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Comments from Academics, Scientists and Clinicians on the EPA Supplemental Notice of Proposed Rulemaking "Strengthening Transparency in Regulatory Science"

Submitted online via *Regulations.gov* to docket EPA-HQ-OA-2018-0259

These comments are submitted on behalf of the undersigned academics, scientists, and clinicians. The co-signers' institutional affiliations are included for identification purposes only and do not imply institutional endorsement or support unless indicated otherwise.

We appreciate the opportunity to provide comments on the U.S. Environmental Protection Agency (EPA) supplemental notice of proposed rulemaking "Strengthening Transparency in Regulatory Science."[1] EPA received extensive public comments in opposition to the rule, including from the National Academies of Sciences, the University of California and other leading health, medical and scientific organizations. EPA has failed to respond to those comments or engage with these affected stakeholders. Unfortunately, EPA's supplemental proposal does not address the substantive scientific, technical and legal issues raised in the previous public comments.

The original problems with the rule remain, and the supplemental proposal expands the scope of the rule to cover **all** scientific data, which could include, *"environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, engineering models, data on environmental releases, exposure estimates, quantitative structure activity relationship data, and environmental studies."*[2] This expansion could result in eliminating many scientific studies from EPA's consideration if those studies failed to provide underlying data; some of these studies are the basis of EPA's regulations such as the National Ambient Air Quality Standards under the Clean Air Act. This is also directly in contrast to EPA's previous statements that "Whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications."[3] It is deeply troubling that, if this rule were codified, EPA would not use the "best available science," to inform its decisions and protect the public's health. [4]

As scientists and health professionals, we strongly value open science which includes data sharing and full reporting of methods - but this supplemental proposal would not improve data sharing, replicability, or transparency in decision-making, as detailed below.

It is highly inappropriate for EPA to be moving forward on such a significant regulation while the nation is grappling with the COVID-19 pandemic. Although the original comment period was extended by 30 days, a full 90 additional days of public comment should be required. Further, the proposed rule could place barriers on the use of critical scientific information in a time of public health crisis, especially considering that this rule and accompanying supplement would impact EPA's ability to utilize the "best

[1] EPA (2020). Strengthening Transparency in Regulatory Science. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322

[2] EPA (2020). Strengthening Transparency in Regulatory Science. Pg. 15400 Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322

[3] EPA (2016) Plan to increase access to results of EPA-funded scientific research. pg. 4-5 Available: https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

[4] 15 USC §2625 (h)

available science," and "adequate information," which, in this case, could have fatal consequences.[5] As highlighted in a letter to Administrator Wheeler from Senator Carper (D- DE), and as we detail below, the rule as it exists now could lead EPA to limit the evidence base and exclude "high quality" studies based on an availability criteria that has no scientific justification.[6,7] We are strongly opposed to this regulation and recommend that EPA withdraw the proposed rulemaking immediately.

Our comments address the following main points:

1. **EPA should withdraw this proposed rule immediately.**
2. **EPA's supplemental proposal still does not present any analyses of benefit-cost, children's environmental health risks or environmental justice in support of the rule, which are required under executive orders 12291, 13045, and 12898.**
3. **EPA should not promulgate significant new regulatory and scientific practices based on untested approaches for securing private information.**
4. **EPA should focus on implementing its own plan to increase access to results of EPA-funded scientific research.**
5. **EPA has expanded the scope of the rulemaking in two important ways that will undermine the use of science in decision making:**
    a. **Expanded the type of data to which the rule would apply, changing from dose-response data to all environment and health related data**
    b. **Expanded the scope of types of EPA products to which this would apply from pivotal regulatory decisions to include influential scientific information.**
6. **EPA's proposed definition of research data is in conflict with accepted and referenced definitions of research data, is internally inconsistent within the supplement, and does not reflect an accurate understanding of the data process in research.**
7. **EPA proposes to 'downgrade' studies that do not make their underlying data and models available which is inconsistent with science.**
8. **EPA is still allowing for the Administrator to make case-by-case exemptions and has expanded it to include Age of Data/Year, which could introduce bias and lead to potential cherry picking of studies.**

We appreciate the opportunity to provide public input. Please do not hesitate to contact us with any questions regarding these comments.

