

To

The National Toxicology Board of Scientific Counselors

Regarding:

**Draft NTP Monograph on the
State of the Science Concerning Fluoride Exposure and Neurodevelopmental and
Cognitive Health Effects: A Systematic Review NTP Monograph April 2023.**

https://ntp.niehs.nih.gov/ntp/about_ntp/bsc/2023/may/wgrptbsc20230400.pdf

Comments May, 2023

Bill Osmunson DDS MPH



Washington Action for Safe Water
King County Citizens Against Fluoridation

INTRODUCTION

In 2015, I was one of those nominating fluoride to OHAT, NTP and passed on to the Board of Scientific Counselors, for review of Developmental Neurotoxicity, another nomination for Cancer, and another for harm to the Thyroid. Additional risks including dental fluorosis and more than a dozen other risks should be reviewed by NTP.

I am a Comprehensive and Cosmetic Neuromuscular Dentist, with Masters in Public Health, now in my 48th year treating patients, including treating the functional and cosmetic harm of dental fluorosis. For about 25 years I promoted fluoride topical and ingestion. I was confident both had benefit. Then I read the science on both sides of the controversy and became opposed to fluoride ingestion because fluoride is highly toxic, causes damage, and has minimal if any benefit. I had been giving credit to fluoride when better dental health comes predominantly from higher socioeconomics, diet and hygiene. Without significant benefit, any risk of harm or expense is unacceptable. My intent now, is to protect the public from iatrogenic harm caused by authorities.

The BSC "Recommendations" are good. Although doubt has been raised on the publication of the monograph and NTP has every right to be discouraged with the controversy, 8 long years, 700+ pages; however, consider that this difficult task will have the greatest public health benefit and be the crown jewel of your career. Your work is most critical for the health of the millions, their success in school, work, home and friendships. Bravo to each of you!!!

Part I. Five additional recommendations are presented below, first some rationale
Part II. The American Dental Association does not have reliable judgment.

The title of the "State of the Science" implies a comprehensive balanced document and the title should be changed or combined with the M-A and reconciled.

The NTP has spent about 8 years on one of perhaps 20 health risks of fluoride. An uncertainty factor, margin of error, intraspecific variation in humans is essential to protect everyone, not just the mean. We do not have all the evidence. We also have uncertainty, and the public protection should supersede policy and corporate interests. If people want to ingest fluoride, we have other sources which provide freedom of choice especially for chemically sensitive sub-populations.

RATIONAL FOR THE FIVE RECOMMENDATIONS BELOW

A. Monograph Preface: *“it (Monograph) provides a comprehensive and current assessment of the scientific literature on fluoride as an important resource to inform safe and appropriate use.”* The monograph is not comprehensive and already dated. The SoS attempts to protect fluoride ingestion policy assuming benefit and the SoS is in conflict with the M-A. The Meta-Analysis and comments by reviewers do not dispute that fluoride is a “known” developmental neurotoxin. The question is dosage. Further research will refine our understanding but is unlikely to counter this determination. The public does not like mandated medication with even an approved drug.

B. The public health crisis of a non-infectious idiopathic pandemic of excess fluoride exposure caused and administered by authorities, demands urgent attention. When a clinician makes a mistake, the patient can be harmed. When public health makes a mistake, millions can be harmed.

To illustrate the urgency, consider 220 million fluoridated in the USA X 1.5% of the population at each age X 8 years NTP review X 2+ IQ points lost X an estimated \$500/IQ/year lost income X 40 years of work (assuming steady state of IQ loss) = an estimated \$1 trillion in lost future wages during NTP’s 8 years reviewing the developmental neurotoxicity of fluoride. Socioeconomic harm, lower health from lower income, increased incarceration, increased frustration and divorce, increased dropouts, increased special education and fewer gifted children with crushing environmental

justice harm are all related to IQ loss and probably more loss than the lost wages. Just the costs of treating cosmetic and functional dental fluorosis (not all is treated) far exceeds the cost of any alleged cost savings.

C. When we seriously contemplate authorities mass medication of everyone regardless of individual total exposure, when about 2 out of 3 have a biomarker of excess exposure (dental fluorosis), with an unapproved drug (no FDA NDA), lacking their doctor's prescription, lacking an approved label or known dosage, lacking an uncertainty factor, with only one RCT (finding no statistical benefit,) with an industrial waste product contaminated EPA contaminant, and no Federal Agency accepting jurisdiction; then the M-A reporting harm requires emergency action on the part of authorities.

D. NTP must not protect the toxin and flawed policy. Dental and public health professions, need a clear statement of known harm for some of the public. Adding the M-A increased confidence rather than lowered the confidence.

E. The NTP's partner, the FDA/CDER, is charged by the FD&C Act to regulate substances with intent to prevent disease in man. The FDA first determines efficacy at a specific dosage with quality science, RCTs. If efficacy at a specific dosage has good evidence, then safety at that dosage is determined and then label. The FDA CDER process is correct, logical and well established to protect the public.

In contrast, the NTP works backwards, requiring proof of harm, without an uncertainty factor or margin of error (as though we have the final word on science), assuming all humans have the same effect from fluoride, assuming everyone has the "mean" exposure, and assuming significant efficacy.

F. An over-riding flaw of the S.o.S. is the assumption by some in OHAT/NTP/NIEHS/NASEM/HHS/CDC/ADA and reviewers that ingested fluoride has significant benefit and mass medication without consent needs to be protected.

Weighing a "benefit risk" without a clear determination of benefit or lack of benefit has protected the "risk" assessment in the minds of some.

G. Fluoride is to be regulated as a drug when used with intent to prevent disease. NTP must not assume benefit. Focus on risk, protect the public.

H. Just as fluoride topical in toothpaste has been FDA CDER approved, promoters of fluoride ingestion must gain FDA CDER approval. Circumventing FDA CDER NDA has caused serious harm and should be considered an authority administered pandemic or as the EPA scientists reported, "borders on a criminal act."

Congress 21 USC 321 (g)(1)(B) and all state drug laws I've read, define a drug as a substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals. The "INTENT" of use is key to whether it is a drug and the FDA determines intent in part as "well known to the public."

Monograph Introduction starts out assuming benefit without reservation and never backs down or qualifies the assumption.

Recommendation #1. Abstract and Introduction start out: *"Fluoride. . . is widely promoted for its dental and overall oral health benefits."*

And: *"Monograph should be used to inform a careful analysis of data concerning the potential risks as **well as benefits** of fluoride."* p 284 NTP Answer to comment.
(emphasis supplied)

Topical is FDA CDER NDA approved with reasonable science, systemic is not FDA CDER approved but is well promoted. NTP is correct, but the statement implies scientific benefit and the FDA CDER has determined the evidence is incomplete. Stop promoting an unapproved drug or at least provide a balanced monograph.

Risks have been ignored. I treat dental fluorosis, known harm from excess fluoride exposure, both cosmetic and functional damage. The damage to teeth has more harm than benefit. Dismissing even the cosmetic dental fluorosis harm is not reasonable. If someone scratched your car, it would only be cosmetic, but certainly would be damage. Dentists placing black mercury fillings are not always the best judges of cosmetic harm. Fluoride increases the risk and prevalence of functional harm, chipped, cracked, fractured and broken teeth. Dentists seldom diagnose the fluorosis in part because the dental profession is the only health care profession without required diagnostic codes. In court, the ADA testified it has no duty to protect the public from harm. The ADA protects dentists.

Recommendation #1 sample wording “Fluoride is highly toxic with a Probable Toxic Dose estimated at 5 mg/kg body weight. Fluoride is exempt from toxic and poison laws when regulated as a pesticide or drug. Topical fluoride in toothpaste went through the drug approval regulatory process and gained approval with a label on dosage referring to 0.25 mg. The Drug Facts, include warning, “keep out of reach of children under 6 years 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 years and older: . . . Do No Swallow, to minimize swallowing use a pea-size amount in children under 6, supervise children’s brushing until good habits are established.””

If we assume 50% (30% to 70%) of fluoride exposure is from water, the concentration of fluoride in water should be about half the FDA concern or 0.125 mg/L, similar to Grandjean’s¹ 2021 Benchmark Dose Analysis for pregnancy of about 0.2 mg/L fluoride in water.

¹ Grandjean P, Hu H, Till C, Green R, Bashash M, Flora D, Tellez-Rojo MM, Song PXX, Lanphear B, Budtz-Jørgensen E. A Benchmark Dose Analysis for Maternal Pregnancy Urine-Fluoride and IQ in Children. Risk Anal. 2022 Mar;42(3):439-449. doi: 10.1111/risa.13767. Epub 2021 Jun 8. PMID: 34101876; PMCID: PMC9831700.

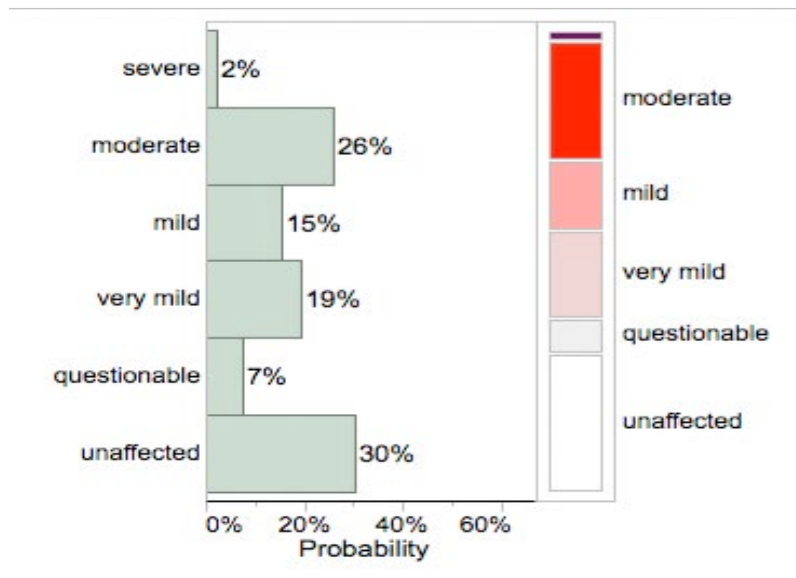
In simple terms, topical fluoride has benefit, systemic has little or none and has potential for great harm.

Mechanism: Fluoride works by interacting topically after teeth erupt. The evidence for its effectiveness when applied to erupted teeth is well supported. Fluoride incorporation into developing teeth is very minor and does not contribute to caries prevention. Fluoride is not a nutrient nor essential for any bodily function. A very small amount of ingested fluoride makes its way to saliva to provide some topical fluoride after tooth eruption, but this amount is 50 to 100 fold less than what is obtained from fluoride naturally occurring in food and beverages. Enamel and dentin demonstrate significant transport hindrance. The effective pore radii of the transport pathways in the enamel are approximately 0.7-0.9 nm.

