April 12, 2005

Response to testimony given by Richard Maas, PhD, MSPH, MS in Oregon Senate on April 4, 2005 on Fluoridation

(as per Fax dated April 8, 2005 from Myers OR Dental Assn)

By

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Summary:

The negligible amounts of lead and arsenic in water fluoridated with fluorosilicic acid are considerably lower than as described by Richard Maas and provide no evidence of risk to health. Maas ignores that the majority of fluoridated water samples have shown no evidence of lead or arsenic and further uses typical adult water consumption values when discussing children under 5 years of age. Maas's extrapolations to large populations are based on incorrect assumptions. With the benefit accrued from water fluoridation in reducing the burden of dental caries, and the lack of credible evidence of harm or potential harm, there is no justification for changing the public health policy of water fluoridation.

1. Statement by Richard Maas:

EPA's "Action Level" for lead in drinking water of 15 parts per billion (ppb) (which is the same as μg/L) is NOT a health-based standard.

Response by Howard Pollick:

There is evidence from California's Proposition 65 that this action level is health-based. According to Prop 65 regulations it has been determined that oral exposure to 15 micrograms/day of Lead and 10 micrograms/day of Arsenic poses no significant risk. (Title 22, California Code of Regulations. ARTICLE 7. NO SIGNIFICANT RISK LEVELS. Section 12705. Specific Regulatory Levels Posing No Significant Risk. (b).(1). November 2004)
http://www.oehha.ca.gov/prop65/law/pdf_zip/RegsArt7.pdf)

The Action Level for lead has been set at 15 parts per billion (ppb) because EPA believes, given present technology and resources, this is the lowest level to which water systems can reasonably be required to control this contaminant should it occur in drinking water at their customers' home taps. These drinking water standards and the regulations for ensuring these standards are met, are called National Primary Drinking Water Regulations. All public water supplies must abide by these regulations. (Reference: Accessed at
http://www.epa.gov/safewater/contaminants/dw_contamfs/lead.html)

2. Statement by Richard Maas:

EPA's Health-based standard is reflected by their Maximum Contaminant Level Goal (MCLG) which is set at zero ppb in recognition of the fact that ANY amount of lead exposure causes some permanent neurological damage to a child.

Response by Howard Pollick:

There is the implication in that statement that there is evidence that even the slightest trace of lead causes such damage, whereas that has not been established.

In 1974, Congress passed the Safe Drinking Water Act. This law requires the U.S. Environmental Protection Agency (EPA) to determine safe levels of chemicals in drinking water which do, or may, cause health problems. These non-enforceable levels, based solely on possible health risks and exposure, are called Maximum

Contaminant Level Goals (MCLGs).
The MCLG for arsenic and lead have been set at zero because EPA believes this level of protection would not cause any of potential health problems. Since lead contamination generally occurs from corrosion of household lead pipes, it cannot be directly detected or removed by the water system. Instead, EPA is requiring water systems to control the corrosiveness of their water if the level of lead at home taps exceeds an Action Level.

3. Statement by Richard Maas:

Recent medical studies (e.g. Canfield et al. New England Journal of Medicine, 2003) show that even the CDC's now antiquated standard of a 10 µg/dL Blood Lead Level (BLL) is associated with a 7.4 point IQ deficit!

Response by Howard Pollick:

In 1990, the U.S. Department of Health and Human Services established a national goal to eliminate Blood Lead Levels (BLLs) >25 µg/dL by 2000; a new goal targets elimination of BLLs >10 µg/dL in children aged <6 years by 2010."

Canfield et al (Canfield RL, Henderson CR Jr, Cory-Slechta DA, Cox C, Jusko TA, Lanphear BP. Intellectual impairment in children with blood lead concentrations below 10 microg per deciliter. N Engl J Med. 2003 Apr 17;348(16):1517-26.) found that blood levels below the goal of 10 µg/dL (0.1 ppm) of lead in blood may be of consequence in lowering IQ. Canfield et al estimated a loss of 7.4 points on the IQ scale as a result of going from one to 10 µg/dL of lead in blood. (later revised to 6.3 – Jusko TA, Canfield RL, Henderson CR Jr, Lanphear BP. Comments on "Recent developments in low-level lead exposure and intellectual impairment in children". Environ Health Perspect. 2005 Jan;113(1):A16.
http://ehp.niehs.nih.gov/docs/2005/113-1/correspondence.html)

It is very important to remember that:
a. 1µg/dL is 10 ppb.
b. Ingestion of 10 ppb of lead in water does not produce 10 ppb of lead in blood, since the body excretes and dilutes most of it. Thus it should not be interpreted that 10 ppb of lead in water will reduce IQ.

