



**Statement on Behalf of Karl A. Racine
Attorney General for the District of Columbia**

**Public Hearing
Proposed Rule: Strengthening Transparency in Regulatory Science
83 Fed. Reg. 18768 (Apr. 30, 2018)**

July 17, 2018

**Environmental Protection Agency
William Jefferson Clinton East Building
Main Floor Room 1153
1201 Constitution Avenue NW
Washington, DC 20460**

Good afternoon, my name is Sarah Kogel-Smucker, Special Assistant Attorney General at the Office of the Attorney General for the District of Columbia. I am commenting on behalf of Karl A. Racine, the Attorney General for the District of Columbia. EPA's proposed rule, Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18768 (Apr. 30, 2018), is a solution in search of a problem. Instead of strengthening ways in which EPA can benefit from advances in scientific studies, the proposed rule limits EPA's access to important studies and hampers the development of regulations needed to protect the public health and welfare of the residents of the District of Columbia and the nation. The proposed rule should be withdrawn. In these comments I will briefly address why the proposed rule limits the use of valid, peer-reviewed scientific data, violates several environmental statutes, and lacks sufficient detail to be appropriately evaluated and implemented.

First, the proposed rule impedes EPA's decision-making by creating burdensome, and potentially impossible, barriers to the use of certain scientific studies needed to determine the impacts of pollutants and toxic materials on air quality, water quality, and human health. The proposed rule requires that EPA's significant regulatory decisions be justified only by studies based on dose response data and models that are available to the public. 83 Fed. Reg. at 18773-74. This requirement limits EPA's ability to rely on otherwise peer-reviewed, scientifically-valid studies that do not, or cannot, make their data publicly available because of confidentiality concerns. For example, EPA used the landmark Harvard Six Cities Study, demonstrating a dramatic link between premature mortality and air pollution, as part of its justification for key clean air regulation.¹ The study has been rigorously, independently peer-reviewed but the

¹ See National Ambient Air Quality Standards for Particulate Matter; Final Rule, 62 Fed. Reg. 38652, 38670, 38676, 38689-90 (July 18, 1997) (discussing the role of the study D.W. Dockery et al., *An Association Between Air Pollution and Mortality in Six U.S. Cities*, 329 NEW ENGLAND

subjects were promised confidentiality and the data is not public.² Studies with confidential data can still be appropriately peer-reviewed through the use of confidentiality agreements, and subject to rigorous scientific scrutiny over their methods and conclusions. Where cost effective and appropriate, use of open, or publicly available, data should be encouraged. EPA, however, should not provide blanket limits on the use of studies that cannot be made public because they contain confidential health or business information. Scrubbing studies of such information may be impossible while still keeping the study reproducible.³ The proposed rule may also have important implications for rules subject to periodic update, like the Clean Air Act NAAQS, if EPA can no longer use the same or similar methods that were used to support the existing rules.⁴

Second, the proposed rule violates several environmental statutes because it hinders EPA's ability to rely on best available science, or the most up-to-date information, as they require. The Clean Air Act, Clean Water Act, Safe Drinking Water Act, Toxic Substances

JOURNAL OF MEDICINE 1753–1759 (1993), commonly referred to as the Six Cities study, in setting the 1997 National Ambient Air Quality Standards (“NAAQS”) for Particulate Matter); *see also* *NRDC v. EPA*, 902 F. 2d 962, 974 (D.C. Cir. 1990) (declining to delay review of the PM10 NAAQS rulemaking due to concerns raised by industry challengers about the integrity of the Six Cities study database).

² *See* National Ambient Air Quality Standards for Particulate Matter; Final Rule, 62 Fed. Reg at 38689-90 (discussing the peer review of the Six Cities study, the scientific debate over it, and why the raw data was not public); *see also* Memorandum from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to Members of the Chartered SAB and SAB Liaisons at 4, [https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/\\$File/WkGrp_memo_2080-AA14_final_05132018.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf) (last visited July 9, 2018) (discussing the peer review of the Six Cities study).

³ *See, e.g.,* Neil Pearce and Allan H Smith, *Data Sharing Not as Simple as it Seems*, ENVIRONMENTAL HEALTH 10, 107, *available at* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3260112/> (last visited July 9, 2018) (describing how removing unique identifiers from a data set may not sufficiently protect confidential personal information).

⁴ *See, e.g., Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 358, 365, 372 (D.C. Cir. 2002) (upholding EPA's Clean Air Act NAAQS for ozone and particulate matter based, in part, on epidemiological studies).

Control Act, and Emergency Planning and Community Right-to-Know Act all require certain decisions or regulatory criteria be based on the most up-to-date science.⁵ These criteria are described as “best available science,” “latest scientific knowledge,” and “best available public health information.”⁶ The proposed rule would illegally limit EPA’s ability to rely on best available science in violation of these statutes.

The nearly 700,000 residents of the District of Columbia rely on EPA to protect their health and environment. While air quality in the District has improved over the last several decades, many residents who face disproportionate exposure risks because of where they live or work still face risks to their health from air pollution. For example, the American Lung Association’s 2018 State of the Air report gave the District a failing grade for the period from 2014-2016 because of the number of days that the air was unhealthy for vulnerable populations due to high levels of ozone.⁷ The District’s vulnerable populations, including the estimated 10,415 children in the District with asthma, are entitled to protection from unhealthy air.⁸

⁵ See Toxic Substances Control Act, 15 U.S.C. § 2625(h), (k) (2018); Clean Water Act, 33 U.S.C. § 1314(a)(1) (2018); Clean Air Act, 42 U.S.C. § 7408(a)(2) (2018); Emergency Planning and Community Right-to-Know Act, 42 U.S.C. § 11023(d)(2) (2018).

⁶ Toxic Substances Control Act, 15 U.S.C. § 2625(h), (k) (requiring that the Administrator, in decisions based on science, “use scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed *in a manner consistent with the best available science*” (emphasis added)); Clean Water Act, 33 U.S.C. § 1314(a)(1) (requiring that criteria for water quality “accurately reflect[] *the latest scientific knowledge*” (emphasis added)); Clean Air Act, 42 U.S.C. § 7408(a)(2) (requiring air quality criteria “accurately reflect *the latest scientific knowledge* useful in indicating the kind and extent of all identifiable effects on public health or welfare” (emphasis added)); Emergency Planning and Community Right-to-Know Act, 42 U.S.C. § 11023(d)(2) (requiring that a determination to add a chemical to the Toxics Release Inventory “be based on *generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies*, available to the Administrator” (emphasis added)).

⁷ American Lung Association, State of the Air 2018, District of Columbia: District of Columbia, <http://www.lung.org/our-initiatives/healthy-air/sota/city-rankings/states/district-of-columbia/district-of-columbia.html>.

⁸ *Id.*

Because people of color and children living in poverty disproportionately suffer from childhood asthma, environmental justice demands that EPA continues to use advances in scientific research to improve air quality through appropriate regulations. EPA should not be artificially hampered in this duty just because the data or models from a high-quality, peer-reviewed study are not publicly available.

Lastly, the proposed regulations are too vague to be meaningfully evaluated and successfully implemented. For example, it is unclear whether section 30.7 requires EPA to conduct its own peer review of all pivotal regulatory science and, if so, whether EPA has the capacity or capability to perform those reviews. *See* 83 Fed. Reg. at 18774. Likewise, the exemption process does not provide sufficient standards to ensure that the Administrator makes consistent determinations. *Id.* For these reasons, the proposed rule should be withdrawn. Subsequent EPA transparency initiatives, if any, should be based on consultation with the National Academy of Sciences and should not restrict EPA's ability to rely on the universe of best available science when promulgating regulations. Thank you for the opportunity to comment today.