

**Stop fluoridation until proponents provide  
FDA CDER approval fluoridation  
is safe and effective.**

- **JURISDICTION OVERSIGHT – FDA CDER**
- **BENEFIT – No:** 6 decades of FI in Milwaukee & 2X state caries rate  
(20% vs 37.5% 3<sup>rd</sup> graders <http://www.chawisconsin.org/documents/MMSexecsum12.11.pdf>)
- **RISKS – Yes:** brains, bones, teeth, etc.
- **EXPOSURE – Too Much:** water, foods, pesticides, dental  
& medical products, etc.

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[www.IAOMT.org](http://www.IAOMT.org) [www.fluoridealert.org](http://www.fluoridealert.org)  
[www.slweb.org](http://www.slweb.org) [www.washingtonsafewater.com](http://www.washingtonsafewater.com)*

# FLUORIDATION IS CONTROVERSIAL :

The science is incomplete and not quality.

- **A. Not one Study corrects for Unknown Confounding Factors**
- **B. Not one Prospective Randomized Controlled Trial**
- **C. Socioeconomic status usually not controlled**
- **D. Inadequate size**
- **E. Difficulty in diagnosing decay**
- **F. Delay in tooth eruption not controlled**
- **G. Diet: Vitamin D, calcium, strontium, sugar, fresh and frozen year around vegetables and fruit consumption not controlled.**
- **H. Total exposure of Fluoride not determined**
- **I. Oral hygiene not determined**
- **J. Not evaluating Life time benefit**
- **K. Estimating or assuming subject actually drinks the fluoridated water.**
- **L. Dental treatment expenses not considered**
- **M. Breast feeding and infant formula excluded**
- **N. Fraud, gross errors, and bias not corrected.**
- **O. Genetics not considered**

# FDA CDER HAS OVERSIGHT JURISDICTION

FDA CDER has the experts to evaluate the controversy.

CONGRESS DEFINES *DRUGS*:

***“Articles intended for use in the  
... prevention of disease ...”***

21 USC 321 (g)(1)(B)

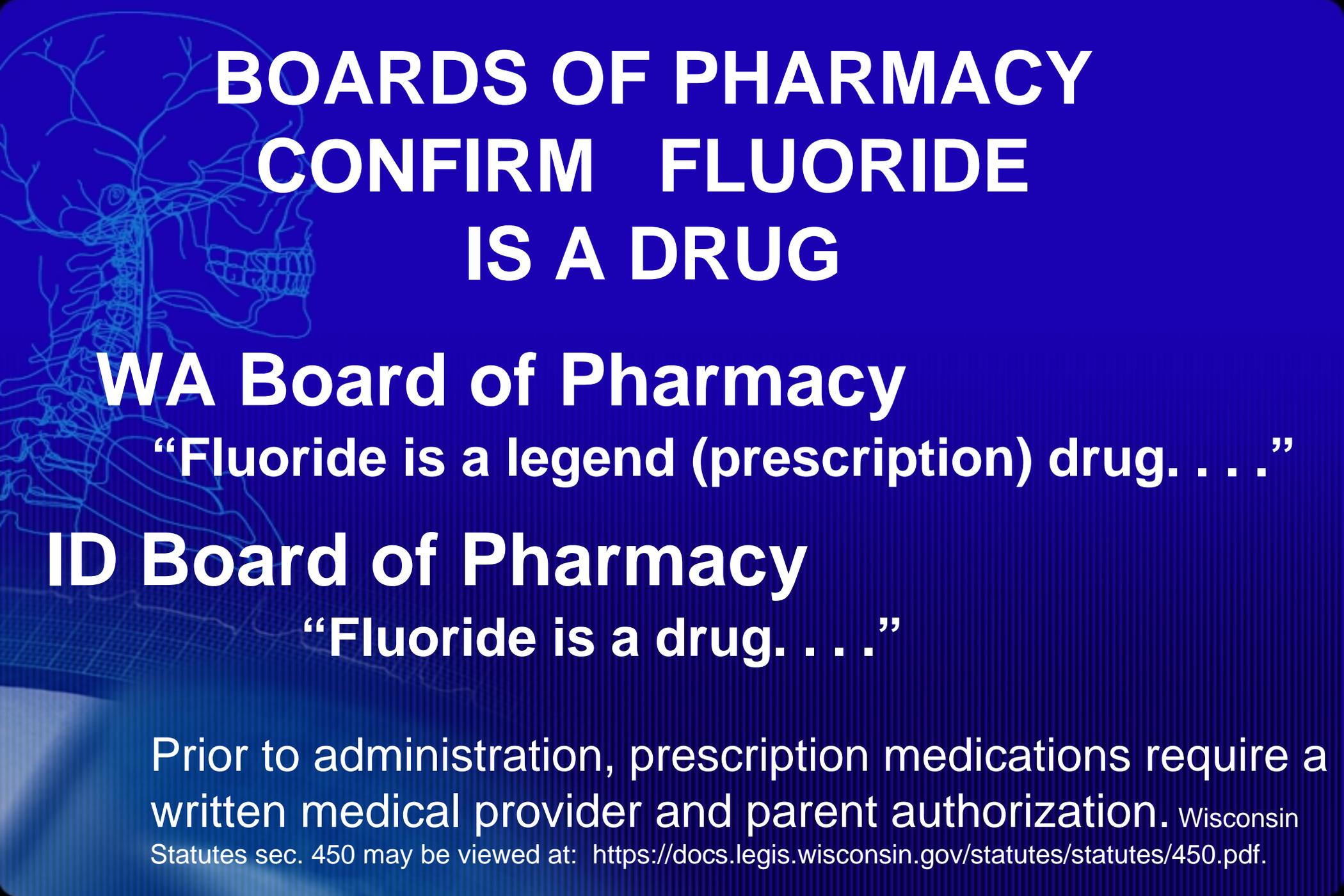
**Wisconsin Defines Drugs** sec. 450.01(1)(10)(a),(b),(c),(d).

“Any substance recognized in the official U.S. Pharmacopoeia”

“Any substance involved in the . . . treatment or prevention of disease or other conditions in people.”

**FDA testified to Congress that fluoride  
is a drug.**

Congressional Investigation 2001



# **BOARDS OF PHARMACY CONFIRM FLUORIDE IS A DRUG**

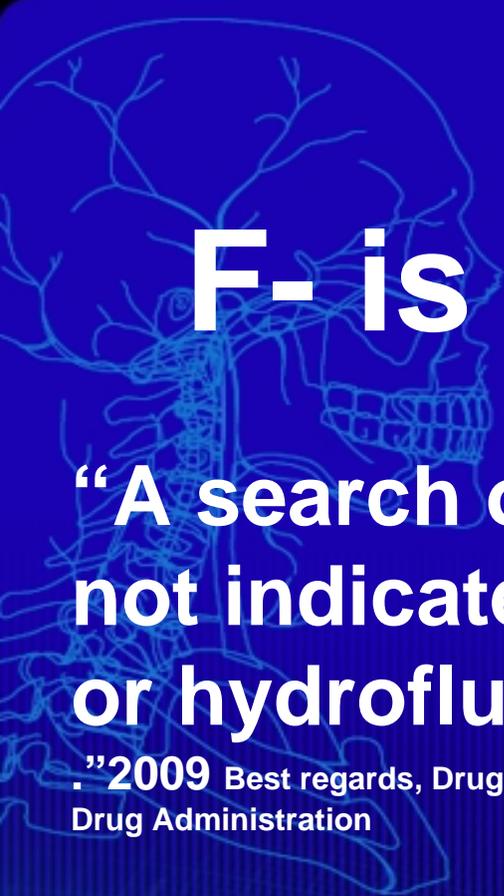
## **WA Board of Pharmacy**

**“Fluoride is a legend (prescription) drug. . . .”**

## **ID Board of Pharmacy**

**“Fluoride is a drug. . . .”**

Prior to administration, prescription medications require a written medical provider and parent authorization. Wisconsin Statutes sec. 450 may be viewed at: <https://docs.legis.wisconsin.gov/statutes/statutes/450.pdf>.



# FDA Confirms: F- is an Unapproved Drug

**“A search of the Drugs@FDA database . . . does not indicate that sodium fluoride, silicofluoride, or hydrofluorosilicic acid has been approved . . .**

**.”2009 Best regards, Drug Information SH, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration**

**FDA CDER ADVISES: “Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers’ health at risk.”**

<http://www.nabp.net/publications/assets/OR082008.pdf> Oregon Board of Pharmacy 8/08 Newsletter

**Although the 1955 court held that fluoridation is a public health measure** (*Froncek v. City of Milwaukee*),

**Since 1955 drug laws have become more precise.**

**1962 Kefauver-Harris Amendments to ensure efficacy and safety**

**1962 Consumer Bill of Rights (Pres. JF Kennedy) the right to safety, be informed, to chose and be heard.**

**1966 Fair Packaging and Honest Labeling**

**1974 Safe Drinking Water Act (EPA)**

**1981 Human Subjects Protection**

**1988 FDA Act**

**1988 Prescription Drug Marketing Act**

**1990 Safe Medical Devices Act**

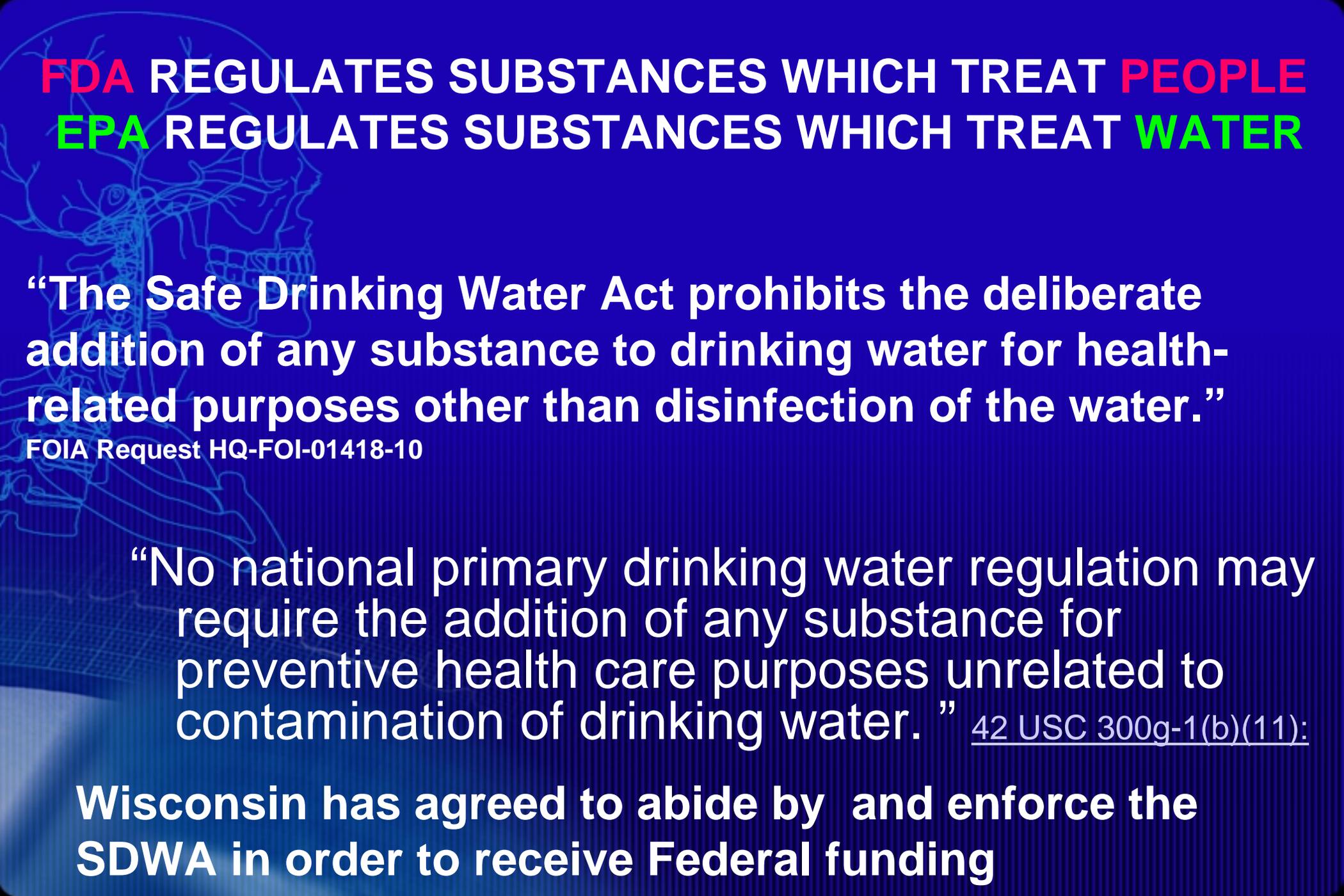
**1997 FDA Modernization Act**

**1997 “Protection of Children”( Executive Order 13045)**

**1998 Pediatric Rule**

**2002 The Best Pharmaceuticals for Children Act & Office of Combination Products**

**2005 Drug Safety Board**



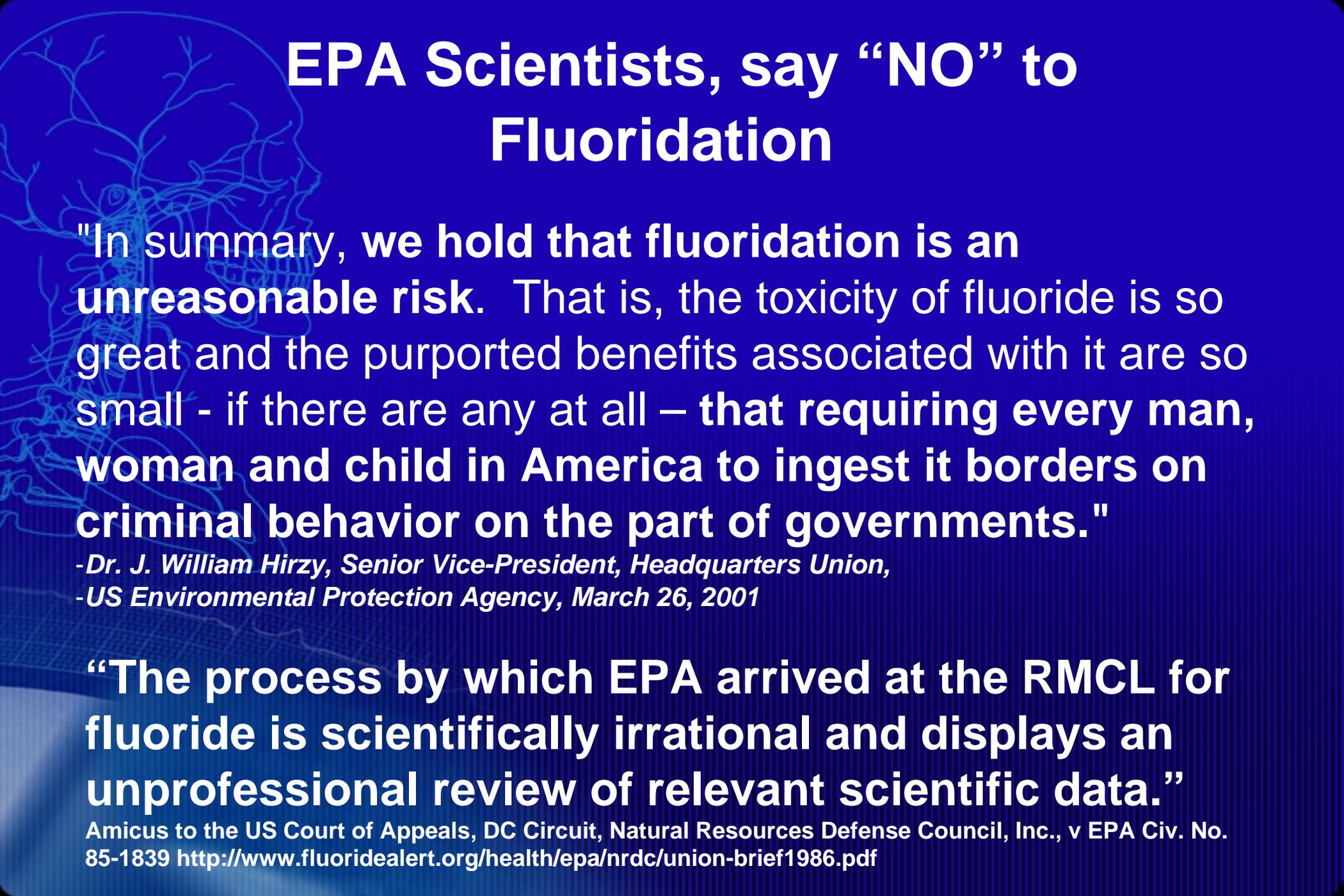
**FDA** REGULATES SUBSTANCES WHICH TREAT **PEOPLE**  
**EPA** REGULATES SUBSTANCES WHICH TREAT **WATER**

**“The Safe Drinking Water Act prohibits the deliberate addition of any substance to drinking water for health-related purposes other than disinfection of the water.”**

**FOIA Request HQ-FOI-01418-10**

**“No national primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water.”** 42 USC 300g-1(b)(11):

**Wisconsin has agreed to abide by and enforce the SDWA in order to receive Federal funding**



# EPA Scientists, say “NO” to Fluoridation

**"In summary, we hold that fluoridation is an unreasonable risk. That is, the toxicity of fluoride is so great and the purported benefits associated with it are so small - if there are any at all – that requiring every man, woman and child in America to ingest it borders on criminal behavior on the part of governments."**

*-Dr. J. William Hirzy, Senior Vice-President, Headquarters Union,  
-US Environmental Protection Agency, March 26, 2001*

**“The process by which EPA arrived at the RMCL for fluoride is scientifically irrational and displays an unprofessional review of relevant scientific data.”**

Amicus to the US Court of Appeals, DC Circuit, Natural Resources Defense Council, Inc., v EPA Civ. No. 85-1839 <http://www.fluoridealert.org/health/epa/nrdc/union-brief1986.pdf>

# **CDC: Ingestion of fluoride is not likely to reduce tooth decay**

CDC (1999). Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries. MMWR, 48(41); 933-940, October 22

**CDC: “It is not CDC’s task to determine what levels of fluoride in water are safe.”** <http://www.cdc.gov/fluoridation/safety.htm> 5/26/2012

## **MANY HAVE EXCESS FLUORIED IN SERUM**

**CDC: “Normal serum fluoride levels are <20 mcg/L (0.02 ppm) but varies substantially. . . .”** <http://www.bt.cdc.gov/agent/sulfurylfluoride/casedef.asp>

Taves ('66) normal <0.013 ppm

Sowers controls 0.05 ppm (4<sup>th</sup> quartile)

Sandhu controls 0.042 ppm and tumors at 0.072 ppm (Xiang 0.064 ppm)

Zang controls 0.04 ppm and 8 IQ loss 0.08 ppm

Rathe controls 0.025 ppm and stones at 0.12 ppm

Hossney (2003) Mother’s Milk most samples - none detected



# The American Dental Association Does Not have Jurisdiction

To the Superior Court of the State of California Case  
No. 718228, Demurrer (October 22, 1992) the ADA said,

**“The American Dental Association (ADA) owes no legal duty of care to protect the public from allegedly dangerous products . . . . Dissemination of information relating to the practice of dentistry does not create a duty of care to protect the public from potential injury.”**

A Pea Size of  
Tooth Paste has  
0.25 mg of F-  
The same as 1 glass  
of fluoridated water.



Use helps protect against cavities

**Warnings**  
Keep out of reach of children under 6 yrs. of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions** • adults and children 2 yrs. & older: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist • do not swallow

- to minimize swallowing use a pea-sized amount in children under 6
- supervise children's brushing until good habits are established

95161872

If someone wants to ingest more fluoride,  
swallow a baby pea size of toothpaste

of Centers reported 24,087 exposures  
 fluoride. [medicine](#)



# INFANT

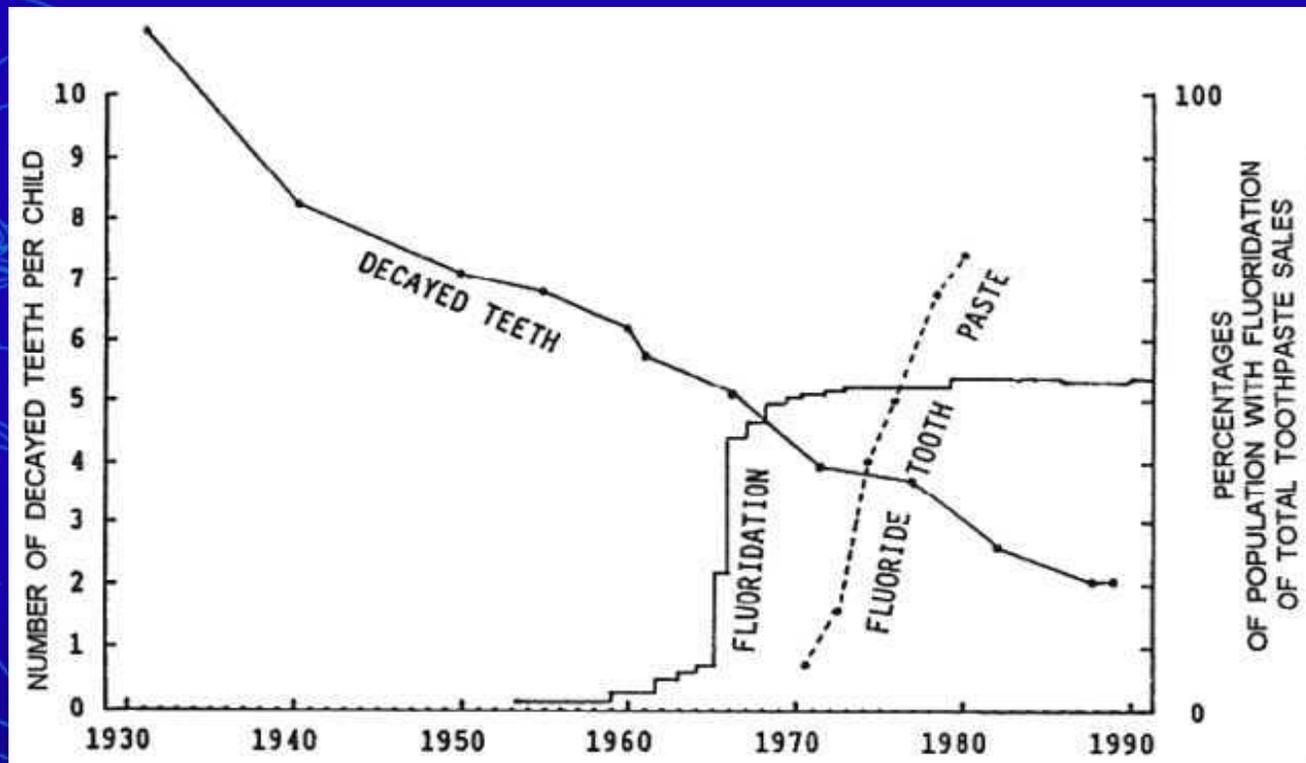
**Mother's Milk: most samples,  
fluoride is not detected**

**Mean 0.004 ppm F** NRC p. 33



**Early Childhood Caries (ECC), is not due to an inadequate ingestion of fluoride while these teeth were developing which occurs in utero &/or during the first few months of life. [ECC is generally caused by sleeping with a bottle of milk, juice or sugared pacifier. ]**