The term “optimal” fluoride intake as used by reviewers is a marketing term not based on quality science or the FDA CDER. Concentration is not a dosage. The absence of fluoride does not cause any disease and benefit from ingestion of fluoride is disputed and controversial with incomplete data. 97% of Western Europe² does not fluoridate their water and has similar caries rates as fluoridated countries.

Dental fluorosis is a biomarker of excess fluoride and 2 out of 3 have dental fluorosis. Too many are ingesting too much fluoride.

² https://fluoridealert.org/content/water_europe/



Neurath et al 2019,³ NHANES 2012 data above. When fluoridation started the public was assured fewer than 15% of the public would get dental fluorosis, we now have close to 70% of children with dental fluorosis. Too many are ingesting too much and the CDC states: **“Ingestion of fluoride is not likely to reduce tooth decay.”**⁴

Leverett⁵ 1997 is the singular published Randomized Control Trial of prenatal fluoride supplements and preventing dental caries and reported no statistical significance.

A Cochrane Review 2015⁶ used observational studies and reported benefit for children but insufficient information for benefit to socioeconomic groups, increased caries when stopping fluoridation, or benefit for adults.

³ Neurath C, Limeback H, Osmunson B, Connett M, Kanter V, Wells CR. Dental Fluorosis Trends in US Oral Health Surveys: 1986 to 2012. *JDR Clin Trans Res*. 2019 Oct;4(4):298-308. doi: 10.1177/2380084419830957. Epub 2019 Mar 6. PMID: 30931722.

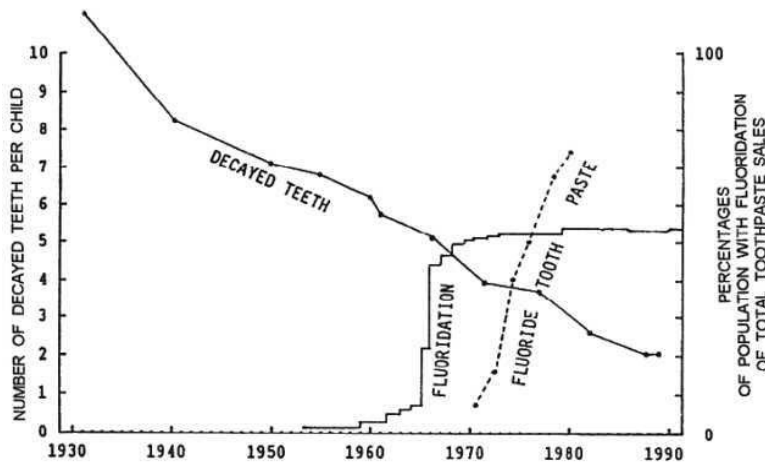
⁴ Achievements in Public Health 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries. *MMWR*, 48(41); 933-940, October 22, 1999..

⁵ Leverett D, H, Adair S, M, Vaughan B, W, Proskin H, M, Moss M, E: Randomized Clinical Trial of the Effect of Prenatal Fluoride Supplements in Preventing Dental Caries. *Caries Res* 1997;31:174-179. doi: 10.1159/000262394

⁶ heozor-Ejiofor Z, Worthington HV, Walsh T, O’Malley L, Clarkson JE, Macey R, Alam R, Tugwell P, Welch V, Glenny A, Water fluoridation to prevent tooth decay, Cochrane Review, June 18, 2015

Observational studies have serious limitations. For example,.

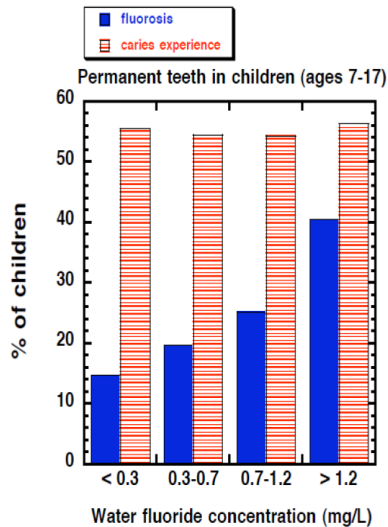
- **A. NOT ONE STUDY CORRECTS FOR UNKNOWN CONFOUNDING FACTORS** such as what caused the huge decline in dental caries by more than half prior to fluoridation and fluoride toothpaste? That unknown(s) is more powerful than fluoride ingestion or topical.



- **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 ROUND 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 WATER.**
- **L. DENTAL TREATMENT EXPENSES NOT CONSIDERED**
- **M. MOTHER'S F EXPOSURE, BREAST FEEDING AND INFANT FORMULA EXCLUDED**
- **N. FRAUD, GROSS ERRORS, AND BIAS NOT CORRECTED.**
- **O. GENETICS NOT CONSIDERED**

The following graph is data from Iida. With increased fluoride exposure dental fluorosis prevalence increases. However, benefit is minimal if any.

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



The National Toxicology Program (NTP) mentions alleged benefits of fluoride but not the PTD (probable toxic dose) of fluoride. Witford suggests the PTD is estimated at 5 mg/kg body weight and 15 mg.⁷

For example, fluoride fits within the definition of "highly toxic" and "poison" laws as a substance which (various wording and criteria) can cause serious illness or death with less than 6,778 mg. [**RCW 43.20.050**] Fluoride is exempt from poison laws when regulated as a pesticide or drug. Boards of Pharmacy and the FDA have confirmed fluoride is a drug when used with the intent to prevent disease in humans.

⁷ Whitford GM. (1987). Fluoride in dental products: safety considerations. Journal of Dental Research 66: 1056-60.

Recommendation #2. Recommendation NTP should make a clear distinction between the FDA approved topical use of fluoride and the unapproved systemic use of fluoride with the intent to prevent dental caries. And, NTP should be consistent with the FDA label on fluoride toothpaste.

Sample wording: “The US Food and Drug Administration defines a [DRUG](#) in part, as “intended for use in the diagnosis, cure, mitigation treatment, or prevention of disease. Fluoride is well known to the public to have intent to prevent dental caries. The fluoride toothpaste label is applicable to fluoride from other sources, with a warning “do not swallow.” Topical fluoride has FDA CDER NDA approval with a label and simple dosage, pea or smear size amount containing about 0.25 mg of fluoride, consistent with this meta-analysis.” See also See 21 USC 321 (G)(1)(B).

- A. Ingested fluoride marketed with intent to prevent dental caries is an unapproved drug.
- B. The FDA has warned manufacturers of fluoride supplements, they are unapproved, the evidence of efficacy is incomplete. Drug Digest 1975
- C. The FDA testified to Congress that fluoride is a drug. (Honorable Ken Calvert 2000).
- D. The FDA Orange Book of approved drugs does not list Fluoride or Sodium fluoride for ingestion with intent to prevent or mitigate dental caries.
- E. Washington State and Idaho Boards of Pharmacy have confirmed fluoride is a drug.

F. The EPA Ass. General Counsel, Water Law Office 2/14/2013 responded, "The FDA, remains responsible for regulating the addition of drugs to the water supply for health care purposes."

G. The FDA has approved fluoridated toothpaste which has good RCT studies, has passed the drug approval process, and as with all drugs has a drug label including warnings such as do not swallow. The FDA warning is for 0.25 mg of fluoride, about the same as a large glass of so called "optimally" fluoridated water, "do not swallow."

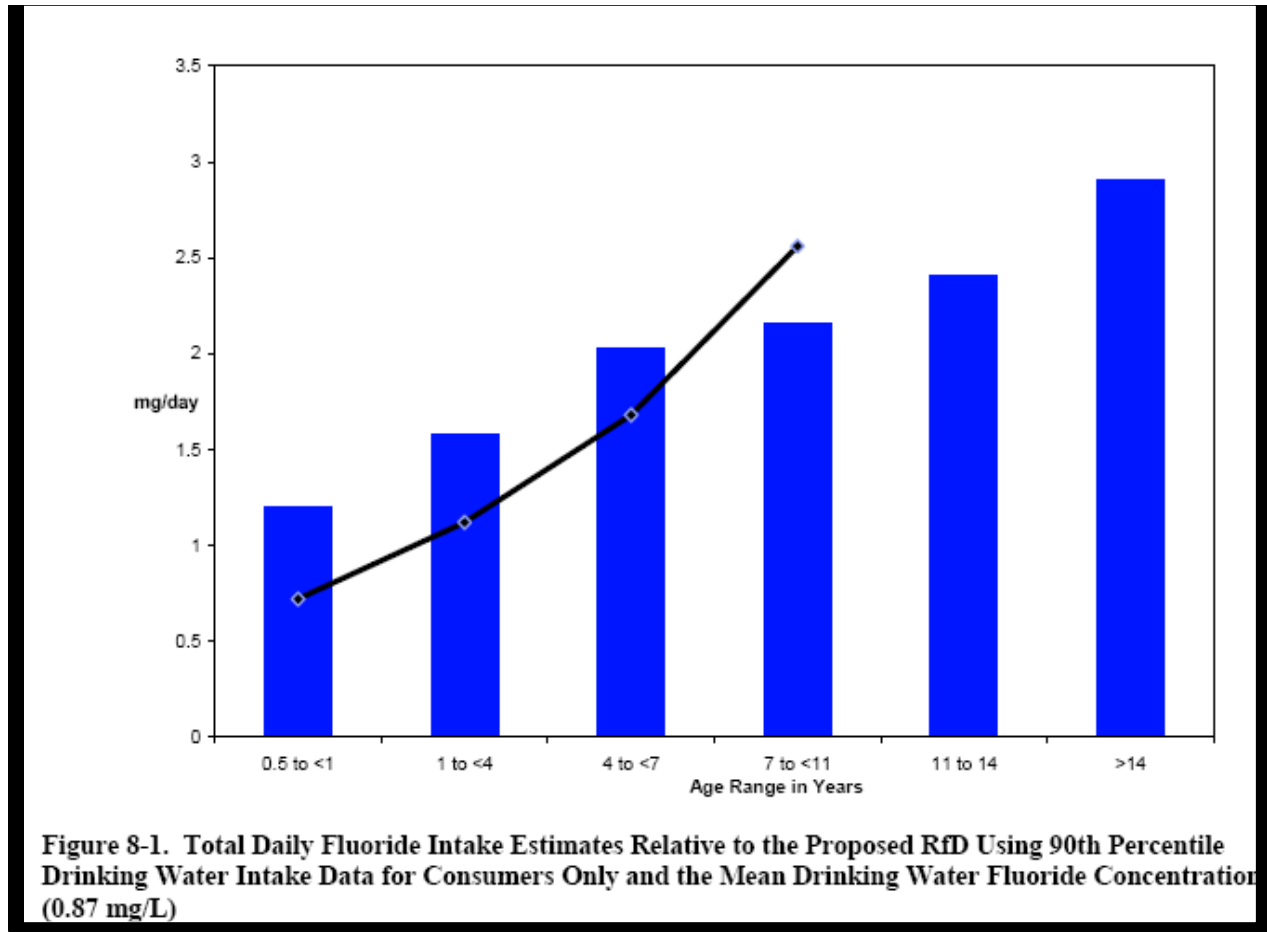
H. The FDA warned fluoride supplement manufacturers "there is no substantial evidence of drug effectiveness as prescribed, recommended or suggested. . . marketing is in violation of . . . the FFD&C Act." (1975).

