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United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6175

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March 24, 2020

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency
1301 Constitution Ave. NW
Washington, DC 20460

Dear Administrator Wheeler:

I write to urge you to withdraw EPA's proposed rule entitled "Strengthening Transparency in Regulatory Science," a sweeping policy intended to limit the use of science in EPA rulemaking. The ongoing COVID-19 pandemic has illustrated the importance of ensuring rapid access and response to scientific information, as well as the utilization of that information. Unfortunately, if this rule is finalized, I fear the result will be just the opposite.

This rule, first proposed on April 24, 2018,¹ has been criticized by a wide range of elected officials,² health professionals,³ scientific experts^{4,5} and other⁶ stakeholders.⁷ These criticisms stemmed in large part from concerns that if implemented, the rule would undermine the scientific integrity of the agency's decisions and violate the Administrative Procedure Act and environmental laws that require the best available science to be considered, would bias the agency against using independent academic research, would result in less protective environmental rules (and revisions to existing rules), and could discourage patients from agreeing to participate in important research studies due to a concern that their personal information might not be kept private because of the rule's requirement that raw data be publicly available in order for EPA to be authorized to use the study.

The March 3, 2020 release of EPA's supplemental proposed rule⁸ has only heightened these concerns. I particularly wish to highlight two specific concerns, in addition to the wide-ranging issues that I and others have previously expressed:

¹ <https://www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations>

² <https://www.carper.senate.gov/public/index.cfm/2018/4/carper-leads-epw-democrats-in-questioning-pruitt-s-effort-to-limit-epa-s-use-of-science>

³ <https://www.lung.org/assets/documents/advocacy-archive/comments-from.pdf>

⁴

https://science.sciencemag.org/content/360/6388/eaau0116?ijkey=ad15ef498c27731afbd3cffb3650793edb1d57f9&kytype2=tf_ipsecsha

⁵ <https://s3.amazonaws.com/ucs-documents/science-and-democracy/secret-science-letter-4-23-2018.pdf>

⁶ <http://blogs.edf.org/health/files/2018/08/EDF-comments-on-censored-science-proposal-final.pdf>

⁷ <https://www.lung.org/assets/documents/advocacy-archive/comments-from-69-public.pdf>

⁸ [https://www.epa.gov/sites/production/files/2020-](https://www.epa.gov/sites/production/files/2020-03/documents/supplemental_notice_of_strengthening_transparency_in_regulatory_science.pdf)

[03/documents/supplemental_notice_of_strengthening_transparency_in_regulatory_science.pdf](https://www.epa.gov/sites/production/files/2020-03/documents/supplemental_notice_of_strengthening_transparency_in_regulatory_science.pdf)

EPA has expanded the scope of its rule

In its supplemental proposal, EPA has expanded the scope of the rule to apply, not just to scientific information that could be used as the agency undertakes significant regulatory actions, but to all influential scientific information⁹ that could “have a clear and substantial impact on important public policies or private sector decisions.” EPA has also expanded the rule to apply to all data and models, not the more limited dose response data and models to which the first version of this proposed rule applied.

COVID-19 provides an example of the public health risks of this proposal

EPA has responded to concerns that the rule might prevent the use of important studies that cannot be reproduced or for which the underlying data cannot be made public due to privacy or other concerns by creating a process for such studies to be independently validated or receive an exemption from the rule. However, I believe that placing time-consuming barriers to the use of scientific information could in some cases be more than a mere annoyance or ministerial task; it could be fatal. The following are three examples of research that would seem highly applicable to EPA’s responsibilities to respond to the COVID-19 pandemic:

- A March, 2020 survey¹⁰ of existing research that describes the interaction of several coronaviruses on surfaces with biocidal agents. EPA is responsible¹¹ for recommending disinfectants for use against SARS-CoV-2 and other pathogens.
- A 2003 paper¹² which describes a statistical correlation between SARS fatalities in China and higher exposure to air pollution, information that could be relevant to EPA air officials as new criteria pollutant standards or air quality advisories for those at risk of the most adverse effects of COVID-19 are developed.
- A 2015 paper¹³ that describes the challenges associated with the sterilization and disposal of medical waste contaminated by Ebola. EPA worked jointly¹⁴ with CDC to develop disposal and sterilization guidelines and could be called on to do the same for SARS-CoV-2.

If EPA’s rule was in place, before these studies could be used by EPA decision-makers there would, at minimum, be a time-consuming review needed in order to determine a) whether they meet the rule’s requirements and/or b) whether they require independent validation or a case-by case exemption from the rule’s applicability before they could be used for EPA decision-making purposes. Even if these and other relevant studies were ultimately deemed to be eligible for use under this rule, this rule would clearly establish barriers and delays to using available science to inform EPA’s response.

⁹ https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm

¹⁰ <https://www.ncbi.nlm.nih.gov/pubmed/32035997>

¹¹ <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>

¹² <https://ehjournal.biomedcentral.com/articles/10.1186/1476-069X-2-15>

¹³ <https://onlinelibrary.wiley.com/doi/abs/10.1002/wmh3.164>

¹⁴ <https://archive.epa.gov/pesticides/oppad001/web/html/ebola-efficacy-claims.html>

However, it is also possible that studies that could be usefully relied upon during a pandemic or other crisis would be systematically excluded from being used in EPA's scientific and regulatory efforts well before the next pandemic or other crisis occurs if this rule is finalized. For example, since the proposed rule would systematically exclude studies that do not meet EPA's criteria for independent validation, critical studies that would otherwise inform influential scientific information will not be used or incorporated into key documents such as the Integrated Scientific Assessment for Particulate Matter. This document is informed by studies that show that air pollution exposure increases the risk of developing lower respiratory infection.¹⁵ An examination of Table 5-10 of this document reveals that many of these studies are epidemiological papers analyzing the numbers of hospital visits or other medical outcomes in locations all around the world on days when air pollution is high. It is highly likely that some or all of these studies would be presumptively excluded from being used by EPA's rule, which means that they could cease to be incorporated into updates of EPA's Integrated Scientific Assessment, and thus excluded from being used both to inform EPA's criteria air pollutant regulatory efforts as well as to inform policymakers seeking to assess the influence of air pollution on and develop and implement measures to mitigate COVID-19 (or other future national or global challenges).

I urge you to withdraw this proposal, which I believe is irresponsible, and instead do all that you can to encourage the use of science in furtherance of EPA's mission to protect human health and the environment, rather than suppress it. Thank you for your attention to this important matter. If you have any questions, please feel free to ask the appropriate member of your staff to contact Michal Freedhoff (Michal.Freedhoff@epw.senate.gov) of the Environment and Public Works Committee staff. With best personal regards, I am,

Sincerely yours,

Thomas R. Carper
Ranking Member

¹⁵ http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=539630 See Table 5-10