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Written Comments of the Environmental Protection Network on the Scientific Advisory Board Draft Report (10/16/19) on the Environmental Protection Agency's (EPA) Proposal to Regulate the Use of Science in EPA Rules

To: EPA Administrator Andrew Wheeler and the Chartered Scientific Advisory Board (SAB)

We thank the Science Advisory Board (SAB) and the United States Environmental Protection Agency (EPA) for the opportunity to provide these written comments on the SAB's draft report on EPA's proposed "transparency" rule. The Environmental Protection Network (EPN) is an organization comprised of over 450 EPA alumni volunteering their time to protect the integrity of the EPA, human health and the environment. We harness the expertise of former EPA career staff and confirmation-level appointees to provide an informed and rigorous defense against current efforts to undermine public health and environmental protections.

Overview

Our main points include the following:

- The process EPA has followed in involving the SAB and the public in the development and review of this rule itself has been anything but transparent. Notably, the subject of this commentary, SAB's draft report, was completed on October 16, 2019, and yet it was not made available for public review until New Year's Eve, with an announced 10-day deadline for public comments.
- The draft SAB report has done a service by pointing out a large number of conceptual and practical deficiencies in the proposed rule as well as the lack of any attempt to assess the potential costs, benefits, and risks associated with actually implementing the rule. While the report provides some suggestions for addressing select issues, perhaps the most important point raised in the full report is the following:

> "*In general, the SAB finds that the EPA has not fully identified the problem to be addressed by the Proposed Rule. The EPA must comply with federal transparency and data integrity laws and, as discussed in this report, some additional requirements of the Proposed Rule may not add transparency, and even may make some kinds of research more difficult.*"

We agree completely. In fact, the agency has *not* demonstrated the need for this proposed regulation. In the past, EPA has shown the flexibility to handle significant data issues, including reanalysis, when they have arisen. EPA can continue to use its existing procedures as it moves towards improving transparency along with other federal agencies. The agency can better address evolving scientific information related to dose-response issues by issuing guidance (e.g., the ongoing effort to update existing cancer risk assessment guidelines and adopting new guidelines for additional endpoints) without trying to craft a fixed regulation that would make the need for reanalysis more important than any other criteria for evaluating the scientific literature used for regulatory decision-making.

- EPN notes that the critical SAB finding highlighted above (draft report, page 6, lines 14-18) is conspicuous by its absence in the executive summary and the cover letter. We strongly recommend that this finding be given appropriate prominence in both summaries. Accordingly, EPA should consider an alternative non-rule-based approach to making progress on transparency that has far less complexity and costs, while avoiding legal and related environmental risks. As noted above, much of the draft SAB advice for clarification and guidance could be implemented without the need for rulemaking.
- Implicit in the draft cover letter, and explicit in many of the individual comments, including those by supporters of the thrust of Administrator Wheeler's proposal, is that if EPA wants to proceed, it will need to take much more time to consider fully the many specifics, nuances, and recommendations identified by the SAB in their review of this major new rule and to conduct a thorough analysis of the economic costs, the loss of more productive research, and the potential risks to environmental protection. We believe that a statement to that effect should be included in the summary and cover letter. Equally important is that SAB should request to see any supplemental or re-proposal of a transparency in regulatory science rule at the time it is provided for interagency review. This would allow the SAB to evaluate the extent to which EPA is willing to go to address your concerns and recommendations.

EPA continues to ignore both legal and sound policy considerations in dealing with the SAB and the Public in developing this Rule.

Throughout the development and subsequent review process of the proposal to regulate the use of science in EPA regulations, the agency has not shown any significant interest in the views of the scientific community. In the spring of 2018, the leadership of the agency was in a rush to judgement to issue a proposal. As a result, it did not provide a role for its own career scientific and science/policy experts in crafting the proposal or in assessing its potential impacts. It never included the rule in its regulatory agenda, or otherwise notified or consulted with the SAB, much less requested a review of the draft proposal as required by law. Likewise, it did not solicit the advice of the National Academy of Sciences (NAS) on provisions that would change the decision logic for the selection of dose-response models used in risk assessment from those previously recommended by the NAS. In its hurry, EPA management did not even ask for an interagency review to solicit the views of other agencies that conduct research and/or use health effects science in developing policies and regulations.[1]

[1] According to the revised dates on OMB's Reginfo.gov site, OMB received the draft proposal on Thursday, April 19th, and cleared it just four days later, on Monday, April 23rd. Given the intervening weekend, there clearly was no time available for interagency discussion.

