American Thoracic Society

American Journal of Respiratory and Critical Care Medicine ® | American Journal of Respiratory Cell and Molecular Biology ® | Annals of the American Thoracic Society ® | ATS Scholar™ Open Access

May 15, 2020

Andrew Wheeler
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue N.W.
Washington, D.C 20460

Re: RIN 2080-AA14

Administrator Wheeler:

On behalf of the 16,000 members of the American Thoracic Society, I am writing to express our serious concerns about the EPA's Supplemental Notice of Proposed Rulemaking for the Strengthening Transparency in Regulatory Science (EPA–HQ–OA–2018–0259/RIN 2080 AA14)) (hereinafter the "Supplemental Notice"). The American Thoracic Society ("ATS") is a medical professional organization of physicians, researchers, nurses, respiratory therapists and allied health professionals dedicated to the prevention, detection, treatment, and cure of respiratory disease, critical illness and sleep disordered breathing. Our members treat patients whose illnesses were caused or worsened by air pollution. Members of the ATS are also engaged in basic, human, clinical and epidemiological research studies on the health effects of air pollution and are among the leaders in the field. The ATS's peer-reviewed scientific journals publish cutting edge research studies on the health effects of air pollution. Many of the studies published by our members and in our journals have informed the EPA's decision-making on National Ambient Air Quality Standards ("NAAQS") and other policy actions.

Despite the requirement that actions taken under the housekeeping provision only apply to intra-agency procedures, the intended and unintended consequences of the Supplemental Notice would place new responsibilities on the ATS scientific community and their ability to bring the best possible information to understand the effects of air pollution on the patients we serve. Our many members who engage in environmental health research have a thorough understanding of the practical aspects of the proposed actions and it is with this background we offer the following comments.

EXPANSION OF SCOPE

The ATS notes with concern the expanded scope of the rule outlined in the Supplemental Notice. The original proposed rule, while using imprecise terms in its use of terms like "pivotal regulatory science," at least provided some clarity in that it was limited to discrete aspects of the EPA's regulatory authority (standards, exposure thresholds, and dose-response relationships). However, the Supplemental Notice abandons this narrow application and without any offered rationale now extends the proposed rule to apply to nearly every aspect of the EPA's work including all standard setting, any preliminary scientific assessments, reports, and enforcements

We help the world breathe®
PULMONARY · CRITICAL CARE · SLEEP

1150 18th Street, N.W., Suite 300
Washington, D.C. 20036 U.S.
T. 202-296-9770 F. 202-296-9776 | thoracic.org

that use externally generated peer-reviewed science as a basis for reporting, action or decision. While it is clear that EPA intends that this rule could apply to virtually any EPA action, it is not specified which specific agency actions will actually be covered under this rule, which individual(s) will be responsible for deciding if an action will be covered, and at which point in the process can this decision be made or revised. This lack of clarity is likely to lead to inconsistent application of these new requirements.

Moreover, in an era of limited EPA funding, the expanded scope of the supplement potentially would overrun the Agency's capacity to review data and the studies relevant to any review process. Just handling these challenges for a single agency action, such as reviewing the Particulate Matter ("PM") NAAQS with its over 2,000 references, would be an enormous undertaking and it begs the question whether any newly adopted system hosted by the EPA can handle what it is requesting in the Supplemental Notice.

Even before this new expansion of scope, it was already apparent that the Agency would be unable to handle the immense logistical and technical challenges this new rule would create. As a matter of practice, the EPA has previously not provided web-based or clearinghouse depots for the posting of data, assuring quality control, nor have they provided a system to ensure database integrity and maintenance. This has been the case even in more innocuous situations that don't involve personal privacy and proprietary issues. Even with this dramatic expansion in the scope of data sharing requirements, there has been no indication that the EPA is ready or willing to take the responsibility to develop such a clearinghouse website to house data and the associated information or metadata, including defining a structure with all protections and securities. Such a data system is beyond the scope and complexity of any data system the EPA has previously developed for its internal use nor does it easily fit the existing models used by the Agency, such as the one used for its Air Quality System for monitoring data. This system is fully contracted, maintained and assessed outside the direct control of the Agency. Given that the EPA will be unable to handle all of these new responsibilities, it is clear that this Supplemental Notice will instead impose tremendous burdens on researchers and scientists outside the Agency.

BURDEN FALLS TO SCIENTISTS EXTERNAL TO EPA

The Supplemental Notice states, "(t)he rule would not regulate the conduct or determine the rights of any entity outside the federal government. Rather, it exclusively pertains to the internal practices of the EPA." The EPA bases this statement on its use of the Housekeeping Act and holds that how it reviews and uses scientific literature—based on the availability of publicly reported data—is an internal EPA matter and has no impact on the larger public. The ATS takes issue with the EPA's position that the proposed policy "exclusively pertains to the internal practices of EPA." If implemented, the proposed policy would impact a wide range of external stakeholders, including scientists, research volunteers who participate in environmental health studies and the general public.

1150 18th Street, N.W., Suite 300
Washington, D.C. 20036 U.S.
T. 202-296-9770 F. 202-296-9776 | thoracic.org

While the specific mechanisms regarding how this rule would be carried out has not been described in either the original proposed rule or this latest supplement, it is clear that many of the burdens of this Supplemental Noticel would fall to the individual investigators and their institutions. At a minimum, there would be a shared responsibility between individual researchers and EPA staff to carry out the requirements of the Supplemental Notice. Given that the burden of these new requirements far exceeds the EPA's capacity, most of these new responsibilities imposed by the Supplemental Notice would necessarily fall on individual researchers outside of the Agency to complete.

Some specific areas where there is a lack of clarity on the proposed balance of these new shared responsibilities include:

- How will an investigator know if their study is being considered as part of an agency action that would fall under this rule? Will the EPA directly contact individual researchers or is it expected that individuals must preemptively be aware of these requirements and act accordingly?
- Who will determine what comprises a complete data set sufficient to meet the requirements of this new rule?
- Who will determine what is adequate with regards to the tiered access proposed in the supplement?
- Who will be responsible for hosting the data, and providing funding for data hosting, so that it can be made available to the public?
- Who is responsible for screening those that request the data to determine which tiered level of data should be made available to them?
- Who is responsible for interactions between those requesting data and those hosting the data in order to ensure those requesting the data can access only those tiers that they are eligible to receive?
- Who is responsible for mitigating any dispute between those requesting data and those hosting the data with regards to data access based on the proposed tiered system as well as the sufficiency of the provided data to enable the proposed reanalysis in the new rule?
- When will data be required to be available in order to be included in informing EPA actions?

The reality is that the answer to all these questions is the same: the EPA proposes to wield capricious authority to determine if researchers have complied with these new requirements without providing any resources, clear guidance, or accountability for how this new rule will be applied as part of future agency actions.

Contrary to the EPA's assertions in the supplement, this proposed rule would dictate the conduct of scientists outside the federal government and would place burdens on individual researchers that would go beyond just the time and resources required to adhere to these new requirements. If promulgated, the proposed rule would place an enormous strain on

1150 18th Street, N.W., Suite 300
Washington, D.C. 20036 U.S.
T. 202-296-9770 F. 202-296-9776 | thoracic.org

researchers as they decide whether they are able to comply with the rule. On one hand, if a scientist does not share the data out of concern for violating consent agreements and breaching subject privacy, then the EPA will give less weight to the study in policymaking. On the other hand, if a scientist inadvertently discloses information in a way that violates data use agreements or contractual obligations, they may leave themselves open to legal action, dismissal, or have restrictions placed on their ability to conduct research in the future. This is not an easy decision for scientists committed to generating and disseminating knowledge useful for the public good.

PRACTICAL PROBLEMS WITH THE NEWLY PROVIDED DEFINITION OF "REANALYSIS"

EPA has clarified in the Supplemental Notice that the proposed actions are no longer premised on "replication" but rather on "reanalysis" of published scientific studies. However, the existing discussion of reanalyzing data is problematic, with potentially severe consequences to quality and pragmatism. EPA states,

> *A reanalysis is when you conduct a further analysis of data. A person doing a reanalysis of data may use the same programs and statistical methodologies that were originally used to analyze the data or may use alternative methodologies, but the point is to analyze exactly the same data to see if the same result emerges from the analysis* (emphasis added).

Using the same data, program and statistical methodologies should yield similar results to published studies and is a viable definition of what it could mean to perform a reanalysis of a published study. Using different statistical software while using the same data and methodologies could also potentially be a useful form of reanalysis to ensure that results are not driven by quirks in the specific software used by study authors but this rule goes far beyond that definition.

In terms of the provided definition in the Supplemental Notice, reanalysis using “alternative methodologies” should not necessarily be expected to deliver the same results as the original study. Even in cases when alternative methodologies do provide the same results, these results would need to be interpreted differently given that an alternative methodology was employed. This is a far cry from what is traditionally referred to as a reanalysis in which new information or variables are added to a previous analysis to test new research questions. Reanalysis studies of this type can be informative, but it has never been the expectation that someone interested in conducting such a study is entitled to having someone else do the majority of the work in preparing all of the data for continued study.

The proposed rule also suggests data disclosure is that this data reanalysis will be completed by “stakeholders”, who will have the opportunity to “reanalyze the data and models and explore the sensitivity of the conclusions to alternative assumptions while accessing only the data and aspects of the models that they need”. There is a lack of clarity over who the “stakeholders” involved in this analysis may be, and the suggestion that they may cherry pick data to force into

models that support “alternative assumptions” goes directly against the scientific process and certainly looks at least superficially like exactly the sort of bias the EPA is hoping to avoid with their rule. While good faith use of alternative methodologies to test sensitivity of various inputs is good scientific practice, expecting the same research data to yield the same results when put through alternative methodologies, potentially employed by undefined stakeholders who have the potential to intentionally introduce bias, is not a credible deployment of the scientific process.

While the lack of quality guidelines for “alternative methodologies” is intrinsically problematic, there are larger and more fundamental issues with the EPA discussion of reanalysis. The Supplemental Notice only requires data be made publicly available to support reanalysis. The Supplemental Notice does not discuss circumstances in which reanalysis might actually occur and how the Agency would respond to such activities. Simply put, the Supplemental Notice creates a new, complex and potentially resource- and time-consuming process at the EPA without any discussion of parameters by which they would respond to the very activity that they are hoping to enable.

EPA’S DISCUSSION OF HOW “RESEARCH DATA” WILL BE USED IS INTERNALLY INCONSISTENT

EPA proposes a definition of data as, “recorded factual material commonly accepted in the scientific community as necessary to validate research findings.” While this definition appears straightforward, the discussion in the Supplemental Notice of how these data may be used reveals the EPA’s fundamental misunderstanding of exactly which data are necessary and sufficient to validate or replicate research findings.

For example, multiple epidemiological studies have shown that human exposure to air pollution has measurable morbidity and mortality impacts. The analyses use several inter-related data sets to reach their conclusions, including: location data of the research participants, individual-level data of the research participants, community-level demographic and socio-economic information, meteorology data, mortality data, and air pollution exposure data. The collection and preparation of each of these primary data sets are only the first steps in the research process. Researchers must then make decisions on how these data sets relate – how to extrapolate the air pollution exposure data measured at fixed location correlates to estimated air pollution exposure of study participants at a variety of locations; how variables like heat impact mortality; and when studying one pollutant, how multi-pollutant exposures impacts study findings. Evaluating these data sets requires multiple fields of scientific expertise including toxicologists, epidemiologists, physicians, statisticians, physiologists, and methodologist just to name a few. These assumptions, model developments and interactions ultimately generate a “final data set” from which the study findings are determined, which in turn advance and expand our understanding of the study topic.

The Supplemental Notice's discussion of research data toggles between the Agency requesting all of the underlying datasets, including meta-data, versus only requesting a final data set on

1150 18th Street, N.W., Suite 300
Washington, D.C. 20036 U.S.
T. 202-296-9770 F. 202-296-9776 | thoracic.org

which statistical analysis may be performed. Parts of the Supplemental Notice imply that the EPA is requesting public access to the original primary data to support any re-analysis effort the EPA or other scientists may choose to implement. Other parts of the discussion imply that the Agency is seeking the final data set that includes the interactions between all the underlying data points. The former requirement risks issues with personal health data, trade secrets, and so on, and would result in an enormous amount of data files that would need to be made available.

If the EPA is truly seeking the research data as defined, then providing the research data sets alone – absent the decisions on how researchers choose to link those research data sets - will not allow EPA staff or any external body to truly validate the study findings. Should a third party use those base data sets and apply their own modeling assumptions, they are not validating the original study, they would be in fact conducting a new research study. Thus access solely to the final data set, lacking the underlying interactions and assumptions between multiple fields of primary data, may avoid excess burdens in regards to making sense of the large number of disparate data files that would need to be provided but is ultimately insufficient to allow for any meaningful reanalysis. The EPA's alternating and confusing discussion of data shows that the Agency has not yet fully thought through implementation of the proposed policy.

DISCARDING OR WEIGHTING EXTERNAL SCIENTIFIC INFORMATION

The Supplemental Notice includes two options for how the EPA will address studies that do not meet their new data disclosure requirements. The first option is to ignore the scientific data altogether. The Supplemental Notice states, "the Agency will only use pivotal regulatory science and/or pivotal science if the data and models are available in a manner sufficient for independent validation."

Ignoring the available research is not only bad public policy, it also violates previous guidance that direct the Agency to use the best available science. The Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA is based on a document by the same title governing all federal agencies (2002).[1] Both clearly state that information is provided in an objective (accurate, clear, complete and unbiased) manner, which cannot be done if information is incomplete. The same guideline states that information that has been subject to formal, independent, external peer review may generally be assumed to be objective.[2] It is also clear "a replication exercise" when there are "ethical, feasibility or confidentiality restraints", is unnecessary provided that the original dissemination met agency criteria for high quality. In fact, the EPA guideline specifically stresses the importance of avoiding "new and potentially duplicative or contradictory processes" and "unnecessary

[1] EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-008 (Oct. 2002), https://www.epa.gov/sites/production/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf.

