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Brooke Dickson
Office of Information and Regulator Affairs
Office of Management and Budget
Washington, D.C. 20503

Ms. Dickson:

On behalf of the American Thoracic Society, I want to express our appreciation for the opportunity to comment on the "Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies" published in the June 28 Federal Register.

The American Thoracic Society (ATS), founded in 1905, is an independently incorporated, international professional and scientific society which focuses on respiratory and critical care medicine. The ATS has approximately 13,500 members. The Society's members help prevent and fight respiratory disease around the globe, through research, education, patient care and advocacy. As such, we are keenly interested in ensuring that the information disseminated by the Federal government is reliable and accurate.

Regulation Not Necessary

The ATS believes that existing policy already provides adequate assurances that scientific information disseminated by the federal government is of high quality. The peer review process is the best mechanism to ensure the quality of scientific data. In our opinion, the proposed guideline will only add complexity and confusion to the important role the federal government plays in the release of valuable scientific data.

Troublesome Definition of Terms

The proposed guideline provides definitions that the⁴ATS finds troubling. The definition of several key terms will give individuals or organizations, who may oppose the moral or economic implications of a line of scientific inquiry, a tool to lodge frivolous challenges to quality data. Facilitating frivolous challenges to quality research will delay important scientific work and will ultimately hurt the public.

Useful to the Public

The ATS is concerned that the proposed guideline will require agencies to consider whether information is, "useful to all users of the information, including the public." The "public" is not a monolithic entity. Information of tremendous value to a small subset of the public will be of little or no value to the public at large. As defined in the proposed guideline, the term "useful to the public" will likely become an obstructionist tool used to thwart the dissemination of valuable information.

Substantially Reproducible

The ATS is concerned with the term "substantially reproducible." The proposed guideline requires that federal agencies ensure that data be substantially reproducible. Such a requirement may severely impede dissemination of important information. Does OMB state that information *should be able* to be replicated or that it *must be* replicated before it conforms to the requirement of the proposed guideline? What standard will satisfy agency reviewers that information is "reproducible?" The ATS strongly recommends the substantially reproducible requirement be stricken in the final guideline.

Underlying Data

The ATS is extremely concerned about the implications of the term "underlying data." The ATS strongly recommends that final definition and interpretation of the term explicitly exclude lab notes, telephone records, medical records, administrative records or any other daily research work product. Giving the public's frivolous access to such records through the proposed guideline would have chilling impact on the conduct of research.

Relationship to Extramural Research

The proposed guideline is unclear on how it will impact extramural research funded by federal agencies. The proposed guidelines would require the dissemination of "other information in order to ensure an accurate, clear, complete and unbiased presentation..." The proposed guidelines further require the identification of the sources of the disseminated information (to the extent possible, consistent with confidentiality protections) so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. This statement is extremely concerning to the research community in that it implies that the proposed guideline on extramural research data would be subject to public review, above and beyond the peer review process. Applying the proposed guideline to extramural research would severely interfere with peer review, publication and the entire scientific enterprise. We strongly

recommend that the final rule explicitly exempt extramural research data.

Reporting Requirements

The proposed guideline requires that all federal agencies provide a yearly report documenting the “number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines...and that such complaints were resolved.” Reporting the number of complaints without also reporting on whether such complaints were valid will likely present a distorted picture of the quality of agency data. One can easily envision a federal agency releasing data on a politically sensitive topic and being flooded with complaints regarding the quality of the data. The sheer number of the complaints would have no impact on whether the data were of quality and meet the requirement established by OMB.

The ATS sincerely appreciates the opportunity to comment on the proposed guidelines and hopes that OMB will address our concerns in drafting the final guideline.

Sincerely,

A handwritten signature in black ink that reads "Adam Wanner". The signature is written in a cursive, flowing style.

Adam Wanner, MD
President