Finally, the agency originally allowed only a 30-day comment period on this stunning proposed departure from decades of past best practice in the assessment and use of science, a period that would have closed one day before a long-scheduled meeting of the full SAB on May 31, 2018. The SAB learned of the rule only after a press conference and subsequent news stories. This rushed and largely secret process illustrates a complete disinterest in transparency in the formulation of public policy, much less in science. [2]

As the draft SAB report notes, at that May 31st meeting, the SAB identified the transparency proposal as an action that merited SAB review. Accordingly, the SAB chair wrote a June 28, 2018, letter to the Administrator, advising him that "the SAB should consider the Proposed Rule's Scientific and Technical Basis." Even allowing for the change in Administrators, Andrew Wheeler's highly delayed response in April of 2019 shows how low a priority agency management placed on obtaining external scientific input from the SAB on the proposal. In addition to the nearly ten-month delay, the Administrator endeavored to severely limit the scope of SAB's review.

We commend the committee chair and members for their continuing efforts to encourage the agency to take SAB's comments and recommendations on the proposal seriously, as well as their subsequent decision to provide a more complete consideration and review of the scientific and technical issues associated with the proposal in the draft report. We recommend that the brief history of this process in the draft SAB report be expanded to provide a more complete documentation of the key SAB and EPA interactions from the time SAB learned of the proposal to the production of its report.

The Administrator's April 19, 2019, letter to the SAB also overlooked an important detail in the 1978 Environmental Research, Development and Demonstration Authorization Act (ERDDAA) legislation; that law requires EPA to provide the SAB with the opportunity to examine any proposal and its underlying science *at the same time* it is provided to the Office of Management and Budget (OMB) for interagency review. This means *before* it is actually proposed for public comment. Thus, in not providing any information on the transparency rule to SAB ahead of the proposal last year, EPA not only broke the spirit of early warning procedures established to ensure compliance, but also actually violated the law.

Unfortunately, EPA's recent habit of ignoring the SAB and requirements of ERDDAA has continued. As has been widely reported, EPA has prepared a supplemental notice that attempts to address a few of the issues many have raised in comments on the original proposal and submitted it for interagency review. Yet EPA still has not shared that notice with the SAB. The SAB should be permitted a chance to review and comment on any such supplement before EPA makes final decisions on whether and how to issue a rule to regulate the science it uses.

Finally, EPN notes that the draft SAB letter and report to the Administrator is dated October 16, 2019. Yet the EPA SAB website did not provide the public with access to SAB's advice until December 31, 2019. We

[2] It is useful to contrast this process with the one EPA followed for a less far-reaching change in science/policy assessment that took place largely in 2006. As documented elsewhere, EPA management established a process to improve the timeliness and efficiency of the National Ambient Air Quality Standards (NAAQS) review process, including review of the relevant scientific criteria and policy assessment of the standards. EPA staff in these areas were heavily involved in the initial stages. EPA staff formulated some approaches and first consulted with the Clean Air Scientific Advisory Committee (CASAC) and later other stakeholders. There followed a public workshop that involved stakeholder and public comments. No rulemaking was necessary, and EPA ultimately adopted a revised process in 2006 that was updated slightly in 2009. By relying on agency expertise and external science advisors in the development of these changes, EPA management avoided some of the more unfortunate complications that appear in the science/transparency proposal. Historical Information on the NAAQS Review Process: https://www.epa.gov/naaqs/historical-information-naaqs-review-process

believe it is unusual for a completed draft SAB report on a proposed rule to be withheld for such a prolonged period . In this case, we are interested in learning who is responsible and the rationale for a two-and-a-half-month delay in sharing the report with the public. Certainly, the release of the draft SAB report on New Year's Eve and a request for written comments from the public ten days later was not only unreasonable, but provides additional evidence about how little the agency values public comments on these issues.