The average amount of lead in fluoridated water as a result of treatment with fluorosilicic acid is less than 0.1 ppb (billion) which is 100 times less than 10 ppb. Thus fluoridated water will have no effect on IQ.

4. Statement by Richard Maas:

They also conclude that the first small amount of lead exposure causes the most neurological damage to a young child and that additional exposure causes only moderately more damage.

Response by Howard Pollick:

While Canfield et al make that conclusion, Maas provides no caveats to the study, although the authors themselves state that: "As with any observational study, it is not possible to draw causal inferences from these findings." Nor is there any evidence provided that fluoridated water is associated with increases in blood lead levels.

5. Statement by Richard Maas:

Thus the low level but widespread lead exposure sources must be especially avoided if possible.

Response by Howard Pollick

While recognizing that no threshold level that is considered likely to affect health and safety, even if a threshold level of concentration in blood would be 1 μg/dL (10 ppb), this does not equate to 10 ppb in foods and beverages ingested.

6. Statement by Richard Maas:

Example 1: Consuming Water with 10 ppb Lead

A. Assume 2L/Day ingestion for drinking and cooking (pasta, rice, oatmeal etc) x 10 μg/L = 20 μg/day

B. EPA and FDA: 6 μg/day of Lead ingestion = 1.0 μg/dL increase in BLL: Therefore, 20 μg/day = BLL increase of 3. μg/dL

C. Canfield et al (2003): A BLL increase of 10 μg/dL = 7.4 IQ drop…Therefore consuming water with 10 ppb of Lead = 2.5 point IQ drop!

Response by Howard Pollick:

A. This assumes a water concentration of 10 μg/L Lead (10 ppb). This also assumes an intake of 2 liters of water per day. The children in Canfield et al were under 5 years of age; water intake for that age group is much less. Children one to ten years old ingest an average of 435 ml/day (90% confidence interval is 414 to 457 ml/day), and children less than one year old ingest an average of 513 ml/day (90% confidence interval is 460 to 567 ml/day) (United States Environmental Protection Agency. Office of Water EPA-822-R-00-008. ESTIMATED PER CAPITA WATER INGESTION IN THE UNITED STATES April, 2000. Based on Data Collected by the United States Department of Agriculture's 1994–96 Continuing Survey of Food Intakes by Individuals)

Thus for children under 5 years of age, drinking less than 0.6 L per day, consumption of lead from water containing 10 μg/L (10 ppb) lead = less than 6 μg/day.

B. If 6 μg/day of lead ingestion is equivalent to 1.0 μg/dL BLL, then consuming water at 10 μg/L (ppb) would result in a Blood Lead Level of 1.0 μg/dL, which is the threshold of measurement of lead in blood. Note that if water contains 0.1 μg/L of lead, then consumption of 0.6 L/day would result in an (unmeasurable) BLL of 0.01 μg/dL.

C. Even though Canfield's original data showed 7.4 IQ point drop as BLL increase from 1 μg/dL to 10 μg/dL, there would have to be a greater than 6 μg/day level of lead ingestion to show any measurable increase in Blood Lead Levels. This is not likely given the EPA figures on water consumption of children under age 5 years.

6. Statement by Richard Maas:

Example 2: Incidental Lead Contamination of Fluorosilicic Acid Used for Water Fluoridation

A. Fluorosilicic acid used for fluoridation is a waste product of phosphate mining and usually has picked up relatively large amounts of lead during the mining/leaching process.

Response by Howard Pollick:

WRONG: Fluorosilicic acid is not waste and has VERY SMALL amounts of lead. Fluorosilicic acid (FSA) is a chemical used to fluoridate the majority of community water systems in the US. (Reference: Centers for Disease Control and Prevention. Fluoridation census 1992. Atlanta, Georgia: US Department of Health and Human Services, Public Health Service, CDC, September 1993.) When FSA is diluted to produce the required adjusted fluoride concentration of drinking water recommended for the protection of public health (range of 0.7 – 1.2 parts per million), there may be minute amounts of contaminants. Existing regulations and standards require that these contaminants, including arsenic and lead, be at levels considered safe. Evidence shows that the concentrations of these contaminants are very low and meet all regulatory requirements for safety.