[2] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies. Section V; 3a, b, i.

administrative burdens".[3] The EPA statement also endorses ensuring information integrity, describing the importance of avoiding altering information, including changes or modifications.[4] In the case of the EPA Science Policy Council Guidance for Evaluating and Documenting the Quality of Existing Scientific and Technical Information, a quality management plan based on EPA evaluation criteria for objectivity is advised.[5] The current suggestion of avoiding objective information because it was generated independently directly scuttles the EPA's own document for generating a sufficient quality assessment approach.

Alternatively, EPA is proposing to, "give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because they are publicly available or because they are available through tiered access when the data includes CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects." This is also absent of any scientific justification. The "greater consideration" option is not fully discussed with no details provided about how the Agency would go about providing a weight to an individual study based on the availability of underlying data.

This presents a considerable potential to introduce bias. For instance, studies which contain PII are most likely to reflect specific health outcomes at an individual level, where the existing detail promotes mechanistic understanding and generalizability by clearly defining the impacted population. As well, without CBI and proprietary data, analyses are not sufficiently informed of the true impact on business practices, management and economic outcomes. Ethical research practices do not allow confidential data to be released, and competitive industrial practices equally disincentivize data sharing at this detailed level.

As it currently stands, the EPA is only bound to consider high-quality information generated through a robust peer review process. This existing process allows the EPA to weight studies by their quality rather than by arbitrary "standards" that force potentially inappropriate data disclosure. By removing or minimizing what is potentially the most reliable and detailed data, the quality, interpretation and usability of EPA analyses will be compromised at best and incontrovertibly biased in a way that is not reflective of reality, creating significant harm to business and individuals, at worst.

The Supplemental Notice states that EPA will, "provide a short description of why greater consideration was given," but fails to outline what "greater consideration" means in practical terms. Are 10 studies that don't meet the data sharing requirements, but reach a similar finding,

---

[3] *Id.* Section 4 page 10.

[4] *Id.* Section 4.5 page 13.

[5] EPA, Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA/240/B-06/001 (Feb. 2006), https://www.epa.gov/sites/production/files/2015-06/documents/g4-final.pdf; *see also* EPA, Guidance for Evaluating and Documenting the Quality of Existing Scientific and Technical Information, Addendum to: A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, (Dec. 2012), https://www.epa.gov/sites/production/files/2015-05/documents/assess3.pdf.

outweighed by 1 study that does meet the data sharing requirement, but has a contrary finding? Without detailed, consistent guidelines delineating exactly how studies will be weighted, as well as how missing data will be accounted for, the quality of this new document in no way approaches the quality of the EPA's existing documents that define inclusion and exclusion criteria, currently based on publication quality judged by rigorous scientific standards. The Supplemental Notice brings forward a new and complex process without any consideration to ensure that information is "accurate, clear, unbiased and complete", as mandated by the federal government, let alone how the policy will be practically implemented.

Federal agencies should have the ability to individually evaluate and weight scientific studies based on the strength of the science using criteria such as participant selection, disclosure of methods and authentication of reagents, quality of exposure assessment, strength of association, consistency, specificity, temporality, evidence of dose-response, biological plausibility, and assessment of potential bias or confounding. Weighing studies based on their ability to comply with EPA Federal Housekeeping internal requirements is unscientific, arbitrary, burdensome and capricious. It hinders the EPA by depriving the agency of some of the best science on which it might make its decisions.

ADMINISTRATOR DISCRETION

The proposed rule gives excessive authority to the Administrator. Under current statute, the regulatory review process of the CAAA 1970 provides the Administrator with the authority and responsibility to make final regulatory and policy decisions after hearing staff recommendations based on internal review of the science as well as from independent review groups, such as the Clean Air Scientific Review Committee, and countless outside commentaries through the public review process. The Supplemental Notice would provide even more discretionary authority to the administrator allowing him/her to reach into the domain of scientific research to selectively pick and choose scientific studies on which to base regulatory decisions. Such cherry-picking is fraught with danger and potential corruptive forces, not the least are implicit or explicit biases.

Moreover, it is unclear if the Administrator can do this simply on data access or the "quality" of the science as perceived. As noted earlier, the Supplemental Notice effectively creates a false choice where in nearly every action the EPA takes that is informed by external science, the agency would either have to ignore the available high quality science generated by external sources that does not meet arbitrary standards or successfully navigate a new set of bureaucratic requirements for now in this supplement nearly every aspect of EPA's work under the supplement's expanded scope.

The rule grants the Administrator sole and untethered authority to waive when the rules for inclusion or exclusion can be applied, effectively granting the Administrator discretion on which aspects of the EPA obligations he or she chooses to acknowledge and implement as well as which to ignore. This unstructured augmentation of authority with no overview, recourse, or appeal process is inconsistent with normal administrative decision processes historically used in the EPA and undermines the spirit of transparency used to justify this proposal. While the

1150 18th Street, N.W., Suite 300
Washington, D.C. 20036 U.S.
T. 202-296-9770 F. 202-296-9776 | thoracic.org

Administrator should and does have great discretion on setting agency priorities and policies, implementation of this proposed rule would grant the Administrator excessive authority to selectively pursue or ignore the EPA's many statutory obligations.

Uncertainty and a lack of clarity at every step of the process is not remedied by giving a single individual discretion to decide when these data requirements can be waived and when these data requirements have been satisfied. The idea that good faith efforts by researchers to comply with the requirements of the proposed rule, in the absence of clear guidance by the Agency, could be unilaterally rejected by the administrator with no apparent recourse for the investigator is contrary to good governance.

EPA DOES NOT HAVE AUTHORITY UNDER THE FEDERAL HOUSEKEEPING STATUTE TO PROMULGATE THE SUPPLEMENTAL NOTICE

The Supplemental Notice of Proposed Rulemaking

As noted above, the Supplemental Notice significantly expands the scope of the EPA's April 30, 2018 Proposed Rule to affect nearly every aspect of the Agency's work—including all standard setting, any preliminary scientific assessments, reports, and enforcements that use externally generated peer-reviewed science as a basis for reporting, action, or decision.[6] Specifically, the Supplemental Notice expands the Proposed Rule to apply to any "influential scientific information" used by the EPA, rather than only "significant regulatory decisions."[7] The Supplemental Notice also includes an alternative proposal under which EPA would consider studies based on non-publicly available data, but give them less weight than studies based on publicly available data.[8] This alternative proposal does not remedy the rule's numerous glaring problems, and, like the primary proposal, is arbitrary and would lead to a chilling effect on research.[9]

In addition to expanding the Proposed Rule's scope, the Supplemental Notice invokes a new source of authority for the rule—the Federal Housekeeping Statute, 5 U.S.C. § 301. However, EPA does not have the authority to promulgate this rule pursuant to the federal Housekeeping Statute.

