 1992 *Fluoridation Census*³⁵: (a) Number of utilities using specific additives as reported by those that fluoridate their water; (b) Populations served by specific additives (millions of people) of those drinking supplementally fluoridated water (does not include waters with naturally occurring fluoride).

Although 25% of the utilities reported using NaF, this corresponds to only 9.2% of the U.S. population drinking fluoride-supplemented tap water. The ease in handling NaF rather than fluorosilicates accounts for the disproportionate use of NaF by utilities serving smaller populations. On the other hand, the cost savings in using fluorosilicates result in large systems using those additives instead. The reduced cost of large volume offsets the costs associated with handling concentrated stocks of the fluorosilicates, which require accommodations similar to hydrochloric acid, which is sometimes used to adjust pH. In acidic solution, the dissociation and hydrolysis of fluorosilicic acid, which occurs upon dilution, is given by eq 1. In drinking water, pH is adjusted with the addition of base (e.g., NaOH, NaHCO_3). $\text{H}_2\text{SiF}_6(\text{aq}) + 4\text{H}_2\text{O}(\text{l}) = 6\text{HF}(\text{aq}) + \text{Si}(\text{OH})_4(\text{aq})$ (eq1).³⁴

While there may be evidence of toxicity of these substances when workers involved in their production are not protected, there is no credible evidence of toxicity when they are diluted for use in fluoridated water. Fluorosilicic acid is diluted with water from an initial aqueous concentration of about 23–24% by about 1:250,000–1:300,000 when used for fluoridating

water.³⁶ This produces the final concentration of between 0.7–1.2 mg/L, the specific level set according to CDC guidelines.³⁷

Concerns have been raised about arsenic and lead in fluorosilicic-acid-treated water.^{38,39} However, there is no credible evidence that this is of concern.⁴⁰ Urbansky and Schock add:

The vast preponderance of the lead(II) in nearly all tap waters originates from the plumbing materials located between the water distribution mains and the end of the faucet used by the consumer.

Arsenic and lead may be present at minute undetectable concentrations, well below all current (50 ppb) and proposed (10 ppb) EPA standards. Following dilution with water, the calculated range of arsenic concentrations in the finished water contributed by fluorosilicic acid feed is 0.10 to 0.24 µg/L (parts per billion, ppb).³⁶ The analytic detection limit for arsenic is 2 µg/L, so the amount added by the fluorosilicic acid would not be detected.³⁶ In Fort Collins, the concentration of lead in the source waters was below the detection limit for lead in the department's laboratory of 1.0 µg/liter (ppb). Because lead levels are below the detection limits both before and after the addition of fluorosilicic acid, the actual changes in lead concentrations were not measurable.³⁶

Masters and Coplan have alarmed the public with their reports linking fluoridation, increased lead levels and crime.^{39,41} Urbansky and Schock criticize the conclusion reached by Masters and Coplan by stating:

Interestingly, the bibliographies of the Masters and Coplan study most strongly asserting the adverse effects of silicofluoride shows only a single reference related to sampling of drinking water or the control of lead or other metals by water treatment, so the level of awareness in the design of the studies and interpretation of the data is highly questionable. By not measuring or statistically testing numerous other water and plumbing characteristics that could correlate with lead(II) levels with equal to or greater statistical significance than those relationships that were put forth, the studies of [Reference 2] are intentionally biased towards what appears to be a preconceived conclusion. Even simple analytes that are known to affect lead mobility, such as pH or alkalinity, or analytes known to play important dietary roles in health, such as calcium, sodium or magnesium, were not reported to be measured in their study, so possible confounding variables are conspicuously excluded from evaluation.

... Recent reports [41, 39] that purport to link certain water fluoridating agents, such as fluorosilicic acid and sodium fluorosilicate, to human lead uptake are inconsistent with accepted scientific knowledge. The authors of those reports fail to identify or account for these inconsistencies, and mainly argue

on the basis of speculation stated without proof as fact. The sampling scheme employed in the studies is entirely unrelated to any credible statistically-based study design to identify drinking water lead and fluoride exposure as a significant source of blood lead in the individuals. The authors use aggregated data unrelated in space and time and then attempt to selectively apply gross statistical techniques that do not include any of thousands of other possible water quality or exposure variables which could show similar levels of correlation utterly by accident. Many of the chemical assumptions are scientifically unjustified, are contradicted by known chemistry data and principles, and alternate explanations (such as multiple routes of PbII exposure) have not been satisfactorily addressed. The choice in water fluoridation approach is often made for economic, commercial or engineering reasons that may have a regional component that could also be related to various community socio-economic measures, and so should not be considered to be a purely independent variable without investigation. At present, the highly-promoted studies asserting enhanced lead uptake from drinking water and increased neurotoxicity still provide no credible evidence to suggest that the common practice of fluoridating drinking water has any untoward health impacts via effects on lead(II) when done properly under established guidelines so as to maintain total water quality. Our conclusion supports current EPA and PHS/CDC policies on water fluoridation.⁴⁰

Nevertheless, concerns have been raised about the acidity of drinking water that may be created by fluoridation. According to Urbansky and Schock, "one cannot demonstrate that an increase in blood lead(II) ion levels can be linked to acidity from SiF_6^{2-} hydrolysis any more than one can demonstrate it results from consuming soft drinks." Additionally they state: "Note that the species PbSiF_6^0 is present at such low concentrations that we would expect to find *only one molecule of this complex in more than 1,000 liters of tap water* at pH 6, which of course, far exceeds the volume possible for water consumption and the human stomach."

