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Dr. Elias Zerhouni
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
Sent via Email: ez26y@nih.gov

Dear Dr. Zerhouni,

Knowing of your concerns about ensuring scientific integrity in the work of the NIH, we wish to draw your attention to a very troubling situation which has developed in an important NIH-funded study on fluoride and osteosarcoma.

Professor Chester Douglass of Harvard, a lead investigator of the project, has been charged by the Environmental Working Group (EWG) with misrepresenting the study's findings. (1) More specifically, Douglass has been charged with misrepresenting the results of an NIDCR-funded PhD Dissertation conducted by his own doctoral student, Elise Bassin.

For her dissertation, Bassin analyzed the case/control data that Douglass had compiled from U.S. hospitals in the early 1990s under a grant from the NIEHS. In analyzing the data, Bassin found that males exposed to fluoridated water during their "mid-childhood growth spurt" (ages 6 to 8) had a significantly increased risk of developing osteosarcoma later in life. Bassin described these findings (in a dissertation that Douglass and four other Harvard scientists reviewed and approved) as "remarkably robust." (2-4)

Bassin's dissertation was completed in May of 2001. A *Wall Street Journal* science writer recently sent her thesis to several expert reviewers who found it to be of "publishable quality." (5) The head of oral health at the Centers for Disease Control, William Maas, told the *Wall Street Journal* that Bassin "did great shoe-leather epidemiology." (5) According to EWG, "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." (6)

However, despite the merits of Bassin's analysis, and despite the taxpayer dollars that funded it (via both NIDCR and NIEHS), her findings were never released. Hence, prior to the Fluoride Action Network obtaining a copy of the thesis earlier this year, the only publicly available information on Douglass' 13-year NIH study, was a very brief summary that Douglass published

in 1995 in the *Journal of Dental Research*. (7) In that summary, Douglass reported no association between fluoride and osteosarcoma. In the summary, he stated that a more comprehensive analysis would be forthcoming. However, it's now been 10 years, and Douglass has yet to publish this promised analysis.

Now that we have learned what his data showed, Douglass' failure to disclose these findings is deeply troubling and the Fluoride Action Network is formally asking the NIH to remove him from the study.

Adding to our concern is the fact that Douglass has a possible conflict of interest in the outcome of this study because he is a consultant to Colgate (he edits their quarterly Oral Care Report). Colgate is one of the world's largest manufacturers of fluoridated toothpaste – a major source of fluoride exposure during childhood.

In addition to removing Douglass from the study, we would ask that the NIH demonstrate that none of the other study members have conflicts of interest either, which would include ties to the government's fluoridation program.

Finally, in our view, the ultimate safeguard for the public is an NIH commitment that the data of the study, not just the conclusions, be made available for independent analysis and review.

I hope that you agree that since the public, through your agency, has paid for this study, it is critically important that any ongoing work is not only conducted honestly, but is perceived to be conducted honestly. Not only are the lives of many young men possibly at risk but the trust of millions of American parents is at stake.

In summary therefore, we are asking the NIH:

- 1) Remove Chester Douglass from this ongoing study.
- 2) Demonstrate that there are no conflicts of interest with any of the other study group members.
- 3) Commit to making the data used in the 1995 [Douglass] and 2001 [Bassin] reports available promptly for independent analysis and review. The schedule of the NRC Fluoride Toxicology panel dictates that this disclosure needs to occur in the next several weeks to allow this important review panel to fully consider this data.
- 4) Commit to making the more recent data available as soon as possible so that it can also be available for the NRC's review of fluoride. Much of this data has now been compiled for years.

Sincerely,

Paul Connett, PhD,
Executive Director,
Fluoride Action Network

References:

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<http://www.fluoridealert.org/health/cancer/bassin-2001.pdf>
3. Fluoride Action Network, "Revisiting the Fluoride-Osteosarcoma connection in the context of Elise Bassin's findings: Part 1", March 21, 2005.
<http://www.fluoridealert.org/health/cancer/fan-nrc.part1.pdf>
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5. Wall Street Journal, "Fluoridation, Cancer: Did Researchers Ask the Right Questions?", July 22, 2005. <http://www.fluoridealert.org/news/2323.html>
6. http://ewg.org/issues_content/fluoride/20050627/pdf/ltr_strother_20050627.pdf
7. Journal of Dental Research. "Fluoride Exposure and Osteosarcoma," 1995;74:98.
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