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May 18, 2020

The Honorable Andrew Wheeler
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Comment for supplemental notice of proposed rulemaking, "Strengthening Transparency in Regulatory Science." Docket ID No. EPA-HQ-OA-2018-0259

Dear Administrator Wheeler,

We write to submit comment on the supplemental notice of proposed rulemaking (SNPRM) entitled, "Strengthening Transparency in Regulatory Science." This proposed rulemaking undermines the ability of the Environmental Protection Agency (EPA) to protect human health and the environment and contravenes the Agency's statutory responsibility to use the best available science in promulgating health-protective regulations. For the reasons outlined in this letter, we believe this rulemaking is not only dangerous, but is fundamentally flawed by failing to justify a legitimate purpose beyond arbitrary, political manipulation of the Agency's science-based work. Its legacy lies in the failed *Secret Science Reform* Acts of 2014[1] and 2015[2] and the *Honest and Open New EPA Science Treatment (HONEST) Act of 2017*[3], bills that passed out of the House Committee on Science, Space, and Technology under Republican leadership but that the Senate did not see fit to consider. This attempt to implement the provisions of failed legislation through rulemaking is an inappropriate circumvention of the authorities granted to the executive branch by the Constitution.[4] The executive branch cannot exercise such legislative powers.

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[1] "H.R. 4012 – Secret Science Reform Act of 2014," Congress.gov, February 6, 2014, accessed here: https://www.congress.gov/bill/113th-congress/house-bill/4012
[2] "H.R. 1030 – Secret Science Reform Act of 2015," Congress.gov, February 24, 2015, accessed here: https://www.congress.gov/bill/114th-congress/house-bill/1030
[3] "H.R. 1430 – HONEST Act," Congress.gov, March 8, 2017, accessed here: https://www.congress.gov/bill/115th-congress/house-bill/1430
[4] United States Constitution. Art. I § 1

Below we have outlined a number of questions and concerns that we feel must be addressed before the Agency moves to finalize this rule.

1. EPA is proposing to expand the scope of this rulemaking to apply to influential scientific information as well as significant regulatory actions.

EPA's expansion of the rule to encompass influential scientific information (ISI) as well as significant regulatory actions is disturbing. ISI informs most of the Agency's significant policy decisions. In recent years, scientific products as varied as chemical draft risk evaluations, integrated science assessments, Integrated Risk Information System (IRIS) toxicological reviews, and a scientific assessment of the impact of climate change on human health have all been designated as ISI.[5] These scientific products are the foundation of the Agency's understanding of public health and environmental risk. By imposing arbitrary limitations on the scientific studies that can be considered in the drafting of these products, the rule threatens to undermine the integrity of the scientific analysis being conducted at the very beginning of the Agency's policymaking process.

The SNPRM fails to provide any evidence in support of the idea that making data and models publicly available would improve the quality of ISI in any way. It fails to provide any justification at all for such a sweeping expansion of the scope of the rule, which makes it difficult for the public to assess the extent of the impact that the rule would have on the Agency's ability to consider the best available science. EPA should remove ISI from the scope of the rule. If it insists on maintaining ISI within the scope of the rule, EPA must address why it decided to apply the rule to ISI as well as significant regulatory actions and provide a detailed explanation of the factual evidence that it used to justify its decision.

2. EPA is proposing to expand the scope of this rulemaking to apply to data and models, not only dose-response data and dose-response models.

The vast majority of commenters criticized the original proposed rule for how drastically it would limit EPA's ability to use the best available science in regulatory decisions. However, in the SNPRM, EPA cites "some public comments" in its decision to *expand* the rule beyond the original "dose-response data and models" to a "broader applicability" to all data and models. EPA appears to have cherry-picked the small minority of comments that agree with this misguided effort and used them to justify an expansion of the rule.

