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December 23, 2003

Dr. Margo Schwab  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
725 17<sup>th</sup> Street, N.W.  
New Executive Office Bldg., Room 10201  
Washington, D.C. 20503

Dear Dr. Schwab:

On behalf of the American Bar Association (“ABA”) and its more than 400,000 members nationwide, I am pleased to submit comments on OMB’s proposed draft Bulletin on “Peer Review and Information Quality.”<sup>1</sup> As Chair of the ABA Section of Administrative Law and Regulatory Practice, I have been authorized to express the ABA’s views on this important matter.

The American Bar Association has adopted a policy specifically regarding the use of peer review in the context of risk assessments by federal agencies.<sup>2</sup> While the peer review addressed in OMB’s proposed draft Bulletin is not so limited, the guidance contained in the Bulletin would encompass risk assessment peer review. Our comments on that guidance are limited to where peer review is used in the context of risk assessments, although they may logically extend to other situations as well.

### WHEN SHOULD PEER REVIEW BE USED?

The ABA supports OMB’s efforts to ensure the quality of the scientific information that may be the basis for or used in risk assessments by the federal government, and the ABA believes that peer review can play a useful role in ensuring the quality of such information. At the same time, the ABA recognizes that peer review adds expense and delay to the use or dissemination of information.

The draft Bulletin proposes that agencies conduct “appropriate and scientifically-rigorous peer review” on all “significant regulatory information” that agencies intend to disseminate, which is defined as any information relevant to regulatory policies that satisfies the “influential test” in OMB’s Information-Quality

<sup>1</sup> Proposed Draft Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54023 (2003).

<sup>2</sup> ABA resolution on risk assessment, adopted by the ABA House of Delegates in August 1999 (found at <http://www.abanet.org/adminlaw/risk02.pdf>).

Guidelines.<sup>3</sup> The Information Quality Guidelines define “influential” information as any information that an agency can “reasonably determine” “will have or does have a clear and substantial impact on important public policies or important private sector initiatives.”<sup>4</sup> The draft Bulletin permits agencies to design appropriate peer review procedures for “significant” regulatory information, but regarding “especially significant” regulatory information, it specifies procedures that an agency is to follow. It further defines “especially” significant regulatory information” as information that is disseminated in support of a “major regulatory action,” has a possible impact of \$100 million or more, or is determined by the Administrator of OMB to be of “significant interagency interest” or “relevant to an Administration policy priority.”<sup>5</sup> In other words, peer review *must* be performed whenever scientific or technical information relevant to regulatory policies will have a “clear and substantial impact on important public policies or important private sector initiatives,” but agencies are afforded flexibility in how to conduct such peer reviews. If, however, the possible impact exceeds \$100 million, the information is to be used in “major regulatory action,”<sup>6</sup> or OMB determines the information is “of significant interagency interest or is relevant to an Administration policy priority,” then specified peer review standards are to be followed.

While the ABA applauds OMB for allowing some flexibility in the former case, we do not believe it has gone far enough to account for the costs of peer review in either case. The ABA policy on when peer review in risk assessments is appropriate weighs the benefits from peer review of complex factual or theoretical issues against the costs of added expense and delay. Rather than weigh the costs and benefits of peer review in determining when to require it, OMB has required it when the *effect* of the information is significant and has required specific procedures for the peer review when the *effect* of the information is especially significant. The difference from the ABA policy is critical. That is, OMB is not triggering a peer review requirement on the basis of the complexity, novelty, or controversial nature of the scientific or technical information, when peer review may well play a positive role, but on how the information will be used. While OMB may well conclude that even complex, novel, or controversial technical or scientific information, if it will be not be used for any significant purpose, does not justify the time and expense of peer review, we would suggest that, when the scientific information is *not* complex, novel, or controversial, peer review is also inappropriate, even if the information is to be used for a significant, or even an especially significant, purpose. Peer review is simply not the correct mechanism to address the significant use of routine, established, or accepted scientific information.<sup>7</sup>

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<sup>3</sup> §2, *id* at 54027.

<sup>4</sup> §V9, Information Quality Guidelines, 67 Fed. Reg. 8452, 8460 (2002).

<sup>5</sup> §3, Proposed Draft Bulletin, *supra* note 1, at 54028.

<sup>6</sup> The proposed Bulletin defines “major regulatory action” by reference to Section 4(f)(1) of Executive Order 12866: “Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.”

<sup>7</sup> The preamble to the proposed Bulletin appears to recognize this in the context of some types of technical information, when it states that “most routine statistical and financial information, such as that distributed by the Census Bureau, the Bureau of Labor Statistics and the Federal Reserve,” would not be subject to peer review. Proposed Draft Bulletin, *supra* note 1, at 54026.

Accordingly, the ABA recommends that OMB limit its categorical requirement for peer review to those situations in which the scientific information is at least arguably complex, novel, or controversial. Moreover, consistent with the ABA policy that, when peer review is needed, its scope should be tailored to the issues that require review, and the extent of the effort should be proportionate to the size and complexity of the risk assessment, we recommend that OMB limit the requirement to use its specified procedures to those situations in which the scientific information is particularly complex, novel, or controversial.

### **PEER REVIEW PROCESS**

The draft Bulletin states that with respect to peer review of “especially significant regulatory information” reviewers should be selected “primarily on the basis of necessary scientific and technical expertise.”<sup>8</sup> Moreover, the draft Bulletin states that when agencies choose reviewers from the pool of such qualified experts, they should strive to find those who are “independent” of the agency, who “do not possess real or perceived conflicts of interest,” and who “are capable of approaching the subject matter in an open minded and unbiased manner.” The draft Bulletin provides a list of factors for agencies to consider in assessing whether a person satisfies these criteria.

The ABA policy on peer review in risk assessments was premised on the understanding that expertise and independence are the key qualifications for reviewers. Therefore, we agree with OMB’s focus and conclusion on both these issues. The ABA policy also understood that it would be preferable, where feasible, to identify reviewers who have neither employment nor consultancy relations with the agency, industries, or citizen groups concerned. Thus, we also agree with OMB’s list of factors, with one caveat. The list includes a situation in which a person is currently receiving or seeking substantial funding from the agency involved. We agree that this should be a factor but believe that of equal concern is when a potential reviewer is currently receiving or seeking substantial funding from a private company or an industry or citizen group with a stake in the information involved. There is, however, no factor listed in the draft Bulletin reflecting such a situation, although the draft Bulletin in another place treats agency and private industry entanglements equally.<sup>9</sup> Accordingly, we recommend that OMB amend its list of factors to include situations in which a potential reviewer is seeking or receiving such private funding.

### **CORRECTION REQUESTS**

The draft Bulletin proposes that agencies provide to OMB within seven days a copy of each non-frivolous request for information quality correction, but that an agency need not provide a copy if it posts the request on its website. The draft Bulletin further proposes that an

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<sup>8</sup> §3, Proposed Bulletin, supra note 1, at 54027.

<sup>9</sup> See §4.b., Proposed Bulletin, supra note 1, at 54028.

agency provide OMB upon request a copy of the agency's draft response and consult with OMB before the response is issued.<sup>10</sup>

The draft Bulletin, however, perhaps as an oversight, does not provide for any publicly available record of such interaction between OMB and an agency. As a result, under the proposed process, OMB could make decisions concerning the public availability of regulatory information without any acknowledgment of its role. Further, OMB might even make such decisions on the basis of information and lobbying that is unknown to the public, let alone the agency that received the correction request.

Prior to E.O. 12866, OMB was in a similar situation with respect to rulemaking review, but that Order provided disclosure requirements to assure transparency. The current administration has reaffirmed its commitment to those transparency requirements.<sup>11</sup> The ABA has adopted a formal policy position concerning OMB's oversight in the context of rulemaking. In particular, the ABA has recommended that any government entity designated by the President to oversee the rulemaking process should: (1) issue a concise written explanation in the rulemaking record whenever it returns a rule with a change; (2) reveal in the rulemaking record any communications with Congress or non-governmental persons pertaining to the rule; and (3) regularly publish a list of all proposed or final rules for which review was concluded.<sup>12</sup> Information correction requests may involve rulemaking. Accordingly, we suggest that OMB consider providing the same disclosure with respect to information requests that it provides with respect to rulemaking.

#### WEBSITE NOTIFICATION

OMB has previously urged federal agencies to put non-frivolous information correction requests on the agencies' websites,<sup>13</sup> and the draft Bulletin requires agencies that do not do so to provide a copy of such requests to OMB within seven days. The American Bar Association has adopted a formal policy position that "agencies should explore means to maximize the availability and searchability of existing law and policy on their websites," including making available "all agency rules and regulations, and all important policies, interpretations, and other like matters

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<sup>10</sup>§7, *id.* at 54029.

<sup>11</sup>*See* Memorandum for OIRA Staff From John D. Graham (Oct. 18, 2001) (indicating that OIRA would follow the disclosure procedures defined in §6(b)(4) of Exec. Order 12866). OIRA makes available for public inspection logs or copies of certain communications with parties outside the Executive Branch regarding rules under review, makes the relevant regulatory agency aware of communications submitted to OIRA by outside parties, and, after a review is complete and the rule published, makes available certain materials associated with the review, including the rule text submitted for OIRA review. *Id.*

<sup>12</sup>ABA resolution on presidential oversight of the rulemaking process, adopted by the ABA House of Delegates in February 1993. (found at <http://www.abanet.org/adminlaw/>). The Administrative Conference of the United States (ACUS) has recommended similar procedures. Presidential Review of Agency Rulemaking (Recommendation 88-9), 1 C.F.R. §305.88-9 (1992).

<sup>13</sup>Memorandum for President's Management Council from John Graham, Agency Draft Information Guidelines (June 10, 2002).

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which members of the public are likely to request.”<sup>14</sup> Accordingly, we respectfully request that OMB renew its earlier request that agencies post copies of non-frivolous information correction requests on their websites.

Thank you for your consideration of our comments. If you would like to discuss the ABA’s views on these important matters in greater detail, please feel free to contact me at (503) 768-6606.

Sincerely,

A handwritten signature in black ink that reads "Bill Funk". The signature is written in a cursive, slightly slanted style.

William Funk

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<sup>14</sup>ABA resolution on agency web pages, adopted by the ABA House of Delegates in August 2001 (found at <http://www.abanet.org/adminlaw/federal02.pdf>).