[6] Strengthening Transparency in Regulatory Science, 85 Fed. Reg. 53, 15,397 (March 18, 2020).
[7] *Id*. at 15,398.
[8] *Id*. at 15,399.
[9] Kelsey Brugger, *Critics: Secret science rule will spur 'public health crisis,'* GREENWIRE (April 15, 2020) https://www.eenews.net/greenwire/2020/04/15/stories/1062882421.

EPA is Not an Executive Department Subject to the Federal Housekeeping Statute

The Housekeeping Statute permits "what the [Administrative Procedure Act] terms 'rules of agency organization, procedure, or practice,' as opposed to substantive rules."[10] Specifically, the statute grants "the head of an executive department" the authority to govern internal departmental affairs.[11] The statute allows for the promulgation of regulations "for the government" of the 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."[12] Congress amended the statute in 1958 to add a second sentence stating, "[t]his section does not authorize withholding information from the public or limiting the availability of records to the public."[13]

The Housekeeping Statute, by its express terms, applies only to the heads of "executive department[s] or military department[s]."[14] EPA is not one of the fifteen executive departments listed in 5 U.S.C. § 101, nor is it a military department.[15] The EPA's own Office of Legal Counsel ("OLC") has agreed that 5 U.S.C. § 301 does not apply to the EPA, stating in one OLC opinion that "the difficulty here, however, is that section 301 confers regulatory authority only to 'heads of Executive departments and military departments' and not the heads of other executive agencies, such as EPA."[16] Congress used the term "executive department" in this statute, while in other provisions it uses the term "agency."[17] Such differences are typically presumed intentional by the Supreme Court, meaning that "executive department" and "agency" do not refer to the same things.[18] Therefore, the executive departments listed in 5 U.S.C. § 101 are the only government entities to which the Housekeeping Statute directly applies.

---

[10] 85 Fed. Reg. 53 at 15,397 (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 309 (1979)).

[11] 5 U.S.C. § 301. The statute also applies to the head of military departments.

[12] 5 U.S.C. § 301.

[13] *Id*.; *Chrysler Corp*., 441 U.S. at 310.

[14] 5 U.S.C. § 301.

[15] The executive departments are the Departments of: State, Treasury, Defense, Justice, Interior, Agriculture, Commerce, Labor, Health and Human Services, Housing and Urban Development, Transportation, Energy, Education, Veterans Affairs, and Homeland Security. 5 U.S.C. § 101.

[16] EPA Office of Legal Counsel Opinion: *Authority of EPA to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property* 32 Op. O.L.C. 79 (May 28, 2008), *available at* https://www.justice.gov/sites/ default/files/olc/opinions/attachments/2015/06/23/op-olc-v032-p0079.pdf.

[17] *See* 5 U.S.C. §§ 302, 305. *See Authority of the Office of Government Ethics to Issue Touhy Regulations*, 25 Op. O.L.C. 13, 15 (Jan. 18, 2001).

[18] *Authority of the Office of Government Ethics to Issue Touhy Regulations*, 25 Op. O.L.C. at 15; *see Bates v. United States*, 522 U.S. 23, 29–30 (1997) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)); *see also Duncan v. Walker*, 533 U.S. 167, 173 (2001).

There are other executive branch agencies that have been found to be excluded from the Housekeeping Statute. For example, the Office of Government Ethics ("OGE") may not issue regulations pursuant to 5 U.S.C. § 301 because OGE is not an executive department.[19] OGE may only issue regulations concerning the production of agency records pursuant to other authority,[20] and regulations concerning employee testimony on official matters can be issued pursuant to the implied authority conferred on it by its own organic statute, 5 U.S.C. § 401.[21] Similarly, no OLC opinion has found that EPA may issue any regulation pursuant to the Housekeeping Statute.[22] EPA even admits that the Housekeeping Statute does not apply directly to EPA, instead arguing that "EPA gained housekeeping authority through the Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970)."[23]

The Reorganization Plan No. 3 of 1970 Does Not Explicitly Grant Housekeeping Authority to EPA

It is not apparent anywhere in Reorganization Plan No. 3 of 1970 (the "Plan") that Congress or the President intended the Housekeeping Statute to apply to the newly created EPA. The Plan was prepared by President Richard Nixon and transmitted to the Congress on July 9, 1970 in accordance with Chapter 9 of Title 5 of the United States Code.[24] One of the purposes of 5 U.S.C. § 901 is "to promote the better execution of the laws."[25] The President's accompanying message to the Congress explained that the EPA was being created to rationally and systematically organize the government's environmentally related activities, specifically related to air, water, and land.[26] The President noted that research on pollutants and their impact on the total environment was "critical" for the measurement of the success or failure of the country's pollution abatement efforts.[27] One of the primary functions of EPA established under the Plan is "[t]he conduct of research on the adverse effects of pollution and on methods and equipment for controlling it, the gathering of information on pollution, and the use of this information in strengthening environmental protection programs and recommending policy changes."[28]

---

[19] *Authority of the Office of Government Ethics to Issue Touhy Regulations*, 25 Op. O.L.C. at 15.

[20] OGE may issue "Touhy" regulations concerning the production of agency records pursuant to 44 U.S.C. § 3102. A "Touhy" regulation refers to *U.S. ex rel Touhy v. Ragen*, 340 U.S. 462 (1951).

[21] 25 Op. O.L.C. at 15.

[22] *But see Authority of EPA to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property*, 32 Op. O.L.C. 79 (concluding that although the housekeeping statute does not apply to EPA, the Administrator of the EPA does have housekeeping authority under EPA's organic statute).

[23] 85 Fed. Reg. at 15,397.

[24] Reorganization Plan No. 3 of 1970, U.S. ENVIRO. PROTECTION AGENCY (July 9, 1970) *available at* https://archive.epa.gov/epa/aboutepa/reorganization-plan-no-3-1970.html.

[25] 5 U.S.C. § 901(a)(1).

[26] Reorganization Plan No. 3 of 1970.

[27] *Id*.

[28] *Id*.

Section 1 of the Plan establishes the EPA's existence.[29] Section 2 of the Plan transfers to the EPA Administrator various functions of other agencies, such as the Department of the Interior's ("DOI") jurisdiction over the Federal Water Quality Administration and the Federal Water Pollution Control Act.[30] Sections 2(a)(2)–(8) transfer other various discrete functions to EPA, while retaining some environmentally related functions in the Department of Health, Education, and Welfare, the DOI, and the Department of Agriculture.[31] Section 2(a)(9) transfers "[s]o much of the functions of the transferor officers and agencies *referred to in or affected by the foregoing provisions* of this section as is *incidental to or necessary for* the performance by or under the Administrator of *the functions transferred by those provisions* or relates primarily to those functions."[32]

Section 2(a)(9) is not a catch-all provision that would allow the EPA Administrator broad housekeeping authority, as EPA now appears to assert.[33] By its express terms, Section 2(a)(9) only grants the EPA Administrator authority "incidental to or necessary for" carrying out the functions detailed in the "foregoing provisions of this section"—that is, Section 2(a)(1) through (8).[34] This position is supported by the fact that Section 2(a)(9) specifies some functions that fall under the authority of Section 2 and some specific functions that should be "excluded," including the functions of the Bureau of Reclamation under section 3(b)(1) of the Water Pollution Control Act.[35] Section 2(b) of the Plan goes on to specify some functions that will be transferred under this authority, including the DOI's Water Pollution Control Advisory Board, the boards provided for by the Federal Water Pollution Control Act, and the Department of Health, Education, and Welfare's Air Quality Advisory Board.[36] The specificity of the language used throughout Section 2 of the Plan, and particularly in Section 2(a)(9), demonstrates that the Plan was not intended to transfer every imaginable function from DOI and other agencies to the EPA.