EPA cites comments that point out the fact that the terms "data," "models," and the qualifier "dose-response" were used inconsistently throughout the text. To smooth over its sloppy drafting, EPA is broadening all instances to the most expansive possible application of the rule. The Agency lists nine examples of study types that would now fall under this expanded scope,

[5] Environmental Protection Agency, "Science Inventory," viewed April 1, 2020, accessed here: https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm.

including a handful – bioaccumulation data, data on environmental releases, and exposure estimates, to name a few – that would very clearly impact EPA's ability to use public health studies and confidential business information to regulate toxic chemicals in the air and water. EPA seeks to remedy its initial sloppiness – a bad faith, surgical attack on epidemiological research – with a brute force attack on all research that informs the Agency's statutory responsibility to protect the environment and public health. EPA failed to discuss how the broader applicability of the rule would improve the Agency's ability to consider the best available science in rulemaking. The Agency also failed to cite any evidence in support of broader applicability. EPA must justify its decision to expand the rule beyond dose response data and models as a function of the Agency's mission, rather than the imperative to address logical weaknesses in the proposed rule.

3. EPA is expanding the factors the Administrator would consider in determining whether to grant an exemption to the proposed availability requirements for using data and models in significant regulatory decisions and influential scientific information.

Both the proposed rule and the SNPRM offer to grant the EPA Administrator the authority to exempt a study from the requirements imposed by the rule. This is a loophole that would allow the Administrator – a political appointee – to singlehandedly waive the proposed data requirements when they see fit, undermining EPA's justification for the rule in the first place and introducing the potential for politicization of rulemaking by, for example, exempting industry studies reliant on confidential business information (CBI) while excluding public health studies from consideration. The supplemental expands upon this authority by providing further justification for the exemption, noting that a reason to exempt studies might be if they were conducted under different standards, practices, and technological capabilities that might have hindered the collection of underlying data. It is noteworthy that EPA does not propose to give such studies an automatic exemption, though such a process would be easy to establish by simply declining to apply the rule retroactively to any study published before its finalization. Instead, the rule leaves this exemption authority entirely in the hands of a political appointee – in a position that has rarely been occupied by a scientist – who would not possess the training necessary to make these decisions in an objective and informed manner. By placing this exemption authority in the hands of the Administrator, EPA is undercutting its career scientists' ability to use their expertise to inform rulemaking, substituting the whims of a political appointee for the professional, trained judgment of Agency scientists. It is unclear why the Agency felt this addition in any way addressed the public outcry about the inappropriateness of this exemption authority, as expressed in countless public comments on the original rule. The Agency still has not addressed those concerns and must do so. EPA should eliminate the Administrator's exemption and determine clear characteristics that qualify studies for automatic exemptions, such as the date of publication or the use of sensitive PII and CBI. The Agency should define these characteristics as broadly as possible to preserve its ability to consider the best available science.

4. EPA is proposing definitions for the terms "capable of being substantially reproduced," "data," "independent validation," "model," "publicly available," and "reanalyze."

EPA defines "reanalyze" in the SNPRM as "to analyze exactly the same data to see if the same result emerges from the analysis by using the same or different programs and statistical methodologies that were originally used to analyze the data." The proposed definition for "reanalyze" would introduce the risk of data manipulation into the Agency's regulatory process. By naming "different programs and statistical methodologies" as legitimate methods for the reanalysis of a body of data, the Agency would permit external entities with vested interests to deliberately deploy biased methodologies in order to reach different results from the same data. Analyzing data with different methodologies will frequently lead to different results, but the Agency does not explain how the existence of different results would help improve the Agency's policymaking. EPA also lacks any objective means to evaluate the superiority of one methodology over another as a part of the reanalysis process. The proposed definition would therefore result in confusion about how a study should be interpreted and undermine the role of scientific data in the Agency's regulatory process. EPA must clarify why its proposed definition of "reanalyze" permits different methodologies to be used in reanalyzing study data, describe the process that it will utilize to assess divergent methodologies, and justify how the definition is consistent with the Agency's obligation to consider the best available science.

