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U.S. Environmental Protection Agency
EPA Docket Center
Office of Research and Development Docket
EPA-HQ-OA-2018-0259
Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Docket No. EPA-HQ-OA-2018-0259: Strengthening Transparency in Regulatory Science, Supplemental Rule

On behalf of the Union of Concerned Scientists (UCS), I submit this comment to the Environmental Protection Agency (EPA) to oppose this proposed rule, as modified by the supplemental notice. The additions and clarifications outlined by the supplemental notice only amplify the threats this proposal poses to EPA's ability to use the best available science to carry out its mission of protecting public health and the environment.

With more than half a million supporters, UCS is a science-based nonprofit working for a healthy environment and a safer world. Our organization combines independent scientific research and citizen action to support innovative, practical solutions and secure responsible changes in government policy, corporate practices, and consumer choices.

UCS supports transparency in the science policymaking process as a feature of good governance. However, while this rule has transparency in its name, it would not help EPA achieve its purported goal of openness of data or of the policy process. To the contrary, the proposal politicizes the process of relying on the best available science by using a non-scientific criterium – public availability of unanalyzed data – to determine the importance of scientific evidence.

In issuing this proposed rule, EPA claims that it would be making science more transparent, but does not provide any objective analysis of what approaches would be most helpful to the public or how the proposal would affect public participation in the regulatory process. In other words, the proposed rule, as modified by the supplement, still contains no clear statement of what problem the agency is trying to address and for what purpose. The supplemental notice makes clear that the proposal would require EPA to judge studies based on their data availability, rather than on scientific rigor, and it would force researchers to choose between protecting privacy and security and allowing their work to be used in EPA decisionmaking. The rule, as modified by the supplemental notice, does nothing to advance the cause of transparency in the broader scientific community. The scientific community can and does work on making science more accessible and reproducible. This issue is best addressed with the full involvement of scientists and scientific institutions, not through the EPA's Trojan horse transparency proposal.

EPA's proposed rule, as modified in the supplemental notice, has three fundamental flaws that render it harmful for EPA's ability to use science to protect public health and the environment. First, the agency offers insufficient justification and analyses to support the rule. The proposal includes no analyses of the rule's effect on EPA's mission and work, no assessment of the rule's costs or benefits, and no indication of the problem that the rule would address. Second, the proposal would restrict the agency's ability to implement and enforce mission-critical laws by arbitrarily excluding or downweighting studies whose data cannot be made publicly available.[1] Third, the rule would grant the EPA administrator broad authority to exempt individual studies or entire policy decisions from the rule's provisions on a case-by-case basis. This provision invites scientific integrity abuses at EPA because it would give the administrator unprecedented power to choose what science gets used or sidelined, decisions that should be made by the agency's scientific experts based on established criteria of what qualifies as best available science. Further, giving fiat power to the administrator to exclude certain studies from the requirements of the rule undermines the supposed intent of the rule. For these reasons, and those that will be explained in greater detail in this comment, EPA must not move forward with this rulemaking.

Lack of authority to enforce rule will violate laws

The supplemental notice offers a different source of authority for the proposed rule, changing from a range of statutes to the Federal Housekeeping Act. The Act reads that "The head of an *Executive department* or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property" (emphasis added).[2] EPA is not an "executive department" of the federal government.[3] Even if the Federal Housekeeping Act applied here, it is meant to cover procedural rules, which the Administrative Procedure Act (APA) defines as "rules of agency organization, procedure or practice," not substantive rules, like this proposed rule, that would prevent an agency from fulfilling its statutory duties.

The proposed rule, as modified in the supplemental notice, would clearly interfere with the agency's use of the best available science. For example, the policy violates laws like the Toxic Substances Control Act (TSCA) and the Safe Drinking Water Act (SDWA) because of the statutory requirement to use the "best available science." That requirement does not make exception for the agency to effectively ignore certain scientific information of high quality simply because the unanalyzed data cannot be made public for reasons of privacy, confidentiality, or intellectual property. According to judicial precedent, "best available science" is defined as "all existing scientific evidence relevant to the decision" and a body of evidence that "cannot ignore existing data."[4] In addition to the "best available science" requirements, TSCA also requires EPA to take into consideration information "that is reasonably available to the Administrator."[5] EPA's own regulations define that term as "information that EPA possesses or can reasonably generate, obtain, and synthesize . . . , whether or not that information is confidential business information, [sic] that is protected from public disclosure..."[6] Not only would this proposed rule conflict with TSCA's mandate to consider the best available science, it would challenge the method by which EPA can review the weight of the scientific evidence, which in rulemaking for TSCA is defined by a systematic review method.[7] These reviews consider the entire body of scientific evidence, so the exclusion of certain studies based on

whether the raw data and models are publicly available would render these reviews, as mandated, impossible.

Further, the Clean Air Act (CAA) has requirements to update pollution standards that provide for an "adequate margin of safety" to protect public health.[8] This determination can only be reliably made using the best available science. This proposal would, however, prevent EPA from using the best available science to set pollution standards that would provide for an adequate margin of safety, because the proposal excludes studies where the raw data and other underlying information cannot be made public. Because of this, EPA should not cite the CAA as a source of statutory authority. Further, the CAA encourages a close partnership with the National Academy of Sciences (NAS) and other independent scientific institutions. When EPA is considering a proposal to reinterpret how it uses science in regulatory decisions, it should first and foremost consider comments from and engage with NAS and similar bodies, which, for this rule, EPA did not.

In fact, virtually all of EPA's statutory mandates require the use of the best available scientific evidence. Congress did not state in any of these laws that the agency shall only consider scientific evidence derived from studies where the underlying unanalyzed data is publicly available, nor that the evidence considered should be solely at the Administrator's discretion.

Additionally, while EPA does not cite the Administrative Procedures Act (APA) as a source of its authority, this proposal would be violating the law because the agency would be arbitrarily and capriciously selecting which information to use in decisionmaking. This is especially true given section 30.9 of the rule, which would allow the administrator to exclude certain studies from the rule's requirements on a case-by-case basis. Furthermore, under the APA, agencies are required to consider and respond to all information presented in the docket. If EPA chooses to ignore a portion of this evidence because it cannot access or publicize the underlying data, models, and codes, such action would be arbitrary and capricious.

In its proposed rule, as modified by the supplemental notice, EPA continues to ignore that there are likely to be significant costs associated with implementation, especially of a tiered access system. When EPA staff were tasked last year with studying the impacts of a similar legislative proposal entitled the Honest Act of 2017, they found that it would burden the agency, waste taxpayer dollars, and "significantly impede EPA's ability to protect the health and the environment of Americans." The Congressional Budget Office analysis of that legislation found that it would cost upwards of $250 million to implement.[9] It is clear that the current proposal would create a tremendous time and resource burden on EPA and on scientists outside of the agency, who would be forced to track down, collect, compile, and post (including any statistical methods needed to conceal private information) all the data, models, code, and other analytical tools for each of the hundreds of studies EPA cites on any given decision. And because of the very broad scope of the rule as clarified in the supplement, the agency should consider it economically significant to the public, compelling EPA to conduct a regulatory impact analysis under executive order 12866. If this proposed rule applies to all science used by EPA, and EPA clearly takes many actions that are economically significant to the public, how can this rule, which affects every one of those actions, not be economically significant?