The draft SAB report provides substantial support for the comments of EPN and of many other public commenters, who view the EPA proposal to regulate science as a solution searching for a problem.

The draft SAB report has done a service by pointing out a large number of conceptual and practical deficiencies in the proposal as well as a lack of any attempt to assess the potential costs and benefits associated with actually implementing them. While the report provides some suggestions for addressing select issues, perhaps the most important point raised is the following:

> "*In general, the SAB finds that the EPA has not fully identified the problem to be addressed by the Proposed Rule. The EPA must comply with federal transparency and data integrity laws and, as discussed in this report, some additional requirements of the Proposed Rule may not add transparency, and even may make some kinds of research more difficult*."

This statement is fully consistent with the major argument made by EPN and many thousands of other commenters who question the need for a rule that is more likely to degrade rather than enhance the use of science in environmental regulation. EPA offers no support for its assertion that there is a replication "crisis" (83 FR 18770) in studies that have been used to support major decisions for EPA programs.[3,4] The proposal does not cite a single instance where a study used by EPA for any type of regulatory action (including "pivotal regulatory science" used for major rules) was shown to be flawed due to a lack of access to the underlying data.

It is somewhat ironic that the SAB letter cites the competitive solicitation that the Health Effects Institute (HEI) used to find an analysis team for the Six-City and ACS project noted above as a model for EPA to follow if it is interested in more reanalysis of existing studies. OMB's Data Quality Guidelines also cite the successful HEI-sponsored reanalysis as a model for an approach that would meet the guidelines.[5] However,

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[3] EPA's proposal ignores the fact that the two studies most often cited as a cause for concern about transparency (Dockery et al, 1993; Pope et al. 1995) were successfully *reanalyzed* and *reproduced* by an independent team of qualified investigators (Krewski, D., Burnett, R.T., Goldberg, M. Hoover, K., Siemiatycki, J., Jerrett, M., Abrahamowicz, M. and White, W. H. 2000. "Investigators' report". In *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate air pollution and mortality. Special report*, 7–244. Cambridge, MA: Health Effects Institute.).
Moreover, at last count, the literature contains dozens of additional studies using different data sets and involving different investigators that *replicate* the essential findings of these two studies (see, e.g., R.T. Burnett. 2018; *Particulate Matter Reproducibility and Air Pollution Epidemiology.* Presentation to Health Effects Institute 2018 Annual Conference, Chicago, Il., April 30, 2018). https://www.healtheffects.org/cdn/farfuture/prvBPJ1viddR3LQIwQGszgOOZfSQnlK4WANcnfSePGQ/mtime:1525981635/sites/default/files/burnett-reproducibility-hei-2018.pdf

[4] Goldman LR, Silbergeld EK. 2013. Assuring access to data for chemical evaluations. *Environmental Health Perspectives* 121:149-15223229062. Link, Google Scholar. These authors examined 79 data-related requests to EPA under the Information Quality Act between 2002 and 2012 and found only two requests from the public for raw data. Both were eventually granted.

[5] OMB's Data Quality Guidelines state: "Even in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect

the reason HEI has no current plans in this area is that EPA and industry sponsors have placed a far higher priority on spending limited resources on new scientific studies that develop improved methodologies to address key science/policy questions. At the same time, HEI has promoted increased transparency in terms of sharing methods and models as well as the development and/or use of data from sources that are available to qualified researchers.[6]

This example highlights the major opportunity costs presented by the adoption of a regulation that would require or encourage a substantial increase in expenditures to enable and conduct more reanalyses of existing research. HEI spent $1 million for the reanalysis and alternative model specifications for two studies. If even half of the major cohort studies cited by EPA in the current particulate matter (PM) NAAQS Policy Assessment as directly relevant to supporting a change in the standards were required to be reanalyzed, the cost could easily run into the tens of millions of dollars. This would inevitably result in reduced resources that might otherwise go to new work using more advanced approaches. Of equal importance, the time it would take to conduct these reanalyses as well as to conduct alternative dose-response modeling would either delay development of the standards, or unnecessarily deprive EPA of the ability to use all of the latest relevant scientific information in the review. The latter is otherwise required by statute, in this case the Clean Air Act.

