



June 26, 2006

Edward Ohanian, Director
Health and Ecological Criteria Division
Office of Water
U.S. Environmental Protection Agency
Washington, D.C. 20460

Dear Dr. Ohanian:

This letter is to record our conversation last Friday, June 23 dealing with EPA's plans for dealing with drinking water standards for fluoride.

On August 5, 2005 a coalition of eleven of EPA's labor unions wrote to Administrator Johnson asking him to take certain actions acknowledging the significance of Elise Bassin's epidemiology work that shows an increased risk of osteosarcoma in young boys who drink "optimally" fluoridated water. Later that month you replied in a letter addressed to Dwight Welch and me stating that, among other things, the Agency was awaiting the outcome of the National Research Council's (NRC) review of fluoride health effects, which would include a review of Dr. Bassin's work. You noted that at the time of the union letter Dr. Bassin's work had not been published or subjected to peer review.

As we discussed in our conversation, both the NRC review and Dr. Bassin's epidemiology study have now been published – Dr. Bassin's work appears in *Cancer Causes and Control* and was subjected to peer review for that article (as well as, I must point out, for her doctoral dissertation. As one who holds the Ph.D. degree yourself, you know that a doctoral dissertation is subject to several levels of peer review. These include review by a candidate's doctoral study committee of professors and a dissertation defense seminar.).

I inquired of you what the Agency's plans are for next steps. You said that your staff had completed its review of the NRC report and you had developed a time-frame for

risk assessment work that would be the next step. You noted that you had sent the proposed time-line up your chain of command for approval by the Office Director and Assistant Administrator. You noted that one issue facing the Agency was the list of research recommendations made by the NRC committee.

Now that Dr. Bassin's study has been published and the Agency has completed a staff-level review of the NRC report, which, among other comments on the possible carcinogenicity of fluoride, lays out a case (including historical precedent EPA actions on other pollutants such as dibromochloromethane and trichloroacetic acid) for the Agency's need to decide whether an MCLG of zero or a safety factor of up to 10 might need to be applied to a reference dose (RfD) based on "a precursor response to tumors," EPA should wait no longer to take timely and effective action to warn the public about the potential carcinogenic risks from exposure to fluoride.

As the unions noted in the August 5, 2005 letter to Administrator Johnson when we urged him to take action, for the Agency to continue bureaucratic rumination into the unforeseeable future while unnecessary exposure of young boys to increased cancer risk continues and expands is not in the public interest.

There is no reason justifiable by public health considerations for EPA to delay further issuing an Advanced Notice of Proposed Rulemaking stating that EPA is considering either: establishing an MCLG of zero; or applying a safety factor of 10 to a new RfD for fluoride which would lead to an MCLG (e.g.) in the range of 0.05- 0.2 mg/L.

On behalf of the eleven unions coalition which authored the August 5, 2005 letter, I am,

Sincerely yours,

/S/

J. William Hirzy, Ph.D.
Vice-President
National treasury Employees Union Chapter 280

cc: Eleven signatories of August 5, 2005 letter
Ephraim King, Director, OST
Benjamin H. Grumbles, Assistant Administrator, OW
Cynthia C. Dougherty, Director, OGWDW
Stephen L. Johnson, Administrator



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 25 2006

OFFICE OF
WATER

J. William Hirzy, Ph.D
Vice President
National Treasury Employees Union Chapter 280
EPA Headquarters
Washington, DC 20460

Dear Dr. Hirzy:

Thank you very much for your letter of June 26, 2006, concerning EPA's plans for dealing with drinking water standards for fluoride. As I mentioned during our conversation on June 23, 2006, the Health and Ecological Criteria Division (HECD) in the Office of Water was in the midst of developing a plan for next steps to be reviewed by the senior management. I am happy to inform you that we recently completed our review of the National Research Council's (NRC) report on fluoride and have developed a preliminary plan for conducting the recommended risk assessment. This plan is undergoing internal review at this juncture. Meanwhile, HECD has undertaken a number of additional activities, which are outlined below.

HECD is in the process of retrieving key published papers that will form the basis for a dose-response assessment to support a noncancer reference dose (RfD) and/or cancer risk assessment for fluoride. The published paper by Elise Bassin et al. (2006), is one of the key papers being reviewed by HECD. However, the NRC report recommends that EPA also examine the large "hospital-based, case-control study" by the Harvard School of Public Health, which was expected to be published this summer. The importance of this second study about fluoride and cancer risk is echoed in the letter to the editor from Dr. Chester Douglas, the advisor for Dr. Bassin's thesis, which was published in *Cancer Causes and Control* along with Dr. Bassin's paper. Dr. Douglas cautions readers not to "generalize and over-interpret the results of the Bassin et al. paper and to await the publications from the full study, before making conclusions, and especially before influencing any related policy decisions." HECD will not be able to fully assess the cancer data until the study by Dr. Douglas is published.

NRC recommended that EPA "develop an MCLG that is protective against severe enamel fluorosis, clinical stage II skeletal fluorosis and bone fractures, as well as a better estimate of total exposures (relative source contribution) for individuals." HECD is presently collecting the primary data necessary to begin the noncancer risk assessment recommended by NRC, while awaiting the second publication from the Harvard School of Public Health.

If you have any further questions, please contact me, at (202) 566-1117 or Joyce Donohue at (202) 566-1098.

Sincerely,



Edward V. Ohanian, Ph.D.
Director, HECD