The proposed rule also violates Executive Order 12898, which requires the agency to assess the environmental justice impact of the rule. EPA states that the rule is not subject to the EO because "it does not establish an environmental health or safety standard." But EO 12898 states that each agency should analyze the research comparing environmental and human health risks borne by disproportionately impacted communities and use the information to make judgments about the impacts of its "programs, policies, and activities."[10] This proposed rule would indeed result in EPA's limited access to epidemiological health studies that shed light on the health impacts of environmental contaminants on communities of color and low-income communities, likely perpetuating the lack of adequate safeguards put in place to protect these individuals from harm.

Lack of input from EPA's own scientists and broader scientific community
It is clear from the number of questions posed by the agency in its proposed rule and supplemental notice about how the rule might be implemented, and from the outcry and alarm from the scientific community, that the agency did not consult with scientists or respected national scientist organizations as it crafted the rule.[11]

The 2018 proposed rule claimed that it "builds upon prior EPA actions in response to government-wide data access and sharing policies," citing EPA's 2016 *Plan to Increase Access to Results of EPA-Funded Scientific Research,* the EPA's Scientific Integrity Policy, the *Open Data Implementation Plan,* the *EPA Open Government Plan 4.0,* and the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*. But in its proposed rule and supplemental notice, the agency gives no details on how this policy will expand upon those established internal policies, nor justifies why this policy is going through the formal rulemaking process when all these efforts to improve transparency and access to data are already underway. Importantly, these existing policies largely govern science and policy procedures within EPA; in contrast, this proposed rule attempts to dictate how science is produced outside the agency, clearly stepping beyond the provisions of current EPA policies and practices.

EPA also incorrectly claims that the rule follows accepted practices on open science that major science journals and the NAS have adopted. In fact, the editors-in-chief of *Science*, *Nature*, *PLoS, Proceedings of the National Academy of Sciences (PNAS)*, *Cell*, and *The Lancet* issued a statement in 2018 and again in 2019 that this policy would exclude important studies from consideration in the rulemaking process, thus adversely impacting the decisionmaking process. The open data initiatives adopted by these journals acknowledge that Transparency and Openness of Promotion (TOP) standards "recognize the array of workflows across scientific fields and make the case for data sharing at different levels of stringency; in not every case can all data be fully shared."[12] These standards are in accordance with OSTP's 2013 memo *Increasing Access to the Results of Federally Funded Scientific Research*, which notes the importance of making data available in realizing the goal of increased transparency in the federal government, while protecting confidentiality, personal privacy, confidential business information, and "preserving the balance between the relative value of long-term preservation and access and the associated cost and administrative burden."[13]

The demand for obtaining the raw data related to EPA rulemaking does not appear to be significant and would not justify the excessive burden it would place on the agency. One study,

which looked at the 79 requests made between 2002 and 2012 through the Information Quality Act to EPA that asked the agency to correct or reconsider the data supporting its regulatory decisions, found only two requests asking for the raw data.[14] One possible explanation for this low number is that the public already has access to the science EPA relies on and can fully access methods, summary data, results, and interpretations, as can all peer reviewers. In developing the National Ambient Air Quality Standards (NAAQS), for example, EPA collects all relevant data and studies used to develop the Integrated Science Assessment and the merits of those scientific studies are publicly debated by the Clean Air Scientific Advisory Committee and pollutant review panel. The need for access to raw data is entirely unnecessary and arbitrarily precludes the use of critical studies.

Records released through a Freedom of Information Act (FOIA) request confirm that EPA staff are aware that the agency does not need to have access to the underlying raw data, codes, etc. to promulgate regulations. During the development of this proposed rule, Dr. Nancy Beck, the Deputy Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, emailed colleagues "for awareness" that in the 2002 court decision *American Trucking Association v. EPA*, it became evident that, if EPA were required to have access the raw data of peer-reviewed scientific studies, the agency would not be able to use a significant amount of important scientific literature.[15] The courts, through that decision and through *Coalition of Battery Recyclers Association v. EPA*, have made it clear that EPA is not required to obtain or analyze raw data in order to use independent scientific studies that are published in peer-reviewed journals to regulate.

Furthermore, among those not consulted in the crafting of this rule was the National Academies of Sciences, Engineering, and Medicine (NASEM), which has held several committee meetings and carried out a series of reports detailing how scientific literature can be evaluated transparently without the full disclosure of underlying datasets.[16] In a comment on the rule, NASEM urged EPA to seek objective and expert guidance on the rule and its implementation and offered itself as an independent review body.[17] The Bipartisan Policy Center (BPC) was also cited in EPA's proposed rulemaking and had to clarify in a comment to the agency that "the proposed rule is not consistent" with its report on the use of science in policymaking that EPA cited in "substance or intent." While BPC supports enhanced transparency, "the report never suggested excluding studies from consideration in developing regulation if data from those studies were not publicly available."[18]

The proposal has faced widespread opposition from the scientific community, academic institutions, states, and decisionmakers.[19] In fact, nearly 1,000 scientists asked former EPA Administrator Scott Pruitt to abandon this proposal, arguing it "would greatly weaken EPA's ability to comprehensively consider scientific evidence" and undermine the agency's capacity to protect Americans from serious health threats.[20]

EPA's Science Advisory Board (SAB) workgroup, which is tasked with reviewing the agency's regulatory agenda and recommending places where SAB review is merited, wrote a memo recommending that the SAB review the merits of the rule because "it deals with a myriad of scientific issues for which the Agency should seek expert advice from the Science Advisory Board." Some of the areas flagged by the memo include the lack of assessment of the impact of

data restrictions on current or future rulemaking, the fact that EPA did not solicit input from the scientific community, and that the rule does not acknowledge the strides in transparency that have already been made by the epidemiologic science community.[21] For the reasons that the SAB laid out in its May 12, 2018 memo, and reasons we articulated in this comment to EPA, this proposed rule would effectively change the way EPA uses science in its rulemaking and thus how the SAB can review agency actions. After a near-unanimous vote concurring with the memo, the SAB wrote in a June 28, 2018 letter to former administrator Scott Pruitt that "[the] SAB urges the Agency to … request, receive, and review scientific advice from the SAB before revising the proposed rule."[22] Instead of tasking the SAB with review of the full rule, Administrator Wheeler waited nearly a year and finally asked that the SAB look into a narrow slice of the rule, CBI and Personally Identifiable Information (PII) in April 2019.[23]

However, because the SAB was concerned with many other aspects of the rule and what its implementation would mean for EPA's ability to use the best available science in decisionmaking, it also reviewed the full rule as a body. Its draft letter on the proposed rule, issued in December 2019, called it a "license to politicize the scientific evaluation required under the statute based on administratively determined criteria for what is practicable."[24] Its final letter, issued in April 2020, echoed the same concerns.[25] We agree with SAB's concerns, andEPA should have involved SAB far earlier in the development of this rule. Perhaps if it had, the rule would not blatantly violate best scientific practices and would not be the target of opposition throughout the scientific community.[26]

Moreover, because of the timing of the review, SAB's letter did not cover the extent of the supplemental notice. EPA submitted a supplemental rule to the OMB before receiving recommendations from the SAB on the full proposal, hearing only member consultations related to a narrow question about confidential business information and personally identifiable information and doing that only after SAB raised concerns that it had not reviewed the proposed rule prior to its publication. It is almost certain that, at this stage, the SAB's review and recommendations will come too late to adequately inform the rule's development. The final letter and report have not been issued and a 60-day comment period will not give the SAB enough time to meet and provide consensus-based recommendations for the substantive clarifications made to the rule.

