AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE

Directorate for Science and Policy Programs

1200 New York Avenue, N.W.
Washington, DC 20005
Tel: 202 326 6600
Fax: 202 289 4950

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Ms. Brooke Dickson
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW, Rm. 10236
Washington, DC 20503

Dear Ms. Dickson

I am writing to communicate the views of the American Association for the Advancement of Science (AAAS) Committee on Science, Engineering and Public Policy and the AAAS-ABA National Conference of Scientists and Lawyers on the proposed guidelines for implementing Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554), published in the *Federal Register* on the June 28, 2001. Section 515 tasks the Office of Management and Budget (OMB) with issuing government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) by Federal agencies." AAAS is the world's largest multidisciplinary science association, with over 138,000 members and more than 250 affiliated scientific, engineering, and medical societies representing all disciplines of science. As the publisher of the world's preeminent peer-reviewed scientific journal, *Science*, we are committed to ensuring data quality in both research and policy. Given our long-standing commitment to excellence in scientific research, we are concerned that the language and requirements of the proposed rule reflect a lack of appreciation for the way in which science is conducted. As currently written, the proposed guidelines could make it more difficult to produce, in a timely and efficient manner, the science that is necessary to inform the development and implementation of critical public policy.

We acknowledge OMB's efforts to ensure that information disseminated by the federal government meet some "basic information quality standard," and we agree with the underlying principle that agencies should be encouraged "to rely, to the extent possible, upon existing agency processes for evaluating information dissemination activities rather than require the creation of new and potentially duplicative or contradictory processes." The scientific research enterprise has, for decades, utilized a valued system for preparing, reviewing, analyzing, and publishing research and development (R&D) results. Federal agencies prepare their annual R&D budgets and vet them through OMB for approval before officially submitting R&D budgets to Congress for authorization and appropriations. Individual grants are awarded after an exhaustive merit-based evaluation process. The peer review process is a time-tested method for ensuring quality before research is published. In addition, the scientific community has utilized the peer review process, science advisory boards, regulatory commissions, ethics committees, and review boards as a means for assessing and protecting the integrity and rigor of the research enterprise as a whole. Each step of the process validates that the research conducted, the knowledge that is created, and the scientific information that is disseminated is sound, of high quality, and of importance to our nation as a whole.

While OMB's objective of improving the quality of information disseminated by the federal government is laudable, the proposed guidelines as written single out scientific information in a manner that creates an impediment to the creation and dissemination of scientific information.

Section on Definitions

The statute sets out four terms (quality, utility, objectivity, integrity), which the proposed guidelines, in Sections V(1)(A), V(1)(B) and V(1)(C), translate into three principles (useful to all users; presented in an accurate, clear, complete, and unbiased manner; protected from unauthorized access or revision), which are then collapsed into one term (quality). You rightly noted that these terms are closely interrelated concepts, and yet the translation of these terms to attain "quality" is too vague and thereby open to interpretation.

In the first underlying principle for achieving the "quality, utility, objectivity, and integrity" concepts, OMB states that the information should be "useful to all users" including the public, and that "reproducibility and transparency" need to be taken into account. The term "useful" is a subjective term, and the federal government has many "publics" from K-12 students to doctoral students, from industry contractors to congressional authorizing committees. Public use of government information is a fluid process and what one consumer of information finds useful at any given time another will not. In addition, the ability of any one agency to make information "useful to all users" is a difficult—if not impossible—task. We concur with OMB that the Paperwork Reduction Act definition of "practical utility," which has been used by agencies for the past 20 years, has "focused not only on usefulness to the agency, but also—as appropriate—on the usefulness to the public." Therefore, we recommend that the term "practical utility" continue to be used rather than the phrase "useful to all users."

Within Section V(1)(B)(ii)(a), the proposed guidelines require that with respect to scientific research information, "the results must be substantially reproducible upon independent analysis of the underlying data." First, it is not clear who must conduct the independent analysis. All federal agencies that conduct R&D have internal procedures in place for reviewing information before it is disseminated. The peer review process is a highly effective and accepted method for ensuring quality before research is published. Scientific commissions and review boards are established to analyze peer review research when developing new regulations or health standards. Does this constitute independent analysis, or must groups outside of federal agencies also analyze the data? AAAS feels that it is important that the integrity of scientific research, the internal procedures that federal agencies have in place for reviewing scientific information, and the peer review process remain intact. OMB should clarify the term "independent analysis" and, continue to honor its own underlying principle that agencies be encouraged to rely "upon existing agency processes for evaluating information dissemination activities."

A second concern is the phrase "must be substantially reproducible." Reproducibility is used as if it were a test for quality or objectivity. While reproducibility is used in scientific research to demonstrate the quality of research results, this oversimplifies the work of many research fields. Some scientific information is unique and can never be "reproduced." For example, it is difficult to "reproduce" a field experiment under unique climate conditions, or a health study carried out over a ten-year period. Other information may rely upon data generated from computer-modeling techniques that incorporate certain assumptions. If different assumptions are chosen, that information may not be "reproducible." In addition, some information incorporates extremely large data sets that could be cost-prohibitive to reproduce. For example, the National Institutes of Health (NIH) Human Genome Project has almost completed a map of the human genome. The result of this project is the culmination of work conducted by other federal agencies, numerous

countries, academic institutions, and private-sector companies. Is it sufficient for NIH to test the reproducibility of sample sections of the sequence, or should NIH be required to "reproduce" the entire genomic sequence before disseminating this information to other scientific researchers who can use the information in diagnostic testing of diseases?

The term "substantially" is also troublesome and is a subjective term that is open to a wide range of interpretations in the context of scientific research. Does this term refer to a quantifiable number of times that research results have been reproduced? Or does this refer to a margin of error requirement whereby an agency must show that the results were reproduced with a ±.05 error rate? This subjectivity, coupled with the word "must" also creates a worrisome scenario. Is an agency forbidden to disseminate data that are not proven to meet this requirement? Can an affected person sue a federal agency to require that the agency follow this condition? AAAS is extremely concerned that such a broad phrase as "must be substantially reproducible" will discourage valid scientific information from ever being disseminated or even published because the results have not been "substantially reproduced" in a manner that would meet the OMB guidelines. This would be harmful to our nation's research enterprise since the very nature of scientific research relies on free and open dissemination of research results.

AAAS also finds the term "underlying data" problematic in the context of the "substantially reproducible" phrase. As a professional society that includes scientists from all disciplines, we are acutely aware of the differences across scientific fields in the types of data collected. A definition that fails to take into account, for example, the difference between data generated by a survey instrument and perishable specimens (e.g., blood and tissue samples or rare fossil remains) will inevitably prove to be disruptive to the course of research and will adversely affect the production of valuable knowledge for society. Federal agencies do share data resulting from intramural research conducted within their laboratories, while respecting national security interests, proprietary rights, and confidentiality laws. However, unique cases do arise. For example, both NASA and NSF have aggressively promoted the sharing of data in the research they support. Nevertheless, these organizations decided to restrict access to a piece of a Martian meteorite in order to reduce the risk of contamination. This common sense recognition of important differences undermines the notion of a one-size-fits-all interpretation of "underlying data." AAAS recommends that federal agencies be given the flexibility to define "underlying data" in a manner that will allow them to meet their distinctive statutory missions, and continue to respect national security interests, proprietary rights, and confidentiality laws, while also adapting them to meet unique requirements that may arise over time.

If the intent of the proposed OMB guidelines is to protect against data entry errors or calculation errors with respect to scientific information, then AAAS recommends that language in the guidelines address those issues directly.

Reporting and Correcting Requirement

In the original statutory language in P.L. 106-554, the establishment of administrative mechanisms under Section 515(b)(2)(B) is not covered by the "not later than 1 year after the date of issuance of guidelines" of Section 515(b)(2)(A). As AAAS interprets this language, the statute does not limit the amount of time to establish administrative procedures. Given the issues involved that we have detailed above, AAAS believes this is wise; it allows the individual agencies time to see how guidelines work in practice before beginning administrative procedures to enforce the guidelines. In addition, it provides the agencies an opportunity to track—what AAAS believes will be inevitable—frivolous claims against scientific information. Therefore, AAAS recommends that the proposed guidelines respect the original statutory language, and only

require agencies to file a report outlining procedures for ensuring data quality standards within one year of the final OMB guidelines. Federal agencies should not be required to detail administrative mechanisms within the one year time frame. Our specific concerns regarding the reporting and correcting requirement follow.

Section 515(b)(2)(B) requires agencies to establish administrative mechanisms to allow "affected persons" to "seek and obtain correction." "Correction" should be limited to discovering and rectifying errors in data entry and computation; it should not be interpreted so broadly as to include legitimate differences within the research community over data collection methods, assumptions made in the course of analysis, or standards of proof or persuasiveness. An overly broad interpretation of "correction" will burden the agencies with the task of resolving the very controversies that drive research forward.

The principles for "quality, utility, objectivity, integrity" coupled with the "substantially reproducible" and "allow affected persons to seek and obtain correction" clauses will leave scientists open to frivolous claims by those with opposing viewpoints with the burden-of-proof placed upon the agencies. There is no reciprocal burden-of-proof requirement for the affected persons. They do not have to show comparable scientific expertise, they do not have to reveal the quality, objectivity, and integrity of their claims, nor do they have to divulge any direct or indirect connections to groups affected by the information. Rather than creating a more transparent process—which is a goal of the original Paperwork Reduction Act—the proposed guidelines are creating more bureaucracy and indeed inviting more impediments to scientific progress. In so doing, it could have a chilling effect upon the scientific research process as a whole.

Care should be taken to limit the definition of "affected persons" to those persons who are of the type already affected by an agency's actions, i.e., those who would have a right to appeal an action taken by the agency to a federal court under the Administrative Procedure Act. The term "affected persons" in the agency's guidelines should not be ambiguous, undefined, or broadly interpreted, as this may inadvertently allow persons who disagree with information, but who are not in any other way affected by action of the agency, access to administrative processes and/or court challenges to prevent dissemination of the information.

With regard to reporting complaints to the Director of OMB, AAAS would like to impress upon OMB not to assume that that the number of complaints reflects negatively upon the "accuracy" or the "quality" of scientific information. In some cases it may be the result of the controversial nature of a specific research field. In today's complex world, research in bioengineering, climate change, and genetics can generate controversy. Even within the scientific community some scientists may interpret scientific evidence in a manner different from the original researcher. This is part and parcel of the process. The scientific research enterprise is a continuous process that is driven by additional research that adds to our knowledge and understanding of the world and universe that we live in. Federal agencies should not be overly burdened with procedures that hinder research.

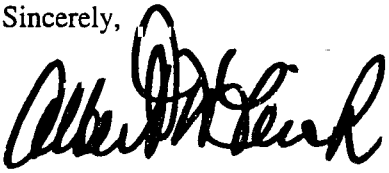
Closing Remarks

Finally, the statutory language in P.L. 106-554 does not require OMB to devote special attention to specific types of information, or to establish separate guidelines for different types of information, or to distinguish how different types of information should meet quality standards. One would infer that Congress, with an interest in maintaining a decentralized government, was trying to provide individual agencies enough flexibility to establish procedures for ensuring quality standards that met their unique information-gathering and dissemination needs. Singling

out scientific research is contrary to the original intent of the legislation and cannot be considered a reasonable implementation of the statutory language.

AAAS believes that the draft guidelines as proposed by OMB, however well intentioned, will have a deleterious effect on scientific research. We hope that OMB will give our concerns and recommendations significant consideration. Given the many complex issues raised, the short timeframe for analyzing and addressing the issues, and the mandate to publish final guidelines by September 30, 2001, we respectfully encourage OMB to request that Congress extend the September 30 deadline. This will allow sufficient time to adequately address and reflect on the potential impact that these guidelines will have on the scientific research process.

Sincerely,



Albert H. Teich
Director