Table 1. Caries prevalence and fluorosis prevalence with water fluoride concentration.[a]

Water fluoride concentration mg/L	Children with no caries %	Mean DMFS score[b]	Children with fluorosis[c] %	Mean severity of fluorosis[d]
< 0.3	53.2	3.08	13.5	0.30
0.3 - < 0.7	57.1	2.71	21.7	0.43
0.7 - 1.2	55.2	2.53	29.9	0.58
> 1.2	52.5	2.80	41.4	0.80

[a] Data for permanent teeth of children ages 5-17 (caries experience and DMFS score) or 7-17 (dental fluorosis), with a history of a single residence, from Tables 2 and 5 of Heller et al. (1997).
[b] Decayed, missing, or filled tooth surfaces (permanent teeth).
[c] Includes very mild, mild, moderate, and severe fluorosis, but not "questionable."
[d] Dean's Community Fluorosis Index.

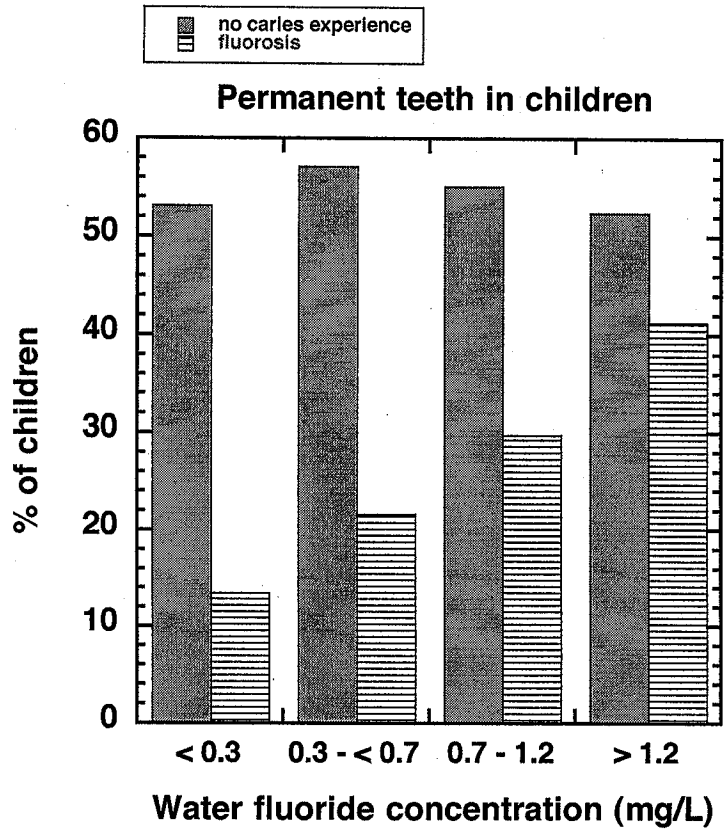

Fig. 1. Percent of children with no caries experience in the permanent teeth (DMFS = 0) and with fluorosis, with respect to water fluoride concentration. Data are shown as % of total children having no caries experience (blue) or having fluorosis (very mild, mild, moderate, or severe, but not questionable; red). Numerical values are provided in Table 1 of these comments and were obtained from Tables 2 and 5 of Heller et al. (1997).

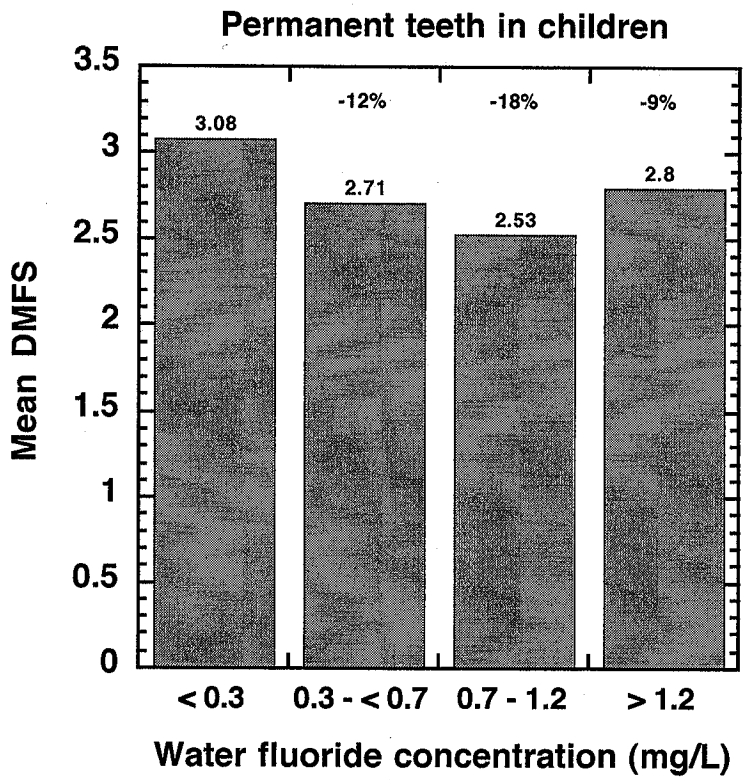

Fig. 2. Mean DMFS score (decayed, missing, or filled permanent tooth surfaces in permanent teeth), with respect to water fluoride concentration. Numerical values are provided in Table 1 of these comments and were obtained from Table 2 of Heller et al. (1997). The percent difference with respect to the lowest fluoride group is also provided.

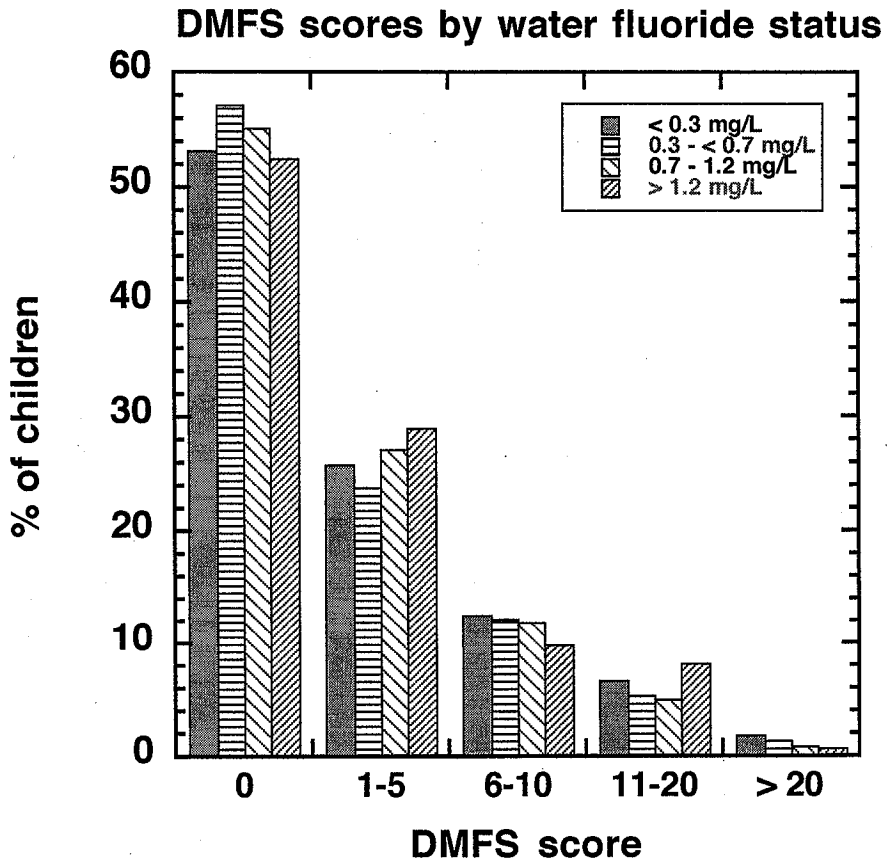

Fig. 3. Percent of children by DMFS score, with respect to water fluoride concentration. Data are shown as % of total children in a given group according to the number of decayed, missing, or filled tooth surfaces in the permanent teeth (DMFS). Data were obtained from Table 2 of Heller et al. (1997).

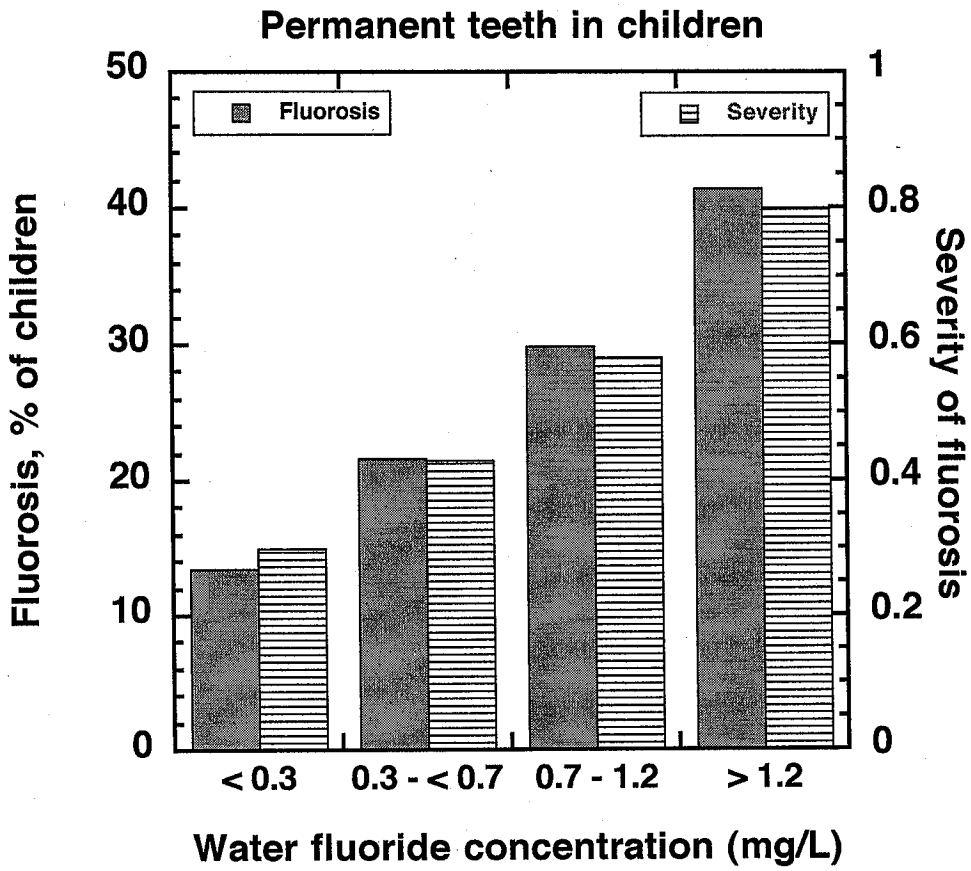

Fig. 4. Fluorosis prevalence and severity with water fluoride concentration for children ages 7-17 with a history of a single continuous residence. Data are shown as (left) % of total children having fluorosis (very mild, mild, moderate, or severe, but not questionable) or (right) severity of fluorosis by Dean's Community Fluorosis Index. Numerical values are provided in Table 1 of these comments and were obtained from Table 5 of Heller et al. (1997).

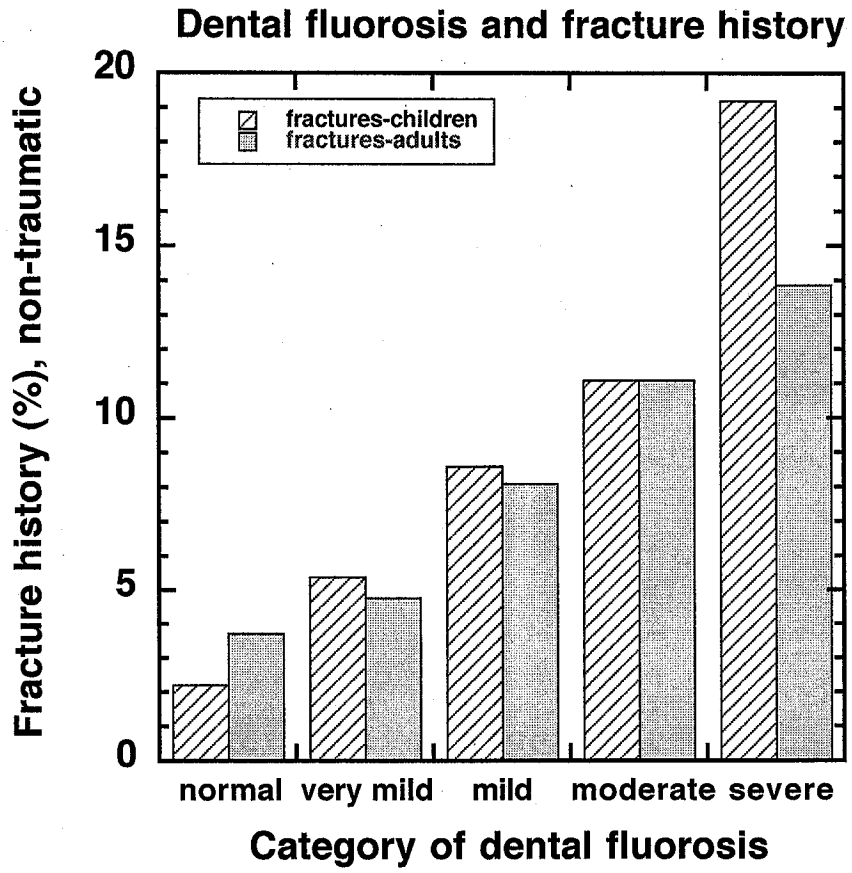

Fig. 5. Fracture history with category of dental fluorosis for children (ages 6-12) and adults (ages 13-60). Numerical values were obtained from information in Tables 5 and 6 of Alarcón-Herrera et al. (2001).

