

August 8, 2001

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

Dear Ms. Dickson:

The Federation of American Societies for Experimental Biology (FASEB) appreciates this opportunity to comment on the Office of Management and Budget's (OMB) "*Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*" ("*Proposed Guidelines*"). FASEB is comprised of 21 societies with more than 60,000 members, making it the largest coalition of biomedical research associations in the United States. Our mission is to enhance the ability of biomedical and life scientists to improve, through their research, the quality of life for all people.

FASEB strongly supports the legislative intent of the OMB guidelines: to "ensur[e] and maximiz[e] the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by federal agencies." [Comments preceding *Proposed Guidelines* by Donald R. Arbuckle, Deputy Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, June 28, 2001 ("*Arbuckle comments*").] Indeed, as biomedical researchers whose work depends on the excellence of our own data, we are acutely aware of, and sensitive to, the importance of accurate data and have worked closely over the years with federal agencies to foster the timely collection and dissemination of high quality and accurate information.

Our concerns lie in the translation of these laudable goals to agency administrative guidance. While we applaud OMB's effort to address the government's broad-ranging information dissemination activities "through... guidelines tailored to [the individual] agency's programs, dissemination activities, and information resources management and administrative practices....;" its willingness to allow agencies to "weigh the costs (... including...costs attributable to agency processing effort, respondent burden, maintenance of needed privacy, and assurances of suitable confidentiality) and the benefits of higher information quality in the development of such information....;" and its promise to ensure that the guidelines "apply in a common-sense and workable manner....[without] impos[ing] unnecessary administrative burdens..." (*Arbuckle comments*); we do not believe that the proposed guidelines will in fact accomplish these important objectives. We cite, for example, the following concerns:

Member Societies

- The American Physiological Society
- American Society for Biochemistry and Molecular Biology
- American Society for Pharmacology and Experimental Therapeutics
- American Society for Investigative Pathology
- American Society for Nutritional Sciences
- The American Association of Immunologists
- Biophysical Society
- American Association of Anatomists
- The Protein Society
- The American Society for Bone and Mineral Research
- American Society for Clinical Investigation
- The Endocrine Society
- The American Society of Human Genetics
- Society for Developmental Biology

Associate Members

- American Peptide Society
- Association of Biomolecular Resource Facilities
- Society for the Study of Reproduction
- Teratology Society
- Radiation Research Society
- Society for Gynecologic Investigation
- Environmental Mutagen Society

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1. *definitions* - The proposed guidelines contain definitions of “quality,” “utility,” “objectivity,” and “integrity” which are both vague and not statutorily required. FASEB is deeply concerned that these definitions, which invite subjective interpretation, might provide a basis for objection to scientific research results by those whose political, religious, or moral views differ from the findings of research scientists. FASEB strongly urges OMB to ensure that any final definitions be accompanied by an explanation that makes explicitly clear that these *Proposed Guidelines* and the guidelines subsequently issued by covered agencies cannot be used as a tool to challenge scientific findings or advances that may be objectionable on grounds other than their scientific merit (as determined through the peer review process). Further, FASEB urges that those who are authorized to challenge an agency’s compliance with the *Proposed Guidelines* (“affected persons [may] seek and obtain correction of information maintained and disseminated by the agency that does not comply with these OMB guidelines”) be required to demonstrate both a scientific basis for their challenge and the absence of a conflict of interest (e.g., commercial interest) that would turn the *Proposed Guidelines* from a policy benefitting the general public to a lobbying or litigation tool.

FASEB is also concerned that these definitions might inadvertently undermine an important part of the research process. Since scientific research results are intended to be verified and re-verified and built upon through additional research and subsequent studies, preliminary research may well later prove to be unsubstantiated or incomplete. Nevertheless, dissemination of this research plays a valuable role in the scientific process and should not be hindered by administrative definitions that would discourage or penalize the sharing of early or preliminary data or results.

In addition, the *Proposed Guidelines* require that the information disseminated be “useful to all users of the information, including the public,” something that is inherently impossible in the context of scientific research. While high quality scientific research results (as determined through the peer review process) should be disseminated, such information is likely to be “useful” to only some but not all “users” (i.e., relevant members of the scientific community), and is very unlikely to be useful to the public. The *Proposed Guidelines* must recognize that by its nature, scientific research is more likely to be “useful” to the public in the future, long after the dissemination of the information has occurred.

2. *meaning of “substantially reproducible”* - The *Proposed Guidelines* require that “the results must be substantially reproducible upon independent analysis of the underlying data.” This requirement raises several troubling questions, among them the following:

- 1) “substantially reproducible” is not defined, and yet the *Proposed Guidelines* require “scientific research information” to be “substantially reproducible.”
- 2) Who will conduct these studies and who will pay for them?
- 3) How can research studies which may have taken place over a period of years and which used biological substances be “substantially reproduc[ed]”? While confirming or contradicting scientific results is at the heart of the scientific process, FASEB is not sure that the term “substantially reproducible” as used in the *Proposed Guidelines* acknowledges this reality.

3. *“underlying data”* - FASEB is deeply concerned about the definition of “underlying data” and what this would be interpreted to include. We urge OMB to ensure that any definition or interpretation of this term exclude the daily work product of research scientists, including lab notebooks, medical records, and administrative records such as telephone logs. Such information should be protected from public

scrutiny (absent a legally authorized subpoena or statutory requirement) both to ensure the free thinking and exchange of ideas among scientists and to prevent a paralyzing administrative and regulatory burden on working scientists.

4. *relationship to extramural research* - While the *Proposed Guidelines* clearly cover intramural researchers in federal agencies, it is unclear what, if any, impact these *Proposed Guidelines* will have on extramural researchers. Because the *Proposed Guidelines* would require the dissemination of "other information...in order to ensure an accurate, clear, complete, and unbiased presentation,..." and would 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," FASEB questions whether the *Proposed Guidelines* require extramural researchers to open their research data to public scrutiny. This would undermine the peer review process, inhibit the early exchange of scientific data and results, and create an enormous administrative and regulatory burden. FASEB would, therefore, strongly oppose the inclusion of extramural research within these *Proposed Guidelines*.

5. *reporting requirements* - FASEB understands that agencies covered by these OMB guidelines will be statutorily required to report, on an annual basis, "the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines...and how such complaints were resolved." FASEB is concerned, however, that the number of complaints received, rather than the validity of the complaints received, could unfairly impact the reputation of an agency and/or its funded investigators. A large number of complaints on a scientific matter could simply reflect a controversial issue - or an organized advocacy effort - rather than the excellence of the science.

Finally, OMB requests of those providing comment on these guidelines to identify other information areas that may need attention and to provide suggested guidelines for these areas. Because of the many "closely interrelated concepts" addressed in the *Proposed Guidelines* (see *Arbuckle Comments*), FASEB urges an additional comment period to address any other areas that OMB includes de novo as well as any modifications that OMB makes as a result of this comment period.

FASEB looks forward to working with the National Institutes of Health and other federal agencies which sponsor biomedical research to ensure that the agency-specific guidelines which result from OMB's *Proposed Guidelines* implement their legislative intent while addressing the needs of working scientists and the established practices governing quality scientific research.

Respectfully yours on behalf of FASEB and its 21 member societies,



Robert R. Rich, MD
President