COLUMBIA LAW SCHOOL

SABIN CENTER FOR CLIMATE CHANGE LAW

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

Re: Supplemental Notice of Proposed Rulemaking Regarding EPA's Proposed Strengthening Transparency in Regulatory Science Rule (Docket ID No. EPA-HQ-OA-2018-0259)

To Whom It May Concern:

The Climate Science Legal Defense Fund ("CSLDF") and Sabin Center for Climate Change Law ("Sabin Center") submit these comments in response to the Supplemental Notice of Proposed Rulemaking ("2020 SNPRM") issued by the Environmental Protection Agency ("EPA" or "Agency") on March 18, 2020, in relation to the proposed rule titled "Strengthening Transparency in Regulatory Science" ("Proposed Rule").[1] In the 2020 SNPRM, EPA proposes significant changes to the original version of the Proposed Rule published on April 30, 2018 ("2018 Proposed Rule").[2]

CSLDF submitted comments opposing the 2018 Proposed Rule on August 16, 2018.[3] CSLDF explained that adoption of the 2018 Proposed Rule would impair EPA's ability to establish important public health safeguards and cause significant harm to public health researchers, and the scientific endeavor more generally. Despite that, however, EPA is now proposing to adopt an expanded version of the Proposed Rule that would be even more damaging. CSLDF and the Sabin Center strongly oppose the proposal and, as explained further below, assert:

- EPA has failed to provide any convincing justification for the Proposed Rule, which

[1] Strengthening Transparency in Regulatory Science, Supplemental Notice of Proposed Rulemaking, 85 Fed. Reg. 15396 (Mar. 18, 2020) [hereinafter "2020 SNPRM"].
[2] Strengthening Transparency in Regulatory Science, Proposed Rule, 83 Fed. Reg. 18768 (Apr. 30, 2018) [hereinafter "2018 Notice"].
[3] Letter from CSLDF to EPA Re: Comments of the Climate Science Legal Defense Fund on EPA's Proposed "Strengthening Transparency in Regulatory Science" Rule, 83 Fed. Reg. 18,768 (April 30, 2018), Docket ID No. EPA-HQ-OA-2018-0259 (Aug. 16, 2018) [hereinafter "CSLDF Comments"].

represents a dramatic change in the Agency's longstanding policy regarding the use of scientific studies.

- The 2020 SNPRM not only fails to address concerns about the impact of the Proposed Rule on EPA decision-making and scientific research, but compounds them by significantly expanding its scope.

- Even with the changes proposed in the 2020 SNPRM, the Proposed Rule will result in significant amounts of valid and relevant science being excluded from Agency decision-making.

- The 2020 SNPRM still gives the Administrator unfettered discretion to create exceptions to the Proposed Rule, raising significant concerns about bias and subjectivity in its application.

- The Proposed Rule (both in its original form and as amended in the 2020 SNPRM) is not merely an internal rule of agency procedure, but rather a substantive rule binding on outside parties, and is therefore not authorized under the Federal Housekeeping Statute.

For these reasons, the Sabin Center and CSLDF submit that adoption of the proposed rule would exceed EPA's statutory authority, and be arbitrary and capricious in violation of the Administrative Procedure Act ("APA").

I. EPA Has Still Not Adequately Justified the Proposed Rule

In its Notice announcing the 2018 Proposed Rule, EPA claimed that it is needed to ensure the validity of the scientific information relied upon by the Agency, and enhance the transparency of regulatory processes.[4] While the earlier comments submitted by CSLDF and others clearly show that is not the case, EPA has doubled-down on its claim, but again offered no evidence to support it.[5]

It is well established that agency actions must be based on a consideration of relevant evidence and accompanied by a clear statement of how that evidence supports the action taken.[6] As the Supreme Court explained in *Federal Commissions Commission v. Fox Television Stations, Inc.*, an agency must supply "good reasons" for reversing a previously held position.[7] Those reasons must be especially compelling where, as here, the agency's new position "rests on factual