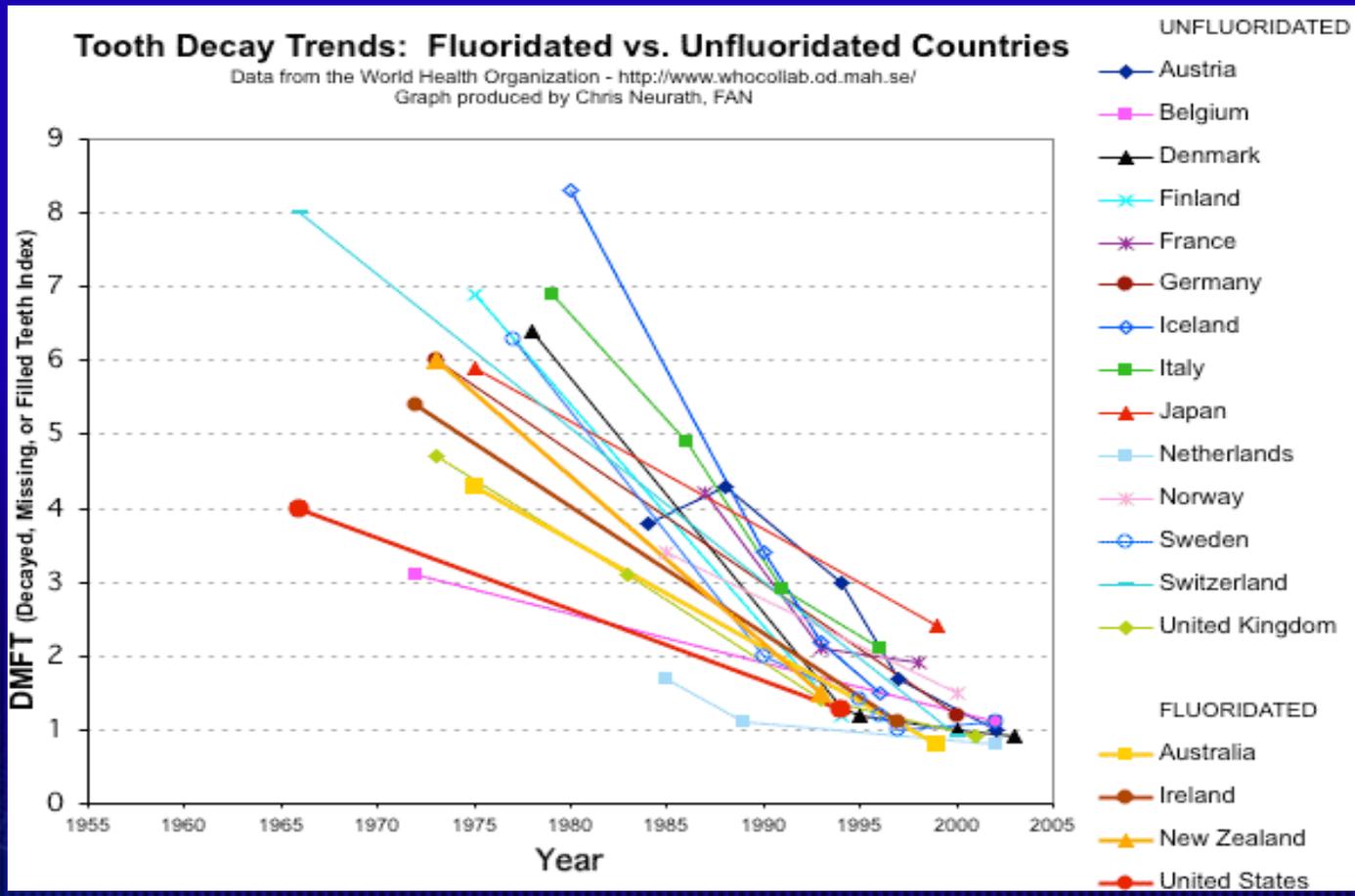
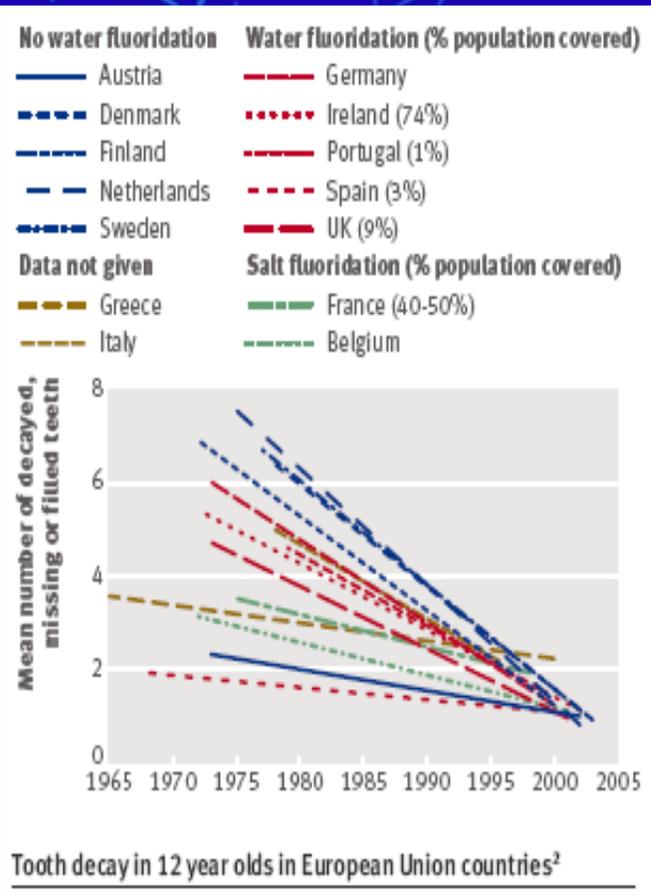