Clarified regulatory language expands rule to its detriment

The supplemental notice clarifies that in addition to data and models underlying significant regulatory actions, the rule would apply to influential scientific information, which broadens the scope of the rule significantly. It would mean that EPA would restrict the types of studies it uses for a range of scientific work products including, but not limited to, "state-of-science reports, technology assessments, weight-of evidence analyses, meta-analyses, risk assessments, toxicological profiles of substances, integrated assessment models, hazard determinations, exposure assessments, or health, ecological, or safety assessments," as defined by OMB.[27] This is in direct conflict with the established EPA peer review guidelines and program systematic review procedures, like those of the Integrated Risk Information System (IRIS).

Further, the reason for making the data underlying influential scientific information and pivotal regulatory science available, according to the notice, is so that EPA can reanalyze studies using

the original data to confirm the findings and show that they are "capable of being substantially reproduced." This is a slight departure from the 2018 proposed rule that conflates reproducibility and replicability as the standard for pivotal regulatory studies. By shifting the focus to reanalysis, the agency clarified that the underlying data must be made available so that interested stakeholders (i.e., regulated industry) may take the original data and modeling methods to confirm reproducibility and "assess potential analytical errors and variability in the underlying assumptions of the original analysis." The goal of the rule is clearly not to increase transparency, but to introduce a new avenue for stakeholders with enough time and resources to recalculate study data to better meet deregulatory outcomes.

As noted above, the EPA provides no evidence that "analytical errors" are a significant or widespread problem in the studies relied upon by the agency – nor is there evidence of difficulties created by a lack of sensitivity analyses. This further indicates that the agency has not thought through this proposal.

The phrase "capable of being substantially reproduced" comes directly from a 2001 OMB guidance meant to help agencies align best practices for weighing the scientific evidence.[28] The broader scientific community tackles reproducibility in many ways, and EPA has already created its own policies on peer review and information quality based on those guidelines.[29] EPA's new transparency rule would add in an impossible requirement for public access to raw data and model coding, clearly stepping beyond the provisions of current EPA policies and practices and beyond the needs of the agency. Suffice it to say that the agency has not shown that the current review process does not catch simple calculation errors or that an epidemic of calculation mistakes is plaguing agency science.

EPA already has methods for reviewing the quality and strength of scientific studies. And the agency doesn't need to reanalyze each and every study informing an air quality standard or a pesticide regulation decision, because the processes of peer-review and external science advice are trusted ways to ensure that researchers asked the right questions, designed the study according to best practices, and made the appropriate assumptions to reach their conclusions.

EPA's draft rule, as modified in the supplemental notice, reveals that the agency wants to use original data and methods to reanalyze rules and prove that they are reproducible before using them to support a rule. In fact, the supplemental notice still has not clarified what it means by "capable of being substantially reproduced," and it contradicts itself. In the notice, EPA defines "capable of being substantially reproduced" as "independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error" but goes on to cite a NAS workshop report that defines reproducibility as "producing something that is very similar to that research, but is in a different medium or context. In other words, a researcher who is reproducing an experiment addresses the same research question from a different angle than the original researcher did."[30] EPA is disguising its quest to cherry-pick evidence with unclear definitions of reanalysis, independent validation, and "capable of being substantially reproduced."

Apart from conflicting definitions, the ability for a study to be reproduced or replicated should not be held as the gold standard for checking the credibility of a study.[31] In its 2018 proposed rule, EPA argues that part of the reason for the policy is to allow regulators to better determine

that key findings are "valid and credible." The benchmark upon which validation and credibility are measured for the purposes of this rulemaking are through the relative reproducibility of studies, even though there are certainly other criteria that agency scientists currently use to evaluate a study's credibility. In fact, the very same OMB document cited within the rule, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, details this nuance. In the 2002 guidelines, OMB writes:

> "Making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections… In situations where public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken."[32]

This language acknowledges that the exclusion of studies solely because the data cannot be made public is insufficient justification, especially considering the ethical implications of making such data widely available. As the OMB guidelines affirm, there are other ways that the agency can verify the independence and credibility of a study, such as by evaluating its research design, methods, data summaries, and degree of alignment with similar studies in the field. EPA scientists should have the flexibility to use scientific criteria to judge the rigor and validity of the evidence. In fact, EPA already does this well, and the rule does not point to any evidence to the contrary.

There are many reasons why a study might not be able to be reproduced or replicated, not the least of which is to protect the privacy, trade secrets, intellectual property and other confidentiality concerns associated with the underlying data. Challenges also arise when studying environmental hazards. Observational data must be used for certain studies of air and water pollution and it is often not possible or ethical to recreate the conditions under which people were exposed to a contaminant. Even OMB acknowledges that the reproducibility standard cannot be applied to all science: "OMB urges caution in the treatment of original and supporting data because it may often be impractical or even impermissible or unethical to apply the reproducibility standard to such data. For example, it may not be ethical to repeat a 'negative' (ineffective) clinical (therapeutic) experiment and it may not be feasible to replicate the radiation exposures studied after the Chernobyl accident."[33]

Even if the goal of this rule were to solve the reproducibility dilemma, end users of the data like EPA cannot singlehandedly address large-scale challenges in the scientific community. Lingering issues remain, like the lack of infrastructure and resources needed to ensure privacy protections for sensitive data. The NAS touched on this in a recent report, arguing that funding agencies should invest in the research and development of open-source tools and related trainings for research so that transparency is fostered at the beginning of the scientific process, instead of being used as an opportunity to exclude crucial public health studies that have already been conducted.[34]

Right now, the agency uses best practices that allow for a weight of the evidence approach, and this rule would not only change the process but codify it, making it much harder to reverse. Part of that codification would be to add the nonscientific criterion "data availability" to the list of assessment factors that the EPA will use to determine the quality of a study. These factors have been guiding EPA's data quality procedures since 2003 and include soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review. They help the agency to assess the context surrounding the objectiveness and integrity of scientific information and to determine how to use it in its weight of the evidence approach.

The last factor, "evaluation and review," is where the agency *already* independently validates the research without using underlying data by asking the following questions:

> *"a) To what extent has there been independent verification or validation of the study method and results? What were the conclusions of these independent efforts, and are they consistent?*
> *b) To what extent has independent peer review been conducted of the study method and results, and how were the conclusions of this review taken into account?*
> *c) Has the procedure, method or model been used in similar, peer reviewed studies? Are the results consistent with other relevant studies?*
> *d) In the case of model-based information, to what extent has independent evaluation and testing of the model code been performed and documented?"*[35]

These guiding questions ensure that the agency does not have to fully reanalyze every study and can instead focus on the weight of the evidence approach, which "considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together." Including data availability in the weighting injects an arbitrary parameter, unrelated to study quality and reliability.

One option offered in the new notice would allow the EPA, if considering a study whose underlying data are not made available, to place less weight on the results "to the point of entirely disregarding them," even if the research and results were strong and compelling, met the highest scientific standards, and had undergone extensive scientific peer review. In other words, EPA would give the most weight to studies with publicly available data rather than to studies that provide the strongest scientifically supportable evidence. Because there are many environmental health studies relying on medical data and other private information, the rule's restrictions would mean that the best available science could be excluded.

Moreover, reanalyzing every study used by the EPA is unattainable, and setting a goal of reanalysis may give stakeholders excessive power to weaken EPA's regulatory decisions. For example, under the Clean Air Act, the EPA must assess residual risk of air pollution impacts of industrial facilities on communities. This is one of the very few places in which EPA must legally consider disproportionate impacts on communities. It does so by calculating residual risk for communities near facilities. If communities face residual risk over a certain threshold, the EPA must do more to protect that community from being disproportionately harmed. Under the

supplementary proposal, industry and others could pick apart the modeling done by the agency and challenge the agency's assessment of risks to communities.

The supplemental notice also provides, for the first time, a definition for "publicly available," which EPA defines as "lawfully available to the general public from federal, state, or local government records; the internet; widely distributed media; or disclosures to the general public that are required to be made by federal, state, or local law." In this definition, EPA wrongly applies a catch-all approach to transparency, as a recent paper in *Environmental Health Perspectives* points out:

> "Strategies designed to serve some goals of the open science movement may be inadequate for achieving other goals. For example, efforts to provide access to all the data underlying a study may be helpful for enabling other scientists to reanalyze the results and identify weaknesses that could undermine its reproducibility. However, providing all that data may do little to help citizens or policymakers understand the overall significance of the study or the crucial limitations or weaknesses associated with it…Additional strategies—such as effective two-way communication between the scientists who designed the study and those using the information—might be needed to clarify the information needed by decision makers."

The study authors also explain that providing all of the raw data to members of the public or decisionmakers without synthesizing and interpreting it could result in misinterpretation of the findings altogether.[36] Because of the potential downsides of transparency measures done poorly, the authors suggest that "ill-conceived efforts at transparency could, ironically, inhibit the progress of science by draining scarce resources that could be used more effectively elsewhere." This is precisely what the EPA's proposed rule, as clarified by the supplemental notice, will do for government environmental and public health work.

In the 2018 proposal and the supplemental notice, EPA suggests that the rule apply to "significant regulatory actions" under Executive Order 12866, which governs regulatory planning and review, is overly broad, and would allow for even more politicization of science in EPA rulemaking. EO 12866 defines "significant regulatory action" as having an annual economic effect of $100 million or more; interfering with actions taken by other agencies; altering the budgetary impact of entitlements, grants or user fees; or raising "novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order."[37] This elastic clause would grant the agency or OMB's Office of Information and Regulatory Affairs (OIRA) the discretion to categorize any rule as significant, depending on an administration's priorities.

Finally, EPA's proposed rule alludes to the use of good laboratory practices (GLP) and standardized test methods, where "available and appropriate." This would bias EPA's literature review toward industry-funded GLP studies, even though GLP practices are more about recordkeeping than quality of research design. For example, in a study reviewing the quality of GLP literature on the chemical bisphenol A (BPA), the authors concluded that "simply meeting GLP requirements is insufficient to guarantee scientific reliability and validity."[38] While GLP studies should not be excluded from EPA's consideration, the highest-quality assessment that

EPA can conduct would be a systematic review approach that considers all relevant data and establishes criteria for evaluating study quality, as recommended by NAS.

Tiered-access and weighting approaches are problematic and do not address central concerns

The supplemental notice offers a tiered-access approach, and alternatively, a weighting option for addressing research with underlying data that cannot be made public; both options are unworkable and will restrict the science that EPA can use to carry out its mission to protect public health and the environment.

The tiered-access approach is impractical and problematic for EPA's ability to use the best available science in several key ways. First, the tiered-access approach fails to address the central concern of the draft rule—that it would require the release of private data in order for EPA to be able to use studies that rely on such data. Under a tiered-access approach, which would allow select researchers to gain access to sensitive data, the vast majority of studies that rely on non-public data – data such as personally identifying information, Confidential Business Information, and intellectual property – would still be prohibited from use by the EPA. This is because restrictions on disclosure of such data (as detailed in the next section) would still apply, even when such data are released to a select few researchers in a tiered-access system. For example, the EPA relies on many studies that use personally identifying health data. To use such data, researchers obtain ethics approval from Institutional Review Boards and sign legal agreements with hospitals, health maintenance organizations (HMOs), and other bodies that prevent them from sharing health data publicly. These legal and ethical obligations still apply, even if a tiered-access system exists. Thus, sharing health data in a tiered-access system would require researchers to breech legal and ethical agreements, as described in detail in the next section. Researchers would be unlikely to participate in such a system if their research relies on sensitive data. Consequently, EPA will not be able to use much relevant research relying on nonpublic data, even if a tiered-access system is offered.

Further, even for the subset of research studies that could be shared within a tiered-accessed system, implementation of such a system would be onerous, costly, and infeasible for several reasons. Deidentification of data would be an immense undertaking and is not feasible in many cases and for many study designs, particularly because EPA is concerned with environmental threats. To understand environmental threats, researchers often must know the precise locations of parameters such as environmental exposure and health effect occurrences in a subject population. In many studies, these locations are personally identifying. It is difficult and often impossible to release this data in a way that protects study subjects' identities,[39] and this exercise would be required under the tiered-access approach proposed in the EPA's supplemental notice. Moreover, while the rule does not make this clear, researchers would bear the burden of deciding and implementing the tiered-access system for their data, according to EPA's conversations with Congress.[40]

EPA's supplemental notice points to the U.S. Centers for Disease Control and Prevention's (CDC's) Research Data Center as a model, and EPA has referenced other practices by CDC and the U.S. Food and Drug Administration (FDA) as relevant models for the agency to follow in implementing a tiered-access approach. However, there are significant reasons that these CDC

and FDA systems will not work for EPA. Unlike CDC and FDA, EPA is primarily focused on environmental threats, and deidentification of personal health data is challenging and sometimes impossible, as noted above. By contrast, data from clinical drug trials used by FDA and medical data aggregated at the hospital or county level used by CDC can often more readily be disclosed publicly, because doing so will not reveal identities of study subjects.

