COMMENTS CONCERNING THE MEETING OF THE SCIENCE ADVISORY BOARD ON HOW TO PROVIDE THE PUBLIC WITH "SECURE ACCESS" TO CERTAIN TYPES OF INFORMATION ROUTINELY PROTECTED FROM SUCH DISCLOSURE

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My name is William Jordan. I offer my comments as the former Deputy Director of EPA's Office of Pesticide Programs (OPP), and my views reflect my experience from working at EPA for over 40 years, both in OPP and EPA's Office of General Counsel. My comments are intended for consideration in conjunction with the Science Advisory Board (SAB) meeting on August 27, 2019, to discuss certain aspects of EPA's proposed regulation, referred to as the "Strengthening Transparency in Regulatory Science" proposed rule [hereinafter referred to as the "proposed Transparency Rule"].

The Federal Register notice announcing the SAB meeting states the purpose of the meeting as follows:

> EPA's proposed rulemaking (83 FR 18768, April 30, 2018) [the proposed Transparency Rule] contains the following statements: (1) "When promulgating significant regulatory actions, the Agency shall ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation." (2) "Information is considered publicly available in a manner sufficient for independent validation when it includes the information necessary for the public to understand, assess, and replicate findings." (3) "Where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." Therefore, EPA has requested a consultation with the SAB on mechanisms for secure access to personally identifying information (PII) and confidential business information (CBI) as discussed in the proposed rule consistent with existing laws and policies that protect PII and CBI.

In my view, the provisions of the proposed Transparency Rule cited above use such vague language in clauses (1) and (2) that it seems impossible for the SAB to provide useful guidance about how EPA could arrange for "secure access" to PII and CBI in a manner that would both satisfy the requirement in clause (1) and protect the confidentiality of PII and CBI as promised by clause (3). Moreover, the cited provisions appear to have the perverse effect of causing EPA to make decisions without the benefit of all relevant, scientifically sound information.

I have three points:

- first, clauses (1) and (2) are unclear about how much CBI or PII would have to be made available, but it seems they would require disclosure of all such information requested by a member of the public;
- second, it is not clear how providing a member of the public "secure access" to CBI and PII would comport with the kinds of protections that existing laws require; and
- third, given the apparent conflict between clause (3) and clauses (1) and (2), the proposed Transparency Rule would appear to require EPA to exclude many studies from regulatory consideration, but, based on my experience in EPA's Office of Pesticide Programs, such a result should rarely, if ever, be necessary.

As a threshold matter, the scope of disclosure required by the proposed Transparency Rule is unclear. I infer that, under clauses (1) and (2), EPA intends for any member of the public to be able to have access to all information he or she wants in order to "understand" an EPA rulemaking. The standard in clause (1) – that information shall be "publicly available in a manner sufficient for independent validation" – is both broad and vague. What is "sufficient"? What is "independent validation"? Although clause (2) purports to define the phrase in clause (1), it uses wording which is also inherently imprecise – "necessary for the public to understand, assess, and replicated findings." The word, "necessary," is particularly subjective and invites claims by members of the public that additional information that is protected from disclosure as PII or CBI would allow them to understand, replicate, or assess the subject rulemaking. Because "understand[ing]" and "assess[ing]" a rulemaking reflect the state of mind of the requestor, it seems as though EPA would have little or no basis for refusing to deem a requested piece of information as "necessary" for the requestor. In sum, the language in the proposed Transparency Rule relating to what PII and CBI must be disclosed can be interpreted to reach all types of CBI and PII. Given the wide variety of information that might fall within the broad categories of CBI and PII, it seems unlikely that the SAB could formulate ways of giving access to each type of information that would be appropriately "secure."

My second comment concerns the legality of the kind of arrangements on which the EPA is asking the SAB to advise. Clause (1) would require EPA to make information "publicly available." At the same time, clause (3) states that "Where the Agency is making information publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." Many laws, regulations, and / or agreements entered into by investigators with research participants would prevent the public release of CBI and PII. The laws governing the release of PII and CBI, in particular, are quite specific about who may obtain protected information and under what conditions. Any effort to expand the scope of the recipients or to modify the circumstances of access requires a legal analysis of the relevant statutes to determine whether EPA can make such changes. In the absence of such an analysis, it seems premature for the SAB to offer any advice on what methods of access would be consistent with existing laws and regulations.

Further, the plain implication of the Federal Register notice is that EPA would be giving access to protected information to any member of the public so long as the access was "secure." It is

not clear however, what "secure access" means, but it probably means delivery of information in a manner that preserves the confidentiality of the information and / or the privacy of the individuals identified. Presumably, providing access in a secure manner might involve putting some constraints on the use of the information by the recipient. Among other things, it is worth exploring whether and how EPA could enforce any such constraints.

My third comment concerns the apparent conflict between clause (3) and clauses (1) and (2). It seems likely that under clause (3) EPA will not be able to disclose all CBI and PII that a member of the public might request pursuant to the standard in clause (1). Although not raised either in the Federal Register notice and by charge to the SAB, EPA's apparent course of action in such a situation would then be to exclude all such studies from consideration in its regulatory decision making. Since many studies contain some data classified as PII or CBI, the Agency's proposed Transparency Rule could have the consequence of severely limiting the scope of data used to make decisions about how to protect human health and the environment. (At the very least, given how broad and vague the standard in clauses (1) and (2) is and the uncertainty about how clause (3) would affect the operation of clauses (1) and (2), it would be difficult to predict how EPA would apply these provisions in any particular situation.)

Thus, the SAB should address not only the charge question relating to providing "secure access," but also the additional question of how these three clauses would affect EPA's ability to consider studies containing CBI and PII. In doing so, I hope and expect that the SAB would express its support for the following principles:
a) it is essential for EPA to consider all scientifically sound, relevant information in its regulatory decisions; and
b) the interest of the public in a transparent regulatory system can be met without routinely disclosing CBI or PII.

My work over four decades in EPA's Office of Pesticide Programs has reinforced the importance of following these principles. When making regulatory decisions about a pesticide, OPP routinely examines all information available from pesticide applicants, registrants, other government agencies, and the scientific literature. Moreover, each year, EPA OPP receives thousands of scientific studies from companies seeking to register a pesticide or to maintain a registration. Virtually every scientific study contained CBI and a significant portion contained PII. Nonetheless, OPP has successfully used the data in its regulatory decision-making and described the underlying information in its risk assessments in a way that a broad range of stakeholders has found acceptable, even when they could not see the portions of the studies that were protected from disclosure. Even though the regulatory actions taken by EPA under the pesticide laws are outside the scope of the proposed Transparency Rule, OPP's experience could serve as a useful model for how the rest of the agency could effectively meet both the goals of transparency and protection of CBI and PII. In fact, I think that, to a very great extent, all of the other regulatory programs in EPA follow an approach similar to that used in OPP.