The Environmental Protection Agency’s “Strengthening Transparency in Pivotal Science” Rule: Don’t Let History Repeat Itself

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The Environmental Protection Agency’s (EPA) “Strengthening Transparency in Pivotal Science” rule, known by its critics as the Censoring Science rule, was enacted in the final days of the Trump administration (1). The rule restricted consideration, for policy purposes, of evidence from scientific studies for which underlying data could not be made publicly available for independent validation and analysis. This rule was widely denounced by public health researchers and organizations, including the American Thoracic Society, for imposing a barrier that could not be realistically met by observational research and for the harmful public health repercussions that could result. The rule eerily resembled past industry-sponsored efforts to block the use of unwelcome science demonstrating the harmful effects of pollutants.

On February 1, 2021, the rule was revoked following legal challenges based on the EPA’s lack of authority to enact it and its conflicts with the Clean Air and Water Acts (2). Given its revocation, it may be tempting to forget about this misguided rule and move onto addressing the numerous other pressing environmental and public health problems. Unfortunately, history has a way of repeating itself, as evidenced by the fact that the motivation for this rule dates back to the 1997 revision of the National Ambient Air Quality Standard for particulate matter. Accordingly, we herein provide the historical context behind the rule and review its critical flaws. We argue that the scientific community, government agencies, and policy makers must continue efforts to promote scientific integrity, liberal data sharing, reproducibility, and transparency while establishing enduring safeguards against threats to evidence-based regulatory decision-making.

Historical Context of the Rule

The initial “Strengthening Transparency in Regulatory Science” rule was proposed in 2018 (3). The rule purported to increase the transparency and validity of scientific research used to inform EPA regulations and statements by requiring all “influential science” to have available the underlying raw data. A 2020 supplement to the rule increased its scope and introduced a bureaucratic value system for the use of research for rulemaking, prioritizing studies based on their extent of data sharing rather than scientific merits (4). The presidents of the National Academies of Sciences, Engineering, and Medicine warned that the rule could result in the EPA discarding valid evidence (5), and the American Thoracic Society testified against the rule to Congress in 2019 (6). Against these and other strong objections from the scientific community, the Censoring Science rule was finalized on January 6, 2021 (1, 7, 8).

The rule resembles attempts by the tobacco industry to discredit scientific findings that posed risks to sales (Figure 1). In 1990, the...
Tobacco industry affiliates opposed and attempted to discredit EPA report on environmental tobacco smoke (ETS)

RJ Reynolds Tobacco Company Memo attempts to prevent federal agencies from regulating ETS

U.S. House appropriations bill amendment proposed that would require researchers with federal grants to make available all raw data

Philip Morris tobacco company attempts to gain access to raw data from Fontham study linking ETS to lung cancer mortality

U.S. House of Representatives passes “Secret Science Reform Act of 2015”

EPA proposes “Strengthening Transparency in Regulatory Science” Rule

EPA releases “Strengthening Transparency in Regulatory Science - Supplemental Notice”

EPA finalizes “Strengthening Transparency in Pivotal Science” Rule

Environmental Information Exchange Network (EIEN) established

Shelby Amendment of Freedom of Information Act (FOIA) Passed

NIH requires Data Sharing Plan

Registration required on ClinicalTrials.gov

ClinicalTrials.gov Results Database becomes available to public

EPA requires Scientific Data Management Plan (SDMP)

International Committee of Medical Journal Editors (ICMJE) requires all clinical trials to include data sharing statements

Data sharing plan required by ClinicalTrials.gov

New NIH Data Sharing Policy comes into effect

Figure 1. Timeline of major threats to scientific integrity and public health alongside data management and sharing policies enacted to increase scientific transparency and public data access. EIEN = Environmental Information Exchange Network; EPA = Environmental Protection Agency; ETS = environmental tobacco smoke; FOIA = Freedom of Information Act; ICMJE = International Committee of Medical Journal Editors; NIH = National Institutes of Health; SDMP = Scientific Data Management Plan.
EPA released a report on environmental tobacco smoke (ETS), which eventually led to its classification as a group A carcinogen in 1992 (9). Over 70% of the critical comments made against this report were from tobacco industry affiliates, who often attacked the methodology of underlying epidemiologic research and called for the inclusion of non–peer-reviewed and industry-sponsored literature into the final assessment (10). A subsequent 1996 internal memo from tobacco lawyer Chris Horner highlights how he advised industry partners to lobby government to impose “procedural hurdles” focused on “process as opposed to scientific substance” to complicate the EPA’s ETS regulation (11). In 1997, the Philip Morris tobacco company developed their “Sound Science Project Plan,” outlining intentions to lobby lawmakers to mandate data sharing from epidemiologic studies and to sway public opinion by “linking ETS findings to junk science.” (12) They emphasized that support could be sought from members of Congress “dissatisfied with proposed ozone/particulate matter regulations,” advancing the common motivations underlying attempts at preventing ETS and air pollution regulation.