[4] 2018 Notice, *supra* note 2, at 18769.
[5] *See e.g.,* 2020 SNPRM, *supra* note 1, at 15340 (discussing the need for "reanalysis" of data underlying scientific research).
[6] Motor Vehicle Mfrs. Ass'n. v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 43 (1983) (an agency must "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made). *See also* Fed. Commc'n Comm'n v. Fox Television Stations, Inc., 556 U.S. 502, 513 (2009) (an agency must "examine the relevant data and articulate a satisfactory explanation for its action").
[7] Fox Television Stations, Inc., 566 U.S. at 515.

findings that contradict its prior policy."[8] In such cases, the agency must provide "a more detailed justification than what would suffice for a new policy created on a blank slate," including a "reasoned explanation" for disregarding the facts and circumstances on which its prior policy was based.[9] In the absence of such an explanation, the agency's action must be considered arbitrary and capricious in violation of the APA.

EPA has not provided any justification for its newfound view that the validity of scientific research can only be assessed if the underlying data are disclosed.[10] That view is at odds with the widespread consensus within the scientific community that existing peer review processes, which do not require data disclosure, are sufficient to ensure the validity of scientific research.[11] Recognizing this, in 2016 EPA concluded that the availability of underlying data "does not affect the validity of the scientific conclusions from peer-reviewed research publications."[12] Now, less than four years later, EPA has suddenly changed its view. Neither the 2018 Notice nor the 2020 SNPRM acknowledge the change, much less provide a reasoned explanation for it.[13]

In the 2020 SNPRM, EPA baldly asserts that the Proposed Rule is needed to ensure agency practices are consistent with new guidance from the Office of Management and Budget ("OMB"), but does not explain why.[14] Nor could it, since the referenced guidance—an April 2019 *Memorandum on Improving Implementation of the Information Quality Act*[15]—does not require EPA to adopt the Proposed Rule or even support its stated reasons for doing so. Indeed, whereas EPA claims that access to underlying data is needed to ensure the validity of scientific

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[8] *Id*.

[9] *Id*. at 515-516. *See also* U.S. Sugar Corp. v. Envtl. Prot. Agency, 830 F.3d 579, 626 (D.C. Cir. 2016) (when an agency reverses a previous policy and "its new policy rests upon factual findings that contradict those which underlay its prior policy," it must "provide a more substantial explanation or reason . . . than [would be required] for any other action").

[10] This was recognized by EPA's Science Advisory Board in its review of the Proposed Rule. *See* Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Rule titled Strengthening Transparency in Regulatory Science 18 (2020), https://perma.cc/D34M-979N [hereinafter "SAB Review"] (EPA has not adequately explained "why existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate, and how the Proposed Rule will improve transparency and the scientific integrity of the regulatory outcomes").

[11] Jeremy Berg et al., Joint Statement on EPA Proposed Rule and Public Availability of Data, 360 Science (May 4, 2018), https://science.sciencemag.org/content/360/6388/eaau0116. This view is also shared by the Office of Management and Budget. *See* Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8454 (Feb. 22, 2002) [hereinafter "OMB Guidelines"] ("[W]e regard technical information that has been subjected to formal, independent, external peer review as presumptively objective").

[12] EPA, Plan to Increase Access to Results of EPA-Funded Research 4-5 (2016), https://www.epa.gov/open/plan-increase-access-results-epa-funded-scientific-research.

[13] As discussed in Part III *infra*, EPA has implied that it has not previously had a coherent policy with respect to the use of scientific studies, but that is not the case. EPA's approach is similar to that at issue in Physicians for Social Responsibility v. Wheeler, wherein the D.C. Circuit Court of Appeals held the agency had acted arbitrarily, including because it failed to adequately explain its change in position. *See* Physicians for Social Responsibility v. Wheeler, 2020 U.S. App. LEXIS 12727 (D.C. Cir. 2020).

[14] 2020 SNPRM, *supra* note 1, at 15399.

[15] OMB, Memorandum for the Heads of Executive Departments and Agencies re: Improving Implementation of the Information Quality At (M-19-15) (Apr. 24, 2019), https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf.

research, the memorandum indicates that this can be achieved through peer review.[16]

EPA also points to OMB's 2002 *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*[17] but, again, they do not support adoption of the Proposed Rule. While the Guidelines do call for increased transparency in science, they also recognize that transparency does not necessarily require disclosure of the data underlying research studies, and that such disclosure can raise ethical and/or other issues.[18] The Guidelines thus require agencies to adopt an approach that balances the need for transparency against "other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections."[19] Rather than attempt such a balance, EPA has declared a blanket standard, under which it must ignore or give lesser weight to studies for which the underlying data are not available, even if those studies have been independently verified (e.g., through peer review) and the researchers have valid reasons for withholding the underlying data. This is discussed further in Part II(B) below.

