

ORAL Statement of Lynn R. Goldman, MD, MS, MPH

May 31, 2018

Submitted to: the US Environmental Protection Agency Science Advisory Board

EPA Planned Action: NPRM “Strengthening Transparency in Regulatory Science”

Mr. Chairman and members of the EPA Science Advisory Board, it is my honor to testify to you in support the SAB workgroup’s May 12 memo recommending that the SAB review the agency’s April proposed rulemaking, “Strengthening Transparency in Regulatory Science.”

I am Dean of the Milken Institute School of Public Health at the George Washington University. In the past, I served as Assistant Administrator for what’s now called the Office of Chemical Safety and Pollution Prevention at the US Environmental Protection Agency (EPA).

I will summarize my comments which I have provided in writing.

- This NPRM suffers from lack of involvement of the scientific community.
- There is no clear justification is given for why the rule is needed.
- The proposed rule is a dramatic departure from how the EPA and other US regulatory agencies, and similar agencies internationally, develop dose response assessments in the context of regulatory decisions.
- The rule would have a number of adverse consequences:
 - EPA would have to ignore high quality research or attempt to compel submission of raw data for dose response assessment, which has never been deemed to be required by any expert body;
 - EPA would risk of disclosure of personal information of people volunteering for human subjects’ research. With the Internet and “big data”, this is increasingly a challenge;
 - EPA and researchers would require resources for preparation, curation and secure storage of such data;
 - EPA actions for some number of the more than 1,000 risk assessments performed annually would be delayed;

- In cases where obtaining raw data is not feasible, best available science would be unavailable to the EPA for systematic review.
- By restricting access to data and causing delays in EPA processes this proposal threatens EPA's ability to protect public health and the environment.
- The NPRM includes a provision for the EPA to waive this requirement. No clear decision criteria are provided to allow EPA scientists and stakeholders to understand when and how such waivers might be granted. It thus appears that this requirement could be applied in an arbitrary and capricious manner that does not reflect science judgment.
- The NPRM would overturn years of regulatory science policy development and create an unfortunate precedent for EPA in the creation of science policy by rulemaking rather than guidance, thus freezing EPA's risk assessment processes in the future.

Conclusion

In conclusion, the proposed rule would make major changes and cause significant delays in how EPA uses science to make hundreds of regulatory decisions every year. It would overturn years of internal guidance and precedent, and advice from scientific experts outside of EPA. It would be burdensome, for the agency and researchers alike. I strongly urge the SAB to recommend the Administrator:

- (1) Do not use the agency's regulatory authority to prescribe specific risk assessment processes. Period.
- (2) Do not adopt any major changes to EPA's rules or policies related to the use of science in rule-making until EPA has received clear scientific advice from the SAB and other authorities.