Appendix I

ADVERSE EFFECT REPORT

The EPA (Environmental Protection Agency) professionals are correct and have not withdrawn their 2001 statement made through their union when they used judgment to weigh the benefits with risks: *"In summary, we hold that fluoridation is an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."*[1]

FLUORIDATION IS NOT SAFE AND CAUSES AND CONTRIBUTES TO HARM

The EPA has no empirical data on the effects of fluosilicic acid or silicofluorides on health and behavior.[2] No federal or state health agency has evaluated silicofluorides on health and behavior. The absence of safety data is neither proof of harm nor proof of safety; however, it is incumbent on those removing individual freedom with the use of police powers to provide the highest level of confidence and evidence for safety.

The EPA determines maximum levels of contaminants (MCL) which are permitted in water. To ensure these levels are safe, Congress has mandated an independent review of the EPA standards every 10 years. The EPA requested the NRC to review its maximum contaminant level (MCL) standard to meet Congressional requirements.

In 2006, after three years of review, the NRC unanimously agreed in a 500-page report that 4 ppm of fluoride in water is too high to be protective of human health and that the EPA needs to determine a new safe MCL level. (Contact me if you want a copy.) In order to evaluate 4 ppm, the NRC committee looked at risks from fluoride at much lower levels than 4 ppm. The NRC committee was prohibited from evaluating the practice of fluoridation.[3]

> Robert J. Carton PhD, an EPA environmental scientist, commented on the NRC report and said, *"Fluoride in Drinking Water was misdirected by EPA management and the committee identified only adverse health effect known with total certainty: rather than to the intent of the Safe Drinking Water Act which requires the EPA to determine 'whether any adverse effects can be reasonably anticipated, even though not proved to exist.' The NRC review includes extensive information on other possible health effects of fluoride, such as endocrine effects and effects on the brain. On the basis of this information and the proper interpretation of the SDWA, the following are all adverse health effects: moderate dental fluorosis, stage I skeletal fluorosis (arthritis with joint pain and stiffness), decreased thyroid function, and detrimental effects on the brain, especially in conjunction with aluminum. The amount of fluoride necessary to cause these effects to susceptible members of the population is at or below the dose received from current levels of fluoride recommended for water fluoridation. The recommended Maximum Contaminant Level Goal (MCLG) for fluoride in drinking water should be zero".*[4]

Even though the NRC was misdirected, the "committee concluded unanimously with over 500 pages of evidence that the present MCLG of 4 mg/L for fluoride should be lowered."[5] The margin of safety between adding fluoride to 1 ppm and as yet an undetermined level somewhere below 4 ppm is not adequate. 4 years later and the EPA has not lowered the MCLG level.

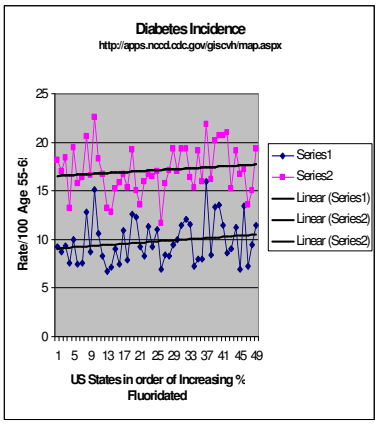
Some of the concerns raised by the NRC 2006 report include:

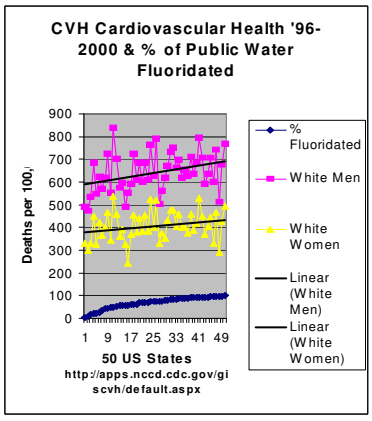
1. Dental Effects: *"The damage to teeth caused by severe enamel fluorosis is a toxic effect that is consistent with prevailing risk assessment definitions of adverse health effects. . . occurs at an appreciable frequency, approximately 10% on average,. . . at or near current MCLG of 4 mg/L."*[6] The variation of exposure does not permit an adequate factor for safety.

2. Bone Fractures: *"Overall, there was consensus among the committee that there is scientific evidence that under certain conditions fluoride can weaken bone and increase the risk of fractures."*[7] Bone fractures in the elderly are difficult to heal and frequently result in premature death.