**Fluoridation did not prevent decay before fluoridation started.  
No research controls for unknowns reducing decay.**

**The FDA CDER has to date rejected fluoride new drug applications because of lack of evidence of efficacy**

# Tooth Decay has declined regardless of fluoridation or fluoride salt.



Chen et al, BMJ 5 October 2007

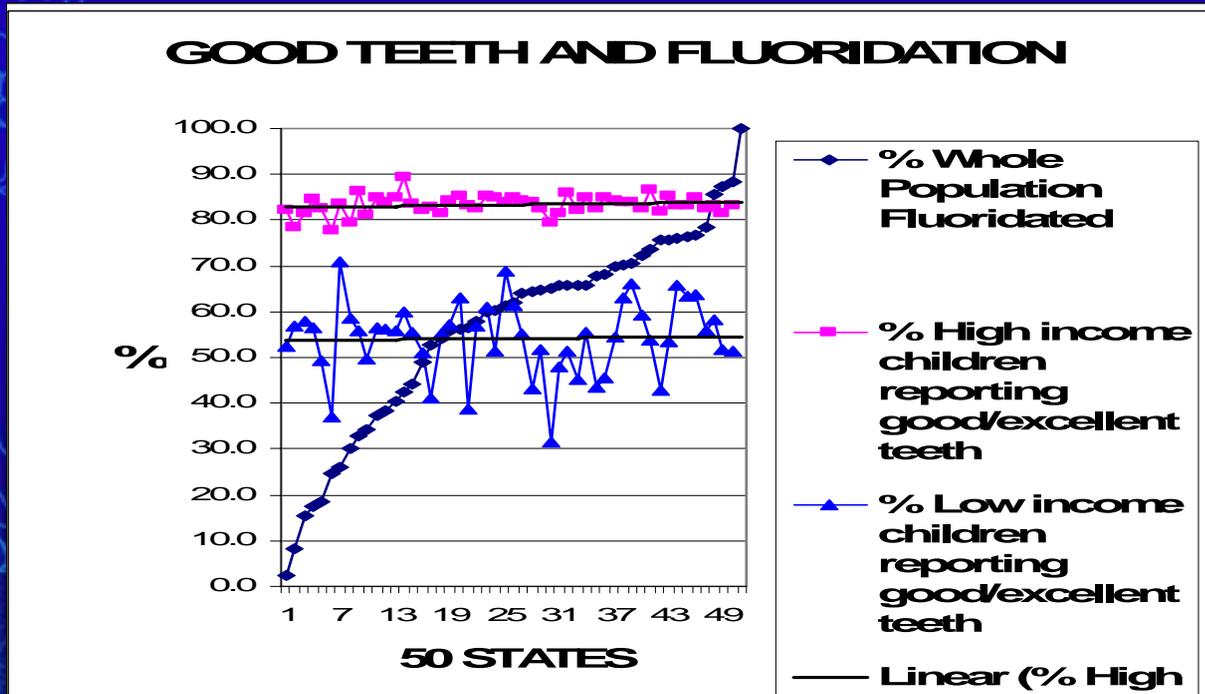
Neurath

## Fluoridated vs. Unfluoridated Countries.

**Tooth Decay Trends for 12 Year Olds:** Data from World Health Organization. (Graph by Chris Neurath).

<http://www.fluoridealert.org/health/teeth/caries/who-dmft.html>

# RANKING 50 STATES FLUORIDATION DOES NOT IMPROVE TEETH



For the Rich

Or the Poor

- Higher Income = Better Teeth
- No significant common cause

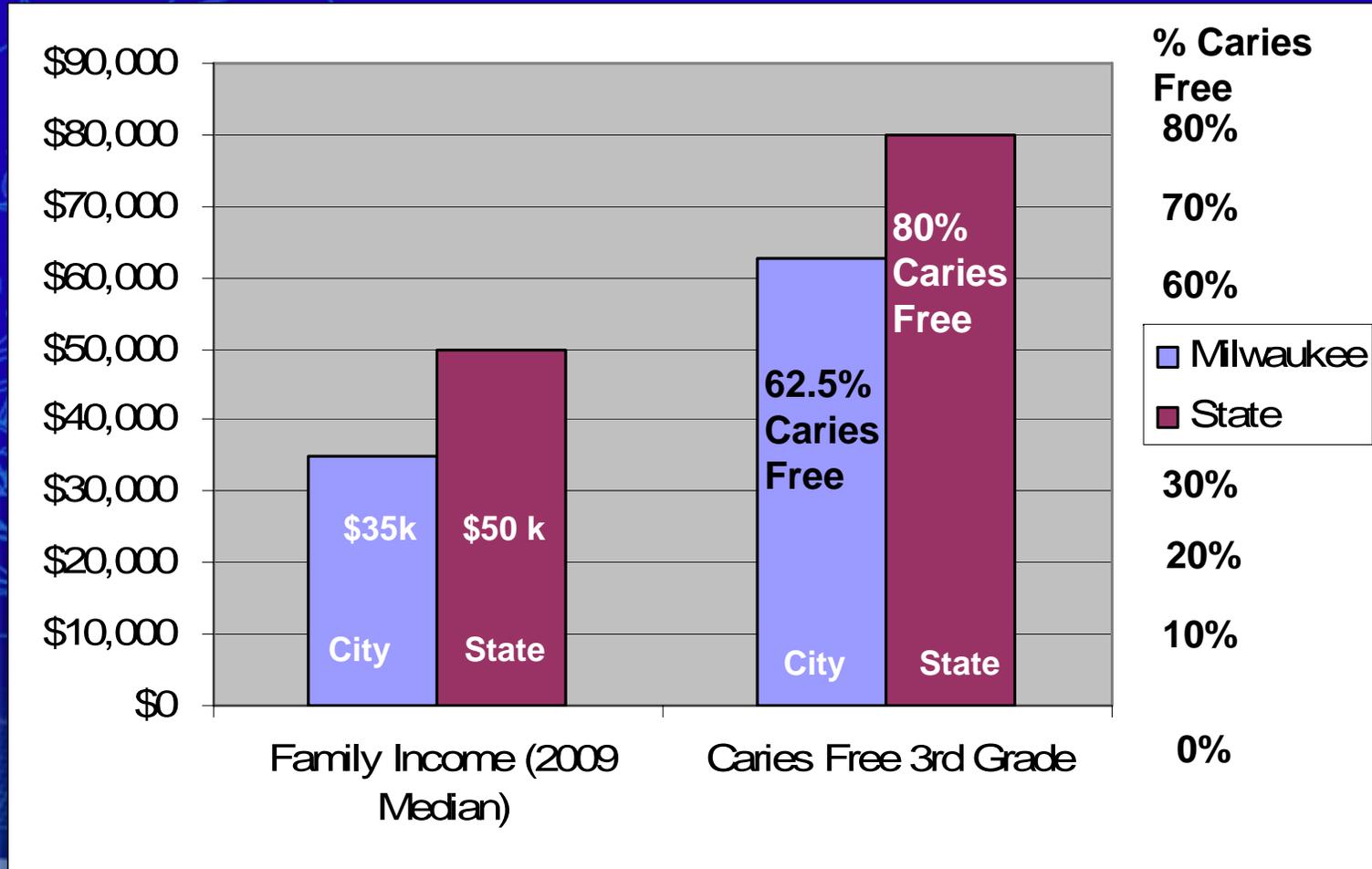
<http://mchb.hrsa.gov/oralhealth/portrait/1cct.htm> National Survey of Children's Health.

U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau.

The National Survey of Children's Health 2003. Rockville, Maryland: U.S. Department of Health and Human Services, 2005

[http://www.cdc.gov/oralhealth/waterfluoridation/fact\\_sheets/states\\_stats2002.htm](http://www.cdc.gov/oralhealth/waterfluoridation/fact_sheets/states_stats2002.htm) <http://pubs.usgs.gov/circ/2004/circ1268/htdocs/table05.html>

# Milwaukee City vs Wisconsin State



**6 DECADES OF  
FLUORIDATION**

[www.city-data.com](http://www.city-data.com)

**MAKING MILWAUKEE SMILE**

<http://www.chawisconsin.org/documents/MMSexecsum12.11.pdf>

# Fluoridation does NOT reduce dental expenses

Portland – **Not fluoridated** \$176/yr. dental expenses (children)

Van., WA - **Fluoridated** \$180/yr. dental expenses (children)

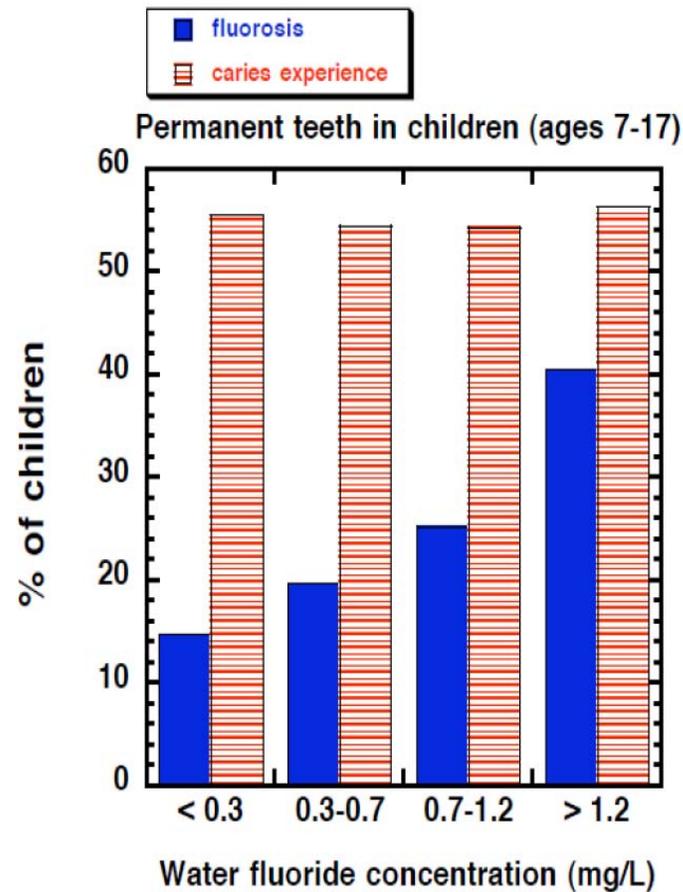
1995 Data, Published 2007 Maupome JPHD

**Claims of cost benefit are based on estimates of assumptions and two uncontrolled studies**

Locale	Estimated at member age	
	NF (\$)	CWF (\$)
Portland metro	n= 30,967	n= 3,185
	10 1,054	1,108
	39 1,224	1,300
Marion County	80 2,101	2,253
	n= 1,482	n= 3,763
	10 1,097	1,086
Clark County	39 1,236	1,200
	80 1,882	1,686
	n= 4,006	n= 4,404
	10 1,261	1,130
	39 1,408	1,287
	80 2,059	1,978

6 year dental expenses

lida, H., and Kumar, J.V. 2009. The association between enamel fluorosis and dental caries in U.S. schoolchildren. JADA 140:855-862.



**Blue lines indicate increasing dental fluorosis with increased fluoride intake. Red lines indicate similar dental decay regardless of fluoride water concentration.**

# Cosmetic treatment Cost \$16,000-\$24,000



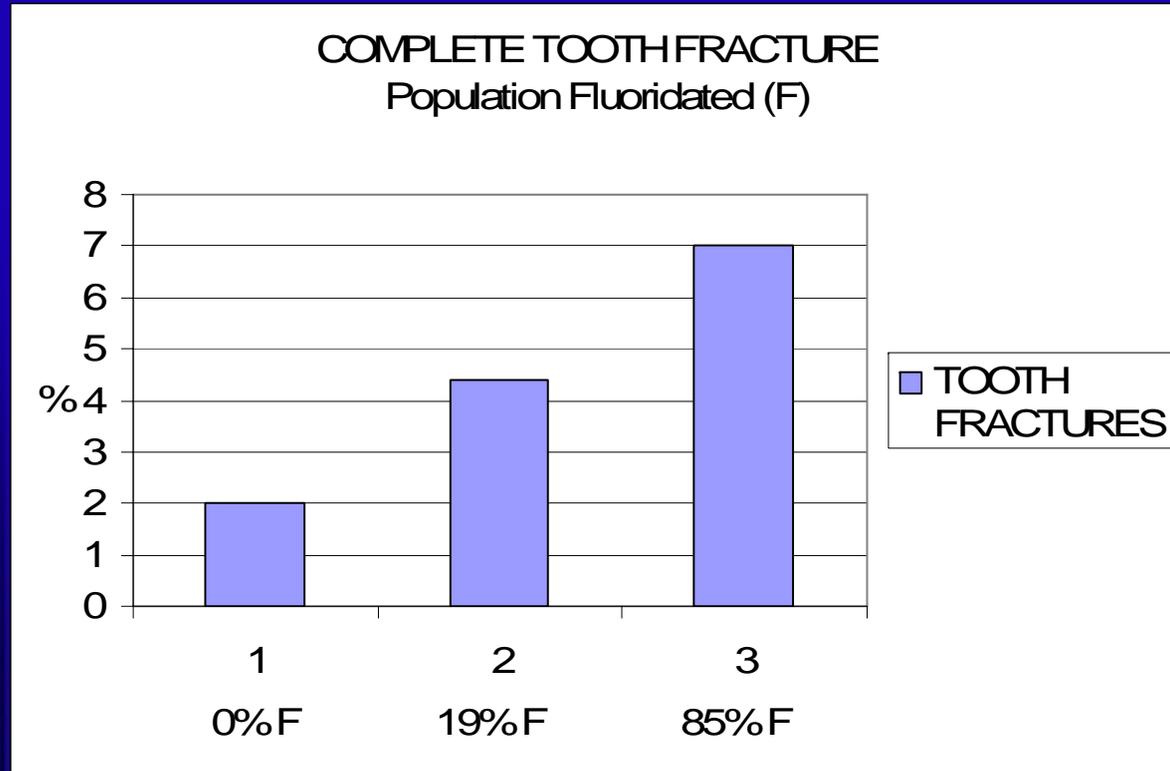
CDC reports 41% of kids have dental fluorosis.



