

Congress of the United States

House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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January 7, 2021

The Honorable Joseph R. Biden, Jr.
President-Elect of the United States of America
1401 Constitution Avenue, N.W.
Washington, D.C. 20230

Dear President-Elect Biden:

The past four years have been painful for all those who care about the environment and public health. Under the Trump Administration, environmental safeguards have been weakened, career environmental scientists within the federal government have been marginalized, and the very role of science itself in environmental policymaking has come under assault. The epicenter of this attack on our environment has been the Environmental Protection Agency (EPA). During your recent successful campaign for the presidency, you spoke with great passion about the importance of rebuilding the EPA in order to achieve your priorities of strengthening environmental protections, combating climate change and promoting environmental justice for vulnerable communities. I support these goals wholeheartedly and eagerly anticipate the opportunity to partner with your administration in enacting policies to attain them.

Yet the EPA cannot be fully restored to its necessary role as a champion of the nation's environment unless the Trump Administration's worst initiatives to sabotage the Agency are swept away. I write to highlight one of the most pernicious of these efforts: the so-called "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" rule, which the Agency recently finalized on January 6. This regulation would prohibit EPA from properly considering scientific studies in its regulatory process unless those studies have made their underlying data publicly available. As a result, it will undermine your environmental agenda for as long as it is allowed to remain in place. The rule is designed to exclude critical science from EPA policymaking and to tie the Agency's hands as it seeks to address our most pressing environmental challenges. I urge you to move swiftly on Day One against this rule, and to use all legal and administrative means at your disposal to do so.

The concept behind the misnamed "Strengthening Transparency" rule has a long and unfortunate history. The earliest outline of the idea can be traced back to the tobacco industry in the 1990's, when

the industry decided that it would be more effective to cast doubt on the foundational scientific studies underpinning public health warnings against cigarette smoke than to confront those warnings directly.¹ The basic template for the rule emerged with the *Secret Science Reform Act of 2014*, which sought to compel EPA to obtain the raw data of scientific studies before it could use those studies to inform Agency regulations.² Under the leadership of the former Republican Chairman of the House Committee on Science, Space, and Technology, Representative Lamar Smith, the *Secret Science Reform Act* and its successor bills passed the Republican-led House of Representatives three times but failed to receive a vote in the Senate.³ Confronted with the likelihood that these bills would never become law, former Chairman Smith petitioned then-EPA Administrator Scott Pruitt in January 2018 to implement the legislation as an Agency regulation.⁴ Former Administrator Pruitt quickly agreed, and the subsequent rulemaking process – which excluded career employees and was driven entirely by political appointees – culminated in the proposed “Strengthening Transparency” rule in April 2018.⁵

Since the emergence of the original proposed rule, each iteration of the rule has been met by a nearly unanimous chorus of vehement opposition from the scientific community, including environmental and public health organizations, as well as Congressional Democrats, veterans of the Agency and even current employees registering their dissent. The proposed rule received roughly 600,000 public comments, a nearly unprecedented outpouring of concern that was overwhelmingly opposed to the rule.⁶ Groups ranging from the American Association for the Advancement of Science and the Union of Concerned Scientists to the American Lung Association and the Michael J. Fox Foundation for Parkinson’s Research, along with countless others, registered their opposition.

In response, EPA issued a supplemental notice of proposed rulemaking in March 2020, ostensibly to address the concerns raised by public comments.⁷ Yet the supplemental rule did nothing to lessen the danger. In fact, in several key areas, the supplemental rule actually broadened the scope and made the rule even more destructive to the Agency’s ability to protect public health and the environment.⁸ EPA’s own top career expert on the Agency’s use of human subjects research wrote a formal internal dissent to the rule, arguing that it would compromise EPA’s scientific integrity and prevent the Agency from fulfilling its mission to protect the public against dangerous environmental and public

¹ David Merritt Johns and Karen Levy, “How Trump’s war on science is borrowing from the tobacco industry playbook,” *Washington Post*, December 13, 2019, accessed here: <https://www.washingtonpost.com/outlook/2019/12/13/how-trumps-war-science-is-borrowing-tobacco-industry-playbook/>.

² “H.R. 4012 – Secret Science Reform Act of 2014,” Congress.gov, Introduced on February 6, 2014, accessed here: <https://www.congress.gov/bill/113th-congress/house-bill/4012>.

³ The last version of the bill was H.R. 1430, The HONEST Act, introduced on March 8, 2017, passed by the House of Representatives on March 29, 2017, and never voted upon by the Senate. “H.R. 1430 – HONEST Act,” Congress.gov, Introduced on March 8, 2017, accessed here: <https://www.congress.gov/bill/115th-congress/house-bill/1430>.