Nowhere in the Plan is the Housekeeping Statute mentioned, nor is the transfer of housekeeping authority to EPA mentioned. As already stated, the Housekeeping Statute applies only to the heads of military departments and the heads of the 15 "executive departments" listed in 5 U.S.C. § 101. The Plan does not explicitly add EPA to this list of executive departments. EPA offers no support for its broad claim of housekeeping authority other than noting that the

[29] *Id*.
[30] *Id*.
[31] *Id*.
[32] *Id*. (emphases added).
[33] *See* 85 Fed. Reg. at 15,397.
[34] Reorganization Plan No. 3 of 1970, at Section 2(a)(9). Indeed, any doubt that the language "the foregoing provisions of this section" in Section 2(a)(9) refers to Section 2(a)(1) – (8), is resolved later in the same sentence where it is explained that the "incidental to or necessary for" authorities transferred to the Administrator pertain to "the functions *transferred by those provisions* . . ." (e.g., Sections 2(a)(1) – (8)).
[35] *Id*.
[36] *Id*.

Administrator is the head of the EPA, and that the Plan transferred functions and authorities of "various agencies and executive departments" to EPA.[37]

However, the transfer of discrete functions, boards, and authorities to EPA does not equate to the transfer of sweeping housekeeping authority. Section 2(a)(9) only transfers those functions "incidental to or necessary for" the performance of the previously mentioned transferred functions. The authority to promulgate rules such as the Strengthening Transparency in Regulatory Science rule—which drastically alters the agency's process for considering scientific studies in its decision-making process—does not follow from the grant of "incidental to" or "necessary" functions authorized under Section 2(a)(9) of the Plan.

Even if EPA Has Housekeeping Authority, the Supplemental Notice Far Exceeds the Scope of the Housekeeping Statute

Even assuming for the sake of argument that the Housekeeping Statute applies to EPA, as some courts have stated without support,[38] EPA cannot rely on the Housekeeping Statute to promulgate the Strengthening Transparency in Regulatory Science rule because the rule far exceeds the Housekeeping Statute's scope.

The Supplemental Notice is Not a Regulation Pertaining Solely to Intra-Agency Procedure

The Housekeeping Statute only allows the heads of executive and military departments to issue regulations for "govern[ing] [the] department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records."[39] EPA's position is that the Housekeeping Statute authorizes the EPA Administrator to promulgate organizational intra-agency rules in order to ensure the functioning of the agency.[40] The Supplemental Notice at issue—which limits the types of scientific studies that the agency considers when creating of rules and in other decision-making contexts—is not a regulation pertaining merely to intra-agency procedure.

The interpretive authority on the nature of 5 U.S.C. § 301 comes primarily from the Supreme Court's opinion in *Chrysler Corp. v. Brown*.[41] There, the Supreme Court held that the legislative history of 5 U.S.C. § 301 did not indicate that the statute created any substantive legislative power to promulgate rules authorizing the release of trade secrets or confidential business

[37] 85 Fed. Reg. at 15,397.

[38] *EPA v. General Elec. Co*., 197 F.3d 592 (2d Cir. 1999) ("The Federal Housekeeping Statute, 5 U.S.C. §301, authorizes government agencies such as the EPA to adopt regulations regarding 'the custody, use, and preservation of [agency] records, papers, and property.'"); *see also US ex rel. Touhy v. Ragen*, 340 US at 468.

[39] 5 U.S.C. § 301.

[40] 85 Fed. Reg. at 15,397.

[41] 441 U.S. 281, 309 (1979).

information.[42] The Court went on to specify that the Housekeeping Statute should be read to authorize the creation of procedural rules, but not "substantive rules."[43]

Courts have noted that substantive or "legislative type rules" are those that are often promulgated in compliance with the notice and comment process outlined in the Administrative Procedure Act,[44] since rules "issued by an agency pursuant to statutory authority . . . must conform with any procedural requirements imposed by Congress."[45]

These substantive rules are not authorized under the Housekeeping Statute. In *Chrysler Corp.*, this meant that the confidential information given to the government in the form of trade secrets could not be released under the authority of a § 301 regulation because to do so properly would require the agency to exercise substantive legislative power.[46] Similarly, here, the use of the notice and comment process and the nature of the Supplemental Notice—which limits the types of scientific information considered by EPA in all standard setting, and any preliminary scientific assessments, reports, and enforcements that use externally generated peer-reviewed science as a basis for reporting, action, or decision—indicate that the Strengthening Transparency rule is "substantive," rather than merely "procedural" or "interpretive," and therefore cannot be authorized by the Housekeeping Statute.[47]

The very cases and authorities that EPA cites in its Supplemental Notice, among others, are distinguishable from the Proposed Rule. For example, the EPA's OLC opinion, "*Authority of EPA to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property*," concluded that the EPA Administrator could set rules for employee conduct on the job as well as outside of the workplace that might undermine the "efficient operation of the Department."[48] This scenario regarding liability for breaching personnel and property rules is clearly a matter of "internal departmental affairs."[49] The management of employees and personal property is clearly "incidental to" and "necessary for" the effective performance of the agency.[50] The rule did not relate to the substantive work of the EPA, like the Supplemental Notice at issue here does.

---

[42] *Id*.
[43] *Id*. at 301; *see also Morton v. Ruiz*, 415 U.S. 199, 232, 236 (1974) (noting that a characteristic of a substantive rule is that it "affect[s] individual rights and obligations.").
[44] *See United States v. Manafort*, 312 F.Supp.3d 60, 75 (D.D.C. 2018) (noting that substantive or "legislative type rules" are often promulgated in compliance with procedures imposed by Congress, such as requirements for notice and comment set forth in the Administrative Procedure Act).
[45] *Chrysler Corp*., 441 U.S. at 302–03.
[46] *See id*. at 310.
[47] *Id*. at 301–03.
[48] 32 Op. O.L.C. 79.
[49] *Id*.
[50] *Id*.; *see also* 5 U.S.C. § 301.

Additionally, in *Boron Oil Co. v. Downie*, the Fourth Circuit held that an EPA regulation under 5 U.S.C. § 301 allowing employees to resist subpoenas to testify in state court was valid.[51] *US ex rel. Touhy v. Ragen*, a case oft-cited by courts interpreting § 301, the Supreme Court held that the Department of Justice ("DOJ") could resist a subpoena for documents pursuant to an intra-agency rule promulgated under the authority of 5 U.S.C. § 22, the predecessor to the current Housekeeping Statute.[52] Clearly, the scenarios in *Boron Oil* and *Touhy* relating to an agency's discretion to resist subpoenas are authorized under the housekeeping statute because they directly relate to "preservation of agency records and papers." However, just because the DOJ may resist subpoenas with the help of § 301, does not make § 301 applicable to the EPA broadly or authorize the promulgation of the Supplemental Notice specifically.

