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To: '"OMB_peer_review@omb.eop.gov"' <OMB_peer_review@omb.eop.gov>

cc: Meg Gallogly <Mgallogly@TobaccoFreeKids.org>
Subject: Comments Re: Revised Information Quality on Peer Review

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May 25, 2004

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Dr. Schwab:

The Campaign for Tobacco-Free Kids, the American Heart Association, the American Lung Association, and the American Cancer Society are writing to express our concerns over the Office of Management and Budget's (OMB) Proposed Bulletin on Peer Review and Information Quality. As national health organizations that regularly translate and disseminate scientific information for the public, we are keenly aware of the need for objective and reliable scientific information. However, we believe that this proposal for peer review gives too much oversight of scientific peer review to an administrative agency, lacks clarity in how this will affect the operations of scientific agencies, and will not ultimately improve current peer review processes. Indeed, this proposal cuts to the fundamental integrity of the scientific process. While we acknowledge the significant improvements that have been made to the Information Quality Bulletin for Peer Review, we urge OMB to address the concerns outlined in this letter by withdrawing or significantly revising the proposed Bulletin.

First, we are concerned that OMB's proposal transfers the responsibility for determining whether scientific data are of sufficient quality from scientists and scientific bodies to an administrative agency. While the Bulletin includes language that indicates some flexibility for agencies, there are critical areas where OMB (or ORIA) appears to play an important oversight role. In this revision of the Bulletin, OMB remains responsible for determining what information is subject to the stricter review protocol, controlling exemptions and approvals of review plans, prescribing a process that does not distinguish between agencies with different missions and products, and determining the degree of diversity in reviewer viewpoints.

Second, the guidelines for peer review are unevenly applied. A more prescriptive peer review approach is mandated for health, safety, and environmental issues, while information relating to national security, accounting, budget, financial, and trade is exempt. Information related to all of these issues has a significant impact on policymaking. Policies affecting the health of Americans, such as clinical guidelines, should not be unnecessarily slowed or burdened.

Third, the proposed process will consume more time and resources from agencies already spread too thin. The proposed process requires agencies to develop a peer review plan, post information on planned reviews every six months, and provide reviewers with access to key studies and underlying data and models. Additionally, agencies must consider individual versus panel review, timing, the scope of the review, the selection of reviewers, disclosure, public participation, and disposition of reviewer comments. The Bulletin also requires that all peer review information be posted and available for public comment. These requirements are

potentially burdensome and could lead to unnecessary delays in the dissemination of scientific information.

The fourth area of concern is the guidelines for peer reviewers. The Bulletin prohibits scientists employed by the sponsoring agency from serving as reviewers of highly influential scientific information and suggests that "significant consulting and contractual relationships with the agency may raise issues of independence or conflict…" However, the Bulletin does not preclude private industry scientists with significant consulting and contractual relationships from participating as peer reviewers. This may undermine the development of a strong science base and decision-making by favoring private sector interests over other, equally important interests. Additionally, this may restrict highly qualified scientific experts from serving on review panels.

Finally, we believe that the proposal is unnecessary. We are not aware of any studies or evaluations that indicate that the current peer review processes used by science producing agencies are flawed or lacking in scientific rigor. The studies cited in the Bulletin are either outdated or irrelevant because they have little or nothing to do with peer review processes. If there are specific, well-documented problems with peer review, they can be addressed in a targeted manner. Lacking clear evidence of widespread problems, the impact of these proposed guidelines is potentially counterproductive.

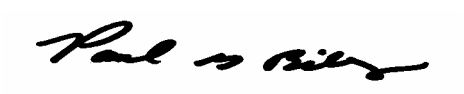
Based on these concerns, we ask that OMB withdraw or significantly revise the proposed Bulletin. The Bulletin, if implemented as proposed, could negatively affect the quality and timeliness of scientific information disseminated. Placing the development and control over the dissemination of scientific information in the hands of an administrative agency could potentially affect the interpretation of scientific research and, ultimately, lead to less science-driven decisions on public health issues. We strongly believe that agencies producing scientific information should maintain responsibility for the development and review of scientific information. The ultimate judge of the science driving public health policy and practice should be scientists.

Thank you for the opportunity to comment on this important matter.

Sincerely,

Daniel E. Smith
National Vice-President
Federal & State Government Relations
American Cancer Society

William V. Corr
Executive Director
Campaign for Tobacco-Free Kids



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