Additionally, the proposed definition for "reanalyze" does not address how EPA would incorporate any completed reanalyses into its policymaking. A number of critical questions remain undiscussed in the SNPRM. Would the Agency be required to consider a reanalysis alongside the original study, or would it pick and choose analyses to consider? Will the Agency publicly explain its decision to incorporate a reanalysis into a work product? How would the Agency compare a reanalysis to the original study? Will a reanalysis be required to go through peer review? If a reanalysis does not undergo peer review, would it receive equal consideration to an original peer-reviewed study, or would the Agency consider the absence of peer review as a factor in determining the value of the reanalysis? Would the Agency be compelled to delay the finalization of a rulemaking until the completion of a relevant reanalysis?

All of these questions represent important practical considerations for the Agency. If the Agency affords equal weight to any non-peer reviewed reanalysis as it does for a peer reviewed study, it calls into question whether Agency rulemakings are truly considering the best available science. This also introduces questions about how EPA is satisfying the Information Quality Act, which requires that all significant regulatory information from federal agencies be peer reviewed, as well as EPA's own information quality guidelines.[6]

Finally, if the Agency intends to synchronize its rulemaking process to the timelines for reanalyses, it must explain how it can do so and still comply with statutory deadlines, given that a reanalysis of a major study may take years to complete. For example, the Health Effects Institute (HEI) initiated its reanalysis of the Harvard Six Cities Study in April 1997 and did not conclude the reanalysis until July 2000.[7] HEI engaged in a lengthy but necessarily exhaustive

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[6] EPA, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," viewed May 4, 2020, accessed here: https://www.epa.gov/sites/production/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf.

[7] Health Effects Institute, "Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality," July 2000, accessed here:

process that encompassed the creation of an expert panel, vetting for conflicts-of-interest, convening a public workshop, developing approaches for accessing and reviewing data, assessing the data, and submitting the reanalysis for peer review. HEI's process provided a model for the scientifically robust reanalysis of a public health study; given the complexity of its task, it was unavoidably costly and time-consuming as well. The SNPRM contends that the opportunity for independent validation of external studies is an important factor in ensuring the credibility of Agency science, but it does not address how Agency rulemaking would facilitate the time and cost considerations that will accompany credible independent efforts to reanalyze scientific data.

The Agency's failure to address these questions creates significant gaps in the rule. The definition of "reanalysis" should be revised to provide clarity on these points.

In the SNPRM, EPA defines "data" as "the set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party." This definition for "data" is so broad that it would make practical implementation of the rule virtually impossible.

An analyzable data set from which only "obvious errors have been removed" would encompass almost all of the raw data generated by scientific researchers over the course of a study. EPA would be obligated to ensure the public availability, in an organized format, of raw temperature data, meteorological data, pollution values, and all of the other vast amounts of raw data that provide the basis for epidemiological studies and other research. A single research study can contain a massive number of large files – hundreds of files for any given study – and require its own unique code simply to maintain the necessary organization. The rule does not explain the logistical methods that EPA would use to process and manage this enormous amount of data, or how the Agency would make it accessible to the public. EPA does not currently possess any internal data storage system capable of performing this task, and the rule does not address how the Agency would develop the additional capacity necessary to comply with its parameters. The rule does not even clarify whether the Agency intends to develop an internal data storage system at all, or whether the Agency would impose data storage obligations on external parties. The proposed definition of data is impractical and demonstrates a lack of understanding about the process of conducting scientific research. EPA should adopt a different definition for data or explain how it will implement the rule according to the proposed one.

5. EPA is proposing that the Agency will only use pivotal science if the data is available in a manner sufficient for independent validation, including, for studies with restricted data and models, if there is tiered access to these data and models.

EPA addresses the limitations to publishing CBI and personally identifiable information (PII) by proposing "tiered access" to the underlying data and models deemed too sensitive to publish. The SNPRM describes tiered access as "creating multiple versions of a single dataset with varying

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https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air.

levels of specificity and protection." This proposal is vague and impracticable. If EPA expects researchers to implement this system, then the Agency is creating enormous new requirements for the research community.