Sincerely,

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[5] 15 USC §2625 (h)-(i) and 15 USC §2601 (b)(1)
[6] Frazin, R. (2020, March 25). Democrat calls on EPA to withdraw 'secret science' rule. Retrieved April 10, 2020, from https://thehill.com/policy/energy-environment/489551-democrat-says-epa-should-withdraw-secret-science-rule
[7] EPA (2020). Strengthening Transparency in Regulatory Science. Pg 15399. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322

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DETAILED POINTS:

1. EPA should withdraw this proposed rule immediately.

The supplemental proposal still does not address how this action fits with the Agency's mission of protecting human health and the environment and the Agency has still failed to consult with critical stakeholders.

The proposal continues to have fundamental flaws and this supplement will not improve the use of science for decision-making; EPA has failed to provide a reasonable science or policy rationale supporting these actions. EPA and numerous other agencies (such as the Food and Drug Administration (FDA)) routinely make regulatory decisions without having access to "all data and models." [8] Lacking "access to part or all of the data and Models" or "not hav[ing] the authority to provide access to part or all of the data and models," [9] does not prevent EPA from determining the validity of scientific methods and conclusions and using science to inform decisions, as EPA repeatedly states in its own plan to increase access to results of EPA-funded scientific research.[10] Overall, the proposed rule and supplemental proposal is not consistent with the principles of open science,[11,12] and continues to lack a scientific basis or policy rationale.

Throughout this process, EPA has not consulted with critical stakeholders, including scientists, health professional and communities. We have grave concerns with the fact that since the 2018 proposal, EPA still has not consulted with the stakeholders or organizations facing serious, long-term implications from this rule: scientists; medical researchers and health professionals; universities; hospitals; peer-reviewed journals/publishers; and communities who participate in research studies. Further, there are numerous studies considered by EPA that are funded by NIH, which has stringent rules around participant confidentiality. Therefore, EPA should have consulted with the NIH. Additionally, given the importance of this rule, EPA should have also consulted with scientific experts via the National Academies of Science, Engineering, and Medicine. If EPA has consulted with these critical stakeholders, it should publicly release a report akin to an Interagency Scientific Assessment regarding how it addressed any comments or concerns around the impacts of this rule.

EPA's Science Advisory Board (SAB) issued a report earlier this year outlining that it was: *"concerned that key considerations that should inform the rule appear to be omitted or presented with no analysis - for example, it is not clear how many of the studies EPA currently relies upon to take important regulatory actions would meet the public disclosure standards in the proposal, whether EPA has assessed how many of those studies would be feasible to provide underlying information, or what the impact of precluding those studies would be on EPA's decision making and its ability to protect public health / environment."*[13]

[8] EPA (2020). Strengthening Transparency in Regulatory Science. Pg 15402. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322

[9] Id.

[10] EPA (2016) Plan to increase access to results of EPA-funded scientific research. pg. 4-5 Available: https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

[11] Nosek, B. A., Alter, G., Banks, G. C., Borsboom, D., Bowman, S. D., Breckler, S. J., … Yarkoni, T. (2015). Promoting an open research culture. *Science*, *348*(6242), 1422–1425. doi: 10.1126/science.aab2374

[12] Thorp, H. H., Skipper, M., Kiermer, V., Berenbaum, M., Sweet, D., & Horton, R. (2019). Joint statement on EPA proposed rule and public availability of data (2019). *The Lancet*, *394*(10214). doi: 10.1016/s0140-6736(19)32945-9

[13] EPA. (2019). Science Advisory Board (SAB) Draft Report (10/16/19). Pg. 31. Available: https://yosemite.epa.gov/sab/sabproduct.nsf/WebBOARD/8A4DABC3B78F4106852584E100541A03/$File/Science+and+Transparency+Draft+Review_10_16_19_.pdf

The SAB also had concerns about the scientific and technical challenges and feasibility of implementing some of the rule's requirements, recommending that the Agency provide more detail on how it can meet the requirement to clearly identify and make publicly available all studies relied upon when it takes "significant final agency action," among other recommendations. [14] The SAB has also not been additionally consulted, even though they have identified important flaws in the proposal.

EPA should not implement this proposal for any Agency decision, whether major or minor. EPA is responsible for making numerous decisions that directly impact public and environmental health, and the Agency is legally mandated to make these decisions in a timely manner, based on the full body of credible scientific evidence. This rule will undoubtedly lead to EPA using inadequate science for making decisions, which in turn will lead to poor protections and harm to the public's health.

2. EPA's supplemental proposal still does not present any analyses of benefit-cost, children's environmental health risks or environmental justice in support of the rule, which are required under executive orders 12291, 13045, and 12898.

Executive Order 12291: Benefit-Cost Analysis for Major Rulemaking

EPA fails to quantify the benefits of the proposed rule to society, and the Congressional Budget Office estimated the costs of similar proposals to the Agency alone at approximately $100-250 million a year.[15] Executive Order 12291 requires Agencies to complete a benefit-cost analysis for any major rule which has an annual impact of $100 million or more.[16] The Congressional Budget Office analyses therefore indicate that this proposal is potentially a major rule, and EPA has failed to demonstrate that it is not. Therefore, the Agency is required to complete a benefit-cost analysis. For the benefit-cost analysis, a National Academies of Sciences (NAS) Workshop report also recommends: "In addition to estimating the value of data access, efficient and balanced policy requires accurately assessing the disclosure risks (and associated social cost) posed by microdata [individual level data] and linking."[17]

Further, the Congressional Budget Office's analyses were underestimates, as they did not include the costs to research/ academic scientists. Making datasets publicly available along with "associated protocols…and detailed descriptions of how to access and use such information" would entail significant time and costs to format, prepare and, in the case of human data, attempt to de-identify individual results from the men, women and children who participated in the study. Further, such re-analyses almost always require the participation of the original researchers to provide additional information and support, which costs personnel time and resources.[18] A 2013 memo from the Office of Science Technology and Policy on increasing data access acknowledges these costs and directs agencies to

[14] Id. Pg. 6.

[15] Congressional Budget Office. Cost Estimate: H.R. 1030 Secret Science Reform Act of 2015. March 11, 2015. Available: https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf
Congressional Budget Office. Cost Estimate: H.R. 1430 Honest and Open New EPA Science Treatment (HONEST) Act of 2017. March 29, 2017. Available: https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf

[16] Executive Order 12291. 46 FR 13193, 3 CFR, 1981. Available: https://www.archives.gov/federal-register/codification/executive-order/12291.html

[17] National Research Council (2000). *Improving Access to and Confidentiality of Research Data: Report of a Workshop.* Committee on National Statistics, Christopher Mackie and Norman Bradburn, Eds. Commission on Behavioral and Social Sciences and Education. Washington, D.C.: National Academy Press. Pg. 11

[18] National Research Council. 2002. *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of a Workshop*. Washington, DC: The National Academies Press. https://doi.org/10.17226/10302.

"Allow the inclusion of appropriate costs for data management and access in proposals for Federal funding for scientific research."[19]

In contrast, the supplemental proposal contains no provisions that address the funding needed for academic scientists to make their datasets publicly available and support re-analyses— and if the data are not publicly available, EPA may downgrade or fail to incorporate it in relevant policymaking.

Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

Regarding Executive Order 13045 In the Supplemental Proposal, EPA indicates that it *" interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk."*[20]

However, EPA has still failed to consult with critical stakeholders (as outlined in Point 1 of these comments) on the impacts of the Science Transparency Rule on children's health. Environmental health regulatory and science actions impacted by this rule and supplemental proposal may disproportionately affect children's health. For example, National Ambient Air Quality Standards (NAAQS) for pollutants such as PM2.5[21], ozone[22] and lead[23] all have highly relevant and important studies showing that children can be more sensitive and susceptible to these pollutants. Therefore, we strongly assert that EPA is required to conduct an analysis under Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks.[24]

Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Regarding Executive Order 12898*, "EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard."*[25] However this proposed rule and supplement do not exist in a vacuum. If codified, this rule will have long-lasting impacts to the procedures that govern standards that may adversely impact human and environmental health. As has been shown by multiple studies, environmental hazards such as poor air quality disproportionately burden the health of low-income communities and communities of color, despite meeting federal standards.[26] As this may result in a relaxing of such standards, it will likely have a more significant negative impact in communities of color and low-income populations.