Even for the subset of EPA-relevant studies for which disclosure of data in a tiered-access system is feasible, such a system would be costly for the agency to implement and maintain and impractical, if not impossible, for individual researchers to do so. In turn, a system would likely be costly for those seeking to access the data. CDC's Research Data Center, for example, costs researchers thousands of dollars to access. It is unlikely that stakeholders such as the public and community groups would pay such high costs to access data that has already been vetted through peer-reviewed studies. The exception is regulated industry, which is likely to be the only EPA stakeholder group interested and able to access data housed in a tiered-access system. In fact, the supplemental notice makes clear that the rule's intent is to allow stakeholders the opportunity to "reanalyze the data and models and explore the sensitivity of the conclusions to alternative assumptions…"[41]

As an alternative to the tiered-access system, the supplemental notice offers a weighted approach. In this, research based on data that cannot be made fully public could be used by EPA, but such research would be given less weight than research with fully public data. This alternative approach would arbitrarily downgrade legitimate scientific research and diverges from established scientific procedures to evaluate the legitimacy of scientific evidence, such as literature reviews, systematic reviews,[42] Cochrane reviews,[43] and meta-analyses.[44] EPA relies on crucial scientific work that utilizes personal health data (which cannot be made fully public) to further our understanding of public health impacts of environmental threats. As a result, a significant quantity of the scientific research used by EPA would be downweighted under this approach. The ability of a study's underlying data to be made public has nothing to do with study quality; thus, a weighted approach would arbitrarily and unfairly tilt the scales against EPA's full consideration of the most relevant and important scientific research.

EPA offers no details as to how it would keep sensitive or confidential information private

Even with the clarifications provided in the supplemental notice, the proposed rule offers no information on where the raw data collected would reside, how the resources to manage the data would be obtained, or how EPA would deal with legally and ethically protecting confidential or sensitive data. Ensuring all this extra information is received, stored, and made publicly accessible would be no small undertaking. EPA's proposed rule references a system used by the National Institutes of Health (NIH) to collect health data,[45] but the NIH system is not publicly accessible and requires significant resources to manage and share with researchers – a clear contradiction to the administration's apparent interest in transparency. At a time when EPA's budget and capacity continues to decrease,[46] it is unreasonable for the agency to initiate such an undertaking.

In the proposed rule, as modified by the supplemental notice, EPA does not sufficiently consider the issues involved with redacting data, such as the fact that simply redacting a name or a few pieces of information will not adequately protect an individual's identity. Since the rule's

supplement listed possible privacy protections for only three types of data (confidential business information, proprietary data, and data that cannot be anonymized), we can assume that the agency believes that a simple anonymization process is enough to fully and completely protect people's confidential data – but a simple anonymization process is at odds with the legal and ethical frameworks developed to protect human participants in scientific studies. For instance, the Health Insurance Portability and Accountability Act (HIPAA) requires that medical information be protected by a set of administrative, physical, and technical safeguards,[47] and a scientist who releases raw anonymized data to the public could be in violation of their Institutional Review Board (IRB) approval,[48] which governs a study's informed consent process. Furthermore, the release of underlying human health data may include participants who cannot consent to such a process, like participants who have died, and it may discourage people to sign up for future research studies. In a rare joint statement on the proposed rule, the editors of six prominent scientific journals[49] wrote that some data "cannot be shared openly; even anonymized personal data can be subject to re-identification, and it has been a longstanding practice for agencies and journals to acknowledge the value of data privacy adjustments."

A simple anonymization process is inadequate to protect personal data. Simple steps like an Internet search[50] or database query search[51] can re-identify research participants. Research using 1990 census data found that around 87 percent of Americans can be identified with just three data points: their zip code, gender, and date of birth.[52] One paper found that with just 15 characteristics (like age, gender, and marital status), a machine learning program could re-identify 99.98 percent of Americans from an anonymized database.[53] Another paper found that a research participant's region of residence could be deduced from prominent environmental studies with 80 to 98 percent accuracy.[54] Re-identifying people from an anonymized database could prove particularly damaging for research on issues like child abuse, sexual assault, and mental illness. And data that include genetic information could reveal sensitive information about the relatives of the research participants, including those not yet been born.

Redacting data *and* protecting privacy is difficult and time-consuming. It can also strip data of their value, as when completely public data is de-identified to such an extent that the information garnered becomes useless. For example, when it comes to understanding the impacts of pollution on health, you cannot redact information like age and location because it is vital to understanding the health impact of the contaminant. Furthermore, EPA is statutorily responsible for characterizing pollutant exposure to at-risk subpopulations, such as the elderly, young people, Indigenous people, and people of color. If subjected to the rigid transparency requirements outlined by the proposed rule and supplemental notice, many studies of at-risk groups would have raw data that could not be made available because it would too easy to identify individuals, even with redactions of some personal information. Cohort studies, which can rely on small populations with unique characteristics, would be particularly affected.

EPA did not ask commenters how it might be able to manage privacy protections of patient health data, but if it had, the answer would be clear: it would be nearly impossible for EPA to strike an appropriate balance between redacting data to protect privacy and maintain its utility.

EPA also appears to be more concerned with protecting industry data and confidential business information than with protecting public health information. This disparity is exemplified by the

fact that the agency requests commenters to provide feedback on how to balance protections for copyrighted and confidential business information but does not seek similar advice on how to protect patient health data. Furthermore, emails obtained by UCS through a FOIA request show that top EPA officials responsible for drafting the proposed rule, including Dr. Nancy Beck and her colleague Dr. Richard Yamada, the Deputy Assistant Administrator for the Office of Research and Development, struggled with how to incorporate exemptions and limit the rule's impact on industry data.[55] Dr. Beck's comments on protecting confidential business information also resemble her testimony in front of a Senate Homeland Security and Government Affairs subcommittee, where she represented her former employer, the American Chemistry Council, whose members have a significant financial interest in EPA regulatory matters.[56]

The proposed rule and supplemental notice's focus on protecting industry over protecting the public health research community illustrates the agency's disinterest in seeking actual transparency in decisionmaking. Instead, EPA is seeking an opportunity to protect data for the industries it is supposed to regulate, at the expense of science-based public health safeguards. This bias is affirmed by Dr. Yamada's response to an email from Dr. Beck, in which he writes that he "didn't know about the intricacies of [confidential business information]" and that the agency would have to "thread this one real tight!" [57]

Consideration of unscientific models for determining health effects

It is problematic that the proposal demands additional consideration of non-linear concentration-response models and that the supplemental notice did not remove this provision. Instead, the supplemental notice expanded this provision to include all models, not only dose-response models. This expansion increases the proportion of EPA work where this rule would disrupt current processes to develop and implement models on environmental threats. Inclusion of such models beyond what is already in established epidemiologic and toxicologic literature and left to the scientific judgment of experts in and outside of the agency is not scientifically justified.[58] Model uncertainty and the appropriateness of using different kinds of models are already considerations carried out by scientists and are verified during the peer-review process. In fact, EPA's 2009 guidance[59] on this topic specifically recommends that a model can be appropriately used to inform rulemaking if the model is evaluated using well-established scientific practices like peer review, data quality control, and sensitivity and uncertainty analyses.