First, this undermines EPA's claim that the rule "would not regulate the conduct or determine the rights of any entity outside the federal government." This would undercut the already dubious notion that this rule falls under the Agency's authority under the Federal Housekeeping Statute. Furthermore, describing such requirements simply as "multiple versions of a single dataset with varying levels of specificity and protection" is excessively vague for such a monumental overhaul of how the Agency considers science in its rulemaking. If the intent is for the researcher to determine the appropriate level of access, who would determine whether a researcher's determined access levels appropriately met the requirements of the rule? Would researchers be expected to review the applications for reanalysis in perpetuity? Has a cost analysis been done to assess the burden this rule would place on researchers and on the institutions hosting the data? What happens if a research team has since disbanded? Does EPA expect researchers in other countries to work with the Agency to manage such a data access system so their studies can be used by the United States government? If EPA intends for the scientific community to adopt – and potentially implement – these dataset and access requirements, it is not offering researchers a meaningful description of the parameters on which they can comment.

The SNPRM references a pilot project with the Centers for Disease Control (CDC) involving a secure data enclave for sensitive EPA datasets. If EPA intends to use CDC resources to implement this rule, the Agency's argument that it is merely an internal procedure matter is far more complicated than stated. Was CDC involved in writing this rule? Do they have the resources to host EPA's data and models and moderate tiered access? Will CDC be making the decision as to who can access the data and at what level? Will CDC be reviewing applications for access? The SNPRM does not address any of these questions. If EPA intends to make its arrangement with the CDC permanent, and establish the CDC as the host of a secure data enclave for studies considered in Agency rulemaking, EPA must clearly articulate its rationale for partnering with a separate federal agency rather than performing the work internally. EPA must also describe how such an unusual arrangement would be structured. It must be clear that the CDC is involved in this rulemaking.

If, instead, the Agency plans on instituting and maintaining a "tiered access" system of its own, a host of implementation questions are unanswered in the text of the supplemental. Where will such a system be housed within the Agency? EPA is not a data management agency – does it have the capability to manage a large amount of sensitive data? Does EPA have a robust cybersecurity strategy? The *Secret Science Reform Act of 2014,* a legislative precursor to this SNPRM, was estimated by the Congressional Budget Office to cost "$250 million annually over the next few years" should it have passed into law[8] – how much will this SNPRM cost, and what

[8] "Congressional Budget Office Cost Estimate – H.R. 1030 Secret Science Reform Act of 2015," Congressional Budget Office, March 11, 2015, accessed here: https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf

money will EPA use to undertake a project of this magnitude that has not been authorized by Congress? Does EPA have staff who are capable of running this system? How many people will EPA need to hire? How will members of the public apply to access the sensitive data? Who at EPA will determine external access to the data, and at what tier? Who at EPA will determine what parts of the datasets belong in each tier of the system? How will this address restrictions put on PII protected by the Health Insurance Portability and Accountability Act, the National Institutes of Health, and Institutional Review Boards, which contain no applicable "tiered access" exemptions from privacy requirements? The Agency's solicitation for public comments on this matter is insufficient given the paucity of details on this proposed solution to the publication limitations of sensitive data.

6. EPA is proposing that, other things being equal, the Agency will give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation.

In addition to the tiered access proposal, EPA offers another vague suggestion for comment – a weighted system for considering studies based on the public availability of the underlying data and models. "Other things being equal" – a nonsensical and arbitrary standard for this nonsensical system – the Agency will choose studies that should be given "greater consideration" and will provide a short explanation of its decision. While EPA presents this as an answer to criticism that important studies will be eliminated from consideration, it in fact elevates the public availability of data to the most important factor in its scientific decision making. All studies go through a rigorous peer review process prior to publication, and as a result, the scientific community does not use the so-called potential for "independent validation" as a metric for quality of a study. Furthermore, EPA is not transparent about what such weighting would mean. Would EPA develop objective metrics to determine when and how "greater consideration" would be given to certain studies, or would decisions be made on a case-by-case basis without any established procedures? Could EPA explain away ignoring a pivotal public health study by simply saying it was given "less consideration," implying that it did in fact inform a problematic new pollution standard? How would the weighting system impact existing weighting metrics used, such as the greater consideration given to human health studies over animal studies in National Ambient Air Quality Standards reviews? While human health studies with the most medical information are currently given the most weight, animal studies will have no data-sharing complications – will the science-based metrics be overturned with a system based entirely on transparency of data?

