Childhood Asthma Leadership Coalition

August 16, 2018

The Honorable Andrew Wheeler, Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Submitted via Regulations.gov

Re: Proposed Rule, "Strengthening Transparency in Regulatory Science," RIN 2080-AA14; Docket ID No. EPA-HQ-OA-2018-0259

Dear Acting Administrator Wheeler:

The undersigned organizations are part of the Childhood Asthma Leadership Coalition, and represent leading advocates and experts in childhood asthma, public health, environmental health, poverty, housing, health care, and health care economics. We write to strongly oppose the Environmental Protection Agency's (EPA) proposed rule, "Strengthening Transparency in Regulatory Science."[1] The rule provides that pivotal studies would need to rely on data that are available "in a manner sufficient for independent validation." We are deeply concerned that in reality this provision would limit the use of research that could improve the lives of children with asthma, favoring deregulation over reasonable policymaking to protect and promote health.

Asthma affects one in 12 children, and is particularly prevalent among low-income populations.[i] EPA regulations play a vital role in protecting these children. For example, by reducing environmental airborne asthma triggers, 1990 amendments to the Clean Air Act prevented an estimated 1.7 million asthma exacerbations between 1990 and 2010.[ii] An earlier peer-reviewed EPA Report to Congress found that in 1990 alone, pollution reductions under the Act prevented 850,000 asthma attacks and 1.3 billion cases of acute respiratory distress.[iii] Congress intentionally embedded peer-reviewed research in the foundation of the Clean Air Act and required regular reviews of the science.

The validity of the science underlying EPA regulations has continued to withstand scrutiny. In the creation of the first national standard for fine particulate matter (PM2.5) in 1997, members of Congress and other scientists called into question the science underlying the decision. To review the research, the EPA referred both studies to an independent third-party, which examined the data and developed a report confirming the original findings.[iv] The latest Integrated Science Assessment for particulate matter cites nearly one thousand peer-reviewed studies, and

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[1] EPA, "Strengthening Transparency in Regulatory Science," RIN 2080-AA14. Available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

underwent two separate external reviews for validity.[v,vi] The peer-reviewed research continues to find strong associations between exposure to outdoor air pollution and rates of asthma.[vii,viii] We wholeheartedly agree that EPA should continue to utilize strong, evidence-based policymaking to protect children from negative health effects like asthma. However, we are concerned that, rather than support scientific rigor, EPA's proposal will undermine evidence-based regulation:

1. **Data that is relevant and appropriate for policy may not always be publicly-available in ways that meet the proposed rule's standards, or whatever criteria could be applied to future policy actions under the proposed regime**. Epidemiologic data, in particular, often involves personal identifiers that can make full disclosure challenging – particularly retroactively, if participants have already agreed to be involved under more restrictive disclosure terms. The health impacts of EPA's decisions must be considered based on the full range of information available. Fortunately, the core skills that equip scientists to create good research enable them to assess it by judging the logic of the research design, the clarity of the methodology, and the acknowledgement of previous results.[ix] The application of these skills is what makes the peer review process so vigorous.

2. **The proposed rule would encourage data dredging and deconstruction that are the antithesis of good science**. Epidemiological studies consider a huge number of variables and can relate them to a variety of outcomes in order to determine one significant association, such as the impact of poor air quality and asthma. Data dredging involves systematically retesting data sets such as those underlying epidemiologic studies through multiple models and statistical tests in order to produce desired outcomes. The proposed rule would allow regulated industries to request data and subject it to endless dredging to slow or entirely forestall regulation that would hurt their economic interests. Similarly, data "deconstruction" is a term that has been used to describe a variety of sophisticated attacks on data, including reconsidering raw data through unreliable models and confounding data to obscure findings of harm. By explicitly requiring that the EPA consider a vast array of alternative models, which may be prepared by outside stakeholders, the proposed rule has the potential to buoy well-financed stakeholders who benefit from undermining good science and stalling sound policy by enforcing their ability to endlessly test and manipulate data.[x]

3. **The proposed rule grants the EPA Administrator broad authority to exclude from consideration findings for which the data is deemed insufficiently transparent.** The rule sets up EPA as a gatekeeper for acceptable science, choosing when to allow waivers of transparency requirements, without clear criteria. We are concerned that this lack of standards would simply hand industry another tool for influencing the exclusion of data that supports stronger regulation and the inclusion of data that points against regulation.

From a process standpoint, we also note that the Science Advisory Board (SAB) should have been given the opportunity to consider the EPA's proposed rule before it was released for public input. The SAB has advised the EPA about the quality of the scientific information utilized in policymaking and EPA research programs and plans for over 40 years. This Board has an ethical

responsibility to remain impartial, consider public input, and consider the best scientific evidence available when making decisions. The SAB's analysis would have provided unparalleled insight into the potential effects of the proposed rule.

The EPA has already saved lives and improved the quality of life for millions of children with asthma. Groundbreaking public health research is a core component of the EPA's regulatory process, and should not be undermined by EPA's own policies. Therefore, we urge EPA against moving forward with this proposed rule, and recommend that EPA solicit SAB review of any action regarding the standards around EPA research, to ensure that the EPA continues to promote the consideration of high-quality research that protects public health.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Jane Sheehan at Families USA, 202-628-3030 or at jsheehan@familiesusa.org.

Sincerely,

Allergy & Asthma Network
Association of Asthma Educators
Asthma and Allergy Foundation of America
Families USA
Green & Healthy Homes Initiative
Health Resources in Action, Inc.
Healthy Schools Campaign
Regional Asthma Management and Prevention (RAMP)
Trust for America's Health

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[i] https://www.cdc.gov/nchs/fastats/asthma.htm
[ii] https://www.epa.gov/clean-air-act-overview/progress-cleaning-air-and-improving-peoples-health
[iii] https://www.epa.gov/sites/production/files/2015-06/documents/contsetc.pdf
[iv] https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air
[v] https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=201805
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[ix] http://science.sciencemag.org/content/early/2018/04/30/science.aau0116
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