More recently, in *United States v. Manafort*, the District Court for the District of Columbia held that DOJ special counsel regulations were not "substantive rules" that created individual rights but were merely statements of internal departmental policy.[53] Citing *Chrysler Corp.*, the court agreed with the DOJ that the regulations were not intended to create any rights and were "matters of agency management or personnel."[54] DOJ did not seek notice and comment for the special counsel regulations, and DOJ even used language in those regulations stating that they did not create "any rights, substantive or procedural, enforceable at law . . . by any person or entity, in any matter, civil, criminal, or administrative."[55] This type of language has been found by courts to effectively disclaim the creation of any enforceable rights.[56]

Clearly, here, EPA has not followed the same steps as DOJ did in the promulgation of the special counsel regulations at issue in *United States v. Manafort*. EPA's Supplemental Notice is distinguishable from DOJ's special counsel regulations and other procedural rules because it is being promulgated under the notice and comment process, does not use language disclaiming the creation of any rights enforceable at law, and creates a new qualitative measure for the agency's consideration and use of science in the agency's fundamental functions. Accordingly, the Supplemental Notice is a substantive rule that falls outside the scope of the Housekeeping Statute.

The Supplemental Notice Imposes Implicit Obligations on Parties Outside of the Federal Government by Limiting the Types of Science EPA Will Consider

The Supplemental Notice imposes implicit obligations on parties outside the federal government, including on researchers and potential study participants. Researchers are often obligated to protect the confidentiality of study participants, and the Supplemental Notice would

[51] *Boron Oil Co. v. Downie*, 873 F.2d 67, 69 (4th Cir. 1989); *see also U.S. ex rel Touhy v. Ragen*, 340 U.S. 462 (1951); *EPA v. General Elec. Co*., 197 F.3d 592 (2d Cir. 1999).
[52] *U.S. ex rel Touhy v. Ragen*, 340 U.S. 462 (1951).
[53] *United States v. Manafort*, 312 F.Supp.3d 60, 75 (D.D.C. 2018).
[54] *Id*.; *Chrysler Corp*., 441 U.S. at 302; Office of Special Counsel, 64 Fed. Reg. 37,038, 37,041 (July 9, 1999).
[55] *United States v. Manafort*, 312 F.Supp.3d at 75; 28 C.F.R. 600.10.
[56] *United States v. Manafort*, 312 F.Supp.3d at 75.

require researchers to either breach those confidentiality agreements or risk the loss of willing study participants. For example, The Harvard Six Cities Study is a seminal research study on the effects of air pollution on human health started in 1975 with 8,000 participants.[57] This study was validated, reanalyzed, and reproduced by organizations that were given restricted access to the underlying data, but under the Supplemental Notice, the study would be blocked from EPA's use or consideration because the underlying data are not publicly available.[58]

In at least two instances the D.C. Circuit Court of Appeals has recognized that studies for which the underlying data are not publicly available may constitute the "best available science."[59] In *American Trucking Associations, Inc. v. EPA*, the court held that the Clean Air Act did not require EPA to make underlying data public where EPA relied on the study itself and not the raw underlying data.[60] The court agreed with EPA's argument that requiring the agency to obtain and publicize the relevant data "would be impractical and unnecessary."[61] In *Coalition of Battery Recyclers Association v. EPA*, the court again upheld EPA's reliance on non-publicly available data, reasoning that EPA relies on studies and their results rather than the raw data underlying those results.[62]

In limiting the agency's use of studies whose underlying data are not publicly available, the Supplemental Notice substantively impacts and places obligations on the scientific community. Importantly, and contrary to the EPA's position that the Supplemental Notice "does not regulate any entity outside the Federal Government,"[63] scientists and researchers will have to take time-consuming steps to make the data underlying their studies publicly available in order to have their study considered by EPA. Given the time- and money-intensive process of making a study's data publicly available, it is possible that fewer scientific studies will be performed and made available to the scientific community. A similar chilling effect could occur due to an awareness by potential study participants or researchers that underlying data will be released to the public, potentially subjecting them to privacy intrusions or harassment by regulated industry.[64]

---

[57] Dockery, D.W., et al., *An association between air pollution and mortality in six US cities*, 329(24) New England J. of Med., 1753–59 (1993).

[58] *See* Environmental Defense Fund's Comments on the 2018 Proposed Rule; Dockery, D.W., et al., at 1753–59.

[59] *See Am. Trucking Associations, Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002); *Coal. Of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010).

[60] *Am. Trucking Associations, Inc. v. EPA*, 283 F.3d at 372.

[61] *Id.* at 372 (quoting National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,689 (July 18, 1997).

[62] *Coal. Of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010).

[63] 85 Fed. Reg. at 15,397.

[64] *See e.g.,* Kelsey Brugger, *Critics: Secret science rule will spur 'public health crisis*,' GREENWIRE (April 15, 2020) https://www.eenews.net/greenwire/2020/04/15/stories/1062882421; Michael Halpern, *Corporations and Activists are Exploiting Open Records Laws. California is Trying to Change That*, UNION OF CONCERNED SCIENTISTS (Feb. 22, 2019) https://blog.ucsusa.org/michael-halpern/corporations-and-activists-are-exploiting-open-records-laws-california-is-trying-to-change-that; *see also* Michael Halpern, *Freedom to Bully: How Laws Intended to Free*

Additionally, the EPA has already established an array of rigorous review techniques that go beyond the typical scientific journal peer review process to ensure that the best available science is used.[65] Imposing this new public availability of data obligation negates the purpose of these "rigorous reviews" and the already-strict review imposed by the scientific community.[66] Courts have held that agencies "cannot ignore available…information."[67] Plaintiffs and petitioners can establish a violation of a statutory "best available science" requirement imposed on the agency by "point[ing] to any scientific evidence that the agency failed to consider."[68] The Ninth Circuit Court of Appeals has also held that "the best available data requirement . . . prohibits [an agency] from disregarding available scientific evidence that is in some way better than the evidence [it] relies on."[69] Under the Supplemental Notice, EPA would not consider some scientific studies that are potentially more accurate and robust than the studies it does consider based upon the arbitrary criterion of the public availability of the study's underlying data.

EPA's alternative approach described in the Supplemental Notice involves considering scientific studies without publicly available data, but giving them less weight than studies with publicly available data.[70] This approach—likely a response to the backlash EPA received over the 2018 Proposed Rule[71]—also falls outside of the scope of the Housekeeping Statute for the same reasons as the original proposal. Assigning weight to scientific studies based on the irrelevant criterion of whether or not the underlying data sets are available to the public is not merely an

---

Information Are Used to Harass Researchers, 1, 12, CENTER FOR SCIENCE AND DEMOCRACY AT THE UNION OF CONCERNED SCIENTISTS (Feb. 2015) https://www.ucsusa.org/sites/default/files/attach/2015/09/freedom-to-bully-ucs-2015-final.pdf.

