Testimony of Bernie Goldstein, M.D.

First – my deepest thanks to the Union of Concerned Scientists for their hard work in putting on this public hearing.

I have an influential scientific model, which I wish were wrong. It predicts that I am the oldest person at this hearing and, with 54 years of experience, have the longest tenure in performing what I personally believe to be pivotal and scientifically influential environmental health studies.

Science is a web. Disentangling one part of the web from another is almost impossible. For fine particulates, Sidney Laskin in the 1940s first showed that fine particles penetrated deeply into the lung and were more toxic than coarse particles.

A fine particulate standard could not be set under the 1970 Clean Air Act. Many confirmatory approaches in laboratory animals were needed, not all initially supporting the Laskin findings. Also needed was a robust monitor to measure fine particles, which took years and much controversy. But without these studies, we could not have had either the Harvard Six City study nor the American Cancer Society study, which have been poster children for the alleged need for transparency. Further, the acceptance of their findings depends upon the literally thousands of studies that have since confirmed these findings. Again,

not unanimously. Let me emphasize that none of the studies that I've already referred to fit the Supplement's definition of "Replication" or "Reanalysis." They fit this new term called "Reproduction."

The definitions given in the Supplement are mostly handwaving or not applicable to environmental epidemiology. One approach we use in science, while imperfect, is to look at journal citations of a paper.

Biological plausibility is almost uniformly referred to as a factor in EPA's description of the scientific analysis underlying regulation. As much of the studies related to biological plausibility that are cited by EPA are not dose response models, they will clearly be affected by the new approach.

As defined in the December 2019 Particulate ISA, "biological plausibility is part of the weight-of-evidence analysis that considers the totality of the health effects evidence, including consistency and coherence of effects described in experimental and observational studies." Each of the six health effects chapters contains a section on biological plausibility. The chapter on cardiovascular effects in its first 100 references were not studies in humans so were unrelated to dose response. I found 21, a 26% increase. In addition, the section on biological plausibility referenced the previous ISA, so these arguably were also influential. There was not always complete agreement among

the studies. The lack of agreement in all of the areas I've mentioned is not surprising given the complexity and inherent challenges of environmental human health studies. But that is the crucial point, without a clear definition, the Administrator is free to cherry pick which studies he or she wishes to call on.

Finally, these decision points and new definitions should be added to the many aspects of this overall proposal that should have been reviewed by EPA's Congressionally Mandated Scientific Advisory Board.