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June 25, 2012

Gerald Steel PE
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Dear Mr. Steel,

I am qualified as an expert in fluoridation by knowledge, research and experience. I serve on the American Academy of Pediatrics' Council on Environmental Health, the National Medical Association's Environmental Health Task Force and Physicians for Social Responsibility. My curriculum vita is enclosed for your review. In my opinion, the bulk fluoridation products, fluorosilicic acid, sodium fluorosilicate, and sodium fluoride, are not "safe and effective" to aid in the prevention and prophylactic treatment of dental caries disease when used to make fluoridated public drinking water at 0.7 to 1.3 ppm of fluoride ion.

I am concerned that health risk assessments have not been conducted on fluoridated water, leaving at-risk groups unprotected. Furthermore, Environmental Protection Agency (EPA) standards and American Academy of Pediatrics (AAP) guidelines have been neglected. Fluoride exposure dose calculations demonstrate that infants who consume formula mixed with fluoridated water exceed the EPA's reference dose by 5 times the safety limits. The AAP changed their official policy statement in 1995, warning against the consumption of fluoridated water in babies under 6 months old. The public at-large still has not been notified of these health and safety precautions.

Sincerely,

Yolanda Whyte, MD

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EDUCATION

1995-9	M.D.	University of Wisconsin School of Medicine	Madison, WI
1990-4	B.S.	Howard University	Washington, DC

OTHER MEDICAL TRAINING

Sept. – Oct. 1999	Radiology and Pediatric Urology Externship Hadassah Hospital	Jerusalem, Israel

MEDICAL LICENSURE GA 055352, since 2002

PROFESSIONAL EXPERIENCE

January 2006 - Present	**Children's Environmental Health Advocate and Lobbyist** Communicate public health and pediatric health threats from environmental contaminants to members of US Congress, Georgia Congress, White House, EPA, Georgia EPD, and city councils. My work includes speaking engagements to schools and community groups
October 2006 - Present	**Pediatrician** Locum tenens assignments with various agencies throughout Georgia and the Indian Health Service
November 2004 – July 2006	**Director of Pediatrics** In-patient and outpatient practice at Bacon County Hospital and a rural health clinic. Alma, GA

MEDICAL MISSIONS

January 2012	***Haiti*** As Co-Medical Director, coordinated a health team of US and Haitian participants to provide healthcare and training to approximately 1,600 patients at a school-church complex and an orphanage in Port-au-Prince. Espwam and Lighthouse Covenant International- Philadelphia, PA
July 2010	***Haiti*** As Medical Director, coordinated a health team to provide health education and medical care to over 400 patients at a church in Carrefour. Espwam-Philadelphia, PA
October – November 2006	***Vietnam*** Taught a neonatal resuscitation program and provided pediatric medical care at hospitals, rural clinics and schools in 3 regions of Vietnam. Project Vietnam/ AAP-Orange County, CA
August 2006	***Jamaica*** Gospelfest, medical and spiritual mission providing basic health screenings at a few churches, an orphanage, and a park, in collaboration with live music entertainers in Montego Bay. Community Spirit- Orlando, FL
August 2004	***Guyana*** Project providing HIV screening, education, workshops, and medical care in urban and rural areas of Guyana, South America. Deskan Institute-Atlanta, GA
January – March 2000	***Ghana*** Independent pediatric mission trip in primary care and tropical medicine at Adidome Hospital. Adidome in the Upper Volta Region

ADVOCACY WORK/ LOBBYING	
May 21-22, 2012	**Safe Chemicals Act of 2011, S. 847** Along with other members of the 'Stroller Brigade'/ Safer Chemicals Healthy Families campaign, held a rally on the mall and lobbied members of Congress to support this bill which will make sure chemicals in consumer products are tested to be safe before placed on the market.
May 3, 2012	**North Fulton Legislators Session Review Meeting** Advocated for strong health protective environmental policies with pediatric considerations to local Georgia State Senators and Representatives, focusing on air pollution and coal ash disposal.
April 26-27, 2012	**Coal ash amendment, Transportation Bill** Along with Physicians for Social Responsibility and Earthjustice, lobbied members of U.S. Congress to block this amendment, and briefed the White House Council on Environmental Quality and the EPA. Communicated public health and pediatric threats from unregulated exposure to the heavy metals, carcinogens, genotoxic and radioactive toxins in coal ash, with special implications for Georgians.
April 12-13, 2012	**Renew Better Pharmaceuticals and Devices for Children Act (BPCA) and Pediatric Research Equity Act (PREA)** Along with the American Academy of Pediatrics, lobbied members of U.S. Congress to support reauthorization of these bipartisan laws to improve drug labeling, research testing and incentivize the development of pediatric medical devices, in order to protect children.
September 19-20, 2011	**Sham Peer review** Along with the National Whistleblowers' Coalition, lobbied key members of U.S. Congress to support fair peer review processes for physicians.
August 18, 2011	**GA EPD Plant Washington coal plant permit** Opposed this permit, citing the disproportionate health impact that toxic air emissions like NOx, SO2, lead, mercury, greenhouse gases, etc. released from coal power plants have on children, local residents, and other vulnerable groups. Sandersville, GA
July 18-19, 2011	**Clean air policies** Along with the U.S. Climate Action Network, lobbied members of U.S. Congress, to support strong clean air policies including the Clean Air Act, stressing public health threats especially to children, and other vulnerable populations.
May 26, 2011	**EPA Mercury Air Toxics Rule** In support of power plants to slash mercury emissions by 90% within 3-4 years. Reduce arsenic, lead and other hazardous air pollutants which all contribute to disease and premature death. EPA Headquarters, SE region. Atlanta, GA
March 28-30, 2011	**Clean Diesel, Clean Construction, DERA (Diesel Emissions Reduction Act funding)** Engaged in strategic planning for diesel clean-up measures with the Clean Air Task Force. Lobbied members of U.S. Congress, briefed the Transportation Committee and EPA on the health effects from particulate matter, elemental carbon and other harmful air emissions.
February 2011	**EPA Environmental Justice Hearing** Gave medical testimony on how children, especially those of African-American descent, are disproportionately affected by air pollution.
September 1, 2010	**EPA Transport Rule** Supported reductions of sulfur dioxide and nitrogen oxide emissions in 23 Eastern and Midwestern states, stressing implications on public health and children's health. Public Hearing EPA Region 4, Atlanta, GA
June 2010	**SCHIP Funding for Children** Lobbied members of Congress with the American Academy of Pediatrics to protect funding of state children's health insurance programs

January 5, 2010	**EPA National Ambient Air Quality Standards for Sulfur Dioxide Proposed Rule** In support of reductions of sulfur dioxide emissions to 50-100 ppb, 3havg, stressing health implications to those with heart and lung disease, and risk of preterm birth
March 7, 2008	**Ozone Regulation** In support of Georgia Congressional proposal to lower 1997 EPA 8h ozone standard from 80ppb to 75ppb, stressing heath implications to those with heart and lung disease
June 2006	**Healthcare Funding** Along with the American Medical Association, lobbied U.S. members of Congress to preserve Medicaid/Medicare funding
ADVOCACY WORK/ MEDICAL TESTIMONY	
May 31, 2012	**Water Fluoridation** City Council, Milwaukee, WI
May 15, 2012	**Water Fluoridation** Children's rally and City Council, New York City, NY
February 29, 2012	**Water Fluoridation** City Council, Alexander City, AL
March 2011	**Water Fluoridation** City Council, Sandy Springs, GA
April 2010	**Child Rights Advocacy** Georgia Advisory for Children with Special Needs Hearing. Forsyth, GA
OTHER May 24, 2011	Joint Letter to US Congress, urging them to limit lead in toys and other children's products, in response to proposed legislation that would weaken those restrictions.

SPEAKING ENGAGEMENTS	
April 15, 2012	**Children's Environmental Health** Global Health and Humanitarian Summit. Emory University, Atlanta, GA
January 18, 2012	**Path to Becoming a Pediatrician** Junior High and High School students at Fishers of Men Ministry, Port-au-Prince, Haiti
October 27, 2011	**Air Pollution from Coal Plants** Fall Alliance for Clean Energy. Atlanta, GA
August 10, 2011	**Stress** Catholic Charities of Atlanta. Atlanta, GA
June 2011	**Air Pollution** Catholic Charities of Atlanta. Atlanta, GA
April 3, 2011	**Global Health and Humanitarian Summit** Child Rights Advocacy. Emory University, Atlanta, GA
November 2, 2010	**Water Fluoridation** Northeast Georgia Children's Environmental Health Coalition. Teleconference Presentation
RESEARCH TRAINING	
Jan. – July 1995	**National Institutes of Health (NIH) Pre-Doctoral Fellow** Studied the molecular genetics of rare inherited skin disorders using linkage and candidate gene analysis. Laboratory techniques included PCR, gel electrophoresis, radio-labeling and sequencing. Genetics Studies Section, Laboratory of Skin Biology, NIH. Bethesda, MD

June – Aug. 1994	**American Society for Microbiology (ASM) Research Fellow** Studied the evolutionary pattern of vesicular stomatitis virus (VSV), comparing this RNA virus with its monoclonal antibody resistant mutant (MARM). Virology and Immunology Laboratory, Department of Biology, University of California, San Diego. LaJolla, CA
OTHER Sept. 1991 – Apr. 2004	**Supervisor, Common Cause** Promoted from telephone fundraiser, supervised of a shift of 25 employees involved in political campaign finance reform. Common Cause/Public Interest Communications. Washington, DC

PUBLICATIONS

Whyte, Yolanda. OpEd: *Pro & Con: Should the EPA issue stronger limits on mercury emissions*? Atlanta Journal Constitution. May 25, 2011

Whyte, Yolanda. *Community Advocate: Your Personal and Community Resource Directory*. Atlanta: Self-published; Spring 2009

Whyte, Yolanda. Help our Children Breathe Clean Air. *GA Sierran* March/April 2009: p 9.

Richard G, Lin JP, Smith L, **Whyte YM**, Itin P, Wollina U, Epstein E Jr., Hohl D, Giroux JM, Charnas L, Bale SJ, DiGiovanna JJ. Linkage Studies in Erythrokeratodermias: Fine Mapping, Genetic Heterogeneity, and Analysis of Candidate Genes. *Journal of Investigative Dermatology* 109(5): 666-671, Nov 1997

AD HOC REVIEWER

12/19/02	Journal of the National Medical Association

HONORS & AWARDS

2004	Morehouse Pediatric Residency Teaching Award
2002-4	Pediatric Chairperson, Morehouse Residency Association
2003-4	Resident Representative, Georgia Chapter American Academy of Pediatrics
1996-7	UW Medical Student Association Leadership Award
1995	NIH Intramural Research Training Award
1994	American Society for Microbiology Fellowship Award
1993-4	Golden Key National Honor Society
1990-4	Howard University Dean's List

PROFESSIONAL AND EXTRACURRICULAR ACTIVITIES

2012	Member, U.S. Green Buildings Council
2009-10	Member, Board of Directors, SAFE Place for Kids-Boys homeless shelter. Austell, GA
2008	Federal Emergency Management Agency's Community Emergency Response Team
2007-current	Member, Howard University Alumni Association
1990-current	Member, University of Wisconsin Alumni Association
2002	Member, Board of Directors, Central Florida Police Athletic League. Orlando, FL

PROFESSIONAL MEMBERSHIPS

Medical Association of Atlanta
American Academy of Pediatrics
AAP Council on Environmental Health
National Medical Association
NMA Environmental Health Task Force
Physicians for Social Responsibility
Union of Concerned Scientists

Water Fluoridation & Tooth Decay: Results from the 1986-1987 National Survey of US Schoolchildren

Fluoride

Volume 23, No. 2; April, 1990; pp 55-67

by John A. Yiamouyiannis, Ph.D.

SUMMARY: Data from dental examinations of 39,207 schoolchildren, aged 5-17, in 84 areas throughout the United States are analyzed. Of these areas, 27 had been fluoridated for 17 years or more (F), 30 had never been fluoridated (NF), and 27 had been only partially fluoridated or fluoridated for less than 17 years (PF). No statistically significant differences were found in the decay rates of permanent teeth or the percentages of decay-free children in the F, NF, and PF areas. However, among 5-year olds, the decay rates of deciduous teeth were significantly lower in F than in NF areas.

KEY WORDS: Dental caries; Fluoridation; Schoolchildren; Tooth decay.

Introduction

It has become widely accepted among dental and public health professionals that fluoridation reduces tooth decay by one-half to two-thirds (1,2). However, recent studies by public health dentists in New Zealand, Canada, and the United States have reported similar or lower tooth decay rates in nonfluoridated areas as compared to fluoridated areas (3-6). Moreover, findings in the United States and worldwide show that, over the last 25 years, reductions in tooth decay rates in nonfluoridated areas are comparable to those in fluoridated areas (7-9).

From 1986 to 1987, dentists trained by the US National Institute of Dental Research (NIDR) performed dental examinations on 39,207 schoolchildren, aged 5-17, in 84 areas throughout the United States. This survey allowed a comparison of tooth decay of large numbers of people from a large number of areas, some of which have been fluoridated and some of which have not.

Materials and Methods

Through the United States Freedom of Information Act, we obtained a printout of the dental records and a list of the 84 areas used in this survey. From these data, we calculated the number of decayed and filled deciduous teeth (dft) and the number of decayed, missing, and filled permanent teeth (DMFT) for each record and entered the resulting data into a

computer. All calculations were triple-checked before being entered into the computer and all computer entries were double-checked.

By computer, each record (including the dft and DMFT scores of each student) was placed in the appropriate age group. For each of the 13 age groups, average dft and DMFT rates per child were determined for each of the 84 areas. Age-adjusted DMFT rates for 5- to 17-year olds were calculated by adding the DMFT rates for each of the 13 age groups and dividing by 13 (10).

We obtained the data regarding the fluoridation status of the areas surveyed from Natural Fluoride Content of Community Water Supplies, Fluoridation Census 1969, Fluoridation Census 1975, and Fluoridation Census 1985, all published by the US Public Health Service. In some cases, local authorities were also contacted to determine the fluoridation status of an area.

