Unfinished Business: Congress and Fluoride

Presented by Dr. J. William Hirzy
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This presentation has been authorized by the Executive Board of Chapter 280 of the National Treasury Employees Union which represents professional employees at the headquarters of the U.S. Environmental Protection Agency (EPA). In making it, I am representing the union, and not serving as a representative of EPA, in whose employ I am a senior scientist in the Risk Assessment Division of the Office of Pollution Prevention and Toxics.

Initial Congressional Hearings

The last time the U.S. Congress held full fledged hearings on the issue of fluoride toxicity was in the Fall of 1977. Concern over fluoride's possible carcinogenicity was then the main issue under investigation, though some witnesses, including Albert Burgstahler, also pointed out other reported adverse effects. Congress had held hearings on the cancer issue in 1975 as well, when John Yiamouyannis and Dean Burk first brought national attention to the cancer issue with their epidemiology study of fluoridated versus non-fluoridated cities. In 1952 and again in 1957 Congress convened hearings on the rapidly developing national program of promoting water fluoridation, noting deficiencies in the research reported by the Public Health Service as part of that agency's promotional efforts. Thus over a period of 25 years the Congress held four sets of hearings – about one every six years.

It has now been almost 30 years since the Congress has deemed it advisable to call witnesses before it to ascertain whether this purported public health measure is living up to claims of benefits made for it, or whether it is in fact contributing to declines in the health of not only Americans but citizens of other countries who have climbed on America's fluoridation band wagon.

The set of hearings in the 1950's and 1970's did have certain useful results. First, the deficient research methods used by the PHS were uncovered and have resulted, over time, in other, better, investigations into the efficacy of water fluoridation. This has led to studies in the U.S, Canada, the United Kingdom and New Zealand, all of which have shown how over-blown the PHS's original conclusions were in this regard. Claims of 60 percent reductions in caries rates have now been revised downward to about 15 percent maximum (in the U.K. study), and possibly to statistical and clinical insignificance in the other studies. One must acknowledge, however, that these subsequent studies have been done after the wide spread introduction of other fluoride treatment modalities, such as tooth paste, which might have affected the findings of little if any benefit from water fluoridation.

Second, the concerns over carcinogenicity led to the National Toxicology Program undertaking the bioassay on sodium fluoride, whose originally reported results were, "clear evidence of carcinogenicity in male rats." These results were down-graded in a highly controversial review exercise to, "equivocal evidence of carcinogenicity in male rats," which conclusion led Dr. William Marcus to publicly object to the down-grade for which he was fired from his job as Senior Toxicologist in EPA's Office of Drinking Water. Dr. Marcus was subsequently reinstated after a lawsuit against EPA in which the judge stated that he believed Dr. Marcus was fired because of his public stance on fluoride. No disciplinary action was ever taken against those in EPA responsible for firing Dr. Marcus.

Congressional Inquiries of 1997/2000

The next evidence of Congressional interest occurred in 1997 when, prompted by the work of Jeff Green of Citizens for safe Drinking Water and NTEU Chapter 280, the House Science Committee's Subcommittee on Energy and Environment made inquiries of EPA, the Food and Drug Administration (FDA), the NSF, Inc., the Centers for Disease Control (CDC), and the National Academy of Science (NAS). The responses received from these organizations in some cases prompted a second round of questions, the responses to which are enough in themselves to warrant Congressional hearings. The letters of inquiry and agency responses can be seen at www.keepersofthewell.org.

For example, here is a summary of some of the second round questions posed to EPA and the responses:

1. **Question:** What has EPA done in response to questions about fluoride's neurotoxicity and lack of chronic toxicity data on silicofluorides raised in 1998 by Drs. Hirzy and Murphy in connection with the Children's Health Test Rule? **Response:** We will consider the neurotoxicity data if and when we do a review of the MCL/MCLG for fluoride. Their complaint over lack of chronic toxicity data has been preempted by development of a voluntary testing program between EPA and industry, and silicofluorides will be evaluated to see if they are appropriate for consideration by the voluntary testing program.

2. **Question:** Do you interpret the Safe Drinking Water Act as requiring EPA to protect sensitive subpopulations and people who drink more than 4 liters of water per day? **Response:** If EPA does a review of the MCL/MCLG we will seek more data on these subpopulations and their dose-response to fluoride and then seek public comment on the findings as required by law.