Fluorosilicic acid is not a waste product but a by-product or co-product of phosphate mining. The American Water Works Association (AWWA) has specified that FSA must contain 20 to 30% active ingredient, a maximum of 1% hydrofluoric acid, a maximum of 200 mg/kg heavy metals (as lead), and no amounts of soluble mineral or organic substance that can cause health effects. A typical product contains a maximum of 23% of the acid, a minimum of 18.22% fluorine, a maximum of 0.02% heavy metals (as lead), and <1.00% hydrofluoric acid. Analyses of tap water treated with silicofluorides (e.g., samples from Seattle, WA, San Francisco, CA, and Ft. Collins, CO) have revealed insignificant lead and arsenic levels (CSDS, 2001). (Reference: Sodium Hexafluorosilicate [CASRN 16893-85-9] and Fluorosilicic Acid [CASRN 16961-83-4] Review of Toxicological Literature. *Prepared for* Scott Masten, Ph.D. National Institute of Environmental Health Sciences P.O. Box 12233 Research Triangle Park, North Carolina 27709 Contract No. N01-ES-65402. *Submitted by* Karen E. Haneke, M.S. (Principal Investigator) Bonnie L. Carson, M.S. (Co Principal Investigator) Integrated Laboratory Systems P.O. Box 13501 Research Triangle Park, North Carolina 27709. October 2001. Accessed as a .pdf file at http://ntp-server.niehs.nih.gov/htdocs/Chem_Background/ExSumPDF/Fluorosilicates.pdf

B. The NSF International (the official certifying agency for drinking water additives) has determined that the average amount of lead added to drinking water from Fluorosilicic Acid addition is 0.40 ppb with a maximum from several samples of 1.1 ppb.

Response by Howard Pollick:

WRONG: The average amount was less than 0.1 ppb (only 7 of more than 100 samples had any lead) and there was only one of more than 100 samples that had 1.1 ppb.

While not measurable by itself by most laboratories, this equates to a daily ingestion of 0.80 µg/day (2.2 µg/day max.) of lead which in turn equates to an estimated average IQ deficit of 0.13 points (max. 0.37 pts)

Response by Howard Pollick:

WRONG: The assumption is WRONG. Given that children under 5 years of age consume less than 0.6 liters per day of water, the minute level of less than 0.1 µg/L (ppb) of lead in water would be equivalent to less than 0.01 µg/dL BLL which has not been to be associated with ANY change in IQ.

If, for example, the 223,000 children in Oregon under age 5 are exposed to this much lead each year, this equates to at least a total statewide IQ loss of 29,000 IQ points for this cohort of children. Over 20 years (4 groups of children 0-5 yrs of age), this is a statewide IQ loss of 116,000 pts.

Response by Howard Pollick:

WRONG: Extrapolating a WRONG assumption only increases the ERROR in this calculation.

This is in addition to any other lead exposure sources from water of lead-based paint etc.

Response by Howard Pollick:

WRONG: Lead-based paint does not produce increased lead exposure from water, but from dust. The principal sources of lead exposure for children in the United States are house dust contaminated by leaded paint and soil contaminated by both leaded paint and decades of industrial and motor vehicle emissions. Lead was widely used in paint through the 1940s. Although lead use declined during the 1950s and 1960s, and lead was banned from residential use in 1978, lead remains a hazard in homes built before the ban, especially in pre-1950 housing. (Reference: Meyer PA, Pivetz T, Dignam TA, Homa DM, Schoonover J, Brody D; Centers for Disease Control and Prevention. Surveillance for elevated blood lead levels among children--United States, 1997-2001. MMWR Surveill Summ. 2003 Sep 12;52(10):1-21. Accessed at http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5210a1.htm)

