August 16, 2018

Comments from Academics, Scientists and Clinicians on the EPA Proposed Rule "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) Proposed Rule "Strengthening Transparency in Regulatory Science."[1] As scientists and health professionals, we strongly value open science which includes data sharing and full reporting of methods. Using credible and best available science for government regulation and policy clearly has substantial benefits for the public's health. Government, academia, and health care have made considerable effort to invest in strong science, identifying and reducing biases, increasing transparency and reproducibility, and developing focused study questions that address policy-related needs. We support the need to continue these investments.

However, this proposed rule would not improve data sharing, replicability, or transparency in decision-making as detailed below. In fact, it would have quite the opposite effect by seriously hindering the Agency's ability to adequately protect the public's health through the virtual elimination of independent scientific evidence from consideration. The language of the rule is confusing, contradictory, and poorly and incorrectly referenced with little science or policy foundation. This suggests the rule authors lack understanding of the scientific process.

Further, risk assessment and other scientific methods utilized by the agency should not be the subject of rulemaking, which would freeze those methods in time and prevent EPA from staying abreast of rapidly advancing scientific methods and thus access to the best available science.

We are strongly opposed to this regulation and recommend that EPA withdraw the proposed rulemaking immediately.

Our comments address the following main points.

RECOMMENDATIONS

1. **EPA should withdraw this proposed rule immediately.**
2. **EPA should focus on implementing existing initiatives and guidelines for improving data sharing and transparency at federal agencies.**

PROBLEMS WITH THE RULE

3. **The scientific sources cited for the basis of the rule do not support the proposed rule.**
4. **EPA did not consult with critical stakeholders, including scientists, health professional and communities.**

[1] Federal Register Vol 83, No 83. Monday, April 30, 2018. Pp 18768-18774

5. **EPA 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.**
6. **The terms "pivotal regulatory science," "replication," "reproducible," and "research data," are not defined or are problematic.**
7. **The rule's requirements for specific types of defaults, test methods, dose-response models and/ or analyses are not supported by current science.**
8. **The rule is counter to mandates in the reformed Toxic Substances Control Act (TSCA) to use the best available science and systematic reviews for chemical evaluations.**
9. **Data de-identification and masking techniques cannot ensure confidentiality and can degrade the accuracy of data for further analysis.**
10. **The rule is inconsistent with medical ethics and existing legal requirements to ensure the privacy and/ or confidentiality of human data.**

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

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RECOMMENDATIONS

1. EPA should withdraw this proposed rule immediately.

<u>The proposed rule does not address how this action fits with the Agency's mission of protecting human health and the environment.</u>
The rule has many fundamental flaws and will not improve the use of science for decision-making. Overall, the rule is not consistent with the principles of open science,[2] inappropriately codifies how science should be conducted, and codifies science-policy decisions in direct conflict with consensus reports from the NAS.

Specifically, the rule inappropriately codifies particular data analysis approaches (such as dose-response modeling) and other scientific decisions that should be made based on empirical considerations. This will hinder scientific inquiry and lead to inaccurate results. Rulemakings should not cover scientific methods or approaches which are constantly advancing with scientific innovations and discoveries. To use the best available science, the Agency needs to be able to adapt and implement changing science, which this rule would prevent it from doing.

As such, 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 public health protections.

2. EPA should focus on implementing existing initiatives and guidelines for improving data sharing and transparency at federal agencies.

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.[3] The objectives were developed in consultation with the National Science and Technology Council and with input from the public. To increase public access to science funded and used by the government, EPA should ensure it is in full compliance with the provisions of this memo.

Through collaborative efforts, academia, medical scientists, industry and publishers have developed several protocols and guidelines specifically designed to improve reporting and evaluation of studies that will improve the quality and transparency of the interpretation of findings. These protocols and

[2] Berg J, Campbell P, Kiermer V, Raikhel N, Sweet D. Joint statement on EPA proposed rule and public availability of data. Science. 2018;360(6388).

[3] 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

guidelines, such as CONSORT[4], ARRIVE[5] and STROBE[6], do not require public access to all study data and will still improve the scientific basis of evaluating studies. EPA should utilize these existing tools to evaluate study quality and build on this work already done by the scientific community.

Data sharing guidelines from the National Institutes of Health (NIH) are applicable to the sharing of final research data for research purposes.[7] As the NIH guidelines have already undergone an extensive deliberative process with input from the scientific community, EPA should reference these guidelines in its grants and/ or cooperative agreements.

Finally, providing secure access to data for research purposes also improves data sharing and is an alternative to requiring publicly available data.[8] EPA should consider the National Center for Health Statistics Research Data Centers[9] as a model—these centers have successfully provided access to sensitive information without breaches of privacy/ confidentiality.

PROBLEMS WITH THE RULE

3. The scientific sources cited for the basis of the rule do not support the proposed rule.

The rule states "The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science,"[10] and provides a list of citations. However, a number of the sources cited directly contradict the proposed rule. As such, the rule does not have a solid scientific or policy rationale, further supporting our recommendation that EPA should withdraw this proposed rule immediately.

In particular, EPA cites National Academy of Sciences (NAS) studies and deliberations on the very important issue of data sharing and transparency, but the NAS reports contain conclusions that are in contradiction to the rule, such as:

- Clear statements that unfettered public access to data for any purpose, as proposed in the rule, is inappropriate, risky and unjustified. For example their reports state: "Since unrestricted access can cause harm to individuals and also conflicts directly with respect for individual autonomy, it is not an appropriate policy,"[11] and "The panel concludes that no one way is

[4] Moher D, Jones A, Lepage L, for the CONSORT Group for the C. Use of the CONSORT Statement and Quality of Reports of Randomized Trials. JAMA. 2001 Apr 18;285(15):1992.

[5] Kilkenny C, Browne WJ, Cuthill IC, Emerson M, Altman DG. Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research. PLoS Biol. 2010 Jun 29;8(6):e1000412.

[6] Dwan K, Altman D, Clarke M, Gamble C, Higgins J. Observational Studies: Getting Clear about Transparency. PLoS Med. 2014 Aug 26;11(8):e1001711.

[7] NIH. Data Sharing Policy and Implementation Guidance. March 5, 2003. Available: https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#app

[8] 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.

[9] CDC. NCHS Research Data Center (RDC). December 2015. Available: https://www.cdc.gov/rdc/index.htm

[10] Federal Register Vol 83, No 83. Monday, April 30, 2018. Pg. 18770

[11] 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. 20

optimal for all data users or all purposes,"[12] and "The actual data collected for statistical purposes from households, individuals, business establishments, and other organizations through censuses and surveys under a pledge of confidentiality are never made available to users."[13]

- Acknowledgement that all parties' interests in and purposes for performing an analysis and/ or validation of data would not be beneficial, as assumed in the rule, and thus protections are required. For example: "If not carefully considered, a reanalysis may be used as a tool to delay action. It also requires the participation of the original investigators,"[14] and "[The panel recommends] restriction of access to public-use data to those who agree to abide by the confidentiality protections governing such data and the institution of meaningful penalties for willful misuse of those data."[15] This recommendation is meant to address potential use of data for non-research purposes, such as by marketers and companies for advertising.
- Assertion that simple de-identification of private information is not enough to protect an individual's data, which is counter to statements in the rule: "Statistical disclosure involves using data available outside the survey to breach the protection thought to have been afforded a survey data set by various data deletion and masking techniques."[16]

The proposed rule also cites the Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity[17] but this memo states that "scientific or technological findings or conclusions considered or relied on in policy decisions" should be made available to support transparency—not that all data should be publicly available.

4. EPA did not consult with critical stakeholders, including scientists, health professionals and communities.

We have grave concerns with the fact that EPA did not consult 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, despite citing policies from the National Institutes of Health and the National Science Foundation, EPA does not appear to have conducted any inter-agency consultation

[12] National Research Council. (2005). *Expanding Access to Research Data: Reconciling Risks and Opportunities.* Panel on Data Access for Research Purposes, Committee on National Statistics, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press. Pg. 2

[13] Id. Pg. 66

[14] 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. Pg. 22

[15] National Research Council. (2005). *Expanding Access to Research Data: Reconciling Risks and Opportunities.* Panel on Data Access for Research Purposes, Committee on National Statistics, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press. Pg. 4

[16] National Research Council. (2005). *Expanding Access to Research Data: Reconciling Risks and Opportunities.* Panel on Data Access for Research Purposes, Committee on National Statistics, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press. Pp. 59-60

[17] The White House. Memorandum for the Heads of Executive Departments and Agencies 3-9-09: Scientific Integrity. Available: https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09

on the rule. EPA's Science Advisory Board (SAB) also notes that EPA is legally mandated to make proposed regulations available for SAB review, which the Agency failed to do.[18]

5. EPA 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.

The proposed rule states: "EPA believes the benefits of this proposed rule justify the costs."[19] However, EPA does not include a citation or benefit-cost analysis to support this statement, which is a direct contradiction of the stated purpose of this proposed rule—transparent analyses to support rulemaking. EPA fails to quantify the benefits to society, and the Congressional Budget Office estimated the costs of similar proposals to the Agency alone at approximately $100-250 million a year.[20] 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.[21] 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 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."[22]

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.[23] A 2013 memo from the Office of Science Technology and Policy on increasing data access acknowledges these costs and directs agencies to "Allow the inclusion of appropriate costs for data management and access in proposals for Federal funding for scientific research."[24]

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[18] EPA Science Advisory Board. Memorandum: Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14). May 12, 2018.

[19] Federal Register Vol 83, No 83. Monday, April 30, 2018. Pg. 18772

[20] 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

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

[22] 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

[23] 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.

[24] 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.

In contrast, the proposed rule 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 would not incorporate it in relevant policy-making. In contrast, industry scientists will have financial motivation to provide their data because this could reduce or eliminate regulations that apply to their company's products, ultimately having the effect of increasing profits. This would create a situation in which data EPA considers in decisions would be heavily skewed towards industry studies – and 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.[25,26,27,28] An influx of industry-funded studies with financial conflicts of interest would likely bias the final results of EPA's analysis, leading to less stringent regulations and policies than with consideration of unbiased studies— with the ultimate result of reducing protections for the health of families.

All environmental health risks impacted by this rule may disproportionately affect children, so EPA is required to conduct an analysis under Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks.[29] Additionally, this rule proposes to establish a standard that will impact environmental health, likely having a more significant negative impact in minority and low-income populations, so it is also subject to Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations.[30]

6. The terms "pivotal regulatory science," "research data," "replication," and "reproducible," are not defined or are problematic.

'Pivotal regulatory science' is not scientific terminology and this phrase is not used in the scientific literature. The proposed rule defines pivotal regulatory science 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." This definition appears to attempt to delineate a smaller subset of relevant studies that would be 'pivotal regulatory science.' But the term is not useful because the entire body of relevant scientific evidence would meet the definition of pivotal regulatory science. This is because a properly conducted assessment considers the entire body of evidence in the evaluation, integration and development of conclusions. For example, though there may be one study or several studies that contribute to the numerical calculation of a point of departure, the rest of the body of scientific evidence is used to make determinations that also are important in the magnitude of the benefit-cost calculation, including: (1) uncertainty factors used in calculations of risk; (2) whether particular sub-populations are susceptible and need greater protections; (3) the modeling of dose-

February 22, 2013. Pg. 5. Available: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

[25] Mandrioli D, Silbergeld EK. Evidence from Toxicology: The Most Essential Science for Prevention. Environmental Health Perspectives. 2016;124(1):6-11.

[26] Lundh A, Sismondo S, Lexchin J, Busuioc OA, Bero L. 2012. Industry sponsorship and research outcome. Cochrane Database Syst Rev 12:MR000033

[27] 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

[28] Barnes DE, Bero LA. 1998. Why review articles on the health effects of passive smoking reach different conclusions. JAMA 279:1566–1570.

[29] 62 FR 19885, April 23, 1997.

[30] 59 FR 7629; February 16, 1994

response; (4) the likely occurrence and severity of potential health effects; (5) population exposure levels, etc. A typical EPA assessment draws upon hundreds to thousands of studies, and according to this definition all of the underlying data of those studies would need to be made publicly available.

The proposed rule points to a definition of "research data" that is extremely broad, but explicitly excludes medical information or information that could be used to identify a particular person in a research study.[31] Therefore, the definition of research data directly conflicts with the requirement in the rule to make all information publicly available that would be needed to complete a reanalysis. Also, there are many different kinds of data generated in a research study, as shown in the diagram below. The rule treats all these data as if they were the same when that is not the case, again indicating the lack of scientific input into this rulemaking. A 2013 memo from Office of Science Technology and Policy recognizes different data types and specifies that study meta-data, not individual-level data, should be made publicly available.[32]

[31] From the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards: Research data means the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples). Research data also do not include:

(i) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and

(ii) Personnel and medical information and similar information 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.

[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. Pg. 5. Available: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

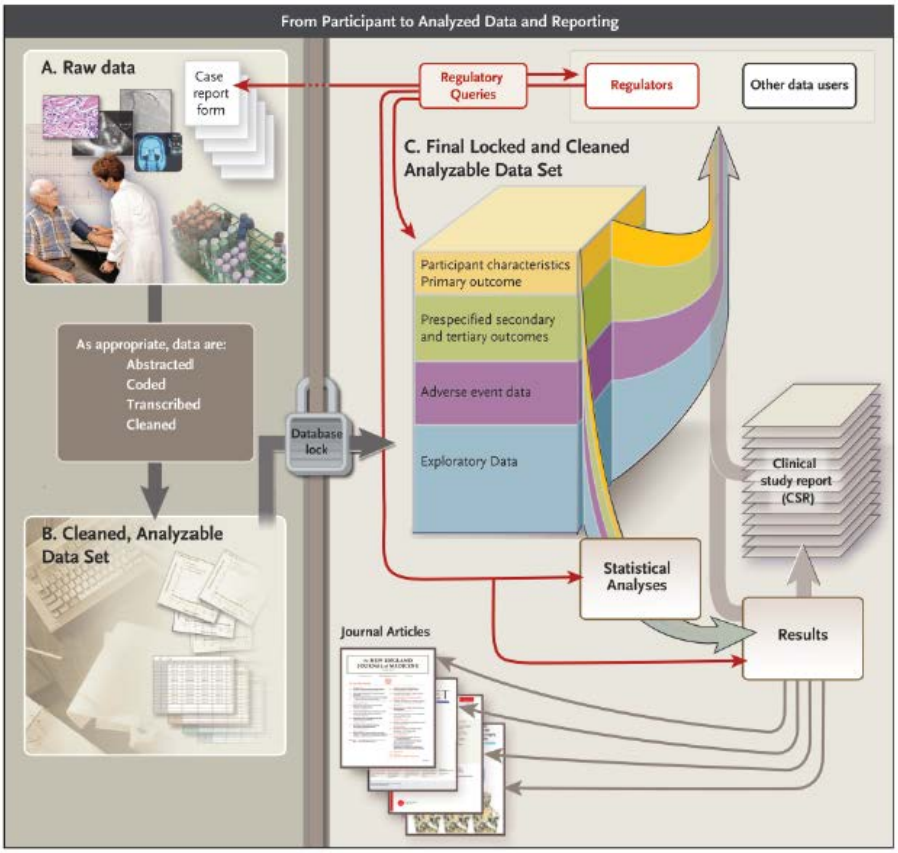

Figure (reproduced from IOM): Data flow from participant to analyzed data and reporting.[33]

Reanalysis, Replication and Reproduction

The rule uses the terms "replication," "reproducible" and "validation and analysis" in an imprecise way that suggests EPA believes they are interchangeable, which is not the case. These terms have specific scientific definitions, as paraphrased below from an NAS workshop report.[34] In the following discussion, we are using the terms as defined by the NAS.

- *Reanalysis* is conducting a further analysis of data. A person doing a reanalysis of data may use the same programs and statistical methodologies that were originally used to analyze the data or may use alternative methodologies, but the point is to analyze exactly the same data and see if the same result emerges from the analysis.
- *Replication* means that a scientific experiment or a trial to obtain a consistent result is repeated. The repeated experiment uses exactly the same protocols and statistical programs but with data from a different population. The goal is to see if the same results hold with data from a different population.
- *Reproduction* means producing something that is very similar to the original research, but in a different medium or context. A researcher who is reproducing an experiment addresses the

[33] IOM (Institute of Medicine). 2014. *Discussion framework for clinical trial data sharing: Guiding principles, elements, and activities.* Washington, DC: The National Academies Press.

[34] National Academies of Sciences, Engineering, and Medicine. 2016. Principles and obstacles for sharing data from environmental health research: Workshop summary. Washington, DC: The National Academies Press. doi: 10.17226/21703.

same research question but may use different methodologies or experimental measurements than the original researcher did.

The proposed rule argues that data and methods should be made available in sufficient detail that one could redo the analysis. Thus, the proposed rule appears to be primarily concerned with reanalysis rather than replicating experiments even though the citations for this section of the rule[35] are focused on issues with replication of experimental findings, not reanalysis. Additionally, there is no documentation to support that there is a replication crisis related to reanalysis of data.

Further, re-analysis, replication and reproduction are inappropriate as the sole metrics for judging study quality. First, a re-analysis of a study's data alone cannot verify or invalidate scientific findings without the requisite attention to evaluating the research design, methods, uncertainties, biases, and consistency with existing publications. Second, certain situations are impossible to recreate or should not be, due to the severity of health outcomes or the circumstances surrounding the exposures.[36] For instance, emergency responses to the 2010 Deepwater Horizon explosion and oil spill or a decade-long prospective cohort study on lead exposure in drinking water and adverse effects on childhood IQ would be difficult to replicate or reproduce. We cannot and would not want to repeat these disasters, but this does not mean the studies based on them are invalid—on the contrary, such studies are often peer-reviewed and highly regarded, contributing critical scientific evidence for hazard and risk assessment. Thus, replication and reproduction represent only one aspect of the overall criteria used to judge the credibility of science.

7. The rule's requirements for specific types of defaults, test methods, dose-response models and/ or analyses are not supported by current science.

The proposed rule states that "EPA will use peer-reviewed information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments." It is not appropriate to require use of standardized test methods (guideline studies) and good laboratory practice (GLP) studies as described below.

Guideline, GLP studies and study quality

Guideline and GLP studies – mostly sponsored by industry to meet regulatory requirements - don't necessarily use modern methods for evaluating chemicals and are not designed to address issues with evaluated health effects from low-dose exposures, complex and systemic endocrine effects, behavioral or learning effects, metabolic perturbations, or upstream effects like reduced sperm count or reduced anogenital distance which are predictors of infertility. Furthermore, GLP and Guideline studies are not consistently associated with higher quality research, proper study

[35] Federal Register Vol 83, No 83. Monday, April 30, 2018. Pp 18770

[36] Environmental Data and Governance Initiative. Public Protections Under Threat at the EPA: Examining Safeguards and Programs That Would Have Been Blocked by H.R. 1430. March 2017. Available: https://envirodatagov.org/wp-content/uploads/2017/03/Public-Protections-under-Threat-at-the-EPA.pdf

design or correct statistical analysis.[37, 38] Much of the research available in the scientific literature is hypothesis driven-- for example, exploring mechanisms to explain how a particular detrimental health impact occurs. These experimental protocols are tailored to address the question being asked and generally there are no standardized test methods that could be followed. Yet, these experimental findings are critically important contributions to the body of scientific evidence. For the highest quality scientific assessment, a systematic review approach which considers all relevant scientific evidence and evaluates study quality according to established criteria should be used, as recommended by the NAS.[39] Inappropriately using GLP as a measure of study quality would lower the overall quality of the assessment because other studies which are higher quality and/ or more directly relevant to the study question would be downgraded or excluded.

In general, when assessing the body of evidence, EPA should consider both individual study quality and the overall quality of the body of evidence which requires consideration of all the relevant scientific literature. To not do so could potentially bias the assessment, as stated by the NAS. [40] A scoring system should not be used to evaluate study quality. Specifically, we note that empirically validated approaches in the clinical sciences such as Cochrane discourage using a numerical scale scoring approach for evaluating study quality because calculating a score requires choosing a weighting scheme for each component, which generally is nearly impossible to justify.[41] Furthermore, a study might be well designed to eliminate bias, but because the study failed to report details in the publication under review, it will receive a low score--most available scoring systems include a mix of risk of bias and reporting biases which is inappropriate. Additionally, quality scores have been shown to be invalid for assessing risk of bias in clinical research.[42] The current standard in evaluation of both clinical and environmental health research calls for reporting each component of the assessment tool separately and not calculating an overall numeric score.[43]

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[37] Myers, J. P., F. S. vom Saal, et al. (2009). "Why public health agencies cannot depend on good laboratory practices as a criterion for selecting data: the case of bisphenol A." Environ Health Perspect 117 (3): 309-15.

[38] Vandenberg LN, Ågerstrand M, Beronius A, Beausoleil C, Bergman Å, Bero LA, Bornehag CG, Boyer CS, Cooper GS, Cotgreave I, Gee D, Grandjean P, Guyton KZ, Hass U, Heindel JJ, Jobling S, Kidd KA, Kortenkamp A, Macleod MR, Martin OV, Norinder U, Scheringer M, Thayer KA, Toppari J, Whaley P, Woodruff TJ, Rudén C. A proposed framework for the systematic review and integrated assessment (SYRINA) of endocrine disrupting chemicals. Environ Health. 2016 Jul 14;15(1):74.

[39] National Research Council. Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, D.C.; 2014.

The National Academies of Sciences. Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, D.C.: National Academies Press; 2017.

National Academies of Sciences, Engineering, and Medicine. 2018. *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25086.

[40] Id.

[41] Juni, P., A. Witschi, R. Bloch, and M. Egger. 1999. The hazards of scoring the quality of clinical trials for meta-analysis. JAMA 282(11):1054-1060.

[42] Id.

[43] Higgins, J.P.T., and S. Green, eds. 2008. Cochrane Handbook for Systematic Reviews of Interventions. Chichester, UK: John Wiley & Sons.

The rule also states that "EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies that explore: A broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity." These mandates inappropriately dictate how scientific studies should be conducted and are not supported by current science as described below.

Dose-response models

Scientists use dose-response modeling for various purposes, such as testing for trends in data, generating hypotheses, and estimating risk. Models that fit the data equally well are common and the choice between these multiple models needs to be carefully addressed, such as by considering biological plausibility, parsimony, and the degree of protection to human health afforded. Simply using a greater number of models is unlikely to improve results without considering the model's assumptions and whether they fit the dataset, the goal of the analysis, and many other issues. Therefore, giving priority to studies based on the number or range of models used is scientifically inappropriate. This would create an incentive for fitting inappropriate models to data without scientific justification, with subsequent outputs that are inaccurate. Also, nowhere in the proposed rule does the Agency expressly address the issue of being protective of human health (their primary goal) which should be a key criterion used to select a final model for estimation.

There are many dose-response analyses that could be applied to any data set, and any analysis contains numerous assumptions regarding an underlying statistical distribution for the data, models for mean response, variance structures, shapes, etc. Through countless analyses and applications to many different kinds of datasets, scientists have pinpointed a reduced set of models that are most accurate for specific types of data, and thus are widely accepted with empirical basis. By dictating model choices without empirical basis, the rule sets a dangerous precedent of prescribing how science should be done. Progress in science is made by constant updates and revisions in response to new discoveries and information; setting analytical methods in stone through an ill-conceived policy can only hamper scientific advancements and innovation.

The rule states without references or citations that "…there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects," and mandates that "EPA shall evaluate the appropriateness of using default assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis." There are two fundamental problems with these statements. First, the conclusions on linearity vs non-linearity in dose-response are incorrect and second, the mandates to reconsider defaults are not consistent with NAS recommendations.

Whiting, P., Harbord, R. and Kleijnen, J., 2005. No role for quality scores in systematic reviews of diagnostic accuracy studies. *BMC Medical Research Methodology*, *5*(1), p.19.

Whiting, P., Savović, J., Higgins, J.P., Caldwell, D.M., Reeves, B.C., Shea, B., Davies, P., Kleijnen, J. and Churchill, R., 2016. ROBIS: a new tool to assess risk of bias in systematic reviews was developed. *Journal of clinical epidemiology*, *69*, pp.225-234.

Linear, no-threshold dose-response

Contrary to the rule's statement about growing evidence of non-linearity in concentration-response functions, the body of empirical evidence points to the opposite—that for most chemicals and pollutants, there is likely no safe threshold on a population level because of background exposures and pre-existing vulnerabilities (see Figure below). [44] The rule mandates reconsidering using a linear, no threshold dose response, but the NAS recommends exactly the opposite in considering low-dose effects: "The committee recommends that cancer and noncancer responses be assumed to be linear as a default." [45] The statements and mandate in the rule regarding linear and threshold dose-response are not supported by the science.

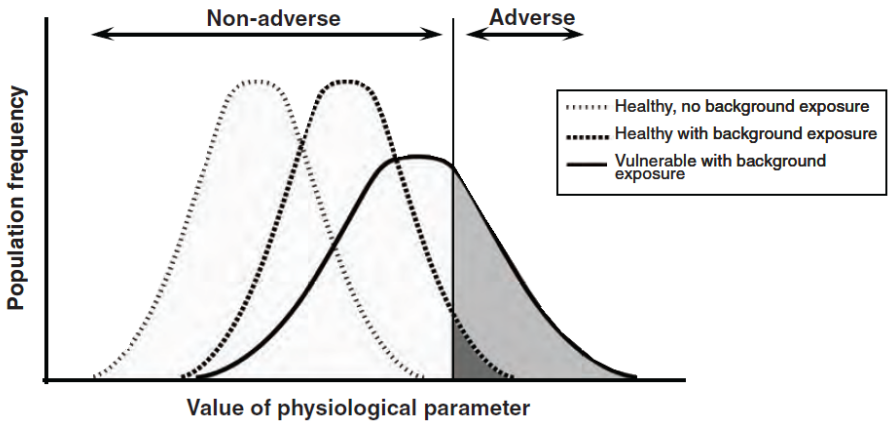

Figure (reproduced from NAS): Value of physiologic parameter for three hypothetical populations, illustrating that population responses depend on a milieu of endogenous and exogenous exposures and on vulnerability of population due to health status and other biologic factors. [46]

Defaults

The rule mandates re-consideration of established science-based defaults on a case-by-case basis. This is in direction contradiction to NAS recommendations for an effective default policy: "Defaults need to be maintained for the steps in risk assessment that require inferences beyond those that can be clearly drawn from the available data or to otherwise fill common data gaps." [47] The NAS warned that should established defaults be reconsidered on an ad hoc basis, it would "…create further vulnerability to challenge and delay that could affect environmental protection and public health." [48] Therefore, the NAS further recommends that EPA should establish criteria to determine if departure from a default is warranted: "Criteria should be available for judging whether, in specific cases, data are adequate for direct use or to support an inference in place of a default." [49] The proposed rule does not address this issue.

[44] National Research Council. Science and Decisions: Advancing Risk Assessment. Washington, D.C.: National Academies Press; 2009. Pg. 131
[45] Id. Pg. 180.
[46] Id. Pg. 131
[47] Id. pg. 192
[48] Id. pg. 190
[49] Id. pg. 192

The NAS highlights that health protective defaults are important because they incorporate factors that reflect the range of variability and susceptibility in the population to ensure risks are not underestimated. [50] Consistent with the NAS, we recommend that the default should always be used for factors that are known to influence risk unless there is chemical-specific data that support increasing or decreasing it. For example, EPA's defaults should include:

- Inter-human variability, general
- Inter-human susceptibility to carcinogens, adult
- Inter-human susceptibility to carcinogens, early life (including prenatal)
- Inter-human susceptibility to non-carcinogens, early life (including prenatal)
- Animal findings are relevant to humans
- Findings from one route of exposure are considered representative unless data show otherwise

Further, we support updating established defaults to account for newer science demonstrating that EPA's typical safety factor of 10 is insufficient to account for variability due to life stage, genetics, underlying disease status, and external stressors that may be due to poverty or other difficult life conditions. [51]

8. The rule is counter to mandates in the reformed Toxic Substances Control Act (TSCA) to use the best available science and systematic reviews for chemical evaluations.

Reformed TSCA requires the use of the "best available science" for decision-making under the Act.[52] In contrast, this proposed rule mandates EPA to ignore well-conducted, relevant studies simply because all the data are not publicly available and/ or may not conform to the rule's invalid assumptions about GLP/ Guideline and dose-response modeling; this is inconsistent with the TSCA statute and the Agency's legal mandate.

Further, EPA's rule delineating risk evaluation procedures under TSCA mandates the use of systematic review methods.[53] Systematic reviews consider the entire body of scientific evidence and provide the most comprehensive, accurate and transparent evaluations of chemicals. In a systematic review, the quality and strength of all relevant individual studies is considered to reach an overall conclusion about the body of evidence, without requirements for data re-analysis or public access to data.[54] This proposed rule would prevent EPA from completing systematic reviews as its regulation mandates for chemical evaluations because it would prohibit the Agency from considering studies where the data were not publicly available and downgrade studies based on criteria not related to actual study quality, such as GLP.

[50] Id. Ch. 4-6
[51] Id. Ch. 4-6
[52] 15 USC §2625(h)
[53] Federal Register, Vol. 82 No. 138. July 20, 2017. Pp. 33726-33753
[54] Woodruff TJ, Sutton P. The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. Environ Health Perspect. 2014 Oct;122(10):1007–14.

9. Data de-identification and masking techniques cannot ensure confidentiality and can degrade the accuracy of data for further analysis.

The proposed rule is unrealistic about the limitations of data masking, coding and de-identification techniques in two critical ways: (1) the ability of these techniques to preserve privacy/ confidentiality and (2) the ability to perform useful and accurate analyses on data once these techniques have been applied.

According to an NAS Workshop report: "Statistical disclosure involves using data available outside the survey to breach the protection thought to have been afforded a survey data set by various data deletion and masking techniques. Re-identification of respondents may be increasingly possible because of high-speed computers, external data files containing names and addresses or other direct identifiers as well as information about a variety of individual characteristics, and sophisticated software for matching survey and other files." [55] Re-identification is not hypothetical; study participants, including children, have been identified from data sets which were thought to be sufficiently masked:

- "In an experiment to discover whether confidentiality could be preserved while opening the data for public review, the study investigators attempted to disguise the identity of the study participants. They deleted as many features as possible from the questionnaires, such as the name, the state file number, the mother's maiden name, and the name of the person providing the information. However, they needed to retain a minimum set of features if other scientists were to be able to replicate the basic findings of the study…They found that even this minimum set of features could allow for identification of research participants."[56]
- "The next large-scale reidentification she did was a case in southern Illinois for the Department of Public Health. She reidentified children in a cancer registry."[57] (See this reference for an extensive discussion of re-identification.)

Often, identifying information is a metric key to a study's data analysis and conclusions, such as when home addresses are used as a basis to estimate exposure measures for pesticides[58] or other pollutants. In this case, no meaningful analysis could be conducted with de-identified data where home addresses have been removed to ensure participant privacy. Thus, for these types of studies, data de-identification and masking do not provide a viable solution that would both allow re-analysis and protect participant privacy.

Finally, these techniques affect both the utility of data and the accuracy of an analysis that uses such data. According to two different NAS workshop reports: "A fundamental problem with efforts to protect

[55] National Research Council. (2005). *Expanding Access to Research Data: Reconciling Risks and Opportunities.* Panel on Data Access for Research Purposes, Committee on National Statistics, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press. Pp. 59-60

[56] 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. Pg. 11

[57] National Academies of Sciences, Engineering, and Medicine. 2016. Principles and obstacles for sharing data from environmental health research: Workshop summary. Washington, DC: The National Academies Press. doi: 10.17226/21703. Pg. 55

[58] Shelton JF, Geraghty EM, Tancredi DJ, Delwiche LD, Schmidt RJ, Ritz B, et al. Neurodevelopmental Disorders and Prenatal Residential Proximity to Agricultural Pesticides: The CHARGE Study. Environ Health Perspect. 2014 Jun 23;122(10):1103–9.

individuals from identification…is that as more is done to deidentify or anonymize the data, the less useful the information is for statistical analyses,"[59] and "Researchers expressed serious concern about the impact of statistical disclosure limitation techniques that distort variable relationships and that may have an unanticipated (or even anticipated) impact on modeling results."[60] This indicates that in many cases, the results of a re-analysis completed with de-identified or masked data would necessarily be different than the original study, which runs counter to the rule's stated intent of using these techniques to allow public disclosure of data and validation of scientific findings.

10. The rule is inconsistent with medical ethics and existing legal requirements to ensure the privacy and/ or confidentiality of human data.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)
Medical records, including those used for research, are subject to strict requirements governing the use and disclosure of such information mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[61] HIPAA requires researchers to protect identifiable information and provides that such information may only be disclosed for research purposes with the written consent of the person providing the information.[62] There are both civil and criminal penalties for violations related to data disclosures.[63] The proposed rule does not consider HIPAA requirements and how they would affect the ability to make protected health information publicly available, nor does it address who would assume potential liability if identifiable information was disclosed to comply with rule.

Institutional Review Boards (IRBs)
The proposed rule would have a serious impact on academic or industry research projects getting an approval through an Institutional Review Board (IRB), who review research projects to ensure the protection of human rights. IRBs trace their roots back to 1974, when the Department of Health Education and Welfare promulgated regulations on the Protection of Human Subjects.

All academic/industry research projects involving human subjects must obtain IRB approval, which ensures that the specific research protocol protects human rights. Participants must be notified about the degree to which the confidentiality of their records will be maintained, and the IRB also considers risks to the participants and how use of the information obtained may adversely impact the rights and welfare of the subjects.[64]

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[59] National Academies of Sciences, Engineering, and Medicine. 2016. Principles and obstacles for sharing data from environmental health research: Workshop summary. Washington, DC: The National Academies Press. doi: 10.17226/21703. Pg. 52

[60] 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. 9

[61] Public Law 104 – 191

[62] National Research Council. (2005). *Expanding Access to Research Data: Reconciling Risks and Opportunities.* Panel on Data Access for Research Purposes, Committee on National Statistics, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press.

[63] 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.

[64] Id.

For a researcher who wishes to comply with the proposed "transparency" rule and have their data considered by EPA, obtaining IRB approval would be extremely difficult because: (1) the researcher would have to make participant data publicly available and would not be able to ensure privacy/ confidentiality; and (2) the researcher would have no control over how data they make publicly available would be used—it could very well be used in a way that adversely impacts research subjects through privacy invasions or weakening of protections that safeguard communities.

The result of this dilemma is that either researchers would choose not to pursue research with human subjects, stifling scientific discovery; or that they will forgo compliance with the EPA proposed rule to obtain IRB approval and their research will be ignored by EPA.