3. **Question:** Is EPA satisfied that the doses of fluoride delivered under an MCLG of 4 mg/L, along with other exposures via dental products, foods, etc, do not cause adverse health effects? **Response:** EPA continues to support an MCLG of 4 mg/L as protective of public health. We have collected exposure and dental fluorosis data over the past year and we will carefully evaluate these data.

The implication of these questions and responses is that EPA was not considering the information extant in 1998 on any adverse effect other than dental fluorosis to be serious enough to warrant immediate attention either through testing or consideration of change in the MCL/MCLG. In essence, EPA's responses indicated a blasé attitude about fluoride toxicity and the intentional exposure of millions of Americans to untested chemicals that are considered hazardous waste (silicofluorides) under the Resource Conservation and Recovery Act.

Here are summaries of two examples of questions and responses from CDC:

1. **Question:** Why did the Carlos and Brunelle study on efficacy use affected tooth surfaces rather than the Decayed, Missing, Filled Teeth (DMFT) index? **Response:** That study aimed to get data on effects by surface types, and we found that 90 percent of caries occur in pits and fissures (chewing surfaces), "*that are not as affected by the beneficial effect of fluoride.*" (emphasis added)

2. **Question:** Does CDC subscribe to the recommendations of the American Medical Association that children under six months of age should receive no fluoride? **Response:** Neither the AMA nor others recommend "no fluoride" for children less than six months of age, but the American Academy of Pediatrics recommends beginning fluoride supplements at age six months in non-fluoridated communities.

The implications of these questions and responses are that: 1) CDC admits fluoridation has little or no effect on caries developing where most in fact develop; and 2) CDC doesn't bother to respond with the actual doses of fluoride recommended for infants, even though it goes to great length in citing a list of efficacy studies, and this can be interpreted as a dodge from admitting that infants six months of age who drink more than one cup of "optimally" fluoridated water per day receive more fluoride than the recommended supplementation dose.

Here is a summary of several questions put to the Food and Drug Administration:

Questions: If health claims are made for a fluoride-containing product, is the product considered a drug? Have any New Drug Applications been received for such a product intended for ingestion? **Response:** Fluoride containing products that make health claims are drugs. Existing products of that type intended for ingestion, such as fluoride-containing vitamins are being reviewed for efficacy under provisions of the 1962 Drug Amendments Law.

The implication here is that FDA recognizes that fluoride-containing vitamins and supplements are drugs, has known that since they came on the market, and yet in the 35 years between passage of the 1962 Drug Amendment Law and this inquiry from Congress, no review for efficacy was undertaken, reason unknown.

Here is a summary question posed to the National Academy of Sciences and its Institute of Medicine (IOM) regarding the IOM's Dietary Reference Intakes (DRI)

publication and the recommended tolerable upper intake level (UL), which is set at 10 mg/day for persons 9 years of age and older:

Question/Comment 1: The DRI states that Stage III (crippling) skeletal fluorosis can occur with 10 years or more exposure to fluoride at 10 mg/day or greater. **Response:** The DRI states that Stage I skeletal fluorosis can occur under those exposure conditions.

Question/Comment 2: Does NAS/IOM consider acquisition of Stage I or Stage II skeletal fluorosis at any time in life acceptable? **Response:** No.

Question/Comment 3: What does NAS/IOM consider the minimum dose at which Stage I skeletal fluorosis can occur? **Response:** This can occur with exposures at or greater than 10 mg/day for 10 or more years.

Since it is well recognized (although incredibly it was denied by Hershel Horowitz of the IOM panel at a public meeting in September 1997) that fluoride accumulates in calcifying tissue to the extent of about 50 percent of the ingested dose, the implication is clear: a person 9 years of age ingesting the UL of 10 mg/day of fluoride will, in his or her twenties or thirties, have accumulated enough fluoride to experience at least Stage I skeletal fluorosis.

Unfortunately, Congress accepted these responses and similar ones from the other questions without further follow up or action of any kind. Here, clearly is a major piece of unfinished business for the Congress.

