Environmental Protection Network

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SUMMARY
Testimony to the SAB on Mechanisms for Secure Access to PII and CBI in the Proposed Censored Science Rule
August 27, 2019

On Tuesday, August 27, 2019, the Science Advisory Board (SAB) held a public teleconference to consult with EPA on mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) as discussed in the proposed censored science rule. The rule would restrict the use of scientific studies in setting rules and agency policies, if the data and models that support the studies are not available for public review. This is a direct attack on long-accepted scientific approaches and presents a real threat to human health.

EPN member Dr. Bernard Goldstein, former EPA Assistant Administrator for the Office of Research and Development (ORD), chair of the Clean Air Scientific Advisory Committee (CASAC), and a member of both the National Academy of Medicine and the American Society for Clinical Investigation, presented testimony on behalf of the Environmental Protection Network (EPN).

As in previous testimony, EPN once again finds it highly inappropriate to advance a major new plan on how to utilize the scientific literature for regulatory purposes without asking advice from the SAB about the whole plan. EPN also notes that none of the proposed approaches under consideration inherently can guarantee no risk of release of personal information.

Dr. Goldstein emphasizes the following practical and ethical issues of the proposal in his testimony:

- **EPA's proposal creates a cumbersome barrier to international collaboration investigating studies of humans that are potentially relevant to EPA's environmental regulations.** International studies are becoming an ever-increasing percentage of total environmental health research. The censored science rule raises many logistical questions that have not been answered: How will EPA get the raw data? Will authors, in particular non-U.S. authors, agree to have their data made available to EPA?
- **EPA is responsible for anticipating new threats, another duty hindered by the proposed rule.** If EPA is compelled to respond to a new threat, will the agency require the raw data from foreign scientists not willing to share? If the Administrator makes an exception, will that stand up to legal scrutiny if there were a negative study published by the industry including shared data? Scientists able to contribute to answering new questions would be limited by this rule, which forbids crossover of scientists who receive EPA funding and serve in advisory roles.
- **Recall bias is a common problem in epidemiological studies, compounded by the length of time between the possible exposure and the epidemiological investigation.** Will the possibility that disagreements between investigators or Institutional Review Boards (IRB) about whether their study conforms to EPA's new requirements contribute further to delays in the response of scientists to environmental disasters?
- **The "equipoise," or uncertainty principle, could be used by an IRB to refuse to allow investigators to hand over raw data to EPA.** Although controversial, many IRBs interpret their mandate as including whether the proposed study is scientifically valid. If not, there would be no ethical basis on which to expose humans to any risk – including having their personal information at risk of disclosure.
- **Environmental health studies of humans rarely consist of the double-blind studies required by FDA.** These studies are therefore inherently more subject to confounding.