[65] Memorandum by Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science 4 (May 12, 2018) (noting that this Proposal does not take into account EPA's other vetting mechanisms including several expert panels).

[66] Kelsey Brugger, *Critics: Secret science rule will spur 'public health crisis*,' GREENWIRE (April 15, 2020) https://www.eenews.net/greenwire/2020/04/15/stories/1062882421 (quoting Rep. Paul Tonko (D-N.Y.) as stating that the research system in place is already working, "only 2 out of 10,000 papers are retracted in the U.S. . . . [T]he system is strong. The system is fair").

[67] *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988).

[68] *Safari Club Int'l v. Salazar* (In re Polar Bear Endangered Species Act Listing & Section 44(d) Rule Litig. – MDL No. 1993), 703 F.3d 1, 9 (D.C. Cir. 2013).

[69] *Kern Cty. Farm Bureau v. Allen*, 450 F.3d 1072, 1080 (9th Cir. 2006).

[70] 85 Fed. Reg. at 15,399 ("However, under the alternative approach in this supplemental proposal, EPA would consider using all available high-quality studies but give greater consideration to those two studies with data available for independent validation.").

[71] *See* Environmental Defense Fund's Comments on the 2018 Proposed Rule (on file with author); *see also* Comments of the Attorney Generals of Multiple States on the 2018 Proposed Rule (on file with author); American Thoracic Society's Comments on the 2018 Proposed Rule (on file with author).

intra-agency rule of procedure as it will impact EPA's actions across the breadth of the substantive statutes it administers.

THE SUPPLEMENTAL NOTICE VIOLATES THE STATUTORY COMMANDS OF MANY ENVIRONMENTAL STATUTES

In addition to the Housekeeping Statute, EPA's Supplemental Notice cites a number of substantive environmental statutes—such as, the Clean Air Act ("CAA"), the Clean Water Act ("CWA"), the Safe Drinking Water Act ("SDWA"), the Resource Conservation and Recovery Act ("RCRA"), the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), the Emergency Planning and Community Right-to-Know Act ("EPCRA"), the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), and the Toxic Substances Control Act ("TSCA")—as providing the basis for the Agency's authority to promulgate this SNPRM.[72]

Like the Housekeeping Statute, these substantive provisions do not grant EPA the authority to issue the Strengthening Transparency in Regulatory Science Rule. Specifically, the rule violates the statutory provisions of a number of these statutes, which require the Agency to consider high-quality scientific information. Furthermore, neither the general rulemaking provisions of the environmental statutes nor the Housekeeping Statute grant EPA the authority to promulgate a rule that overrides explicit statutory directives.

Environmental Statutes Impose Certain "Quality of Information" Requirements

EPA's Supplemental Notice is at odds with provisions of multiple environmental statutes which require the Agency to consider certain high-quality scientific information. For example, the SDWA requires that the issuance of national drinking water regulations be based on the "*best available, peer-reviewed science* and supporting studies conducted in accordance with sound and objective scientific practices."[73] TSCA requires the EPA Administrator to ensure that evaluation and regulation of toxic substances is "consistent with the *best available science*" and to use all scientific information that is "*reasonably available*" when making related decisions.[74] The CWA and the CAA require that water and air quality criteria determinations be based on the "*latest scientific knowledge*."[75] Lastly, EPCRA requires that some actions "be based on *generally accepted scientific principles* or laboratory tests, or *appropriately designed and conducted* epidemiological or other population studies."[76]

Each of these provisions directs EPA to incorporate a certain quality of scientific information into its rulemaking decisions made pursuant to the statute. In particular, these requirements are

[72] 85 Fed. Reg. at 15,397.
[73] 42 U.S.C. § 300g-1(b)(3)(A)(i) (emphases added).
[74] 15 U.S.C. § 2625(h), (k) (emphases added).
[75] 33 U.S.C. § 1314(a)(1); 42 U.S.C. § 7408(a)(2) (emphasis added).
[76] *Id.* § 11023(d)(2) (emphases added).

designed to ensure the scientific validity of the information upon which EPA bases its actions. Mandating a high-quality scientific basis for regulatory actions is necessary to guarantee the best possible protections for public health and welfare and to minimize partisan influence in scientific decision-making.

The Supplemental Notice, however, would impermissibly prohibit the agency from considering of relevant and high-quality scientific studies whenever the data underlying the study are not publicly available—in direct contravention of the statutory directives that mandate, for example, consideration of the "best available science." None of the provisions requires, or even suggests, that EPA only consider information that is publicly available. It strains the plain meaning of words like "best," "latest," and even "appropriate" to suggest that they permit the unscientific requirement that all data be publicly available.

EPA "cannot ignore available . . . information."[77] Courts have held that "best available data" requirements "prohibit[] [an agency] from disregarding available scientific evidence that is in some way better than the evidence [it] relies on."[78] Furthermore, a plaintiff may establish a violation of a "best available science" requirement by "point[ing] to any scientific evidence that the agency failed to consider."[79] The Supplemental Notice would undoubtedly preclude EPA from considering certain studies and scientific information that is "better" or the "best available," simply because the study's underlying data is not publicly available, thereby failing to satisfy Congressional directives and undermining the quality of regulatory decisions.

Likewise, EPA cannot avoid the statutory directives to consider high-quality scientific information simply by assigning a lesser weight to such information when the underlying data are not publicly available, as the Agency alternatively proposes. The Supplemental Notice's alternative proposal is designed to have largely the same pernicious effects as flatly prohibiting consideration of studies lacking publicly available data. Just as with the primary proposal, EPA's alternative proposal would limit the agency's consideration of the best available science in making important regulatory decisions, and is, therefore, arbitrary and capricious.

The effect of the Proposed Rule is inconsistent with EPA's view that the Supplemental Notice is "intended to be consistent with the statutes that EPA administers and EPA plans to implement this procedural rulemaking in accordance with all applicable statutory and regulatory requirements."[80] EPA attempts to resolve this inconsistency by stating that "in the event the

---

[77] *San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 602 (9th Cir. 2014) (quoting *Kern Cty. Farm Bureau v. Allen*, 450 F.3d 1072, 1080-81 (9th Cir. 2006) (quoting *Conner v. Burford,* 848 F.2d 1441, 1454 (9th Cir. 1988)).

[78] *Kern Cty. Farm Bureau*, 450 F.3d at 1080 (citing *Southwest Ctr. for Biological Diversity v. Babbitt*, 215 F.3d 58, 60 (D.C. Cir. 2000)).

[79] *See Safari Club Int'l v. Salazar* (*In re Polar Bear Endangered Species Act Listing & Section 4(d) Rule Litig. - MDL No. 1993*), 709 F.3d 1, 9 (D.C. Cir. 2013).

[80] *See* 85 Fed. Reg. at 15,398.

procedures outlined in the proposed rulemaking conflict with the statutes that EPA administers, or their implementing regulations, the statutes and regulations will control."[81] However, as discussed below, EPA lacks the statutory authority to issue a rule this broad, even when it claims that it will avoid statutory conflicts.