3. Endocrine Effects: *"The chief endocrine effects of fluoride exposures in experimental animals and in humans include decreased thyroid function, increased calcitonin activity, increased parathyroidhormone activity, secondary hyperparathyroidism, impaired glucose tolerance, and possible effects on timing of sexual maturity. Some of these effects are associated with fluoride intake that is achievable at fluoride concentrations in drinking water of 4 mg/L or less, especially for young children or for individuals with high water intake."*[8]

   Synthroid, a medication to treat decreased thyroid function, has been reported as the 5th most commonly prescribed drug in the USA. Ranking the US states in order of the percentage of the whole population fluoridated, both diabetes and cardiovascular heart disease increase with the increase in percentage of the population fluoridated, supporting the NRC concern.



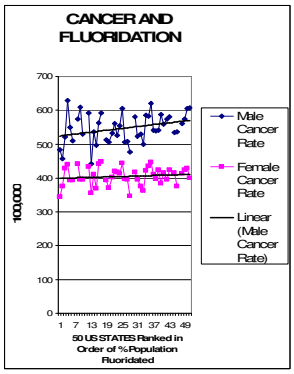


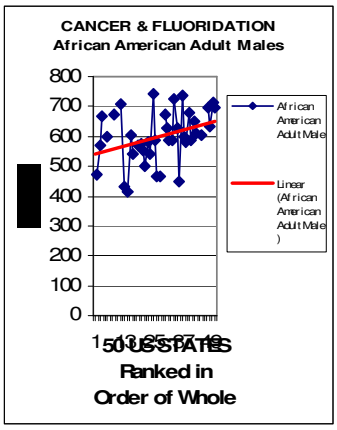
4. Effects on Other Organ Systems: *"A potentially susceptible subpopulation comprises individuals with renal impairments who retain more fluoride than healthy people do."*[9] The National Kidney Association has withdrawn their support of fluoridation.

5. Genotoxicity and Carcinogenicity: *"Overall, the results are mixed, with some studies reporting a positive association and others no association."*[10]

Mixed reports are certainly not evidence of safety. A recent peer-reviewed study from the Harvard School of Dental Medicine reported a strong association between water fluoridation and adolescent male cancer of bone supporting two previous studies.[11] It appears subsets of the population are at risk. When the entire population without looking at subsets of the population is used in a study or when the study is funded by fluoride manufacturers, an association is not always found.

When ranking the states in order of the percentage of whole population fluoridated, an increase in cancer is seen in more highly fluoridated states, again support for the NRC concerns (see graphs below). Comparing osteosarcoma rates and fluoridation rates in countries such as Indonesia and Kenya also finds a significant relationship between fluoride and cancer.





A distinct increase in cancer can be found in more highly fluoridated states, especially for subpopulations such as African American males[12]

A few words from the President's Council:

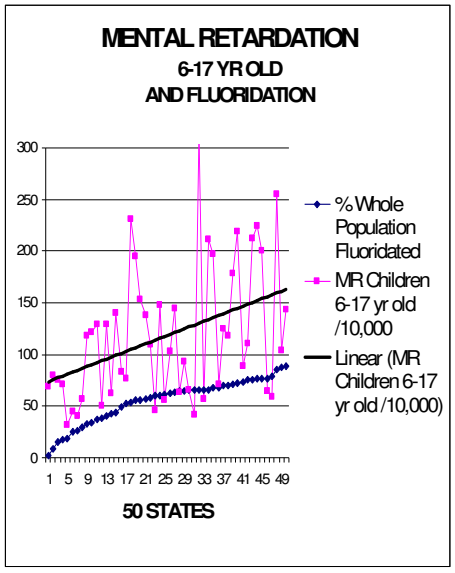
> "Regulation of Environmental Contaminants
>
> The prevailing regulatory approach in the United States is reactionary rather than precautionary. That is, instead of taking preventive action when uncertainty exists about the potential harm a chemical or other environmental contaminant may cause, a hazard must be incontrovertibly demonstrated before action to ameliorate it is initiated. Moreover, instead of requiring

industry or other proponents of specific chemicals, devices, or activities to prove their safety, the public bears the burden of proving that a given environmental exposure is harmful. Only a few hundred of the more than 80,000 chemicals in use in the United States have been tested for safety.

