

Oral Statement as Prepared for Delivery by

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House Committee on Science, Space, and Technology

Hearing on "Strengthening Transparency or Silencing Science?
The Future of Science in EPA Rulemaking"

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Good morning Chairwoman Johnson, Ranking Member Lucas, and Distinguished members of this Committee. I am Linda Birnbaum, recently retired after 40 years of federal service. I was Director of NIH's National Institute of Environmental Health Sciences and of the HHS' National Toxicology Program the past 10 years. Prior to that I spent 19 years at EPA, for most of it directing the Agency's largest health research division. I have conducted scientific research to better understand how the environment impacts our health, and have published over 800 peer reviewed papers, book chapters, and reports.

I am a member of the National Academy of Medicine, the recipient of the North Carolina Governor's Award for Science, former president of the Society of Toxicology, Vice-president of the International Union of Toxicology, chair of the Toxicology

Division of the American Society of Pharmacology and Experimental Therapeutics, and the recipient of multiple honorary degrees and awards. I have always been involved in the conduct of research, much of which has been used in making policy decisions. My work, and that which I have overseen, has involved basic biomedical research, toxicology, and public health. I have never been a regulator myself.

My comments today are those of a private citizen and do not reflect the views of NIEHS, NIH, or HHS. I want to focus on 3 basic issues. The first is the core values of scientific studies which involve people. Because it is unethical to intentionally expose people to chemicals of concern, observational human studies compare populations who have differing exposures. People provide personal information, such as medical information as well as behaviors, in confidence that their own data will not be openly shared. Human studies require confidentiality to be conducted. It is unethical to reveal individual human data. In many epidemiology studies, scientists and subjects work closely together in design, conduct, interpretation, and communication of the findings. Thus, the second point is that the impact of EPA's proposed transparency rule will make it not only more difficult for human studies to be conducted ethically, but in many cases will make it impossible to use any information collected, not only prospectively, but

looking back at the vast treasure trove of existing investigations.

The third point involves EPA's mandate to use the best available science to protect the environment and public health. Scientific knowledge is constantly evolving. While a given experiment may answer one question, it invariably raises others. There is always some uncertainty in science, but that does not mean that decisions cannot be made, which is why it is so important to use ALL the data. While I am a toxicologist, that does not mean I prefer using animal data when data from people exists! Nature is inherently conservative, and studies in various animal models can inform us about the potential for human risk. We can investigate observed effects mechanistically in animal and cell culture models and then ask whether the same mechanisms exist in humans. Such approaches all provide biological plausibility to human observational studies. When we have several epidemiology studies in different populations conducted by various investigators and achieve the same results, and there is supporting animal and mechanistic evidence, why would we think that we can't believe the findings?

Why would we want to rely solely on 20th century methodologies in the 21st century? Good Laboratory practice only assures that we know what was done, NOT that the right

question was asked. The same can be said of some guideline studies, which may be appropriate when you are looking for effects of pharmaceuticals in an individual, rather than effects of environmental exposures on a population. Small effects may not be measurable in an individual but may have large impacts on a population. For example, developmental exposure to lead results in a loss of several IQ points in a population, which has significant economic and societal costs, but you can't know whether each of us would be a little smarter if we hadn't been exposed to lead. Today we have systematic review of the lead data which confirm that there is no safe level for lead. In fact, the more we look at population data, there is no threshold for many exposures, including arsenic, mercury, and air pollution. Thresholds are often a function of analytical methodology. Why would EPA want to enshrine threshold approaches in regulation?

EPA's proposed transparency rule in fact will block the use of the best science. It will prevent EPA from using the best available science in making policy. In fact, it will practically lead to the elimination of science from decision making. EPA's current proposal would silence science and block its ability to meet its mission of protecting human health and the environment.

Thank you. I welcome your questions.