Average DMFT (and dft) rates for F, NF, and PF groups were calculated for each age. Average-age-adjusted DMFT (and dft) rates for the F, NF, and PF groups were calculated by taking the average of age-adjusted rates for the respective groups (10).

The percentage of "caries-free" children was calculated for each age group for each area. Age-adjusted "caries-free" rates were also calculated. A student was considered to be "caries-free" so long as they had no DMFT or dft. For example, a child who had lost all their teeth and no longer had any left to be decayed or filled would not be recorded as a "caries-free" student.

Through the United States Freedom of Information Act, we also obtained residence data for each of the above schoolchildren which allowed us to calculate tooth decay rates for those in F, NF, and PF areas who had lived at the same residence for their entire life.

The two-tailed t-test was used to determine 95% confidence intervals and to determine statistical significance (at the 95% confidence level). A two-sided Wilcoxon rank sum test (11) was used to determine whether there was a statistically significant difference (at the 95% confidence level) in the rank order of DMFT rates of F and NF areas.

Results

Table 1 presents the number of students examined and the age-adjusted DMFT rate for each of the 84 areas in the order of increasing tooth decay rate. There is no statistically significant difference in the rank order of the age-adjusted DMFT rates of F and NF areas. As can be seen by examination of column 1, there is no clustering of fluoridated areas at the top of the table. In the quartile with the lowest age-adjusted DMFT rates, 9 are non-fluoridated, 3 are partially fluoridated, and 9 are fluoridated. In the quartile with the highest DMFT rates, 5 are nonfluoridated, 10 are partially fluoridated, and 6 are fluoridated. Table 1 also indicates that there is no biased geographical distribution of F and NF areas that is hiding some potential decay preventive effect of water fluoridation.

Table 1

The number of children examined and the average-age-adjusted DMFT, dft, and "caries-free" rates for 5- to 17-year olds in each of the 84 areas in the order of increasing age-adjusted DMFT rate. F refers to areas fluoridated before 1970; PF refers to areas which are only partially fluoridated; PF(x) refers to areas fluoridated in the year "x"; NF refers to areas that are not fluoridated.

Water	Area	No.	DMFT	dft	Caries-free
NF	Buhler, KS	543	1.229	0.810	44.7%
F	El Paso, TX	451	1.321	0.777	43.5%
NF	Brooklyn, CT	410	1.420	0.693	47.6%
F	Richmond, VA	475	1.435	0.715	45.6%
F	Ft. Scott, KS	491	1.442	0.774	38.2%
F	Prince George, MD	443	1.491	0.539	48.0%
NF	Cloverdale, OR	354	1.494	0.872	40.4%
PF(71)	Alliance, OH	467	1.584	0.549	44.6%
NF	Martin, Co., FL	440	1.587	0.677	41.0%
F	Andrews, TX	455	1.588	0.893	35.8%
NF	Coldspring, TX	406	1.589	1.144	33.8%
F	Tulsa, OK	504	1.602	1.075	35.5%
NF	Palm Beach, FL	476	1.613	0.896	34.5%
PF	Hocomb, MO	558	1.628	0.883	40.3%
NF	Kitsap, WA	564	1.635	0.769	42.9%
F	St. Louis, MO	491	1.638	0.711	39.1%
PF (82)	Houston, TX	488	1.662	0.819	41.8%
F	Clarksville, IN	428	1.678	0.747	40.4%
NF	Grand Island, NE	535	1.719	0.789	40.7%
F	Ft. Stockton, TX	415	1.722	0.891	33.4%
NF	San Antonio, TX	422	1.736	0.895	39.3%
F	Cherry Creek, CO	441	1.757	0.727	36.5%
F	Tuscaloosa, AL	475	1.809	0.963	32.0%
PF	Marlon Co., FL	545	1.817	0.944	28.8%
F	Cleveland, OH	486	1.819	0.715	39.9%
NF	Allegany, MD	458	1.834	0.735	38.3%
PF (78)	Norwood, MA	434	1.841	0.640	39.9%
F	Alton, IL	511	1.859	0.843	37.6%
NF	Shamokin, PA	462	1.861	1.023	32.2%
NF	Lodi, CA	573	1.878	1.197	33.0%
PF	Bullock Creek, MI	472	1.879	0.766	36.7%
PF (82)	Marlboro, MA	386	1.885	0.613	40.8%
PF (81)	Allen, TX	445	1.905	0.674	38.7%
F	San Francisco, CA	456	1.908	1.031	36.3%
NF	E. Orange, NJ	401	1.909	0.796	38.0%

PF (71/60)	Lincoln/Sudbury, MA	436	1.923	0.758	37.8%
NF	Conejo, CA	620	1.930	0.811	41.7%
NF	Lakewood, NJ	450	1.933	0.698	38.0%
F	New York City-2	336	1.953	0.812	34.9%
PF	Bethel, WA	540	1.958	1.072	34.3%
F	Beach Park, IL	518	1.970	0.878	35.2%
PF	Rising Star, TX	370	1.971	0.909	28.7%
F	Philipsburg, PA	499	1.983	0.982	33.2%
F	Lanett, AL	503	1.994	0.978	31.9%
PF (82)	Plainville, CT	436	2.006	0.795	39.3%
NF	Wichita, KS	496	2.036	0.878	33.5%
NF	Newark, NJ	494	2.038	0.869	35.9%
PF	Knox Co., TN	530	2.056	1.152	31.3%
NF	Los Angeles, CA	540	2.063	1.039	33.0%
F	Pittsburgh, PA	415	2.064	0.781	34.1%
PF (70)	Lincoln, NE	476	2.076	0.825	31.5%
NF	Newton, KS	464	2.083	1.225	31.1%
PF	Lakeshore, MI	486	2.088	0.781	32.6%
NF	New Paltz, NY	350	2.110	0.751	34.8%
F	Bemidgl, MN	485	2.124	1.001	29.3%
NF	Alpine, OR	397	2.133	0.974	34.7%
NF	Canon City, CO	463	2.160	1.118	33.1%
NF	Wyandank, NY	396	2.161	0.828	34.7%
NF	Milbrook, NY	332	2.179	0.716	32.2%
NF	Chowchilla, CA	551	2.181	1.073	33.0%
F	New York City-1	503	2.190	0.627	37.9%
PF (82)	Baltic, SD	487	2.193	0.974	27.8%
PF (71/74)	Blue Hill, NE	480	2.218	0.855	29.6%
NF	Crawford, PA	492	2.222	0.996	28.5%
PF (74)	New Orleans, LA	459	2.251	0.953	27.4%
PF (70)	Memphis, TN	464	2.253	0.763	33.1%
PF	Madison Co., MS	493	2.259	1.455	26.4%
F	Milwaukee, WI	478	2.349	0.909	32.1%
NF	Tooele, UT	519	2.372	1.458	24.3%
NF	Chicopee, MA	453	2.389	0.862	34.2%
PF	Cambria, PA	532	2.460	1.039	27.1%
PF (75)	Springfield, VT	444	2.489	0.838	32.1%
F	Dearborne, MI	491	2.496	1.167	26.3%

F	Maryville, TN	466	2.512	1.287	22.9%
PF (81)	Taunton, MA	445	2.515	0.903	31.0%
F	Greenville, MI	556	2.558	1.191	25.3%
PF	Hart/Pentwater, MI	455	2.584	1.344	24.1%
F	Philadelphia, PA	463	2.649	0.824	26.0%
PF	Sup. Union #47, VT	487	2.710	0.907	28.1%
NF	Cutler/Oroal, CA	528	2.796	1.742	19.2%
F	Brown City, MI	512	2.972	1.229	22.5%
PF (83)	Lawrence, MA	339	3.012	1.262	17.6%
NF	State of Hawaii	293	3.294	1.375	23.9%
PF	Concordia, Co., LA	424	3.767	1.508	12.4%

There is no statistically significant difference between the average DMFT rates for the F and NF groups at any age (Figure 1). The average DMFT rates of the PF groups are higher than those of the F and NF groups at every age with the exception of 14-year olds.

There is no statistically significant difference in the average-age-adjusted DMFT rates among the F, PF, and NF groups (Table 2). The average-age-adjusted DMFT rates in F and NF areas are 1.96 and 1.99, respectively. The 95% confidence interval for the DMFT rate in F areas minus the DMFT rate in NF areas is (-0.19, 0.25); thus we can rule out, with a certainty of 95%, the possibility that the DMFT rate in F areas is more than one-fourth of a tooth less than in the NF areas. We can also rule out, with a certainty of 95%, the possibility that the DMFT rate in NF areas is more than one-fifth of a tooth less than in the F areas.

Table 2

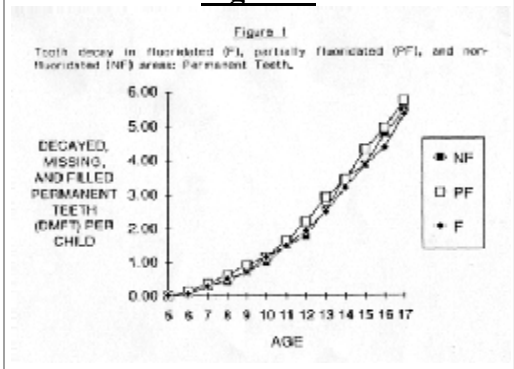
Average-age adjusted DMFT rates for 39,207 U.S. schoolchildren and 17,336 life-long resident schoolchildren in 84 areas throughout the United States. Standard deviations are given in parentheses.

		Total		Life-long	
	No. of Areas	No. of Students	DMFT	No. of Students	DMFT
Fluoridated	27	12,747	1.96 (0.415)	6,272	1.97 (0.465)
Partially Fluoridated	27	12,578	2.18 (0.465)	5,642	2.25 (0.470)
Nonfluoridated	30	13,882	1.99 (0.408)	5,422	2.05 (0.517)

To make certain that the absence of a statistically significant difference between the DMFT rates of schoolchildren living in F and NF areas was not the result of the mobility of schoolchildren, or their sex and racial compositions, DMFT rates were determined for **1.]** those who spent their entire lives in one household and **2.]** for white males and white females. The results in Table 2 show that for life-long residents, there is no statistically significant difference in average-age-adjusted DMFT rates in F and NF areas. In addition, there are no statistically significant differences in tooth decay rates between permanent residents of F and NF areas at any age (Figure 2A). If water fluoridation were to have

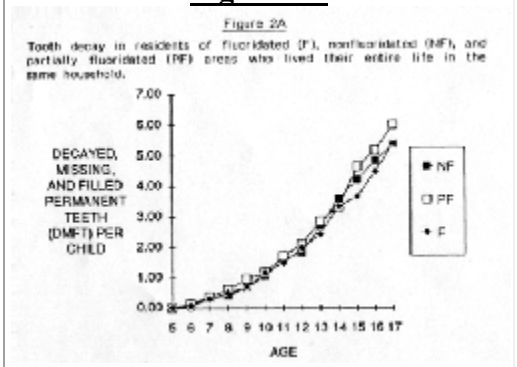
reduced tooth decay as measured by DMFT, tooth decay rates for lifelong residents living in fluoridated areas should be lower than residents who had not spent their entire lives in these areas. This was not found to be the case. Figures 2B and 2C show that among white males and white females (which make up about 70% of all the children studied), there is no significant difference in DMFT rates in the F and NF areas at any age group.

Figure 1



(Click to enlarge image)

Figure 2A



(Click to enlarge image)

Figure 2B

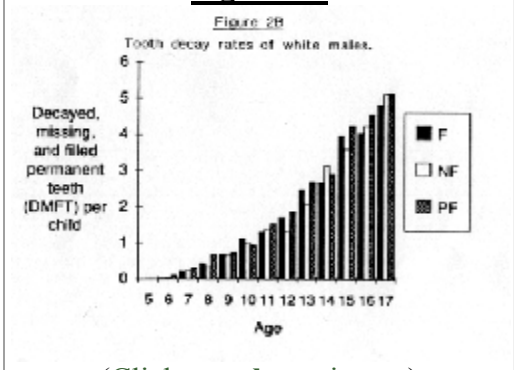


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Figure 2C

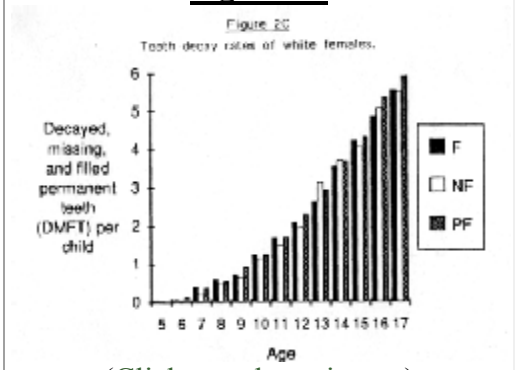

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Figure 3

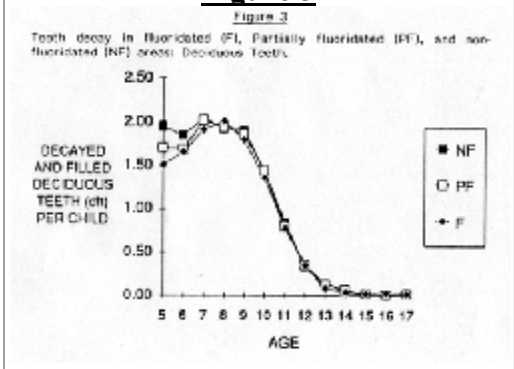

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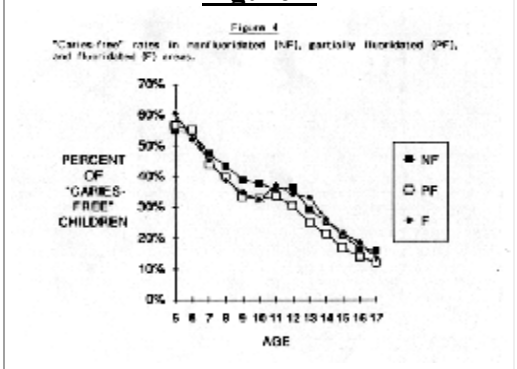
Figure 4



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In contrast, notably lower tooth decay rates were observed in the deciduous teeth of young children living in F areas. The 5-, 6-, and 7-year-olds in the F group have dft rates 22%, 9% and 6% lower than those of the NF group, respectively (Figure 3). Although the average-age

adjusted dft rates for F, NF, and PF groups were not significantly different statistically, they were higher for the NF groups (0.96, +0.25) for the PF groups (0.93, +0.24), which in turn is slightly higher than the F group (0.89, +0.19).