Accordingly, the inclusion of models beyond what is established in the scientific literature and left to the scientific judgment of experts is not only scientifically unjustified, but risky.[60] Downgrading the importance of linear models and forcing the consideration of non-linear models, like J-shaped or U-shaped curves, may bias results such that they fall out of line with the best scientific practices. The force-fitting of non-linear models, without scientific justification, could even bias the data to such a degree that low doses of a pollutant may appear less harmful – or even beneficial – to the health of person.

The proposed rule claims "there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects," but no evidence is cited. In fact, the opposite is true. Historically, a broad range of models have been considered in risk assessment, and the body of evidence from animal and human studies has tended toward linear dose-response models and away from models that assume a threshold below which

substances are safe. For example, the current science on ambient air pollution exposure and health effects confirms such an approach, with little evidence for non-linearity found in concentration-response relationships for ambient particulate matter and ground-level ozone concentrations.[61] The National Academies of Sciences, Engineering, and Medicine (NASEM) in 2009 published a report concluding the need for a focus on linear dose-response models and directing EPA to implement this approach.[62]

Concerningly, if scientifically unjustified weight is given to non-linear models to assess relationships between pollutants and health in EPA policy decisions, these decisions are likely to disproportionately affect the sensitive populations that EPA is charged with protecting. For ozone and particulate matter, for example, evidence suggests that health effects (including mortality, cardiovascular effects, and respiratory effects) below the current NAAQS are more pronounced for the elderly, children, low-income individuals, and African Americans.[63] These problems are bound to get exacerbated when the science underlying health-protecting policies is compromised and skewed away from accurately modeling harms that occur at low doses. Underserved communities face threats from a wide variety of pollutants and other stressors, which even at low doses can result in cumulative impacts[64] that magnify health risks. As a result, setting ambient air quality standards based on models that assume no effect, or assume lower effects of pollutants at lower concentrations, are likely to disproportionately harm these sensitive populations. Thus, implementation of this proposal could exacerbate existing inequities in people's exposure to harmful pollutants.

Lack of detail on interagency impacts

EPA does not operate in a vacuum: other federal or state agencies are involved in EPA's decisionmaking. For example, section 404 of the Clean Water Act requires EPA and US Army Corps of Engineers to collaborate on the review of permits to discharge certain material into US waters, and EPA and FDA collaborate to create tolerances for pesticide residues in food. However, EPA clearly did not seek input from all relevant agencies during the development of the proposed rule, as the Department of Defense submitted its full comments to the regulations.gov docket in August 2018 – months after the rule was released for public comment.[65] There is little detail on how EPA would implement this rule, let alone how it would coordinate with other entities on shared responsibilities affected by this rule.

EPA's ability to coordinate with other agencies during a disease outbreak, such as COVID-19, may be negatively affected by the implementation of this rule, as modified by the supplemental notice. Interagency coordination during an outbreak requires a fast response to prevent, contain or mitigate the disease based on the best available science. If agencies have different definitions of how science should be used to inform decisionmaking processes, an inter-agency group will be less likely to respond quickly and efficiently to the disease, thereby resulting in increased morbidity and mortality among the affected population.

For instance, EPA is currently working with CDC, FDA, and other agencies to help mitigate the threat posed by the COVID-19 pandemic. One area of promising research from more than a dozen research groups worldwide[66] falls under EPA's purview:[67] how the testing of wastewater for the novel coronavirus can act as an evidence-based way to determine the total number of infections in a community. Researchers believe that this methodology could serve as a non-

invasive, early-warning tool to alert communities to new COVID-19 infections and offer a community-level picture of how the disease has spread. However, an interagency public health measure based on this methodology will need to reference certain clinical studies to answer key questions, like how long people excrete the novel coronavirus and how much virus is being excreted at different stages of the disease.[68] Because these clinical studies often contain confidential medical information, the publishing of these data, even in an anonymized form, risks reidentification of patients and exposing their confidential medical information. Consider, for instance, a study by Chen et al. (2020),[69] which compared fecal samples and the clinical profile of COVID-19 patients in China in January and February 2020. If this anonymized data were to be published, then reidentification efforts could reveal the participant's underlying health conditions, like diabetes and chronic obstructive pulmonary disease. If the study authors declined to provide EPA with the study's underlying participant data, EPA could not utilize this important scientific evidence, derailing any interagency effort to incorporate the study's findings into a federal pandemic response. In other words, EPA's proposed rule could, in times of crisis, slow or stifle life-saving discoveries in public health.

Broad implications for numerous EPA programs

The proposed rule, as modified by the supplemental notice, makes clear that the rule applies not only to "pivotal regulatory science," but to all "influential science" conducted by the agency, greatly expanding the impacts of the proposal on the agency's ability to fulfill its mission of protecting public health and the environment. Limiting EPA's use of science to studies where raw data are made publicly available, or downweighting research otherwise, would adversely impact the way that many EPA offices use science in the rulemaking process. As required by statute, the EPA must have access to the best available science to carry out its charges – but the proposed rule would hinder the agency's ability to use the best available science, because EPA relies frequently on studies with underlying data that cannot be made public. Notable examples are described below.

For example, on its current review of the National Ambient Air Quality Standards for particulate matter (PM) and ozone, EPA is required to set standards at levels that protect public health and welfare. Under the proposed rule, however, EPA would likely be unable to consider much of the scientific research linking PM and ozone pollution with adverse health impacts like premature death, cardiovascular diseases, and respiratory illness, because many such studies rely on personal health data. This would obstruct EPA's efforts to set health-protective standards.[70]

Another example of EPA public health protections that would be inhibited by this rule, as clarified by the supplemental notice, is in regards to the insecticide chlorpyrifos. The rule could restrict EPA's ability to consider critical epidemiological studies, conducted by Columbia University, that showed that in utero exposure to the chemical was linked to negative neurodevelopmental impacts.[71] The health data was collected from mothers on condition of confidentiality. If this research were ignored or deprioritized, EPA would lack evidence of chlorpyrifos' direct human health impacts and could make a policy decision that does not protect the public, especially children.

This rule, as modified by the supplemental notice, would also impact EPA's work on per- and polyfluoroalkyl substances (PFAS) contamination in the environment, The agency is currently

touting its four-step action plan to tackle PFAS, but the proposed rule would severely limit the agency's ability to use much of the human health data gathered on these chemicals, thus hindering EPA's ability to set a strong maximum contaminant level for the two most common PFAS, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), in drinking water, or to make any other science-based regulatory decision.[72] Over two dozen human health studies have been published in peer-reviewed journals since a settlement agreement was reached in a lawsuit against the maker of PFOA, DuPont, and people living near a DuPont plant in West Virginia.[73] The studies rely on interviews, questionnaires, and blood samples from 69,000 individuals and examine links between PFOA exposure and a variety of health outcomes.[74] Because these data include protected personal information,[75] the study's researchers could not comply with EPA's proposed rule by making the data public. As a result, some of the best available science identifying probable links between PFAS and diseases such as thyroid disease, testicular and kidney cancer, pregnancy-induced hypertension and preeclampsia, and diagnosed high cholesterol would be omitted from EPA consideration,[76] and EPA decisionmaking on PFAS would be wholly inadequate to protect exposed populations.

