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Subject: Comments of the U.S. Chamber of Comments on Revised Information Quality Bulletin on Peer Review

- COMMENTS - Proposed Revised Bulletin on Peer Review and Information Quality\_OMB



COMMENTS -  
Proposed Revised Bu.

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CHAMBER OF COMMERCE  
OF THE  
UNITED STATES OF AMERICA

WILLIAM L. KOVACS  
VICE PRESIDENT  
ENVIRONMENT, TECHNOLOGY &  
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May 28, 2004

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 Building  
Room 10201  
Washington, D.C. 20503

**Re: Comments on OMB's *Revised Information Quality Bulletin on Peer Review***

Dear Dr. Schwab:

The U.S. Chamber of Commerce (Chamber), the world's largest business federation, representing more than three million businesses of every size, sector, and region, provides the following comments concerning the Office of Management and Budget's (OMB) proposed *Revised Information Quality Bulletin on Peer Review* (Revised Bulletin)<sup>1</sup>.

The Chamber supports OMB's efforts to provide a mechanism, peer review, for pre-dissemination review of Agency work products to ensure Agencies meet data quality standards. However, we believe that the Revised Bulletin deviates significantly from this purpose and has fundamental problems that must be resolved prior to any final Bulletin or process being established. The Chamber is sufficiently concerned about these problems that it cannot support a final Bulletin until these issues are satisfactorily addressed.

In particular, the fundamental flaws about which the Chamber has deep concerns include:

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<sup>1</sup> OMB, "Revised Information Quality Bulletin on Peer Review" 69 FR 23230 – 23242.

1. There is a complete procedural and substantive exemption of National Academy of Sciences (NAS) peer reviews and reports irrespective of the procedures actually followed by NAS in any specific instance, the quality of the scientific review performed, or the extent to which the review strayed into policy matters reserved for the government to decide. As OMB has acknowledged, peer review serves many purposes and is generally not a guarantee of "objectivity" as that term is defined in OMB's information quality guidelines. However rigorous NAS' peer review procedures might be, it therefore cannot be presumed that NAS reports satisfy the objectivity standard. We are concerned that, without a credible opportunity or rebuttal that applies consistent procedures and criteria, agencies would make precisely this inference;
2. Agencies are given permission to arbitrarily select which elements of the Revised Bulletin to comply with, thereby enabling existing agency practices to continue without change despite the defects in such practices previously noted by OMB, and in some cases, implicitly authorizing agencies to engage in substandard peer review practices;
3. There are no provisions enabling affected parties to contest any agency determination of applicability, peer review type, panel selection, Charge, or any other peer review program element as it applies to a specific case;
4. There are insufficient limitations on the use of proprietary information and models; and
5. There is a marked absence of procedures by which third parties might establish that an agency or third-party peer review failed to actually comply with applicable or appropriate peer review procedures.

Relevant to these and other issues of concern, the Chamber's comments are as indicated in the following two Parts of this letter: Part A compares the Chamber's comments on OMB's initial *Proposed Bulletin on Peer Review and Information Quality* (Bulletin)<sup>2</sup> to the Revised Bulletin. Part B contains additional specific Chamber comments on the Revised Bulletin.

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<sup>2</sup> 68 FR 54023-54029.

## I. PART A

### A. DIFFERENCES BETWEEN THE BULLETIN AND THE REVISED BULLETIN

In its original set of comments<sup>3</sup> about OMB's Bulletin the Chamber raised several issues of concern. Below, the Chamber discusses those issues that were previously raised with regard to the Bulletin, now reiterated with regard to OMB's Revised Bulletin.

#### 1. Excessive Agency Discretion

The Chamber believes that the changes made by OMB, when taken together, provide agencies clearly excessive discretion. There is virtually no reform provision in the Revised Bulletin that is truly compulsory because OMB has set no genuine minimum standard of performance. We are especially concerned about the following statement: *To be considered "adequate" for purposes of the [peer review of influential scientific information], a peer review need not comply with all of the requirements of this Bulletin.*

Very few scientific information disseminations or scientific assessments will be "highly" influential if OMB raises the threshold from \$100 to \$500 million, as it now proposes to do<sup>4</sup>. Virtually all influential scientific information covered by the Revised Bulletin would be covered only by Section II, and there is no specific requirement that can reasonably be determined to always apply. Though more demanding in theory, the provisions of Section III ("highly" influential scientific information) contain qualifying language that renders them ineffective in practice.

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<sup>3</sup> December 15, 2004 comments of the U.S. Chamber of Commerce to OMB concerning the "Proposed Bulletin on Peer Review and Information Quality" *Federal Register*, 68:54023-54029, September 15, 2003.

<sup>4</sup> The threshold would apply to "potential effects" that could arise "in any year." If this language is interpreted as present estimated annualized costs, OMB reports reviewing only three regulatory actions in 2003 that had agency-estimated costs this large.

OMB compounds these defects by neglecting to establish mechanisms for affected parties to contest what they believe to be inappropriate agency interpretations or applications of the Revised Bulletin. The Chamber cannot support a process reform which, by its inherent design, is incapable of yielding its stated objectives.

## **2. Need for Definitional Consistency**

The Chamber previously suggested that there is a need for consistency of definitions between OMB's Information Quality Guidelines and the Bulletin. In particular, the Chamber suggested that OMB examine both documents, identify all the term of art ambiguities, and then harmonize, clarify, and where possible, simplify the language to remove any apparent confusion. OMB has now included a section that defines key words, phrases, and concepts and appears to have assured that the two documents are in conformity. Nonetheless, some ambiguity remains, and where such absence of clarity arises, the Chamber comments further in Part B below, specifically, in reference to Section I – Definitions of the Revised Bulletin.

## **3. Concerns About Peer Review and Transparency**

The Chamber previously commented that there should be no presumption as to the adequacy of the peer review of articles published in scientific journals, and the Revised Bulletin no longer contains any statement about the adequacy of peer review of information appearing in scientific journals.

In regard to peer review, OMB also comments:  
*Publication in a peer reviewed scientific journal may mean that adequate peer review has been performed. However, because the intensity of journal review is highly variable, there may be cases in which an agency determines that a more rigorous or transparent review process is necessary....<sup>5</sup>*

This statement in effect permits each agency to establish its own arbitrary rules and procedures concerning how it will, determine when journal peer review is adequate, the criteria it will use to make these determinations, and the extent to which any of this will be either transparent or reproducible. Agencies also would be free to deny affected parties any effective mechanism to show that their determinations were illogical, erroneous or inconsistent with previous determinations. This approach would enable agencies to make politically expedient or policy-driven decisions and simply state that they had complied with their own rules. As such, the Chambers believes that this approach is less desirable than even the status quo, in which journal peer review is typically viewed as a desirable although not necessarily sufficient requirement for ensuring scientific soundness. OMB should establish a process that ensures that sound science prevails in any regulatory activity in which science matters. We do not believe that permitting each agency to establish its own rule will accomplish this objective.

The Chamber further suggests that OMB should include the following statement in the Revised Bulletin<sup>6</sup>: *Agencies may rely on external peer reviews only to the extent that scientific uncertainties are clearly identified and characterized to the fullest practicable extent and that this information becomes a part of the public record.*

#### **4. Need for Transparency of Peer Reviewers**

The Chamber argued for the use of open peer review and creative uses of the Internet, which together provide for much more comprehensive participation by the scientific community when scrutinizing scientific work products. The Chamber also argued that the identity, financial interest, and potential bias of all peer reviewers must be disclosed.

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<sup>6</sup> This statement should be included in the Revised Bulletin in both §II – Peer Review of Influential Scientific Information and §III – Additional Peer Review Requirements for Highly Influential Scientific Assessments.

The Revised Bulletin leaves the choice of the peer review mechanism (e.g., open, extensive, limited, partial, etc.) to the discretion of the individual agencies, but advises that in selecting an appropriate peer review process the agencies should consider the complexity, novelty, and likely (regulatorily relevant) impact of the information that is to be reviewed.

Although specific instructions are provided to agencies concerning necessary qualifications and vetting of prospective peer reviewers, it does not appear that there is any advocacy by OMB for a completely open peer review process. Some possible clarifications to this issue are indicated below in Part B, in particular, the Chamber's discussion of Section II and Section IX of the Revised Bulletin. OMB also leaves to the discretion of the individual agencies the issue of whether or not there should be full public disclosure of the identity of all peer reviewers and an association of their remarks with their identity. The Chamber continues to insist that there must be full public disclosure of the identity of all peer reviewers and an association of their remarks with their identity, and we strongly reiterate this position here.

## 5. Confidential Information and Secret Models

The Chamber opposes (with some qualifications as previously noted<sup>7</sup>) the use of confidential data and proprietary models as the basis, in whole or in part, for development of regulations. OMB does not explicitly condemn the use of confidential data and models about which the Chamber has concerns. Instead, in addition to leaving such matters to the discretion of the individual agencies, OMB states: *Specialists attempt to reach a consensus by weighing the accumulated evidence*<sup>8</sup>.

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<sup>7</sup> Footnote 3, *Ibid.*

<sup>8</sup> 69 FR 23234

This does not go nearly far enough, as it could be construed as permissive of consideration of virtually any information, and it therefore remains the case that the issue of what reasonably constitutes the evidence to be weighed has never been resolved. At a minimum, OMB should clearly state: *In any and all instances where comparable non-proprietary information (data and models) is available in the public domain and is accessible to all stakeholders, such information shall be used instead of confidential data and proprietary models. Moreover, in instances where the use of confidential data and proprietary models cannot be avoided, agencies are required to clearly state in the public record the extent to which this circumstance may prejudice a scientific assessment and indicate what plans will be implemented to avoid the use of such confidential data and proprietary models in future regulatory activities.*

We believe that the above point of concern is so fundamental that we cannot support OMB's Revised Bulletin unless it is satisfactorily addressed. OMB should permit proprietary models only in rare cases (e.g., national security, terrorism, intellectual property); as a last resort when no reasonable alternatives are available; and subject to the "robustness checks" standard in the Information Quality Guidelines.

## **6. Waiver Provisions**

The Chamber contends that OMB's waiver provisions are too broad and should be further qualified. For example the Chamber believes that OMB should clarify, and in particular, explicitly qualify, the waiver provision in order to avoid the creation of regulation by judicial fiat. The Chamber's view is that without qualifying this provision of the Bulletin, the requirement to regulate based on sound scientific information could be ignored simply by deliberately entering into a consent decree that, by its design: 1) makes impossible the prospect of conducting a transparent peer review; and 2) deliberately ignores any reasonable alternative consent decree constructions that could have allowed for a reasonable peer review to occur.

In Part B of these comments we request that additional language be inserted into Section VII of the Revised Bulletin to further clarify this issue. The Chamber is concerned that once peer review is waived in order to disseminate information that ought to have been peer reviewed, circumstances may arise in which this issue cannot be revisited.

**7. Procedural Uncertainties**

The Chamber observes that it is unclear whether OMB's instructions, in the aggregate, mean that dissemination shall be considered to have occurred only after, at a minimum, the required peer review process, where applicable, is completed.

Except for two editorial corrections, OMB's definition of "dissemination" in the Revised Bulletin is identical to its definition in the Information Quality Guidelines, except for the new disclaimer language, which says that distribution *solely* for peer review does not constitute dissemination. OMB must clearly state that an agency that releases "or makes available:" a draft risk assessment for any purpose other than or in addition to peer review is subject to all information quality provisions applicable to "dissemination."

The only way for an agency to avail itself of the "solely for peer review" exclusion is to include the disclaimer. The conclusion of peer review would not trigger dissemination unless the agency releases the draft assessment without the disclaimer or utilizes it in some other manner.

**8. Open Peer Review**

The Chamber observes that open peer review is desirable and strongly encourages OMB to undertake a pilot study of open peer review.

OMB still takes no evident position on this matter explicitly, however, the discussion in Section IX (Responsibilities of OIRA and OSTP) of the Revised Bulletin appears to leave some room for a revisitation of this issue. We encourage that, rather than farm out the work to some other agency, OMB initiate and conduct its own open peer review project in order to gain a direct, hands-on feel for the possibilities of this approach. Some possible clarifications concerning this issue are indicated below in Part B, in particular, the Chamber's discussion of Section II and Section IX of the Revised Bulletin.

## **II. PART B**

### **A. COMMENTS AND OBSERVATIONS CONCERNING THE REVISED BULLETIN**

The comments that follow pertain in sequence to specific sections of OMB's proposed Revised Bulletin.

#### **1. Overall Evaluation**

The Chamber is seriously concerned that the changes OMB has made are so severe and debilitating as to eliminate the public benefit of having a common, governmentwide minimum standard for peer review. By making virtually every aspect of the Revised Bulletin discretionary to the agencies, OMB has made the success of its peer review innovations completely dependent on the goodwill of federal agencies who have limited interest in and support for independent, external, and rigorous peer review of their own work products.

With so much discretion granted to the agencies, it is essential that governmental peer review be accompanied by effective mechanisms for affected parties to intervene when they believe agency implementation to be inadequate or

defective, and that there be firm, centralized and accountable oversight. The Revised Bulletin lacks any such provisions, and given the breadth of discretion granted to agencies the Chamber is unable to support any final Bulletin that fails to include effective intervention and oversight tools.

a. **Section I: Definitions**

**Issues That Should be Addressed Further  
Concerning the Meaning of the Term  
*Dissemination***

If an archival record is publicly accessible, why isn't it considered *disseminated*?

More clarity is advised concerning what is encompassed in the phrase *adjudicative processes* and why these processes are excluded from what is considered *disseminated*.

Also, the disclaimer should be revised to read: *This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been officially disseminated by [the agency], and should not be construed to represent—in final or any other form—any agency determination or policy. All other uses of the information are prohibited.*

**Issues That Should be Addressed Further  
Concerning the Meaning of the Term *influential  
scientific information***

The passage that reads...*means scientific information the determination of which the agency reasonably can determine that dissemination of which will have or does have a clear and substantial impact on important...*<sup>9</sup> is confusing, and we suggest it should be revised for clarity.

### **Issues That Should be Addressed Further Concerning the Meaning of the Term *scientific assessment***

Are peer reviews considered to be *scientific assessments*?  
They are not identified as such in this Revised  
Bulletin.

Peer reviews should not be construed as scientific  
assessments as long as they are reviews of scientific  
assessments. Simply being labeled “peer review”  
does not make it so. Many peer reviews of  
controversial risk assessments contain substantial  
new analysis that arguably renders them new  
scientific assessments<sup>10</sup>.

A related issue is agency response to comment  
documents issued following a peer review. It  
appears that such documents are generally not  
covered scientific assessments requiring peer review;  
otherwise, the process would be legitimately  
criticized as an endless loop. However, in some  
cases agencies embed within their nominal response  
to comments documents new scientific  
assessments<sup>11</sup>. The new material in such documents  
ought to be construed as a “scientific assessment”  
subject to applicable peer review requirements. This  
begs the question whether the provisions of any peer  
review Bulletin can be enforced—an agency  
determined to evade effective peer review can  
circumvent it by using its response to comments  
document as the vehicle for disseminating  
information that cannot withstand rigorous peer  
review.

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<sup>10</sup> Under the Revised Bulletin, any peer review of an agency risk assessment by The National Academies that contains a new risk assessment would be exempt under the Revised Bulletin because any product of The National Academies would be exempt irrespective of the peer review procedures actually followed or its scientific quality—a fatal weakness, in our view, of the Revised Bulletin.

<sup>11</sup> See, e.g., Environmental Protection Agency, “Disposition of Comments and Recommendations for Revision to “Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization (External Review Draft, January 16, 2002),” online at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=72117>.

Does inclusion of *weight-of-evidence* analyses in this definition, by inference, include the weight-of-evidence analyses that are performed by agency decision makers in developing regulatory policy and instruments, such as rules and guidance? Also in regard to this issue—and particularly as these activities are left to the discretion of the individual agencies—the concept of what constitutes a weight-of-evidence analysis (e.g., what scientific information should be considered and how should it be weighted, etc.) and how the weight-of-evidence process will be carried out remains entirely unclear.

**b. Section II: Peer Review of Influential Scientific Information**

**Issues That Should be Addressed Further Concerning the Paragraph Beginning With *In General***

The Chamber notes that in the Revised Bulletin, OMB has removed the statement that “peer review undertaken by a scientific journal may generally be presumed to be adequate.” Related to this issue, the Chamber suggests that OMB include a statement in the Revised Bulletin, such as: *Agencies may rely on external peer reviews only to the extent that scientific uncertainties are clearly identified and characterized to the fullest practicable extent and that this information becomes a part of the public record.*

**Issues that Should be Addressed Further Concerning the Paragraph Beginning With *Adequacy of Peer Review***

The *adequacy* of a peer review is left to the individual agencies to decide. For any peer review bulletin to be effective, OMB must establish meaningful minimum standards that prevent agencies from following inadequate peer review practices. Absent

some further explanation by OMB, the interpretation of what constitutes adequate peer review is likely to be applied in an extremely inconsistent manner among the various agencies. A significant related defect in the Revised Bulletin is the absence of procedures by which third parties might establish that a peer review was inadequate.

OMB should also consider whether there is a need for further discussion of the terms *sufficiently rigorous*, as well as *novelty and complexity*. Absent some further discussion by OMB, the interpretation of what these terms mean is likely to be construed in an inconsistent manner by the various agencies. This significant weakness of the Revised Bulletin must be addressed.

#### **Issues That Should be Addressed Further Concerning the Paragraph Beginning With *Choice of Peer Review Mechanism***

We recommend that OMB change the phrase *Peer reviewers shall be selected on the basis of necessary ...* to read *...Peer reviewers shall have and shall be selected on the basis of the necessary ...*

We recommend that OMB change the phrase *...and should not have participated...* to read *...and shall not have participated...*

#### **Issues That Should be Addressed Further Concerning the Paragraph Beginning with *Transparency***

We recommend that OMB change the phrase *A detailed summary or copy of the reviewers' comments, as a group or individually, shall be made available to the public*

*and... to read ... A **complete** copy of the reviewers' comments, as a group or individually, **inclusive of any dissenting comments**, shall be made available to the public and...*

We recommend that OMB change the phrase *Agencies shall consider comments of the reviewers* to read *Agencies shall consider **all** comments of the reviewers.*

c. **Section III: Additional Peer Review Requirements for Highly Influential Scientific Assessments**

**Issues that Should be Addressed Further Concerning Paragraph 2a, *Expertise and Balance* under the topic *Selection of Reviewers***

We recommend that OMB *italicize* the word “scientific” in the passage “...to fairly represent the relevant *scientific* perspectives and fields of knowledge...” This will help emphasize that it is *scientific* rather than policy perspectives that are relevant for selecting candidates for *scientific* peer reviews.

**Issues That Should be Addressed Further Concerning the Paragraph Beginning With *Opportunity for Public Participation***

With regard to information distributed solely for the purpose of pre-dissemination peer review, we strongly recommend that OMB add a comment such as: *This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been officially disseminated by [the agency], and should not be construed to represent—in final or any other form—any agency determination or policy.*

Other than information distributed solely for the purpose of pre-dissemination peer review, i.e., any other distribution, or distribution for any other or additional purpose, constitutes dissemination—OMB and agencies should clearly state that such dissemination shall not be construed as pre-dissemination peer review.

The Revised Bulletin would reduce rather than expand opportunities for public participation in peer review.  example, the text allows that “[a]gencies *may* decide that peer review should precede an opportunity for public comment;”<sup>12</sup> then again, OMB would grant them unfettered discretion to schedule public comment later, or not at all.

The Revised Bulletin also permits agencies to hold peer reviews in secret. For example, OMB states that an agency “shall, whenever possible, provide a vehicle for the public to provide written comments, make an oral presentation before the peer reviewers, or both,” but only “[i]f an agency decides to make a draft assessment available publicly available at the same time it is submitted for peer review (or during the peer review process).”<sup>13</sup>

The Chamber believes that these changes are significant steps backward. The public credibility of peer review depends on transparency, public access and meaningful opportunities for participation.

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<sup>12</sup> 69 Fed. Reg. 23236.

<sup>13</sup> *Ibid* at 23241 (emphasis added).

### **Issues That Should be Addressed Further Concerning the Paragraph Beginning With *Peer Review Reports***

For reasons stated previously<sup>14</sup>, the Chamber insists that transparency of process is absolutely essential and that the specific comments, identities, and qualifications of all individual peer reviewers must be made known and available to the public.

We recommend that OMB change the passage that reads *The peer review report should either summarize the views of individual reviewers (either with or without specific attributions...* to read *The peer review report must present in complete form all the views of individual reviewers (with specific attributions...*

We recommend that OMB change the passage that reads *The agency is required to prepare a written response to the peer review report explaining:...* to read *The agency is required to prepare a written response to the peer review report(s) explaining:...*

#### **d. Section IV: Alternative Procedures**

The complete and non-rebuttable exemption for The National Academies, on both matters of procedure and substance without any meaningful provision for rebuttal, is a fatal defect of the Revised Bulletin. However credible and balanced NAS reports might be in general, the NAS follows highly opaque procedures that, in many cases, are fundamentally incompatible with the twin goals of information quality and public credibility. OMB's

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<sup>14</sup> Footnote 3, *Ibid.*

advice that agencies adopt policies and procedures similar to those of the NAS<sup>15</sup> unwittingly invites them to mimic its lack of transparency and limited accountability. The Chamber cannot support any final Bulletin that retains this language.

Does choosing an allowed alternative to the requirements indicated in Section II and Section III of the Revised Bulletin relieve individual agencies from their obligations under, for example, the Information Quality Guidelines? The language in Section XI (Judicial Review) of the Revised Bulletin appears to assure that this will not be the case, however, further clarification on this matter in Section IV would be helpful to remove any uncertainties or ambiguities.

As but one example concern, regulatory policymaking that relies **only** on *...scientific information produced by the National Academy of Sciences*<sup>16</sup> (NAS)...carries with such a permitted reliance the implicit presumptions that: 1) the National Academies product is in and of itself a sufficient scientific foundation for regulatory policymaking; and 2) that there is no further necessity or obligation for agencies to carry out any additional weight-of-evidence considerations that draw upon other possible sources of credible scientific information or expert advice, despite the indisputable fact that there are many other credible scientific resources and experts that agencies can access. Such a regulatory

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<sup>15</sup> “In response to comments, this revised Bulletin encourages agencies to consider using the panel selection criteria employed by the NAS.” See Revised Bulletin at 2.

<sup>16</sup> NB: The correct term is “The National Academies”, not “National Academy of Sciences”. The former is comprised of four organizations: the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council. Regulatory language that refers only to the “National Academy of Sciences” neglects the capabilities and expertise of the other three organizations of which The National Academies is comprised.

stance, as outlined in Section IV, therefore diminishes the importance of the concept and use of weight-of-evidence and possibly relieves policymakers from making fully transparent how science information *in toto* is fully integrated into the regulatory decision making process.

At a minimum<sup>17</sup>, all the Alternative Procedures indicated in Section IV of this Revised Bulletin (and more generally the Revised Bulletin in its entirety) should explicitly include a provision that inclusively allows for the reasonable consideration of any and all sound scientific information, regardless of whether based on information presented in peer reviewed science journals, reports of The National Academies<sup>18</sup>, or other information resource(s).

e. **Section V: Peer Review Planning**

**Issues That Should be Addressed Further Concerning the Paragraph Beginning With *Peer Review Plans***

As noted in comments previously submitted by the Chamber, and for the reasons stated therein<sup>19</sup>, the Chamber believes that an intense effort must be made to assure that the number of competent peer reviews is as large as possible (and feasible). Moreover, the Chamber continues to assert that a peer review mechanism that can accomplish this objective is an **open scientific peer review mechanism** [See also the comment below concerning Section IX (Responsibilities of OIRA and OSTP)].

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<sup>17</sup> If not otherwise already allowed by existing law.

<sup>18</sup> Here, the use of the phrase “The National Academies” and not “National Academy of Sciences” is deliberate; see Footnote 16.

<sup>19</sup> Footnote 3, *Ibid.*

**f. Section VI: Certification in the Administrative Record**

No specific comments.

**g. Section VII: Safeguards and Waivers**

**Issues That Should be Addressed Further Concerning the Paragraph Beginning With *Privacy and Confidentiality***

With regard to the passage ...*in a manner that respects (i) privacy interests...*, does the phrase *privacy interests* include the interests of peer reviewers who do not wish to have their identities revealed? If it does, then this phrase *privacy interests* excludes from use by agencies the option of **open** peer review in which peer reviewer identities are made known to the public. We ask OMB for a clarification of this matter, and if this proviso does in fact exclude open peer review, we state our objection to this proviso and ask OMB to include an explicit statement that open peer review is not excluded.

**Issues That Should be Addressed Further Concerning the Paragraph Beginning With *Waiver***

Does the statement regarding what the agency head may waive or defer implicitly include waiver or deferral of peer review so that the mandates of a court-ordered consent decree may be satisfied? If so, the Chamber reiterates its previously stated<sup>20</sup> concern about regulation by judicial fiat and restates here our prior comment in regard to this issue, specifically, that the waiver provisions should be further qualified to remove any possible ambiguities about this matter.

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<sup>20</sup> Footnote 3, *Ibid.*

We recommend that OMB change *If the agency head waives the peer review requirements prior to dissemination, peer review **should** be conducted as soon as practicable thereafter* to read, *If the agency head waives the peer review requirements prior to dissemination, peer review **shall** be conducted as soon as practicable thereafter. Moreover, if the activity for which a waiver is granted is preliminary to a subsequent rulemaking, such as a rulemaking required by a court-ordered consent decree, then the peer review must be completed before the rulemaking is final.*

**h. Section VIII: Exemptions**

In exemption 2, we recommend that OMB change the passage that reads *...to qualify for this exemption, scientists **are advised to** include in their information product a clear disclaimer that...* to read as follows: *...to qualify for this exemption, scientists **shall** include in their information product a clear disclaimer that...*

In exemption 3, what exactly does *adjudication* implicitly include? We recommend that OMB include a statement such as the following: *This Bulletin does not cover official disseminations that arise in adjudications and permit proceedings except as follows: The agency must determine whether the influential dissemination is scientifically or technically novel (e.g., a major change in accepted practice) and likely to have precedent-setting influence on future adjudications or permit proceedings; if so, then such dissemination is covered by this Bulletin.*

**i. Section IX: Responsibilities of OIRA and OSTP**

As noted in comments previously submitted by the Chamber and for the reasons stated therein<sup>21</sup>, the Chamber continues to assert its belief that a more desirable peer review mechanism than that indicated in this Revised Bulletin is an **open scientific peer review mechanism**. However, the Chamber

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<sup>21</sup> *Ibid.*

recognizes that, for the purposes of federal government agency peer reviews, the feasibility of such an undertaking must first be proven out—such as through a pilot project—before it can be implemented. Therefore, the Chamber strongly recommends that a discussion of this issue be undertaken through the interagency work group that will be chaired by OSTP and OIRA.

**j. Section X: Effective Date and Existing Law**

No specific comments.

**k. Section XI: Judicial Review**

Selection of the \$500 million value as the cut-off for what is considered to be *highly influential* scientific information appears inconsistent with the cut-off value indicated in the Information Quality Guidelines. As such, it represents a further dilution of the guidelines. Therefore, OMB should discuss why this cut-off value of \$500 million has been established, because, for example, the inconsistency may lead to uncertainties about rights of judicial review of this Revised Bulletin. We note further that few regulatory actions will qualify with the threshold set so high, that there is no clear mechanism for determining whether this threshold has been exceeded, and there is no procedural method by which to contest agency determinations.

Dr. Margo Schwab

May 28, 2004

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The Chamber appreciates the opportunity to submit these comments and thanks the Office of Management and Budget, and the Office of Information and Regulatory Affairs for considering the views of the U.S. business community on this important subject.

Sincerely,

A handwritten signature in cursive script, appearing to read "William L. Kovacs".

William L. Kovacs