EPA Improperly Relies upon the General Rulemaking Authority Granted by Environmental Statutes as a Basis for the Supplemental Notice

EPA attempts to support the Supplemental Notice, in part, with the same environmental statutes that require it to consider the best available science. For example, in the Proposed Rule, EPA cites section 103 of the Clean Air Act, which provides that the Administrator shall "conduct . . . research . . . and studies relating to the causes, effects (including health and welfare effects), extent, prevention, and control of air pollution" and is authorized to "collect and make available . . . the results of and other information . . . pertaining to such research and other activities."[82] EPA also cites CAA section 301(a), which provides that the Administrator is authorized to "prescribe such regulations as are *necessary*" to carry out EPA's functions under the Act.[83] EPA points to similar provisions for all major environmental statutes, each of which contain the same requirement that regulations promulgated under the Administrator's general rulemaking authority must be necessary.[84]

Courts have consistently "decline[d] to read open-ended power" into general statutory grants of rulemaking authority, such as CAA section 301(a).[85] Rather, the authority imparted by such provisions is limited to actions that are necessary and appropriate for enforcing and carrying out the specific statutory mandates enacted by Congress.[86] In the case of the CAA, this means that any rule promulgated under the authority of section 301(a) must be connected back to the actual purpose and goals of the Act—to protect and enhance public health and welfare through air pollution prevention.[87] Although EPA relies on such grants of general rulemaking authority, it

---

[81] *See id.*

[82] 42 U.S.C. §§ 7403(a)(1), (b)(1); *see also* Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768, 18769 (April 30, 2018) (Proposed Rule).

[83] 42 U.S.C. § 7601(a) (emphasis added).

[84] *See* 83 Fed. Reg. at 18,769 (invoking, in addition to CAA sections 103 and 301, Clean Water Act sections 104 and 501; Safe Drinking Water Act sections 1442 and 1450(a)(1); Resource Conservation and Recovery Act sections 2002(a)(1) and 7009; Comprehensive Environmental Response, Compensation, and Liability Act sections 115 and 311; Emergency Planning and Community Right-to-Know Act section 320; Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1) and 136r(a); and Toxic Substances Control Act section 10); 85 Fed. Reg. at 15,397 (clarifying that EPA relies upon RCRA section 8001 instead of section 7009; CERCLA section 115 instead of section 116; and adding CWA section 501 as an additional source of authority).

[85] *See Nat. Res. Def. Council v. Reilly*, 976 F.2d 36, 41 (D.C. Cir. 1992).

[86] *Global Van Lines, Inc. v. Interstate Commerce Comm'n*, 714 F.2d 1290, 1295 (5th Cir. 1983).

[87] *See* 42 U.S.C. § 7401(b)(1)–(4), (b)(c).

fails to articulate any connection between the Strengthening Transparency in Regulatory Science Rule and the purposes or goals of each individual substantive statute.

EPA fails to—and indeed cannot—demonstrate that the Strengthening Transparency in Regulatory Science rule is both necessary and appropriate for carrying out a particular statutory directive. As discussed in detail above, the rule is not only unnecessary to carry out EPA's functions, but also in direct opposition to a number of specific statutory "quality of information" provisions. It is well established that agencies may not rely on general statutory grants of rulemaking authority to promulgate regulations that are inconsistent with more specific statutory directives.[88]

Even if the Strengthening Transparency in Regulatory Science Rule Fell Within the Scope of EPA's Housekeeping Authority, EPA Cannot use This Authority to Override Specific Statutory Directives

Just as EPA cannot base the Supplemental Notice on the general rulemaking authority granted by environmental statutes, it also cannot justify its action on the authority, if any, granted under 5 U.S.C. § 301. First, as detailed above, the Housekeeping Statute likely does not apply to EPA. Further, even assuming that it does apply, the authority granted by the Housekeeping Statute is not broad enough to override EPA's specific environmental statutory directives. Simply put, the EPA cannot use the guise of an internal procedural rule—which this rule clearly is not[89]—to contravene explicit quality of information provisions in the substantive environmental statutes the agency is responsible for administering.

The Housekeeping Statute is "simply a grant of authority to the agency to regulate its own affairs."[90] The statute does not provide a general, independent basis for deviating from a specific statutory mandate or limiting the scope of other provisions. Where the SDWA, for example, requires EPA to consider the "best available, peer-reviewed science," EPA cannot use this rule to effectively alter the statutory text to require the best, *publicly available*, peer-reviewed science.[91] Thus, even if the Proposed Rule were limited to regulation of internal agency procedures, which it is not, EPA cannot use such housekeeping as a pretext for modifying the statutory provisions requiring consideration of the best available science.

EPA must base its decisions on such criteria as the latest scientific knowledge, the best available, peer-reviewed science, and/or generally accepted scientific principles or laboratory tests. Neither the environmental statutes nor the federal Housekeeping Statute suggests that EPA, in deciding how it will handle scientific information, can reject or attribute lesser weight to

---

[88] *Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1063-64 (D.C. Cir. 2014); *see also Global Van Lines*, 714 F.2d at 1293-97.

[89] *See supra*, pgs. 9–13.

[90] *Chrysler Corp. v. Brown*, 441 U.S. 281, 308-12 (1979).

[91] *See* 42 U.S.C. § 300g-1(b)(3)(A)(i).

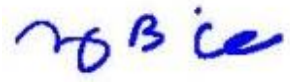
scientific evidence that otherwise meets those criteria solely because the underlying data are not publicly available. EPA's Proposed Rule both lacks sufficient legal authority and unlawfully contradicts the environmental statutes that the Agency is tasked with implementing.

CONCLUSION

The ATS appreciates the opportunity to comment on the proposed supplement rule. The scientific community already has implemented a wide range of policies to ensure greater sharing of scientific data. Clinical trials must be registered in a public registry (e.g., clinicaltrials.gov). Many de-identified datasets are placed in data repositories. Further, many academic journals, including those of the American Thoracic Society, require authors to include a data disclosure plan with their manuscript submission. The proposed supplemental rule fails to identify why these current and ongoing efforts to maximize transparency, insomuch as is legally possible, is not sufficient for EPA to meet their statutory obligations to utilize the best available science in carrying out the mission of the Agency. It also continues to fail to explain how the practical and legal limitations of full data disclosure of sensitive information is remedied by the proposed tiered access plan and exacerbates all of these problems by giving sole authority to the Administrator to determine when and how these new rules would apply.

The proposed rule is fundamentally flawed, provides insufficient consideration of how the proposal would be implemented and rests on questionable statutory authority. We strongly urge EPA to withdraw the proposal.

Sincerely,



Mary B. Rice, MD
Chair, ATS Environmental Health Policy Committee

Kevin Cromar, PhD
Vice Chair, ATS Environmental Health Policy Committee

We help the world breathe®
PULMONARY · CRITICAL CARE · SLEEP
1150 18th Street, N.W., Suite 300
Washington, D.C. 20036 U.S.
T. 202-296-9770 F. 202-296-9776 | thoracic.org