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Via Email: OMB_peer_review@omb.eop.gov

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
New Executive Office Bldg., Room 10201
Washington, D.C.

Dear Dr. Schwab:

The Section of Administrative Law and Regulatory Practice of the American Bar Association is pleased to submit comments on OMB's Revised Information Quality Bulletin on Peer Review.¹ The views expressed herein are presented on behalf of the Section of Administrative Law and Regulatory Practice. They have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the position of the Association.

The Administrative Law and Regulatory Practice Section applauds the Office of Information and Regulatory Affairs for its response to the comments filed on its Proposed Bulletin on Peer Review and Information Quality.² In particular, we wholly approve of the manner in which you dealt with a number of issues specifically raised by the American Bar Association. Nevertheless, the new bulletin does present three new issues that give us concern.

Adjudications

In this proposed bulletin, for the first time, OIRA specifically addresses adjudications. Initially, the bulletin and accompanying description state generally that "dissemination" "excludes distribution limited to . . . adjudicative processes." See I.3., at 69 Fed. Reg. 23230, 23239 (2004). Later, however, under Exemptions, the bulletin states that "Agencies need not have peer review conducted on information that is: . . . 3. Disseminated in the course of an individual agency adjudication or permit proceeding (including a registration, approval, licensing, site-specific determination), unless the

¹ Revised Information Quality Bulletin on Peer Review, 69 Fed. Reg. 23230 (April 28, 2004).

² Proposed Draft Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54023 (2003).

agency determines that the influential dissemination is scientifically or technically novel and likely to have precedent-setting influence on future adjudications and/or permit proceedings.” This appears to create a contradiction – adjudicatory processes are initially said not to involve dissemination at all but then disseminations made in the course of an adjudication are exempted from the peer review requirements (an unnecessary exemption if there is no dissemination, as defined, involved in adjudicatory processes), unless the information is both technically novel and precedent setting. This contradiction should be clarified.

Assuming that the intent is to cover adjudications involving both technically novel and precedent-setting decisions, given the attention devoted to them in the descriptive material, we would strongly counsel OIRA to reconsider that inclusion. There are several reasons for our concern.

First, the extension of peer review to any adjudications would be a novel extension of OIRA’s authority. The Proposed Bulletin put out for comment in September 2003 did not include adjudications. Moreover, the specific authorities cited as the basis of the bulletin do not themselves reach adjudications. The Paperwork Reduction Act specifically excludes collections of information during the conduct of an administrative adjudication (44 U.S.C. § 3518(c)(1)(B)(ii)); E.O. 12866 by its terms does not reach adjudications; and OMB’s Information Quality Guidelines, implementing the Information Quality Act, specifically exclude from the term “dissemination” information “prepared and released in the context of adjudicative processes.” Whatever the President’s constitutional authority to direct the means by which certain adjudications are conducted both by executive agencies and independent regulatory agencies, such as the Federal Communications Commission, the Federal Energy Regulatory Commission, the Nuclear Regulatory Commission, and even the Occupational Safety and Health Review Commission, as well as others, no case has been made in the preamble to the revised bulletin to justify this novel extension.

Second, we believe there may be significant practical problems in extending peer review to agency adjudications, even only those that might be both technically novel and precedent setting. While the preamble appears to exclude categorically a number of identified types of adjudications, it is not clear why a site specific NEPA assessment, for example, if it were both technically novel and precedent setting, would be excluded. Indeed, it is not clear what would be included or what was intended to be included. For example, a decision by the Benefits Review Board of the Department of Labor regarding a former miner’s entitlement to Black Lung Benefits, or a decision by the Patent and Trademark Office to issue a patent on an allegedly new and nonobvious technology, might involve a technically novel and precedent-setting application of scientific information. Would these decisions be required to be submitted to peer review?

