The Academy of Toxicological Sciences

June 20, 2018

Environmental Protection Agency
Office of the Science Advisor
1200 Pennsylvania Avenue NW
Washington, DC, 20460

RE: Docket ID No. EPA–HQ–OA–2018–0259

Dear Administrator Pruitt,

The National Academy of Sciences (NAS) is a private, non-profit society established by an Act of Congress in 1863. The NAS is charged with providing independent, objective advice to the nation on matters related to science and technology. It is in this context that the Federal Judicial Center and National Research Council, which are entities within the NAS, generated the 3rd edition of the "Reference Manual on Scientific Evidence". The Manual defines credentials for members of the judiciary to use toward identifying experts in the field of toxicology. Among those criteria is certification as a Fellow of the Academy of Toxicological Sciences (ATS).

The ATS is a 501c3 professional scientific organization certifying over 250 toxicologists (Fellows of the Academy) worldwide for their expertise and sound scientific judgment. Certification is based on a deliberate, in-depth peer review. The purpose of this professional recognition is to ensure a high standard of professional education, experience and practice for toxicology professionals engaged in the generation and translation of toxicology data and information for the protection of environmental and public health. The Board of Directors of the ATS includes professionals from private industry, academics and government. The service of Board members who are federal employees is consistent with the values articulated in the Office of Science and Technology Policy's 2010 memorandum on Scientific Integrity. This memorandum instructs "Heads of Executive Department and Agencies" to strengthen the actual and perceived credibility of government research by ensuring policy decisions undergo independent peer review by qualified experts. It is in these contexts that the members of the ATS Board of Directors are delivering the following review comments and recommendations. The opinions expressed are those of the ATS Board of Directors and are not necessarily those of their private, academic or government employers.

We have read with great interest the recent proposed Environmental Protection Agency (EPA) rule, "Strengthening Transparency in Regulatory Science" (ENVIRONMENTAL PROTECTION AGENCY

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40 CFR Part 30 [EPA–HQ–OA–2018–0259; FRL–9977–40– ORD] RIN 2080–AA14) and are writing to provide specific comment on three aspects.

Ignoring data or declaring it invalid for use solely on the basis of public availability is inappropriate.

We agree that regulatory decisions should be rooted in the best science, as noted in the opening statement of the Background section of the proposed rule. We also believe that often there is much to be gained by allowing all data to be scrutinized. We support the concept of open data and efforts towards transparency in the data used in regulatory decision-making. We assert, however, that there are often valid reasons that some critical data cannot be shared indiscriminately. Primarily these concerns are related to the use of human data where privacy concerns are paramount. Although we acknowledge that it often is possible to remove information that explicitly identifies individual subjects, it is not always possible to ensure complete anonymity without eliminating the meaning and utility of the data.

As an example, anonymizing a data set is particularly problematic for clinical or epidemiology studies that link exposures from specific sources or locales with health outcomes. These studies may be geographically restricted, affecting single communities or neighborhoods, for which it is very possible to link particular health outcomes with specific individuals. Such studies can be extraordinarily powerful in identifying public health threats. Two examples are the linkage of birth defects with mercury discharge in Minamata Bay, and male infertility after occupational exposure to dibromochloropropane (DBCP). Although the health consequences of these incidents were profound, the number of affected individuals was limited, such that it would have been possible to identify them were all the data to have been freely available. Yet, the regulatory decisions that have been made based on studies of these incidents have undoubtedly been beneficial to the public. Refusal to have used these studies because the data were not publicly available would be contrary to EPA's public health mission.

An exemption system that would allow data from some studies to be included, but not others, based on anything other than scientific merit sets a negative precedent.

The FR notice states several potential strategies to protect confidential and private information, such as "*Requiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements*"; **none of these require ignoring or invalidating relevant data for consideration.**

We also acknowledge that the proposed rule includes a provision allowing the Administrator to exempt significant regulatory decisions on a case-by-case basis. We appreciate the importance of including such a proviso and we advocate <u>that decisions on such exemptions should not be made by the Administrator, but rather by an independent scientific body</u> and should be based on the data value and utility relative to the decision to be made, whether or not deidentifying the data is possible without compromising the data's value or interpretability, or as outlined in the

examples above, are derived from small cohorts wherein it is not possible to effectively anonymize the data.

We urge you to recognize the significant positive outcome of regulatory decisions on studies that do not contain fully publicly transparent data. The public benefit of these studies far outweighs the concerns that this FR attempts to correct and is contrary to the mission of the EPA to protect and enhance public health. We also urge you to extend the comment period to at least 90 days.

Thank you for the opportunity to provide input to the Final Rule.

Sincerely,

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President, 2017-2018

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