**Well-documented  
Risk**

Photos Courtesy of Dr. Stephen J. Markus

# CUSP FRACTURES

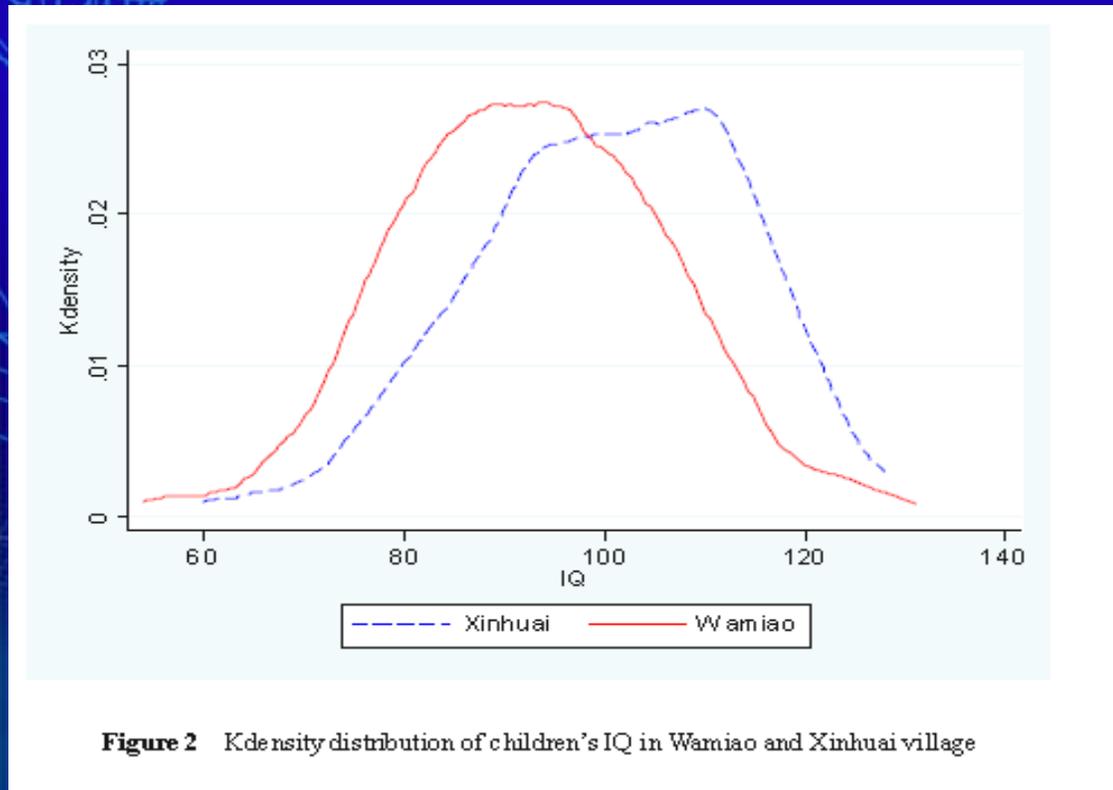


Geurtsen Quintessence 2003  
Patel Prim Dental Care 1995  
Bader Com Dent Oral Epi 1996 and 2001 and JADA 2004  
Vieira Eur J Oral Sci 2006  
Fennis Int J Prosth 2002  
Osmunson Fluoride 2007

8 IQ point drop comparing 0.04 ppm to 0.08 ppm fluoride serum concentration

CDC advises normal < 0.02 ppm

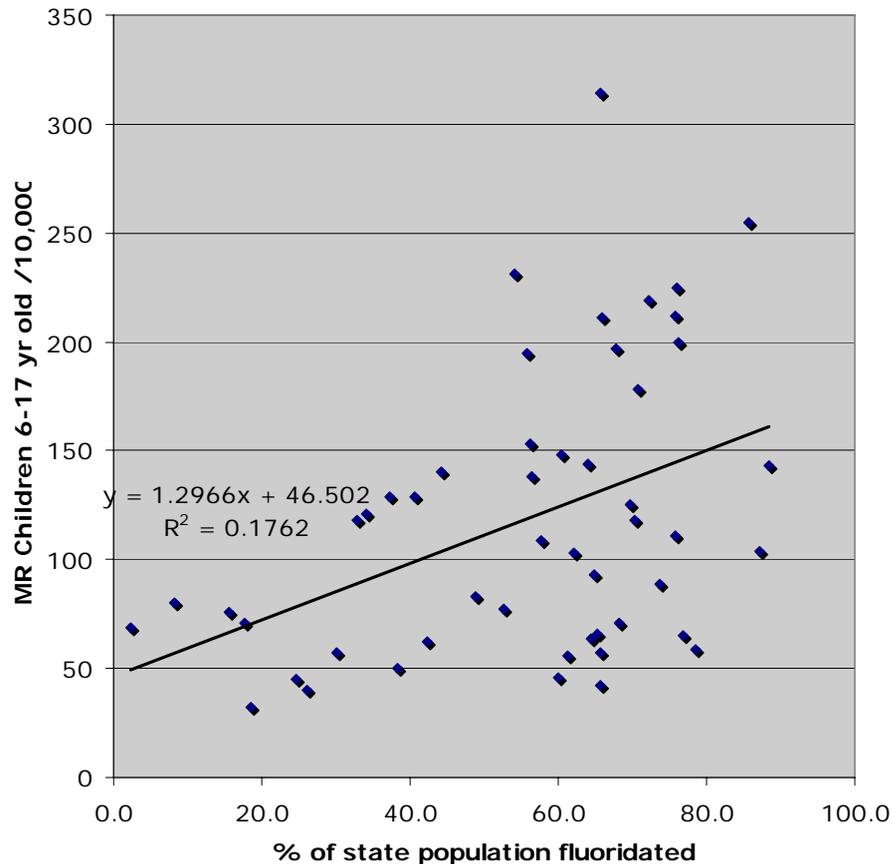
Many have more than 0.10 ppm serum fluoride concentrations



Xiang presented the referenced graph of the 2003 and 2005 data in Fluoride again in 2010. The 2010 was withdrawn because it was substantially similar to his earlier work.

# MENTAL RETARDATION

FLUORIDATION'S EFFECT ON MENTAL RETARDATION  
1992



Triple mentally retarded  
 $\frac{1}{2}$  standard deviation drop in IQ  
8 IQ drop

24+ human studies

2 fetal studies

100+ animal studies

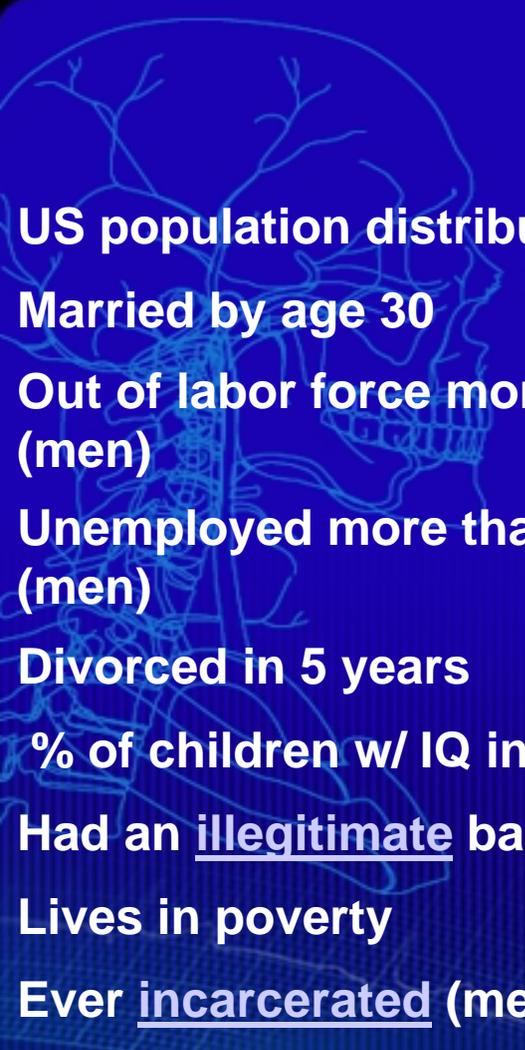
100's of invetro and invevo studies

**FLUORIDE CAUSES BRAIN DAMAGE**

<http://apps.nccd.cdc.gov/giscvh/map.aspx> <http://apps.nccd.cdc.gov/nohss/FluoridationV.asp>

