ORAL STATEMENT FROM ROY N. GAMSE TO THE US EPA SAB
REGARDING "STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE"
AUGUST 27, 2019

Thank you for the opportunity to provide comments for your consideration as you respond to the charge from EPA on the proposed regulation on Strengthening Transparency in Regulatory Science.

I am Roy Gamse. 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 believe strongly that this proposed self-regulation by EPA is a mistake which, well-intentioned or not, will have the effect of removing from consideration the most relevant and useful research on human health effects of pollution and toxic chemicals. Further, this regulation could force relaxation of current regulations under statutes which require regular reconsideration because the valid research on which they were based could not today pass the requirements of this proposed rule.

In three minutes, I cannot convince you. So I will tell you that the single most important thing for you to do is to read and discuss the "**Comments of the International Society for Environmental Epidemiology (ISEE) on EPA's proposed rule on Strengthening Transparency in Regulatory Science."** The ISEE is the professional society with the expertise most relevant to EPA's charge to the SAB. The ISEE submitted its comments previously to EPA, but cannot speak today because of a simultaneous conference overseas. Since the SAB members have not seen them, I have attached them to my written submission. **SAB members, if you do nothing else in your review, you must read this document.** The ISEE shows with explicit examples how masking has not and will not work to protect privacy. Hence, t**he ISEE recommends that EPA withdraw the proposal** in part because the "masking" of personal identities assumed by EPA cannot be reliably done and still allow reanalysis of the research.

One more key point: **If this proposed self-regulation is such a good idea, why is it proposed just for EPA** rather than as legislation or regulations applying to all health-regulating agencies?
There is no reason whatsoever that the same logic would not apply to regulations promulgated by the Occupational Safety and Health Administration (OSHA), the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), and others. Why regulate only EPA and not any other regulatory agency?

Simple answer: the effects of this regulatory proposal would cut both ways. Imagine the Food and Drug Administration being forbidden to approve new drugs unless the research justifying their use were subject to these same regulatory prohibitions. The privacy protections imagined in this proposal would not protect patient identities any more than they would subjects of research considered by EPA. Drug approvals would likely grind to a halt -- as would EPA regulations for air quality standards, hazardous materials exposures, pesticides exposures, drinking water concentrations, etc.

This proposed self-regulation would make no sense for the FDA and it makes no sense for EPA. **Your answer to EPA should be that it is impossible to be certain that privacy protections would not be violated, so approving this approach would eliminate the use of the best research to support EPA regulation. It should be rejected.**

Thank you.