The proposed rule would also adversely impact the science used in EPA's risk evaluation of asbestos, which the agency is currently drafting. In November 2019, the US Court of Appeals for the Ninth Circuit[77] ruled that the Toxic Substances Control Act (TSCA) requires EPA to address the ongoing use and disposal of previously manufactured products containing asbestos ("legacy asbestos") in its risk evaluation. However, under the proposed rule and supplement, EPA would likely be unable to consider pivotal studies on legacy asbestos' impact on human health. For instance, a 2014 study[78] by National Institute for Occupational Safety and Health (NIOSH) researchers found that firefighters are twice as likely to die from malignant mesothelioma, a cancer largely attributed to asbestos exposure, than the US population. To determine these results, researchers compiled health data, personnel data, and data from previous studies over a 60-year period. Navigating the institutional and ethical hurdles to publish an anonymized version of these data would be prohibitively difficult, thus ensuring that, per EPA's proposed rule, the study would be omitted from consideration in the risk evaluation. No matter a study's quality, the proposed rule, as modified by the supplemental notice, would restrict the available science and allow the harms of asbestos exposure to slip through the cracks.

The rule's application to influential science at EPA would also fundamentally change how the Integrated Risk Information System (IRIS) is able to use the best available science to conduct risk evaluations for a range of environmental contaminants.[79] Currently, IRIS conducts systematic reviews and evaluates studies based on scientific criteria, not whether the underlying data is made publicly available. Adding this requirement would cause EPA to exclude or downweight key epidemiological studies that should be used to develop risk values. A version of the nearly final *Handbook for Developing IRIS Assessments,* which was leaked to *InsideEPA*, details its systematic review process and lists the criteria for determining a study's inclusion in a review.[80] Among the evaluation criteria for a study to be given a low or uninformative rating, and thus given lower weight, are demonstrated bias or serious flaws in the method or data reporting.[81] Nowhere in this handbook does IRIS suggest that a study be excluded or downweighted using the criteria of public availability of data, which is in line with other systematic review best practices in the greater scientific community.

Furthermore, the supplemental notice makes clear that the proposal would apply to new EPA rulemaking processes that occur on legally mandated cycles and rely on previously produced scientific studies. As a result, this rule would be deeply problematic for many EPA programs with such reoccurring rulemakings, such as National Ambient Air Quality Standards for criteria pollutants, because it would conflict with the basis for a range of EPA statutes, causing confusion as to how the agency can pursue its mission to protect the environment and public health when it cannot even adequately implement its own rules.

The proposed rule would make it harder for EPA to use science to protect public health, which is a stated requirement in its key environmental statutes and central to the agency's mission.

Implications for external researchers

The proposed rule, as modified in the supplemental notice, would also adversely impact academic researchers and the ability of independently produced research to inform EPA decisionmaking. This would break with decades of precedent of EPA freely utilizing all available, relevant research to ensure its decisions rely on the best available science. Under the supplemental notice, it is clear that even EPA-funded research could be prevented from informing the agency's decisions, because EPA funds much research that relies on health data, and other kinds of data that cannot legally or ethically be made public.

Epidemiologists and medical researchers conducting scientific studies follow study design criteria that are established in their fields. Consider, for example, the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) criteria of essential items that authors can use as they design observational studies. The STROBE initiative deems transparency crucial but does not include any criteria that would require the underlying data to be made publicly available.[82]

Further, as external researchers conduct systematic reviews or meta-analyses on particular health outcomes, public availability of data is not among the criteria for study appraisal in the widely accepted Cochrane Systematic Review method. The five criteria used to appraise and downweight studies are related to study quality, not the availability of data, and include "limitations in the design and implementation of available studies suggesting high risk of bias; indirectness of evidence; unexplained heterogeneity or inconsistency of results; imprecision of results; and high probability of publication bias."[83] Imposing a requirement that is disconnected from the realities of the research world would put the quality of EPA's assessments and the agency's reputation in the scientific community at risk.

Not only would the rule clash with established human health study design and practices, but the supplemental notice and draft rule would prevent critically important research from being used to inform EPA's decisionmaking on public health protections. For example, the EPA funded four university-based Clean Air Research Centers between 2011 and 2016 to better understand complex air quality and health issues—research that directly informed the agency's air pollution standards, required under the Clean Air Act.[84] The four centers have generated hundreds of research publications and helped answer crucial scientific questions that inform how EPA can best protect public health, including that of at-risk subpopulations, from ambient air pollution, with an adequate margin of safety.[85] The centers' contributions include understanding of

multipollutant mixtures on health outcomes; stratification of health effects across geographies and populations; characterization of air pollution measurement error; and improved measurement and characterization of traffic emissions and their health outcomes. Dr. Gretchen T. Goldman, Research Director at the Union of Concerned Scientists' Center for Science and Democracy, contributed to this research with several studies[86] that informed current and past EPA decisions on air pollution standards on ozone and particulate matter.[87] Under the proposed rule, as modified by the supplemental notice, the EPA would be prevented from using much of this crucial research, because it relies on personal health information that cannot legally or ethically be disclosed in many cases.[88] Such restrictions on EPA's ability to rely on relevant scientific research on air pollution and health—even research that EPA itself funded—will hinder the agency's ability to enact health-protective National Ambient Air Quality Standards and other public health and environmental protections that the agency is charged with enacting.

Further, placing the burden of making underlying data available in a tiered-access system would be an excessive amount of work unachievable for many, and this may make researchers wary of participating in policy-relevant research. This potential effect is antithetical to the stated goals of the proposed rule.

Implications for impacted communities

Restricting the use of scientific evidence to inform the EPA's policymaking process is likely to hamstring efforts to monitor and protect people from environmental health hazards, the burdens of which will fall disproportionately on underserved communities.

There is overwhelming evidence[89] that low-income communities,[90] Indigenous communities,[91] and communities of color[92] are more likely to live at the fenceline of industrial and resource-extracting facilities, which spew pollutants into the communities' air, water, and soil and increase the risk of severe health problems[93] like asthma, cancer, and premature death. These problems are bound to be exacerbated when the science underlying health-protective policies is compromised. Underserved communities face threats from a wide variety of pollutants and other stressors, which even at low doses can result in cumulative impacts[94] and magnify health risks. Therefore, the proposed rule, as modified by the supplemental notice, poses additional dangers to disenfranchised communities by limiting EPA's access to the epidemiological studies that can shed light on the impacts of environmental contaminants on marginalized communities.