EPN supports the goal of increasing transparency in ongoing scientific research, as well as the practice of providing as much access to information from existing and older studies as possible, consistent with privacy issues and available resources. The core science/policy problem with EPA's proposal is that it elevates what it calls "transparency" above all other attributes of a published study as a criterion for assessing its value. Thus, a study that has been replicated many times by different investigators using different data may be excluded from consideration, while one that uses an inferior database that is publicly available would be considered. This preemption not only excludes existing studies with potentially important scientific and policy relevant insights, but also would eliminate additional prospective studies that otherwise might continue to exploit some of the largest and/or most useful data sets that cannot be made fully available to the public. Further, much valuable work of importance to EPA's decision processes is being published by scientists outside of the United States. Obtaining the additional information may not be possible, both because of the unwillingness of such scientists to cooperate in view of the experience of US investigators, and because of very different and often more stringent rules in other countries related to the sharing of confidential data.[7]

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intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard. For example, a qualified party, operating under the same confidentiality protections as the original analysts, may be asked to use the same data, computer model or statistical methods to replicate the analytic results reported in the original study. See, e.g., "Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality," A Special Report of the Health Effects Institute's Particle Epidemiology Reanalysis Project, Cambridge, MA, 2000. 67 FR at 8456

[6] Examples include the MOSES human clinical studies of ozone and Assessing Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution epidemiology studies that address new methodologies, including application of causal inference methods, alternative concentration response functions, and alternative large-cohort databases in the U.S., Canada, and Europe. One of these programs uses the very large Medicare data set, noted in the draft SAB comments, which can and has been accessed by other qualified research groups. https://www.healtheffects.org/system/files/dominici-rr-200-report.pdf

[7] See, in general, the public comments on the EPA proposal by the International Society for Environmental Epidemiology (ISEE), available at: http://www.youreventinfo.org/ISEE/Documents/ISEE_Comments_on_EPA-HQ-OA-2018-0259-0001FINAL_ISEE_submitted.pdf, which also highlight restrictions in releasing data used in significant Canadian and European air pollution epidemiology studies.

The draft SAB report makes clear why EPA's suggested approach of an ad hoc exemption by the Administrator does not reduce the potential damage of such restrictions:

> *"The SAB finds that exclusion of segments of the scientific literature with the possibility of inclusion of selected elements based on non-scientific considerations represents a significant shift in science-based decision making. Such a change could easily undercut the integrity of environmental laws, as it will allow systematic bias to be introduced with no easy remedy. The proposed exception process applies no constraints on how this mechanism could be used or that it be restricted to the issue of confidential data. Such a proposal is inconsistent with the scientific method that requires all credible data be used to understand an issue and to allow systematic review to evaluate past research."*

The entire process envisioned in the proposed rule is wholly inconsistent with scientific practice[8] and EPA's use of science in regulatory decisions over the last five decades. Where studies with novel results appear, EPA' scientific assessments can note the lack of replication as a limitation, and in a number of cases, EPA has made arrangements for reanalyses for particularly important studies.[9] EPA's science, risk, and policy assessments are themselves peer-reviewed by SAB panels; CASAC; the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Science Advisory Panel (SAP); and the Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemical (SACC) to further ensure the evaluation of studies take place in context of the relevant scientific literature. It is particularly troubling here that EPA has not provided any analyses of the potential impacts of the proposal on existing regulations or how widely it might affect key studies that support the Integrated Risk Information System (IRIS) risk assessments, many of which are decades old, that are used to support regulations for multiple statutes. If anything, adopting this approach has the potential to create chaos and would serve to decrease public confidence in the objectivity and credibility of EPA's assessments of scientific information, as well as decisions on future regulations and cost-benefit assessments.

It is therefore not surprising that many scientists and scientific publications, who otherwise may strongly support the benefits of increased data sharing for new scientific research, have rejected the proposal's preemption of existing studies based on availability of raw data. Ioannidis, who EPA quoted in their proposal as supporting transparency in science, reacted strongly to the proposal in a PLOS editorial,[10] noting that "If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim." As the draft SAB report notes, editors of several science journals whose policies and articles on data sharing were cited in the proposal issued a joint statement on the proposal stating that:

> *"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*

[8] This is buttressed by the SAB draft report, page 15, lines 12-21.

[9] See D.S. Greenbaum; Bachmann, J.D.; Krewski, D.; Samet, J.M.; White, R.; and R.E. Wyzga, Particulate Air Pollution Standards and Morbidity and Mortality: Case Study. *American Journal of Epidemiology*, Volume 154, Issue 12, 15 December 2001, Pages S78–S90, https://doi.org/10.1093/aje/154.12.S78. See also Goldman and Silbergeld *Ibid.*

[10] Ioannidis JPA (2018). All science should inform policy and regulation. PLoS Med 15(5): e1002576. https://doi.org/10.1371/journal.pmed.1002576

> *decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes*."[11]

EPN believes that EPA should avoid the complexities, costs, and risks associated with trying to regulate the use of science in regulatory decisions. Instead, the agency can continue to use and improve its existing procedures via policy guidance as it moves to improving transparency in research and regulation in concert with other federal agencies, as has been done over several decades. The agency can better address evolving scientific information related to dose-response issues through guidance (e.g., the ongoing effort to update existing cancer risk assessment guidelines and adopting new guidelines for additional endpoints) without trying to craft a fixed regulation that would make the need for reanalysis more important than any other criteria for evaluating the scientific literature used for regulatory decision-making. As noted above, some of the draft SAB advice for clarification and guidance can be implemented without the need for cumbersome and difficult-to-revise rulemaking.

Section 3.4 of the draft report provides substantial support for our views. In particular,

> *"There appears to be consistency among analyses of how to address transparency that are orthogonal to the proposed rule. There is no justification in the Proposed Rule for why 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." (page 17, lines 2-11).*

EPN strongly recommends the salient points made in the main body of the draft SAB report that would support the more flexible approach of continuing to improve transparency through policy and guidance should be included in the executive summary and the cover letter. At a minimum, the major SAB finding highlighted above (draft report, page 6, lines 14-18) should be given prominence in the letter and the executive summary.

If EPA wants to proceed toward a final rule, it should address the many problems and omissions identified by the SAB.

Implicit in the draft cover letter, and explicit in many specific and individual comments, including those by supporters of the thrust of Administrator Wheeler's proposal, is that if EPA wants to proceed, it will need to take much more time to consider fully the many specifics, nuances, and recommendations identified by the SAB in their review of this major new rule and to conduct a thorough analysis of the economic costs, the loss of more productive research, and the potential risks to environmental protection. We believe that a statement to that effect should be included in the executive summary and the letter to the Administrator. Equally important is that the SAB should request access to any supplemental or re-proposal of the transparency in regulatory science rule at the time it is provided for interagency review. This would allow the SAB to evaluate how far EPA is willing to go to address your concerns and recommendations.

[11] Berg et. al (2108) Joint statement on EPA proposed rule and public availability of data. *Science* 04 May 2018: Vol. 360, Issue 6388, eaau0116DOI: 10.1126/science.aau0116. *Science*, *Nature*, *PLOS One*, and *Proceedings of the National Academy of Sciences.*

In several places, the draft SAB report mentions the need for additional analysis of impacts and costs. Most prominent is the general statement "*the SAB finds that key considerations that should inform the Proposed Rule have been omitted from the proposal or presented without analysis.*" (letter page 1, lines 38-39). Specific areas of need are more scattered in the report. Examples include the lack of a needed thorough and thoughtful analysis of the potential for decreased efficiency and reduced scientific integrity (page 17, lines 6-10); the need to consult with others[12] regarding mechanisms and costs for collecting, storing, and disseminating data (letter page 2, lines 35-37); and the importance of analyses of the implications of different definitions of raw data (page 4, lines 1-6). Get these and some other examples of needed analysis compiled in a single place.