<http://pubs.usgs.gov/circ/2004/circ1268/htdocs/table05.html> <http://www.cdc.gov/mmwr/preview/mmwrhtml/00040023.htm>

## Economic and social correlates of IQ



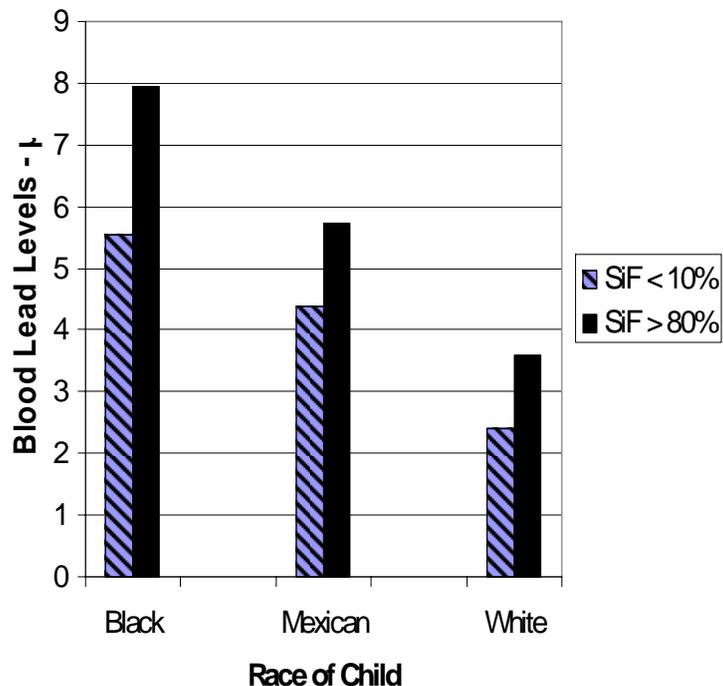
IQ	<75	75-90	90-110	110-125	>125
US population distribution	5	20	50	20	5
Married by age 30	72	81	81	72	67
Out of labor force more than 1 month out of year (men)	22	19	15	14	10
Unemployed more than 1 month out of year (men)	12	10	7	7	2
Divorced in 5 years	21	22	23	15	9
% of children w/ IQ in bottom decile (mothers)	39	17	6	7	-
Had an <u>illegitimate</u> baby (mothers)	32	17	8	4	2
Lives in poverty	30	16	6	3	2
Ever <u>incarcerated</u> (men)	7	7	3	1	0
Chronic welfare recipient (mothers)	31	17	8	2	0
High school dropout	55	35	6	0.4	0

Values are the percentage of each IQ sub-population, among non-Hispanic whites only, fitting each descriptor. Herrnstein & Murray (1994) pp. 171, 158, 163, 174, 230, 180, 132, 194, 247-248, 194, 146 respectively.

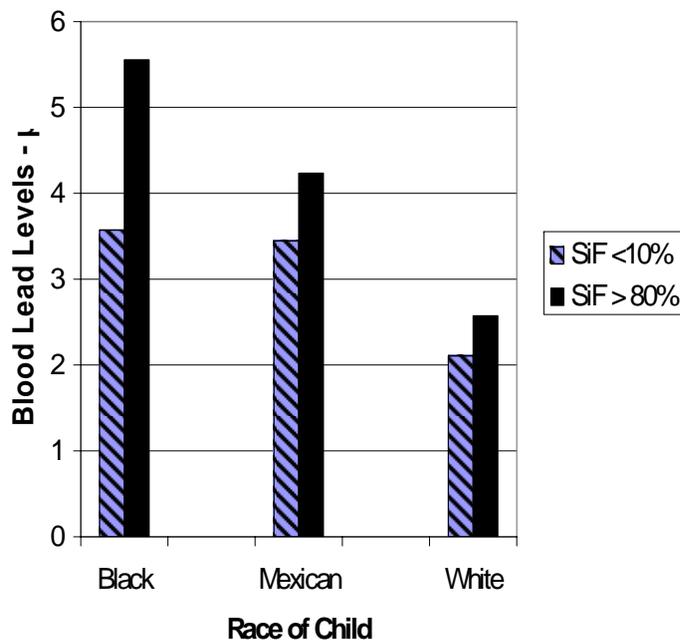
# LEAD: Blood Levels Higher

Coplan, Neurotoxicology. 2007

Average Blood Lead  
NHANES III - Children 3-5  
(Counties over 500,000)



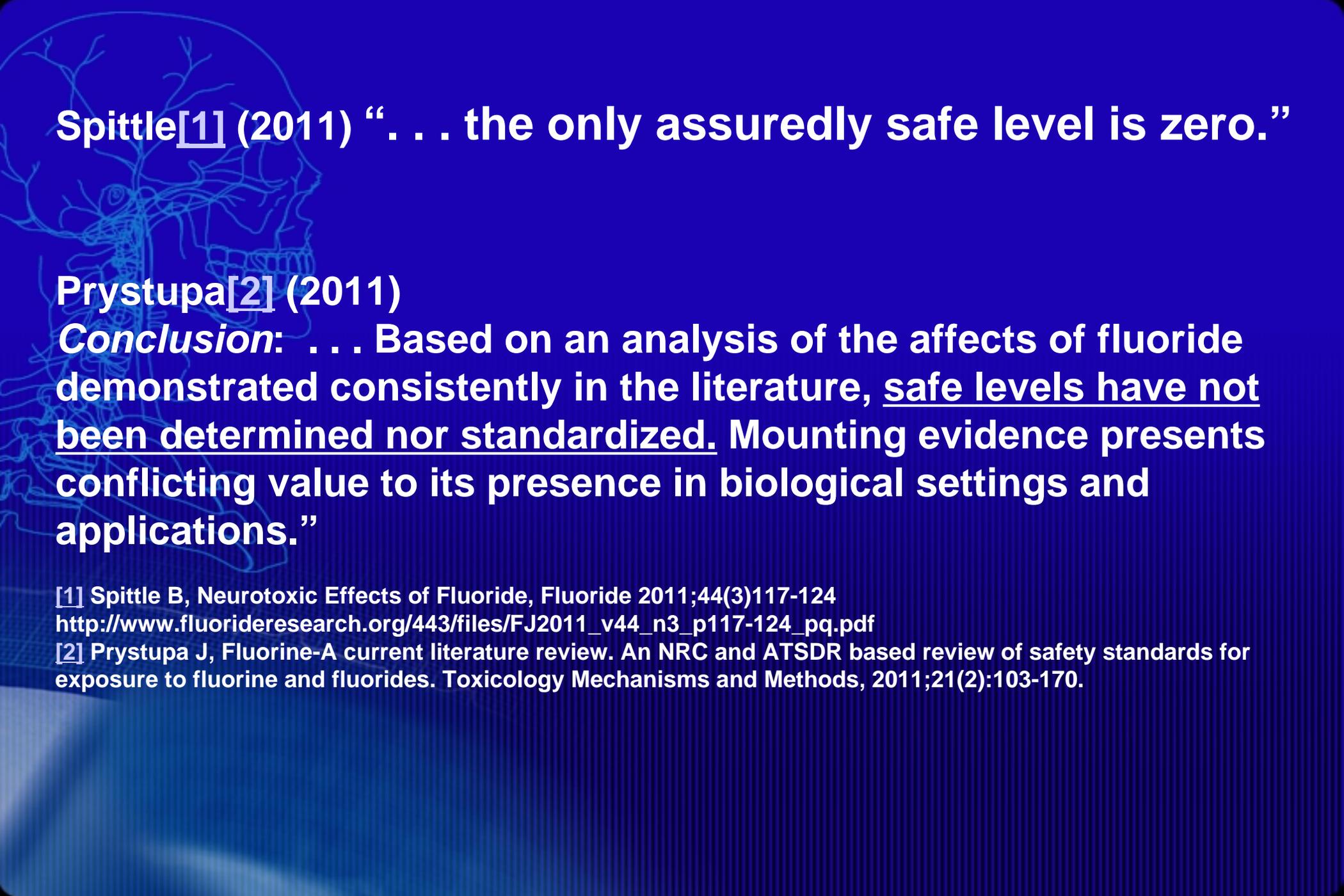
Average Blood Lead  
NHANES III - Children 5-17  
(Counties over 500,000)



For NHANES III Children 3-5, mean blood lead is significantly associated with fluoridation status (DF 3, F 17.14,  $p < .0001$ ) and race (DF 2, F 19.35,  $p < .0001$ ) as well as for poverty income ratio (DF 1, F 66.55,  $p < .0001$ ). Interaction effect between race and fluoridation status: DF 6, F ;3.333,  $p < .0029$ ;

Fluoridation chemicals added to water are a contaminated industrial grade product and may contain:

Arsenic, Lead, Mercury, Beryllium, Vanadium, Cadmium, Radium, Silicon, Bauxite, and Radioactive Materials



**Spittle[1] (2011) “. . . the only assuredly safe level is zero.”**

**Prystupa[2] (2011)**

***Conclusion:* . . . Based on an analysis of the affects of fluoride demonstrated consistently in the literature, safe levels have not been determined nor standardized. Mounting evidence presents conflicting value to its presence in biological settings and applications.”**

[1] Spittle B, Neurotoxic Effects of Fluoride, Fluoride 2011;44(3)117-124  
[http://www.fluorideresearch.org/443/files/FJ2011\\_v44\\_n3\\_p117-124\\_pq.pdf](http://www.fluorideresearch.org/443/files/FJ2011_v44_n3_p117-124_pq.pdf)

[2] Prystupa J, Fluorine-A current literature review. An NRC and ATSDR based review of safety standards for exposure to fluorine and fluorides. Toxicology Mechanisms and Methods, 2011;21(2):103-170.