Efforts to censor science again accelerated with the 2015 “Secret Science Reform Act,” which was strongly promoted by the Republican-controlled House Committee on Science, Space, and Technology. This bill attempted to legislatively mandate that the EPA could not propose or finalize any actions without making all underlying scientific data available for independent reanalysis. The contentious bill passed in the House but was never brought to a vote in the Senate (13).

**Why the Medical Community Objected to the Transparency Rule**

Together, the initial proposed rule and supplement received over one million predominately negative comments from the general public, health professionals, and scientific societies (7, 8). The primary issues highlighted were research participant privacy concerns, unfunded logistical burdens on scientists, and the potential for the rule to enable deregulation that would adversely impact public health.

The data sharing requirements imposed by the rule would have conflicted with research participant privacy requirements, especially given the stated intention to make raw data from all considered studies available for “independent validation” (3, 14). This was of paramount concern for environmental health studies, which often collect detailed protected health information to control for environmental and demographic confounders when characterizing the impact of pollutants on health (15). Reidentification of participants from such studies is a real risk. For example, researchers successfully reidentified 25% of participants in an air pollution epidemiology study by matching deidentified data with publicly available datasets and using commercial software (16). Rapid advances in artificial intelligence are likely to only increase this risk. Such hazards of disclosure could also discourage future participation in epidemiological research. Ironically, the only way around these data sharing requirements was to receive an exemption from the politically appointed EPA administrator through an undefined process not made transparent in the rule.

From a logistical standpoint, the rule lacked data storage or sharing plans, processes for requesting data access, and allocation of funding for handling requests. The conceptual and technical burden would instead fall upon researchers, who would be unlikely to have the capacity to provide this structural support. Furthermore, the terms “reproducibility” and “replication” were often used incorrectly and interchangeably, without incorporation of the National Academies of Sciences, Engineering, and Medicine’s definitions of these terms (1, 3, 4). These concepts differ in that reproduction requires the same analysis to be performed on the same data, whereas replication involves confirming previous results using new data (17). The rule would not have helped to achieve either goal, as it focused on enabling reanalysis to evaluate “sensitivity to alternate assumptions,” which would introduce the risk of biasing toward results favoring independent stakeholder interests.

Lastly, the rule posed a significant threat of relaxation of pollutant standards. Under the rule, most studies collecting individual-level data would not have met the data sharing requirements and, as a result, would have been given less weight when developing EPA health-based pollution standards and policies. There was justified suspicion, based on historical precedent, that exclusion of such studies was the intent of the rule. By devaluing findings of studies for which raw data cannot be shared because of privacy constraints, the EPA would have given less consideration to the many observational studies that historically informed the setting of air quality and other environmental standards, which save millions of life-years annually in the United States (18).

**Recommendations for the Current Administration**

The Censoring Science rule might have failed under any administration because of critical flaws of feasibility, ethics, and justification. However, the emergence of this rule and its many historical precedents highlight the need to protect against future attempts to censor science in environmental and public health regulation. It is in the interest of every individual, regardless of political affiliation, for decision-makers to use the best available science when developing policies and regulations that affect public health.

Fortunately, the broader scientific community continues to advance research transparency and reproducibility by enacting policies and procedures that facilitate data sharing within a framework that protects research participant privacy and proprietary interests (Figure 1). More work is needed to ensure that these enduring goals of research transparency and evidence-based decision-making are pursued without risk of extreme deviations with each presidential or congressional election. Instituting common guidelines across federal agencies to pursue these goals while mandating appropriate privacy protections and fair consideration of observational research should facilitate transparency and reproducibility across all agencies relying on human health studies. In cases in which research may have substantial impacts on regulatory development, independent not-for-profit organizations such as the Health Effects Institute can be used to perform secure and independent reanalyses, as has been done for a number of pivotal air pollution studies previously (19). These approaches may prevent insidious efforts targeting specific types of health research (e.g., research on pollutants, tobacco, or drug products) that might produce unwelcome findings for certain industries.
Scraping the ill-conceived Censoring Science rule was an essential step in enabling the EPA to use the best available evidence to protect public health and the environment. However, without more permanent safeguards to protect the use of science by the EPA and other agencies, history may be doomed to repeat itself.

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