



OFFICE OF THE VICE PRESIDENT - RESEARCH AND INNOVATION

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May 13, 2020

Administrator Andrew R. Wheeler  
Environmental Protection Agency  
William Jefferson Clinton West Building  
1301 Constitution Ave, N.W.  
Washington, D.C. 20460

**RE: Docket ID [EPA-HQ-OA-2018-0259](#) Supplemental notice of proposed rulemaking:  
Strengthening Transparency in Regulatory Science**

Dear Administrator Wheeler:

I write on behalf of the University of California (UC) system with regard to the Supplemental notice of proposed rulemaking, "Strengthening Transparency in Regulatory Science," published in the *Federal Register* by the Environmental Protection Agency on March 18, 2020.

The UC system is comprised of ten research-intensive campuses, six medical schools, and three affiliated U.S. Department of Energy national laboratories. As a system, UC receives approximately \$6 billion annually in extramural research awards and is the nation's largest academic recipient of federally funded research and other university-based projects.

In May 2018, UC submitted a comprehensive comment letter in response to the April 2018 "[Strengthening Transparency in Regulatory Science" proposed rule](#). In the letter, we stated that the proposed rule unadvisedly limits the kind of scientific research that should be considered in decisions affecting human health and our environment. Unfortunately, the Supplemental notice expands the scope of the proposed rule rather than provides clarifications or reconsiders the consequences resulting from not using the best available science in regulatory decision-making. UC urged the EPA to rescind the original proposed rule, and we insist that EPA withdraw this Supplemental notice as well.

The UC system has serious concerns about the Supplemental notice. First, we believe that the Supplemental notice expands upon the original proposed rule which unnecessarily restricts the use of rigorous science in environmental regulatory and policymaking, to the detriment of the public's health and trust in the regulatory process. Second, we believe the proposed Supplemental notice does not respect the contributions and privacy of human research participants. Third, the Supplemental notice expands the arbitrary case-by-case exemptions for including studies in rulemakings and influential scientific information. We explain each one of our concerns below.

## I. Supplemental Notice Expands Upon The Original Proposed Rule

The original proposed rule requires scientists to publicly disclose underlying dose response models and data before the EPA would consider a study's conclusions when setting regulatory standards that impact public health and the environment. The Supplemental notice expands the scope of the proposed rule to apply to all data and models, not just the more limited dose response models and data. In addition, the EPA expands the proposed rule to apply to not just how the agency would set regulatory standards but to all influential scientific information that could "have a clear and substantial impact on important public policies or private sector decisions."

The EPA notes the Supplemental notice modifies information presented in the proposed rule to ensure consistency with the April 2019 Office of Management and Budget (OMB) Memorandum to the Heads of Executive Departments and Agencies entitled [Improving Implementation of the Information Quality Act](#) (OMB M-19-15). This OMB memorandum requires agencies to develop information quality assurance procedures that are applied before disseminating information. The UC would like to point out that OMB M-19-15 is intended to facilitate transparency in how federal agencies *disseminate* information, not in how they *form* regulatory or policy decisions. It is understandable that when issuing regulations, scientific information helps to provide the rationale for decisions; however, not being able to publicly disclose all sensitive data does not justify the EPA dismissing the use of important scientific work that could very well inform regulatory and policy decisions.

Furthermore, the OMB M-19-15 draws upon replicability and reproducibility as part of the framework. While UC supports efforts to facilitate data sharing, UC believes that reproducibility and replicability are not the only metrics for quality assurance but rather are a piece of the broader research integrity landscape that UC strives for. Moreover, there are limits to reproducibility and replicability. Certain situations are either impossible to recreate or should not be due to the severity of health outcomes or the circumstances surrounding the exposures. For instance, emergency responses to the 2010 Deepwater Horizon explosion and oil spill or a decade-long prospective cohort study on lead exposure in drinking water and adverse effects on childhood IQ would be difficult and unethical to replicate or reproduce. Considering the severity of the health outcomes, dismissing research due to this rigid transparency rule would result in regulatory delays in EPA's charge to protect human and environmental health.

