

American Society for Biochemistry and Molecular Biology

ROBERT D. WELLS
President

Institute of Biosciences and Technology
Texas A&M University
Texas Medical Center
2121 West Holcombe Blvd.
Houston, TX 77030-3303
Tel: (713) 677-7651
Fax: (713) 677-7689
Email: rwells@ibt.tamu.edu

August 13, 2001

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

Dear Ms. Dickson:

I am writing on behalf of the American Society for Biochemistry and Molecular Biology (ASBMB) to comment on "Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies". The proposed guidelines were published in the *Federal Register* on June 28, 2001 (66 FR 34489).

At the outset we want to stress that scientific research is based upon the principle of peer review, which focuses on assuring the quality of scientific research conducted by individual scientists. It is not the purpose of peer review to assure the objectivity of a scientist's research, because each individual scientist approaches his or her research in a subjective manner. However, it is precisely the resulting clash of subjective ideas that leads to objectivity in science as a whole, as different explanations for observed phenomena are measured against each other through study, debate, and painstaking replication. Explanations that prove wanting soon disappear or fade into obscurity. In short, scientific information of poor quality is in the long run corrected or marginalized under the already-existing system. Therefore, for the sake of the advancement of science, and for the maintenance of an individual's reputation, it is a paramount goal of all scientists to produce data and other scientific information that is of the best quality possible and that will withstand the vigorous clash of ideas.

That having been said, I must note that ASBMB has a number of serious problems with many aspects of these proposed guidelines. The Office of Management and Budget (OMB) asked for comment on whether the guidelines strike an appropriate balance between trying to assure the quality of information but at the same time not creating excessive administrative burdens on agencies. We do not believe the notice successfully strikes such a balance; on the contrary, we believe it opens the door to a great deal of administrative burden. More seriously, it also amounts to an attack on the peer review

system and on federally-funded science itself. Our major concerns are summarized below.

First, key terms that are the standard for compliance in the guidelines are not defined, and there is such a major element of subjectivity in what would be required to comply with them that the notice seems to be unenforceable. The guidelines as a whole are also frequently self-contradictory and vague.

For example, OMB asked for comment on the definitions of the terms "quality", "utility", "objectivity", and "integrity". However, we are unable to find any definitions of these terms in the proposed guidelines. There is a lengthy discussion about how inter-related the terms are, and how they should "address three aspects of the information that is to be disseminated". But the reality is that these terms are not defined.

It may seem to the drafters of this proposal that these terms are self-explanatory, but in fact they are not, at least as far as science and regulatory policy is concerned. Let us consider the term "objectivity" by way of example.

Under these proposed guidelines, "objectivity" is a goal that agencies are expected to attain in the assurance of data quality. However, as we discussed above, in the realm of science there is very little data that can be called "objective", since the nature of the questions asked can and often does color the nature of the data gathered. But even leaving this problem aside, once one enters the realm of interpretation of data, all pretense to "objectivity" disappears. Different people can and do draw different conclusions from the same data, and it is not reasonable to characterize one set of conclusions as "objective" and another not.

Also troubling is the use of the term "accurate" as part of assessing the quality, utility, objectivity and integrity of information. Obviously, everyone wants data to be accurate (as the term is commonly defined) and that is a goal all scientists strive for in their work. But the fact is that information can be accurately reported, be published in good faith with no intent to defraud or falsify, but in the long run turn out to be insignificant or irrelevant or even wrong. However, as we read these proposed guidelines, a federal agency with such information on its website—that is, published in good faith but subsequently proven to be wrong—would be subject to second-guessing by any "user" of information on the agency website. This is an open invitation to the creation of large administrative burdens on the agency.

Requiring scientific data to be "substantially reproducible upon independent analysis of the underlying data" is also very problematical. Every major term in this phrase needs to be rethought. First, some scientific data is useable or significant only after years or decades of collection. To reproduce this data would take additional years or decades. It is not reasonable to expect such data to be "substantially reproducible", particularly by users with no scientific training, with agendas other than scientific accuracy, or without the resources to carry out such data collection.

Second, “independent analysis” implies that peer review is inadequate for the vetting of most scientific information. In fact, to the contrary, peer review is by far the best method for insuring the quality of research before it is published. While peer or merit review is not without problems (as most scientists will readily admit) there is no better system for evaluating the worth of scientific ideas than the open and critical review of data by persons qualified to assess the merit of the work and with no vested interest in whether the work is published or not. Unfortunately, this notice requires an agency to give serious attention to “independent analysis” of published work that has already been peer reviewed. This second level of analysis can be carried out by any “user” of the information regardless of that user’s ability to understand the work, and without assurance or proof from the user that he is as equally unbiased as the scientist. This is a very serious mistake.

The term “underlying data” is not defined. If OMB finalizes this set of proposals, we recommend that only published data be available for “independent” review, in accordance with the changes adopted in OMB Circular A-110 a year or so ago. To require that agencies respond to complaints regarding raw or unpublished data supporting published material would have a chilling effect on research publication.

We are also concerned about the extent to which this notice will apply to extramural researchers. As you know, many scientists at colleges and universities receive grant funds from federal agencies such as the National Institutes of Health (NIH). Frequently, Federal agencies disseminate information to the public in the form of brochures or reports that are often based on information generated by extramural researchers. This notice seems to imply that there would be circumstances where an agency would be subject to the same kinds of administrative burdens if an extramural researcher’s work became the target of “independent analysis”.

Another concern relates to the requirement that federal agencies report each year on the “number and nature of complaints received” about data they disseminate. This seems to imply that merely because information generates a lot of complaints, it does not meet basic quality standards. In fact, a large number of complaints about a particular scientific document may only demonstrate that the research is controversial, not that the quality is flawed.

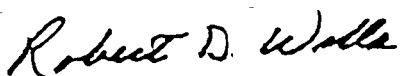
Finally, the deadline for your agency to produce final regulations—September 30, or a mere six weeks from the closing date for comments from the community—is wholly inadequate for OMB to address the problems contained in this notice. We recommend you try to convince Congress to extend the deadline for final regulations in some way, although we realize this will probably be difficult. If this is not possible, we hope and expect that as the various federal agencies move ahead with complying with OMB’s requirements, each will allow an additional public comment period before proceeding with final regulations.

These are only a few of the many problems we see in this notice, and it is our hope that OMB will find a way to avoid having to proceed with finalization of these seriously flawed proposed guidelines.

The American Society for Biochemistry and Molecular Biology is a nonprofit scientific and educational organization with a membership of over 10,000 biochemists and molecular biologists, most of whom teach and conduct research in colleges and universities throughout the United States. The Society publishes the *Journal of Biological Chemistry*, one of the world's preeminent peer-reviewed life sciences journals. ASBMB's headquarters are located in Bethesda, Maryland.

Please let us know if you would like additional information or clarification of our views on other aspects of the proposed guidelines.

Sincerely,



Robert D. Wells
President