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Via Https://www.regulations.gov

Thank you for the opportunity to comment on the Environmental Protection Agency's (EPA) proposal to strengthen transparency in regulatory science.[1] The comments below are intended to help EPA clarify the proposal's basic rationale, and to rebut those who, in Orwellian fashion, denounce efforts to ensure the validity of regulatory science as an assault on science and public health.

Brief Summary of the Proposal's Rationale

EPA seeks to ensure that the data and models used in scientific studies that are "pivotal" to "significant" regulatory actions "are publicly available in a manner sufficient for independent validation."[2] The proposal's rationale may be summarized as follows.[3]

1. The best available science should serve as the foundation of EPA's regulatory actions.
2. Science that is pivotal to significant regulatory action should meet high standards of objectivity, transparency, and reproducibility.
3. The best means of assuring such quality is to make regulatory science available to the public for independent analysis and validation.
4. Independent review is particularly necessary for evaluating dose-response 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.
5. Such dose-response functions typically drive the calculation of regulatory benefits, the stringency of regulatory standards, and the determination of safe ("reference") levels or exposures.
6. EPA solicits comment on how to ensure that, over time, more of the data and models underlying regulatory science are available for independent validation in a manner that is consistent with law, patient privacy, and confidentiality agreements between researchers and subjects.

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[1] Environmental Protection Agency, Strengthening Transparency in Regulatory Science, Proposed Rule, 83 FR 18768-18774, April 30, 2018, https://www.gpo.gov/fdsys/pkg/FR-2018-04-30/pdf/2018-09078.pdf
[2] 83 FR 18768
[3] 83 FR 18769-18771

7. Techniques developed over the past half century to mask, code, and de-identify personal medical information should enable EPA to increase access to research data without damage to privacy and confidentiality rights.
8. Such techniques include requiring applications for access; restricting access to data for purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements.

Key Issues: Linear-No-Threshold, Peer Review, and Replication

EPA proposes to reassess its past reliance on the "default assumption" that certain pollutants—notably fine particulate matter ($PM_{2.5}$) from fossil-fuel combustion—are deadly at any concentration or exposure above zero. That "linear-no-threshold" (LNT) assumption has not been validated, conflicts with considerable evidence, and flouts the basic toxicological maxim that "the dose makes the poison."[4] LNT is an open sesame for regulatory excess, fostering the impression that air pollution, even at today's historically-low levels, is a public health emergency.

Under the proposal, EPA will "clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions."

To that end, EPA will conduct "independent peer review" of "all pivotal regulatory science used to justify regulatory decisions." Peer reviewers will address "the strengths and weaknesses" of the assumptions underlying dose-response data and models.[5]

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[4] See Joel M. Schwartz and Steven F. Hayward, *Air Quality in America: A Dose of Reality on Air Pollution Levels, Trends, and Health Risks* (Washington, DC: AEI Press, 2007), pp. 121-136, http://www.globalwarming.org/wp-content/uploads/2012/06/Schwartz-Hayward-Air-Quality-in-America.pdf; Steve Milloy, *Scare Pollution: Why and How to Fix the EPA* (USA: Bench Press, 2017); Laura C. Green and Sarah R. Armstrong, "Particulate matter in ambient air and mortality: toxicologic perspectives," *Regulatory Toxicology and Pharmacology*, Volume 38, Issue 3, December 2003, Pages 326-335, https://www.sciencedirect.com/science/article/pii/S0273230003000990; James E. Enstrom, "Fine Particulate Matter and Total Mortality in Cancer Prevention Study Cohort Reanalysis," *Dose-Response: An International Journal*, January-March 2017:1-12, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5407529/pdf/10.1177_1559325817693345.pdf; S. Stanley Young, Richard L. Smith, Keneth K. Lopiano, "Air quality and acute deaths in California, 2000-2012," *Regulatory Toxicology and Pharmacology*, 88 (2017) 173-184, https://junkscience.com/wpcontent/uploads/2017/11/Young-2017-CA-data-RTP.pdf; and S. Stanley Young, PhD, FASA, FAAAS, Comment Letter on Executive Order 13777, "Enforcing the Regulatory Reform Agenda," Docket ID No. EPA-HQ-OA-2017-0190, file://cei-fs01/Folder%20Redirections/marlo.lewis/Downloads/Comment.pdf.