⁴ Juliet Eilperin and Brady Dennis, “Pruitt unveils controversial ‘transparency’ rule limiting what research EPA can use,” *Washington Post*, April 24, 2018, accessed here: <https://www.washingtonpost.com/news/energy-environment/wp/2018/04/24/pruitt-to-unveil-controversial-transparency-rule-limiting-what-research-epa-can-use/>.

⁵ Scott Waldman and Niina H. Farah, “Smith pitched Pruitt on ‘secret science.’ Now it’s happening,” *E&E News*, April 20, 2018, accessed here: <https://www.eenews.net/stories/1060079655>.

⁶ Lisa Friedman, “EPA to Limit Science Used to Write Public Health Rules,” *New York Times*, November 11, 2019, accessed here: <https://www.nytimes.com/2019/11/11/climate/epa-science-trump.html>.

⁷ Kelsey Brugger, “Trump admin expands reach of secret science proposal,” *E&E News*, March 4, 2020, accessed here: <https://www.eenews.net/stories/1062516587/>.

⁸ *Id.*

health exposures.⁹ Sadly, the Trump Administration refused to listen to the nearly universal opposition from scientists, experts and advocates, and it remained determined to pursue the rule as a final gift to the polluting industries that have long sought to weaken the EPA. Now that the rule has been finalized, the fears of the scientific community and the American people are closer than ever to being realized.

The principles of the so-called “Strengthening Transparency” rule have taken different forms throughout the years, from legislation to the various drafts of the recent rulemaking process, and the fundamental problems that have always existed remain embedded within the final rule. The rule’s implementation would unquestionably tie the hands of your administration in upholding science-based environmental and health regulations:

Public health studies would be excluded from consideration in health-protective regulations.

The rule’s legislative precursor, the *Secret Science Reform Act*, was specifically developed to exclude landmark public health research from pollution regulations. Former Chairman Smith introduced the Act after years of attempting to obtain the raw data from the Harvard Six Cities Study and the American Cancer Society Study.¹⁰ Epidemiological research underpins the studies that are most valuable in understanding how pollutants affect human health. The best of these studies are based on a wealth of personally identifiable information (PII) that should not – and often cannot – be made public. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), the National Institutes of Health (NIH), and research institutions’ own Institutional Review Boards (IRB) all mandate strict privacy protections that would make obtaining research funding mutually exclusive from publishing a study that could clear the arbitrary “transparency” threshold put in place by the final rule. Additionally, any study that tried to meet the rule’s requirements for allowing raw data to be made publicly available would encounter difficulty recruiting participants, who would be expected to sign consent forms allowing sensitive personal data to be accessed by the public. Thus, the final rule deliberately creates a conflict between the mandatory privacy protections of epidemiological research and the Agency’s regulatory process that would prevent critical scientific research from being incorporated into EPA public health regulations.

Existing and future regulations would be gutted. In communications with Congress and in its responses to stakeholder criticisms, the EPA has claimed that the rule will not have any effect on existing regulations. This is misleading. The Clean Air Act and criteria air pollutant regulations under the National Ambient Air Quality Standards (NAAQS), which are required to be reconsidered periodically, would be gutted should the rule be implemented. The health-protective standards that have been set are based on the best available evidence from epidemiological research, and eliminating them from the body of research would result in a dangerous backsliding of pollutant regulations. Additionally, the final rule states explicitly that past scientific studies will be subject to the rule’s “transparency” requirements, regardless of when they were published or the data management and retention norms that existed at the time. If past scientific research supporting existing regulatory standards must be excluded in the future when those standards are updated, the Agency’s ability to uphold public health protections will be drastically weakened.

⁹ Lisa Friedman, “EPA’s Final Deregulatory Rush Runs Into Open Staff Resistance,” *New York Times*, November 27, 2020, accessed here: <https://www.nytimes.com/2020/11/27/climate/epa-trump-biden.html>.