[19] Executive Office of the President, Office of Science Technology and Policy. Memorandum for the Heads of Executive Departments and Agencies: Increasing Access to the Results of Federally Funded Scientific Research. February 22, 2013. Pg. 5. Available: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

[20] EPA (2020). Strengthening Transparency in Regulatory Science. Pg. 15404. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322

[21] EPA. (2019). Integrated Science Assessment (ISA) for Particulate Matter (Final Report, 2019). EPA/600/R-19/188. Available: https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=347534

[22] EPA. (2013). Integrated Science Assessment (ISA) for Lead (Final Report, Jul 2013). EPA/600/R-10/075F. Available: https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=255721

[23] EPA. (2019) Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants (External Review Draft).EPA/600/R-19/093. Available: https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=344670

[24] 62 FR 19885, April 23, 1997.

[25] EPA (2020). Strengthening Transparency in Regulatory Science. Pg. 15404. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322

[26] Bell, M. L., & Ebisu, K. (2012). Environmental inequality in exposures to airborne particulate matter components in the United States. *Environmental health perspectives*, *120*(12), 1699–1704. https://doi.org/10.1289/ehp.1205201

Therefore, we additionally assert that this rule, contrary to EPA's opinion, is subject to Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.[27]

3. EPA should not promulgate significant new regulatory and scientific practices based on untested approaches for securing private information.

In the supplemental proposal, EPA indicates that it "*…is currently conducting a pilot study using the RDC's secure data enclave to host EPA datasets in a restricted use environment. Development of standard data repositories is still ongoing."*[28] In essence, EPA is proposing to change the scientific basis of their rulemaking based on an untested and unverified method for data security enclaves.

There has been a nascent but growing body of research on data security. Researchers in 2015 were able to reidentify 90 percent of their study population as unique individuals and to uncover their records, knowing just four random pieces of information, due to the uniqueness of human behavior.[29] A more recent study in 2019 modeled the likelihood of individual reidentification in a "heavily incomplete" anonymized dataset, and found "that 99.98% of Americans would be correctly re-identified in **any** dataset using 15 demographic attributes."[30](emphasis ours This research shows how, with only a few pieces of information, current technology can already deidentify data that scientists currently consider sufficiently anonymized. Therefore, EPA needs to put out a rule that has a tested security method in place, not a 'plan' for a system that has not been tested and evaluated. EPA should not be basing regulations on pilots, but rather should focus on implementing EPA's own 2016 *Plan to increase access to results of EPA-funded scientific research*.[31]

4. EPA should focus on implementing its 2016 EPA Plan to increase access to results of EPA-funded scientific research.

A 2013 memo from the Office of Science and Technology Policy discusses policy principles and the development of federal agency plans to increase public access to federally funded research.[32] The objectives were developed in consultation with the National Science and Technology Council and with input from the public. In response, EPA developed the 2016 *Plan to increase access to results of EPA-funded scientific research*.[33] (2016 EPA Plan) The 2016 EPA Plan differs from the supplementary proposal in three critically important ways.

