I wish to express my support — in the strongest possible terms — for the EPA's Proposed Rule, "*Strengthening Transparency in Regulatory Science*." My advocacy for this proposed strengthening of transparency is based on my 50+ years of experience in genetics/genomics (hypothesis-driven) research as a physician-scientist — including limited experience with the Cincinnati-based EPA Staff.

Briefly, to describe my career**:** After a BA degree in chemistry/biology, I earned an MS degree in biophysics, combined with MD degree (at the time, no combined MD/PhD program was available). After pediatrics internship and residency at UCLA, I spent 20+ years in genetics-genomics-pharmacology research and clinical medicine at National Institutes of Health (Bethesda MD), and then another 20+ years as physician-scientist at University of Cincinnati and Cincinnati Children's Hospital. While at the University Cincinnati Medical Center, I brought in (directly and/or indirectly) well over $100 million in NIH grants. I founded the Center for Environmental Genetics (CEG) in 1992 — which just last year received another renewal (PI = Shuk-Mei Ho) until spring 2022.

I am author/coauthor of more than 650 publications and (on Google Scholar) my current ***h*-index** is **119** with >62,000 "citations by my peers" (the average *h*-index for a tenured professor is about 35-40). In fact, ***on the March 2016 Google Scholars list***, among the "most cited authors in all fields, combined, and for all time since 1900" — I was ranked ***among the top 640*** (with Sigmund Freud, Eric Lander and Paul Krugman above me, Einstein and Linus Pauling below me). I've received numerous national and international recognitions for my work in genetics, evolutionary biology, and clinical genomics. I was elected AAAS Fellow in 1994.

In this proposal, the EPA aims to strengthen the transparency of the science it considers "pivotal" to its significant regulatory actions — by ensuring that "the data and models underlying the science are publicly available in a manner sufficient for validation and analysis." It cites existing authorities and policies, but acknowledges, "EPA has not previously implemented these policies and guidance in a robust and consistent manner." The proposed rule would not directly regulate non-governmental entities, but instead would require EPA "to ensure that the regulatory science underlying its actions is made immediately publicly available in a manner sufficient for independent validation."

The preamble says the policy is "designed to provide a mechanism to increase access to dose-response data, and to models underlying pivotal regulatory science — in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants, protection of proprietary data and confidential business information, and other compelling interests." In the long run, by means of this newly proposed rule, EPA aims "to change agency culture and practices regarding data access so that all scientific justifications for regulatory actions are truly available for validation and analysis."

From personal experience, during my early years at the University Cincinnati Medical Center, I tried repeatedly to interact with EPA staff members at their nearby facility in Cincinnati. They strongly urged/encouraged me to apply for an EPA "start-up" grant, which I did (twice; 1993 & 1994). Both times my grant was rejected without any explanation as to why my proposal had been turned down. Subsequentl, I gave up with this "EPA sttart-up grant-proposal nonsense," and I submitted an R01 proposal to NICHD, which was funded without any problem (NIH R01 ES07058 "Transgenic zebrafish**:** sentinel for aquatic pollution," 1 Mar 1995 – 28 Feb 1999).

From some of the online comments suggesting that "EPA should not demonstrate transparency in their dose-response studies" — from my own personal experience as PI of clinical R01s, I must strongly disagree with such a fallible nonsensical "straw man." One such statement**:** ("*Human studies could only be used by EPA if the investigators surrender confidential data (including personally identifiable information, trade secrets and commercial and financial information) that the investigators had promised the study subjects and institutional review boards would never be released. While the EPA might agree to redact these data before public posting, they could be given to anyone who signed a confidentiality agreement designed by the agency. Implications for the protections of human subjects and informed consent under the Common Rule (the Federal Policy for the Protection of Human Subjects) have yet to be*

evaluated." These statements are categorically untrue**:** all NIH clinical studies can only be approved for funding, if the investigators "surrender personally identifiable information — as it pertains to statistical reevaluation of the data and corroboration of the methods employed to study such data, which in turn might lead to public regulatory policy." In other words, EPA clinical studies should be held to the same high standards as all NIH clinical studies.

Another nonsensical online comment includes**:** "*Requiring all raw data to be made publicly available before a study can be utilized in EPA decision-making, will cut off EPA from foundational research that has informed EPA's work since the inception of the agency. The proposed rule sets an implied standard that peer-reviewed scientific research data that are not publicly available are not rigorous enough for use in decision making.*" This implied standard is absolutely true. Why should a secretly "insider-peer-reviewed" elitist group evaluate and approve something for public policy that affects millions of citizens, as well as billions of U.S. dollars in taxpayers' money?

Another nonsensical online comment includes**:** "*Whereas epidemiological studies often contain patient information and must maintain individual privacy, other studies may rely on public and private-sector funding sources that limit access to underlying data for proprietary reasons. The EPA's proposed rule risks rejecting this valid scientific evidence and fundamentally mischaracterizes the way science is conducted and made available for decision-making. By limiting the science EPA can use in policies and regulations, EPA will ultimately constrain itself to smaller groups of studies and risk biased outcomes. If the pool of research is smaller — which is what this proposed rule will lead to — that smaller pool utilized creates an inherent bias and thus the rulemaking process will yield distorted results*." This irrational conclusion also makes no sense. As PI on a number of clinical R01s over the years, I had these same restrictions, and my epidemiologist colleagues were in no way restricted by rigorous NIH rules in obtaining any size of cohort that we wished to obtain.

"*In the section of the proposed rule titled 'Public Availability of Data and Models,' the EPA notes that it is seeking greater transparency and public access to "dose-response data and models underlying pivotal regulatory science." Access to these data and models is also expected to be made available in a 'fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security.' The problem is that these two statements are incompatible. EPA cannot have access to dose-response data and models that are by law protected. Therefore, the rule is concerning, because it cannot comport with current laws protecting privacy. Thus, it ultimately limits the use of science containing legally protected data, much of which is specifically conducted to protect health and the environment.*" What about all genomic studies? They are secret and confidential, but it is now possible to identify the gender, race, ethnicity, and in many cases even specific countrues and/or regions within a country, in which the parents of the donor were born. ***In conclusion, there is absolutely no reason under the sun why EPA clinical studies should not be held to the same high standards as all NIH clinical studies***.

Sincerely yours,

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