Beyond the issue of which decisions would be subject to peer review, the mere attempt to apply peer review to an adjudication also raises practical concerns. Again using the Benefits Review Board example, the Board, of course, would not be the source of the scientific information. The information would be provided, as in any adjudication, by one of the parties to the proceeding – here the former miner or the coal company to be assessed the claim. Moreover, it would be submitted at the trial stage before the

administrative law judge hearing the case and rendering the initial decision. Traditionally in an administrative adjudication, the validity of scientific information submitted by a party is assessed by the administrative law judge both as to admissibility and as to the weight it should be afforded. The administrative law judge's decision as to the technically novel evidence could be precedent setting. If the judge intends to rely on the evidence of the proponent or the evidence of the opponent, is the judge to invoke peer review, and if so, how? If the case is appealed by the losing party to the Benefits Review Board, is the Board supposed to undertake peer review?

In short, we believe there are a number of unexamined issues involved in attempting to extend peer review to any adjudications, whether they be FCC electromagnetic determinations in antenna siting, NRC safety determinations made in reactor decommissioning decisions, EPA corrective action decisions, or all the other individual adjudications involving scientific or technical information that may well be novel and may well be precedent setting. It may be that some peer review in the adjudicatory context is desirable and appropriate, but we believe that such review at least raises procedural complexities not present in other forms of agency dissemination. OIRA should separate peer review in adjudications from the other uses of peer review covered by this bulletin and institute a separate inquiry focused on adjudications in particular.

Independence in Highly Influential Scientific Assessments

We have two concerns with the Revised Bulletin's new rule essentially prohibiting the use of agency scientists in peer review sponsored by the agency with regard to highly influential scientific assessments.

Our first concern relates to what constitutes the "agency" in this context. That is, the Department of Health and Human Services is an "agency," but it includes a number of other agencies within it, including the Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control and Prevention, and others. Read literally, the ban on agency scientists participating in an agency-sponsored peer review could prevent an NIH scientist from participating in an FDA-sponsored peer review and vice versa. We hope that this was not intended and that the intended meaning of "agency" here was the particular office or subdivision of the agency sponsoring the peer review, so that only a scientist employed by that office or subdivision would be subject to the proposed ban. However, the definition of "agency" in the Paperwork Reduction Act, which by reference is the definition for purposes of the Bulletin, specifically defines agency to mean "any executive department . . . or any independent regulatory agency," suggesting the macro view of an agency rather than viewing each of a department's components as separate agencies.

Our second concern goes to the ban itself, even as applied at the office or subdivision level. That is, as a general matter, OIRA responded to the comments on the Proposed Bulletin by granting agencies increased flexibility in their implementation of peer review. Here, however, the Revised Bulletin actually reduces the flexibility that existed in the Proposed Bulletin. There it was recognized, as it is generally in the Revised Bulletin, that expertise is the most important factor in selecting peer reviewers. The Proposed Bulletin, with respect to its "especially significant regulatory information," spoke in terms of

“striv[ing] to appoint experts who, in addition to possessing the necessary scientific and technical expertise, are independent of the agency. . . .” We support such striving, because it retains the possibility that the necessary expertise is only available (perhaps to obtain the balance required by section III.2.a. of the bulletin) from a scientist employed by the office or subdivision. If further safeguards are deemed necessary, we would not object to requiring an agency to make a special finding that utilizing the employee is necessary to obtain the requisite expertise. In our view, the only categorical bar should be against a scientist peer reviewing research or assessments that he or she was actually involved with.

Definition of Highly Influential Scientific Assessments

The requirements of section III apply to scientific assessments that “could have a clear and substantial impact on important public policies (including regulatory actions) or private sector decisions with a potential effect of more than \$500 million in any year.” It is unclear in the quoted language whether the \$500 million potential effect modifies both the private sector decisions and the important public policies, or whether it modifies only the private sector decisions. We believe the better grammatical reading is that the \$500 million effect modifies both the private section decisions and the important public policies, or else there should be an additional “on” before the words “private sector.” Moreover, we believe that the \$500 million effect *should* modify both because such a trigger provides a degree of objectivity and certainty that the words “important public policy” do not convey. We believe the lack of clarity could be cured simply by so stating the intent in the preambular material without changing the actual bulletin text. Currently, however, the preambular material contains the same ambiguity.

We appreciate the opportunity to provide these comments and OIRA’s willingness to seek additional comments on the Revised Bulletin.

Sincerely,

A handwritten signature in black ink, appearing to read "William Funk", with a long horizontal flourish extending to the right.

William Funk
Chair
Section of Administrative Law and Regulatory Practice
American Bar Association