U.S. regulation of environmental contaminants is rendered ineffective by five major problems: (1) inadequate funding and insufficient staffing, (2) fragmented and overlapping authorities coupled with uneven and decentralized enforcement, (3) excessive regulatory complexity, (4) weak laws and regulations, and (5) undue industry influence. Too often, these factors, either singly or in combination, result in agency dysfunction and a lack of will to identify and remove hazards."[1]

6. A very disturbing aspect of the NRC report is the effect of fluoride on the brain. A lowering of IQ by eight to 10 points[13] and an increase in mental retardation[14] are confirmed by comparing the US states ranked in order of whole population on fluoridated water[15] To date 22 studies have found increases in mental retardation or decreases in IQ with increased fluoride exposure. (see graph below).

"The consistency of the results appears significant enough to warrant additional research on the effects of fluoride on intelligence."[16] *"Fluorides also increase the production of free radicals in the brain . . . the possibility that fluorides act to increase the risk of developing Alzheimer's disease."*[17]



[1] The 2008-9 Annual Report, President's Cancer Panel, "Reducing Environmental Cancer Risk, What We Can Do Now" US DHHS, NIH, NCI, http://deainfo.nci.nih.gov/advisory/pcp/pcp08-09rpt/PCP_Report_08-09_508.pdf

7. The NRC found possible effects on timing of sexual maturity. *"Further research is needed"*[18]

8. *"Fluoride is therefore an endocrine disruptor in the broad sense of altering normal endocrine function or response. . . direct stimulation or inhibition of hormone . . . indirect stimulation or inhibition of hormone secretion. . ."*[19]

9. Rheumatoid or osteoarthritis like pain, Preclinical and 3 clinical stages of Skeletal Fluorosis *"More research is needed to clarify the relationship"*,[20]

On dental fluorosis the CDC concludes: *"Between 1999 and 2004, approximately 41% of adolescents aged 12 to 15 and 36% aged 16 to 19 years had enamel fluorosis. Moderate and severe fluorosis was observed in less than 4% in both age groups."*[21]

Dental fluorosis is a known risk of excess fluoride ingestion. Although some consider dental fluorosis simply to be cosmetic, cosmetic damage is still considered damage and can be costly to repair. The surge in "cosmetic dentists" is one indication. At a fluoridation level of 1 ppm, an estimated 12.5% (95% confidence) find cosmetic damage objectionable.[22] Sometimes minor dental fluorosis can be fixed for just a few hundred dollars, and replacements every five to 10 years do not add up to lifetime costs of more than a few thousand dollars. However, more and more patients want high-quality corrections costing tens of thousands of dollars, and a lifetime cost of $100,000 is not unusual. Various ADA estimates suggest 10% to 15% of those on water fluoridation will get dental fluorosis from water fluoridation.

See fluorosis below left picture and repairs at $1,200 per tooth below right:

10. The Nuremberg Code prohibits experimentation on patients without their consent or knowledge. All medical treatments are experimental in nature. The practice of medicine is called "practice" because we should never be so arrogant as to assume we have the "perfect" treatment. Fluoridation must still be considered experimental.

11. Fluoridation does not abide by Title 45 Federal Code which includes to *". . . provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."*

12. *"No informed consent . . . may include any exculpatory language through which the subject . . . is made to waive or appear to waive any of the subject's legal rights. . . the sponsor, the institution or its agents from liability for negligence."*[23]

13. The Human Subjects Review Committee of the University of Washington has set up good guidelines, which generally have been ignored by public health agencies and officials. However, the guidelines apply to the fluoridation experiment. *"Human subjects asked to contribute their time and effort to research should consent to do so freely. The consent should be given only after the subject understands what he or she is consenting to, and any risks that may be involved. Subjects should be assured that there will be no penalties for declining to participate, and that they are free to withdraw from the research at any time after they have given their initial consent."*[24] See also http://www.fluoridealert.org/health/brain/#human.

14. Neither the Food and Drug Administration (FDA) nor the Environmental Protection Agency (EPA) has responsibility for the addition of fluoride compounds to water (the chemicals, toxicity, efficacy, or risks). The EPA is *"prohibited and lacks authority to require the addition of anything for the treatment of humans,"*[25] and the only purpose of the addition of fluoride to water is for the mitigation and treatment of disease in humans and as such is considered a DRUG by the FDA.[26] Drugs are the responsibility of the (FDA);[27] however, the FDA is deferring regulatory action.

