Center for Regulatory Effectiveness

1601 Connecticut Ave, NW – Suite 500 Washington, DC 20009 Tel: (202) 265-2383 Fax: (202) 939-6969 www.TheCRE.com

June 29, 2010

Sent electronically to regulations gov and by fax to OIRA

Office of Information and Regulatory Affairs, Office of Management and Budget Attn: Darcel D. Gayle New Exec. Office Bldg. -- Rm. 10202 725 17th St., NW Washington, DC 20503 fax: (202) 395-7285

Comments on OMB's Draft 2010 Report to Congress on the Benefits and Costs of Federal Regulations; Docket ID OMB-2010-0008; 75 Fed. Reg. 22630 (April 29, 2010)

Dear OIRA:

The Draft Report notes with regard to IQA peer review that "OMB is currently working with the agencies to ensure that the required [peer review agenda and plan] information is posted, and that the web sites are easy to locate and navigate." At 57. We commend OIRA for pursuing this point and exercising its oversight responsibilities under the guidance. However, the Draft Report does not provide much detail of the peer review information posting problems that OIRA is working on with the agencies. On this subject of posting of peer review information for the public, we have the following comments:

1. The IQA peer review guidance does not specifically mention FACA committees.¹ Nevertheless, such committees often provide peer review functions. It appears that some agencies are not posting peer review agendas and plans for FACA committees on their peer review agendas; rather, they are posting relevant FACA committee information only on their advisory committee web pages. The IQA peer review agendas and plans for every agency should include FACA committee reviews as well as non-FACA reviews.

Sometimes FACA peer review committees, or peer review committees similar to FACA committees, are established by statute. The comments here are intended to also cover any such committees.

Center for Regulatory Effectiveness

Jun 29 10 02:13p

2. Related to the above point is the issue of posting of draft charges for public comment. FACA advisory committee websites often post only a "charter," and not a charge. Charters are usually very general, whereas charges usually submit detailed scientific questions to a committee. In addition, the peer review guidance requires that peer review charges for highly influential scientific assessments be posted, and that they contain certain specific instructions for the peer reviewers, such as information on the applicability of the IQA standards and admonitions against inserting into their review any precautionary bias or other forms of policy-oriented bias.

Also, as we noted in our comments on the 2009 Draft Report to Congress, the peer review guidance is unclear on whether charges should be posted in draft for public comment. Because the charge is such a critical aspect of the peer review, it should be open to public notice and opportunity for comment. This is simply good policy, and it appears to be required by OMB's January 2009 Open Government Directive, issued at the behest of President Obama.

FACA committees often post background or meeting information/materials for the public, and that information sometimes includes specific questions that could be considered to be in the nature of a charge. However, the information required by the peer review guidance (such as that regarding bias) is rarely included along with such questions, or otherwise, and this information is not posted in draft, and it is usually posted only a days before a scheduled meeting. A draft charge should be posted a sufficient time prior to a peer review meeting to allow for public comment on the draft charge, consideration of the comments, and revision of the charge before it is sent to the peer reviewers.

3. The peer review guidance is currently largely written as if peer reviewers subject to the guidance will only be reviewing an agency draft scientific document. However, FACA committees are often asked to provide advice that is not based on review of an agency draft scientific document. Often, a FACA committee is asked/chartered to provide advice, recommendations, and views on scientific issues by reviewing a body of scientific literature rather than an agency draft document. Such reviews appear to be covered by the peer review guidance, although the reference to such reviews is somewhat obscure. The guidance states that "if an agency plans to disseminate information supplied by a third party (e.g., using this

Center for Regulatory Effectiveness

information as the basis for an agency's factual determination that a particular behavior causes a disease), the requirements of the Bulletin apply, if the dissemination is 'influential'." 70 Fed. Reg. at 2667, 1st col. This statement of applicability thus covers peer reviews of "third-party" scientific studies and publications even if there is no draft agency document reviewed by the committee. Agencies should be advised that the peer review guidance covers peer reviews of "third-party" scientific information even if there is no review of a draft agency document.

In summary:

Jun 29 10 02:14p

- 1. OIRA should instruct agencies to post FACA peer review information on their peer review agenda, along with the plan (or a link to the plan), along with non-FACA peer review information.
- 2. OIRA should instruct agencies to post draft charges to peer review committees for public comment, allowing a sufficient time for submission and consideration of such comments, and revision of the charge, before submission to the peer reviewers.
- 3. OIRA should remind agencies that the peer review guidance applies to peer reviews of, and development of advise and recommendations based on, thirdparty scientific literature and data as well as draft agency documents.

Thank you for the opportunity to submit these comments.

Respectfully.

William G. Kelly, Sr. July, A.