The text of the SNPRM is similarly vague when it comes to the proposal that the Agency will provide a "short description" of weighting decisions. Who will write this description? Will it be qualitative or quantitative? Will it be based on a standardized rubric or case-by-case? Where will the description be published? Will there be an appeals process?

The SNPRM says this proposal would apply to all data and models regardless of when they were generated, meaning that any and all studies conducted before these data preservation and

publication standards were promulgated could be discounted by the Agency in future rulemakings. The proposal could have radical consequences, but EPA appears to want the public to do the hard work of thinking through its ramifications. Yet the Agency has given the public nothing to evaluate beyond a superficial concept. EPA must provide greater clarity on how such a weighted system would operate in practice, where decision making authority would reside, and what the implications would be for past studies that underpin the Agency's regulatory standards.

7. The EPA is proposing the option of using its housekeeping authority independently as authority for taking this action or in conjunction with the environmental statutory provisions cited as authority in the 2018 proposed rulemaking (as clarified in this supplemental proposal). The Agency continues to consider whether it is appropriate to rely on its authority in the above-referenced environmental statutory provisions (potentially in conjunction with its housekeeping authority). The Agency will consider comments on this issue submitted in response to the 2018 proposal and in response to this SNPRM.

EPA does not possess the legal authority to promulgate this rule. As Members of Congress, we can affirm that Congress has never authorized the Agency to use any "housekeeping authority" in this manner. Furthermore, Congress explicitly rejected the legislative precursors to this rule in the failed Secret Science Reform Acts of 2014 and 2015 and HONEST Act of 2017. In its desperate search for a statutory basis, EPA is attempting to redefine the rule as a procedural matter rather than a change in policy. The federal housekeeping statute was never meant to be used this way, and EPA's verbal sleight-of-hand to justify its use only demonstrates the tenuous nature of the Agency's position.

First, the plain language of the Federal Housekeeping Statute at 5 U.S.C. 301 excludes EPA. The Agency is not one of the 15 Executive Departments listed at 5 U.S.C. 101, which are the Departments explicitly authorized to act pursuant to the Housekeeping Statute.[9] The Agency asserts that it acquired housekeeping authority under the Reorganization Plan of 1970, as determined by the Office of Legal Counsel in a 2008 memorandum opinion.[10] That memorandum opinion was written in response to a narrow question, "whether the [EPA] may hold its employees liable for the negligent loss, damage, or destruction of government personal property or for the unauthorized personal use of agency-issued cell phones", which is in no rational conception related to the action proposed in the SNPRM. Whether the underlying assertion is correct or not, any housekeeping authority possessed by EPA must be narrow and limited in nature, consistent with the Agency's absence from 5 U.S.C. 101 and the language of the Housekeeping Statute itself. Congress established specific criteria for the housekeeping authority in 5 U.S.C. 301, namely that the authority extends to "the government of [the] department, the conduct of its employees, the distribution and performance of its business, and

[9] 5 U.S. Code 101, "Executive Departments," accessed here: https://uscode.house.gov/view.xhtml?req=(title:5%20section:101%20edition:prelim);

[10] "Authority of the Environmental Protection Agency to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property." 32 Op. O.L.C. 79 (2008).

the custody, use, and preservation of its records, paper, and property."[11] This is not catch-all language: it is meant to limit the authority to internal department affairs of a procedural nature, separate from the Agency policymaking process. In other words, the Federal Housekeeping Statute does not provide any authority to enact policies, but merely to manage internal affairs such as record-retention, employee behavior, and property management.