While EPA has provided no valid scientific, legal, or policy basis for its proposed shift in policy, the 2020 SNPRM does allude to one reason the Agency may be adopting the Proposed Rule, namely to allow it to ignore sound science when politically expedient. The 2020 SNPRM makes clear that the data disclosure requirements in the 2020 SNPRM "allow stakeholders to reanalyze the data and models and explore the sensitivity of the conclusions to alternative assumptions."[20] In other words, the Proposed Rule would make it easier for outside parties to cast doubt on peer-reviewed science. Similarly, EPA's statement that the Proposed Rule does not "require that EPA, a member of the public or other entity must independently validate a study before it can be considered"[21] indicates that the Proposed Rule would not improve the quality of the scientific information relied upon by EPA by ensuring it is independently verified, but would instead advance tactics used by industry to avoid regulation.[22]

II. The 2020 SNPRM Compounds, Rather than Addresses, Problems with the Proposed Rule

A. The 2020 SNPRM Unacceptably Expands the Scope of the Proposed Rule

CSLDF and many other commenters expressed alarm at the potential breadth of the 2018

[16] *Id*. at 4 (peer review is an "importan[t] . . . tool for determining fitness of scientific information for policy purposes").
[17] OMB Guidelines, *supra* note 11.
[18] *Id*. at 8460 ("With regard to original and supporting data [underlying scientific research], agency guidelines shall not require all disseminated data be subjected to a reproducibility requirement. Agencies may identify . . . those particular types of data that can practicable [sic] be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints"). See also id. at 8455-8456 ("Agencies are encouraged to address ethical, feasibility, and confidentiality issues with care . . . 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").
[19] *Id*. *See also id*. at 8453 (indicating that "agencies must apply these standards flexibly, and in a manner appropriate to the nature and timeliness of the information" at issue).
[20] 2020 SNPRM, *supra* note 1, at 15399.
[21] *Id*. at 15403.
[22] *See generally*, Naomi Oreskes & Erik M. Conway, Merchants of Doubt (2010).

Proposed Rule. Unfortunately, the amendments proposed in the 2020 SNPRM not only do not address those concerns, but in fact heighten them.

The 2018 Proposed Rule applied only to dose-response data and models underlying pivotal regulatory science that is used to justify significant regulatory decisions. EPA is now proposing to expand the scope of the Proposed Rule in two ways:

1. the Proposed Rule would apply not only to the science relied upon in promulgating significant regulatory decisions, but also in finalizing influential scientific information; and

2. the Proposed Rule would apply to all data and models underlying such science, instead of only dose-response data and models.

EPA offers no explanation for the first change. With respect to the second, EPA asserts that "[t]ransparency of EPA's science should not be limited to dose-response data and dose-response models, because other types of data and models will also drive . . . significant regulatory decisions and influential scientific information."[23] However, as discussed in Part I above, EPA has still not explained why its version of "transparency" is necessary or appropriate.

Contrary to EPA's suggestion, the changes proposed in the 2020 SNPRM do not resolve concerns about the application of the Proposed Rule. In response to the 2018 Notice, many commenters expressed concern that "dose-response" and other key terms were not used consistently, leading to uncertainty as to how the Proposed Rule would be applied.[24] Terms like "dose-response" are still not clearly defined and additional unclear terms have been added. For example, as EPA's Science Advisory Board ("SAB") noted in its review of the Proposed Rule, the new requirement that all "data be made available is vague and, as a result, can be interpreted in different ways."[25] We agree with the SAB that greater clarity continues to be needed in the definitions of terms such as "data and models" and "pivotal regulatory science."[26]

EPA's changes also fail to address broader concerns about the effect of the Proposed Rule. All of the same concerns that CSLDF and other commenters expressed with respect to the original version not only continue to apply, but are increased as EPA proposes to broaden rather than narrow the scope of its application. As CSLDF pointed out in its comments on the 2018 Proposed Rule, many of the studies EPA has traditionally relied on in regulating environmental pollutants necessarily involve confidential human health data.[27] Researchers, and the institutions that employ them, have a legal and ethical obligation to protect the privacy of study participants.[28] If enacted, the Proposed Rule—particularly as expanded in the 2020 SNPRM—would make it much more difficult for researchers to fulfill that obligation and credibly promise study participants that their patient information will remain confidential. This could have a serious chilling effect on the conduct of important public health research in the U.S. Privacy

[23] 2020 SNPRM, *supra* note 1, at 15399-400.
[24] *Id*.
[25] SAB Review, *supra* note 10, at 4.
[26] *Id*. at 5.
[27] *See generally*, CSLDF Comments, *supra* note 3, at 2-3.
[28] *Id*.

concerns would almost certainly hamper such research.[29] Critical lines of scientific inquiry that would have been pursued may not be and the quality of data that is obtained may be poorer than it otherwise would have been.

B. EPA's Tiered Access and Weighted Consideration Options Will Result in Valid Science Being Excluded from EPA Decisions

The 2020 SNPRM acknowledges that, in response to the 2018 Notice, EPA "received a large number of comments stating that [its] approach . . . would likely preclude the use of valid data and models" that cannot be made public because they contain confidential and/or otherwise restricted information.[30] In a purported attempt to address those concerns, EPA is now proposing two alternative approaches, which would allow for limited Agency consideration of studies whose data or models contain restricted information.[31] Both approaches are, however, seriously flawed.

Option 1—under which EPA would consider studies if there is tiered access to restricted data—will not prevent important and relevant scientific information from being disregarded. As scientists discussing the feasibility and usefulness of a tiered or controlled-access approach have pointed out, "controlled access does not permit researchers to curtail national legal and ethical policies on privacy and data protection."[32] While EPA seems to suggest that in many instances privacy issues can be sufficiently addressed through de-identification,[33] EPA's own SAB has concluded that "even de-identified datasets present risks of re-identification."[34] As such, there are some circumstances where scientists simply cannot share data, even if they promise only to share it with a select group of people through a tiered access regime. Even under Option 1, then, EPA would still be forced to disregard large amounts of valuable scientific information where a tiered or controlled-access approach is not legally or ethically permitted.

Even where a tiered or controlled-access approach is theoretically possible, there may be valid practical reasons why such an approach cannot be adopted. There is an ongoing debate among scientists about the utility of tiered access models for human health data and how they can and should work.[35] Some researchers and organizations have indeed begun to use this kind of

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[29] *See* Will Thomas, *Science Committee Renews Scrutiny of EPA Science Transparency Rule*, American Institute of Physics Bulletin, Nov. 20, 2019 (citing a physician representing the American Thoracic Society who suggested the rule could have a chilling effect on individuals' willingness to participate in epidemiological studies).

[30] 2020 SNPRM, *supra* note 1, at 15401-02.

[31] *Id*. at 15402.

[32] Yann Joly et al., *Are Data Sharing and Privacy Protection Mutually Exclusive*, 167 CELL 1150, 1151 (2016). *See also* SAB Review, *supra* note 10, at 10 ("If the participants [in a study] agreed to grant only a select group of researchers access to their personal information, then that consideration should be respected, and such information should not be supplied to additional people for validation. It would probably be impractical, to go back to the participants and request their approval to provide additional people access to personal information").

[33] 2020 SNPRM, *supra* note 1, at 15402.

[34] SAB Review, *supra* note 10, at 9, n.11.

[35] *See* Stefanie Broes et al., *Towards a Tiered Model to Share Clinical Trial Data and Samples in Precision Oncology*, FRONTIERS IN MEDICINE (2018).

approach.[36] However, there is still considerable resistance to tiered access in the scientific community and it has been far from universally adopted, in no small part because of the additional administrative burdens imposed by the tiered-access agreements.[37] There is no indication in the 2020 SNPRM that EPA has considered those burdens or possible approaches for managing them.

