

July 7, 2022

Kevin M. Guskiewicz, PhD Chancellor, University of North Carolina at Chapel Hill E-mail: <a href="mailto:chancellor@unc.edu">chapel Hill</a>, NC 27599

## Re: Ethical Concerns for UNC-Sponsored Medical Experiment on Infants and Children

Dear Chancellor Guskiewicz,

We are writing to alert you to a medical experiment sponsored by UNC-Chapel Hill that we believe poses serious risks to the participants, and violates National Institutes of Health (NIH) guidelines for ethical human research. We have tried to bring this to the attention of the UNC Office of Human Research Ethics (OHRE) and its Institutional Review Board (IRB) but have received no substantive response. In addition to the health risks the study poses to infants and young children, we believe it also poses a reputational risk to the University. The study plans to recruit from a vulnerable population in a predominantly Black community in which many live below the poverty line.

Having received no substantive response from the UNC OHRE and IRB after e-mailing them four times, I am appealing to you to help arrange a meeting so that we can discuss our concerns with OHRE and IRB, the UNC offices responsible for overseeing the safety and ethics of this study.

In our communications to the OHRE and IRB we provided detailed explanations and supporting evidence for why this study poses serious risks to the child participants, and violates NIH ethical guidelines. I've attached our detailed letter of concern, first sent in March 2022, so I will just summarize the main problems with the study here.

The study is led by Dr. Gary Slade of the UNC School of Dentistry, and is a Randomized Controlled Trial (RCT) that will expose infants starting as young as 3 months of age to fluoride in specially bottled water, for four years, to see whether it reduces tooth decay. The problem is: the study ignores what is now a large and growing body of scientific evidence showing that fluoride – at the same levels of exposure as in this study – can cause neurotoxic harm, including loss of IQ and increased risk of ADHD. Experts in the field of neurotoxicity have described the magnitude of the harm as "on par with lead".

The NIH's National Toxicology Program (NTP) has been reviewing the evidence and has identified over 70 published, peer-reviewed human studies, of which the vast majority have found statistically significant associations between fluoride and lowered IQ. Consequently, several top scientific and medical leaders have publicly voiced their concerns with fluoridated water, including Linda Birnbaum, PhD, past director of the National Institutes of Environmental Health Sciences (NIEHS) and NTP; Dimitri Christakis, MD, editor of the *Journal of the American Medical Association Pediatrics*; and Harvard

Professor Philippe Grandjean, PhD MD, one of world's foremost authorities on environmental neurotoxins.

Because of the risk of neurotoxic harm, we believe this study poses serious ethical problems and violates multiple NIH requirements for human research. Not least of the violations is that the Informed Consent release that parents sign to enroll their infants never mentions the neurotoxic risks. But even if the parents were properly informed, the neurotoxic risks to the child participants outweigh any possible benefits. The study's protocol admits that dental benefits from participation are uncertain, and Dr. Slade's own previous work suggests the study is unlikely to produce more than a very modest saving of perhaps 1 cavity per child.

I am very disappointed that UNC's OHRE and IRB have failed to address the serious problems of this study, and have ignored our requests to discuss this further. That is why we are contacting you. In addition to being the chancellor of UNC-Chapel Hill, you are also a neuroscientist who has done extensive research on concussions. As someone attuned to the devastating effects of permanent brain damage, I hope you'll grasp the seriousness of our concerns for the risk this study poses of permanent harm to children's developing brains.

I respectfully request you facilitate arranging a meeting between my organization and the OHRE and IRB so that these concerns can be discussed directly. We would, of course, also be happy to provide you more details and answer any questions you may have.

Thank you for your consideration and I look forward to hearing from you soon.

Sincerely,

## Paul Connett

Paul Connett, PhD

founder, Fluoride Action Network (FAN) and the American Environmental Health Studies Project (AEHSP)

Dr. Connett is a graduate of Cambridge University, with a doctorate in chemistry from Dartmouth College. He taught chemistry and environmental toxicology at St. Lawrence University for 23 years. His areas of expertise include: interaction of metals with biological systems (chromium, lead); build-up of dioxins in food chains; health risk assessment; the problems, dangers and alternatives to incineration; resource management for a sustainable society (Zero Waste); the toxicity of fluoride and the dangers of fluoridation. He is co-author of the book *The Case Against Fluoride* (2011). He has been invited to testify on fluoride toxicity before numerous government and scientific bodies, including the National Academies of Science.

attachment: March 14, 2022 Letter of Concern to UNC OHRE and IRB