[5] 83 FR 18774

However, many peer-reviewed studies do not meet high standards of objectivity and reproducibility.[6] When the peers are colleagues who co-author each other's work, share the same methodological or policy commitments, and depend on the same funding sources, peer review may be little more than pal review.

Thus, the pivotal studies underpinning significant regulation should also allow for post-publication audit by independent researchers. As in the marketplace of goods, so in the marketplace of ideas, competition promotes quality. Rival researchers are more likely than journal editors and peer reviewers to discover flaws in a study's data or methods.

Independent validation is, of course, difficult if the study's authors refuse to share their data. That is a longstanding problem in air pollution epidemiology.

A vast number of EPA air rules depend for their justification on the estimated collateral benefits ("co-benefits") of coincidental reductions in fine particulate matter ($PM_{2.5}$).[7] For example, the so-called Clean Power Plan's estimated $PM_{2.5}$ co-benefits could be as high as $34 billion in 2030, substantially exceeding the rule's estimated climate benefits.[8]

For many years, EPA partly based its $PM_{2.5}$ co-benefit calculations on two foundational studies conducted in the 1990s—the so-called Harvard Six Cities study headed by D.W. Dockery[9] and an American Cancer Society cohort study (CPS II) headed by C. Arden Pope.[10] Despite repeated requests from Congress and promises by former EPA Administrator Gina McCarthy,[11] the researchers still refuse to share their data with independent scholars. Such "secret science" is inherently suspect as partisan and agenda-driven.

For pragmatic reasons, EPA is not proposing to require researchers to divulge data in past studies used to support previous regulatory decisions. Indeed, even with regard to prospective rulemakings, "Nothing in the proposed rule compels the disclosure of any

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[6] David Randall and Christopher Wesler, The Irreproducibility Crisis of Modern Science: Causes, Consequences, and the Road to Reform, National Association of Scholars, April 17, 2018, https://www.nas.org/articles/nas_launches_new_report_the_irreproducibility_crisis

[7] Anne E. Smith, An Evaluation of the PM2.5 Health-Benefits Estimates in Regulatory Impact Analyses for Recent Air Regulations, NERA Economic Consulting, December 2011, http://www.nera.com/content/dam/nera/publications/archive2/PUB_RIA_Critique_Final_Report_1211.pdf

[8] EPA, Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units; Final Rule, 80 FR 64680, https://www.gpo.gov/fdsys/pkg/FR-2015-10-23/pdf/2015-22842.pdf

[9] D. W. Dockery, C. A. Pope III, X. Xu, et al., "An Association Between Air Pollution and Mortality in Six U.S. Cities," *New England Journal of Medicine* 329 (1993): 1753–59, http://www.nejm.org/doi/full/10.1056/NEJM199312093292401

[10] Pope, Thun, Namboodiri, et al., "Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults," *Am J Respir Crit Care Med* Vol 151. pp 669-674, 1995, https://www.ncbi.nlm.nih.gov/pubmed/7881654

[11] House Science, Space, and Technology Committee, "Investigation into EPA's Secret Science," https://science.house.gov/issues/committee-investigation-epas-secret-science

confidential or private information in a manner that violates applicable legal and ethical protections."[12]

To safeguard such protections, the rule includes a provision allowing EPA to exempt significant regulatory decisions on a case-by-case basis if the Administrator "determines that compliance is impracticable" because making all dose-response data and science publicly available would not be consistent with law, patient privacy, or confidentiality.[13]

Nonetheless, "trust us, we're the experts" is no substitute for independent vetting of data and models. EPA therefore solicits comment on "how to incorporate stronger data and model access requirements into the terms and conditions of cooperative agreements and grants."[14]

Attacks on the Transparency Proposal

Critics claim EPA's proposal would unlawfully "censor" and "restrict" regulatory science and that its real objective is to weaken public health protections for the benefit of polluters. They also claim there is no need to revise agency science policy because EPA already uses peer-reviewed research.