I. Fluoride is not a nutrient as the absence of fluoride does not cause any disease and dental caries is not the result of an inadequate intake of fluoride. The FDA was "notified" a health claim would be made for fluoridated bottled water. The claim did not go through the FDA CDER and does not have an NDA. The claim is based on other government agencies who have no authority to approve highly toxic substances.

Recommendation #3. "Mothers who are pregnant or want to become pregnant and children under the age of six should, when possible, avoid drinking water with fluoride concentrations over 0.2 mg/L, do not swallow fluoridated toothpaste, and avoid foods and beverages high in fluoride. Caregivers of infants should avoid mixing formula with water containing more than 0.01 mg/L of fluoride." See 21 CFR 101.14(e)(5) and EPA Fluoride: Exposure and Relative Source Contribution Analysis, 2010

Consider the EPA Figure 8-1 below. Those under seven are at high risk. Those under 6 months of age are ignored. 10% of the public drinking the most water are ignored. Instead of following the NRC 2006 report that the MCLG of 4 ppm is not protective, EPA

changed the RfD definition of safe from 0.06 mg/kg/day to 0.08 mg/kg/day, less protective and kept the MCLG. The percentage above the black line shows about a quarter of children still ingest too much fluoride.



In addition to the fifth BSC recommendation regarding the WHO 1.5 mg/L benchmark.

A word of caution for high-risk individuals:

- A.** Concentration is not dosage. Some drink 10 times the “mean” of about 1 liter/day. Consumption of liquids increases during pregnancy. I'm a big fan of the WHO, but not their position on fluoride exposure. Although more protective than the USA at 4mg/L, WHO uses historic incomplete data, highly influenced by industry and the expense to remove the natural fluoride in some developing areas.

- B. Some are even now using the 1.5 mg/L as a determination for safety. I contacted one of the NTP reviewers and was told NTP science has determined less than 1.5 ppm in water is safe.
- C. The SoS is not consistent with the M-A. The M-A does not show a total exposure based on a “concentration of fluoride in water” is safe or an appropriate measurement.
- D. The NTP’s original Draft determining fluoride to be a “**presumed**” developmental neurotoxic is correct for many but inadequate for infants on formula made with fluoridated water. A specific warning label must be required (recommended) for pregnant mothers and infants not to drink water or have formula made with water.

Recommendation #4. Suggested wording: To protect the public and due to the strength of the evidence, an uncertainty factor & intraspecific factor of 10 would be a prudent public health consideration.

Research on efficacy can and should have RCTs.

Research on harm cannot ethically have RCTs and has greater uncertainty.

An intraspecific factor for those chemically sensitive, harmed with other toxins or have compromised health should be included.

All streams of evidence on risks of fluoride are not included. “Divide and conquer the evidence” can make almost anything appear safe or relatively safe. An uncertainty factor, margin of error is critical.

If for no other reason, the variation in water consumption should require a factor or warning to protect them.

Recommendation #5, the NTP reconcile the disconnect or "disagreement" between the SoS as "safe" < 1.5 mg/L and the M-A data as "not safe".

Concentration is not dosage. For example, infant formula made with 1.5 mg/L fluoride in water is about 350 times higher dosage than mother's milk. Some drink 10 times the "mean." "THERE WAS NO OBVIOUS THRESHOLD FOR WATER" P 325

"decrease of 1.81 points . . . per 1-mg/L increase in urinary fluoride."

"Conclusion. . . an inverse association between fluoride exposure and IQ."

When in doubt, we in health care must protect the patient and public and give the freedom to choose.

In *Doe v Rumsfeld* the Court ruled even under emergency conditions of war, the Government cannot force an individual to be medicated with a substance which has not been specifically approved for the purpose and manner it is intended.

PART II. The American Dental Association does not have reliable judgment.

The American Dental Association (ADA) is an unreliable witness and source of scientific judgment on the draft NTP Monograph. All scientific evidence can and should be challenged and improved. The ADA has reason to delay, challenge, require more research, critique, advise for more reviews for the next 100+ years. Just like big tobacco and other vested interests fight and evade the protection of the public, the ADA profits with delay and the CDC/HHS protect their reputations with delay.

The ADA criticism of the NTP Monograph is a sorry admission the ADA has through its powerful research, lobby, and assets failed to provide the NTP with the very evidence the ADA demands. It is not the tax-payers who should be paying for the research requested by the ADA. The ADA has had 70 plus years to provide the very evidence they now demand. If the ADA does not find the science complete to their satisfaction, then the ADA must do their homework and gain FDA CDER NDA approval.

1. The ADA has testified in the Superior Court of the State of California, Case No. 718228, "The American Dental Association (ADA) owes no legal duty of care to protect the public from allegedly

dangerous products used by dentists.” The ADA is an Association or “union” of paid members to protect the interests of itself and members. In contrast, the duty of the NTP is to protect the public. Community water fluoridation is authority controlled, many in the public over exposed, harmed, and without freedom of choice. Should fluoridation cease, other sources of fluoride are available with freedom of choice. The ADA can then do the necessary due diligence and provide the research of safety and efficacy to the FDA CDER and gain approval.

2. The ADA has significant financial interests in fluoride endorsements and their members (including mine) incomes are increased by both cosmetic and functional treatments. The ADA makes money on fluoride products seal of approval, but nothing on IQ.

3. For most of a century, the ADA has staked their reputation on both topical and ingested fluoride benefits. However, in the more than 70 years of mass medication, if the science of benefit were of high quality the ADA could have generated significant income and attempted to gain FDA CDER approval and then profitably licensing the NDA to water purveyors. ADA could make millions of dollars if they could gain FDA approval. Maybe the ADA tried. However, the FDA has determined the evidence for efficacy is incomplete and it is doubtful, even with RTCs, the FDA would provide FDA CDER NDA approval for medicating people with fluoride, lithium or any other drug through public water. . .and without label as the ADA promotes with fluoride.

4. The ADA will attempt to discredit the NTP draft monograph, just as the tobacco industry fought government oversight. Remember, the financial and reputation of the ADA is at stake and the ADA will fight hard as a vested interest in protecting their claims of “safe and effective” discrediting and challenging the NTP judgment. Indeed, fluoride is safe and effective for the ADA but not the public.

5. The ADA will require more research, more peer reviews, and more empirical evidence will always be desired, but we have enough to start to protect the public health and developing brains. The NTP has had plenty of peer reviews and spent far too long delaying the release of the Monograph and the public has been harmed with over exposure of fluoride and delay in authority oversight.

6. The ADA claims fluoridation is effective; however, the FDA says the evidence is incomplete. If the ADA used the same critical thinking it applies to criticizing the Monograph to the evidence of fluoride’s alleged efficacy, fluoridation would cease. The ADA should look in the mirror.

7. The only way the ADA can have any credibility on fluoride ingestion is to divide and conquer.

a. Divide the evidence of safety from efficacy and do not judge both at the same time.

b. Accept incomplete and lower quality of evidence of efficacy as fact and rip into every word of evidence of harm. The ADA is two faced.

c. Divide the many risks of fluoride ingestion into separate risks and require each risk to have the highest quality of evidence of harm, in the USA population with numerous studies spanning generations. ADA wants judgement on the “proof” of harm from one risk rather than a global view.

d. When known risks are undisputed by “all” scientists such as dental fluorosis, the ADA brushes the claim of harm off as not insignificant. “Just cosmetic harm and hardly detected, some even like the whiter appearance.” As though cosmetics harm is not actual harm. The ADA does not talk about functional harm (chipped, cracked, fractured, or broken teeth) or protecting high risk individuals (pregnant mothers, infants, those drinking the most water) with a warning label.

e. Instead of protecting the public by gaining FDA approval, the ADA has promoted circumventing laws and the least informed vote to medicate their neighbors. The ADA convinced the public but has not convinced the FDA . . .and hopefully not the NTP.

f. A US Environmental Protection Agency (EPA) study by Collins⁸ funded by the EPA with fluoride concentrations between 1.0-4.0 mg/L evaluated the cost of treating dental fluorosis, finding:

“A mean cost for all consultants shows that the estimated costs for restoring function exceeds the cosmetic costs in all categories except the minimum later costs. This represents a new finding and raises an issue that has been overlooked or ignored by previous investigators and the profession. i.e . that repair of the cosmetic discoloration was the only cost involved; or that repair of dysfunction was never considered to be a problem.”

All consultants do not appear to have been cosmetic dentists nor did they estimate life-time costs. The ADA ignores the known harm from fluoride even to the teeth. The ADA protects dentists. Fluoride office treatments cost the patient about \$35. Costs are minimal, a couple dollars, and treatment is provided as part of routine prophylaxis twice a year at no additional treatment time with a nice net profit to the typical dentist with 1,000 patients of over \$60,000. And requiring not a second of the dentist’s time. Topical has benefit, but when a patient objects neither patient nor clinician are comfortable. The concept is to keep the patient thinking fluoride exposure is safe and effective.

⁸ ([Collins, E., V. Segreto, H. Martin, AND H. Dickson](#). ANALYSIS OF COSTS FOR THE TREATMENT OF DENTAL FLUOROSIS. U.S. Environmental Protection Agency, Washington, D.C., EPA/600/5-87/001 (NTIS PB87170817), 1987. Revised 2005. [[EPA Link](#)], Data Revised 08/02/2022 . [EPA Science Inventory](#) Accessed Dec. 27, 2022

Patient #1 (below) has a normal ideal smile with healthy teeth, no fluorosis detected, and was raised predominantly on mother's milk and no formula was made with CWF.



For comparison, Patient #2, (below) diagnosed with Dean's Fluorosis Index of 4, "discrete or confluent pitting," moderate to severe dental fluorosis and has functional damage having chipped, pitted and worn teeth.



Patient #2 was raised mostly on formula made with fluoridated water. Mom was confident significant fluoridated toothpaste was not swallowed and no fluoride supplements ingested.

Moimaz⁹ study of adolescents reported 52% at a fluoride concentration in water of 0.7 mg/L had dental fluorosis. Of the subjects, 95% wished to remove the spots. In contrast to the subjects reported concern, only 14.5% had professionally diagnosed mild, moderate or severe dental fluorosis.

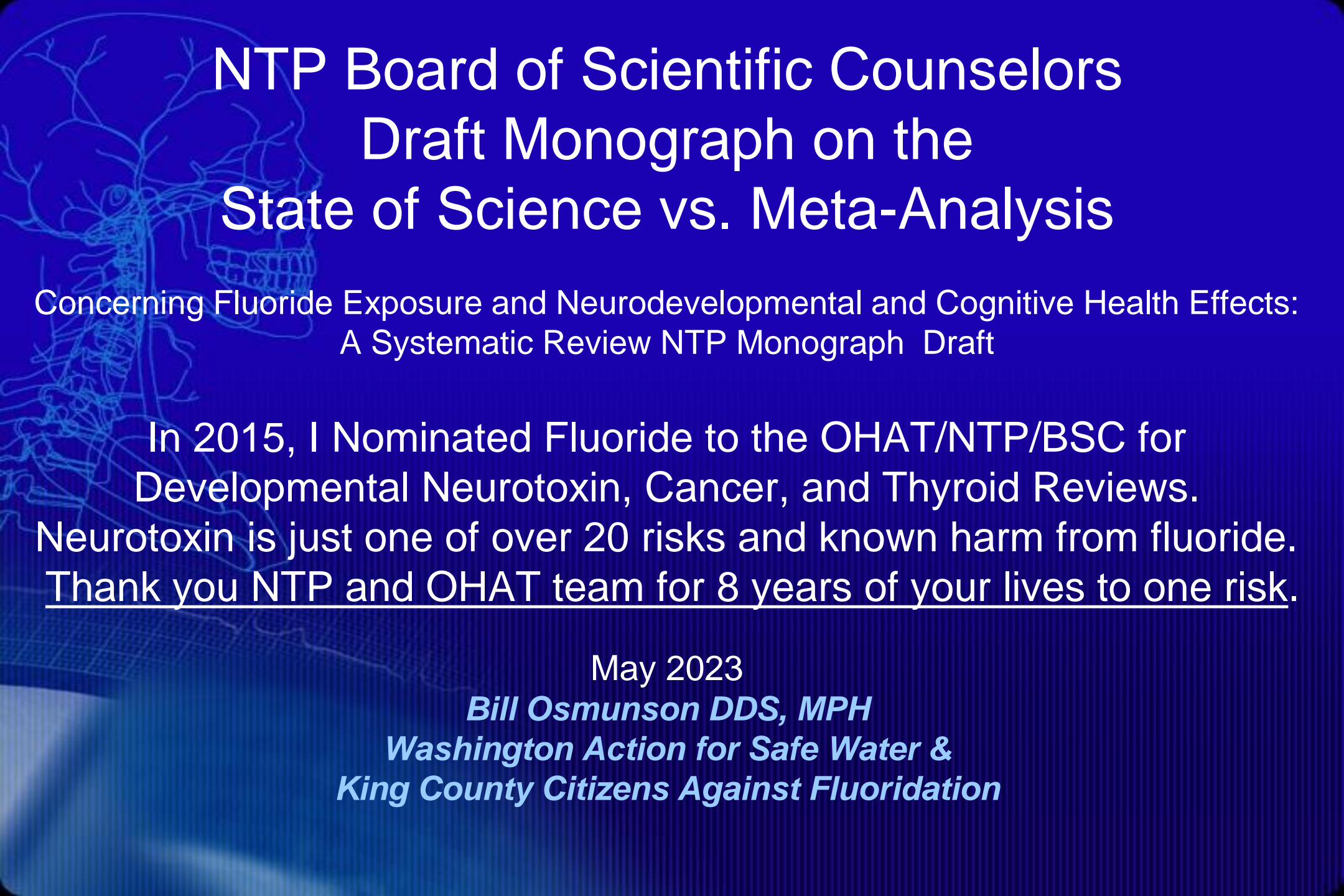
The ADA ignores evidence of known harm from excess fluoride exposure to teeth. Dentists do not diagnose IQ loss or have the background to evaluate neurotoxicity.

Protect the health of the public rather than the financial health of those with vested interests.

Sincerely,

Bill Osmunson DDS MPH

⁹ Moimaz SA, Saliba O, Marques LB, Garbin CA, Saliba NA. Dental fluorosis and its influence on children's life. Braz Oral Res. 2015;29:S1806-83242015000100214. doi: 10.1590/1807-3107BOR-2015.vol29.0014. Epub 2015 Jan 13. PMID: 25590503. [[PubMed](#)]



NTP Board of Scientific Counselors Draft Monograph on the State of Science vs. Meta-Analysis

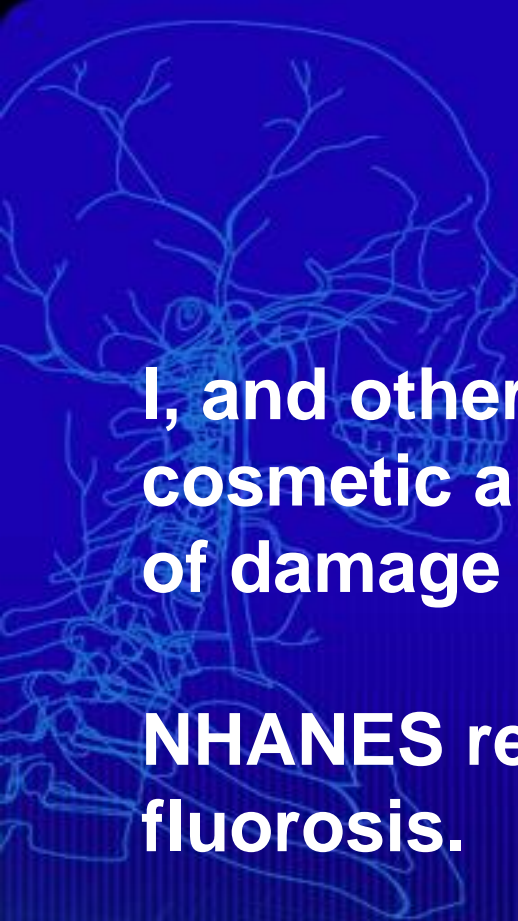
Concerning Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects:
A Systematic Review NTP Monograph Draft

In 2015, I Nominated Fluoride to the OHAT/NTP/BSC for
Developmental Neurotoxin, Cancer, and Thyroid Reviews.
Neurotoxin is just one of over 20 risks and known harm from fluoride.
Thank you NTP and OHAT team for 8 years of your lives to one risk.

May 2023

Bill Osmunson DDS, MPH

*Washington Action for Safe Water &
King County Citizens Against Fluoridation*



I, and other dentists, treat dental fluorosis a known cosmetic and functional harm, about 30 times more cost of damage than the alleged treatment prevented.

NHANES reported 2 out of 3 children have dental fluorosis.

Few dentists diagnose the harm, we simple treat the damage and paid to give even more fluoride.

EPA Scientists said “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.**"

[That is you and me when we protect the toxin]

-Dr. J. William Hirzy, Senior Vice-President, Headquarters Union,

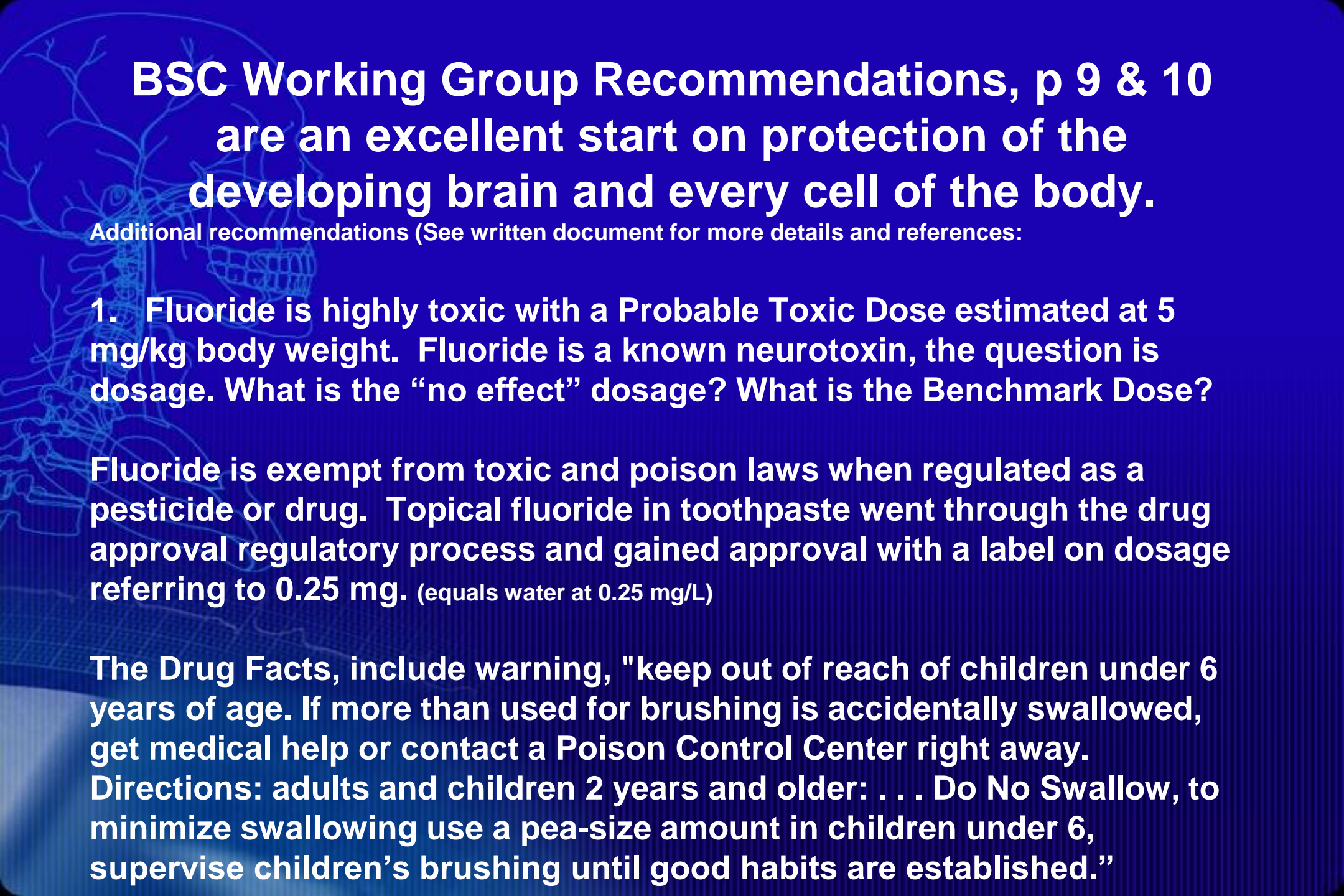
-US Environmental Protection Agency, March 26, 2001



May 1, 1999

WHY EPA'S HEADQUARTERS UNION OF
SCIENTISTS OPPOSES FLUORIDATION

See Handout.



