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Testimony for the Public Meeting of the Science Advisory Board (SAB) Written Comments of Dr. Bernard Goldstein on behalf of the Environmental Protection Network

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I am Bernard Goldstein, MD. I have been involved in environmental health since serving in the US Public Health Service Division of Air Pollution before it was merged into the new US Environmental Protection Agency (EPA) n 1970. I am a Fellow and former President of the Society for Risk Analysis, and an elected member of the National Academy of Medicine for whom I have chaired about a dozen committees mostly related to environmental risk. My past experience includes being appointed by President Reagan as EPA Assistant Administrator for Research and Development. I am here today as part of the Environmental Protection Network, a non-profit organization comprised of over 400 former EPA employees volunteering their time to protect the integrity of EPA and provide an informed and rigorous defense against current Administration efforts to understand public health and environmental protections.

I will abridge my submitted material to speak to the transparency issue. Let me refer you to my short written comments about the proposed revision of EPA's Cancer Risk Guidelines, which give the many reasons why this must be done with the utmost deliberation and care, rather than with a short and sloppy process.

I'll start by explaining why EPA is not Occupational Safety and Health Administration (OSHA), nor is it the U.S. Food & Drug Administration (FDA). A major reason why the SAB exists is because science at EPA is not organized like science at OSHA. EPA has a tremendous advantage in accomplishing science-based regulation by having its own scientific component rather than OSHA, which has the National Institute for Occupational Safety and Health (NIOSH) located in a completely separate agency. But the EPA organizational arrangement has one potentially fatal flaw. By having science and technology located in the same organization as the policymakers, it is easier for politics to interfere with the independence of scientific judgment. The antidote, provided by Congress, is requiring EPA to have very strong external review processes. That is where you, the SAB, come in.

EPA also is not FDA. While the FDA also has very strong congressionally mandated involvement of the external scientific community, the science underlying much of the Food and Drug Administration's decisions differs greatly from that on which EPA regulatory decisions are based – a point that is central to the proposed Transparency Rule. For its drug and medical device decisions, FDA depends heavily on studies with requirements that can simply not be matched by human environmental health studies. The gold standard for FDA is a double blind study in which half of a group of volunteers with a disease are given a placebo or the putative new therapeutic drug, and neither the patient nor the physician knows which until the code is broken. Which of you will volunteer for such a study of a potentially harmful environmental agent? We usually take advantage of temporal, geographical or idiosyncratic differences in exposure to study pollutant effects. Confounding is far more possible. So for replication of studies of the health effects of pollutants on humans, we depend upon the web of multiple studies done by different investigators using different research approaches. And we heavily depend upon independent analysis by external reviewers of the totality of this web to guide and confirm EPA's internal interpretation.

The goal of the primary advocates of this so-called "Transparency Rule" is to obtain raw data that can be used by paid consultants who nitpick to find blemishes in each study. These blemishes are then falsely magnified into scars, as has been done with formaldehyde. The overall goal is to change the consensus processes of science into the confrontational processes appropriate for law. If the SAB is not allowed to analyze the web of peer-reviewed science, including studies for which the raw data is not made available or is no longer available, how will you do your review?

Instead of the close working relationship between SAB and EPA envisioned by Congress, in which the SAB would have been involved in the decision process on this issue from the very beginning, you are disgracefully being treated as technical assistants. Your involvement is being requested solely to fix the problem caused by confidentiality issues. In essence, EPA is on a trip in which EPA leadership has decided where they want to go, what vehicle they will use, and the route they will take. But they suddenly need SAB to fix the flat tire of the Health Insurance Portability and Accountability Act (HIPAA) that is slowing them down. Unless you have your appropriate say in the direction and the process, it would be wrong of you to acquiesce in just fixing the flat tire.

The newly proposed transparency rules will also limit EPA's ability to anticipate or respond to new problems, something for which SAB advice would be highly pertinent. Suppose different groups of scientists in different countries report studies with similar findings of adverse effects of a chemical in use. But being unwilling to waste their time responding to scientifically frivolous attacks by industry consultants, they refuse to share their raw data with EPA. What will EPA do? What if there is one study from industry showing no effects, but having too little power to find the effects reported elsewhere, will EPA and the SAB only be able to consider the underpowered study? Further, what if the Office of Research and Development (ORD) had alertly perceived the problem and had competitively funded academic scientists to begin studying the issue. Under the conflict-of- interest rules, these knowledgeable EPA-funded scientists presumably would not be allowed to serve in an advisory capacity.

Revision of the Cancer Risk Guidelines

I personally welcome an update of EPA's Cancer Risk Guidelines. There is much important and exciting new information about cancer that has developed since these guidelines were released in March 2005. There is a report, which I have not seen confirmed, that states Mr. Wheeler has requested fast- tracking of the Guideline revision process to achieve completion by December 2020. I hope not. The suspicion that the report is true comes from its congruence with the same target date for promulgation of EPA's final decisions on the politically highly sensitive particulate matter and ozone air quality standards. But to be valid, the new cancer guidance document must take into account an enormous amount of pertinent new science. How, if at all, should advances in high throughput testing, or such concepts as mode of action, key cancer characteristics, outcome pathways and others be incorporated into guidance that may not be modified for perhaps yet another 15 years? The National Research Council (NRC) 2017 Committee report "Using 21st Century Science to Improve Risk-Related Evaluations" has well over 500 references in it. In the Toxicology chapter, I counted 176 references, of which 162 (92%) were since 2005. And this 2017 report is already out of date. My own particular interest is how cancer risk determinations would be affected, if at all, by the rapidly evolving information about the role and source of driver mutations that may differ in specifics

and in number for each cancer type. To what extent are driver mutations caused by internally and externally derived processes, and how pertinent is that to risk assessment for external factors? A search of the term "driver mutations" on PubMed on May 31, 2019, revealed 5,055 references including 1,121 reviews. If one looks at the 2005 EPA Cancer Risk Guidelines, driver mutations are not even mentioned.

Ironically, under EPA's new conflict-of-interest rules, those who have been funded by EPA to study some of these modern advances would be prohibited from serving on the SAB and otherwise limited in providing advice to EPA. Further, scientists working in this area would think twice about serving on SAB as it would limit their ability to apply for EPA funding. Does that represent EPA's political leadership's lack of understanding of scientific processes, or is it a cynical ploy to impose political will on scientific truth? Either way, the Science Advisory Board is the nation's defense against the continuing inadvertent or advertent destruction of the scientific base for EPA's decision-making.