

June 27, 2005

Ms. Janice Strother, NIEHS Ethics Coordinator
NH Room 269
MD NH-01
PO Box 12333
Research Triangle Park, NC 27709

Dear Ms. Strother:

During the past week we have had several conversations with NIEHS ethics staff about potential, serious misrepresentations of research results contained in a final report to NIEHS submitted by Dr. Chester Douglass, chairman of the Harvard University School of Dental Medicine's Department of Oral Health Policy and Epidemiology for grant number 5 R01 ES06000.

We are writing to request a formal investigation into this issue, based on the discrepancies described below.

The principle issue of concern is the serious contradiction between the conclusion in the grant report, where Dr. Douglass reports no evidence of a link between fluoride and osteosarcoma, and the findings of the grant-supported publications listed in support of this position that conclude exactly the opposite. By reporting the results of grant-supported publications in this way, it appears that Dr. Douglass may have violated Sec. 93.103 (b) of federal research rules concerning falsification of data and the reporting of research results.

Specifically, in the grant report, Dr. Douglass concludes that there is no evidence of a link between fluoride and osteosarcoma, and references work by Dr. Elise Bassin as one of only two publications supported by the grant that support this finding. The issue is that Dr. Bassin's findings, contained in her doctoral thesis at Harvard, do not support the finding that Douglass reported to NIEHS – but instead resoundingly contradict it. What makes this inconsistency more curious is that Douglass was the lead advisor on the Bassin doctoral thesis. Dr. Douglass personally signed off on Dr. Bassin's research.

In Douglass's grant report to NIEHS he presents only the following conclusions regarding fluoride and bone cancer: "The analysis carried out for the Orthopedic Surgery Research meeting reported an Odds Ratio of 1.2 to 1.4 between fluoride and Osteosarcoma that was not significantly different from 1."

The Bassin doctoral thesis was one of two grant-supported publications cited in support of this conclusion. However, the Bassin work does not support this finding. In contrast, the Bassin doctoral thesis found a strong, statistically significant association between fluoride levels in tap water during the mid-childhood growth spurt and

osteosarcoma in adolescent boys. This is even more noteworthy because the Bassin work is the most rigorous study of the link between bone cancer and fluoride in tap water ever conducted in the United States. Unlike the epidemiology studies that have found no relationship between fluoride in tap water and bone cancer, Bassin focused her analysis on the population of concern (males under 20 years of age) during the relevant period of growth and development. Her study also validated fluoride levels in the tap water consumed during that time period.

The following is just one of several passages from the Bassin thesis describing the link she observed between fluoride in tap water and bone cancer in boys:

"Among males, exposure to fluoride at or above the target level was associated with an increased risk of developing osteosarcoma. The association was most apparent between ages 5-10 with a peak at six to eight years of age. The odds ratio for the high exposure group was 5.16 at 7 years of age with a 95 percent confidence interval of 1.64 to 16.20." (Bassin page 75)

By inaccurately reporting the findings of the Bassin publication, it appears that Dr. Douglass violated Sec. 93.103 (b) of federal research guidelines by falsifying his final report for grant 5 R01 ES06000. Falsification is defined in Sec. 93.103 (b) as follows (emphasis added):

"Falsification is manipulating research materials, equipment, or processes, or changing or *omitting data or results such that the research is not accurately represented in the research record.*" [emphasis added]

This potential violation of ethical standards is made more serious by its enormous public health implications. Millions of boys drink fluoridated water every day, and any health risk as serious as bone cancer that is associated with fluoridation could have a devastating impact on hundreds of children each year. While Douglass might not agree with the conclusions of this work, that is not a justification for misrepresenting it in his final report to federal health officials and taxpayers.

Adding to our concern is the fact that Douglass's misrepresentation of the Bassin findings appears to be part of a pattern.

In a presentation Douglass made to the Royal College of Physicians in London in November of 2002, Douglass concluded that case-control studies showed no association between fluoride exposure and osteosarcoma. This conclusion directly contradicts the findings of the Bassin doctorate that Douglass signed off on in 2001.

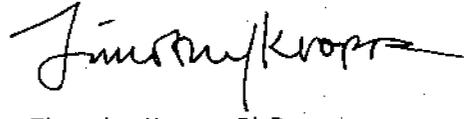
In January 2004, Douglass submitted his final grant report to NIEHS as written testimony to the National Research Council committee studying the toxic effects of fluoride. This appears to be an attempt to use the imprimatur of the NIEHS to influence the deliberations of a National Academy of Sciences committee by submitting an NIEHS grant report concluding that six years of research had found no evidence of a relationship between fluoride and osteosarcoma.

In sum, we are convinced that the evidence presented warrants a full investigation into the worrisome discrepancies in research reporting on the part of Dr. Douglass. We thank you for your attention to this important matter.

Sincerely,



Richard Wiles
Sr. Vice President



Timothy Kropp, PhD
Senior Scientist