Invited Testimony by NTEU Representative

In 2000, prompted by New Hampshire citizens, Senator Bob Smith, Chairman of the Senate Committee on Environment and Public Works invited our union to testify on our concerns about fluoride before the Subcommittee on Fisheries, Wildlife and Drinking Water. I gave the testimony in June of that year, asking for a full hearing on fluoride issues because of its unique status as a chemical recommended by the Federal government to be ingested and bathed in by every man, woman and child in America. I cited specific issues that should be looked into:

1) excessive and un-controlled fluoride exposures;
2) altered findings of a cancer bioassay;
3) the results and implications of recent brain effects research;
4) the "protected pollutant" status of fluoride within EPA;
5) the altered recommendations to EPA of a 1983 Surgeon General's Panel on fluoride;
6) the results of a fifty-year experiment on fluoridation in two New York communities;
7) the findings of fact in three landmark lawsuits since 1978;

8) the findings and implications of recent research linking the predominant fluoridation chemical with elevated blood-lead levels in children and anti-social behavior; and
9) changing views among dental researchers on the efficacy of water fluoridation

I presented detailed reasons why each of these issues was worthy of inquiry and submitted corroborating documentation. I also asked that an epidemiology study be conducted looking for behavioral and bone pathology in the young and that testing be ordered for silicofluorides. The testimony is available on the FAN and Keepers of the Well websites.

The only response or follow up from the Subcommittee was a set of questions from the Chairman and Ranking Member, Senators Crapo and Boxer, respectively, which included asking my views on whether referenda were an acceptable means for deciding whether a community should fluoridate its water and on whether fluoride had any benefits in dental health. My responses were, in effect, that referenda were better than legislated mandates or backroom deals, but that individual freedom of choice cannot be sacrificed on the altar of democratic election processes, and that topical treatment with fluoride seemed to have some benefits, but systemic exposures constituted unreasonable risk.

This situation, with the issues listed above remaining unaddressed, is yet another piece of unfinished business for the Congress.

EPA's Attitude Toward the Fluoride

The Congress should take a hard look at EPA's schizophrenic attitude about water fluoridation and fluoride toxicity and mandate our Agency's scientific integrity on these issues, as if that were needed.

Deputy Assistant Administrator for Water Rebecca Hanmer wrote the noteworthy letter in 1984 in response to a citizen's inquiry about use of hydrofluosilicic acid as a fluoridating agent, to the effect, "It is an ideal solution to a long standing environmental problem…air and water pollution are minimized and a low cost fluoridating agent is thus available to water authorities…"

In 1998 Varner and coworkers, including Karl Jensen of EPA, published in *Brain Research* an important study showing adverse effects on the brain in rats exposed to 1 mg/L fluoride, either as AlF_3 or NaF. In recognition of the significance of that study, the following year a workshop was held at Research Triangle Park. The workshop recommended that: 1) the original study be replicated; 2) the protocol be repeated with rabbits; 3) a toxicokinetic study be done; and 4) neurofilament study be done on transgenic mice. But EPA decided that other water issues, such as nanoparticle and cyanobacteria contamination were higher priority, and as of last year the workshop's recommendation remained in limbo.

EPA's actions regarding approval of sulfuryl fluoride as a fumigant warrant a place in any Congressional hearings on the fluoride issue. While finding a replacement for methyl bromide, an ozone depleting chemical fumigant, may be a laudable goal, the sheer abuse of scientific principles that EPA's pesticide office has perpetrated in trying to show low risk from the switch from methyl bromide to sulfuryl fluoride is breath taking. A detailed critique of EPA's supporting risk assessment can be found on the FAN website, but in short, EPA uses the now discredited MCLG of 4 mg/L fluoride in drinking water as the basis for its risk estimates. The assessment allows a higher dose rate of fluoride to be delivered to infants and children than to adults, flying in the face of the Food Quality Protection Act's requirements that extra protection is to be provided the young. Our union has written to EPA about this issue.

The approval of sulfuryl fluoride by the pesticide office is another example of how that unit of the Agency seems to be paying more attention to the wishes of the pesticide industry rather than to carrying out a mandate to regulate the industry with protection of the public as its foremost duty. Ten EPA unions representing 9000 environmental professionals recently wrote to the Administrator about this unseemly bias in connection with the Agency's re-registration activities on organophosphate and carbamate pesticides, joining EPA's Inspector General with concern that those are not being adequately assessed for their toxicity to the young.