Trace contaminants, such as heavy metals, in fluorosilicate compounds (including FSA) are not permitted to exceed the Maximum Allowable Level (MAL), which is one-tenth of the EPA's regulated MCL (Maximum Contaminant Level) when the product is added to drinking water at its Maximum Use Level. The majority of the more than 100 samples of water fluoridated with FSA, tested by NSF International from 1992 to 2000, did not contain any detectable arsenic or lead. The average concentration of arsenic and lead from all samples was less than 0.1 ppb. Among those 39 samples where arsenic was detected, the average was 0.43 ppb (maximum sample of 1.66 ppb); likewise, among those 7 samples where lead was detected, the average was 0.40 ppb (maximum sample of 1.1 ppb). (Reference: Letter: Stan Hazan. General manager, Drinking Water Additives Certification Program, NSF International to David Spath, California Department of Health Services, Office of Drinking Water. March 30, 2000. Accessible at http://www.dentalhealthfoundation.org/documents/NSFLetter.pdf)

7. Statement by Richard Maas:

II Health Effects of Arsenic in Drinking Water

While we have long known that arsenic is carcinogenic, recent human epidemiologic studies officially compiled and interpreted by the National Academy of Science show conclusively that arsenic is a much more potent (about 200x) human carcinogen than previously indicated from animal studies.

Thus, the National Academy of Science estimates that consuming water at the newly adopted MCL of 10 µg/L represents about a 1/300 lifetime cancer risk (i.e. Far greater than the 1/10,000 to 1/1,000,000 cancer risk permitted for other known carcinogens).

The EPA acknowledges that this MCL is not very health protective but rather represents a major compromise between public health protection and current technical/economic/analytical feasibility.

(Note this risk is so high that several individual states (e.g. CA, NJ) are adopting their own stricter MCLs of 3-5 µg/L).

Also, recent studies (e.g Moore et l) are showing tat of people with existing cancer tumors are exposed to even very low levels of arsenic, these tumors tend to grow much more aggressively with higher fatality rates. This may prove to be an even greater health risk than the direct cancer-causing effects of arsenic but has not yet been incorporated into the risk models.

Again, using the example of Fluorosilicic Acid, its very high arsenic contamination leads to an average diluted concentration as calculated by NSF International of 0.43 ppb which equates to a cancer risk of 1/6970. From several samples NSF found a maximum of 1.66 ppb. This equates to a 1/1800 cancer risk (FAR above the 1/10,000 tp 1/1,000,000 normally permitted.

Response by Howard Pollick:

WRONG: Maas has neglected to include the majority of samples where no arsenic was detected. The majority of the more than 100 samples of water fluoridated with FSA, tested by NSF International from 1992 to 2000, did not contain any detectable arsenic or lead. The average concentration of arsenic and lead from all samples was **less than 0.1 ppb**. Among those 39 samples where arsenic was detected, the average was 0.43 ppb. There was only one sample with a maximum of 1.66 ppb. (Reference: Letter: Stan Hazan. General manager, Drinking Water Additives Certification Program, NSF International to David Spath, California Department of Health Services, Office of Drinking Water. March 30, 2000. Accessible at http://www.dentalhealthfoundation.org/documents/NSFLetter.pdf)

To put this in perspective, if there are say 2.5 million people in Oregon on fluoridated (with fluorosilicic acid) public water supplies, each consuming water with an average of 0.43 µg/L pf arsenic, then the estimated # of additional cancer deaths over the next 70 years would be about 359, or about 5/year. (Nationwide: 28,674 or about 410/yr).

Response by Howard Pollick:

WRONG: There is less than 0.1 ppb arsenic in public water supplies as a result of fluoridating with fluorosilicic acid. Thus there can be NO additional cancer deaths.

8. Statement (Summary and Conclusions) by Richard Maas:

Significant harm and adverse health effects occur from pollutants such as lead and arsenic in drinking water at concentrations well below MCLs or Action Levels.

Significant harm and adverse health effects can occur at levels below the lead and arsenic analytical detection limits of many commercial and certified laboratories (typically 1-2 ppb for lead or 3-5 ppb for arsenic).

Additional exposure to potent toxic chemicals such as lead and arsenic can not be looked at in isolation. ANY purposely added amounts of these substances will cause ADDITIONAL body burdens in combination with other less controllable sources.

MCLs and Action Levels were NOT intended to give license to purposely add additional body burdens of highly toxic chemicals such as these.

Response by Howard Pollick:

The negligible amounts of lead and arsenic in water fluoridated with fluorosilicic acid are considerably lower than as described by Maas and provide no evidence of risk to health. With the benefit accrued from water fluoridation in reducing the burden of dental caries, and the lack of credible evidence of harm or potential harm, there is no justification for changing the public health policy of water fluoridation.