American Dental Association (Paffenbarger Research Center)

**“After 60 years of community water fluoridation we still do not know how much fluoride is required to prevent caries.”**

<http://www.ada.org/prc.aspx#efficacy> 3/3/12 Acc.

**How much fluoride are you ingesting from all sources?**

**How much fluoride do you need or want in blood, dentin, enamel?**

**How much fluoride is safe for teeth, brains, bones, kidneys, etc?**

**Who is responsible for dosage and harm from too much?**

# National Research Council unanimous agreement: EPA's MCL for Fluoride is too high:

## **RISKS**

- Tooth Damage
- Rheumatoid and Osteoarthritic-like Pain
- Bone Cancer
- Bone Fractures
- Thyroid Reduction
- Diabetes
- Obesity
- Kidney damage
- Reproductive problems
- Lower IQ and increased Mental Retardation
- Allergies (overactive immune system)
- Gastrointestinal disorders

Dental Fluorosis White Spots



**“Our analysis shows no convincing effect of fluoride-intake on caries development. A Bayesian analysis of multivariate doubly-interval-censored dental data”  
Fluoridation delays tooth eruption.**

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**JORMA I. VIRTANEN**

*Institute of Dentistry, University of Helsinki, PO Box 41, FIN-00014 Helsinki, Finland*

*Biostatistics (2005), 6, 1, pp. 145–155*

*doi: 10.1093/biostatistics/kxh023*

**“NO”  
Benefit**

# 1. A number of recent cessation studies show that stopping fluoridation does literally nothing to increase overall dental decay.

Komarek et al, A Bayesian analysis of multivariate doubly-interval-censored dental data, Biostatistics 2005 6 pp 145-155 Copy Available.

2. Modern studies find difficulty in measuring the benefits of fluoridation (no difference between fluoridated and non-fluoridated communities) Studies by: Brunelle, Angelilo, Clark, Ismail, Slade, Kumar and in Australia by Armfield JM. Spencer AJ 2004, a very large study found No difference in dental decay in permanent teeth.

3. Not taking into account delayed tooth eruption makes early fluoridation studies “over-estimates of the benefits”.... Fluoride added to drinking water may have simply delayed caries in the past. Hardy Limeback DMD, PhD

Even those flawed studies found 0.6 ppm F better than 1.0ppm. Edward & Strickler

**“NO”  
BENEFIT**

# Fluoride and The Brain

Low iodine and high Fluoride exert  
“severe damage to the human body”

0.8 ppm Iodine and 1-3 mg/L fluoride in urine. Yang Y 1994

## The lowering of IQ by 8 to 10 points

1 Lu Y, Sun ZR, Wu LN, Wang X, Lu W, Liu SS. Effect of high-fluoride water on intelligence in children. Fluoride 2000; 33:74-8.

2 Li XS, Zhi JL, Gao RO. Effect of fluoride exposure on intelligence in children. Fluoride 1995;28:189-92.

3 Zhao LB, Liang GH, Zhang DN, Wu XR. Effect of a high fluoride water supply on children's intelligence. Fluoride 1996;29:190-2.

**RISK**

**21.6% retardation with fluoride 3.14ppm**

**Compared to 3.4% in control village with fluoride at 0.37 ppm**

Tianjin, Fluoride Vol. 33 No. 2 49052 2000, Editorial 49 Fluoride 33 (2) 2000

<http://www.fluoride-journal.com/00-33-2/332-49.pdf>

**Fluoride and low iodine on learning/memory in rats.**

Wang et al, 2004

“Since April of 1999, I have publicly decried the addition of fluoride, especially hydrofluosilicic acid, to drinking water for the purpose of preventing tooth decay.”

See details <http://www.slweb.org/limeback.html>

Hardy Limeback, BSc, PhD, DDS

Associate Professor and Head, Preventive Dentistry

University of Toronto

**“NO”  
BENEFIT**

“I am quite convinced that water fluoridation, in a not-too-distant future, will be consigned to medical history.”

- *Dr. Arvid Carlsson, Winner, Nobel Prize for Medicine (2000).*

“Fewer fillings had been required in the nonfluoridated part of my district than in the fluoridated part.”

1997 John Colquhoun PhD, DDS <http://www.slweb.org/colquhoun.html>

**Decay is not the result of fluoride deficiency.**

Aoba T, Fejerskov O. (2002). Dental fluorosis: chemistry and biology.

*Critical Review of Oral Biology and Medicine* 13: 155-70.

# Blood Lead levels in Fluoridated areas 2X higher for Whites and 6X higher for Blacks

**Confirmation of and explanations for elevated blood lead and other disorders in children exposed to water disinfection and fluoridation chemicals.** Coplan MJ, Patch SC, Masters RD, Bachman MS. Neurotoxicology. 2007 Sep;28(5):1032-42. Epub 2007 Mar 1. "Prevalence of children with elevated blood lead (PbB>10µg/dL) is about double that in non-fluoridated communities"

**When FSA was added "lead concentrations spiked to over 900ppb"**

Effects of fluoridation and disinfection agent combinations on lead leaching from leaded-brass parts. Maas RP, Patch SC, Christian AM, Coplan MJ. Neurotoxicology. 2007 Sep;28(5):1023-31. Epub 2007 Jun 30

**Water treatment with silcofluorides and lead toxicity.**

Masters RD, Coplan M. 1999 International Journal of Environmental Science 56: 435-449.

**Association of silicofluoride treated water with elevated blood lead.**

Masters RD, Coplan MJ, Hone BT, Dykes JF. 2000 Neurotoxicology 21(6): 1091-1100.

**Blood lead concentrations in children and method of water fluoridation in the United States, 1988-1994.** Macek MD, Matte TD, Sinks T, Malvitz DM. Environ Health Perspect. 2006 Jan;114(1):130-4. **Dental School Did not find an increased blood lead level except for older homes.**

**Lead from Leaded auto gas, canned foods, and lead pipes have decreased.**

ADA awarded Kentucky with “50 Year Award” for  
(100%) fluoridation 2003

42% were edentulous, #1 in USA (2002 Mortality Weekly Report)

“With 1.6 to 4ppm fluoride in the water, 50% or  
more past age 24 have false teeth because of  
fluoride damage.” JADA 1944

**“NO”  
Benefit**

Connecticut (87.5% water fluoridated)

Detroit

Boston

all report a crisis with decay and all have water fluoridation.

<http://www.fortwayne.com/mld/newssentinel/7521679.htm?template=contentModules/printstory.jsp>

[http://www.enquirer.com/editions/2002/10/06/loc\\_special\\_report.html](http://www.enquirer.com/editions/2002/10/06/loc_special_report.html)

<http://www.fluoridealert.org/f-boston.htm>

[http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list\\_uids=13678102&query\\_hl=1](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=13678102&query_hl=1)

[http://www.nhregister.com/site/news.cfm?newsid=14472801&BRD=1281&PAG=461&dept\\_id=517515&rfi=8&xb=kasan](http://www.nhregister.com/site/news.cfm?newsid=14472801&BRD=1281&PAG=461&dept_id=517515&rfi=8&xb=kasan)

# GENERAL AGREEMENT

**Dental caries can be painful and expensive.**

**Dental caries are not caused by inadequate fluoride.**

**Too much fluoride increases risk of harm.**

**Fluoridation is controversial.**

**A poor diet and lack of daily clean are significant causes of caries.**

**Topical fluoride has benefit**

**No prospective randomized controlled trials.**

**Most developed countries world wide do not fluoridate water.**

**Fluoride is more toxic than lead.**