To focus in on dft rates among children 5-8, the eight areas which commenced water fluoridation between 1970 and 1978 were removed from the PF group and added to the F group. The 5-, 6-, and 7-year-olds in the new F (F*) group have dft rates 24%, 10%, and 10% lower than those of the NF group, respectively, and the dft rate of 5-year-olds in the F* group is significantly lower ($p < 0.05$) than that of the NF group.

Moreover, among 5-, 6-, and 7-year-old lifelong residents in the F* group, dft rates were 42%, 18% and 11% lower than those of the NF group, respectively, and the dft rate of 5-year-olds in the F* group was significantly lower ($p < 0.002$) than that of the NF group (Table 3). If water fluoridation were to have reduced tooth decay as measured by dft among 5-year-olds, tooth decay rates for lifelong 5-year-old residents living in fluoridated areas should hav been lower than those of residents who had not spent their entire lives in these areas. This was found to be the case. From Table 3, it can also be seen that this large and significant reduction disappears after a couple of years.

Table 3

Percentage change in dft rates in all residents and life-long residents of F and F areas in comparison to NF areas.*

	Total		Life-long	
Age	(NF-F)/NF	(NF-F*)/NF	(NF-F)/NF	(NF-F*)/NF
5	22%	24% ($p < 0.05$)	36% ($p < 0.02$)	42% ($p < 0.002$)
6	9%	10%	14%	18%
7	6%	10%	5%	11%
8	-4%	1%	-5%	1%

Fluoride may have caused a reduction in dft by delaying deciduous tooth eruption. This is consistent with the fact that the dft rate in the F and F* groups reaches a maximum later than in the NF group. Fluoride-induced delays in tooth eruption have been reviewed elsewhere (12, 13) with contradictory conclusions, but more recent studies examining 5-year-olds have indicated delayed eruption that could account for such a difference in tooth decay rates (14).

The percentage of decay-free children in F, PF, and NF areas is 34.5%, 31.9%, and 35.1% respectively. There is no statistically significant difference between the average "caries-free" rates for the F and NF groups at any age (Figure 4).

Discussion

The data presented here are consistent with data reported elsewhere in large US surveys. In 1977, the Rand Corporation examined the tooth decay rate of 25,000 children in (5F and 5NF) nonrandomly selected areas (15). In the three areas in their study that were included in the present study, we compared the tooth decay rates of 12-year-olds. There was good

agreement between this study and theirs with regard to tooth decay rate, after converting DMFS (decayed, missing and filled permanent tooth surfaces) to DMFT (16) and considering the acknowledged 36% decrease in DMFS from 1979-1980 to 1986-1987 (17).

In 1983-84, Hildebolt et al. (4) examined the tooth decay rates of over 6500 Missouri rural schoolchildren from grades 2 (average age 7.5) and 6 (average age 11.5). Among 6th graders living in the most intensively studied regions, the average DMFT + dft rate was 2.07 for those drinking nonfluoridated water and 2.17 for those drinking fluoridated water, compared to the DMFT + dft rate of 2.00 reported for 11-year-olds living in Holcomb, Missouri in our study.

In 1986, Kumar et al. examined 1446 schoolchildren aged 7-14 from Newburgh, New York (fluoridated in 1945) and cohorts from nonfluoridated Kingston, New York (18). The sample selection was nonrandom and had a response rate of only 50-65%. Nonetheless, the age-adjusted DMFT rates observed (1.5 for fluoridated Newburgh and 2.0 for nonfluoridated Kingston) were in line with the corresponding values obtained in this study for communities in the area (1.5 for nonfluoridated New Paltz, New York and 1.7 for fluoridated New York City).

Conclusions

Does water fluoridation reduce tooth decay? **i]** This study and other recent studies (3-8) show that there is currently no significant difference in tooth decay rates in F and NF areas and that decreases in tooth decay rates over the last 25 years have been comparable regardless of fluoridation status; if this is true, there was no significant difference in the tooth decay rates between these areas 25 years ago. **ii]** From 1970 to the present, total fluoride intake studies indicate an average intake of 1-2 mg per day in nonfluoridated areas and 3-5 mg per day in fluoridated areas (19,20); thus, it is difficult to claim that the reason tooth decay differentials between fluoridated and nonfluoridated areas have disappeared is because the fluoride intakes in these areas are now similar. Furthermore, the substantially higher incidence of dental fluorosis in fluoridated areas confirms that residents in these areas are consuming substantially higher levels of fluoride than those living in non-fluoridated areas (21-23). **iii]** Dramatic reductions in tooth decay have occurred in developing countries where there is no water fluoridation (see World Health Organization data) and there is little reason to suspect that there would be elevated levels of fluoride in the food chain (7,9,24,25). **iv]** In addition to recent studies, a number of early studies have also shown no significant reduction in tooth decay as a result of water fluoridation (7, 26-28). **v]** Serious questions have been raised regarding the reliability of earlier studies claiming that fluoridation causes a reduction in tooth decay (29).

Acknowledgments

I thank Kimberly Close-Hittle, Jerry Putnam, Margot Yiamouyiannis, and Opal Kuhn for their help in the calculation and verification of summary data as well as Jill Pitts and Chris Hiatt for their lightning fast speed in entering data into our computer. Without the generosity of Dr. Leo Roy, Dr. Reuben Benner, Dr. H. Charles Kaplan, Dr. Gerald Judd,

Richard Barmakian, John C. Justice, Len Greenall, Mr. and Mrs. Andrew Yimoyines, Wini Silko, AIM International, Inc., and other patrons of the Center for Health Action and the Safe Water Foundation, the preparation and publication of this article would not have been possible. Finally, I thank Ray Fahey for correcting an error we had made in assigning the fluoridation status of E. Orange, NJ.

Addendum

Recently Brunelle (30), using the same database that we used, reported 26% fewer dfs (decayed and filled deciduous tooth surfaces) in children who had always resided in F communities than those who never lived in F communities. This finding agrees reasonably well with the data outlined in our Table 3, which shows a statistically significantly lower dft rate in lifelong 5-year-old residents of fluoridated areas. However, by omission of age-specific data, the Brunelle study covers up the fact that this difference in tooth decay is no longer significant in 6-year-olds and disappears entirely among 8-year-olds.

Another recent study by Brunelle and Carlos (31), which also uses the same database that we used, reports a 17% lower DMFS rate in the F areas. This study has a number of major deficiencies which render the study of little or no value.

1. It contains extremely serious errors. For example, by a cursory inspection, we found two values that are off by 100% or more. In their Table 9, the DMFS figure for lifelong F exposure residents of Region VII should be about 3, not 1.46 as reported. From their Table 3, the percent of 5-year-olds who have caries is 1.0%, not the 2.7% that can be calculated from the Table (100%-97.3%). When I pointed out this error to Dr. Carlos, he admitted that only 19 out of the 1851 5-year-olds had caries: 19/1851 = 1%, but refused to make the correction (32).

2. It fails to report the tooth decay rates for each of the 84 geographical areas surveyed. This covers up the fact that there is no difference in the tooth decay rates of the fluoridated and nonfluoridated areas surveyed. The Brunelle/Carlos study even fails to list the area studied. As a result, they produce misleading illustrations; for example, their Figure 3 implies that Arizona and New Mexico have the lowest tooth decay rates, when, in fact, not a single area was surveyed in either of the two states.

3. It fails to control for geographical differences in tooth decay rates by indiscriminately and disproportionately bunching children from all parts of the country into 2 groups, F and NF.

4. It fails to do the statistical analysis (or even provide the data, i.e. the standard deviation and sample number) necessary to determine whether the values found for F and NF areas are significantly different. Our calculations show that even if their data were accurate, the 17.7% figure does not reflect a statistically significant difference between the F and NF groups.

5. It fails to report the data for approximately 23,000 schoolchildren who were not life-time residents of either the F or NF areas (the PF group). If fluoridation reduced tooth decay, the

DMFS rate of the PF group should have been greater than that of the F group and less than that of the NF group. Our data indicate that the PF group would have had a DMFS rate higher (although not significantly higher) than either the F or NF groups.

6. It fails to report the data for the percentages of decay-free children in F and NF areas. Our data indicate that had these calculations been done by Brunelle and Carlos, the results may have actually indicated better (although not significantly better) dental health in the NF areas.

Brunelle and Carlos, as well as their employer, the NIDR, have recently come under attack for presenting erroneous data and designing poor experiments which promoted the fluoride mouthrinse program (33). The apparent poor quality of their research regarding the 1986-87 survey (30, 31) is not an isolated case.

Read the *Chemical and Engineering News* (1989) article "New Studies Cast Doubt on Fluoridation Benefits" which discusses this study.

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From:	Gerald Steel
To:	Phillips, Theresa (DOH)
Cc:	Audrey Adams; Scott Shock; Bill Osmunson
Subject:	WAC 246-290-460 Rulemaking - Safe level for added fluoride should be set at maximum that is less than 0.7 ppm
Date:	Tuesday, February 23, 2016 11:04:46 AM
Attachments:	NRC (2006) cover and page 49.pdf Expert James Beck - 0.7 ppm F not safe and effective.pdf Expert Bruce Spittle - 0.7 ppm F not safe and effective.pdf Expert Howard Mielke - 0.7 ppm F not safe and effective.pdf Expert Bill Osmunson - 0.7 ppm F not safe and effective.pdf Expert Yolanda Whyte - 0.7 ppm F not safe and effective.pdf Expert Kathleen Thiessen - 0.7 ppm F not safe and effective.pdf Expert David Kennedy - 0.7 ppm F not safe and effective.pdf Hileman New Studies (1989).pdf Yiamouyiannis Water Fluoridation (1990).docx

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I submit this comment on proposed WAC 246-290-460 on behalf of myself and King County Citizens Against Fluoridation.

WAC 246-290-460 proposes an operating range for public water with fluoride added of 0.5 to 0.9 mg/L fluoride in consideration of the HHS Recommendation of 0.7 mg/L (0.7 ppm) as an upper limit for safety. If fluoridation is to continue to be allowed in Washington State based on the HHS Recommendation, fluoride should not be added to take fluoride levels in drinking water above 0.7 ppm fluoride. If the SBOH relies on the HHS Recommendation for safety, the operating range should be "0.7 mg/L fluoride or less" and not "0.5 to 0.9 mg/L". The essence of the HHS Recommendation was to no longer have fluoridation levels above 0.7 mg/L fluoride. The HHS Recommendation explicitly removed the part of the previous PHS recommendation for fluoride levels above 0.7 mg/L fluoride based on safety. The SBOH will not be acting consistent with the HHS Safety Recommendation if they allow operating levels for fluoride to exceed 0.7 mg/L.

Based on the expert opinions attached hereto which all find that fluoridation at 0.7 mg/L fluoride is not safe, we ask the SBOH to consider lower maximum levels of fluoride when it independently sets a maximum level of added fluoride for public water based only on considerations of safety. When considering safety, we ask the SBOH to set aside any consideration of effectiveness of fluoride to prevent tooth decay. RCW 43.20.050(2) gives the SBOH direction to assure safe public drinking water as a primary public drinking water obligation. We request that your staff be directed to consider the following optional operation ranges for fluoride added to public drinking water and to provide available safety evidence for each level: "0.7 mg/L fluoride or less," "0.5 mg/L fluoride or less," "0.3 mg/L fluoride or less," and "no added fluoride." We believe that "no added fluoride" is the only safe level when fluoride additions to drinking water are being considered.

In a separate comment, we present the case that the SBOH cannot consider alleged benefits of fluoridation when it sets its independent standard for safe drinking water. I provide seven attachments from experts on fluoridation and they all state that fluoridation at 0.7 ppm fluoride is NOT "safe and effective". I also attach page 49 from NRC (2006) which shows

that children 1 to 19 drinking water fluoridated at even 1 ppm fluoride will get more fluoride from other sources than they will get from drinking fluoridated water. In the EPA analysis of safety that was used by HHS, the EPA assumed that 7 parts of fluoride consumption came from drinking water and only 1 part (12.5%) came from other sources. (Fluoride: Exposure and Relative Source Contribution Analysis, EPA (2010) at 103-04.) NRC (2006) at page 49 (attached) shows that about 60% of fluoride intake for children 1-19 years old actually comes from other sources. Fluoride intake that historically came from fluoridated water is now coming from other sources. Drinking fluoridated water now causes ingested fluoride to exceed the safe amount for many people. Everyone agrees that the benefits of fluoridation are statistically insignificant as measured for 39,207 schoolchildren in the 1986-87 National Institute of Dental Research (NIDR) Survey. (See Hileman New Studies (1989) and Yiamouyiannis Water Fluoridation (1990) both attached.) Statistically insignificant is a technical term that means, in essence, that the result is likely random and unreliable.

There is NOT consensus among experts that fluoridation at 0.7 ppm fluoride is “safe and effective.” Attached are statements from seven experts that fluoridation at 0.7 ppm fluoride is NOT "safe and effective." Page 8 of the attachment, from expert Dr. David Kennedy, shows a substantial percentage of infants (< 1 year old) get more than the EPA “safe” reference dose of fluoride only counting the fluoride consumed from fluoridated water at 0.8 ppm fluoride. When one considers the data from page 49 of NRC (2006) attached, children (1 to 10 years old) will get substantially more ingested fluoride from other sources than they now get from fluoridated water. If we modify said page 8 and add the fluoride ingested from other sources, the total fluoride intake for children (1 to 10 years old) with drinking water at 0.7 ppm fluoride will be higher than the EPA "safe" reference dose for a substantial percentage of these children. When fluoride intakes from other sources are included, “many members of all age groups exceed EPA’s reference dose.” This will be true with water fluoridated at 0.7 ppm fluoride.