Despite these limitations, EPA is determined to invoke the housekeeping authority for the "Strengthening Transparency" rule because it lacks any other authority. The SNPRM characterizes the rulemaking as "a rule of agency procedure to establish an agency wide approach to handling studies when the data and models underlying EPA's significant regulatory decisions and influential scientific information are publicly available and when those data and models are not publicly available." This characterization contains critical conceptual errors. Most importantly, the phrase "handling studies" is misleading. The rule does not concern how the Agency "handles" scientific studies procedurally; it concerns how the Agency *considers* and *uses* studies in its policymaking process. Additionally, the rule would not create a procedure for an agency wide approach to scientific studies; it would create a new *policy* to categorically change the way certain studies are considered in the regulatory process where no such distinction existed before. EPA seeks to portray a sweeping policy change that would impact every aspect of Agency regulatory activity as a modest procedural change, akin to a change in procedure for record retention or the management of Agency property. Congress never provided any such "housekeeping authority" for this purpose.

EPA's own prior characterizations of the rule undermine its newfound depiction as a mere internal agency procedure. In a press release announcing the proposed rule on April 24, 2018, then-Administrator Scott Pruitt declared "the era of secret science at EPA is coming to an end" because the rule would allow Americans to "assess the legitimacy of the science underpinning EPA decisions that may impact their lives."[12] EPA stated that the proposed rule was "designed to increase transparency in the preparation, identification, and use of science in policymaking."[13] The end of an era, the legitimacy of EPA's science, the use of science in policymaking: these are hardly matters of internal agency procedure. They are fundamental questions about the Agency's policy for the consideration of science in its regulatory process, and they must be governed by the statutory authorities that Congress has enacted for that purpose. EPA cannot claim the authority to implement this policy under the Federal Housekeeping Statute by pretending that the rule is not a sweeping change in policy.

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[11] 5 U.S. Code 301, "Departmental Regulations," accessed here: https://uscode.house.gov/view.xhtml?req=(title:5%20section:301%20edition:prelim).

[12] Environmental Protection Agency, "EPA Administrator Pruitt Proposes Rule To Strengthen Science Used In EPA Regulations," April 24, 2018, accessed here: https://archive.epa.gov/epa/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations.html.

[13] Environmental Protection Agency, "Strengthening Transparency in Regulatory Science," Proposed Rule, Federal Register (83 FR 18768, April 30, 2018), accessed here: https://www.govinfo.gov/content/pkg/FR-2018-04-30/pdf/2018-09078.pdf.

Finally, in regard to the environmental statutory provisions cited in the proposed rule and the SNPRM, we echo the point made by many commenters in response to the proposed rule: Congress has repeatedly mandated that EPA must use the best available science to inform its regulatory process. This is a legal obligation, a clear-cut directive from Congress, and that supersedes any "general authority… to carry out the Agency's functions" under the various environmental statutes.[14]

Conclusion

As Members of the Committee on Science, Space, and Technology, we feel strongly that agencies should never be limited in their ability to consider the best available science in promulgating health-protective regulations and putting out gold-standard assessments. We agree with the members of your handpicked Science Advisory Board that this rule "risks serious and perverse outcomes" and that the Agency has not justified "why existing procedures and norms utilized in 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."[15] We urge you to withdraw this ill-conceived, dangerous proposed rulemaking.

Thank you for your attention to this matter.

Sincerely,

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space, and Technology

Congresswoman Zoe Lofgren

Congresswoman Suzanne Bonamici

Congressman Ami Bera

Congresswoman Mikie Sherrill

Congressman Steve Cohen

Congressman Jerry McNerney

Congressman Ed Perlmutter

Congressman Paul Tonko

Congressman Bill Foster

Congressman Don Beyer

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[14] *Id.*

[15] Letter from the Environmental Protection Agency Science Advisory Board to Administrator Andrew Wheeler, April 24, 2020, accessed here: https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf

Congressman Sean Casten

Congresswoman Jennifer Wexton