

United States Senate

WASHINGTON, DC 20510

May 9, 2018

Administrator Neomi Rao
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Dear Administrator Rao,

We write to express our serious concerns about the Office of Information and Regulatory Affairs' (OIRA) review of the Environmental Protection Agency's (EPA) recent proposed rule on regulatory science, "Strengthening Transparency in Regulatory Science." We seek further information to help us understand and evaluate the process by which the OIRA review was completed.

According to Reginfo.gov, OIRA received the EPA's recent proposed rule, entitled Strengthening Transparency in Regulatory Science, on Thursday, April 19, 2018. EPA Administrator Scott Pruitt publicly announced this proposed rule and signed it three business days later on Tuesday, April 24. Reginfo.gov initially stated that OIRA's review was completed on Wednesday, April 25 – the day after Administrator Pruitt announced and signed the rule. Later, following press inquiries, Reginfo.gov was changed to indicate that OIRA's review was completed on Monday, April 23.

Based on this timeline and series of events, we have serious concerns about the process of reviewing this proposed rule. If the review was completed on Wednesday, April 25 – as originally reported by the Office of Management and Budget – we are concerned that EPA ignored the review by announcing and signing the rule on Tuesday, April 24. If the review was completed on Monday, April 23, we would like to understand how OIRA could sign off on such a novel, complex, and far-ranging rule within three business days of receiving it. OIRA has reviewed more than 50 EPA rules since January 20, 2017, with an average review time of 55 days – far longer than this truncated review.

We are also concerned with the conclusion of this review. On April 12, you testified before a Senate Homeland Security and Governmental Affairs subcommittee. At that hearing, Senator Maggie Hassan asked whether you think it is important to have the best available evidence to inform agencies' decision-making. You responded, "Yes I do, I think having proper scientific and other economic analysis is very important to the rulemaking process." When Senator Hassan asked whether you would support agencies changing their procedures in ways that prevent them from using the best available evidence, you responded, "No, I would not." Despite this response, the proposed EPA rule that OIRA signed off on appears to do just that. Scientists have been clear that this proposal would restrict EPA from using the best available scientific evidence and prevent EPA from considering key research when developing critical clean air and

clean water protections that all Americans rely on. This is exactly the type of policy that you publicly pledged to oppose.

With these concerns in mind, we ask you to provide responses to each of the following inquiries to help us understand OIRA's review of the proposed EPA rule:

1. When did OIRA complete its review of the proposed rule? Do you believe that a few days was sufficient for OIRA to fully review a rule of this magnitude? The average review time for EPA rules over the past year has been 55 days, and OIRA reviews of similarly complex rules often last months – what specific factors allowed this review to be completed so quickly?
2. Why did OIRA change the reported date of completion on Reginfo.gov for this proposed EPA rule? When has OIRA previously changed the completion date for other reviews? Under what authority did OIRA change the date?
3. When did the interagency review of EPA's proposed rule take place? When was it completed? What information did OIRA have from other potentially impacted agencies during this review process, e.g. the Department of Health and Human Services, the Department of Transportation, the Department of the Interior, and the Department of Agriculture? What information did OIRA have from the White House?
4. If Administrator Pruitt signed the proposed rule prior to OIRA completing its review, would that violate sections 7 and 8 of Executive Order (EO) 12866? If so, what steps will be taken as a result, and what steps will be taken to prevent such violations in the future? What processes are currently in place to prevent agencies from proceeding with rules without OIRA approval?
5. Did EPA or other executive officials exert any pressure on OIRA to accelerate this review? Did they discuss the timeline for review? Was OIRA aware that Administrator Pruitt would be testifying before Congress one week after submitting this proposed rule to OIRA? Was Administrator Pruitt's upcoming Congressional testimony communicated to OIRA by EPA? Did OIRA make any effort to sign off on the proposal in advance of that testimony?
6. How many EO 12866 meeting requests did OIRA receive prior to the rule proposal's publication? Please provide a list of all requestors, the date on which the request was made, and on what date the meeting request was granted. If you did not honor any requests prior to the release of the proposed rule, please indicate why.
7. What changes to EPA's proposed rule did OIRA suggest, and when? Which changes were accepted, and why? Which changes were rejected, and why?
8. EPA did not publish a robust cost-benefit analysis in the proposed rule – was any analysis of the costs and benefits of the rule done by EPA in any documentation related to this rule that was submitted to OIRA? Why did OIRA approve this rule without a robust cost-benefit analysis? Did OIRA request that EPA complete a cost-benefit analysis before the rule was completed? If OIRA did not do so, why did it not make such a request? Did OIRA conduct its own cost-benefit analysis?

9. Did OIRA examine lost benefits due to EPA's inability to consider certain scientific studies as a result of this proposal? What analysis was done on lost benefits, and what were the results?
10. Why did OIRA conclude this is not an economically significant rulemaking?
11. The proposed rule solicits comments in numerous areas, indicating it hopes to develop answers during the regulatory process. Proposals with so many outstanding questions are often first released as Advanced Notice of Proposed Rule Makings. Why did OIRA approve this proposal as a Notice of Proposed Rulemaking with so many outstanding questions included? Did OIRA ask or consider asking EPA to issue an Advanced Notice of Proposed Rulemaking instead? If OIRA did ask EPA, why did EPA issue a Notice of Proposed Rulemaking? If not, why?
12. Given the abbreviated nature of this OIRA regulatory review, how would OIRA review a final rule following-up on this proposal differently if EPA eventually submits a final rule to OIRA?
13. Did OIRA object to the publication of this rule at any point in the review process? Why did OIRA sign off on this EPA rule if you had previously stated you would oppose rules that prevent agencies from using the best available evidence in the rulemaking process?
14. Do you believe EPA will be able to comply with both this proposed rule and the Administrative Procedure Act's mandate that requires EPA to consider and respond to every study submitted to it through notice and comment? If so, please describe how.
15. Do you believe EPA will be able to comply with both this proposed rule and the agency's statutory mandates to use the best available science (or other statutory requirements that guide EPA's use of scientific information)? If so, please describe how.
16. Internal EPA documents show that at least one senior agency official at EPA expressed unease with several parts of the policy throughout the agency's drafting process. Were you aware of these concerns prior to or during your review?
17. Since the proposal's release, several organizations have expressed concerns about the policy, including the American Chemistry Council, Science Magazine, the Bipartisan Policy Center (BPC), and the Administrative Conference of the United States (ACUS). As you know, EPA cites to Science Magazine and reports published by BPC and ACUS as support for the new policy. However, Science Magazine and the authors of the BPC and ACUS reports have publicly raised concerns about EPA's proposal, indicating that EPA had not accurately portrayed or appropriately relied upon their work. Did you review these reports to determine whether they supported EPA's conclusions?
18. Do you think this rule will reduce the data evidence available to EPA? If no, please explain why, as the rule will – at the very least – deny the EPA studies based on confidential patient data. If yes, why do you think it is appropriate to restrict the scientific evidence that agencies can consider?

In addition to the above responses, please provide all communications between OIRA and EPA about this proposed rule and all drafts of the proposed rule, as required by section 6(b)(4)(D) of Executive Order 12866. Please also provide all communications or records reflecting contacts between OIRA and any other agency, private party or other party regarding the subject matter of

the proposal. Additionally, please explain why these documents were not included in the public docket release on April 30, 2018.

We appreciate your help in understanding OIRA's review of this proposed rule. As a longtime champion of OIRA's role in the rulemaking process, we trust that you share our belief that OIRA's reviews must be carried out with the utmost rigor, independence, and integrity. Yet the review process and rollout of this rule appears to have been rushed and secretive – which is particularly ironic for a proposal that purportedly aims to improve agency transparency and decision-making processes. The proposed rule is based on limited analysis, making it difficult for the public to provide meaningful input. Moreover, it is our belief that agencies should use the best available evidence to make decisions – a statement you agreed with last month. Limiting the evidence agencies can consider or undermining the scientific process represent serious steps backward in our shared goal of encouraging informed, evidence-based decision-making at agencies.

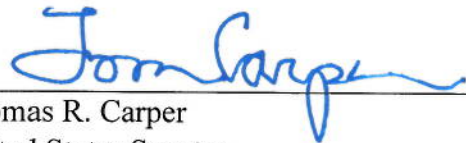
Please provide a written response by no later than May 23, 2018 with responses to these questions and the documents requested. If more time is required to produce these documents, please respond by May 23, 2018 with an anticipated timeline for production. We also request a briefing from OIRA after the written response is sent to help us fully understand your responses. To schedule this briefing and clarify any questions, please contact David Christie in Senator Hassan's office (dave_christie@hassan.senate.gov).

We look forward to your response to help us understand how this review took place and how OIRA reached a conclusion seemingly at odds with your prior public commitments.

Sincerely,



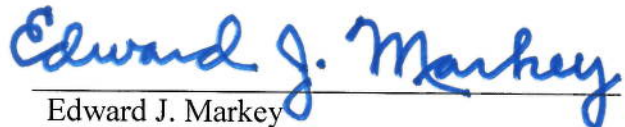
Margaret Wood Hassan
United States Senator



Thomas R. Carper
United States Senator



Claire McCaskill
United States Senator



Edward J. Markey
United States Senator



Kamala D. Harris
United States Senator



Sheldon Whitehouse
United States Senator