American Lung Association.

May 18, 2020

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

Submitted via Regulations.gov

RE: Comments on Supplemental Notice of Proposed Rulemaking (SNPRM) to "Strengthening Transparency in Regulatory Science" Proposed Rule - *Docket ID No. EPA-HQ-OA-2018-0259*

Dear Administrator Wheeler:

The American Lung Association appreciates the opportunity to provide these comments on the U.S. Environmental Protection Agency's Supplemental Notice of Proposed Rulemaking to "Strengthening Transparency in Regulatory Science" Proposed Rule (Docket ID No. EPA-HQ-OA-2018-0259). We strongly opposed the original Proposed Rule. As we explained in our 2018 comments, the proposal would restrict the EPA's use of the best available science to inform public health and environmental protection regulations, at an unacceptable cost to human health.

We know we were not alone in opposing this dangerous proposal. The Agency received over 600,000 comments. Rather than listening to the scientific, medical, and public health experts who oppose the proposal – and safeguarding the role of sound science in EPA's regulatory process – the supplemental proposal expands the scope of the proposed rule. These expansions further undermine the ability of the Agency to fulfill its statutory duties to protect human health and the environment.

Despite the vague and arbitrary alternatives in the SNPRM for handling research that relies on confidential patient information, the Supplemental Proposed Rule retains the deeply problematic provision at the core of EPA's original proposal: that such research is excluded in EPA policymaking. The proposed alternatives – tiered access and diminished consideration – that purport to create limited exceptions in no way ameliorate the concerns with the original Proposed Rule, and in fact create additional legal and scientific obstacles. Both alternatives unacceptably restrict the scientific research that EPA uses to inform "influential scientific information" or uses as the basis for public health and environmental protection regulations.

The Proposed Expansions of the Scope of the Rule Amplify the Harmful Consequences of the Proposal

The Supplemental Proposed Rule expands the scope of the Proposed Rule in multiple ways, which together amplify the negative impacts to health that the Lung Association has already identified. The Supplemental Proposed Rule clarifies that the proposal would apply to 1) studies that underlie the development of influential scientific information, not just those that drive significant regulatory decisions; and 2) all data and models, not just dose-response data and dose-response models. In other words, with very limited exceptions, the requirements would apply to all science on which the agency relies for policymaking. These expansions will further hinder the Agency's ability to effectively protect the public from air pollution and other environmental threats.

The Proposal Would Block the Use of Seminal Health Studies

Far from making science more transparent, EPA's proposal would – despite any clarifications and modifications made in the Supplemental Proposed Rule – block the use 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."[1]

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]."[2] 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.[3] 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."[4]

The tobacco attorneys recommended expanding this approach to other industries,[5] 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[6] and the 1995 American Cancer

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[1] Princeton University. Research Integrity and Assurance: Research Data Security. 2018. Accessed at https://www.princeton.edu/ria/human-research-protection/data/.

[2] Memo from Christopher C. Horner, Bracewell & Patterson, L.L.P. to Tim Hyde and Randy Johnson, R.J. Reynolds Tobacco Company. December 23, 1996. UCSF Library and Center for Knowledge Management. Truth Tobacco Industry Documents. Accessed at https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=jhxk0020

[3] U.S. Environmental Protection Agency. 1992. Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders. EPA Document Number 600/6-90/006F. (600690006F)

[4] Memo from Horner, December 23, 1996. p. 2.

[5] Memo from Horner, December 23, 1996. p. 5.

[6] Dockery DW, Pope III CA, Xu X, Spengler JD, et al. 1993. An Association between Air Pollution and Mortality in Six U.S. Cities. *N Engl J Med*. 329:1753-1759.

Society (ACS) Study[7] --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.

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 ($PM_{2.5}$) 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.[8] 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.[9]

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.[10] Since these studies, other research has confirmed their findings as well, including some studies that used publicly available datasets.[11] 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.

The Agency's New and Modified Approaches for Addressing Data and Models that Cannot be made Public are Ambiguous, Impractical, and, Ultimately, Would Continue to Restrict the Use of the Best Available Science

At the outset, the Supplemental Proposed Rule retains the central premise of the original Proposed Rule: that research and scientific studies that rely on confidential patient information are, as a starting point, excluded in EPA policymaking. The vague and arbitrary options in the SNPRM for handling such research do not correct this fundamental problem. The Supplemental Proposed Rule provides that restricted data and models may be considered "publicly available in a manner sufficient for independent validation" (allowing for the use such research in EPA policymaking) if the data and models are available through a "tiered access" process. The Agency does not,

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[7] Pope III CA, Thun MJ, Namboodiri MM, Dockery DW et al. 1995. Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults. *Am J Respir Crit Care Med.* 151: 669-674.

[8] Couzin J. "Making science an open book" *U.S. News & World Report*, March 29, 1999.

[9] Health Effects Institute. 2000. Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality: A Special Report of the Institute's Particle Epidemiology Reanalysis Project. Health Effects Institute, Cambridge MA. P. 1.

