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Administrator
U.S. Environmental
Protection Agency
1200 Pennsylvania Avenue,
NW Washington, DC 20460

July 17, 2018

Re: Docket No. EPA-HQ-OA-2018-0259
Strengthening Transparency in Regulatory Science

Dear Administrator:

On behalf of members of the Medical Society Consortium on Climate and Health (Consortium), I am writing to oppose the proposed rule referred to above. The proposed rule will not strengthen regulatory science but would instead require EPA to ignore the best available peer-reviewed scientific evidence and may violate patient confidentiality. It would also likely dampen scientific process by creating barriers to the use of quality research in EPA science. The proposed rule is counter to both scientific integrity and transparency, and likely will the harm the health of the public.

The Consortium represents 21 medical societies with a combined membership of over a 550,000 doctors.^A We seek to inform the public and policymakers about the health harms of climate change and the health benefits of solutions to climate change. The most important solutions are to decrease the burning of the fossil fuels that create carbon pollution and make any continued burning far more efficient. Efficiency means that there is less pollution associated with generating energy. Considerable progress has been made in efficiency of energy generation over the years.

Between 1990 and 2010, the Clean Air Act prevented over 160,000 premature deaths, 54,000 cases of chronic bronchitis, 130,000 acute myocardial infarctions, 1.7 million asthma exacer- bations, and 13 million lost work days.^V Landmark academic studies guided the EPA to implement policies leading to these dramatically positive outcomes.

^A American College of Physicians (ACP), American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), American College of Obstetrics and Gynecology (ACOG), the American Academy of Allergy Asthma & Immunology (AAAAI), American College of Preventive Medicine (ACPM), American Podiatric Medical Association (APMA), American Geriatrics Society (AGS), Academy of Integrative Health and Medicine (AIHM), American Association of Community Psychiatrists (AACCP), National Medical Association (NMA), Society of General Internal Medicine (SGIM), American Telemedicine Association (ATA), Society of Gynecologic Oncology (SGO), the California Chapter of American College of Emergency Physicians (ACEP-CA), American College of Osteopathic Internists (ACOI), American Medical Association (AMA), American Psychiatric Association (APA), American Medical Women's Association (AMWA), American Academy of Dermatology (AAD), American College of Lifestyle Medicine (ACLM).

These included studies by the American Cancer Society linking air pollution to lung cancer^{vi} and studies linking lead exposure to antisocial and delinquent behavior.^{vii,viii}

EPA's proposed rule would no longer allow EPA scientists to use much of the scientific evidence that formed the basis of these life-saving regulatory policies. The proposed rule would drastically and incorrectly limit the types of scientific data that EPA can use when making regulatory changes. Implementing this rule will harm the health of the people physicians provide care for as well as others who live in the same communities. If this rule were in effect, the EPA would be required to disregard some of the best available scientific studies examining the effects of pollutants ranging from lead to harmful chemicals to fine particle pollution and contaminants.

Scientific studies used by EPA to make regulatory changes are already rigorously examined prior to being published in peer-reviewed scientific journals. EPA requires an Institutional Review Board (IRB) to review all scientific studies occurring in an academic institution prior to beginning the study. The IRB very closely reviews all study methods to ensure that the methods are sound and study subjects are protected. Once a study is complete, data involving human subjects must be kept for a minimum of five years after study completion and must be available for IRB review. To publish the data in a scientific journal, scientists not associated with the research study must review the study design to ensure that it is scientifically sound. This includes assessing for "good laboratory practices" and "standardized test methods." In this rigorous peer-review process, which is already required for studies to be considered by the EPA, experts in the field of study not only assess the study's design and methods, but its statistical analysis and conclusions in an objective manner to determine the study's merit and significance. If any of these areas are deemed to be unsatisfactory, the study will not be published. When studies are published, the authors must detail all methods and statistical tests used and this information is presented to the public.

The process of peer-reviewed research is already transparent by design. This proposal would substantially undermine existing transparency protections and the integrity of the scientific basis upon which EPA makes decisions. If fully executed, this rule would greatly weaken EPA's ability to systematically consider all of the best scientific evidence available to inform practice and ensure the protection of the public's health. The rule's requirements would preclude the use of landmark health studies that have previously informed EPA protections.