¹⁰ “Smith to Introduce Bill to Bar EPA from Basing Regulations on Secret Science,” Committee on Science, Space, & Technology Republicans, November 14, 2013, accessed here: <https://republicans-science.house.gov/news/press-releases/smith-introduce-bill-bar-epa-basing-regulations-secret-science>

A new and heavy burden would be placed on the research community. The EPA claims that the final rule falls under its authority under the Federal Housekeeping Statute as an alleged rule of internal agency procedure.¹¹ This assertion is belied by the substantial new obligations that the rule would place upon scientific researchers and their institutions to assume responsibility for making underlying data publicly available. Earlier versions of the rule suggested that EPA could create its own secure data enclave to manage the raw data of studies that contained sensitive information. The final rule abandons any pretense that the Agency is capable of operating such a system, as the Agency's own top career expert on the subject noted in a formal dissent to the rule.¹² However, the lack of a central data infrastructure for the implementation of the rule will inevitably shift the full weight of the logistical burden onto the research community to store, manage, and grant access to the raw data underlying their studies should EPA request it. The result would be a new, resource-intensive and burdensome requirement for research teams and institutions that possess few financial resources to spare and cannot be expected to redirect critical research funding from science to data management at the arbitrary whim of the Agency. EPA should not limit its consideration of crucial research to only those researchers and institutions who might be able to meet this unreasonable bar.

The rule would apply to influential scientific information as well as significant regulatory actions. EPA has expanded the scope of the final rule to include all Influential Scientific Information (ISI). 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.¹³ These scientific products are the foundation of the Agency's understanding of public health and environmental risk. By imposing arbitrary limitations on the consideration of scientific studies 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 impact of weakening these products would not stop at the walls of the EPA. IRIS assessments, for example, are considered the gold standard of toxicological reviews. Outside stakeholders who rely on these assessments, including state and local governments crafting health-protective regulations, would need to find another way to obtain crucial information on pollutants and chemicals to ensure they are not neglecting human health studies unable to be considered by EPA.

The final version of the rule contains all of these disturbing problems and more. Additionally, in its last-minute dash to complete this midnight rule and undermine your Administration, the Agency violated basic tenets of administrative law and disregarded the rights of the American people to understand new regulations before they are implemented. The Administrative Procedure Act (APA) mandates no less than a 30-day waiting period between the finalization of a regulation in the Federal Register and the date that it takes effect.¹⁴ The APA imposes this requirement upon the rulemaking process in order to allow the public, and any affected groups or individuals, a reasonable amount of time to study the new regulation's implications before it begins to be implemented.¹⁵ In this case, the "Strengthening Transparency" rule carries enormous implications for scientific researchers, public

¹¹ 5 U.S.C. 301, "Departmental Regulations."

¹² Thomas Sinks, PhD, Differing Scientific Opinion, accessed here: <https://int.nyt.com/data/documenttools/dissenting-scientific-opinion/8fdd7838c67f4c21/full.pdf>

¹³ Environmental Protection Agency, "Science Inventory," accessed here: https://cfpub.epa.gov/si/si_public_pr_agenda_archive.cfm.

¹⁴ 5 U.S.C. 553, "Rulemaking."

¹⁵ Todd Garvey, "A Brief Overview of Rulemaking and Judicial Review," *Congressional Research Service*, March 27, 2017, accessed here: <https://fas.org/sgp/crs/misc/R41546.pdf>.

health organizations, private sector companies, and members of the public impacted by Agency public health regulations.

EPA, however, exempted the rule from the mandatory 30-day waiting period and implemented it immediately upon publication, inappropriately citing an amorphous “good cause” exemption without proper justification or evidence. In doing so, EPA violated the law. But it is clear that the Trump Administration’s cynical aim was to rush the rule into effect before January 20 at any cost, heedless of the law and the implications for Agency employees and the broader public. This was a sloppy and disgraceful process that reeked of political motivations, rather than a desire to act in the best interests of the American people and the environment. It is my hope that your Administration will closely inspect the final stages of the rulemaking process that were undertaken to complete this tainted rule; and should your Administration discover any legal or procedural violations, that it will respond appropriately and take all necessary and justified steps in light of their existence.

As the Chairwoman of the Committee on Science, Space, and Technology, I am sadly familiar with the danger that this regulation poses to the EPA’s ability to protect the environment and public health. The Committee fought vigorously against the rule and amplified the concerns of scientific organizations, environmental advocates and the general public regarding the rule’s implications for the country. The final version of the rule brings all of its problems to the forefront. It represents the culmination of a pernicious idea that has been pushed for years by opponents of the scientific and environmental values that we both hold dear. I am heartened by the fact that on January 20, you will assume the office of the presidency and possess the authority to prevent the damage that the rule seeks to cause. I urge your administration to prioritize the rollback of this regulation with all of the means at its disposal, and to act swiftly and decisively against it as soon as possible after your inauguration. By doing so, you will be taking an early and critical step towards advancing the goals that both of us wish to achieve over the next two years.

Sincerely,



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