BSC Working Group Recommendations, p 9 & 10 are an excellent start on protection of the developing brain and every cell of the body.

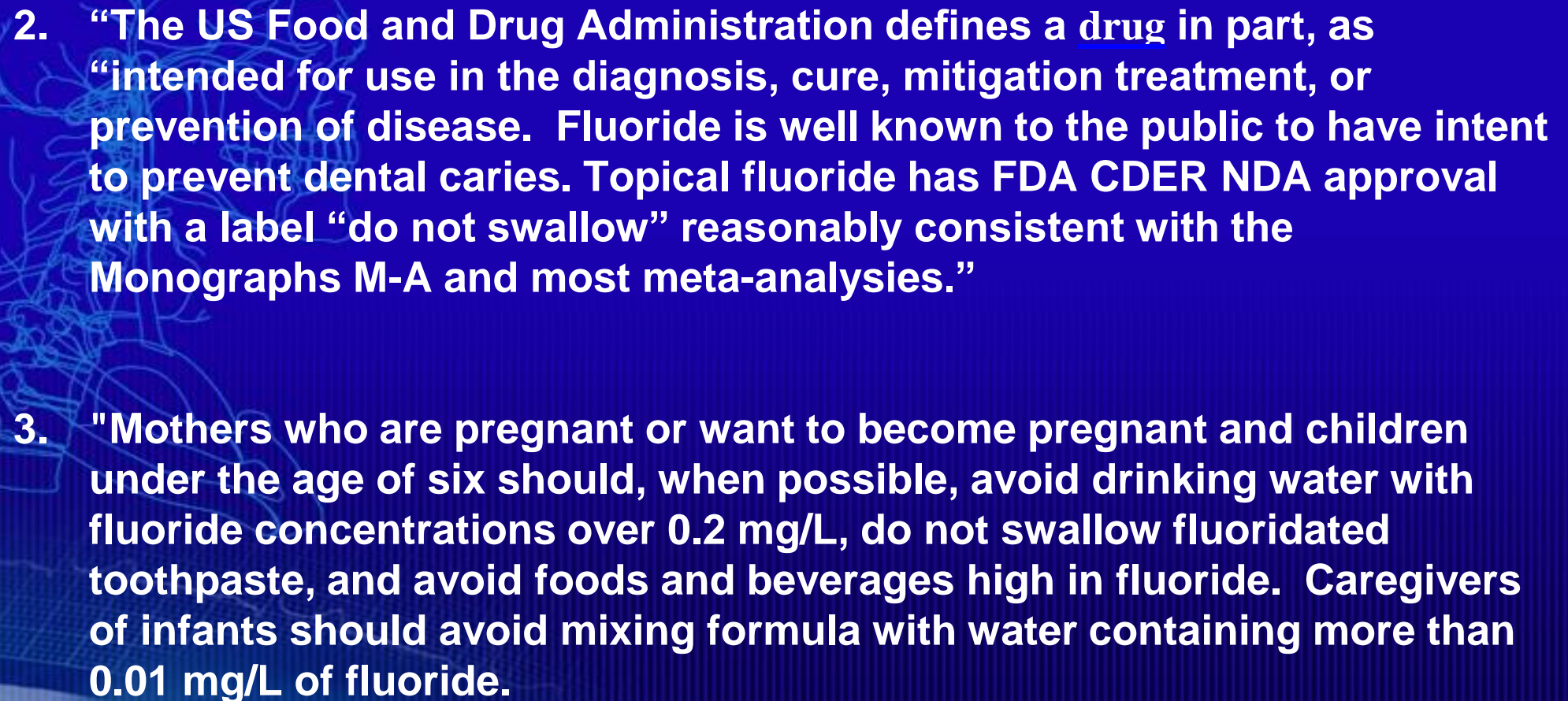
Additional recommendations (See written document for more details and references:

- 1. Fluoride is highly toxic with a Probable Toxic Dose estimated at 5 mg/kg body weight. Fluoride is a known neurotoxin, the question is dosage. What is the “no effect” dosage? What is the Benchmark Dose?**

Fluoride is exempt from toxic and poison laws when regulated as a pesticide or drug. Topical fluoride in toothpaste went through the drug approval regulatory process and gained approval with a label on dosage referring to 0.25 mg. (equals water at 0.25 mg/L)

The Drug Facts, include warning, "keep out of reach of children under 6 years 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 years and older: . . . Do No Swallow, to minimize swallowing use a pea-size amount in children under 6, supervise children’s brushing until good habits are established.”

- 
- 2. “The US Food and Drug Administration defines a drug in part, as “intended for use in the diagnosis, cure, mitigation treatment, or prevention of disease. Fluoride is well known to the public to have intent to prevent dental caries. Topical fluoride has FDA CDER NDA approval with a label “do not swallow” reasonably consistent with the Monographs M-A and most meta-analyses.”**
 - 3. "Mothers who are pregnant or want to become pregnant and children under the age of six should, when possible, avoid drinking water with fluoride concentrations over 0.2 mg/L, do not swallow fluoridated toothpaste, and avoid foods and beverages high in fluoride. Caregivers of infants should avoid mixing formula with water containing more than 0.01 mg/L of fluoride.**



4. the NTP recommend an uncertainty & intraspecific factor of 10.

NTP needs to protect more than just the statistical “mean.”

Some are chemically sensitive, don't excrete fluoride as well as the “mean.”

Some are ingesting too much other toxic chemicals.

Some drink 10 times as much water as the “mean” etc.

5. the NTP reconcile the disconnect or "disagreement" between the SoS as "safe" < 1.5 mg/L and the M-A data as "not safe" and the FDA at 0.25 mg as not safe, do not swallow.

Concentration is not dosage.

Another example, infant formula made with 1.5 mg/L fluoride in water is about 350 times higher dosage of a highly toxic unapproved drug than mother's milk. Mother's milk is not deficient in fluoride.

NTP and reviewers do not have significant objections to fluoride >1.5 mg/L in water as a developmental neurotoxin. Thus, the question is no longer whether fluoride is a known developmental neurotoxin but at what dosage. The M-A and FDA answer that question. Do not swallow.

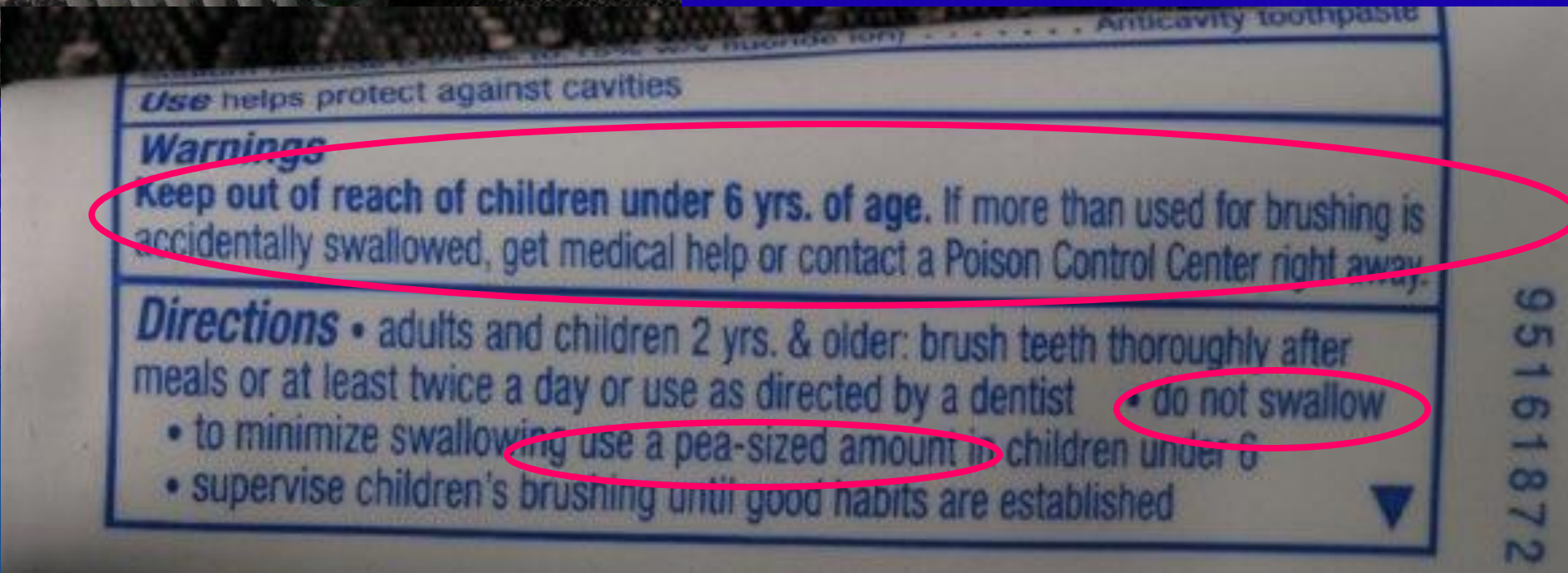


**Fluoride is a known developmental neurotoxin.
There is no lower limit.**

**And what percentage of the population with
developing brains have NTP and reviewers chosen
to protect? 50%, 90%, 100%?**



A pea size of toothpaste has 0.25 mg of F.
Similar to water at 0.125 mg/L assuming 1L/day and 50% exposure is from water. Close to the M-A



“Flexible language”, FDA

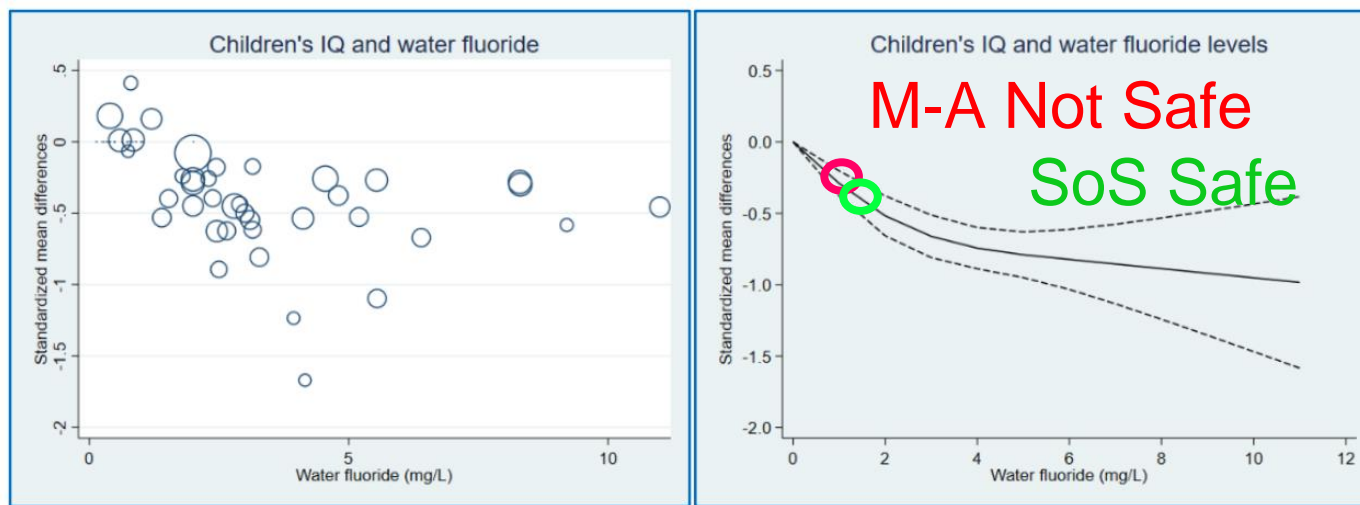
In 2002, the US Poison Control Centers reported 24,087 exposures involving toothpaste with fluoride. emedicine