The language in the 2020 SNPRM also raises questions about whether EPA is proposing to consider studies where participants and researchers have agreed from the outset to a tiered-access approach, or whether the agency is proposing to itself provide tiered access to certain confidential data, even where researchers and study participants have not agreed to such sharing at the outset. Following a discussion of tiered-access, EPA states that "access to underlying data and models that include [personally identifiable information] for the subset of studies that could be considered pivotal science, may be limited to authorized officials and researchers and not provided to the general public."[38] There is no discussion whatsoever regarding who at EPA would make decisions about when access to data should be limited or how, or how EPA would manage the potentially significant additional capacity necessary to make and execute such decisions. Additionally, and more importantly, even an unambiguous tiered access system would not address the fundamental underlying problem: there are situations in which researchers simply cannot make data available, even if they or EPA agree only to share that data with a select group of people.

EPA's Option 2—under which the Agency might consider studies where the underlying data have not been made public but give them less weight—is equally problematic. As discussed in Part I above, EPA has not explained why such studies are inherently unreliable, and thus should be given less weight. To unfairly downgrade some valid and relevant studies without any apparent rationale or specified procedure is arbitrary and capricious in violation of the APA.

As well as being illegal, Option 2 is also unworkable. The language in the Proposed Rule—requiring EPA to give greater consideration to studies "where the underlying data and models are available in a manner sufficient for independent validation"—is inherently vague and open to interpretation.[39] EPA has not provided any information about who will determine whether underlying data and models are available in a "sufficient" manner when, as already discussed and as EPA itself has pointed out, data are sometimes available in a graduated or tiered manner (i.e., data availability exists on a spectrum). Nor has EPA discussed any parameters for making these decisions, or how it will create the necessary infrastructure or capacity to handle such decisions in a timely manner.

The SAB raised similar concerns in its report on the Proposed Rule, noting that the requirement to make data available is unclear, "mak[ing] it difficult to understand the implications of the

[36] *See* Yann Joly et al., *Data Sharing in the Post-Genomic World: The Experience of the International Cancer Genome Consortium (ICGC) Data Access Compliance Office (DACO)*, 8 PLOS COMPUTATIONAL BIOLOGY (2012).
[37] *See generally*, *id*.
[38] 2020 SNPRM, *supra* note 1, at 15043.
[39] *See surpa* Part II(A).

requirement."[40] According to the SAB, depending on how the requirement is interpreted, compliance with it could "be enormously expensive and time consuming."[41] Indeed, the SAB goes so far as to suggest that EPA may have to establish an office on data sharing, or peer review panel or working group to implement the requirement.[42] We share this view. Implementing Option 2 would require so much additional complex review before important agency rulemakings and other actions could be accomplished that a significant and deeply problematic regulatory bottleneck is easily foreseeable. Again, EPA has offered no indication that it has considered these problems nor how it plans to develop the necessary internal infrastructure or capacity to deal with them.

C. Retroactive Application of the Proposed Rule is Unlawful and Inappropriate

In the 2020 SNPRM, EPA suggests that the Proposed Rule may be applied not only to data and models generated after its effective date, but also retroactively to pre-existing data and models.[43] That is both unlawful and inappropriate.

The Supreme Court has made clear that "[r]etroactivity is not favored in the law."[44] Thus, as the Court held in *Bowen v. Georgetown University Hospital*, "a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms."[45] As discussed in Part III below, EPA is purporting to adopt the Proposed Rule under the Federal Housekeeping Statute, which does not expressly authorize retroactive rules.

As well as being unlawful, retroactive application of the Proposed Rule would also have serious, negative impacts. Applying the Proposed Rule retroactively could undermine the scientific bases supporting many of our most important environmental protection programs.[46] Retroactive application would mean that when EPA is, for example, conducting a review of National Ambient Air Quality Standards or considering modifying the list of Hazardous Air Pollutants pursuant to the Clean Air Act, or reviewing Water Quality Standards under the Clean Water Act, it could refuse to consider valid, peer-reviewed epidemiological studies that have supported existing standards if all the underlying data in those studies has not been made public.[47] This could potentially decimate many of the existing pollution standards that unquestionably protect both the environment and human health.

Retroactive application of the Proposed Rule is particularly inappropriate given that, in many cases, there will be valid reasons why the data underlying historic studies cannot be made

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[40] SAB Review, *supra* note 10, at 8.
[41] *Id*.
[42] *Id*. at 5.
[43] 2020 SNPRM, *supra* note 1, at 15399 ("This proposal would apply to reviews of data, models, and studies at the time a rule is developed or influential scientific information is finalized, regardless of when the data and models were generated.").
[44] Bowen v. Georgetown University Hospital, 488 U.S. 204, 208 (1988).
[45] *Id*.
[46] *See generally*, CSLDF Comments, *supra* note 3, at 3.
[47] *Id*.

public. In this regard, the SAB has noted that the underlying data "may have been discarded if they were deemed not necessary to maintain" and, even if they still exist, "the researchers may no longer be alive or in a position to assemble the data."[48] As the SAB also notes, data assembly is time consuming and labor intensive.[49] It is unclear whether EPA would perform the necessary work itself or require researchers to do it. Either way, regulatory decision-making would be delayed, and scientific research hampered.

D. The Proposed Rule Gives the Administrator Unfettered Discretion to Determine Whether Scientific Studies Should be Considered

Despite some purported clarifications in the 2020 SNPRM, the Proposed Rule still gives the Administrator extremely broad discretion to determine when it should or should not be applied.[50] As discussed in CSLDF's previous comments, this could allow arbitrary application of the Proposed Rule to block consideration of studies that support regulation where the Agency does not wish to impose it for political reasons.[51] Conversely, it could allow the Administrator to arbitrarily find that compliance with the rule is impracticable when transparency is not in industry's interest.[52]

Yet again these concerns have been echoed by the SAB. In its report on the Proposed Rule, the SAB noted the lack of any specific criteria for granting exemptions, and indicated that this "may create concerns about inappropriate exclusion of scientifically important studies."[53] Moreover, according to the SAB, "exclusion of segments of the scientific literature, with the possibility of inclusion of other selected information without pre-defined criteria, could allow systematic bias to be introduced with no easy remedy."[54]

III. EPA Lacks Legal Authority to Adopt the Proposed Rule

In addition to being unsupported and unjustified, the Proposed Rule also lacks any statutory basis. Administrative agencies, such as EPA, have only the power conferred on them by Congress.[55] Agencies may, therefore, only adopt regulations where authorized to do so by Congressional statute.[56] In the 2020 SNPRM, EPA claims that the Proposed Rule is authorized under the Federal Housekeeping Statute[57] but, as the Agency itself recognizes, that statute only authorizes the adoption of procedural rules governing agencies' internal affairs.[58] The Proposed Rule goes beyond this, regulating the conduct of outside parties, and thus amounts to a

[48] SAB Review, *supra* note 10, at 5 and 8.
[49] *Id*. at 17.
[50] 2020 SNPRM, *supra* note 1, at 15403.
[51] CSLDF Comments, *supra* note 3, at 12.
[52] *Id*.
[53] SAB Review, *supra* note 10, at 16.
[54] *Id*.
[55] Louisiana Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 371 (1986) ("[A]n agency literally has no power to act . . . unless and until Congress confers power upon it").
[56] Am. Library Ass'n v. FCC, 406 F.3d 689, 691 (D.C. Cir. 2005) ("It is axiomatic that administrative agencies may issue regulations only pursuant to authority delegated to them by Congress").
[57] 5 U.S.C. § 301.
[58] 2020 SNPRM, *supra* note 1, at 15397.

substantive rule, which the courts have repeatedly held cannot be adopted under the Federal Housekeeping Statute.[59]

The courts have interpreted the Federal Housekeeping Statute as a "narrow" grant of authority to agencies to deal with internal "housekeeping" matters.[60] In *Chrysler Corp. v. Brown*, the Supreme Court held that the Federal Housekeeping Statute "authoriz[es] what the APA terms rules of agency organization, procedure or practice as opposed to substantive rules."[61] The court defined "substantive rules" as those that "affect[] individual rights and obligations."[62] Building on that definition, in *American Hospital Association v. Bowen*, the U.S. Court of Appeals for the District of Columbia Circuit ("D.C. Circuit") identified several key features of substantive rules.[63] According to the court, substantive rules typically establish binding standards that create rights, impose obligations, or otherwise "significantly impact" private interests, for example, by "put[ting] a stamp of [agency] approval or disapproval on a given type of behavior."[64]