First, the 2016 EPA Plan's scope appropriately "prospectively covers peer-reviewed scientific research publications in scholarly journals and digital research data that result from EPA-funded research. The

[27] 59 FR 7629; February 16, 1994

[28] EPA (2020). Strengthening Transparency in Regulatory Science. Pg 15402. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322

[29] Montjoye, Y.-A. D., Radaelli, L., Singh, V. K., & Pentland, A. S. (2015). Unique in the shopping mall: On the reidentifiability of credit card metadata. *Science*, *347*(6221), 536–539. Available: https://doi.org/10.1126/science.1256297

[30] Rocher, L., Hendrickx, J.M. & de Montjoye, Y. (2019). Estimating the success of re-identifications in incomplete datasets using generative models. *Nat Commun* **10,** 3069. Available: https://doi.org/10.1038/s41467-019-10933-3

[31] EPA (2016) Plan to increase access to results of EPA-funded scientific research. Available: https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

[32] Executive Office of the President, Office of Science Technology and Policy. Memorandum for the Heads of Executive Departments and Agencies: Increasing Access to the Results of Federally Funded Scientific Research. February 22, 2013. Available: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

[33] EPA (2016) Plan to increase access to results of EPA-funded scientific research. Available: https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

Plan does not apply to research publications or research data generated from scientific research conducted prior to the implementation of the Plan."[34] The 2016 EPA Plan does not apply retroactively, and thus would not impact research underpinning regulations which come up for renewal.

Second, the 2016 EPA Plan emphasizes that data availability does not affect the validity or usability of science, noting:

> "Whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications."[35]
>
> "The validity of scientific conclusions drawn from research publications or their associated research data, or EPA's ability to consider those conclusions and data in its actions, does not depend on compliance with this Plan."[36]

In stark contrast, the supplemental proposal indicates that:

"…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 available*** *in a manner sufficient for independent validation either because the information is publicly available or available through tiered access when the data include CBI, proprietary data, or PII and* ***appropriate techniques have been used to reduce the risk of re-identification.****"*[37] (Emphasis ours)

EPA is proposing to downgrade or exclude science that is not made publicly available or "*cannot be sufficiently de-identified to protect the data subjects,*"[38] This de facto results in a rule that will equate study quality with availability of underlying data. Availability of underlying data is not a measure of study quality or validity – as EPA itself wrote in the 2016 EPA Plan. Further, study quality is dependent on the methods used in the study (further discussed below in Point 7).

Finally, the 2016 EPA Plan is in compliance with EO 12291 (Point 2) and acknowledges the significant costs to researchers that data access may impose, noting "Inclusion of costs for data management and public access may be included in intramural and extramural research proposals."[39] Thus, the 2016 EPA Plan both references and sets up a mechanism for addressing the costs it imposes.

The 2016 EPA Plan is scientifically and technically sound; thus, EPA should abandon the flawed proposed rule and its associated supplemental proposal and focus on implementing the 2016 EPA Plan.

[34] Id. pg. 5.
[35] Id. pg. 4-5
[36] Id. pg. 6
[37] EPA (2020). Strengthening Transparency in Regulatory Science. Pg 15403. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322
[38] Id. Pg 15402.
[39] EPA (2016) Plan to increase access to results of EPA-funded scientific research. pg. 11 Available: https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

5. EPA has expanded the scope of the rulemaking in two important ways that will undermine the use of science in decision making:

a. Expanded the type of data to which the rule would apply, changing from dose-response data to all environment and health related data

In the 2018 Proposed Rule, EPA indicated that the scope was restricted to

"*Dose response data and models means the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact...*" [40]

With this supplement however,

"EPA is modifying the regulatory text initially proposed…so that these provisions would apply to all data and models, not only dose-response data and dose-response models." [41] This would include, but not be limited to, *"environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, engineering models, data on environmental releases, exposure estimates, quantitative structure-activity relationship data, environmental studies, and substantial risk reports."* [42]

This means the rule would apply to all science, as data is common to all science.

This is a major expansion of the supplementary proposal beyond the original rule, and the result would be to eliminate science from EPA's consideration. EPA justifies this broader scope by saying *"[t]ransparency of EPA's science should not be limited to dose-response data and dose-response models, because other types of data and models will also drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions and influential scientific information."* [43]

Additionally, the Agency indicates that "*This proposal would apply to reviews of data, models, and studies at the time a rule is developed or influential scientific information is finalized, regardless of when the data and models were generated,"* [44] meaning that it would apply retroactively to data and models, again a major expansion of the rule's applicability.