Page 9 of Dr. Kennedy’s attachment plots “no effect” levels of fluoride consumption for various impairments. The “no effect” levels represent fluoride intakes at or below which most people are not expected to experience any harmful effects. These “no effect” levels are based on average exposures of study populations and do not include any margin of safety. Many of the reported “no effect” levels are substantially less than the EPA’s reference dose and many members of all age groups will get fluoride in excess of these “no effect” levels just from drinking fluoridated water even at 0.7 ppm fluoride. When the fluoride consumption is doubled, taking into account fluoride ingestion from other sources, many more members of all age groups (1+ years old) will get fluoride in excess of these "no effect" levels. This page of the Dr. Kennedy attachment states, “In order to be ‘safe’ for all members of the population, fluoride intakes for all people must be kept below the lowest ‘no effect’ levels, when all sources of fluoride intake are included, and with an adequate margin of safety.” Dr. Kennedy’s attachment supports expert opinion that fluoridation at 0.7 ppm fluoride is not “safe" and that there should be much less or no

fluoride added to have safe drinking water.

Page 16 of the attachment from expert Dr. Kathleen Thiessen (Fig. 1) shows 0.3 to <0.7 ppm fluoride in drinking water gave the highest level of caries-free experience. It shows caries-free decreases at 0.7 and higher ppm fluoride but it also shows that fluoride in drinking water has little relationship to caries-free experience. In fact, the different levels of caries-free experience plotted are statistically insignificant. It further shows drinking water with <0.3 ppm fluoride causes half the incidence of dental fluorosis compared to that which occurs for drinking water with 0.3 to <0.7 ppm fluoride. This is statistically significant. Drinking water with 0.7 to 1.2 ppm fluoride causes three times as many children to have dental fluorosis compared to drinking water with <0.3 ppm fluoride. This is also statistically significant. The 1999 to 2004 NHANES National Study found less than 40 percent of 12 to 15 year olds in the U.S. were unaffected by dental fluorosis and one in eight of this age group had disfiguring mild, moderate or severe dental fluorosis. (Fig. 3 in http://www.cdc.gov/nchs/data/databriefs/db53.htm.) These numbers will not be reduced with fluoridation at 0.7 ppm fluoride because more people receive fluoridated water today than in the past. Pages 17 and 18 of the Dr. Thiessen attachment (Figs. 2 and 3) show fluoride in drinking water has little relationship to the DMFS (decayed, missing, or filled tooth surface) score for children. Dr. Thiessen's attachment supports expert opinion that fluoridation is not "effective" (in a statistically significant manner) at 0.7 ppm fluoride. The data shows it is more effective at 0.3 to <0.7 ppm fluoride but this is not statistically significant compared to having no added fluoride.

Page 1 of the attachment from expert Yolanda Whyte, M.D. expresses concern that young infants less than 6 months old who consume formula mixed with fluoridated water exceed the EPA's reference dose by 5 times the safety limit and the public is not being notified. Expert Dr. Bill Osmunson states that fluoridation should not exceed 0.02 ppm. He quotes from a 2001 statement by the Senior Vice-President of the Headquarters Union of the EPA that the EPA professionals "hold that fluoridation is an unreasonable risk" because "the toxicity of fluoride is so great and the purported benefits associated with it are so small – if there are any at all." Experts Dr. Howard Mielke and Dr. Bruce Spittle also state that fluoridated water at 0.7 ppm fluoride is not "safe and effective."

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February 2008

NSF Fact Sheet on Fluoridation Chemicals

Introduction

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

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

NSF certifies three basic products in the fluoridation category:

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

NSF Standard 60

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

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

NSF Certification

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

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

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

Fluoride

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

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

Silicate

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

Potential Contaminants

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

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

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

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

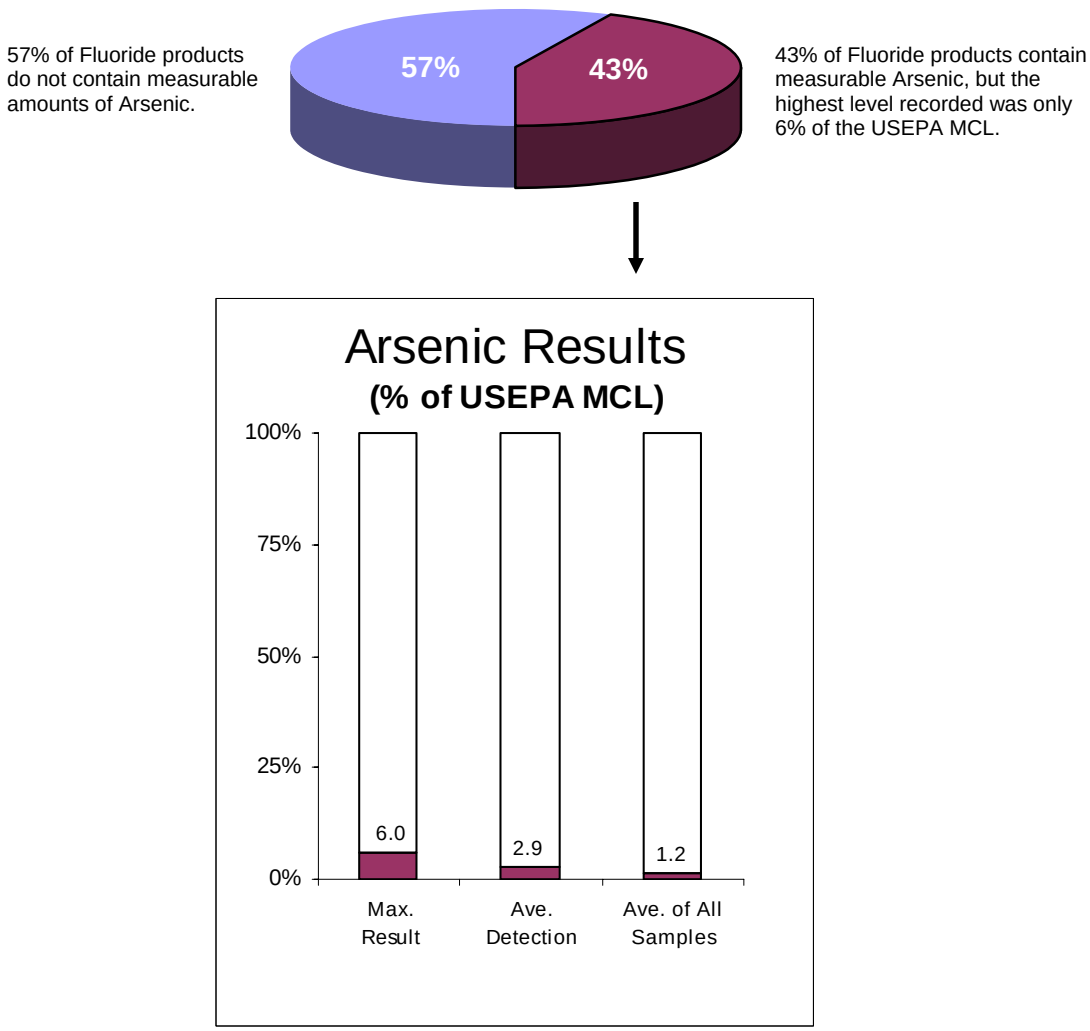
Arsenic

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

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

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

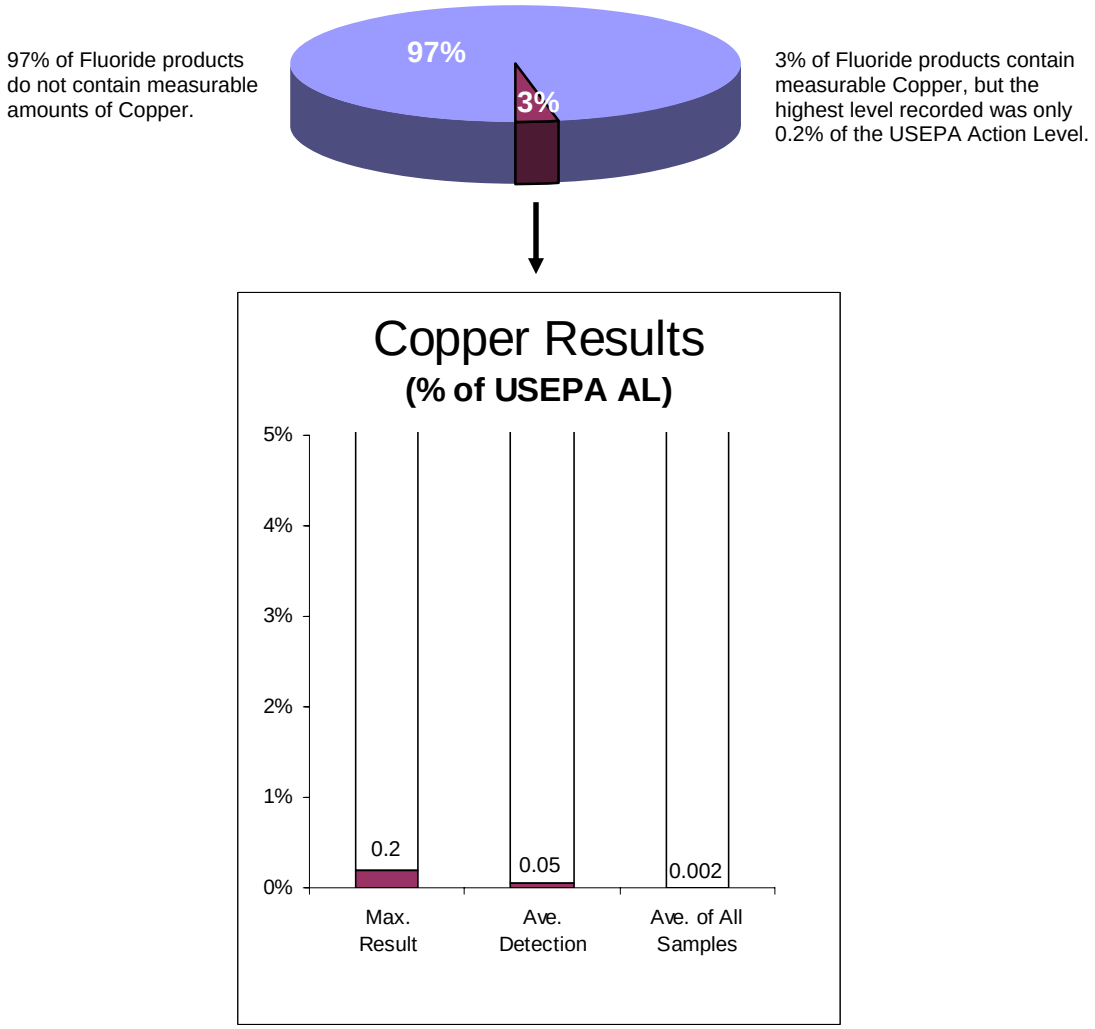
Figure A



Copper

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

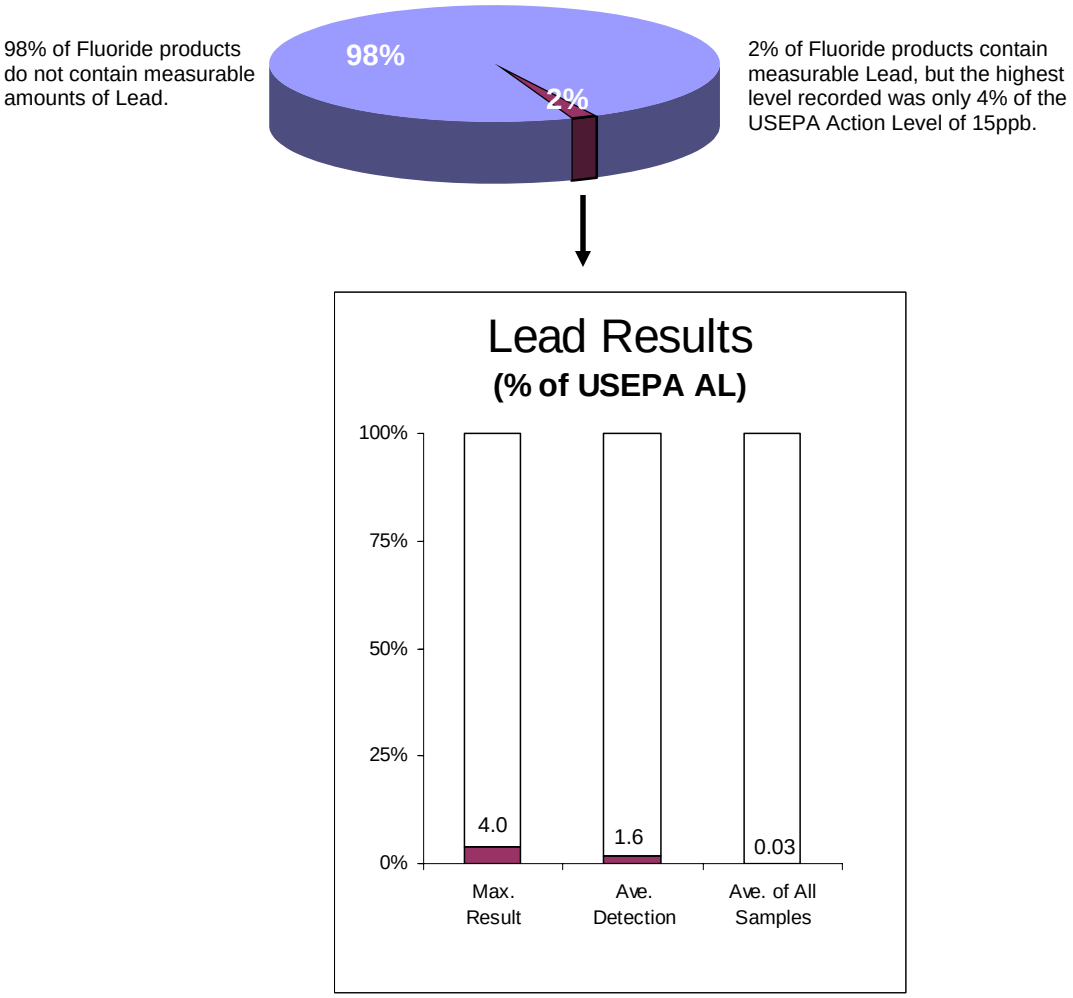
Figure B



Lead

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

Figure C



Radionuclides

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

Summary

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

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

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

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

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

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

Table 1

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

Abbreviations used in this Fact Sheet

ANSI – American National Standards Institute

AWWA – American Water Works Association

AWWARF – American Water Works Association Research Foundation

ASDWA – Association of State Drinking Water Administrators

COSHEM – Conference of State Health and Environmental Managers

EPA – U.S. Environmental Protection Agency

MCL – maximum contaminant level

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

MUL – Maximum use level

NSF – NSF International (formerly the National Sanitation Foundation)

ppb – parts per billion

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

SPAC – Single Product Allowable Concentration

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
1200 Sixth Avenue, Suite 900
Seattle, WA 98101-3140