Censored Science

In a letter to Acting Administrator Andrew Wheeler and other top EPA officials, the Union of Concerned Scientists, Natural Resources Defense Council, and 18 other progressive policy groups claim that "Under Pruitt, EPA . . . proposed to prohibit consideration of scientific studies that rely on confidential health data—a move that would weaken public health protection by excluding many foundational public health studies from consideration in the development of standards."[15]

Those organizations claim that EPA's attempt to end "secret science"—a phrase, incidentally, that never occurs in the proposed rule—should be called the "censored science proposal."[16]

In the same vein, David Michaels, who headed the Occupational Safety and Health Administration under President Obama, claims EPA's proposal violates the Administrative Procedure Act, under which EPA may not refuse to consider comments or studies submitted in rulemakings just because the data are not publicly available.[17]

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[12] 83 FR 18771
[13] 83 FR 18772
[14] 83 FR 18772
[15] Letter to Andrew Wheeler, Henry Darwin, Jenifer Orme-Zavaleta, and Richard Yamada from Union of Concerned Scientists et al., Re: Rescinding former Administrator Pruitt's 2017 policy directive regarding membership of EPA federal Advisory committees, August 6, 2018, https://www.eenews.net/assets/2018/08/06/document_pm_01.pdf
[16] Quoted by Niina Heikkinen, "Greens like 'censored' science or 'secret' science," *ClimateWire*, July 20, 2018, https://www.eenews.net/climatewire/stories/1060089819/search?keyword=EPA+science+policy
[17] Heikkinen, Ibid.

All such criticisms misunderstand or deliberately misconstrue EPA's proposal. Nothing in the proposal states or implies that EPA will not consider studies or comments referencing studies unless the data are fully transparent or the results are independently validated. Rather, EPA proposes to strengthen the integrity and reasonableness of significant regulatory action by increasing its reliance on science that is transparent, reproducible, and independently validated.

EPA is well within its authority to determine that transparent and reproducible science is of higher quality than opaque and irreproducible science. The agency is similarly well within its authority to accord greater weight to higher-quality science than to lower-quality science.

Restricted Science

Molly Rauch, public health policy director of Moms Clean Air Force, warns that the science covered by the proposal "would be the kinds of studies that helped us make public health breakthroughs," such as the Harvard Six Cities study linking air pollution with health and mortality risks.[18] She suggests that EPA's plan to enhance transparency and reproducibility would prevent the agency from acknowledging and acting on future public health breakthroughs.

Rauch apparently has never wondered how she, EPA, or other experts can distinguish a genuine breakthrough from a spurious one if critics are denied access to the underlying data and models. The partisanship endemic to *homo politicus* inclines all of us to applaud studies that seem to vindicate our prejudices and advance our agendas. Thus, it is especially when science is intended to inform significant regulatory decisions that policymakers should insist, to the maximum extent feasible, that the research be transparent and reproducible.

People who profess to be passionate about public health, and who hail D.W. Dockery and C. Arden Pope as heroes, should be among the most enthusiastic about EPA's proposal. Why? Because nothing would do more to advance their agenda than independent validation of their claims that $PM_{2.5}$ kills tens of thousands of Americans every year.

The fact that 20 major advocacy organizations scorn EPA's efforts to make pivotal regulatory science more transparent suggests their real concern is that "many foundational public health studies" may not be reproducible. Or, maybe they think the shortcomings of such studies do not really matter, believing on ideological or partisan grounds that more stringent regulation is always better.

Peer Review

This topic is discussed above. Suffice it to say here that although peer review can help improve a study submitted for publication, it can also block publication of dissenting views. An expert consensus may reflect the weight of evidence. It may also reflect peer pressure and group think. Many peer-reviewed studies later turn out to be non-reproducible.[19] If a

[18] *Heikkinen, Ibid.*
[19] Randall and Wesler, Ibid.

study is pivotal to significant regulatory action, preference should be given to studies that can be independently validated. Independent validation is not possible unless the public has access to the underlying data and models.

Respectfully Submitted,

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