Confidentiality protections and the use of difficult to reproduce epidemiological data are core aspects of public health research. Many of the studies that inform EPA policy to protect the public health are based on IRB-approved studies of the health of human subjects that require data confidentiality. Such studies involve observing the longitudinal effects from exposures to particulate matter, toxic substances, and other pollutants. Replicating such investigations to provide open access data for EPA to use would be morally unacceptable, as it would require exposing people to damaging pollution.

By requiring raw data to be available to the American public, this proposed rule may also violate patient confidentiality practices which are vital to the design and execution

of scientific research. Epidemiological studies often rely on gathering sensitive information from thousands of individuals and are typically protected by confidentiality agreements that prevent researchers from sharing identifiable data. For example, the co-author of the above-mentioned landmark American Cancer Society study has stated that he would have great difficulty publishing all of the study's raw data without violating patient confidentiality.^{ix} Decades of research that has already been performed will not be able to meet EPA's new standards, as the raw data may not be easily accessible and may be protected by confidentiality agreements that cannot be easily changed years after a study has closed. In terms of future studies, researchers may have difficulty recruiting participants if they fear that their confidential information will be made public. Studies will also have great difficulty in being approved by the IRB if raw patient data must be made public.

By requiring reproducibility, this rule may also exclude many landmark public health studies that were so scientifically rigorous and resource intensive that they could not be reproduced, such as the Framingham Heart Study, a 70-year long cardiovascular epidemiologic study, the Diabetes Control and Complications Trial, a 10-year study of the effects of intensive diabetes control on long-term complications, or the Nurses' Health Study, a decades-long study into the risk factors for major chronic diseases in women. Requiring reproducibility may also exclude studies done after landmark ecologic events such as oil spills and natural disasters. This rule does not improve the scientific merit of the studies used for EPA policies and instead creates significant barriers to EPA's assessment of past, current, and future scientific work.

EPA's previous science-based regulatory process has saved countless lives, prevented chronic diseases, and improved the quality of the air and water. The proposed rule will do nothing to advance these goals and instead will prevent evidence-based policies from being enacted. The proposed rule contravenes EPA's mission to ensure that Americans have clean air, land and water, and we strongly urge you not to move forward with it. If you have any questions, please contact me at msarfaty@gmu.edu or by phone at 240-338-7255.

Sincerely,



Mona Sarfaty, MD MPH
Executive Director

ⁱ American Academy of Pediatrics Committee on Environmental Health. "Ambient Air Pollution: Health Hazards to Children." *Pediatrics*, vol. 114, no. 6, 2004, pp. 1699–1707, doi:10.1542/peds.2004-2166.

ⁱⁱ American Academy of Pediatrics Committee on Environmental Health. "Global Climate Change and Children's Health." *Pediatrics*, vol. 120, no. 5, 2007, pp. 1149–1152, doi:10.1542/peds.2007-2645.

ⁱⁱⁱ Exposure to toxic environmental agents. Committee Opinion No. 575. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2013;122:931–5.

^{iv} Di Renzo GC, et al, International Federation of Gynecology and Obstetrics opinion on reproductive health impacts of exposure to toxic environmental chemicals, *Int J Gynecol Obstet* (2015), <http://dx.doi.org/10.1016/j.ijgo.2015.09.002>

^v US Environmental Protection Agency. “The Benefits and Costs of the Clean Air Act from 1990 to 2020 Summary Report.” April 2011, pp. 14-15.

^{vi} American Academy of Pediatrics Committee on Environmental Health. “Ambient Air Pollution: Health Hazards to Children.” *Pediatrics*, vol. 114, no. 6, 2004, pp. 1699–1707, doi:10.1542/peds.2004-2166.

^{vii} American Academy of Pediatrics Council on Environmental Health. “Prevention of Childhood Lead Toxicity.” *Pediatrics*, vol. 138, no. 1, 2016, doi:10.1542/peds.2016-1493.

^{viii} Exposure to toxic environmental agents. Companion to Committee Opinion No. 575. American College of Obstetricians and Gynecologists; American Society for Reproductive Medicine; the University of California, San Francisco Program on Reproductive Health and the Environment. 2013. Retrieved from:

<https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/ExposuretoToxic.pdf>.

^{ix} <https://www.scientificamerican.com/article/landmark-air-pollution-studies-could-be-excluded-by-proposed-epa-rule/>