A critique of this review was included in "Comments on The April 17, 2002 ICCEC Approach to Silicofluorides Study" by Coplan.⁴² The ICCEC is the U.S. Public Health Service National Toxicology Program (NTP) Interagency Committee for Chemical Evaluation and Coordination. Coplan states his concerns about the way in which Urbansky and the EPA and CDC have investigated silicofluorides. For example, he provides the following headings in his review: "EPA's acknowledged ignorance about a position they have adamantly held"; "EPA's continued effort at misdirection"; "Why Urbansky and Schock cannot be trusted"; "Why the CDC cannot be trusted"; "A substantial body of evidence has been submitted to the NTP clearly supporting the need for a comprehensive program of animal testing for health effects from chronic ingestion of SiF treated water. This

is true now and would remain true no matter what the EPA may learn about dissociation chemistry from a contractor selected by EPA employees whose objectivity and scientific integrity are less than impeccable.”

Coplan's comments are in keeping with his stance as an anti-fluoridationist (one who is strongly opposed to the fluoridation of public water supplies).⁴³ It should be pointed out that Urbansky and Schock have been highly critical of the work of Masters and Coplan. It appears that the main thrust of contemporary anti-fluoridation tactics is to assert that the chemicals used in fluoridation are causing problems of one sort or another. Such tactics have emanated from the work of Masters and Coplan.

The toxicology of sodium fluorosilicate and fluorosilicic acid has been reviewed for the EPA.⁴⁴ The authors of that review state:

In water, the compound (sodium fluorosilicate) readily dissociates to sodium ions and fluosilicate ions and then to hydrogen gas, fluoride ions, and hydrated silica. At the pH of drinking water (6.5-8.5) and at the concentration usually used for fluoridation (1 mg fluoride/L), the degree of hydrolysis is essentially 100%. . . Like its salt, its (fluorosilicic acid) degree of hydrolysis is essentially 100% in drinking water. At equilibrium, the fluorosilicate remaining in drinking water is estimated to be <<1 part per trillion.⁴⁰ In addition, exposure to impurities in the fluoridating agent is judged to be of low health risk when properly treated water is ingested. For example, in fluorosilicic acid, iron and iodine are usually below the levels considered useful as a dietary supplement; the phosphorus level is reported to be insignificant; and silver is usually <4 parts per septillion in the fluoridated water.⁴⁵

The Colorado City of Fort Collins has been fluoridating with fluorosilicic acid and has responded to concerns raised about that chemical.³⁶ The Report of the Fort Collins 2003 Fluoride Technical Study Group, April 2003, provides a comprehensive review that includes “The Potential for Increased Contaminant Levels Due to the Use of Hydrofluorosilicic Acid.”

The FTSG's review identified three potential concerns associated with hydrofluorosilicic acid (HFS). 1) co-contamination (i.e., arsenic and lead), 2) decreased pH leading to increased lead solubility or exposure, and 3) potential toxicological effects from incomplete dissociation products of HFS. The FTSG used the raw and finished water quality data for the City of Fort Collins to determine whether the addition of HFS was responsible for the potential addition of contaminants such as heavy metals to the city's drinking water. There was no evidence that the addition of HFS increased the concentrations of copper, manganese, zinc, cadmium, nickel, or molybdenum. The concentrations of arsenic and lead were below the detection limit for the Fort Collins Water Quality Control Laboratory in both the source water and the

finished water and below the maximum contaminant level (MCL) for these naturally occurring elements. There was no evidence that the introduction of HFS changed the pH of the water appreciably. Concern that HFS incompletely disassociates may be unfounded when the fundamental chemical facts are considered. Therefore, it is unlikely that community water fluoridation poses a health risk from the exposure to any of these chemicals present in the water as it leaves the plant. Further studies related to the health effects of HFS are in progress.³⁶

Reeves (fluoridation engineer at the CDC) outlined the process by which the safety of fluoridation chemicals is assured:

Concern has been raised about the impurities in the fluoride chemicals. The American Water Works Association (AWWA), a well-respected water supply industry association, sets standards for all chemicals used in the water treatment plant, including fluoride chemicals. The AWWA standards are ANSI/AWWA B701-99 (sodium fluoride), ANSI/AWWA B702-99 (sodium fluorosilicate) and ANSI/AWWA B703-00 (fluorosilicic acid). The National Sanitation Foundation (NSF) also sets standards and does product certification for products used in the water industry, including fluoride chemicals. ANSI/NSF Standard 60 sets standards for purity and provides testing and certification for the fluoride chemicals. Standard 60 was developed by NSF and a consortium of associations, including the AWWA and the American National Standards Institute (ANSI). This standard provides for product quality and safety assurance to prevent the addition of harmful levels of contaminants from water treatment chemicals. More than 40 states have laws or regulations requiring product compliance with Standard 60. NSF tests the fluoride chemicals for the 11 regulated metal compounds that have an EPA MCL. In order for a product [for example, fluorosilicic acid] to meet certification standards, regulated metal contaminants must be present at the tap [in the home] at a concentration of less than ten percent of the MCL when added to drinking water at the recommended maximum use level. The EPA has not set any MCL for the silicates as there is no known health concerns, but Standard 60 has a Maximum Allowable Level (MAL) of 16 mg/L for sodium silicates as corrosion control agents primarily for turbidity reasons. NSF tests have shown the silicates in the water samples from public water systems to be well below these levels.⁴⁶

Sources of Fluoride Pollution Unrelated to Water Fluoridation

The principal sources of fluoride pollution are industries, particularly phosphate ore production and use as well as aluminum manufacture, mining, and coal burning.^{28,47,48} In the absence of adequate emission control in such settings environmental pollution can be a problem. Such pollution has been a problem in the past in

industrialized countries, and the WHO warns that unless proper environmental safeguards are adhered to, there is a danger of its occurring in developing countries with increasing industrialization. Fluoride pollution is therefore recognized as an industrial hazard; however water fluoridation is not considered a potential source of fluoride pollution.⁴⁶

Arguments of Opponents and Proponents

Whereas anti-fluoridationists try to prevent the unnecessary exposure of living things to fluoride, often in the misguided belief that any amount of fluoride is toxic, pro-fluoridationists try to reduce tooth decay through the judicious use of fluoride, with the understanding that there is an optimum amount, appropriately delivered, that is both beneficial and safe. This distinction leads to a difference in interpretation of the scientific and popular literature on this topic, whether related to the effects of water fluoridation on teeth or other organs of the body, or the effects on the environment. Similarly, there are those who may judge water fluoridation on political or philosophical grounds, such as being supportive or opposed to what government agencies may advocate. Some may have personal or anecdotal experience that is counter to what opponents or proponents recommend. Newbrun has characterized the fluoridation debate as a religious argument.⁴⁹

While opponents of fluoridation are not without their supporters and supporting groups,⁵⁰ almost every reputable, recognized, competent scientific and/or public health organization or government unit endorses fluoridation of drinking water as safe and effective.^{51,52} Furthermore, community water fluoridation has been heralded as one of the ten great public health measures of the 20th century.⁵³

Proponents of fluoridation assert that the dose of fluoride determines whether it is beneficial or toxic, and that there are threshold levels that must be exceeded before there are toxic effects. This is a basic principle of toxicology and is true of every chemical approved for use in treating drinking water. "All substances are poisons: there is none which is not a poison. The right dose differentiates a poison and a remedy." Paracelsus (1493-1541).⁵⁴

While there has been considerable scientific study of the effects of fluorides on health and the environment, there will *always* be the need for more research.²⁹ However, proponents argue that it is not rational that the gains made from water fluoridation should be undone because not all the research has been completed. Further, it is strongly recommended that those communities that have not yet fluoridated their water supplies should do so to protect the dental health of their current and future residents.⁵⁵

Both sides use arguments related to freedom of choice. Those supporting fluoridation argue that the

public water supply is designed to protect public health and it is more important to protect people's health than to protect some people's concern for their freedom to use unfluoridated water.^{56,57} Additionally, pro-fluoridationists invoke the ethical principle of social justice arguing that the safe public health measure is socioeconomically equitable, providing greater benefit to the disadvantaged.¹

Current anti-fluoridation tactics have focused on chemicals used to fluoridate water supplies. As has been shown above, there is no credible evidence to support the notion that the chemicals are unsafe. In the past, tactics have focused on studies that purported to show that fluoridation was linked to cancer and myriad other health problems.⁴⁸ However, such assertions were based on improper science, and numerous subsequent studies found no association between fluoridation and cancer.⁵⁸

CONCLUSION

Scientific evidence supports the fluoridation of public water supplies as safe for the environment and beneficial to people. Reports at the local, national, and international levels have continued to support this most important public health measure. There appears to be no concern about the environmental aspects of water fluoridation among those experts who have investigated the matter. Furthermore, since the chemicals used for water fluoridation are co-products of the manufacture of phosphate fertilizers, and the raw material used is a natural resource (rocks excavated for their mineral content), water fluoridation could accurately be described as environmentally friendly, as it maximizes the use made of these natural resources, and reduces waste.⁵⁹

Note: In the text, the term "fluorosilicic" has been substituted for fluosilicic, hydrofluorosilicic, and hexafluorosilicic (all being synonymous); similarly, "fluorosilicate" for fluosilicate, hexafluorosilicate, and silicofluoride. However, the original terms in all references have not been substituted.

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APPENDIX D

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 Sciences

National Research Council of the National Academies

The National Academies Press, Washington, D.C.

[Submitted separately on CD pursuant to agreement with the Clerk of the Court]