OCT 10 2012

OFFICE OF
WATER AND WATERSHEDS

Mr. Gerald Steel, PE
Attorney at Law
7303 Young Road NW
Olympia, Washington 98502

Dear Mr. Steel:

Your letter dated August 3, 2012, has been forwarded to the Office of Water and Watersheds for a response because my office is responsible for the implementation of the drinking water regulations. In your letter, you reiterate certain provisions of the Safe Drinking Water Act as we described them in letters from our office dated April 7, 2011, and November 17, 2011.

You go on to refer to various sections of the Washington Administrative Code, specifically WAC 246-290-220(3), which addresses treatment chemicals added to drinking water and WAC 246-290-460, which addresses drinking water fluoridation practices.

As noted in the U.S. Environmental Protection Agency (EPA) letter of November 17, 2011, neither WAC 246-290-220(3) nor WAC 246-290-460 are related to the requirements of the Federal Safe Drinking Water Act in Washington State.

You ask if there is any law, regulation, or directive giving the EPA authority to prevent the Food and Drug Administration and/or Health and Human Services from exercising their drug authority to make a finding that fluoride products added to drinking water are drugs and if there is any law, regulation or directive giving the EPA authority to reverse any FDA regulatory action resulting from such a finding. The answer to both of these questions is no. The EPA has no authority to intervene in the actions of these agencies. If you have additional questions, please contact Fredianne Gray, our Regulatory Fluoride expert, at (206) 553-6387.

Sincerely

Christine Taylor for

Daniel D. Opalski
Office of Water and Watersheds

THE MUNICIPALITY OF METROPOLITAN TORONTO (*Respondent*) ..... APPELLANT;

1957
Mar. 21, 22
June 26

AND

THE CORPORATION OF THE VILLAGE OF FOREST HILL (*Applicant*) ..... RESPONDENT.

ON APPEAL FROM THE COURT OF APPEAL FOR ONTARIO

Municipal corporations—Powers—Special statutory provisions—Provision of "pure and wholesome" water supply—The Municipality of Metropolitan Toronto Act, 1953 (Ont.), c. 73, s. 41.

By s. 41 of *The Municipality of Metropolitan Toronto Act,* the council is empowered to pass by-laws, *inter alia,* "to secure to the inhabitants of the Metropolitan Area a continued and abundant supply of pure and wholesome water".

Held (Kerwin C.J. and Locke J. dissenting): Neither this provision nor any applicable provision of any other statute empowers the appellant municipality to provide for the fluoridation of the metropolitan water supply with the object of preventing or lessening the incidence of tooth decay.

APPEAL from a judgment of the Court of Appeal for Ontario (1) dismissing an appeal from a judgment of F. G. MacKay J.A. (2). Appeal dismissed.

H. E. Manning, Q.C., and *A. P. G. Joy,* for the appellant.

J. J. Robinette, Q.C., and *J. Ragnar Johnson, Q.C.,* for the respondent.

THE CHIEF JUSTICE (*dissenting*):—By leave of this Court the appellant, the Municipality of Metropolitan Toronto, appeals from a judgment of the Court of Appeal for Ontario (1) reversing that of F. G. MacKay J.A. (2), and quashing the appellant's By-law 278, passed June 14, 1955. By *The Municipality of Metropolitan Toronto Act, 1953* (c. 73 of the Ontario statutes of 1953), hereinafter called "the Act", the inhabitants of the metropolitan area were constituted a body corporate; the respondent, the Corporation of the Village of Forest Hill, is an "area munic-

*PRESENT: Kerwin C.J. and Taschereau, Rand, Locke, Cartwright, Fauteux and Abbott JJ.

(1) [1956] O.R. 367, 2 D.L.R. (2d) 570.

(2) [1955] O.R. 889, [1955] 5 D.L.R. 621.

1957 CanLII 15 (SCC)

1957
METROPOLITAN TORONTO v. VILLAGE OF FOREST HILL
Kerwin C.J.

ipality" within the limits of the metropolitan district. The council had previously adopted report no. 8 of its Works Committee recommending that the Commissioner of Works be authorized to take the necessary steps to undertake the fluoridation of the metropolitan water supply and by By-law 278 that action was ratified and confirmed. Clause 2 of the by-law provides:

2. That the said Commissioner of Works and all other appropriate officials of the Municipality be and they are hereby authorized and directed to take the necessary steps, forthwith, to undertake the treatment of the Metropolitan water supply by fluoridation and to obtain all approvals required by statute for the installation of the equipment necessary for such treatment.

Part III of the Act is headed "Metropolitan Waterworks System". By virtue of the earlier provisions of this Part the appellant became a provider of water at the wholesale level to the area municipalities. Then comes the important section, s. 41:

41. The Metropolitan Council may pass by-laws for regulating the time, manner, extent and nature of the supply of water from its waterworks system, and every other matter or thing related to or connected therewith which it may be necessary and proper to regulate in order to secure to the inhabitants of the Metropolitan Area a continued and abundant supply of pure and wholesome water, and to prevent the practising of frauds on the Metropolitan Corporation with regard to the water so supplied.

In these proceedings the Court is, of course, confined to the material filed so far as it may be relevant. On behalf of the appellant an affidavit was filed, sworn to by Professor Joslyn Rogers. Professor Rogers was a member of the Association of Professional Engineers and a graduate of the University of Toronto in chemistry; he had been the Professor of Analytical Chemistry at the University from 1918 to 1954 and was a toxicologist of over forty years' experience and was currently practising as a consulting chemist. From his knowledge and experience he was able to state that chemically pure water does not occur in nature and cannot be produced artificially except in small quantities and with considerable difficulty and that, accordingly, water is classified as pure if it is suitable for human consumption and agreeable in taste, smell and appearance. Paragraphs 4, 5 and 6 of his affidavit read:

4. All natural waters contain minerals and such waters would not for that reason alone be classified as impure if the quantity of minerals present does not render the water unpleasant to the senses or prejudicial to health.

1957 CanLII 15 (SCC)

5. Water containing fluorides in concentrations of up to two or three parts per million, which occurs naturally in many parts of North America, is not considered impure because of the presence of the fluoride. If the fluoride was introduced mechanically the water would still be considered pure as the ion added is the same in both cases and is offered to the human body in the same state.

6. To confirm my opinion respecting the classification of water I would refer to the 5th Edition of "The Examination of Waters and Water Supplies" by Thresh, Beale and Suckling at pages 84, 85, 86 and 87 in the Chapter entitled "What Constitutes a 'Pure and Wholesome Water'" which accurately represent my views.

As he indicates, an examination of the pages of the book referred to confirms his opinion.

While it is notorious that chlorine is added to many water supplies, it is argued that the addition of fluoride to a supply otherwise pure and wholesome is really treating it for a medicinal effect. In view of the above evidence I cannot treat any statement of counsel as an admission that the supply here in question before the addition of the fluoride was pure and wholesome. However, even assuming that this supply when treated with chlorine would be pure and wholesome, the only other evidence in the record bearing upon the point is the affidavit of Dr. Andrew L. Chute, Pediatrician-in-Chief of the Hospital for Sick Children, Toronto, and Professor of Pediatrics at the University of Toronto. Paragraphs 3, 4, 5 and 6 of his affidavit read:

3. Tooth decay, by affecting the majority of people in a community, has come to be recognized by the Medical and Dental Professions as one of the major health problems of our time.

4. I have been associated with others in the consideration of the effect of fluoridation of public or communal water supplies.

5. Studies covering a period of over thirty years under a wide variety of controlled conditions have established the effects of the consumption by human beings of fluoridated water.

6. I am convinced from a thorough perusal of these studies that the addition of fluoride in the proportion of one part per million to a public water supply which is deficient in that constituent is a safe measure and is free from any systemic ill-effects. Such treatment renders the water more wholesome as it is effective in reducing tooth decay to the extent of approximately 60% where consumption of such water begins at an early age and continues during childhood and adolescence. The benefits extend into adult life.

These paragraphs indicate that certainly water is rendered more wholesome through the addition of fluoride in the proportion named and, always presuming that the council acts in good faith, I cannot read s. 41 of the Act

1957 CanLII 15 (SCC)

1957

METROPOLITAN TORONTO v. VILLAGE OF FOREST HILL

Kerwin C.J.

in such a way as to declare that in enacting By-law 278 the council of the appellant exceeded its authority. The good faith of the appellant's council was not impugned. I have not overlooked that Dr. Chute states in para. 7 of his affidavit:

> 7. In my opinion fluoridation is a most valuable measure in preserving the teeth and as a result a valuable measure in maintaining health.

This does not alter my opinion that in proceeding as it did the council of the appellant was not invading the realm of public health and, therefore, it is unnecessary to consider the provisions of *The Municipal Act,* R.S.O. 1950, c. 243, *The Public Health Act,* R.S.O. 1950, c. 306, or any other statute referred to. A decision in the contrary sense would raise the question as to the powers so to do, under the relevant statutes, of other municipalities who have added fluoride to their water supplies, but I refrain from discussing their position and restrict myself to a consideration of the power of the appellant's council under the provisions of s. 41 of the Act.

The appeal should be allowed, the order of the Court of Appeal set aside and the judgment of the judge of first instance restored, with costs throughout.

The judgment of Rand, Taschereau and Fauteux JJ. was delivered by

RAND J.:—The question in issue is whether the Municipality of Metropolitan Toronto, under its power, given by s. 41 of its charter (1) to pass by-laws

> for regulating the time, manner, extent and nature of the supply of water from its waterworks system, and every other matter or thing related to or connected therewith which it may be necessary and proper to regulate in order to secure to the inhabitants of the Metropolitan Area a continued and abundant supply of pure and wholesome water, and to prevent the practising of frauds on the Metropolitan Corporation with regard to the water so supplied

can bring about what is called the "fluoridation" of its metropolitan water supply. The process, so-called, is simply the introduction into the water of a minute portion of fluorine, say, one part in one million, for the purpose of promoting the health of the teeth and in particular the elimination of caries, by building up in the bone substance

(1) *The Municipality of Metropolitan Toronto Act, 1953* (Ont.), c. 73.

1957 CanLII 15 (SCC)

a greater resistance to the inroads of decay by foreign matter within the mouth. In the water the fluorine effects no chemical change but becomes merely diffused in solution.

Mr. Manning's contention is short and precise: the duty and the authority of the municipality is to furnish "pure and wholesome water"; admittedly the addition of fluorine does not affect its quality, otherwise wholesome; by its authority to regulate the "nature" of the supply it may introduce into the particular supply such substances as are generally found in water and in its judgment are beneficial to the health of the users; and in regarding such an object we must distinguish between ends and means, that is, the end being wholesome water, the means, an agency of promoting health, rather than the end being to serve a health purpose superimposed on a functional or water means.

Notwithstanding the attractiveness of this argument, I am unable to agree with it. The word "nature" can be satisfied by other and more accustomed meanings than that of a medicinal addition for another than a water purpose. The nature of the supply is too well known for question: it may be taken from a lake, a river or a stream, accumulated in a reservoir, obtained from artesian wells or collected directly from rainfall. Although the exact role of water in the physiological economy was not gone into, the matter of furnishing that indispensable aliment to life has too long been the subject of discussion to leave much doubt of what it means to furnish it in a wholesome quality. That a municipality may purify it, that is, reduce objectionable foreign matter in it by means harmless to its consumers, is universally understood. In the settled understanding, also, a "water supply" comes from natural sources which show differences in their degree of purity. "Purity" itself is well understood although partaking of the impreciseness of any general term. Solutions of different substances are invariably present, but the human body has evolved in an adaptation to them in their normal or subnormal quantities.

Does it lie, in such terms of authority, with a local government to furnish a supply of synthetic water by approximating the ordinary or normal components? If its object was

1957 CanLII 15 (SCC)

1957
METROPOLITAN TORONTO v. VILLAGE OF FOREST HILL
Rand J.

to obtain the ordinary or natural composition of substances in solution so as to furnish what the body has become adapted to receive as water there would be grounds for justifying such a measure; and if it were a matter of choice between a natural supply containing normal quantities of fluorine and one lacking that element, I have no doubt the choice could not be challenged. These involve the matter of furnishing water for its accepted purposes only.

But it is not to promote the ordinary use of water as a physical requisite for the body that fluoridation is proposed. That process has a distinct and different purpose; it is not a means to an end of wholesome water for water's function but to an end of a special health purpose for which a water supply is made use of as a means.