Contrary to EPA's claim, the Proposed Rule is not merely an "internal rule of agency procedure,"[65] but rather a substantive rule, which binds parties outside the Agency. In this regard, we note that the Proposed Rule is similar to EPA's 2001 directive banning agency consideration of third-party human studies ("2001 Directive"), which was held to be a substantive rule in Croplife America v. EPA ("Croplife").[66] In that case, the D.C. Circuit reasoned that the 2001 Directive used "clear and unequivocal language," stating that EPA "will not consider . . . any human studies in its regulatory decision-making."[67] Based on that language, the court concluded that the 2001 Directive bound both EPA and third parties, who were "concretely injured" because they could no longer rely on human studies that had previously been accepted by the Agency.[68] Similarly, the Proposed Rule mandates that EPA "will only use," or under the alternative proposal "will . . . give greater consideration to," studies for which the underlying data are available. As such, the Proposed Rule will prevent or severely impede third parties from relying on other studies, previously accepted by EPA. Those parties are bound by the Proposed Rule, which "put[s] a stamp of . . . disapproval" on their reliance on certain

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[59] *See e.g.,* Chrysler Corp v. Brown, 441 U.S. 281 (1979)
[60] Tafas v. Doll, 559 F.3d 1345, 1365 (1st Cir. 2009) (Bryson J., concurring).
[61] Chrysler Corp., 441 U.S. at 310.
[62] *Id*. at 302.
[63] Am. Hosp. Ass'n v. Bowen, 834 F.2d 1037 (D.C. Cir. 1987).
[64] *Id*. at 1045 & 1047 ("Substantive rules are ones which grant rights, impose obligations, or produce other significant effects on private interests." As such, in determining whether a rule is substantive, the courts look at whether it "has a substantial impact on parties" and, "more broadly, whether . . . [it] encodes a substantive value judgement or puts a stamp of approval or disapproval on a given type of behavior"). See also id. at 1046 (A "substantive rule establishes a standard of conduct which has the force of law in subsequent proceedings") (internal citations omitted)). *Cf*. Chamber of Commerce of the U.S. v. U.S. Dep't of Labor, 174 F.3d 206, 212 (D.C. Cir. 1999) ("Substantive rules are ones which grant rights, impose obligations, or produce other significant effects on private interests . . . [W]hether a rule has the force of law often will bear upon its proper classification as substantive or procedural," but "will not necessarily be controlling").
[65] 2020 SNPRM, *supra* note 1, at 15398.
[66] 329 F.3d 876 (D.C. Cir. 2003).
[67] *Id*. at 881.
[68] *Id*. at 883-884.

studies, thus significantly affecting their interests.

Given the above, EPA's characterization of the Proposed Rule as non-binding[69] is plainly incorrect, and does not undo its substantive effect. EPA points to dicta from *U.S. v. Manafort*[70] to argue that its characterization of the Proposed Rule is determinative.[71] However, as the D.C. Circuit held in *Croplife*, "an agency's characterization of its own action is not controlling if it self-servingly disclaims any intention to create a binding rule with the force of law, but the record indicates otherwise."[72] Here, the record makes clear that the Proposed Rule "impose[s] requirements," which are expressed in mandatory terms.[73] The Proposed Rule thus leaves EPA and third parties with no choice in how to deal with scientific studies.[74]

By preventing the use of studies for which the underlying data are not available, the Proposed Rule reverses long-standing EPA policy, which further indicates that it is a substantive rule not authorized under the Federal Housekeeping Statute. Indeed, in *Alcarez v. Block*, the U.S. Court of Appeals for the Ninth Circuit held that a key feature of substantive rules is that they "create[] new" or "change existing law or policy."[75] EPA implies that it has not previously had a coherent, existing policy regarding the use of scientific studies,[76] but that is not the case. For at least the last two decades, EPA has consistently relied on studies for which the underlying data are not available, and repeatedly rejected claims that it cannot or should not do so.[77] As far back as 1997, EPA concluded that it was "impractical and unnecessary" to exclude such studies from its review and that doing so "would make it extremely difficult, if not impossible, for EPA to regulate in complex technical areas at the forefront of science."[78] EPA reiterated that view in 2016 and affirmed that it would continue to rely on all relevant studies (i.e., regardless of the availability of the underlying data).[79] The Proposed Rule effects a sudden and, as discussed in Part I above,

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[69] *See e.g.,* 2020 SNPRM, *supra* note 1, at 15398.
[70] 212 F. Supp. 3d 60 (D.D.C. 2018).
[71] 2020 SNPRM, *supra* note 1, at footnote 4.
[72] Croplife, 329 F.3d at 883.
[73] 2018 Notice, *supra* note 2, at 18771. *See also* 2020 SNPRM, *supra* note 1, at 15404-15406.
[74] While the 2020 Proposed Rule provides for the granting of exemptions, allowing use of non-public studies, that does not render it non-binding. *See generally*, Croplife, 328 F.3d at 881 (rejecting EPA's argument that the 2001 Directive is not binding because it allows consideration of human test data if the agency is "legally required" to rely on such data).
[75] Alcaraz v. Block, 746 F.2d 593, 613 (9th Cir. 1984). *See also* Bowen, 834 F.2d at 1045 (substantive rules include those "which effect a change in existing law or policy"); Croplife, 329 F.3d at 885 (the fact that the 2001 Directive "effect[ed] a dramatic change in the agency's established regulatory regime" indicates it is a substantive rule).
[76] *See e.g.,* 2018 Notice, *supra* note 2, at footnote 3 ("Historically, EPA has not consistently observed the policies underlying this proposal").
[77] *See e.g.,* National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 28652, 28689-28694 (July 18, 1997) (EPA is "entitled to rely on . . . studies . . . regardless of the availability of the underlying health data"). EPA's ability to rely on studies for which the underlying data are not publicly available has been affirmed by the courts. *See e.g.,* American Trucking Ass'n v. Envtl. Prot. Agency, 283 F.3d 355 (D.C. Cir. 2002); Coal. of Battery Recyclers Ass'n v. Envtl. Prot. Agency, 604 F.3d 613 (D.C. Cir. 2010).
[78] National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 28652, 28689 & 28692 (July 18, 1997).
[79] House of Representatives, Committee on Agriculture, Hearing to Consider the Impacts of the Environmental Protection Agency's Actions on the Rural Economy, Responses to Submitted Questions

unjustified reversal of that twenty-year policy.

IV. Conclusion

For the reasons discussed above, the Sabin Center and CSLDF strongly oppose adoption of the Proposed Rule, either in its original form or as modified in the 2020 SNPRM. As we have explained, EPA has not provided any convincing justification for the Proposed Rule, which would result in the Agency ignoring or downgrading significant amounts of sound and relevant science in its decision-making. The language in the 2020 SNPRM suggests that EPA is being influenced by inappropriate considerations, such as making it easier for special interests to call science into question. Moreover, in the 2020 SNPRM, EPA has not only failed to address the significant concerns expressed by numerous commenters about the negative effects of the Proposed Rule, but has—again without providing any justification—expanded its scope in a manner that exacerbates these problems. Finally, neither the 2018 Proposed Rule nor the 2020 SNPRM identifies any valid statutory basis for EPA's authority to promulgate the Proposed Rule. Adoption of the Proposed Rule would therefore exceed EPA's statutory authority and be arbitrary and capricious in violation of the APA.[80] We urge EPA not to adopt the Proposed Rule.

Sincerely,

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82 (Sept. 6, 2016) (EPA "does not believe that it is appropriate to refuse to consider published studies in the absence of underlying data. The EPA frequently relies on peer reviewed studies in the public literature without possessing underlying data . . . If the EPA and other governmental agencies could not rely on published studies without conducting independent analyses of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment"). This view is also reflected in several EPA policy documents. *See e.g.,* EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency 21 & 24 (2002), https://www.epa.gov/sites/production/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf (indicating that EPA frequently relies on information where "access to [the underlying] data and models cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections"); EPA Science Policy Council, A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information 7 (2003), https://www.epa.gov/sites/production/files/2015-01/documents/assess2.pdf (noting that, while the accessibility of underlying data is one of several factors to be considered in assessing the quality of scientific information, EPA must also consider whether there are "confidentiality issues that may limit accessibility").

[80] Motor Vehicle Mfrs. Ass'n., 463 U.S. at 43 (holding that an agency action is arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency").