WRITTEN COMMENTS OF ROY GAMSE ON
EPA'S PROPOSED REGULATION ON STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE
AT THE JANUARY 17, 2020, TELECONFERENCE OF THE EPA SCIENCE ADVISORY BOARD (SAB)

Thank you for the opportunity to provide comments on the SAB draft response to US Environmental Protection Agency's (EPA) proposed regulation on Strengthening Transparency in Regulatory Science.

I worked for EPA for 10 years during the Nixon, Ford, Carter and Reagan Administrations. I was Deputy Assistant Administrator, Deputy Associate Administrator, and Acting Assistant Administrator from 1977 to 1981, which included responsibility for the regulation development process and for economic and statistical analysis at EPA.

I compliment the SAB members for identifying a number of problems with EPA's proposed regulation and with its weak justification for adopting it. However, the SAB draft and its transmittal letter are in some instances too vague, making what could be interpreted as optional suggestions to address numerous problems when the problems are too serious and require very strong major actions, if they can be cured at all.

The SAB draft does make a very strong and appropriate statement:

"The EPA's proposed policy of excluding from consideration any study for which underlying data are not made publicly available is not consistent with sound scientific practice."

But it is buried at the bottom of a paragraph in the middle of page 16. To assure that there is no misunderstanding of the SAB's message by EPA or the public, that statement should be highlighted in the cover letter and in the Executive Summary.

EPA DOES NOT IDENTIFY A WAY THAT RESEARCH PARTICIPANTS' CONFIDENTIALITY CAN BE GUARANTEED, HENCE DRAMATICALLY REDUCING THE NUMBER OF STUDIES THAT COULD BE USED AS THE BASIS FOR REGULATIONS.

Your draft acknowledges that personally identifying information (PII) cannot be made available to the public. Yet the public comments on the proposal have demonstrated clearly that with "big data" analysis, even with anonymization, a very significant percentage of individuals can be identified, even without name and address information, unless so much data is masked that there is not enough data to allow reanalysis. For example, the comment on the proposal from the International Society of Environmental Epidemiologists (ISEE) (which I described in your August 27 teleconference and which SAB staff distributed to the SAB members at my request) shows example after example where the masking approach is inadequate. [see ISEE comments, pp. 7 – 11].

So the masking approach that EPA proposes is demonstrably insufficient to permit full public access to data from these studies. The SAB comments suggest some areas of investigation, but neither EPA nor the SAB comments provide a method which with certainty will protect

individuals' private information. Without a clear approach to protecting individual data, promises of confidentiality cannot be made to research subjects, or if they are made, they may not be honored. If researchers are honest in describing the risks that EPA publication may violate the confidentiality expectation, then participation in needed research will decline dramatically. Further, many existing studies based on highly useful cohorts would have to be withdrawn for use in regulatory decisions.

The SAB should be forthright in advising EPA that a yet-unrevealed practical solution to this problem must be identified, explained, and tested, or the proposed approach will fail to provide the research needed for EPA to fulfill its mission.

EPA'S PROPOSED APPROACH CANNOT BE APPLIED TO RESEARCH STUDIES FROM EUROPE AND CANADA.

As the ISEE explained in its comments on the proposal,

"European and Canadian privacy laws reject the idea that personal information from participants in research studies could ever be made public. Indeed, Europe has just tightened its data privacy laws with the General Data Protection Regulation." [ISEE, pp. 3-4]

The ISEE elaborates with an example of research relevant to review of the EPA particulate standard where the Canadian Statistics Act prevents the data from being made public.

EPA has not yet revealed how to surmount this problem. Are European and Canadian research to be ignored in setting EPA standards? Are different transparency standards to be applied to US research than to non-US research? What current EPA rules are based, at least in part, on European and Canadian research? Are the ill-defined exceptions at the Administrator's discretion to be applied liberally to Canadian and European research?

Again, the SAB should be forthright in advising EPA that a yet-unrevealed solution to this problem must be identified, explained, and tested, or the proposed approach will fail to provide the research needed for EPA to fulfill its mission.

Trying to be constructive, I recommend that EPA experts should confer on these two issues with experts from the ISEE and the National Academy of Sciences to try to find a consensus solution to these issues (and possibly others). Unless EPA has an unidentified rabbit to pull out of a hat, I don't see a clear path to transforming this proposal into a regulation whose benefits exceed its costs.

THERE IS NO EVIDENCE (OR LIKELIHOOD) THAT THE BENEFITS OF THIS PROPOSAL WOULD OUTWEIGH THE COSTS THAT WOULD RESULT.

I (along with many other commenters) am concerned that the costs of the rule in terms of lost benefits of regulation combined with the implementation costs will outweigh any alleged (but

not demonstrated) benefits of imposing it. This is particularly the case with respect to requiring full public access to the underlying data from epidemiology studies.

If this were a real EPA regulation that would impose requirements on polluting companies or governments (rather than a restriction placed on future Administrators not required by any statute), a cost-benefit analysis would be required. The SAB has identified the types of costs that would be imposed on EPA, on researchers, on would-be replicators, and on those suffering from excess pollution exposures. In 2015 and 2017, the Congressional Budget Office estimated costs for only EPA of very similar proposed legislation, ranging from millions to hundreds of millions of dollars annually. But EPA has only identified conceptual or alleged benefits without any actual examples, where lack of this rule has imposed costs that would be eliminated by adopting the rule. I have to ask: **Is this a solution in search of a problem?**

It is odd that this regulation would apply only to EPA and not to any other health-regulating agency. Not to Occupational Safety and Health Administration (OSHA) or the Consumer Product Safety Commission (CPSC), or Mining Health and Safety Administration (MHSA), or National Highway Traffic Safety Administration (NHTSA), or the Food and Drug Administration (FDA). If this approach were to make sense, it should be applied to all such agencies and departments by legislation. It makes no sense for them, just as it makes no sense for EPA.

Thank you for considering these comments. The SAB should play a vital role on these issues, including advanced review of any revised proposal or "supplements." You should request (or insist) on such a role. I hope EPA will start listening to you.