Retroactive application of this proposal would eliminate even more science from consideration, as older studies are far less likely to have easily accessible digital data. EPA presents an option where the rulemaking would *"apply only to data and models that are generated (i.e., when the development of the data set or model has been completed or updated) after the effective date of this rulemaking,"* [45] indicating at least one variation which would not apply retroactively.

[40] EPA (2018). Strengthening Transparency in Regulatory Science. Pg 18773. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0001
[41] EPA (2020). Strengthening Transparency in Regulatory Science. Pg 15398. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322
[42] Id. Pg 15400.
[43] EPA (2020). Strengthening Transparency in Regulatory Science. Pg 15399. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322
[44] Id.
[45] Id. Pg 15402.

Often environmental health data is sourced with a great deal of trust from confidential medical records (cohort studies and birth and death certificates). It is implausible for these records to be publicized without risk of re-identification of individuals even if the most current techniques of de-identification are applied (Point 3); ensuring that even the most pivotal and groundbreaking studies underpinning our current regulations will be downgraded or eliminated. (Point 7)

Additionally, there are situations that are either impossible or unethical to recreate due to the severity of health outcomes or the circumstances surrounding the exposures. For instance, emergency responses to the 2010 Deepwater Horizon explosion and oil spill, health impacts from exposures during hurricanes such as Katrina and Rita, or a decade-long prospective cohort study on lead exposure in drinking water and adverse effects on childhood IQ; it would be both impossible and unethical to replicate these studies. Considering the severity of the health outcomes, dismissing or downgrading this critical research due to the Agency's proposed rigid transparency rule may result in regulatory delays in EPA's charge to protect human and environmental health.

Therefore, this proposed rule and supplement is not only out of line with best practices and ethics of medical privacy and research but is out of line with the mission of EPA. Overall, the expansion of the supplemental proposal's scope may have the effect of virtually eliminating science from EPA's consideration.

b. Expanded the scope of types of EPA products to which this would apply from pivotal regulatory decisions to include influential scientific information.

The 2018 Proposed Rule defined ''Pivotal regulatory science'' in two places:

In the background "*as the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated.*" [46]

And in 30.2, *"Pivotal regulatory science means the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions,"* [47]

Previously we commented that the definition appears to delineate a smaller subset of relevant studies that would be 'pivotal regulatory science.' This is because a properly conducted assessment considers the entire body of evidence in the evaluation, integration and development of conclusions. Therefore, that definition was not useful, as the entire body of relevant scientific evidence would meet the definition of pivotal regulatory science. Our previous conclusion still holds, as EPA indicated that it is retaining the definition of pivotal regulatory science, and even more so because of the expansion of the scope of the rule to all data. [48]

The rule supplement further goes on to say that this will also pertain to the science underlying influential scientific information. It defines influential scientific information *as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions (OMB M-05-03)."* [49]

[46] Id. Pg 18770.
[47] Id. Pg 18773.
[48] EPA (2020). Strengthening Transparency in Regulatory Science. Pg 15398. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322
[49] Id. Footnote 5.

This definition essentially includes all decisions and documents that EPA generates which use science, in addition to the already expanded definition of "pivotal regulatory science." This definition also notably doesn't include impact on human health/public health, which again is EPA's mission.

6. EPA's proposed re-definition of research data is in conflict with accepted and referenced definitions of research data, is internally inconsistent within the supplement, and does not reflect an accurate understanding of the data process in research.

Scientific research data are defined as "the digital recorded factual material commonly accepted in the scientific community as necessary to validate research findings." [50] This definition is equivalent to "the final clean data set that is provided with a publication" from the NAS Workshop report *Principles and obstacles for sharing data from environmental health research* (2016).

