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Network



California Pan-Ethnic Health Network

August 15, 2018

The Honorable Andrew Wheeler, Acting Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

Submitted via Regulations.gov

RE: Comments on Proposed Rule "Strengthening Transparency in Regulatory Science" Docket No. EPA-HQ-2018-0259

Dear Acting Administrator Wheeler:

We public health and medical organizations provide comments below on the proposed rule titled "Strengthening Transparency in Regulatory Science." As written, the proposal would allow the Administrator to limit and restrict the scientific research that the U.S. Environmental Protection Agency uses as the basis for public health and environmental protection regulations. On behalf of the health of our patients and the public, we strongly oppose this proposed rule.

#### **EPA Already Uses Transparent, Peer-Reviewed Science**

EPA states in the proposal that "the best available science must serve as the foundation of EPA's regulatory actions." We agree wholeheartedly with that sentence. Congress intentionally embedded peer-reviewed research in the foundation of the Clean Air Act, including requiring regular reviews of the science, explicitly recognizing that EPA needs the most current, peer-reviewed data to protect public health. These expectations also are reflected in other public health laws, including the Toxic Substances Control Act.

Unfortunately, the proposal enables unnecessary restrictions on the use of such science. The title paints the effort as "strengthening transparency," but the result would be just the opposite: the EPA administrator could obscure major, well-vetted research that has found evidence of a wide range of health risks of pollutants, including risks of premature death. If adopted, this change would make it impossible for EPA to arrive at sound



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judgements about the real-world impacts of air pollution and the benefits of cleaner air, resulting in air pollution standards that do not adequately protect health. The sole beneficiaries would be the industries and polluters that would continue to be able to spew their toxic emissions into the air our patients and our communities breathe.

EPA provides no clear rationale for the sweeping changes outlined in this proposed rule, nor have our organizations identified any need for such action. EPA's existing approach toward science, with its detailed review and deliberation of the research, is already transparent and has worked well for decades. Under the existing system, these studies are well-vetted: first, in their peer review and publication by recognized journals; and second, in the review by independent and staff scientists who ask tough questions about the scope, methodology, data sources, and findings during EPA reviews of proposed standards, policies and regulations. The findings are compared with other studies to examine similarities and differences as the scientists resolve the issues in question. Inconsistencies and replicability are explored in depth to understand what can and cannot be concluded from the findings. Simply put, EPA's proposed rule seeks to solve a problem that does not exist.

In the proposal, EPA references other scientific publications in its attempt to defend the rationale for these changes, citing "related policies by some major scientific journals" including *Science* and the *Proceedings of the National Academy of Sciences*. However, the editors in chief of those publications and others refuted that argument in a letter published in April in the journal *Science*, stating:

"It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigorous transparency standards will adversely affect decision-making processes."<sup>1</sup>

#### **The Proposal Would Block the Use of Seminal Health Studies**

Far from making science more transparent, EPA's proposal would allow the blocking of studies that rely on confidential patient information from being used in policymaking. Many studies, including older studies, depend on or have historically used such data that legally cannot be made public. Indeed, patient information is understandably critical to many studies showing health impacts of pollutants. The fact that this information must be kept confidential to protect patients does not make the data any less valid.

Nor can researchers effectively redact identifying data in a way that will protect confidentiality for many of these studies. The risks to privacy from



availability of patient data are recognized in the research and medical profession. For example, Princeton University warns researchers about the importance of data privacy and security, noting that even stripping out personal identifiers does not solve the problem as “the identity of individuals can be inferred by using data sets from multiple sources.”<sup>2</sup>