Eight years since nomination

About \$1 trillion dollars in lost wages for those harmed

220 M fluoridated X 1.46% at each year of age X 8 years X 2 IQ loss X \$500/IQ lost X 40 work years = about \$1 Trillion loss.



eFigure 17. Pooled Dose-Response Association Between Fluoride in Water and Standardized Mean Differences in Children's IQ

SoS: reports moderate confidence when "total fluoride" exposure exceeds **1.5 mg/L** in water. p 82. Water is not "total exposure"

Few dispute fluoride above 1.5 mg/L fluoride concentration in water is a developmental neurotoxin. The dispute is total exposure and dosage.

M-A: "Conclusion. . . an inverse association between fluoride exposure and IQ."

"there was no obvious threshold for water" p 325

"decrease of 1.81 points . . . **per 1-mg/L** increase in urinary fluoride."

Food & Drug Administration (FDA)

For **SAFETY**: **“DO NOT SWALLOW”** (F Toothpaste)

For **EFFICACY**: **"NOT EFFECTIVE"** (F pills)

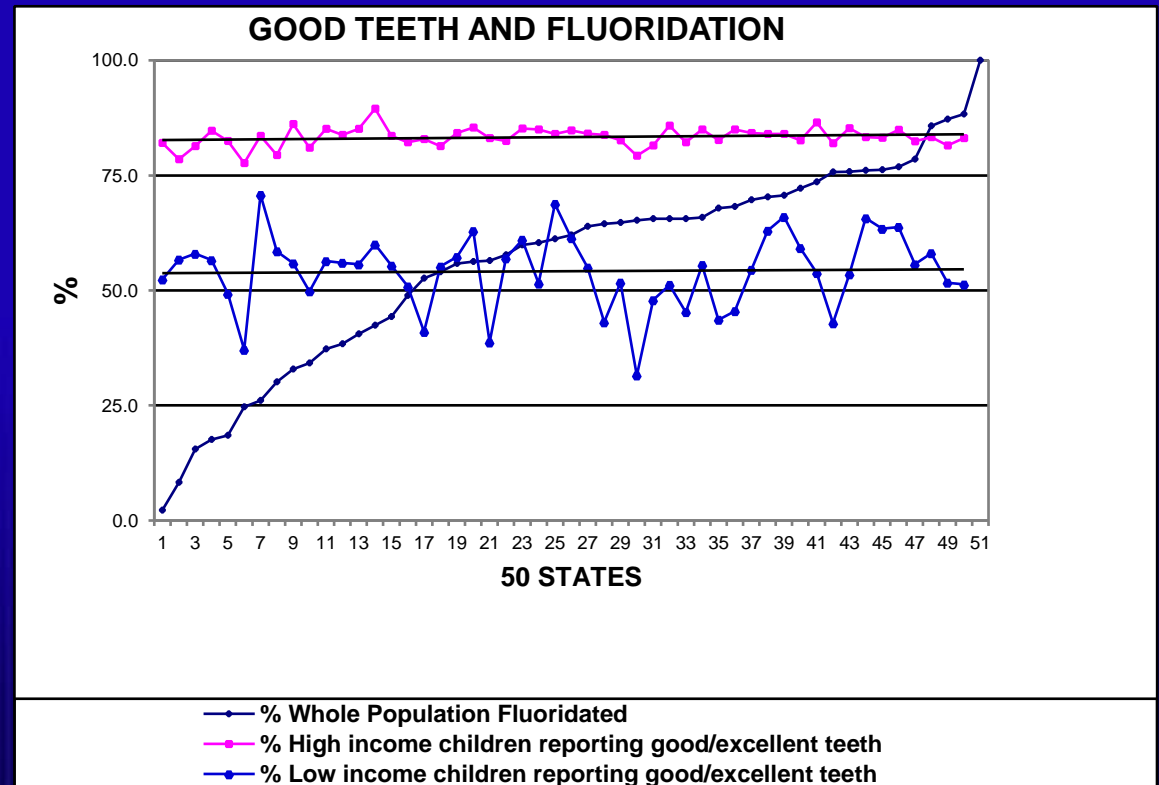
“...there is no substantial evidence of drug effectiveness as prescribed, recommended or suggested in its labeling. . . marketing is in violation of the new drug provisions of the Federal Food, Drug, and Cosmetic Act; they have, therefore, requested that marketing of these products be discontinued.”

FDA Letter to 35 Companies

DRUG THERAPY 1975

NTP used "pharmaceutical intervention" research for support of their meta-analysis,
"May 2023 page 275

Ranking the 50 US States on the percentage of their whole population fluoridated and plotting their reported good to excellent teeth, shows no significant common cause.



- Higher Income = Better Teeth

<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

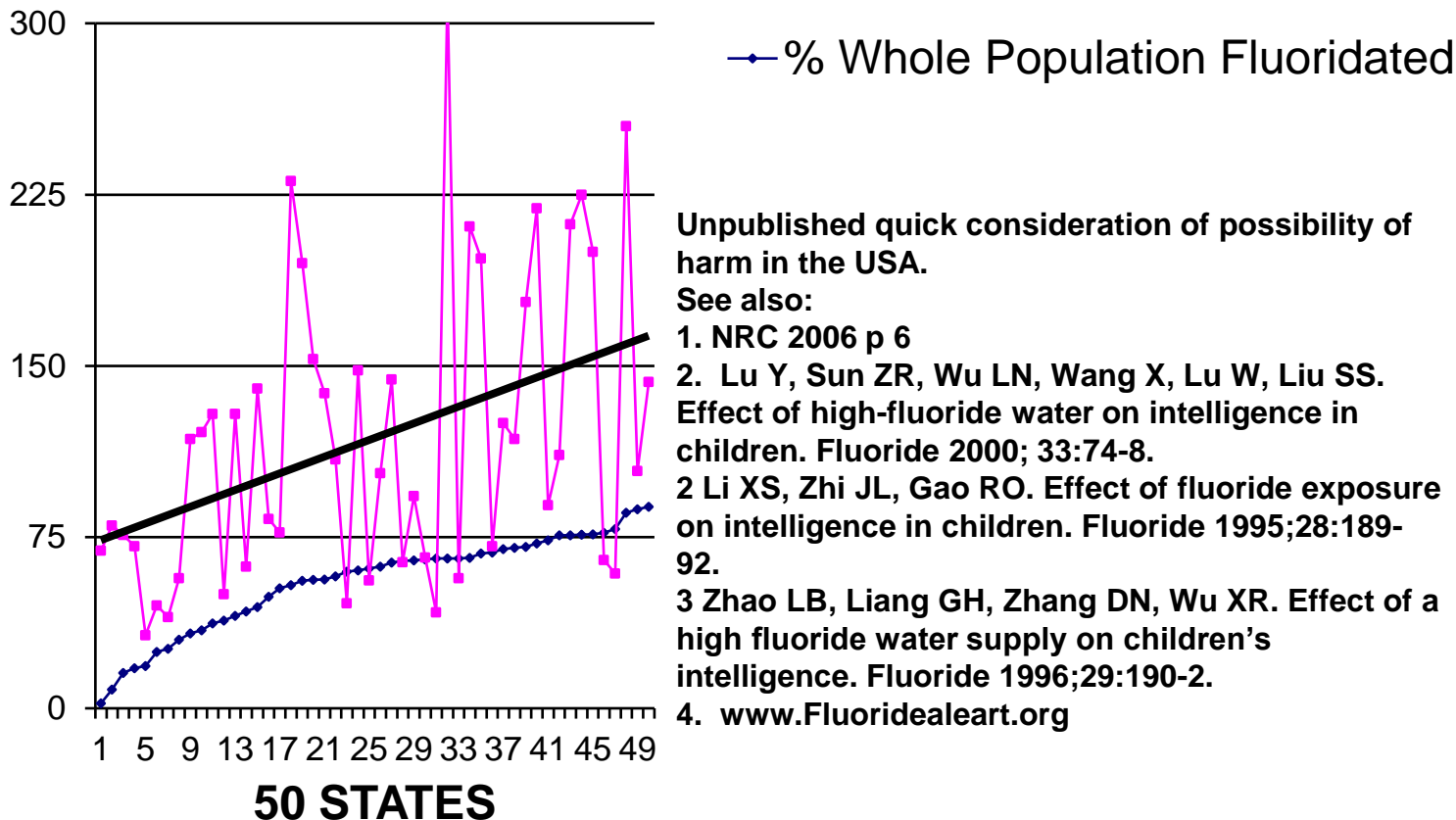
http://www.cdc.gov/oralhealth/waterfluoridation/fact_sheets/states_stats2002.htm <http://pubs.usgs.gov/circ/2004/circ1268/htdocs/table05.html>

MENTAL RETARDATION

6-17 YR OLD

AND FLUORIDATION 2008

More study on the USA population is needed.




Unpublished quick consideration of possibility of harm in the USA.

See also:

1. NRC 2006 p 6
2. 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.
4. www.Fluoridealert.org

<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>



Voters vote to add fluoride to their neighbors based on the marketing of authorities

The public will not read 700+ page Monographs

“ . . . Systematic review . . . require scientific judgments.” Monograph Forward

Judgment incorporates our past and must include all streams of evidence, not just developmental neurotoxicity.

2.

CONGRESS DEFINED *DRUGS*:

“Articles intended for use in the . . . prevention of disease” 21 USC 321 (g)(1)(B)

Intent of use determines regulatory oversight, not whether it is natural or artificial, and regardless of concentration or efficacy.