In contrast, the supplemental proposal indicates that *"'There are raw data, which come straight from the survey or the experiment.* ***There are cleaned-up data, which consist of the raw data modified to remove obvious errors.' (These are the data that are ready to be analyzed to extract relevant information.)*** *"* [51] (Emphasis ours)

The supplemental proposal goes on to define data as *"the set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party."* [52]

'Cleaned-up data' is not the same as a data set in which 'obvious errors' have been removed. Sometimes data cleaning can also involve harmonizing or transforming data so that they are all consistent, it can also involve creating consistency across data dictionaries

Although EPA indicates that its definition of data is consistent with the 2016 EPA Plan, the definition in the 2016 EPA Plan is several steps after the raw data collection (what EPA defines as data ready to be analyzed in this supplement) and contains a list of excluded types of research data. [53] The supplement's definition of research data expands the scope of EPA's reach beyond the intent of any accepted definition for the purposes of either eliminating or downgrading critical scientific research that is inconsistent with a more politicized and nonscientific, motive. The fact that the EPA supplement does not appear to understand the difference between 'raw data' and 'clean data' at best indicates a lack of

[50] Id. Pg 19.

[51] EPA (2020). Strengthening Transparency in Regulatory Science. Pg. 15401. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322

[52] Id.

[53] EPA (2016) Plan to increase access to results of EPA-funded scientific research. Pg 19 footnote 8. "Consistent with the definition in 2 C.F.R. § 200.315(e)(3), research data does not include: Preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues; Physical objects (e.g., laboratory samples); Trade secrets and commercial information; Materials necessary to be held confidential by a researcher until publication of results in a peer-reviewed journal; and **Personnel, medical, and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study**. The following specific examples of scientific research are excluded from this Plan: **Interim results or other preliminary scientific research data not used to generate the results in the final peer reviewed publication**; **Preliminary scientific research documentation beyond the article, supplementary materials, and metadata regarding preliminary research plans, including preliminary study protocols and other preliminary a priori decisions (recognizing that preliminary plans may have changed during the research project);** Information that may disclose intellectual property rights; National security and other classified information." (Emphasis ours). Available: https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

knowledge about the data generation and research process, undermining the Agency's assertion that individual data availability is equal to study quality.

7. EPA proposes to 'downgrade' studies that do not make their underlying data and models available which is inconsistent with science.

EPA introduced 'an alternative approach' for considering studies in its proposed tiered access framework, which it describes will "*other things equal,* ***give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation****."*[54] (Emphasis ours) Thus, EPA is proposing to downgrade the consideration of studies that do not make **underlying data and models** available, as they do not comply with the Science Transparency rule.

The issues with this alternative approach framework are made clear in a scenario EPA proposes in the rule supplement:

*"****If, for example, multiple high-quality studies exist but only two studies have data and models that are available for independent validation and reanalysis****, EPA would only include those two studies as pivotal regulatory science and/or pivotal science in accordance with the 2018 proposed rulemaking. However, under the alternative approach in this supplemental proposal,* ***EPA would consider using all available high-quality studies but give greater consideration to those two studies with data available for independent validation****."* [55] (emphasis ours)

This would codify that study quality is based on availability of underlying data, which is not the measure of study quality. This language is both vague and dangerous in implying that studies that do not make their data available are less informative or of less quality – both of which have no empirical basis. EPA itself acknowledges that potential studies for downgrade or elimination are "high-quality" above, and that scientific findings and research are valid whether or not data are publicly available, a reiteration of the conclusion put forth in EPA's 2016 Plan.[56]

If this model is pursued, EPA can base new and renewed standards on lower-quality science, rather than the "best available science," and "adequate information."[57] The omission of high-quality studies because they do not have available the underlying data could greatly impact the strength of systematic reviews and meta-analyses needed to show the harms of an exposure on a health outcome, and this could lead to conclusions that the evidence-base lacked sufficient weight.

EPA attempts to justify this framework by stating that "*such approaches to increasing access to data and models can often allow stakeholders to reanalyze the data and models and explore the sensitivity of the conclusions to alternative assumptions."*[58] This sets a dangerous precedent, opening the policy- and rule-making processes to potentially endless debate via "reanalysis", "alternative models", and

[54] Id. Pg 15402.
[55] EPA (2020). Strengthening Transparency in Regulatory Science. Pg 15399. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322
[56] EPA (2016) Plan to increase access to results of EPA-funded scientific research. pg. 4-5 Available: https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf
[57] 15 USC §2625 (h)-(i) and 15 USC §2601 (b)(1)
[58] EPA (2020). Strengthening Transparency in Regulatory Science. Pg 15399. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322

"independent validation" by stakeholders who may have a vested financial interest (and capability) to impact or perpetually delay critical policies to protect public and environmental health. [59,60]

It is well documented that financial sponsorship (i.e. source of funding) introduces a risk of bias in the results and conclusions in favor of the regulated industry's interests, including animal studies examining the effect of exposure to atrazine on reproductive or developmental outcomes. .[6162,63,64,65] This has the impact of potentially reducing or eliminating regulations that apply to industry products and ultimately have the effect of increasing profits. Considering that EPA as of yet has failed to detail a strategy on monitoring and accounting for financial conflicts of interest, a potential influx of industry-funded studies with such conflicts of interest may bias the final results of EPA's analysis, leading to less stringent regulations and policies—with the ultimate result of reducing protections for the health of families.

8. EPA is still allowing for the Administrator to make case-by-case exemptions and has expanded it to include Age of Data/Year, which could introduce bias and lead to potential cherry picking of studies.

In the 2018 Proposed rule, section 30.9, EPA indicated that:
"*30.9 -The Administrator may grant an exemption to this subpart on a case-by case basis if he or she determines that compliance is impracticable because: (a) It is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or (b) It is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions…"* [66]

While EPA removed part (b) from the original proposal as it "does not believe that peer review of pivotal regulatory science or pivotal science would be infeasible. Thus, EPA no longer believes the provision is necessary." [67] It also proposed to add "the age of data and models as a factor in the determination that compliance with the rule is impracticable." [68]

While it justifies this exception by indicating (as we do in Point 5a) that this addition is " intended to acknowledge the evolution of best practices for information sharing given innovations in information

[59] Lundh A, Sismondo S, Lexchin J, Busuioc OA, Bero L. 2012. Industry sponsorship and research outcome. Cochrane Database Syst Rev 12:MR000033
[60] Barnes DE, Bero LA. 1998. Why review articles on the health effects of passive smoking reach different conclusions. JAMA 279:1566–1570.
[61] Bero, L., A. Anglemyer, H. Vesterinen and D. Krauth (2016). "The relationship between study sponsorship, risks of bias, and research outcomes in atrazine exposure studies conducted in non-human animals: Systematic review and meta-analysis." Environment international 92-93: 597-604.
[62] Mandrioli D, Silbergeld EK. Evidence from Toxicology: The Most Essential Science for Prevention. Environmental Health Perspectives. 2016;124(1):6-11.
[63] Lundh A, Sismondo S, Lexchin J, Busuioc OA, Bero L. 2012. Industry sponsorship and research outcome. Cochrane Database Syst Rev 12:MR000033
[64] Bero L, Oostvogel F, Bacchetti P, Lee K. 2007. Factors associated with findings of published trials of drug–drug comparisons: why some statins appear more efficacious than others. PLoS Med 4:e184
[65] Barnes DE, Bero LA. 1998. Why review articles on the health effects of passive smoking reach different conclusions. JAMA 279:1566–1570.
[66] EPA (2018). Strengthening Transparency in Regulatory Science. Pg 18774. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0001
[67] EPA (2020). Strengthening Transparency in Regulatory Science. Pg 15403. Available: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322
[68] Id.

generation, access, management and use." [69] **EPA fails to propose any process managing conflicts of interest in terms of data acquisition**. These sections are vague on how and by what measures determinations would be made, opening the door for drawing upon studies driven by unknown interests or by political considerations not in line with EPA's mission. The addition of age of data and utilization of case-by-case exemption leave data inclusion vulnerable to the whims of the Administrator. This is not at all in line with best practices for research nor systematic review and could put EPA in the position of cherry-picking data and leaves the Agency vulnerable to allegations of data misuse.

[69] Id.