Industries and their allies have been pushing to exclude studies for decades, using the same arguments found in EPA’s proposal, targeting research that shows harm to public health from their products or their emissions. In 1996, attorneys working for tobacco industry giant R.J. Reynolds recommended a similar approach requiring review of documents “because, at some point in the future, EPA will most likely be ordered to re-examine ETS [Environmental Tobacco Smoke].”<sup>3</sup> EPA had issued its first report on ETS in 1992, concluding that secondhand smoke was responsible for approximately 3,000 deaths from lung cancer annually in nonsmoking adults.<sup>4</sup> To prepare for the anticipated next report’s likely conclusion of even greater harm from the products, the R.J. Reynolds attorneys developed a strategy to cast doubt on the studies while obscuring the company’s real purpose. As they explained in the memo:



“Because there is virtually no chance of affecting change on this issue if the focus is ETS, our approach is one of addressing process as opposed to scientific substance, and global applicability to industry rather than focusing on any single industrial sector. Thus the examples of questionable science, to justify these standards. Congress must require those examples serve as the test cases.”<sup>5</sup>



Oregon Public  
Health Association



The tobacco attorneys recommended expanding this approach to other industries,<sup>6</sup> which quickly happened. Two of the early industry targets were landmark air pollution studies completed in the 1990s that found solid evidence that particulate matter air pollution could cause premature death. The two long-term studies—the 1993 Harvard Six Cities Study<sup>7</sup> and the 1995 American Cancer Society (ACS) Study<sup>8</sup>—looked at large populations in multiple locations. The Six Cities study began tracking the health of 8,111 adults in six small cities in the United States in the 1970s. The much larger ACS study began with data from 552,138 people in 151 cities collected as part of the American Cancer Society’s Cancer Prevention Study II in 1982. Both studies controlled for smoking, education and other factors that could cause differences in outcomes. Both studies found the particulate matter in the air was linked to increased risk of premature death.

Greater Roanoke Valley Asthma  
and Air Quality Coalition



Maryland  
Public Health  
Association  
(MdPHA.org)





Their size and careful controls on other known risks gave these research findings substantial weight in EPA's review of the particulate matter national ambient air quality standard. EPA incorporated these studies into their review of the research, leading to the first national standard for fine particulate matter (PM<sub>2.5</sub>) in 1997. These studies were challenged in the 1990s by members of Congress and their industry supporters seeking access to the confidential patient information, arguing that the raw patient data should be public since the research was federally funded.<sup>9</sup> Other scientists argued for more investigation of whether confounding factors, insufficient years of data collection or other limitations might mean that the findings were not as powerful as they appeared to be.<sup>10</sup>

Instead of blocking the studies, as this proposal would do, EPA took a logical step and referred both studies to an independent third party, the Health Effects Institute, for a deep-dive review.

There, autonomous reviewers examined the data and developed a report on the two studies that confirmed their original findings.<sup>11</sup> Since these studies, other research has confirmed their findings as well, including some studies that used publicly available datasets.<sup>12</sup> Similar third-party reviews could readily address concerns about existing or future studies as needed.

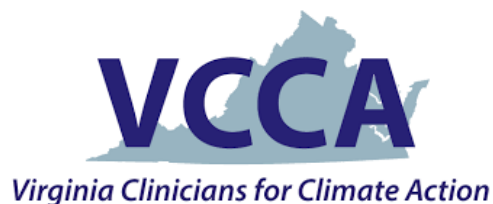
Researchers are currently incorporating more openness in data sharing where appropriate in their investigations. However, as recent public discussions over data collected online demonstrate, the public remains understandably concerned about the use of individuals' private information.

#### **EPA's Process for this Proposal Is Not Transparent**

EPA's pledge of transparency falls flat even in the writing of this proposed rule. EPA failed to alert the Agency's own Scientific Advisory Board to the possibility of this change, as the SAB Work Group noted in a memo to their fellow members, despite its semi-annual schedule for review of scientific and technological questions in upcoming regulations.<sup>13</sup>



## ARIZONA CHAPTER



The proposal also lacks critical information about what it would cover and how it would be implemented. It argues that the research must be “replicable” without defining what that means. Many studies cannot be specifically repeated, especially those that examine the impacts of historic events, such as the exposure of a half-million Americans to no-longer-existing levels of air pollution, or the health effects stemming from a massive oil spill. However, subsequent, similar studies from around the world have echoed their findings on health impacts. Which concept would EPA consider as replication?

This proposal also fails to discuss how EPA would implement this approach. The proposal offers no process for public hearing or even consultation with the SAB over implementation.<sup>14</sup> As written, the proposal would require review and assessment of volumes of existing research and revisions to internal processes yet to be determined. It also seems to give arbitrary decision-making authority to the Administrator to determine the fate of such research. Implementing this proposal would also require staff time and resources that would need to be included in budget proposals; such a massive additional workload cannot be absorbed by EPA’s existing budget without sacrificing other important Agency responsibilities, given the continued budget cuts proposed by the Administration.

Given the lack of any substantiated need for this change, the history of similar efforts led by polluting industries, the seminal health studies that stand to be excluded, the absence of scientific review or support, and the dearth of information on the implementation of this proposed rule, this is an untenable proposal. Our organizations urge EPA to withdraw this proposal and follow the current, effective measures in place to ensure the use of robust, uncensored scientific research to protect the health of our patients and our communities.

Sincerely,

**American Medical Student Association, Virginia Commonwealth  
University Chapter  
Allergy & Asthma Network  
Alliance of Nurses for Healthy Environments  
American College of Physicians**

**American Heart Association**  
**American Lung Association**  
**American Public Health Association**  
**American Thoracic Society**  
**Asbestos Disease Awareness Organization**  
**Association of Schools and Programs of Public Health**  
**Asthma and Allergy Foundation of America**  
**Asthma Coalition of Kern County**  
**Breast Cancer Prevention Partners**  
**California Pan-Ethnic Health Network (CPEHN)**  
**California Public Health Association - North**  
**California Thoracic Society**  
**Center for Climate Change and Health, Public Health Institute**  
**Central California Asthma Collaborative**  
**Central Virginia Asthma Coalition**  
**Children's Environmental Health Network**  
**Colorado Public Health Association**  
**Connecticut Public Health Association**  
**Consortium for Infant and Child Health (CINCH)**  
**Delaware Academy of Medicine**  
**Delaware Public Health Association**  
**Families USA**  
**Fresno Madera Medical Society**  
**Greater Roanoke Valley Asthma and Air Quality Coalition**  
**Hawaii Public Health Association**  
**Health Care Without Harm**  
**Health Officers Association of California**  
**Health Professionals for a Healthy Climate**  
**Idaho Public Health Association**  
**Illinois Public Health Association**  
**Iowa Public Health Association**  
**Kansas Public Health Association**  
**Kern County Medical Society**  
**Louisiana Public Health Association**  
**Maine Public Health Association**  
**Maryland Public Health Association**  
**Maternal and Child Health Access**

**National Association of County and City Health Officials**  
**National Environmental Health Association**  
**Nevada Public Health Association**  
**New Jersey Public Health Association**  
**New Mexico Physicians for Social Responsibility**  
**New Mexico Public Health Association**  
**Oregon Public Health Association**  
**Pennsylvania Allergy and Asthma Association**  
**Pennsylvania Public Health Association**  
**Physicians for Social Responsibility**  
**Physicians for Social Responsibility, Arizona**  
**Physicians for Social Responsibility, DC METRO Chapter**  
**Physicians for Social Responsibility, Maine Chapter**  
**Physicians for Social Responsibility, Pioneer Valley, Mass.**  
**Physicians for Social Responsibility, San Francisco Bay Area Chapter**  
**Public Health Institute of Western Massachusetts**  
**Regional Asthma Management and Prevention (RAMP)**  
**Rodham Institute**  
**Tennessee Nurses Association**  
**Texas Public Health Association**  
**Trust for America's Health**  
**Utah Public Health Association**  
**Virginia Chapter, American Academy of Pediatrics**  
**Virginia Clinicians for Climate Action**  
**Virginia Public Health Association**

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