UC strongly supports the open exchange of information to ensure the validity of research and to advance public knowledge. However, the proposed rule and the Supplemental notice in effect bar the EPA from utilizing scientific information that rests on difficult-to-release information. The best available science must serve as the foundation for EPA's regulatory and policy actions. Congress intentionally and wisely embedded peer-reviewed research in the foundation of the Clean Air Act, including requiring regular reviews of the science, explicitly recognizing that EPA needs the most current, peer-reviewed data to protect the public health. These expectations also are reflected in other public health laws that support the EPA's mission, including the Toxic Substances Control Act. Limiting scientific evidence does not strengthen regulations or policies; rather, it is paramount that the full suite of relevant science, vetted through peer-review, inform the landscape of decision-making. Excluding relevant studies simply because they do not meet unnecessarily rigid transparency standards will adversely affect decision-making processes.

## **II. Supplemental Notice Does Not Respect The Privacy Of Human Research Participants**

The Supplemental Notice explains that when EPA promulgates significant regulatory decisions or finalizes influential scientific information, “the Agency will, other things equal, give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because the information is publicly available or available through tiered access when the data include Confidential Business Information (CBI), proprietary data, or Personally Identifiable Information (PII) and appropriate techniques have been used to reduce the risk of re-identification.” UC believes that efforts to downgrade the consideration of studies that rely on private research participant information from being used in EPA’s policymaking is a disservice to the American public. Many studies depend on or have historically used such data that legally cannot be made public.

Indeed, research participant information is critical to many studies showing the health impacts of pollutants. Data privacy laws largely prevent information from studies involving humans from being made public in the manner being considered by the EPA. As a result, for example, if the EPA proceeds with downgrading or dismissing such science from consideration, the Agency will be excluding from their policy and rulemaking process epidemiology studies linking air pollution to serious outcomes such as death, heart attacks, and strokes; disinfection byproducts to birth outcomes; and, toxic exposure to cognitive function.

The fact that this information must be kept confidential to protect research participants does not make the data any less valid. Nor can researchers effectively redact identifying data in a way that will protect confidentiality for many of these studies. The risks to privacy are well recognized in the research and public health professions. Stripping out personal identifiers does not solve the problem as the identity of individuals often can be inferred by using data sets from multiple sources.

## **III. Supplemental Notice Expands The Arbitrary Case-By-Case Exemptions For Including Studies In Rulemakings And Influential Scientific Information**

In our previous comment letter, the UC expressed concern over the proposed language at subparts §30.2 and §30.9, which allow the EPA to selectively choose studies to meet its agenda. Subpart §30.2 contains an a priori criterion of “pivotal regulatory science” while §30.9 gives the EPA Administrator discretion to issue exemptions from the policy on a case-by-case basis. These sections are vague on how and by what measures determinations would be made, opening the door for drawing upon studies driven by unknown interests or by political considerations rather than, as EPA’s Mission Statement notes, “...the best available scientific information.”

Information provided in the Supplemental notice on these subparts do not ease our concerns as the EPA fails to propose a process for managing conflicts of interest. Additionally, the EPA proposes to use the age of data and models as a factor in the determination that compliance with the rule is impracticable. This addition is not in line with best practices for research nor systematic review, putting the EPA in the position of cherry picking data and leaving the Agency vulnerable to allegations of data misuse.

#### **IV. Learning from the Current Coronavirus Pandemic**

The current COVID-19 pandemic is showing us in real time the necessity of scientific expertise in decision-making. At a speed not seen before, just 10 days after a pneumonia-like illness was first reported among people who visited a seafood market in Wuhan, China, scientists released the genetic sequence of the coronavirus that sickened them. That precious bit of data, available to other researchers who wanted to study it, unleashed a massive collaborative effort to understand the mysterious new pathogen that rapidly spread across the world. If EPA's proposed transparency rule was in place at that moment, it seems like there would be a need to determine a) whether this type of information sharing would meet the rule's requirements and/or b) whether they require independent validation or a case-by case exemption from the rule's applicability before they could be used for EPA decision-making purposes. Even if these and other relevant studies were ultimately deemed to be eligible for use under this rule, this proposed rule would clearly establish barriers and result in fatal delays to using the best available science to inform EPA's actions.

The UC strongly urges the EPA to withdraw its proposed rule and Supplemental notice and to follow the current, effective measures in place that ensure the use of robust scientific research to protect the health of our citizens and our communities.

Sincerely,

A handwritten signature in blue ink that reads "Theresa A Maldonado". The signature is written in a cursive, flowing style.

Theresa A. Maldonado, Ph.D., P.E.  
Vice President for Research & Innovation