The method proposed does not appear to be the only feasible mode of making available to the public what is considered by the municipality to be a desired health ministration. Fluoridation apparently can be provided otherwise than by making it general in the water supply. If that is so, there is here neither that accepted desirability for its use nor an unobjectionable manner of supplying it which in other situations might be influential considerations in the determination of the question raised.

I would, therefore, dismiss the appeal with costs.

LOCKE J. (*dissenting*):—The appellant is a body corporate constituted by c. 73 of the statutes of Ontario, 1953. The expression "Metropolitan Corporation" is defined by the Act to mean the Municipality of Metropolitan Toronto and, by s. 3, it is provided that the powers of the corporation shall be exercised by its council and, except where otherwise provided, its jurisdiction confined to the metropolitan area. The area so defined includes the municipality of the Village of Forest Hill, which is one of the area municipalities referred to throughout the Act.

Of the various powers and duties vested in and imposed upon the appellant, this matter concerns only those dealt with in Part III of the statute under the subheading "Metropolitan Waterworks System".

Section 36 declares that, for the purpose of supplying to the area municipalities water for their use, the metropolitan corporation shall have all the powers conferred by

1957 CanLII 15 (SCC)

any general Act upon a municipal corporation and by any special Act upon an area municipality or local board thereof respecting, *inter alia,* the establishment, maintenance and operation of a waterworks system.

Section 37(1) reads:

> The Metropolitan Council shall before the 1st day of December, 1953, pass by-laws which shall be effective on the 1st day of January, 1954, assuming as part of the metropolitan waterworks system all works for the production, treatment and storage of water vested in each area municipality or any local board thereof and all trunk distribution mains connected therewith, and on the day any such by-law becomes effective the works and mains designated therein shall vest in the Metropolitan Corporation.

By s. 39 it is declared that where all the works of an area municipality for the production, treatment and storage of water are assumed by the metropolitan corporation, the area municipality shall not thereafter establish or operate any such works.

Section 41, so far as it is relevant to the present matter, reads:

> The Metropolitan Council may pass by-laws for regulating the time, manner, extent and nature of the supply of water from its waterworks system, and every other matter or thing related to or connected therewith which it may be necessary and proper to regulate in order to secure to the inhabitants of the Metropolitan Area a continued and abundant supply of pure and wholesome water . . .

By a written report dated May 2, 1955, the Works Committee of the appellant municipality, after an investigation, details of which were disclosed in it, recommended to the council that the Commissioner of Works be authorized to take the necessary steps to undertake the fluoridation of the metropolitan water supply. By a by-law enacted on July 14, 1955, the municipality directed the Commissioner of Works to take the necessary steps forthwith

> to undertake the treatment of the Metropolitan water supply by fluoridation and to obtain all approvals required by statute for the installation of the equipment necessary for such treatment.

Section 101 of *The Public Health Act,* R.S.O. 1950, c. 306, requires the council of any municipality contemplating, *inter alia,* any change in an existing waterworks system to submit the plans, specifications and an engineer's report of the water supply and the works to be undertaken, together with such other information as may be deemed necessary by the Department of Health, to that Depart-

1957 CanLII 15 (SCC)

1957
METROPOLITAN TORONTO
v.
VILLAGE OF FOREST HILL
Locke J.

ment, and declares that no such works shall be proceeded with until the source of supply and the proposed works have been approved by the Department.

The Commissioner of Works applied under the provisions of this section for approval of a change in the existing waterworks system of the metropolitan corporation to provide for the addition of one part per million of fluoride to the water supply. By a certificate dated July 11, 1955, signed by the Minister of Health, the Provincial Sanitary Engineer and the Deputy Minister of Health, it was certified that "the installation of equipment for fluoridation of the water supply" at the waterworks plants of the appellant and the source of water supply and the proposed works had been approved by the Department as required.

The respondent, by notice of motion given as permitted by s. 293 of *The Municipal Act*, R.S.O. 1950, c. 243, applied for an order to quash for illegality the by-law referred to "on the grounds, inter alia, that such by-law is ultra vires and beyond the competence of the said Council". While other grounds of attack were suggested, the only one argued has been that in passing the by-law the council exceeded its powers.

The application was dismissed by Mr. Justice F. G. MacKay (1). That learned judge was of the opinion that it was for the council acting in good faith to determine what treatment, if any, should be given to the water to most effectively carry out its statutory obligation. He was of the opinion that the arguments advanced as to the advisability of adding fluoride were irrelevant and should not be considered, except for the purpose of determining whether it had been shown that the council was not so acting. In his opinion, the evidence supported his view that good faith had been shown.

The unanimous judgment of the Court of Appeal, delivered by the Chief Justice of Ontario (2), reversed this order and directed that the by-law be quashed. In the reasons it is stated that it had been admitted in the Court of Appeal that the water, without the addition of fluoride, was pure and wholesome. Accepting the admission as establishing that fact, it was said that nothing in

(1) [1955] O.R. 889, [1955] 5 D.L.R. 621.

(2) [1956] O.R. 367, 2 D.L.R. (2d) 570.

1957 CanLII 15 (SCC)

The Municipality of Metropolitan Toronto Act, The Public Health Act, The Public Utilities Act, R.S.O. 1950, c. 320, or *The Municipal Act* conferred upon any of the area municipalities power to add some chemical to a pure and wholesome water supply and that the question to be decided was as to whether the respondent had power to do so "for a medicinal purpose". With great respect, I disagree and think the judgment appealed from is based upon a false premise.

In deciding the question whether the by-law was *intra vires* of the council, it was, of course, necessary to determine the exact nature of the action which the by-law assumed to authorize. The uncontradicted evidence is that "a physically or chemically pure water does not occur in nature and has defied all efforts to obtain it". This is the opinion of Joslyn Rogers, a chemical engineer of long experience whose affidavit was filed on the application. Mr. Rogers further said that it cannot be produced artificially, except in small quantities and with considerable difficulty. The admission that the water was pure—if intended as an admission of fact—was, therefore, inaccurate. If intended as meaning that it was "pure" within the meaning of the appellant's Act of incorporation, that was a question of law for the decision of the Court and not to be decided upon the admission of counsel. It should be said that no such admission was made in this Court.

In the extracts from the work of E. V. Suckling, M.B., to whose opinions in this respect Joslyn Rogers subscribes, it is said that wholesomeness is purely a medical question while purity must be physical and chemical. Apart from such evidence, the accuracy of the statement seems obvious. In view of the evidence to the contrary, I would decline in a matter of such moment to act on an admission of counsel in the Court of Appeal that the water supply was, without any addition, either pure or wholesome. That question, which, in my view, is only relevant to the issue as to whether the members of the council have acted in good faith in the exercise of their statutory duties, is to be decided on the evidence adduced upon the application.

1957 CanLII 15 (SCC)

1957
METROPOLITAN TORONTO v. VILLAGE OF FOREST HILL
Locke J.

The only evidence on the question is that of Dr. A. L. Chute, the Pediatrician-in-chief of the Hospital for Sick Children in Toronto and Professor of Pediatrics at the University of Toronto. His affidavit states that tooth decay, by affecting the majority of people in a community, has come to be recognized by the medical and dental professions as one of the major health problems of our time. After saying that studies covering a period of over 30 years under a wide variety of controlled conditions had established the effects of the consumption by human beings of fluoridated water, the affidavit reads:

> 6. I am convinced from a thorough perusal of these studies that the addition of fluoride in the proportion of one part per million to a public water supply which is deficient in that constituent is a safe measure and is free from any systemic ill-effects. Such treatment renders the water more wholesome as it is effective in reducing tooth decay to the extent of approximately 60% where consumption of such water begins at an early age and continues during childhood and adolescence. The benefits extend into adult life.
>
> 7. In my opinion fluoridation is a most valuable measure in preserving the teeth and as a result a valuable measure in maintaining health.

As an exhibit to this affidavit, there is a list of some 65 municipalities in Ontario where natural fluorides are contained in the water supply in concentrations varying from .01 to 2.5 parts per million.

The requirement that the water supply shall be "pure and wholesome" would appear to have originated in the early English statutes. Thus, by s. 35 of the *Waterworks Clauses Act*, 1847, 10 Vict., c. 17, the undertakers operating waterworks are required to provide "a Supply of pure and wholesome Water, sufficient for the domestic Use of all the Inhabitants of the Town or District within the Limits of the special Act". Apparently in recognition of the fact that, as stated in the evidence in this matter, chemically pure water does not occur in nature and cannot be produced artificially except in small quantities and with difficulty, the *Public Health Act, 1936,* 26 Geo.V and I Edw. VIII, c. 49, by s. 111, imposes on the local authority the duty to provide "a sufficient supply of wholesome water for domestic purposes".

The word "wholesome" is used in more than one sense. One of the definitions in the Oxford Dictionary reads:

> Promoting or conducive to health; favourable to or good for health; health-preserving . . .

1957 CanLII 15 (SCC)

The definitions in Webster's New International Dictionary include the following:

> Promoting physical well-being; beneficial to the health or the preservation of health; . . . healthful . . .

The material does not assume to say what are the causes of tooth decay. The evidence, however, shows that the use of fluoridated water does materially reduce tooth decay where consumption begins at an early age, that these benefits extend into adult life and that it is a valuable measure for maintaining health. As the article from Suckling's work shows, water is treated with chlorine, lime and other chemicals or substances for the purpose of rendering it sterile and I would draw the inference from the statements made that doing so renders it less likely to cause typhoid fever or other water-borne diseases.

With respect for differing opinions, I consider that the appellant in discharging its duty to supply water that is wholesome may treat the water with chlorine, lime or other substances to render it sterile and less likely to cause typhoid, or with fluoride to render it less likely to be injurious to the health by contributing to tooth decay.

It is, in my opinion, a necessary inference from the evidence that the water supply in the metropolitan district of Toronto, whatever it may be, is in its natural state lacking in the element fluoride and thus less wholesome than it would be if that were added, to the extent mentioned. If the supply in its natural state contained fluoride to the extent of 2.5 parts to a million, as does the water obtained from the Boone River by the municipality of Essex, and if, in the opinion of the council acting in good faith, it was considered advisable to reduce the fluoride content to one part in a million, I think it would be within the power of the municipality to do so. Indeed, I find it hard to understand why it can be fairly contended that this would be beyond the municipal powers any more than to add chlorine to render the water more wholesome by rendering sterile and harmless some existing constituent in it. If the argument which succeeded in the Court of Appeal is carried to its logical conclusion, it would be *ultra vires* of the appellant to use water of the character used by the municipality of Essex

1957 CanLII 15 (SCC)

1957
METROPOLITAN TORONTO v. VILLAGE OF FOREST HILL
Locke J.

or the 64 other municipalities referred to by Dr. Chute since such waters, in their natural state, contain fluoride in varying proportions.

In my opinion, nothing more is required to sustain the present by-law than the clear provisions of s. 41 of the appellant's Act of incorporation. It is, of course, not suggested that the council has not acted in good faith in attempting to discharge the duties imposed upon it by that section and it is not disputed that the introduction of fluoride, to the extent proposed, will render the water supply more wholesome, assigning to that word the meaning above quoted. The Legislature has deputed the responsibility of determining what steps should be taken to obtain a pure and wholesome water supply to the metropolitan council and not to the Courts.

I would allow this appeal with costs and restore the order of Mr. Justice MacKay.

CARTWRIGHT J.:—I am in general agreement with the reasons of my brother Rand and those of the learned Chief Justice of Ontario, and will add only a few words.

The question is as to the power of the council to enact the impugned by-law, and the answer depends upon the nature of the subject-matter to which it relates. If, on the evidence in the record, it could properly be regarded as action by the council to provide a supply of pure and wholesome water or to render more pure and wholesome a supply of water already possessing those characteristics I would hold it to be valid. But, in my opinion, it cannot be so regarded. Its purpose and effect are to cause the inhabitants of the metropolitan area, whether or not they wish to do so, to ingest daily small quantities of fluoride, in the expectation which appears to be supported by the evidence that this will render great numbers of them less susceptible to tooth decay. The water supply is made use of as a convenient means of effecting this purpose. In pith and substance the by-law relates not to the provision of a water supply but to the compulsory preventive medication of the inhabitants of the area. In my opinion the words of the statutory provisions on which the appellant relies do not confer upon the council the power to make by-laws in relation to matters of this sort.

1957 CanLII 15 (SCC)

In view of the difference of opinion in the Courts below and in this Court, it is fortunate that this is a case in which if we have failed to discern the true intention of the Legislature the matter can be dealt with by an amendment of the statute.

I would dismiss the appeal with costs.

ABBOTT J.:—For the reasons given by brothers Rand and Cartwright, with which I am in agreement, the appeal should be dismissed with costs.

Appeal dismissed with costs, KERWIN C.J. *and* LOCKE J. *dissenting.*

Solicitor for the appellant: C. Frank Moore, Toronto.

Solicitor for the respondent: J. Ragnar Johnson, Toronto.

1957 CanLII 15 (SCC)

*PRESENT: Kerwin C.J. and Taschereau, Rand, Locke and Cartwright JJ.

From:	Gerald Steel
To:	Phillips, Theresa (DOH)
Cc:	Audrey Adams; Bill Osmunson; Scott Shock
Subject:	WAC 246-290-460 Rulemaking - SBOH Lacks Authority to Set Fluoridation Levels and Range
Date:	Tuesday, February 23, 2016 10:45:45 AM
Attachments:	Metropolitan Toronto v. Forest Hill (Village) [1957] S.C.R. 569.pdf Letter from U.S. EPA to Gerald Steel 10-10-12.pdf 2008 NSF-Fact-Sheet_on Fluoridation.pdf

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I submit this comment on proposed WAC 246-290-460 on behalf of myself and King County Citizens Against Fluoridation.