The Washington Department of Health claims only to provide information and does not fluoridate water. The fluoride "hot potato" is passed around and the ultimate responsibility lies with the Washington Board of Pharmacy which has abrogated the responsibility of protecting the public health in failing to follow Washington Code. The Board of Health must not leave the public in harm.

15. Fluoridation violates the principle of the ANSI/NSF testing protocol #60[28] standard, the purpose of which *"is to limit the amount of impurities that a single additive may introduce into the water to no more than 10% of the U.S. federal limit."*[29]

The CDC recommendations of 0.7 to 1.2 ppm fluoride exceeds by over 250% the current U.S. federal EPA limits of fluoride as determined by ANSI/NSF testing protocol #60 standard (as well as lead and arsenic of "0"). The current MCLG of fluoride has been rejected in 2006 by the National Research Council (NRC) as too high.[30]

The NSF (National Sanitation Foundation) does not evaluate safety of the chemicals added to water for the purpose of the treatment or mitigation of disease in humans,[31] nor does it evaluate the named ingredient(s). The NSF evaluates the impurities in the product. (For example, the NSF evaluates how much aluminum is in the fluoride substance to make sure the product will not exceed 10% of EPA MCL levels. The NSF does not evaluate whether the product itself, fluoride, exceeds 10% of the EPA MCL levels.)

16. The weight of scientific evidence in opposition to fluoridation is rapidly growing,[32] and fluoridation in the not too distant future will be consigned to medical history[33] either by good judgment or litigation.[34] Based on the weight of evidence, the Canadian Association of Physicians for the Environment is now in opposition to fluoridation and state, *". . . we believe that fluoridation of drinking water is scientifically untenable, and should not be part of a public health initiative or program."*[35]

17. After 60 years of knowing fluoridation is 250 times the concentration of fluoride in mother's milk, the American Dental Association (ADA) now quietly recommends fluoride-free water for infant formula. Within a few days the CDC followed the ADA, and a few days later the Oregon Department of Human Services followed the ADA and CDC. Although many follow the ADA's lead, the ADA testified in court, *"Dissemination of information relating to the practice of dentistry does not create a duty of care to protect the public from potential injury."*[36]

It is unwise for governments to rely on a non-profit professional association with no duty to protect the public health to determine the safety or efficacy of substances.

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[1] Dr. J. William Hirzy, Senior Vice-President, Headquarters Union, US Environmental Protection Agency, March 26, 2001
[2] Robert Thurau, Chief, Treatment Technology Evaluation Branch, Water Supply and
Water Resources Division EPA Office of Research and Development
11/16/2000 letter to Roger Masters http://www.dartmouth.edu/~rmasters/AHABS
[3] http://www.cdc.gov/fluoridation/safety/reducing_risk.htm
[4] Robert J Carton Guest editorial review Fluoride 39(3)163-172 July-September 2006, Review of the 2006 United States National Research Council Report: Fluoride in Drinking Water
[5] NRC 2006 Fluoride in Drinking Water: A Scientific Review of EPA's Standards; Summary p.2.
[6] NRC 2006 Fluoride in Drinking Water: A Scientific Review of EPA's Standards; Summary p.5
[7] NRC 2006 Fluoride in Drinking Water: A Scientific Review of EPA's Standards; Summary p.6.
[8] NRC 2006 Fluoride in Drinking Water: A Scientific Review of EPA's Standards; Summary p.7.
[9] NRC 2006 Fluoride in Drinking Water: A Scientific Review of EPA's Standards; Summary p.7.
[10] NRC 2006 Fluoride in Drinking Water: A Scientific Review of EPA's Standards; Summary p.8.
[11] Cohn PD. A brief report on the association of drinking water fluoridation and the incidence of osteosarcoma among young males. New Jersey Dept. of Health, Nov. 8, 1992. Takahashi K, Akiniwa K, Narita K. Regression analysis of cancer incidence rates and water fluoride in the USA based on IACR/IACR (WHO) data (1978-1992). J Epidemiol 2001; 11:170-9. Bassin EB, et al. Age specific fluoride exposure in drinking water and osteosarcoma. Cancer Causes Control. 2006;17:421-28.
[12] http://apps.nccd.cdc.gov/nohss/FluoridationV.asp, www.cdc.gov/cancer/npcr/uscs/pdf/2002_USCS.pdf
http://apps.nccd.cdc.gov/nohss/FluoridationV.asp, http://pubs.usgs.gov/circ/2004/circ1268/htdocs/table05.html
[13] 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.
[14] 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
[15] 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
[16] NAS 2006 p6
[17] NAS 2006 p 186
[18] NRC 2006 p.26
[19] NRC p. 223
[20] NAS 2006 p 24
[21] ***Prevalence of Enamel Fluorosis Among 12-19 Year-Olds, U.S., 1999-2004***
http://iadr.confex.com:80/iadr/2007orleans/techprogram/abstract_92598.htm
Table below presents percentages (standard errors) and prevalence of fluorosis, including very mild or higher severity.