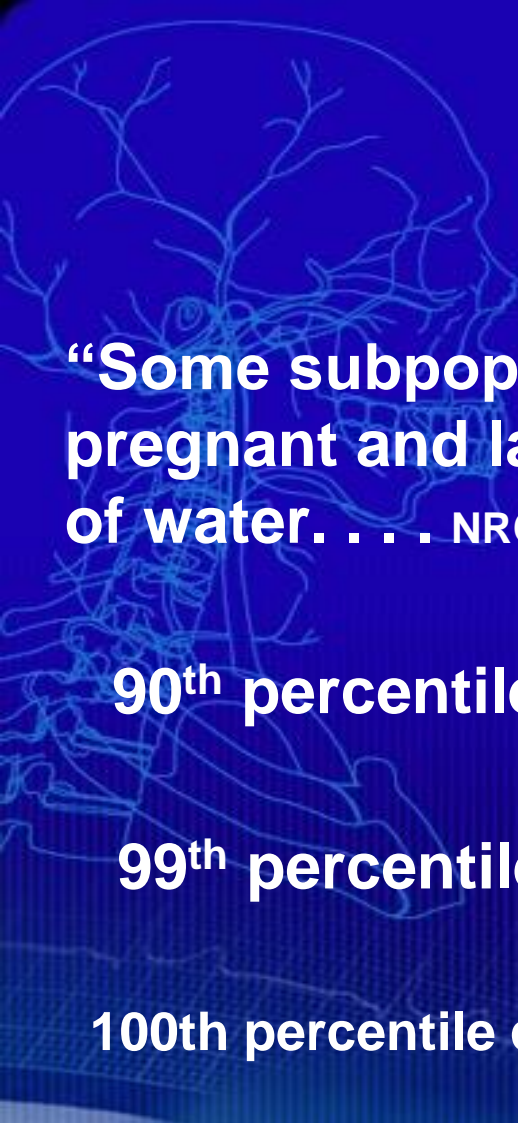
“Fluoride is a legend drug” WSBOH June 4, 2009

FDA testified to Congress that fluoride is a drug.

Congressional Investigation 2001

“The FDA, remains responsible for regulating the addition of drugs to the water supply for health care purposes.”

Steve Neugeboren, Ass. General Counsel, Water Law Office EPA 2/14/2013



Individual Dosage of Fluoride From Water is NOT Controlled.

“Some subpopulations (such as athletes, diabetics, laborors, pregnant and lactating mothers) consume much greater quantities of water. . . . NRC 2006 P 23

90th percentile consume 2.3 L/day or 1.4 mg F/day. NRC 2006 p 379

99th percentile consume 4.8 L/day or 3.4 mg F/day. NRC 2006 p 379

100th percentile consume over 10 L/day, or 7 mg/day from just water NRC 2006

There is no known lower limit

The claim: "All reputable public health agencies support fluoridation" is false.

97% of European governments and dental associations China, Israel, and Japan do not.

[Austria](#) REJECTED: "toxic fluorides" NOT added

[Belgium](#) REJECTED: encourages self-determination – those who want fluoride should get it themselves.

[Finland](#) STOPPED: "...do not favor or recommend fluoridation of drinking water. There are better ways of providing the fluoride our teeth need." A recent study found ..."[no indication of an increasing trend of caries...](#)"

[Germany](#) STOPPED: A recent study found [no evidence of an increasing trend of caries](#)

[Denmark](#) REJECTED: "...toxic fluorides have never been added to the public water supplies in Denmark."

[Norway](#) REJECTED: "...drinking water should not be fluoridated"

[Sweden](#) BANNED: "not allowed". No safety data available!

[Netherlands](#) REJECTED: Inevitably, whenever there is a court decision against fluoridation, the dental lobby pushes to have the judgment overturned on a technicality or they try to get the laws changed to legalize it. Their tactics didn't work in the vast majority of Europe.

[Hungary](#) STOPPED: for technical reasons in the '60s. However, despite technological advances, Hungary remains unfluoridated.

[Japan](#) REJECTED: "...may cause health problems...." The 0.8 -1.5 mg regulated level is for calcium-fluoride, not the hazardous waste by-product which is added with artificial fluoridation.

[Israel](#) SUSPENDED mandatory fluoridation until the issue is reexamined from all aspects.:
June 21, 2006 "The labor, welfare and health Knesset committee"

[China](#) BANNED: "not allowed"

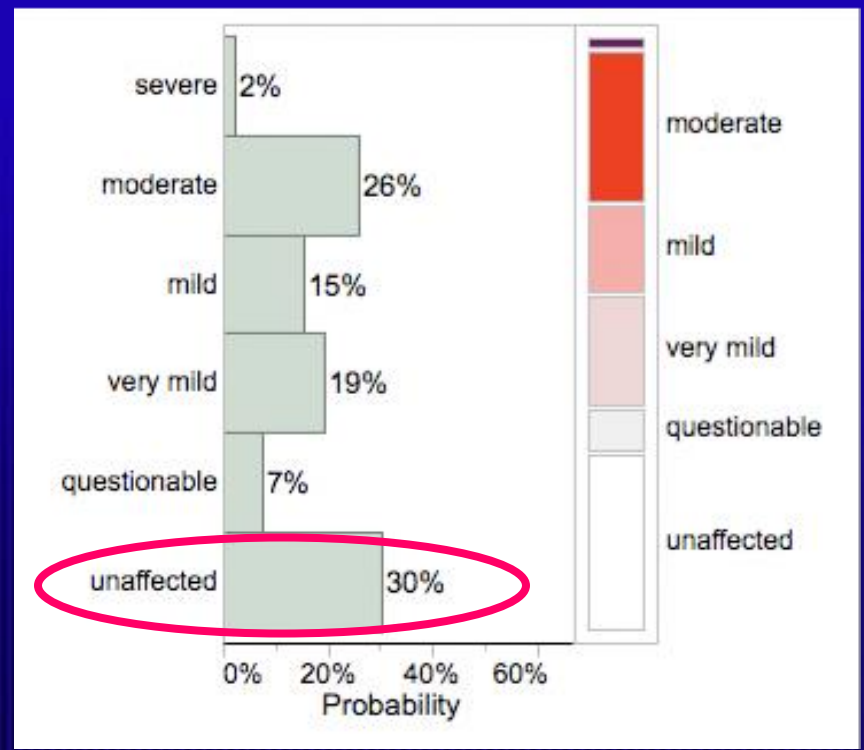
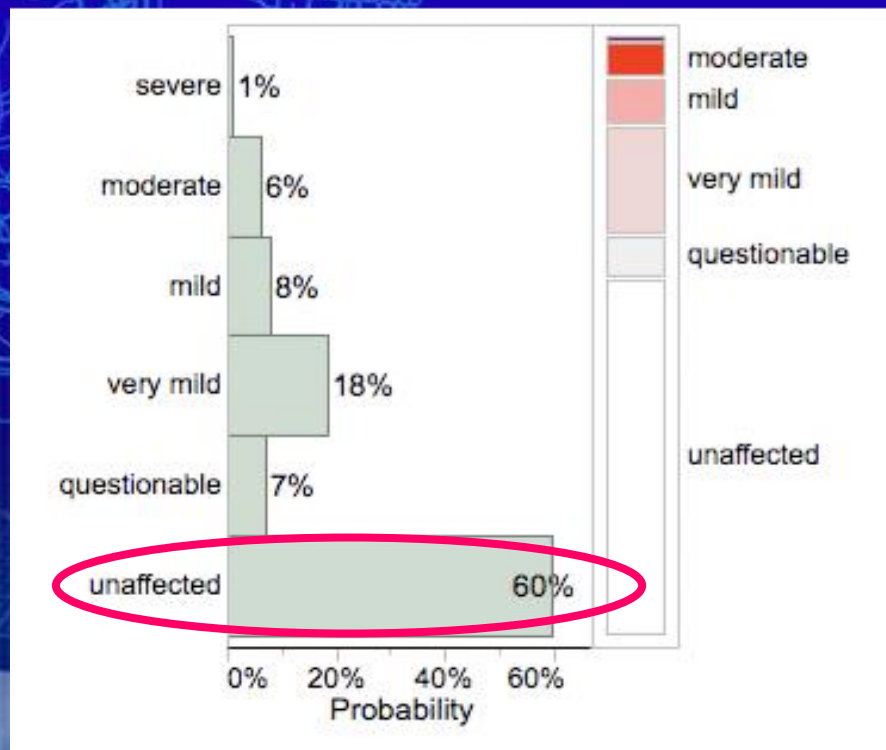
Most European dental associations no longer recommend fluoride supplements, along with the IABDM, IAOMT, AAEM, AAIM, and more.

3.

Many are Ingesting Too Much Fluoride HUGE INCREASES IN DENTAL FLUOROSIS

40% of children , NHANES 2000

60% NHANES 2012



70% dental fluorosis NHANES 2015-2016 (Dong 2021)

WHO

"Dental and Public health administrators should be aware of the total fluoride exposure in the population before introducing any additional fluoride program for caries prevention."

WHO (1994). Fluorides and Oral Health. WHO Technical Report Series 846.

"Estimation of the amount of fluoride ingested from all environmental and dietary sources is important so that rational and scientifically sound decisions can be made when guidelines for the use of fluorides are reviewed periodically and modified."

Pang D, et al. (1992). Journal of Dental Research 71: 1382-1388.

EPA

SDWA: “No national primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water.”

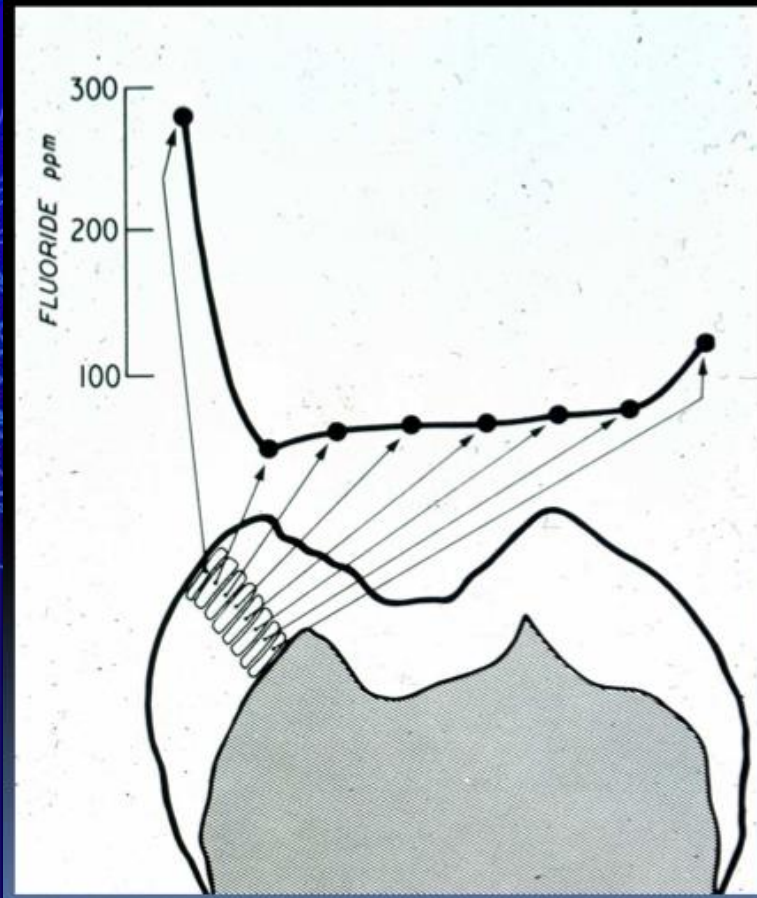
42 USC 300g-1(b)(11):

“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 “Optimal” fluoride tooth concentration
Has been determined.

Fluoride Rich Zone



Mechanism:

The enamel and dentin demonstrate significant transport hinderance.

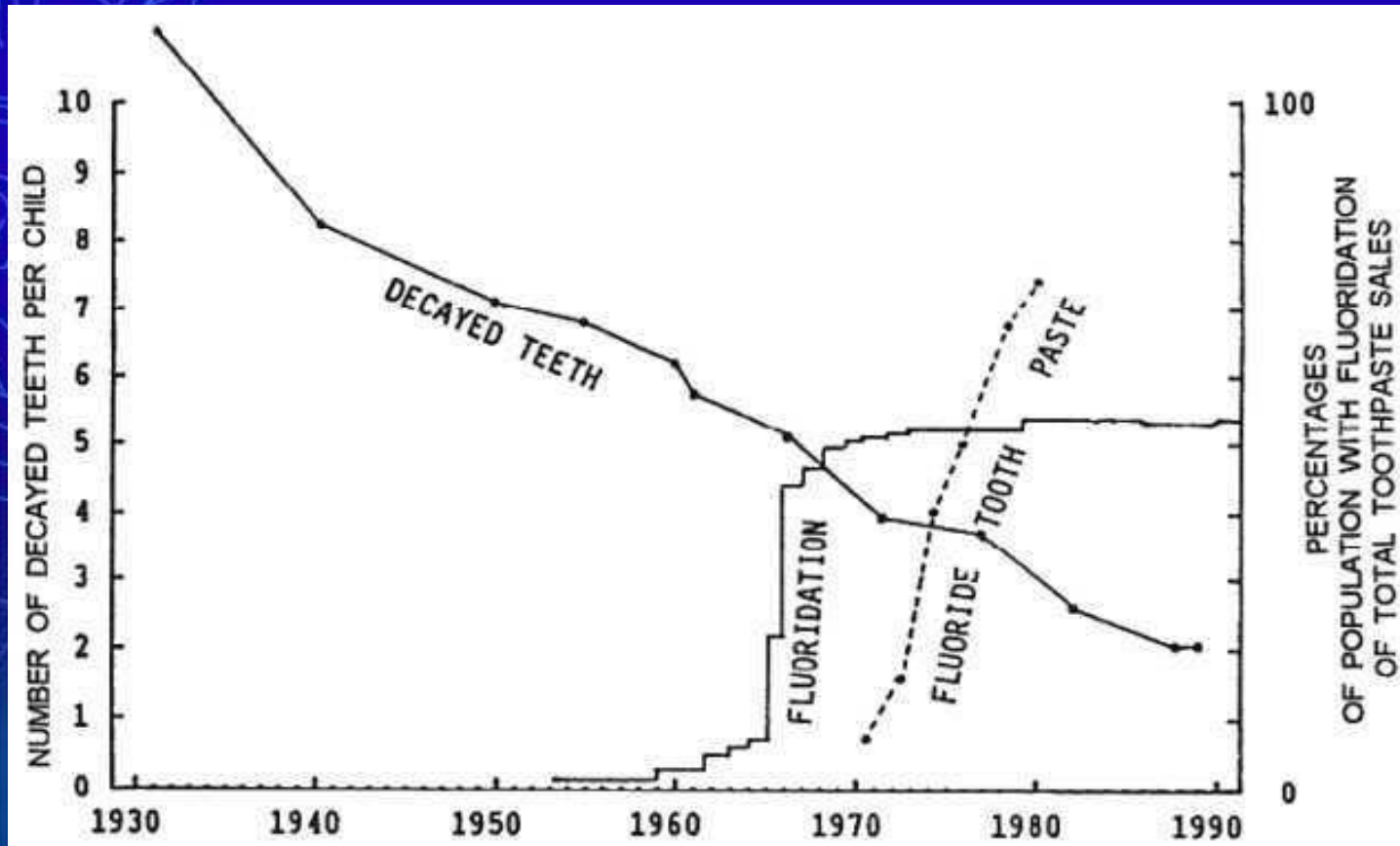
Fluoride in the pulp can't get to the tooth surface where the caries occur.

FLUORIDE EFFECTIVENESS RESEARCH IS INCOMPLETE

Study Limitations often include:

- 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 round 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 water.
- L. Dental treatment expenses not considered
- M. Mother's F exposure, Breast feeding and infant formula excluded
- N. Fraud, gross errors, and bias not corrected.
- O. Genetics not considered

Observational research does not control for the unknown(s) which crushed caries rates prior to the introduction of fluoridated water and toothpaste.



<http://www.fluoride-journal.com/98-31-2/312103-f.htm>
Colquhoun 1997 ISFR Published 1998



1. A number of recent cessation studies show that stopping fluoridation has no impact on overall dental decay.

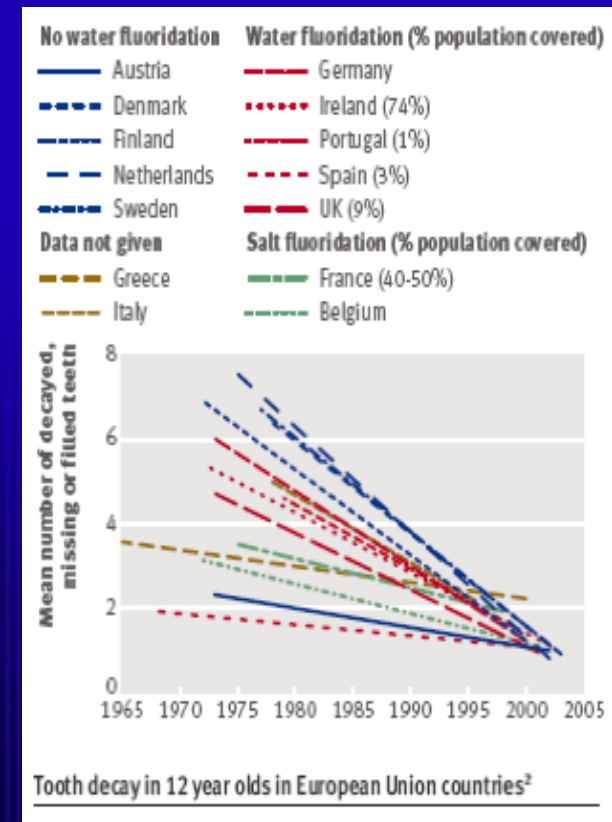
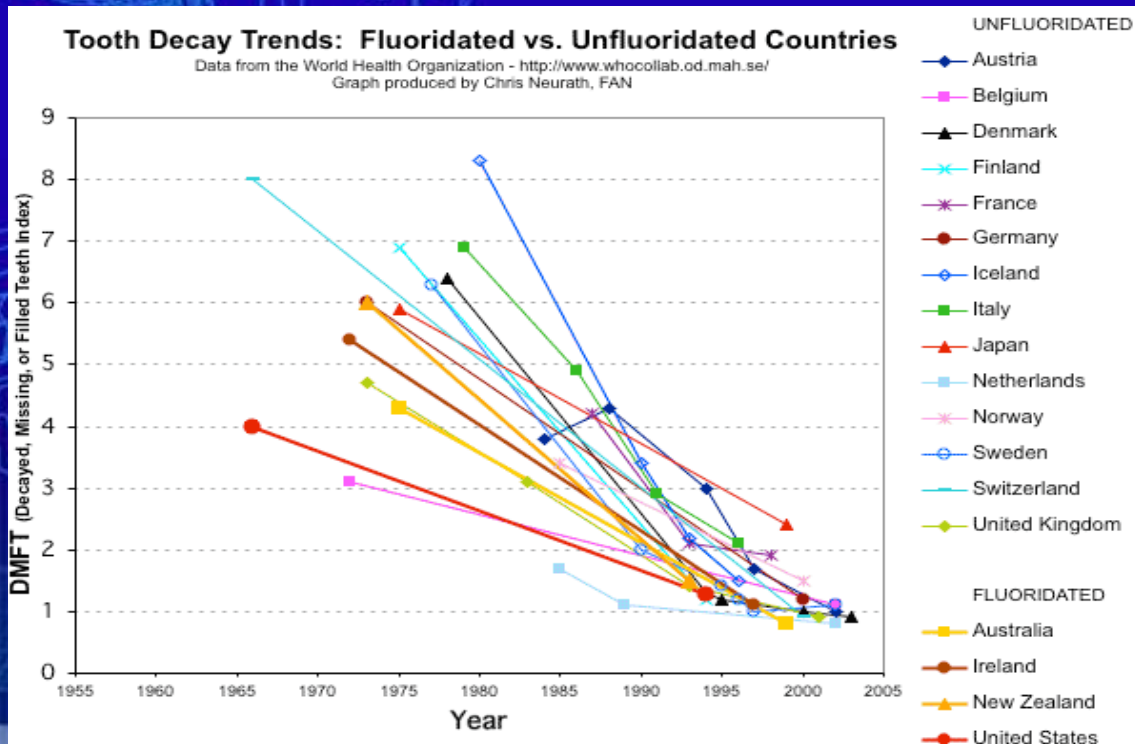
Komarek et al, A Bayesian analysis of multivariate doubly-interval-censored dental data, *Biostatistics* 2005 6 pp 145-155 Copy Available.

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

Fluoridation makes no difference in the incidence of tooth decay.



Fluoridated vs. Unfluoridated Countries.

Chen et al, BMJ 5 October 2007

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>



CDC: “Ingestion of fluoride is not likely to reduce tooth decay.”

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

A systematic review:

“The results show that the reviewed original studies on economic evaluation of caries prevention do not provide support for the economic value of caries prevention.”

Källestål C et al. Acta Odontol Scand. 2003 Dec;61(6):341-6.

Economic evaluation of dental caries prevention: a systematic review.



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

EPA

EPA does not regulate drugs.

The EPA has no “empirical scientific data on the effects of fluosilicic acid or sodium silicofluoride on health and behavior.”

Congressional Investigation 2001

“Natural” calcium fluoride does not easily dissolve.

www.atsdr.cdc.gov/tfacts11.html

FDA

FDA does not regulate public water.

NTP M-A

“there was no obvious threshold for water” p 325 Draft