Proposed WAC 246-290-460(2), (3), and (4) are beyond the authority of the SBOH. This proposed regulation is adopted under the authority of RCW 43.20.050(2). This gives the SBOH authority to "Adopt rules . . . necessary to assure safe . . . drinking water." Other SBOH authorities are not relevant. As pointed out by the Supreme Court of Canada in 1957, authority to ensure pure and wholesome [i.e. safe] drinking water does not extend to authority to regulate the water supply for fluoridation, a special health purpose for which the water supply is made use of as a means of delivery. (Metropolitan Toronto v. Forest Hill (Village) [1957] S.C.R. 569 (attached).)

"It is not to promote the ordinary use of water as a physical requisite for the body that fluoridation is proposed. That [fluoridation] process has a distinct and different purpose; it is not a means to an end of wholesome water for water's function but to an end of a special health purpose for which a water supply is made use of as a means." (Metropolitan Toronto at 574.)

Further, according to U.S. EPA, "neither WAC 246-290-220(3) nor WAC 246-290-460 are related to the requirements of the Federal Safe Drinking Water Act in Washington State." (Letter from U.S. EPA to Gerald Steel 10-10-12 (attached).)

There can be no doubt that the purpose of fluoridation, [i.e. the addition of a fluoride chemical to public water supplies] is for preventing tooth decay (caries, cavities) which is a human disease. (2008 NSF Fact Sheet on Fluoridation Chemicals (attached); 76 FR 2383 at 2385.) Under Washington State Law, both the fluoride chemical and the fluoridated water are drugs when the intended use of the chemical and water is to prevent tooth decay disease.

"The term 'drug' means (1) articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of human beings or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories." (RCW 69.04.009 - similar in RCW 18.64.011(12) and 69.41.010(9).)

Some of the intrastate regulations that apply to drugs are provided in RCW 69.04.410 to - .660. The State Pharmacy Quality Assurance Commission (Commission) is given specific authority in this state to regulate delivery of drugs. The Commission's specific authority over delivery of drugs, overrides the SBOH general authority to keep water safe when it comes to adding fluoride to public water supplies and making fluoridated drinking water itself a drug under state definitions.

"The authority to promulgate regulations for the efficient enforcement of this chapter is hereby vested in the director: PROVIDED, HOWEVER, That the director shall designate the pharmacy quality assurance commission to carry out all the provisions of this chapter pertaining to drugs and cosmetics, with authority to promulgate regulations for the efficient enforcement thereof." (RCW 69.04.730.)

The State Pharmacy Quality Assurance Commission is given independent authority to establish "rules for the . . . distribution, wholesaling, and manufacturing of drugs . . . for the protection and promotion of the public health, safety, and welfare." (RCW 18.64.005(7)) For purposes of this authority:

"'Drugs' means:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;

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

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

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories." (RCW 18.64.011(12) (emphasis supplied).)

Therefore under the RCW's, specific authority is given to the State Pharmacy Quality Assurance Commission to regulate distribution, wholesaling, and manufacturing of fluoridation chemicals and fluoridated waters when those substances are intended for use in the prevention of tooth decay disease in human beings. Because that is the intent of the fluoridation chemicals and fluoridated waters, it is the State Pharmacy Quality Assurance Commission and not the SBOH who has the intrastate authority to regulate fluoridation. In its role in providing safe drinking water, the SBOH may be able to set a maximum concentration of fluoride in public drinking water of 0.7 or 0.5 or 0.3 ppm if fluoride is added, based solely on SBOH analysis of the safety of these concentrations and ignoring any perceived drug benefit of this fluoride. This is likely consistent with SBOH authority under RCW 43.20.050(2) to assure safe drinking water. If the SBOH sets a maximum

fluoride concentration when there is added fluoride based on making public drinking water safe, then it would likely be consistent with its authority to require reporting and testing in proposed WAC 246-290-460 to enforce its new safety standard.

The SBOH may have been misinformed regarding the 5 to 4 Supreme Court case in Kaul v. City of Chehalis, 45 Wn.2d 616, 277 P.2d 352 (1954) where an assignment of error before the Court was whether, under state law, the City was selling drugs. (Kaul at 625.) The Court said this assignment of error along with others was "not well taken" but did not elaborate. (Id.) A review of all of the briefing before the Court (which is available in the archives in the Supreme Court library) shows that while Kaul included this issue in his assignment of errors, he failed to brief this issue. An issue that is not briefed is considered abandoned. For this reason, the Kaul Court did not rule on the merits as to whether Chehalis fluoridated water was a drug subject to state drug laws.

Therefore, the only issue that can be addressed by the SBOH in WAC 246-290-460 is safety of Group A public water supplies. In addressing this issue, the SBOH can establish a maximum fluoride concentration of 0.7 mg/L but does not have authority to set an "optimal" concentration. Clearly, from a water safety point of view the "optimal" concentration for water safety is 0.0 mg/L. It is established that fluoride is not an essential mineral. An essential mineral is a mineral that is necessary for the body or disease will result. People do not get disease when fluoride is eliminated from their diet. Other methods are available to prevent tooth decay disease without ingesting fluoride. The SBOH is acting beyond its authority when it promotes ingestion of fluoride for the intended use of preventing tooth decay disease.

Therefore, the use of the word "optimal" in proposed WAC 246-290-460, subsections (2) and (3) is beyond the SBOH authority and it should be replaced by the word "maximum." Consistent with this concept, the upper end of the range reported in WAC 246-290-460(4) must be 0.7 mg/L. The value of 0.7 mg/L can be based on the maximum level of fluoride for drinking water recommended by the Secretary of HHS published April 2015.

The language in proposed WAC 246-290-460(4) should be modified so that the purveyor takes corrective action when fluoride levels exceed 0.7 mg/l. The SBOH has no authority to set any bottom for an operating range in proposed said subsection (4). It is clear that from a water safety point of view, less fluoride is more safe than more fluoride. Fluoride is well recognized as a contaminant to drinking water. Therefore, under its authority for water safety, the SBOH may set a maximum fluoride level for purveyors adding fluoride to drinking water but it may not set a minimum addition of fluoride using its water safety authority. Therefore proposed WAC 246-290-460(4) must be modified to establish a maximum fluoride content of 0.7 ppm if fluoride is added and to

avoid setting a minimum fluoride content if fluoride is added. The minimum level of fluoride added is solely a decision for the water purveyor and not within the authority of the SBOH.

In separate comments we will address some of the evidence that fluoridated water is not safe at 0.7 ppm. Thank you for your attention to this comment.

Gerald Steel
Attorney at Law
7303 Young Rd. NW
Olympia WA 98502
Tel/Fax (360) 867-1166

Washington Dental Service Foundation

Community Advocates for Oral Health

February 23rd, 2015
Office of Drinking Water
243 Israel Road SE,
Tumwater, WA 98501

Dear Esteemed Members of the Washington State Board of Health,

Thank you for the opportunity to provide comments on proposed changes to WAC 246-290-460, the Water Fluoridation Rule. Community Water Fluoridation has been thoroughly researched and in practice for over 70 years. It is proven to safely reduce cavities for entire communities when provided as recommended by the Department of Health and Human Services (HHS).

Washington Dental Service Foundation (WDS Foundation), a non-profit funded by Delta Dental of Washington, is committed to lasting approaches to improving the oral, and overall health, of people in Washington. With an emphasis on prevention, WDS Foundation works closely with partners to develop and implement long-lasting, innovative programs and public policies. We prioritize educating the public and policy makers on the importance of oral health and how to prevent oral disease

As part of our mission, we support the efforts of the Washington State Board of Health and Office of Drinking Water to ensure that water systems comply with the national standard for Community Water Fluoridation of 0.7 mg/L. Additionally, we agree the provided operational tolerance of 0.5 mg/L to 0.9 mg/L will be sufficient to ensure such a standard is reached; however, with one significant caveat.

In light of modern technological advancements, the availability of skilled labor and advanced training for water operators, it is well within the realm of possibility that a water purveyor could provide fluoridation consistently at 0.6 mg/L and still be within the stated operational tolerance of 0.5 mg/L to 0.9 mg/L as allowed. Hypothetically, by providing fluoridation in a range of 0.5 mg/L to 0.7 mg/L, a system could consistently provide a sub-optimal 0.6 mg/L average fluoride concentration under this rule, despite the recommendation to operate at the standard optimal average of 0.7 mg/L.

We request you provide clear guidance to ensure systems that choose to fluoridate are meeting the HHS standard. With WAC 246-290-460, a community that has decided to fluoridate should be assured they receive the full benefits in reductions of tooth decay. One way to do this would be to clarify that an average of 0.7 mg/L of average monthly fluoridation concentrations be met over the course of reasonable time period or provide a narrow range in which such an average may fall over time. We respectfully request the rule ensure that systems regularly operating at 0.6 mg/L or lower, although technically feasible within the stated operational tolerance, would be considered “out of compliance” or “sub-optimally fluoridated”, and be encouraged and educated to reach an optimal concentration of 0.7 mg/L.

P.O. Box 75983, Seattle, WA 98175-0983 • 9706 4th Ave NE, Seattle, WA 98115
DeltaDentalWA.com

Finally, we agree that notice be given to the Washington Department of Health should a system decide to remove fluoridation. Ideally, this would be done within 90 days prior to such a decision or at minimum, 90 days prior to the removal of community water fluoridation. This would allow more time for the Washington Department of Health to inform local medical and dental practitioners and the public that they will be at higher risk for cavities.

Ensuring that the people in communities that fluoride are provided with optimal fluoridation and fully informed of any changes to that benefit should remain a priority for the Washington State Board of Health.

Thank you for your consideration of these comments.

Sincerely,

Diane Oakes
President and CEO
Washington Dental Service Foundation

From:	Emily Firman
To:	Phillips, Theresa (DOH)
Cc:	Alison Mondi; Chad Lennox; Diane Oakes
Subject:	WDSF Testimony - WAC 246-290-460
Date:	Tuesday, February 23, 2016 8:36:22 PM
Attachments:	image001.jpg BOH Letter (003).pdf

Theresa,

Attached you will find testimony from the Washington Dental Service Foundation regarding suggested rule changes to
WAC 246-290-460. This letter is in addition to the partner letter signed onto along with multiple organizations supporting the Boards position of adopting the national Department of Health and Human Services standard for fluoridation.

Thank you for your thoughtful consideration of our recommendations and dedication to the health and safety of Washington residents.

Sincerely,

Emily Firman

Emily Firman, MPH, LICSW
Senior Program Officer | **Washington Dental Service Foundation**
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Mighty Mouth Logo

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Communities Support the National Standard for Community Water Fluoridation

February 23, 2016

Dear Esteemed Members of the Washington State Board of Health,

We strongly support adjusting WAC 246–290–460 to follow the recommendations of the U.S. Department of Health and Human Services to support community water fluoridation for the prevention of tooth decay. Community water fluoridation remains one of the most effective, inexpensive and safe ways to prevent tooth decay and improve public health. For these reasons, we hope that the final rule will ensure transparency for communities and healthcare providers in the event of changes in local water fluoridation policy.

People of all ages suffer when they experience dental disease. Water fluoridation has been proven to benefit people of all ages and income levels by helping to reduce cavities by at least 25 percent over a person's lifetime – saving money, eliminating pain and preventing dental disease complications. This is especially important because access to affordable dental care continues to be one of the greatest unmet health needs in our state.[1] Though fluoridation cannot substitute for preventive care, adults living in communities that fluoridate are less likely to have oral disease and more likely to keep all of their teeth.[2]

For 70 years community water fluoridation has helped prevent tooth decay. In Washington State, the first water system began to provide fluoride to community drinking water 60 years ago. Every Surgeon General over the past 50 years has recommended fluoridation and it is also endorsed by the American Dental Association, American Medical Association, American Academy of Pediatrics, and the Centers for Disease Control and Prevention. It is the most highly recommended and proven foundation for good oral health.

Thank you for your focus on improving oral health for Washington residents. We encourage the Board of Health to adopt the optimal standard of 0.7 mg/L as recommended by the U.S. Department of Health and Human Services for the prevention of tooth decay.

Sincerely,
(list on following page)

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[1] Washington State Hospital Emergency Room Use Report: http://www.wsha.org/files/127/ERreport.pdf; Veteran's Resource Committee Strategic Plan: http://www.co.clark.wa.us/veterans/Documents/2012VRCStrategicPlanFinal.pdf; Snohomish County Low-income Needs Assessment; http://www.co.snohomish.wa.us/documents/Departments/Human_Services/Community/2010_Snohomish_County_LowIncome_Needs_Assessment_Report-Final.pdf

[2] Fluoridated Water Helps Older Adults Keep Teeth, Study Says. http://www.nytimes.com/2015/03/31/health/fluoridated-water-helps-older-adults-keep-teeth-study-says.html?_r=0

Children's Alliance

Foundation for Healthy Generations

Interfaith Community Health Center

Latino Community Fund of Washington State

Northwest Health Law Advocates

Northwest Kidney Centers

Progreso: Latino Progress

Peninsula Community Health Services

Public Health Roundtable

Seattle Children's

Washington Association of Community & Migrant Health Centers

Washington Dental Service Foundation

Washington Healthcare Access Alliance

Washington State Dental Association

Washington State Dental Hygienists' Association

Washington State Hospital Association

Washington State Medical Association

Washington State Public Health Association

Whatcom Alliance for Health Advancement

From:	Alison Mondi
To:	Phillips, Theresa (DOH)
Cc:	Chad Lennox; Emily Firman
Subject:	Written comments re: WAC 246–290–460
Date:	Tuesday, February 23, 2016 8:22:14 PM
Attachments:	Community letter in support of national standard for community water fluoridation 2.23.16.pdf

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Theresa:

Attached please find a letter signed by statewide and community health organizations in support of the national standard for community water fluoridation. Please let me know if you have any questions; additionally, I would be happy to connect you with any of the organizational signers for further information.

Thank you for your and the State Board of Health's work on this important public health issue,

Alison Mondi
Policy Advocate & Analyst | **Washington Dental Service Foundation**
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