Comment Number: 1k2-94vv-ydou

August 16, 2018

Office of the Science Advisor
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

RE: Comments on 83 FR 18768 - Strengthening Transparency in Regulatory Science Comments

Dear Acting Administrator Wheeler,

Medical Advocates for Healthy Air (MAHA), a network of health professionals across North Carolina, is writing in response to the U.S. Environmental Protection Agency's (EPA) request for comment on U.S. Environmental Protection Agency the proposed rule "Strengthening Transparency in Regulatory Science" (83 FR 18768). While transparency is a commendable goal in the development of any policy, it must be applied in a manner that respects individual privacy rights while in pursuit of credible and honest decisions. MAHA is a strong supporter of EPA's mission to protect human health and the environment utilizing the best available and defensible science as the foundation of sound policy. As such, MAHA sees a direct legal and moral conflict in the proposed transparency rule in its current iteration if the Agency is to pursue its mandated mission.

The implementation of this poorly conceived rule under the laudable light of the word "transparency" will have grave effects on the Agency's ability to protect human health and the environment, and at the same time, opens policy-making to potential distortion. The proposed rule would exclude critical epidemiological and clinical studies derived from human databases. These databases mask patients' personal identifiers to comply with the Health Insurance Portability and Accountability Act (HIPPA). Excluding studies based on these databases will essentially eliminate consideration of the best available science, whose use is mandated under the Clean Air Act. The proposed rule contains a provision for the Administrator's discretionary selection of studies used. This opens the door for personal, political, or other agendas that may well run counter to the mission of EPA. There are no criteria provided as to how this process would unfold.

The scientific community has long been working to improve the transparency and reproducibility of peer-reviewed research through requirements and encouragement from scientific journals, including the leading publications of *Science* and *Nature*[1]. Research manuscript submissions already undergo a critical and extensive peer review process with public declarations of conflicts of interest to publish the work. At the same time, rarely does one scientific publication change prevailing thinking; rather it is the replication of the science and weight of evidence of numerous – sometimes hundreds – of studies that actually influence scientific opinion.

The proposed rule would without doubt impede the development and utilization of new science. Access to human databases would be impeded or restricted, and the cost of doing the research both in investigator time and required funding to develop regulated processes for broad access would be substantial. As an unintended negative outcome, the community of scientists, which has increasingly grown to share the essential data used in research, would be thwarted by those who may be unable or unwilling to share their data, especially post-facto data that were part of the current publications already having gone through the peer review and publication process. The result would be a crippling, if not an elimination of the strong, crucial science that has been the backbone of existent, validated regulatory reviews per the Clean Air Act mandate.

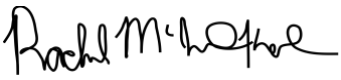
The Clean Air Science Advisory Committee (CASAC) was established in 1977 to explicitly provide a diverse, independent science peer review of all the considered science so the Administrator would have a direct report on the science and policy options to consider in parallel to those of staff. Along with public comment, this proven process has long provided the credible "process" only vaguely described in the proposal. The proposed rule seems not to trust the present process but offers no alternative or specific critique.

Epidemiological and clinical studies are considered the strongest evidence and have been the underpinning of many EPA regulations, perhaps most notably the National Ambient Air Quality Standard (NAAQS) for particulate matter (PM). The Harvard Six Cities[2] and American Cancer Society[3] studies constituted foundational research that helped enact the current PM standard and have been replicated by many other research groups. The database of science for the PM NAAQS has undergone three full review cycles and repeated OMB benefit assessments as to its effectiveness in economic savings and health benefits. As to the science itself, the independent replication of the findings of the Harvard Six Cities study by the Health Effects Institute, a public-private institute, brought the full data to a review team of academic and private sector investigators and laid to rest concerns about analysis approaches and data access. Ironically, in the current transparency proposal, the two studies noted could be excluded from future PM NAAQS reviews because they do not provide confidential and personal identifiable data as would be required – data which would have no bearing on the analyses or the findings.

The proposed rule would likely also include many animal and cellular studies since these do not have confidentiality concerns. However, animal and cellular studies are typically used as supporting evidence for mechanistic information and are not considered the strongest evidence. The National Toxicology Program (NTP) is a federal institution that regularly conducts systematic reviews similar to EPA's reviews though not used for regulation. The NTP Handbook for Systematic Review explains how to rank and review studies based on human, animal and other mechanistic studies. It notes that no evidence from an animal study alone can be used to deem a pollutant as a "known health hazard"[4]. Human health studies must also be considered. If human health studies like epidemiologic studies and controlled clinical studies are excluded because of this proposed rule, it would be very difficult to protect human health since the animal and cellular studies could be considered insufficient evidence for a decision. In addition, many historical toxicological animal studies and other studies might also be excluded as the data banks may not be currently available or constrained by prior disclosure agreements.

For the reasons outlined in these comments, MAHA strongly urges the EPA to not implement the proposed "Strengthening Transparency in Regulatory Science" rule (83 FR 18768) and instead to work with the scientific community to encourage the ongoing efforts to enhance transparency in publication as the journals *Science* and *Nature* have already done.

Sincerely,



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