Beyond the unsupported statement that "EPA believes the benefits of this proposed rule justify the costs," we can find no evidence that EPA has done a serious assessment of the economic and opportunity costs to EPA and researchers, nor the potential adverse impacts to environmental regulations that would increase greatly if the rule were to apply retroactively. It has not released any quantitative assessment of benefits of requiring public availability of data.

The SAB should be aware of relevant analyses of potential economic costs to EPA derived from assessments of the so-called HONEST Act and earlier legislation that provided the model for EPA's proposal. This legislation was restrict EPA's ability to rely on scientific information, but never enacted into law (H.R. 1030 in 2015 and H.R. 1430 in 2017). The Congressional Budget Office (CBO) in consultation with EPA analyzed the costs that would be imposed by these legislative proposals. The 2015 analysis assumed that EPA would reduce the number of studies it relied on by half, but would still need to expend $250 million/year initially in an effort to determine data availability, and where necessary pay for obtaining and disseminating it. Given EPA's intention to "minimize" such costs in its proposed rule, this estimate may be considered an upper bound of the direct costs.

The CBO analysis does not tell the whole story, however, because it did not assess the disbenefits to the regulatory process and to public health of being unable to base regulations on numerous influential studies for which data could not be made available. Considering only the science policy value of the information in multiple original studies that are likely to be lost (e.g., the cohort epidemiology studies noted above, which must limit access to protect privacy) it is reasonable to conclude that their loss would almost certainly outweigh the value of any information gained by subsequent reanalyses of a more limited set of studies, which rely on publicly available databases that are often inferior to those that contain more relevant information.

In the 2017 legislative analysis, the Congressional Budget Office (CBO) estimated a cost ranging from $1 million to $100 million per year, depending on the approach taken by EPA in assessing studies. They

[12] Another important reason to get advice from the broader scientific community relates to questions about whether Institutional Review Boards (IRB) will rule that it is impermissible on ethical grounds to share unpublished data with the public. The issues go beyond the potential for release of personal identifiers. For example, in regards to a study that may be pertinent to regulating an industry that is arguably polluting a community, the industry has the advantage of having greater economic wherewithal to hire its own consultants with the goal of discrediting the stringency of the findings, a disparity which is relevant to environmental justice considerations. An IRB may rule that on the basis of equipoise it would be inappropriate for them to allow release of the unpublished data. We strongly recommend that the NAS or similar organization be funded to thoroughly study these ethical issues.

determined that meeting H.R. 1430 requirements would cost EPA an average of $10,000 per study. EPA officials told CBO that the agency would likely greatly reduce the number of studies it relied on and would not take on the cost of disseminating the underlying data. The proposal reiterates EPA's plan to focus on a more limited number of studies. Under these assumptions, CBO suggested costs could be as low as $1 million/year, but again did not assess the potential implications for existing or future regulations. An unofficial draft response to CBO from unidentified EPA staff strongly disagreed with the lower cost estimates, and expressed concern that the legislation would prevent EPA from using the best available science; this response was never forwarded to CBO.[13] A reasonable interpretation of these analyses is that the new EPA rules strongly risks either high costs or significant restriction of the scientific basis for regulation – or most likely both. These two CBO marks should be included within the SAB's recommendations for cost considerations.

In conclusion, it would be helpful if the final SAB letter could be more specific about the multiple scientific and technical analysis needed to permit sound conclusion on any regulation. These include those already mentioned above, but especially those related to assessing the potential risks to environmental protection, the economic costs to EPA and/or scientific researchers, and the loss of more productive forward-looking research. Such analysis should pay particular attention to the many additional problems that would be created by applying the regulation to already-published studies.

[13] See EPN comments pages 28-34 to EPA available at: https://www.environmentalprotectionnetwork.org/censored-science-comments/