



May 18, 2020

Administrator Andrew Wheeler
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Submitted electronically at www.regulations.gov

Re: Docket ID No. EPA-HQ-OA-2018-0259, Supplemental Notice of Proposed Rulemaking to the Rule “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 supplemental notice of proposed rulemaking (SNPRM) issued by the Environmental Protection Agency (EPA), published in the Federal Register on March 18, 2020. The member institutions of AAMC, AAU, APLU, and COGR are the primary performers of federally funded research.

As outlined in public comments submitted by our organizations in 2018,¹ the original proposed rule (EPA-HQ-OA-2018-0259-0025) would limit the EPA’s use of science in the rulemaking process to those studies for which all underlying data were publicly available and prevent the agency from considering the best available science when developing regulations aimed at protecting human health. The SNPRM presents alternative proposals to address the hundreds of thousands of comments that opposed the approach, but does not remedy the essential flaw in a rule that codifies justifications for selectively dismissing important research that should inform the EPA. Our associations are dedicated to transparency, reproducibility, broad dissemination of the results of federally funded research, and rulemaking based on the best available evidence, but the proposed rule and the alternative proposals contained in the supplement do not advance these goals. 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. If this rule is made final, the EPA will fail to meet a key component in its enabling legislation that requires the agency use the “best available science”² in its regulatory decisions. **We therefore urge the EPA to withdraw the proposed rule and supplemental notice.**

¹ AAMC, AAU, APLU, and COGR comments re: Docket Number EPA-HQ-OA-2018-0259-0025, Strengthening Transparency in Regulatory Science. <https://www.aamc.org/system/files/c/1/490086-aamceparesponseonprnm7-11-18.pdf>

² Reference: EPA enabling legislation, Exec. Order 13563 (76 FR 3821, Jan. 21, 2011) and [2017 Executive Order 13783](#)

The SNPRM expands the scope of the proposed rule to include “influential scientific information” and proposes an alternative approach to regulatory decision-making that would allow the agency to give *greater consideration* to studies in which the underlying data is available for independent validation. The value or merit of peer-reviewed science is not determined by the public availability of the underlying research data, and there is no scientific justification for a rule that directs the agency to selectively weight certain studies over others based on this factor alone. The definition of “influential scientific information” in the SNPRM suggests that the EPA should ignore preliminary studies in which data is not yet or cannot be made available in its current form. This broad definition expands the stated intent of the EPA to narrow the use of evidence in its rulemaking decisions by discarding studies that are not yet final but may have significant implications for human health and the environment.

The incorporation of conclusions from peer-reviewed, quality science is critical to the integrity and effectiveness of the EPA’s regulatory and rulemaking processes and its mission “to protect human health and the environment.” The proposed rule and supplemental information, however, serve only to limit the studies the EPA can consider to those in which the data is publicly available, regardless of quality and value. These efforts limit the EPA’s own ability to engage in evidence-based policymaking and do not address a legitimate need, as *the EPA already has the authority to determine which studies it will consider during rulemaking*. The public notice and comment period provide an opportunity for the agency to communicate the scientific research that supports its proposal. Instead, the rule’s limit on the EPA’s use of science will tie the agency’s hands indefinitely and call into question the integrity of its regulatory decisions.

There are legitimate legal, ethical, historical, and, occasionally, practical reasons that scientific data may not be publicly available. 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.

Nowhere does the SNPRM 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 convened for this purpose. These mechanisms are especially important for past studies whose underlying datasets may be unsuitable or unavailable for public review.

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; for purposes of reproducing or confirming aspects of a particular study; and to avoid duplication of efforts and accelerating discovery. This is a wholly separate issue than the merit and reproducibility of science. For research studies that the EPA does not fund or support, the public availability of data is a retroactive requirement for agency officials rather than a mandate or recommendation to

researchers conducting the science. Policy should be informed by science, but science is not undertaken for the purpose of informing regulatory decisions.

We appreciate the opportunity to provide comments on the EPA's supplement to the proposed rule, "Strengthening Transparency in Regulatory Science." As noted above, our member organizations take the need for evidenced-based policymaking and commitment to scientific integrity and transparency seriously, and we welcome the opportunity to assist the EPA in achieving those objectives. However, the proposed rule does not further those goals and should not be revised through the SNRMP but rather rescinded entirely. EPA scientists should use their unimpeded judgement and the best available science to make regulatory decisions. The use of the best available and most relevant evidence to inform regulations is essential not only for the EPA, but across the federal government to advance public health and environmental protection.

Sincerely,



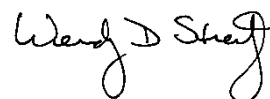
David J. Skorton
President and CEO, AAMC



Mary Sue Coleman
President, AAU



Peter McPherson
President, APLU



Wendy D. Streit
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 155 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 63 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 over 200 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 almost 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.