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November 13, 2019

The Honorable Eddie Bernice Johnson, Chair
The Honorable Frank Lucas, Ranking Member
Committee on Science, Space, and Technology
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairwoman Johnson and Ranking Member Lucas:

The Association of American Medical Colleges (AAMC) is pleased to submit the following July 2018 letter for the record to accompany the House Science, Space, and Technology Committee's November 13 hearing, "Strengthening Transparency or Silencing Science? The Future of Science in Environmental Protection Agency (EPA) Rulemaking."

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The attached letter was submitted by the AAMC and other members of the higher education community in response to the EPA's April 2018 proposed rule, "Strengthening Transparency in Regulatory Science," which seeks to limit the science the agency could consider in rulemaking to research for which all underlying data are publicly available. While EPA Administrator Andrew Wheeler at a September 19 hearing before the committee stated that the agency intends to issue a supplemental proposal to the April 2018 proposed rule, we wish to reinforce the previous comments from the AAMC and its peer institutions, and encourage the EPA to rescind the proposed rule and work with the scientific community on the development of an evidence-based policy that promotes the use of the best science in protecting human health.

The AAMC appreciates the opportunity to submit this letter to reiterate the importance of the use of scientific evidence in agency rulemaking and looks forward to continuing to work with the committee and agencies to ensure that the best available and most relevant scientific findings are used in rulemaking activities to promote the health of all Americans.

Sincerely,

Karen D Fisher

Karen Fisher, JD
Chief Public Policy Officer

July 11, 2018

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Submitted electronically at www.regulations.gov

Re: Docket Number EPA-HQ-OA-2018-0259-0025, Strengthening Transparency in Regulatory Science

The Association of American Medical Colleges (AAMC), Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), and Council on Governmental Relations (COGR), collectively the "Associations," write in response to the proposed rule issued by the Environmental Protection Agency (EPA), published in the Federal Register on April 30, 2018. The member institutions of AAMC, AAU, APLU, and COGR are the primary performers of federally funded research.

In this notice of proposed rulemaking (NPRM), the EPA has set forth a process that limits the science it will consider in critical rulemaking activities to those studies for which all underlying data are publicly available for analysis. Rather than foster the laudable goals of increasing transparency and enhancing the validity and reproducibility of scientific findings, this proposed rule would effectively prevent the EPA from evaluating the *best available* evidence when developing regulations specifically aimed at protecting human health. **While our Associations strongly support transparency, reproducibility, and open science, we have never suggested that scientific research lacks merit or value if the data, for legitimate reasons, cannot be made publicly available or reproduced.** We are particularly concerned when such rationale becomes the justification for ignoring scientific evidence that can save lives. **The Associations, therefore, urge the EPA to withdraw this proposed rule.**

The proposed rule does not advance the type of sound, evidence-based policymaking that is essential for every agency, and particularly important for the EPA, whose activities and regulations have a profound impact on air, land, and water quality, and thus the health of all Americans. **This proposal thwarts the promise of evidence-based policymaking, squarely contradicting the requirement that the EPA use the "best available science"[1] to make its regulatory decisions.** Basing decision-making on only those

[1] Exec. Order No. 13563, 3 C.F.R. 3821 (2011) and Exec. Order No. 13783, 3 C.F.R. 16093 (2017).

studies with publicly available data would drastically curtail the use of key information and studies in the policymaking process and ignore the entire body of scientific evidence built up over years of inquiry.

The NPRM indicates that it "takes into consideration the policies and recommendations of third party organizations who advocated for open science." However, while encouraging greater access to research data and suggesting incentives or necessary infrastructure enhancements to enable data sharing, **most of the cited reports and policies from respected organizations listed do not recommend or support the premise that research should be disregarded if the data are not publicly available.** The recommendations from one such report from the National Academies of Science, Engineering, and Medicine, "*Optimizing the Nation's Investment in Academic Research*,"[2] were incorporated into the 21st Century Cures Act and discuss the potential burdens of data sharing policies, but do not suggest that a policy such as the one being proposed by the EPA would be beneficial.

The NPRM further asserts that the policies are "informed by the policies recently adopted by some major scientific journals," specifically citing the journals *PLOS ONE*, *Science*, and *Nature*. A commentary by the editors in chief of those journals in response to this NPRM refutes this characterization and rejects such a stringent approach, 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 rigid transparency standards will adversely affect decision-making processes."[3]

There are legitimate, reasonable and ethical reasons that scientific data may not be available to the public. This should not invalidate the research or its findings, and should not prevent the research from being used in important EPA rulemaking. In cases where it is not appropriate for data to be made publicly available, there are other mechanisms intrinsic to the scientific process for substantiating the relevance and validity of research results. Large-scale health and environmental studies generally involve sensitive data from human subjects, which may not be fully de-identifiable. In addition, many individuals agree to participate in these research studies through an informed consent process that ensures their data will not be shared in any form. The assurances provided to research subjects are reviewed, along with the entirety of each proposed study, by an institutional review board (IRB) charged with ensuring the ethical treatment of human subjects and their data. As a highly relevant example, data from the landmark "Six Cities" study[4] that established a link between air pollution and human mortality, could not be made

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[2] National Academies of Sciences, Engineering, and Medicine. 2016. *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*. Washington, DC: The National Academies Press. https://doi.org/10.17226/21824.

[3] Berg, J., Campbell, P., Kiermer, V., Raikhel, N., Sweet, D. Joint statement on EPA proposed rule and public availability of data. Science. 2018 May 4:360(6388). http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

[4] Dockery, D.W., Pope, C.A., Xu, X., Spengler, J.D., Ware, J.H., Fay, M.E., Ferris, Jr., B.G., Speizer, F.E. An Association between Air Pollution and Mortality in Six U.S. Cities. N Engl J Med. 1993 329:1753-1759. https://www.nejm.org/doi/full/10.1056/NEJM199312093292401.

publicly available for a number of reasons, including promises that were made to the study participants at time of enrollment. Notably, the outcomes of this particular study have been validated in a number of scientifically rigorous ways and by several independent studies. Nowhere does the NPRM suggest that other mechanisms could be used to give the EPA confidence that the findings should be considered in rulemaking. Such mechanisms include comparing outcomes of several trials from different groups that reach the same conclusions, and vetting the science through expert scientific panels specially convened for this purpose. These mechanisms are especially important for studies conducted in the past, for which the underlying datasets may be wholly unsuitable or unavailable for public review.

In some instances, this proposed rule will directly conflict with Executive Order 13556[5] and the accompanying National Archives and Records Administration implementing directive[6], which place limitations on the release of specific non-classified information involving privacy, security, proprietary business interests, and law enforcement investigations. We would particularly question if controlled unclassified information (CUI) categories limiting the release of information relating to health, genetic information, proprietary business information, pesticide producers and railroad safety analysis records[7] might prevent valid scientific studies based upon these CUI categories from being released and as a result, prevent the best possible scientific evidence from being used to develop regulations aimed at protecting public health and safety.

Even for those studies where the researchers are not specifically prohibited by an IRB or other restrictions from making the data publicly available, **de-identification to maintain privacy is not simply a matter of redacting names from documents, but a complex and resource-intensive process**. Scientific data may be prepared for and shared with other scientists for many reasons, including the development of new hypotheses, new analyses to seek novel patterns or test current suppositions, or for purposes of reproducing or confirming aspects of a particular study, and also to avoid duplication of efforts and accelerating discovery. Weighing the merit of these approaches, the privacy considerations, and the resources needed to accomplish meaningful data sharing is what drives these decisions today, and should continue to be considerations going forward. Policy should be informed by science, but science is not always undertaken for purposes of informing regulatory decisions.

Even the strongest and most sincere supporters of the open science movement have recognized that there is value in research for which underlying data are not made publicly available and acknowledge an imperative to leverage all science to develop policies and regulations.[8] The goals of open science are not advanced through this proposal, which does not provide incentives, funding, or infrastructure for increasing access to data, but simply allows the Agency to disregard important, ethical, well-designed and executed studies.

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[5] Exec. Order No. 13556, 3 C.F.R. 68675 (2010).
[6] 32 C.F.R. pt. 2002 (2016).
[7] National Archives CUI Categories (2018). *Available at:* https://www.archives.gov/cui/registry/category-list.
[8] Ioannidis, J.P.A. All science should inform policy and regulation. PLOS Medicine. 2018 15(5): e1002576. https://doi.org/10.1371/journal.pmed.1002576.

The trend toward data transparency championed by the Associations and by foundations and science agencies around the world is predicated on the view that **peer-reviewed, published studies already have presumptive scientific merit.** In fact, the EPA itself is bound through a recent Executive Order to develop regulations through "transparent processes that employ the best available peer-reviewed science."[9] The proposed rule presumes that peer-reviewed, otherwise credible scientific studies do not merit consideration in the agency's decision making, unless data supporting the study are made publicly available within the agency's specifications. This presumption is not in keeping with the spirit of data transparency as understood by the scientific community. Science does not depend on the public availability of underlying data to indicate quality and reliability of evidence, and public availability of research data is not a proxy for the reproducibility of science. **The Associations urge the EPA to promptly rescind this proposed rule, and to engage with the scientific community to discuss how evidence-based policy should be developed to protect human health and the environment.[10]**

Sincerely,

Darrell G. Kirch	Mary Sue Coleman	Peter McPherson	Anthony P. DeCrappeo
President and CEO, AAMC	President, AAU	President, APLU	President, COGR

The Association of American Medical Colleges (AAMC) is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems; and more than 80 academic societies. The Association of American Universities (AAU) is an association of 60 U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities. The Association of Public and Land-grant Universities (APLU) is a research, policy, and advocacy organization with a membership of 237 public research universities, land-grant institutions, state university systems, and affiliated organizations in the U.S., Canada, and Mexico, that is dedicated to strengthening and advancing the work of public universities. The Council on Governmental Relations (COGR) is an association of over 190 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

[9] Exec. Order No. 13783, 3 C.F.R. 16093 (2017).
[10] United States Environmental Protection Agency. Our Mission and What We Do. https://www.epa.gov/aboutepa/our-mission-and-what-we-do.