

Testimony of
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Good morning, Chairwoman Johnson and Ranking Member Lucas. My name is Jennifer Orme-Zavaleta. I am the Principal Deputy Assistant Administrator for Science in the U.S. Environmental Protection Agency's Office of Research and Development (ORD). I also act as EPA's Science Advisor. My responsibility as the career lead for ORD is to ensure that we provide solid and robust science to inform Agency decisions.

I have worked at EPA since 1981 in the areas of human health and ecological research, risk assessment, policy development, strategic planning, and program implementation. Of the 38 years I've been at EPA, I've spent 25 years in the Office of Research and Development (ORD).

I appreciate the opportunity to talk with you today about EPA's proposed rule to Strengthen Transparency in Regulatory Science.

Transparency and Open Data at EPA

EPA is committed to transparency and giving the public access to its data and research results. In recent years, EPA has made great strides in increasing access to public data. EPA's efforts in these regards span administrations, consistent with goals outlined in the 2013 OSTP memo *Increasing Access to the Results of Federally Funded Scientific Research*, the Evidence-Based Policymaking Act of 2018, and most recently in OMB's 2019 memo *Improving Implementation of the Information Quality Act*. For example, EPA's *Plan to Increase Access to Results of EPA-Funded Scientific Research* was finalized in 2016. Since then, EPA has implemented all three phases outlined in the plan. This includes: actively working to ensure all research publications by our own scientists and the data underlying these publications are publicly accessible, after a one-year embargo period, in the National Institute of Health's PubMed Central; creating a cross-Agency forum to provide oversight for the public access plan and its implementation; releasing an EPA policy to increase access to results (publications and underlying data) of EPA-funded extramural scientific research; and creating training materials so that both intramural and extramural scientists understand EPA's public access requirements. These efforts are all outlined at epa.gov/open.

In addition to these efforts, EPA initiated a rulemaking process in 2018 to increase transparency and public access to scientific data. EPA's proposed rule, *Strengthening Transparency in Regulatory Science*, seeks to ensure that the science underlying EPA's actions is publicly available in a manner sufficient for independent validation. The proposed rule would require that dose-response data and models underlying the studies or analyses used to support the

requirements and/or quantitative analysis of EPA significant regulatory actions, regardless of who generated or funded them, be made publicly available. EPA intends to release a supplemental proposed rule for public comment in early 2020 to provide clarifications on certain terms and aspects of the proposed rule.

While EPA believes that maximizing transparency is important, the Agency understands that there may be instances in which data and models cannot be made available. Thus, the proposed rule states that the Administrator may grant an exception if it is not practicable to ensure that data and models are publicly available.

At a hearing before this Committee just a few weeks ago, Administrator Wheeler discussed this issue and explained that “if we put the science out for everybody to see and understand, then there’d be more acceptance of our regulatory decisions.”

Through these efforts to improve transparency, EPA is working to increase public trust, to help raise understanding about important environmental issues, and to ensure the public has access to information so they can make decisions to protect their health and environment.

Proposed Rule Feedback and Public Comment

EPA issued the proposed rule on April 30, 2018. EPA also held a public hearing in July 2018, where the public could provide comments in person – some of you attended this hearing and provided comments. The public comment period originally closed on May 30, 2018, but after requests from the public, as well as the House and Senate, the public comment period was extended to August 16, 2018. During that time, we received nearly 600,000 comments. More than 9,200 of these were unique comments, many of which raised complex issues. Comments were submitted by: professional organizations and journal editors; states and tribes; state

associations; industry; environmental groups; health groups; labor unions; universities; and the general public. Almost all commenters supported the goal of greater transparency, even if they disagreed with the approach in the proposed rule. These comments covered topics such as: personally identifiable information (PII) and confidential business information (CBI); peer review; costs to non-federal researchers; statutory authority to promulgate the rule; consistency with the Administrative Procedures Act; comparison of the proposed rule requirements with statutory requirements; and more. EPA is currently working hard to address all of these comments.

EPA also solicited feedback from the Science Advisory Board (SAB) on PII and CBI. SAB members are non-EPA scientists, engineers, economists, and other social scientists who are recognized experts in their respective fields. Members come from academia, industry, research institutes, non-governmental organizations, and federal, state, and tribal governments. EPA received SAB's comments on PII and CBI on September 30, 2019. These comments are publicly available and are being considered as we develop the final rule. The SAB is also providing comments on the entire rule – these comments will also be publicly available. We anticipate receiving those comments soon.

Next Steps

EPA has just sent a supplemental rule that provides clarifications on certain terms and aspects of the proposed rule to OMB for review under E.O. 12866. The supplemental proposed rule is designed to provide clarifications on certain terms and aspects of the proposed rule, as Administrator Wheeler noted during his hearing with this Committee in September. Once we get further in the process, we'd be happy to offer briefings on the supplemental rule. The

supplemental rule will be available for public comment in early 2020, and we are committed to ensuring adequate time for public review. EPA anticipates finalizing the rule next year.

Thank you again for the opportunity to appear before you today. I am happy to take any questions you may have.