[10] Health Effects Institute. 2000. Summary of Parts I and II.

[11] Eftim SE, Samet JM, James H, Modermott A, Dominici F. 2008. Fine Particulate Matter and mortality: a Comparison of the Six Cities and American Cancer Society Cohorts with a Medicare cohort. Epidemiology. 19(2): 209-216; Zeger S, Dominici F, McDermott A, Samet J. 2008. Mortality in the Medicare population and chronic exposure to fine particulate air pollution in urban centers (2000-2005). *Environ Health Perspect*, 116: 1614-1619.

however, explain how such a tiered access process would be implemented, aside from a vague and undefined reference to subjecting the release of underlying data to "access and use restrictions."

When selectively releasing restricted data, EPA must nonetheless – as the Agency acknowledges – comply with all relevant laws, including those that protect privacy and confidentiality. With that in mind, to whom would EPA release the otherwise restricted data and under what circumstances? Would the recipient(s) of the restricted information be a subset of the public with demonstrated scientific expertise? How would the Agency decide who receives the restricted information and how will it evaluate the adequacy and integrity of any tiered access review that follows? How would the tiered access process be administered and funded? The proposed regulatory text is devoid of any meaningful answers to these and related questions, and certainly lacks assurances that EPA will, through this process, ensure that the best available science will ultimately inform its decisions, as the law requires.

A reference in the preamble to providing "stakeholders" the opportunity to reanalyze restricted data and models through the tiered access process is revealing. The language affirms our overall concern that this effort is in fact a means of giving industry representatives a chance to cast doubt on studies that show health impacts of pollutants in hopes of achieving watered down regulatory standards, all to the great disadvantage of human health. As we pointed out in our 2018 comments, studies already undergo multiple layers of peer-review, including through staff scientists and independent scientists at the Agency itself.

The Supplemental Proposed Rule lays out an alternative to tiered access, but this approach fares no better, and is equally arbitrary. The alternative approach would allow EPA to consider all studies – even those with underlying restricted data – but the Agency would give less value to the studies with restricted data: "When promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will, other things equal, give greater consideration to studies where the underlying data and models are publicly available in a manner sufficient for independent validation."

Again, no standards or criteria are provided to guide the Agency's discretion under this provision and to ensure that the best available science drives EPA's decision making. How much less consideration would be given to research that relies on confidential patient information and who would make these decisions? Placing a higher value on certain scientific studies over others without clear criteria risks politicizing EPA's decision-making process.

In view of the paramount importance of using the best available science in EPA policymaking, neither of the alternatives – tiered access or diminished consideration – that purport to create exceptions to the general rule of exclusion passes muster. Both alternatives unacceptably restrict the scientific research that EPA uses as the basis for public health and environmental protection regulations.

EPA Has Yet to Articulate Why This Proposal is Necessary or How It Will Strengthen Transparency

EPA has yet to articulate why this proposal is necessary, let alone provide a plausible reason for how it would strengthen transparency in its use of science. As we explained in our 2018 comments, 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 proposal seeks to solve a problem that does not exist.

Indeed, the EPA Science Advisory Board made this exact point in its April 24, 2020 Final Report:

There is minimal justification in the Proposed Rule for why the EPA finds that existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate, and how the Proposed Rule will improve transparency and the scientific integrity of the regulatory outcomes in an effective and efficient manner. It is plausible that in some situations, the Proposed Rule will decrease efficiency and reduce scientific integrity, determining if in fact that will be the case requires a thorough and thoughtful examination that is currently absent in the Proposed Rule. Moving forward with altered transparency requirements beyond those already in use, in the absence of such a robust analysis, risks serious and perverse outcomes."[12]

In addition to the lack of a scientific justification, EPA's legal authorization for the Proposed Rule, as supplemented by the SNPRM, is also wholly lacking. The limited "housekeeping" authority under 5 U.S.C. §301 (assuming it applies, which it likely does not), authorizing some federal agencies to regulate their own internal affairs, may not serve as the legal foundation for a rule that could allow EPA to exclude the best available science from its policymaking. As explained above, excluding the best available science from EPA policymaking is patently at odds with the agency's duties under multiple federal statutes. EPA is proposing here to alter the substantive standards for evaluating scientific research. But the federal housekeeping statute in no way authorizes EPA to make such substantive and impactful changes. Nor may the agency rely on the authority of the federal statutes it administers, which provide no legal basis at all for this proposal.

Conclusion

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. The American Lung Association again urges EPA to withdraw the Proposed Rule, as supplemented by the SNPRM, and follow the current, effective measures in place to ensure the use of robust, uncensored scientific research to protect human health and our communities.

Sincerely,

Harold P. Wimmer
National President and CEO

[12] Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled Strengthening Transparency in Regulatory Science. April 24, 2020. EPA-SAB-20-005. p. 18. Accessed at https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf