vsharpe@cspinet.org
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To: John F. Morrall III/OMB/EOP@EOP

cc: Frank Clemente < FCLEMENT@citizen.org> , Wendy Keegan < wkeegan@citizen.org> , rblum@cspinet.org

Subject: CSPI - Congress Watch Comments to OMB Draft Report

Dear Mr. Morrall,

We are please to submit comments to the the Office of Management and Budget's Draft Report to Congress on the Costs and Benefits of Federal Regulations (Federal Register Vol. 67(60) March 28, 2002). Our comments refer specifically to Chapter 1, Section H, p. 15022-3, on the "Formation of a Scientific Advisory Panel to OIRA."

We have attached our comments below and will send them in hard copy tomorrow.

Sincerely,

Virginia Ashby Sharpe, Ph.D.
Director, Integrity in Science
Center for Science in the Public Interest
1875 Connecticut Avenue, N.W.
Suite 300
Washington, D.C. 20009-5728
(202) 777-8331
vsharpe@cspinet.org

Frank Clemente
Director, Public Citizen's
Congress Watch
215 Pennsylvania Avenue, S.E.
Washington, D.C. 20003
(202) 454-5190
fclement@citizen.org

Rick Blum
Senior Researcher, Integrity in Science
Center for Science in the Public Interest
1875 Connecticut Avenue, N.W.
Suite 300
Washington, D.C. 20009-5728
(202) 332-9110, ext. 322
rblum@cspinet.org

(See attached file: CSPI - Pub Citz comments on OMB draft.rtf)

- CSPI - Pub Citz comments on OMB draft.rtf

May 28,2002

John Moi-rall,
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10235
725 17th Street, NW
Washington, DC 20503
Fax: (202) 395-6974
e-mail jmorrall@omb.eop.gov

Dear Mr. Moi-rall,

We are writing with comments to the Office of Management and Budget's *Draft Report to Congress on the Costs and Benefits of Federal Regulations* (*Federal Register* Vol. 67(60) March 28, 2002). Our comments refer specifically to Chapter 1, Section H, p. 15022-3, on the "Formation of a Scientific Advisory Panel to OIRA" which states that:

> "OIRA is in the process of forming a scientific advisory panel that will suggest initiatives to OIRA, evaluate OIRA's ongoing activities, comment on national and international policy developments of interest to OIRA, and act as a resource and recruitment mechanism for OIRA staff. OIRA envisions that the panel will be comprised of academics with specialized expertise in economics, administrative law, regulatory analysis, **risk** assessment, engineering, statistics, and health and medical science."

This description of the proposed panel does not adequately characterize the purposes and scope of the panel's work, its composition and structure, or the procedures regarding conflicts of interest and disclosure under which the panel will operate. The final Report should specify

The types of initiatives OIRA will seek suggestions about from the panel.

The nature of the evaluation that such a panel will apply to OIRA's activities.

The specific types of policy development on which the panel will comment.

The scope of the panel's work and whether the panel will be asked to provide or assist in substantive assessment of the scientific and economic bases of pai-ticular regulations and guidance.

It would appear that OMB wants to create the scientific advisory panel as a means of inappropriately interfering with the rulemaking process by the agencies that Congress has charged with undertaking the expert analysis. We strongly oppose any effort by OMB to create its own analytic expertise on science issues. It is neither co'st-effectivenor appropriate to supplant these existing sources of expertise on matters relating to federal policy. The recommendations below should be understood as minimum requirements for the composition, structure, peer review, and conflict-of-interest oversight for the proposed panel whatever its ultimate purpose and scope.

Regarding the composition of the panel, it is not clear whether the expertise listed is intended to be exhaustive and, if so, why certain areas of expertise were identified (e.g. health and medical science), but not others (e.g. environmental science or occupational health). Further, it is not clear what the size of the panel will be and whether it will have subcommittees whose members include individuals not on the full panel. Finally, the tenure of panel membership is not specified.

Section H further states that

> "The composition and formation of the panel will comply with the guidance on competent and credible peer review mechanisms espoused by the OIRA administrator in his September 20, 2001, memorandum to the President's Management Council."

Regarding peer review, the September 20, 2001, memorandum (http://www.whitehouse.gov/omb/inforeg/oira_review-process.html) states at p. 3 that

> "OMB recommends that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose to agencies their sources of personal and institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner."

The September 20,2001 guidance on peer review applies specifically to "economically significant and major rulemakings." Although OMB has not made clear the scope of the Scientific Advisory Panel's work, we would expect that the peer review process outlined for agencies would be applied to the management of OIRA's Scientific Advisory Panel regardless of the matter under discussion and its economic significance.

Further, as stated, the guidance on peer review is in the foim of a "recommendation." It would be inappropriate for OIRA not to subject itself to a more robust standard regarding the composition, formation, conflict of interest, and disclosure process of its own Advisory Panel. Thus, the final *Report* should state unequivocally that OIRA will set the highest standard regarding the avoidance of conflicts of interest, the achievement of balance, and public disclosure of information regarding panelists' financial and other potentially biasing affiliations.

To that end, we do not believe that the September 20, 2001 guidance on peer review adequately facilitates the public's right to know about peer reviewer's conflicts of interest.

The September 20,2001 guidance indicates that the peer reviewers will be expected to disclose positions and funding sources to *agencies* but is silent on the agencies' responsibilities regarding subsequent disclosure to the *public*. In its own Panel formation, OMB should distinguish between "information collection" and "disclosure." "Information collection" should be understood as the process that OIRA staff undertake to obtain financial and other relevant information from potential panelists. "Disclosure" should be understood as public disclosure via the OIRA website of relevant information collected from panelists.

For information collection, OIRA should develop a form modeled after the NAS's "Potential Sources of Bias and Conflict of Interest" form and the FDA's Form 3410: Financial Disclosure Report for Special Government Employees." (See enclosures)

Regarding disclosure, service on the OIRA Advisory Panel should be contingent on a waiver of confidentiality regarding relevant financial ties and substantive positions. OMB should practice routine disclosure of all relevant information submitted by nominees. A waiver of confidentiality will make this possible.

We suggest that the OIRA follow the example of a number of biomedical journals that affirm the *absence* of conflicts of interest. An affimiation that there are no conflicts or other sources of potential bias on the Panel should be included in a "Statement on Committee Composition" with posted Advisory Panel membership.

Regarding the initial establishment of the panel and ongoing appointments, OIRA should identify on its website potential members, their areas of expertise, and all relevant financial and other potentially biasing ties prior to a 30-day public comment period. Based on the public comments, OIRA should articulate a process for addition or removal of potential panelists. OIRA should establish a strong conflict-of-interest policy disqualifying potential panelists who have conflicts of interests regarding the particular or general matters under Panel discussion. If OIRA believes that it is not possible to establish a panel of disinterested members, it must establish rigorous procedures for committee recruitment to assure balance on the panel.

OIRA should also clarify the official status that panelists will have as "special government employees." We assume that this panel will, in its "advisory" capacity, be subject to the Federal Advisory Committee Act (FACA) and its regulations regarding transparency and impartiality in the panel's composition, operation, and administration. We reniind OMB that the Health Care Task Force convened under the Clinton Administration was also subject to FACA because it included sub-committee members who were not full- or permanent part-time government employees. (Croley, SP, Funk, WF. "The Federal Advisory Committee Act and Good Government." 14 Yale J. on Reg. 451). In its final *Report*, OIRA must clarify whether and how it plans to comply with the statutory requirements of FACA.

Finally, the draft *Report* states that

> "OIRA envisions that the panel will meet twice each year in Washington, DC. Panel meetings will be open to the public. OIRA expects that the first meeting of this panel will occur this summer."

The final *Report* should specify the panel's work process outside of these formal meetings and should require and facilitate transparency in panelists' communications regarding OIRA/OMB matters.

Again, we strongly oppose any effort on OMB's part to establish its own scientific body to provide analytic expertise on science issues. We urge you to clarify the scope and purpose of the panel and to establish the highest standards of transparency and impartiality for its work.

We would be happy to discuss these matters with you at your convenience.

Sincerely,

Virginia Ashby Sharpe, Ph.D.
Director, Integrity in Science
Center for Science in the Public Interest
1875 Connecticut Avenue, N.W.
Suite 300
Washington, D.C. 20009-5728
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