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Ms. Brooke Dickson
Office of Information and
Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

**[66 FR 34489] Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies**

Dear Ms. Dickson:

I am grateful for this opportunity to comment on behalf of the Association of American Medical Colleges (AAMC) concerning the proposed guidelines on information quality. As indicated by the discussion section of the *Federal Register* notice, the proposed guidelines are extremely broad in scope. The AAMC's comments focus on the guidelines' implications for medical and scientific research, based on our experience as the national representative of all 125 U.S. medical schools, more than 400 teaching hospitals, and 92 academic and professional societies, comprising more than 91,000 faculty members. Our institutions perform over half of the extramural research sponsored by the National Institutes of Health (NIH), the nation's leading agency supporting biomedical and basic science research, as well as conduct research sponsored by other Public Health Service and federal agencies.

From this vantage, the AAMC is deeply concerned that the proposed guidelines would impede communication of valid research findings from scientific and health research and, contrary to federal intent, actually diminish the quality, objectivity, utility, and integrity of federal information by imposing inappropriate standards and layers of review that supersede time-honored processes for scientific review and validation.

**Background**

Congress directed the Office of Management and Budget to promulgate information quality guidelines in Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554). As described in the *Federal Register* notice, Congress' intent in Section 515 is to ensure and maximize the quality of information disseminated by the federal government, particularly given reasonable concerns that the use of the Internet has greatly increased the volume of governmental information available to the public. Neither Congress in writing this legislation nor the OMB in drafting the *Federal Register* notice addressed any specific concerns about the quality of scientific research sponsored, performed, cited, or disseminated by the federal government.

The U.S. Public Health Service (PHS) is prominent both for sponsoring and conducting biomedical and other health-related research in order to promote the health of the public. The information created, collected, and disseminated by the National Institutes of Health, the Centers for Disease Control and Prevention, and their sister PHS agencies is regarded as the most highly influential and respected public health guidance in the world. The federal government must take particular caution that its new proposed guidelines, so broadly cast, not impair the functioning of this remarkably beneficial and effective system.

**Peer Review**

The statutory language in Section 515 requires OMB to provide policy and procedural guidance to federal agencies for ensuring and maximizing the *quality, objectivity, utility,* and *integrity* of information disseminated by the Federal Government. The proposed guidelines, which do not define these terms, stipulate that the terms collectively require information to be presented in an "accurate, clear, complete, and unbiased manner." In contrast to the general and often equivocal language used elsewhere in the notice, the proposed guidelines set a blunt and highly prescriptive standard for "*scientific research information*" within the section on definitions:

> "....With respect to scientific research information, the results must be substantially reproducible upon independent analysis of the underlying data." (Section V.1, paragraph B.ii.a)

This language, which resembles a regulation more than a guideline, is seemingly reinforced in V.1.A: "...[W]hen reproducibility and transparency of the information are relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that reproducibility and transparency have been taken into account."

<u>The AAMC strenuously objects to the proposed standard for scientific research information and urges its removal from the final guidelines.</u> The gold standard for dissemination of scientific and medical research information is publication in a peer-reviewed journal. However, the process of peer review does not and cannot itself ensure the "reproducibility" of published data or its interpretation. Rather, that is the task of the interested scientific community, adequately trained, appropriately equipped and funded, and properly motivated to undertake the demanding effort required to reproduce published scientific findings. When data or findings from the peer-reviewed literature are contested—and contested competently—the discordant data and analyses are themselves submitted for peer review and published as research articles, commentaries, or letters; and so the process continues until the original findings and interpretations have become established, modified, or passed by and discarded. The tension created by this process of discovery, interpretation, challenge, and rediscovery openly communicated through the scientific and medical literature is inherent in the scientific method and fundamental to scientific progress.

In contrast, for OMB to assert reproducibility as the threshold criterion for "quality" of scientific information would set a standard far beyond peer review and would essentially prevent federal

agencies from depending, as does the entire scientific community, on the reliability of the peer reviewed literature. A result less in the public interest is hard to imagine.

Scientists working in the same areas routinely attempt to confirm the published findings of their colleagues, whenever possible, by replicating them. To do so increasingly requires access to, and proficiency in the use of, particular "research tools," e.g., constructed cell lines, transgenic animals, sophisticated instrumentation, or other specialized resources. In some kinds of scientific studies, e.g., long-term epidemiology studies, strict reproducibility of the experimental findings may be limited or precluded by sheer impracticality; consider, for example, the federally supported Framingham Heart Study that has been ongoing for five decades. In no instance, however, can reproducibility be assessed unless the scientific findings are first published and made known.

In some instances, federal agencies may determine that it is necessary for protection of public health and safety to disseminate scientific or health information quickly, without reliance on peer review or being able to wait for the ordinary, time consuming scientific processes of substantiation or refutation to take place. The AAMC believes that clear and transparent procedures for assessing the quality of such information should be established by the agencies themselves in close consultation with the relevant scientific and health communities. In these instances, coordinating guidance from OMB could be valuable in ensuring consistency across agencies.

The standard for dissemination of scientific information is deficient in other respects:

**"Independent analyses"**: The guidelines imply that there is a single independent and bias-free position from which to assess the validity of scientific findings. The history of science proves otherwise. It is axiomatic that each observation and observer is potentially subject to bias, as is each reviewer and commentator. A range of error and uncertainty affects every recorded data element. These errors and uncertainties are attributable to human fallibility, the physical limitations of instruments, experimental methodologies, chance, and especially in biology and medicine, the inherent nature of the subjects under investigation. It is counterintuitive that federal agency officials or "affected persons" (discussed below) would categorically make the most appropriately independent reviewers or referees of such information, as the proposed guidelines seem to imply. Scientific peers, versed in the procedures, methods, and issues under investigation (and who are sufficiently distant from the researcher and findings under scrutiny), are better able to provide balanced assessment about the quality and reliability of reported findings from research.

**"Underlying Data"**: The definition of *underlying data*, noticeably absent from the guidelines, is highly problematic, as was forcefully underscored during the prolonged process of rule-making on Section __.36(c) of OMB Circular A-110 (referred to as the Shelby provision) pursuant to P.L. 105-277. Definitions of *data* may range from a select set of recorded observations sufficient to establish the research findings to all records and materials (raw data) accumulated in the course of investigation. Most commonly,

research data require annotation and formatting to be useful and are comprehensible only to individuals expert in the area of investigation. This fact belies the statement (Section V.1.B.i), in so far as the guidelines relate to the dissemination of data sources from scientific research: "...[T]he agency needs to identify 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." Numerous concerns, in addition to confidentiality, were raised by the federal proposals pursuant to the Shelby provision to identify or provide source data. It was after extensive dialogue with the scientific community and careful consideration of this matter that OMB wisely decided to limit the definition of data, as described at length in 64 FR 43786, section III A and in 64 FR 54926 section II A. The information quality guidelines should not unnecessarily reopen that well-considered decision.

**Exceeding the Statutory Requirement**

In asserting a standard for scientific communication, the OMB has gone beyond the statutory requirement of Section 515. Congress did not require OMB to set a standard for scientific communication, but rather generally to:

> "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information *(including statistical information)* disseminated by Federal agencies." [emphasis added].

The specification of "statistical information" demonstrates that Congress did in fact deliberate on specific types of federal information for OMB to address and that scientific research was not singled out for special attention. Nor is OMB confronted by questions of 515's consistency with other statutes or policies regarding scientific information that need to be addressed or resolved in the proposed guidelines. Neither the Paperwork Reduction Act (44 USC § 3501 et seq.) nor OMB Circular A-130—upon which the proposed guidelines build and are designed to be consistent—distinguish scientific research apart from other types of information, nor do either require scientific information to meet a separate federal standard.

Further, the proposed guidelines promulgate a specific standard for scientific communication that is <u>not</u> reflected in the National Science Foundation Act, the Public Health Service Act, nor, to our knowledge, in any other federal legislation creating or controlling federal research or health programs. The AAMC thinks it entirely unreasonable to believe that the Congress, in an appropriations bill (H.R. 5658) not originally pertaining to a single science or health agency, intended to propose such a fundamental alteration in the federal policies governing the communication of scientific research. It would be far more appropriate to permit the federal agencies overseeing science and health research programs to address standards for communication of scientific information in their own guidelines that are consistent with the totality of their complex statutory and regulatory requirements.

**Mechanisms for Review by "Affected Persons"**

As directed by Congress, the proposed guidelines require that:

> As a matter of citizen review, agencies should establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with these OMB guidelines. (III.3)

Information from scientific or health-related research that is in the possession of or disseminated by federal agencies should not be subject to correction or amendment without stringent qualified scientific review. The perception that the legislation and proposed guidelines could provide a mechanism for vested interests or partisan activists to alter or control federal dissemination of peer-reviewed information has understandably alarmed the scientific community, as it should.

We fully concur with the principle put forward by OMB, that "these administrative mechanisms [for public review] should be consonant with established agency practice, flexible, and appropriate to the nature of the disseminated information." Any requests to amend or alter scientific and technical information must be subject to a commensurately rigorous level of review assuring the appropriate scientific expertise. The OMB final guidelines should not be interpretable as precluding federal agencies from establishing scientific peer review as the preeminent mechanism for guaranteeing the quality of scientific information disseminated by the federal government.

A major concern of the AAMC is that the guidelines include a public review mechanism and the standard for dissemination of scientific research information. The two items could appear conjointly to provide grounds for interested parties to demand access to underlying data, to compel the government to replicate research findings (at great expense and with unnecessary delay), or in other ways impede, discredit, harass or stymie research. The AAMC does not wish the information quality guidelines to be construed as an activist's instrument for circumventing established scientific procedures and assailing research.

**Administrative Burden**

The AAMC is sensitive to the increasing administrative burden tasked to PHS agencies. Various federal hiring freezes and other restrictions have constrained the ability of these agencies to acquire staff even for core missions of the agency. The AAMC does not believe that the efforts of public servants should be further attenuated by supervisory and reporting tasks that are less than minimally contributive to the agencies' effectiveness. While the notice conveys OMB's interest to promulgate guidelines that are consistent with existing agency practices, the notice provides no estimate of the actual burden that would be imposed on agencies. Moreover, the administrative "complaint mechanism" provided in the guidelines (at the direction of the statute), is an open-ended task, because the number of public complaints received will be determined as much by interest group concerns as by the actual quality of the information disseminated. The OMB should work with federal agencies to estimate the administrative and cost impact of the

information quality guidelines. The information would be helpful to the public and to Congress in assessing the merit and practicality of the guidelines.

**Scope of the Guidelines**

The AAMC believes that the scope of the proposed guidelines cannot reasonably be judged to extend to academic or other research institutions that disseminate results of research conducted under federal grants; but we are deeply concerned by the ambiguities in the definitions of *information, government information, dissemination,* and other non-delimiting language in the guidelines. The statutory language of Section 515 builds upon the authorities granted OMB by the Paperwork Reduction Act, which established the Office of Information and Regulatory Affairs. The express purpose of the PRA was to "minimize the paperwork burden" for individuals and non-governmental entities, including "educational and nonprofit institutions" (44 USC § 3501). Any attempted federal restriction on dissemination of academic research would be wholly unacceptable in principle and would likely raise First Amendment considerations. It would moreover be a monstrous burden in practice for academic institutions. The scope and definitions of the final information quality guidelines should explicitly identify the federal sphere to which the guidelines apply, and should specifically exclude academic and other non-federal institutions performing research under federal grants.

**Conclusion**

In closing, we wish to underscore that federal agencies charged with protecting human health and safety occasionally must act on the best information available and do not have the luxury of waiting for "perfection" before crafting administrative guidelines. The approach taken in this notice could seriously threaten public health and safety by tying the hands of the agencies with an unrealistic and impossible standard of "quality."

For these and other reasons, the final guidelines should defer as much as possible to individual federal agencies to develop standards and definitions for dissemination of agency information. Federal science and public health agencies should continue to enlist the advice of the research community in establishment of such guidelines. The AAMC agrees with the OMB in its perception that information quality guidelines developed by federal agencies should also be made available for public comment under the provisions of the Administrative Procedures Act.

In light of these concerns, we recommend the following changes to the proposed guidelines:

1. OMB should not exceed its statutory mandate by prescribing quality standards for scientific research information. Reference to such information, and in particular paragraph ii.a in section V.1.B, should be deleted.

2. Consistent with our first recommendation, references to "reproducibility" or "transparency" of information should be omitted as they may inappropriately apply to dissemination of peer-reviewed scientific research. Issues of the reproducibility of results or the soundness of

underlying data need to be addressed in the peer-reviewed scientific literature, following publication of original findings.

3 Section V.1.B.i. should be amended: "Also, the agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality *and other established* protections)." If references to research "data" are retained in the final guidelines, the term should be defined consistent with definitions in OMB Circular A-110, Section __.36 (d)(2)(i) as revised per the Shelby provision.

4 The scope of the final guidelines and the definitions of *dissemination*, *information*, and other key terms provided in the statute must be made more explicit and consistent with the existing authorities of OMB. The guidelines should not extend to academic or other non-federal institutions receiving federal grants.

OMB should estimate the administrative burden and cost impact of the proposed guidelines on federal agencies.

Finally, we urge OMB to approach Congress and request an extension of the legislated deadline beyond September 30, 2001 in order to provide for publication of a revised set of guidelines and a second public comment period.

For further information or questions regarding AAMC's position, please contact Steve Heinig, Division for Biomedical and Health Sciences Research, 202-828-0488, sheinig@aamc.org.

Sincerely,

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