With the proposed rule's implementation, underserved communities are likely to face exacerbated harms from hazardous chemicals like ethylene oxide (EtO), which is known to increase the risk of certain cancers. When conducting the 2014 National Air Toxics Assessment, EPA determined that a number of communities are now exposed to EtO levels higher than the level that EPA has deemed safe.[95] Because EPA was able to conduct this science-based assessment, it could pursue policy options to alleviate harm. For instance, EPA's Office of the Inspector General[96] recently highlighted the need for EPA to take prompt action to inform and act on concerns from residents living near EtO-emitting facilities. However, if the proposed rule, as modified by the supplemental notice, is implemented, the EPA will lose the ability to rely on important scientific evidence for its internal risk assessments, likely resulting in less protective policies. Communities like St. James, Louisiana—plagued by EtO levels up to 765 times higher[97]

than the levels EPA considers safe—would be unaware about the risks they face and lose the ability to advocate for policy mechanisms that reduce those risks.

Another example concerns the aforementioned chemical class PFAS. EPA is currently developing regulations for PFAS chemicals, like proposing maximum contaminant levels for PFOA and PFOS in drinking water.[98] But because research from the C8 Science Panel studies relied on human health data from tens of thousands of people, this research could be excluded or downweighted under the proposed rule. This would weaken the scientific legitimacy of EPA's regulatory decisions and endanger public health. Since evidence suggests that PFAS contamination occurs far more frequently near communities of color and low-income communities,[99] the proposed rule is likely to disproportionately affect underserved communities.

Proposal rushed through the regulatory process

EPA's proposed rule is not a novel idea. It originated in the 1990s from the tobacco industry, whose lawyers and lobbyists developed a version of the rule in an effort prevent the federal government from regulating secondhand smoke. The goal was – and today, is – to create "procedural hurdles" that would hamstring an agency's ability to implement policy that would protect public health.[100]

Furthermore, records obtained by UCS through a FOIA request clearly illustrate that this proposal has never been about transparency, and definitely not about science. Under the direction of former Administrator Scott Pruitt, the proposed rule was driven by politics, intended to administratively implement the defunct, and misleadingly named, HONEST Act of 2017. One email, sent by an EPA political appointee to his colleagues, sums up this intent. In an email dated January 16, 2018, the staffer writes that the rule, if implemented, would result in "no regulation (going) into effect unless the scientific data is publicly available for review."[101] In proposing this rule, EPA plainly intends to prevent the promulgation of public health and environmental safeguards, rather than increase access to information.

The emails also demonstrate that EPA officials did not engage with the independent scientific community, let alone EPA's own scientists. Documents that UCS obtained through FOIA in October 2018 revealed that EPA's Director of the Office of the Science Advisor, Tom Sinks, did not participate in the drafting of the rule, even though the proposal relates closely to his work on public access to EPA-funded research, human subjects research protection, and scientific integrity. He received the rule only when it was announced by then-Administrator Pruitt.[102]

Furthermore, legitimate questions remain about whether this proposed rule was rushed through the OIRA EO 12866 review process without careful and adequate vetting. EPA submitted the proposed rule for review on April 19, 2018 received edits from OIRA on April 23 and announced the rule in a well-coordinated press conference on April 24. Calendar entries show that planning for this announcement had begun well before EPA submitted the proposal to OIRA.[103] In those few days of OIRA review, however, the proposal grew by four pages, changing the content of the rule by narrowing it to include coverage of those rules with dose response data and models that "pivotal regulatory science," but it is unclear who made those significant changes and why they were made.[104]

The supplemental notice of the proposal also changed significantly after OIRA review,[105] with application of the rule expanding to cover influential scientific information, in addition to pivotal regulatory science and expanding data from dose-response data to all data. If OIRA staff were responsible for substantively editing a proposed rule regarding the role of science in policymaking, there is reason to be concerned about additional political interference.

Finally, bringing this extensive, far-reaching proposal forward during the COVID-19 pandemic is reckless. Public health experts whose input is essential to the evaluation of this proposal are the same experts responding to the public health emergency. Pushing this proposal through the regulatory process at this time diverts critical public health expertise away from controlling the pandemic. Further, public comment is difficult or impossible for populations whose technology access is, because of the pandemic, reduced or eliminated, or whose use of technology might jeopardize their safety. Some households do not have internet access at home and may not have the time and capacity to engage during the public comment period, given social distancing orders in place throughout the country. Others are busy aiding their communities or caring for their families.

Even if now were an appropriate time to hold a comment period, Executive Order 12866 suggests that a 60-day comment period is the *minimum* necessary to afford the public a meaningful opportunity to comment during normal times.[106] This is especially true for a rule that would significantly impact nearly every aspect of EPA's scientific and regulatory work. The supplemental notice is substantially different from the 2018 draft rule. For example, by expanding the rule's applicability from only dose-response research to all research, and from only "pivotal regulatory science" to all "influential science," the supplemental notice dramatically widens the scope of the rule and the research affected by it. Further, the draft rule was vaguely written, limiting the ability of commenters to assess and articulate impacts of such a policy change. In the supplemental notice, EPA provided term definitions that deserve careful, detailed consideration. Despite those significant changes, EPA moved forward with a 60-day comment period, after originally posing a 30-day period, and without a hearing. UCS held an all-day public hearing on April 14, 2020, at which 41 members of the public provided testimony about the proposal, an opportunity that should have been provided by the agency proposing the rule.[107]

Finally, more time is needed because the administrative record for this rulemaking fails to address impacts of the proposed rule as modified by the supplemental notice, including the types and number of studies that would be affected, the costs that the proposed rule would impose on the agency and individual researchers, and how the rule would impact the agency's mission to protect public health and safety. Despite this dearth of analysis, the Administration has deemed this proposal not economically significant. Thus, additional time and more avenues for public comment, including public hearings, are crucial to provide the public and experts with the opportunity to assess the rule's impacts, since the agency has failed to do so.

EPA should not move forward with this rule

Agencies should use the best available scientific information in rulemaking, as guided by their missions and statutory obligations. "Best available" should be used to describe the weight of evidence that only includes science developed according to legitimate, credible processes, free

from undue influence by vested interests. Agency scientists, bolstered by their commitment to a rigorous independent science process, policies that ensure scientific integrity, and appropriate transparency measures, should be trusted to analyze available data and issue policies that consider and appropriately weigh the evidence. All Americans benefit when science is used to inform policy, and the integrity of science in the rulemaking process is imperative for a functional democracy and a safer, cleaner environment for all.

This proposed rule, as modified by the supplemental notice, would force EPA to make decisions based on less information, making it more difficult for the agency to make science-based decisions that protect public health, as its mission requires. The placement of unnecessary restrictions on the studies that EPA can consider when making significant rules stands to affect EPA decisionmaking on everything from air pollution standards to water quality issues to chemical regulation in consumer products, without providing the public with a body of information that supports its case for why this policy is necessary.

Sincerely,

Dr. Andrew A. Rosenberg, Director
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Genna Reed, Lead Science and Policy Analyst
Center for Science and Democracy, Union of Concerned Scientists

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