In another case, following our union's vote to endorse the California Citizens for Safe Drinking Water campaign to repeal the statewide fluoridation mandate, a Branch Chief (the lowest level of management) in the Drinking Water Office sent a letter to all Regional Drinking Water branches saying, in effect, that our vote meant nothing and that it contravened "the Agency's policy on fluoridation." Just two weeks prior to this letter going out, the Assistant Administrator for Water (the highest management level) had sent a letter to the American Dental Association asking that EPA be removed from the list of endorsers of water fluoridation.

EPA's response to 11 of its labor unions asking last August that the Agency take precautionary, non-binding action on the basis of Elise Bassin's epidemiology study was to stall. Ed Ohanian responded to our letter saying that EPA would wait for the results of the National Research Council's (NRC) review of the MCL/MCLG for fluoride before taking any action at all. In our union letter we noted that the NRC report had been long delayed, that upon receipt it would have to be studied, then a risk assessment done, then possibly a new MCL/MCLG proposed after passing through various levels of bureaucratic review and approval, all of which would likely take several years, during which time youngsters would continue to drink fluoridated water and be exposed to unnecessary increased risk of bone cancer.

The NRC report finally came in, and I spoke with Dr. Ohanian in June about what plans EPA had. He told me that the report had been reviewed and a plan for proceeding with a risk assessment and subsequent activity had been put together and was awaiting movement up the management chain to his boss, the Office Director, thence to the

Assistant Administrator for approval. I have memorialized that conversation in a letter to him and upper management in which I reiterated the unions' concern that unnecessary risks were being placed on young boys by EPA's failure to warn the public about the results of the Bassin study through an Advanced Notice of Proposed Rulemaking setting the MCLG at zero.

Congress should ask EPA why, under provisions of the Toxic Substances Control Act, it requires industry to notify EPA within 15 days if it comes into possession of the kind of information EPA has on fluoridation risk, while EPA itself can sit on such information without informing the public about it.

The same 11 labor unions also wrote to key Congressional Committee Chairmen and Ranking Members about the sequestered osteosarcoma study asking for a national fluoridation moratorium, hearings and an investigation of the sequestration. No response was received, though in a follow up meeting with Minority staff of Environment and Public Works Committee, I opened personal communications on this issue and there may be a possibility of some questions posed to EPA in oversight hearings regarding the new MCL/MCLG proposals that are in the works.

Congress should ask EPA why it cannot fund studies confirming (or otherwise elucidating the findings of) the Varner et al. study.

Congress should ask whether a Branch Chief or the Assistant Administrator for Water has the authority to speak on whether EPA has a policy of endorsing fluoridation.

Congress should ask EPA why thousands of its environmental professionals are complaining that the Agency is not living up to its own Principles of Scientific Integrity.

ADA and CDC Responses to the NRC Report

As we all know, since the recent publication of both Elise Bassin's study and the NRC review of the fluoride MCL/MCLG both CDC and ADA have been busy assuring the public and their narrower constituencies that neither of these documents should cause any alarm or prevent fluoridation drives from proceeding apace. Congress should be interested in why a publicly chartered organization like the ADA and an arm of government are saying that neither of these documents has any bearing on the safety of fluoridation.

The NRC report in particular, which says that the 4 mg/L MCL/MCLG is not protective of public health, that at 2 mg/L milder forms of skeletal fluorosis are a risk, and at even lower levels endocrine effects may be occurring should not be ignored by these agencies.

Congress should also take a hard look at the differences between Chester Douglass and his advisee, Elise Bassin. The relationships among Douglass, Colgate and Harvard, would make an interesting point of study, along with the question of whether

any federal law was violated when Douglass reported “no relationship” between fluoridation and osteosarcoma to both the NRC panel and the National Institute of Environmental Health Sciences.

Conclusion

There are ample reasons why Congress should hold hearings on fluoridation and fluoride toxicity. First and foremost, a comprehensive look at this national program has never been undertaken. It is high time that be done.

The Congress would do well to look into why so many other countries refuse to fluoridate or have stopped once having tried it. Arvid Carlsson would make an ideal witness.

The Congress should close the loop on the work started in 1997/2000 with the inquiries by House Subcommittee on Energy and Environment, and it ought to address the concerns I raised before the Senate Subcommittee in 2000.

In matters raised before both of these Subcommittees, as well as in the Bassin/Douglass matter, there is probable cause that malfeasance if not outright violation of law has occurred and that scientific integrity within the federal establishment has been sacrificed on the altar of a program promoted and financed by the federal government that takes away citizens’ rights of self-determination and puts their health and that of their children at risk.