ORAL Statement of Mary B. Rice MD MPH

August 27, 2019

Submitted to: **the US Environmental Protection Agency Science Advisory Board**

EPA Planned Action**: "Strengthening Transparency in Regulatory Science"**

Mr. Chairman and members of the EPA Science Advisory Board, thank you for the opportunity to speak at your meeting today. I am a pulmonary and critical care physician and assistant professor of medicine at Harvard Medical School, where I treat patients with lung disease, and investigate the effects of air pollution on lung health. I am speaking today on behalf of the American Thoracic Society. Our 16,000 members include physicians who treat patients with lung disease, and scientists who study the effects of air pollution on lung health.

We have serious concerns about the EPA's planned rule called "Strengthening Transparency in Regulatory Science" and what it means for our patients. **This proposed rule will allow the EPA to ignore large portions of the scientific literature in making decisions that are supposed to protect human health with an adequate margin of safety.** As a doctor, I would do my patients a disservice if I ignored the best available evidence to guide my decisions.

Medical guidelines are based on the best available evidence, which emerges from multiple peer-reviewed scientific studies, not just one study. In the case of clinical drug trials, some studies can be fully de-identified and can be made available to the public for replication, other studies cannot in order to protect patient privacy. I ask the Science Advisory Board to consider, would you want your doctor to only offer you drugs that have been studied in trials that are posted online in de-identified format, or would you want your doctor to consider the full body of evidence to make treatment decisions? It would be malpractice for a doctor to apply such a "transparency" standard, as proposed for the EPA, to the care of patients, because it would involve ignoring large portions of the scientific literature. Such a standard would lead to misinformed decisions, like offering drugs that have been found to be unsafe, and may deny patients the best treatments that modern medicine offers today. **Patients would suffer and die unnecessarily if the medical community ignored scientific evidence to guide treatment decisions, and the same would be true if the EPA ignored evidence in making decisions about environmental health standards**.

If implemented, this regulation **would function as a roadblock against the use of epidemiologic research in EPA rule-making.** Epidemiologic research involves observing real people living in the real world to see how pollution exposure affects risk of death and disease. Published epidemiologic studies have all been fully vetted by Institutional Review Boards to ensure the research is ethical and protects the privacy of participants. Sharing medical data about real people with real diseases living at

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their home addresses is especially challenging and not always feasible, because the privacy of study participants must be protected. Therefore, the consequence of this new rule will be to prevent most research about health effects of pollution in the real world from informing EPA policy, because the raw, underlying data about the participants of these health studies cannot be shared with the public. Ignoring medical research in regulatory decision-making is the opposite of progress, and is not in the interest of human health.

We wish to emphasize one final point: this "transparency rule" would give the EPA administrator full discretion to choose which studies are acceptable for use by EPA in regulatory decision-making, with no accountability to the public. **Allowing the administrator to cherry pick research in this way is secretive, and flies in the face of any transparent ethical process.**

The EPA has the health of our children in its hands. On behalf of the physicians and scientists of the American Thoracic Society, I strongly urge the Science Advisory Board to advise EPA to abandon this misguided rule for the sake of human health and transparency in regulation.

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