Cycle:	1999-2000		2001-2002		2003-2004		1999-2004	
Age:	12-15	16-19	12-15	16-19	12-15	16-19	12-15	16-19
Unaffected & questionable	60.63 (4.66)	66.25 (4.32)	65.95 (3.18)	70.57 (3.33)	51.58 (3.78)	55.10 (4.59)	60.12 (2.28)	64.55 (2.40)
Very Mild	26.17 (2.99)	21.16 (2.94)	24.82 (2.62)	20.63 (2.32)	34.58 (2.65)	31.96 (3.75)	27.98 (1.61)	24.10 (1.76)
Mild	8.67 (1.49)	6.98 (0.84)	6.57 (1.14)	6.47 (1.05)	10.31 (1.57)	9.67 (0.88)	8.34 (0.81)	7.58 (0.53)
Moderate & severe	4.53 (1.22)	5.61 (1.44)	2.66 (0.40)	2.33 (0.61)	3.52 (0.85)	3.27 (0.94)	3.56 (0.51)	3.78 (0.64)
Prevalence	39.37 (4.66)	33.75 (4.32)	34.05 (3.18)	29.43 (3.33)	48.42 (3.78)	44.90 (4.59)	40.60 (2.23)	36.29 (2.45)

[22] . BMJ 2000 October 7 McDonagh MS et al.

[23] http://www.washington.edu/research/hsd/hsdman4.html
[24] http://www.washington.edu/research/hsd/hsdman4.html
[25] (SDWA Section 1412 (b)(11) ; see also Carton, Robert J.; Review of the 2006 United States National Research Council Report: Fluoride in Drinking Water, Fluoride 39(3)163-172, July-September 2006
[26] House Hearings 2001
[27] FDA House hearings 2001
[28] State of Washington Department of Health 2/1/07 Dr. Osmunson – Summary of Requests March 30, 2006 to Feb. 1, 2007, Appendix B
[29] Response of Cheryl Luptowski 2/8/07 luptowski@nsf.org Response "B", NSF does not evaluate fluoridation products to pharmacy/drug purity or to their dietary products standards, but to the lowest Drinking Water Treatment Chemical Certification Program. However, fluoride compounds do not treat water to make it safer.
Currently the Department adds fluoride to about 1 ppm of fluoride, the current EPA MCL is 2 ppm and 10% of 2 ppm is 0.2 ppm, 500%. MCLG is 4 ppm and NSF/ANSI limits of 10% of 4 ppm would permit a maximum of 0.4 ppm of fluoride and be 250% above NSF standards.
[30] www.nap.edu/catalog/11571.html; Fluoride in Drinking Water: A Scientific Review of EPA's Standards 2006
[31] Letter to Bill Osmunson 2/1/07 from WSDH said, "we enforce a provision of our regulations that requires additives to drinking water be safe, as judged by a third-party testing organization. Usually, the National Sanitation Foundation (NSF) provides this sanctioned service under the ANSI/NSF testing protocol #60 (NSF-60) for drinking water additives." The NSF responded, "Our dietary supplements group has no involvement in testing products that are intended for use in drinking water applications. . . The purpose of the standard (NSF-60) is to limit the amount of impurities that a single additive may introduce into the water to no more than 10% of the U.S. federal limit."
[32] www.nap.edu/catalog/11571.html; Fluoride in Drinking Water: A Scientific Review of EPA's Standards 2006
[33] Dr. Arvid Carlsson, Winner, Nobel Prize for Medicine (2000).
[34] [34] CDC/ADA estimate dental fluorosis from fluoridation at between 18 to 25 million Americans. "Cosmetic" damage is whether repaired or not is still damage and a sign of excess fluoride for that individual.
[35] http://fluoridealert.org/cape.html
[36] The Superior Court of the State of California Case No. 718228, Demurrer (October 22, 1992)

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