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To: Mabel E. Echols OMB\_Peer\_Review/OMB/EOP@EOP  
cc: Science\_Policy\_Team@americanchemistry.com  
Subject: Comments of American Chemistry Council -- attached file

Comments attached; will be submitted separately as message text.

(See attached file: ACC comments on OMB PR guidelines.pdf)

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- ACC comments on OMB PR guidelines.pdf



December 15, 2003

Dr. Margo Schwab  
Office of Information & Regulatory Affairs  
Office of Management & Budget  
725 17th Street, NW  
New Executive Office Bldg., Room 10201  
Washington, D.C. 20503

Re: Proposed Bulletin on Peer Review and Information Quality

Dear Ms. Schwab:

The American Chemistry Council (ACC or the Council) is pleased to submit these comments on the Office of Management and Budget's "Proposed Bulletin on Peer Review and Information Quality" (Bulletin).<sup>1</sup> The Council represents the leading companies engaged in the business of chemistry. Council members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. The Council is committed to improved environmental, health and safety performance through Responsible Care<sup>®</sup>, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$460 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other business sector.

As a science-driven industry, the business of chemistry -- through the Council and individual members companies -- provides significant support for scientific research to better understand and characterize the potential risks from chemical exposures. This

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<sup>1</sup> 68 Fed. Reg. 54023 (Sept. 15, 2003).



support includes \$18 million per year on generic research through our Long-range Research Initiative, and likely hundreds of millions over several years on screening and testing individual chemicals through the High Production Volume chemicals initiative and otherwise. Council members are heavily regulated by federal agencies, and are also affected by numerous agency information products, commonly directed at reducing risks to public health and the environment. Because these rules and disseminations may impose significant costs, it is imperative that they be based on good science that supports accurate, realistic risk assessments for appropriate risk management decisions.

OMB, the Council and many others all recognize that effective peer review is crucial to promoting high-quality science and the resulting regulatory policies. OMB's proposed standards are an important step toward instilling high standards for peer review government-wide. With our long-standing commitment to good science and peer review, Council staff and members have often participated on federal peer review panels along with scientists from other organizations. Like any other potential panel members, Council representatives expect to undergo established screening procedures to ensure their expertise is of the right kind and they are free from conflicts of interest and undue bias. Unfortunately, in recent years scientists employed by companies – and even those who only receive some grant funding from companies to support their research – have come under attack as part of coordinated campaign by organizations seeking to diminish and even eliminate industry participation on government advisory panels. This ongoing assault on the scientific peer review process to promote political goals lends urgency to the need for government agencies to demonstrate an unswerving commitment to independent, objective, and meaningful peer review policies and procedures, such as those proposed in the Bulletin. The Council strongly supports such a commitment.

These comments first address programmatic issues associated with the Bulletin, and then discuss topics related to peer review generally. The comments then focus particularly on peer reviewer selection and the underlying questions of conflict and bias. Finally, we discuss Information Quality Act issues.

### **Executive Summary**

The American Chemistry Council strongly supports OMB's effort to improve federal regulatory policies through independent, objective, and meaningful peer review of significant regulatory information. Overall, OMB's proposed Bulletin on Peer Review and Information Quality would help achieve this goal without imposing overly burdensome requirements on either the agencies required to conduct peer reviews or the peer reviewers who participate in these processes. Following is a summary of ACC's comments, articulated at greater length below.

**Programmatic comments.** ACC believes there is a need for the Bulletin, and that OMB has ample legal authority to issue it. Agencies should find it feasible to implement the Bulletin, based on EPA's experience with peer review, but OMB should still assess the benefits and costs of implementation. Because it "supplement[s]" OMB's Information

Quality Act (IQA) guidelines, the Bulletin will be effective immediately upon agencies. Nonetheless, OMB should require agencies to seek comments on their proposed revisions of their IQA guidelines to incorporate the Bulletin's requirements. For its part, OMB should also post these and other comments on the proposed Bulletin on its web page.

**Peer review comments.**

Scope. OMB should require external peer review, not only for especially significant information, but also for all influential/significant regulatory information that is either:

- precedential or novel,
- particularly controversial, or
- highly complex.

At a minimum, OMB must require Section 3 peer review for information subject to the Safe Drinking Water Act objectivity criteria established in OMB's IQA Guidelines. OMB should also require agencies, in their reports summarizing their peer review plans, to state which "influential/significant" documents they propose to peer review under those procedures. OMB need not impose any peer review requirements for any other types of information.

Science/policy distinction. Peer reviews should focus on scientific questions and not address purely policy questions. However, peer reviewers should be encouraged to opine on issues of scientific judgment.

Journal peer review. The Bulletin should not establish any presumption, rebuttable or otherwise, for documents that have been subject to peer review by a scientific journal. This will not pose a hardship for agencies since important agency documents tend to be analyses of published articles, not articles themselves.

Panel management. Peer reviews should be managed by independent entities (e.g., EPA's Science Advisory Board), not by the agency itself. Face-to-face meetings, conference calls and other real time or dialogic approaches are all superior to letter reviews. Agencies could use standing panels like the SAB, instead of ad hoc entities, to promote collegiality and reduce costs. Peer reviewers, not agency staff, should write the reviewers' report.

Charge issues. The Council supports OMB's proposals regarding the charge to peer reviewers. OMB should also require agencies to provide outside parties a brief opportunity to comment on a draft charge.

Reporting to OMB. OMB should require peer review reports to be included in agencies' semiannual regulatory agendas, and to capture any documents that are planned for peer review, regardless of when they will be disseminated. Agencies should also be encouraged to maintain an evergreen peer review inventory on their websites.

Timing. The Bulletin should establish reasonable but clear timelines for:

- agencies to issue revised IQA guidelines implementing it;
- ensuring that the public has adequate opportunity to comment on proposed reviewers and the draft charge;
- ensuring that the public has adequate opportunity to file comments on the document being peer reviewed (and supporting materials) early enough in the process that the peer reviewers can digest them;
- ensuring that the peer reviewers have adequate time to review the document being peer reviewed (and supporting materials) before their meeting or before their comments are due;
- the peer reviewers to file a report;
- the agency's response to the peer reviewers' report; and
- the agency's response to any public comments that invoke the IQA-- agencies need not respond to other public comments.

Waivers. Agencies that negotiate consent decrees should factor in sufficient time to conduct a peer review of information covered by the peer review standards. Also, the Bulletin should make clear that a "waiver" is really an extension -- i.e., not a basis for evading the peer review requirement, but only permission to wait until the basis for the waiver has passed.

Certification requirement. The Council supports this requirement.

**Conflict & bias issues.** The Bulletin should:

- Carefully distinguish between conflict of interest and bias, recognizing that conflict of interest occurs in narrow circumstances, while bias is much more pervasive;
- Call for exclusion sparingly, and only in cases of true financial conflicts (unless the need for the individual's services outweighs the potential for a conflict of interest);
- In all other cases, instruct agencies to:
  - determine the necessary domains of knowledge;
  - identify the most scientifically and technically qualified individuals within those domains as prospective panelists, and
  - from within that pool, choose panelists that represent the relevant scientific perspectives and the collective breadth of experience. Rather than attempting to match reviewers with "contrary bias," agencies should strive to ensure the overall panel reflects a balance among competing scientific or technical perspectives.

**Information Quality Act Issues.** The Council strongly supports issuance of the Bulletin as a means of implementing the pre-dissemination review mechanism of the IQA.

However, OMB should explain the overlap between the Bulletin and the IQA guidelines, particularly what remedy is available for persons affected by a document that is being peer reviewed. ACC also strongly urges OMB to require agencies to post all non-frivolous IQA correction requests on their websites.

## **Discussion**

### **I. ACC Commends OMB for Proposing Federal Peer Review Standards**

The Council commends OMB's leadership for proposing federal standards to strengthen peer review of regulatory science. As the "supplementary information" in OMB's preamble demonstrates, broad precedent supports high-quality peer review of many kinds of scientific and technical information, including the cost-benefit analyses and scientific inferences that underlie agency work products. If there were any doubt, OMB's Bulletin conclusively makes the case for basic standards of independent peer review. In particular, OMB's preamble raises the critical, but previously neglected, prospect that peer reviewers may have compromised independence because of their ties to agencies, either as employees or due to financial dependence. For raising public awareness of peer review's importance, and associated issues, OMB deserves unstinting praise.

When mistrust runs so high, and when the credibility of peer reviews is so much at stake, transparency must rule to the maximum extent possible. OMB is to be commended for so thoroughly integrating transparency into its proposed peer review standards. The Council strongly supports the Bulletin's emphasis on "proper and clearly-articulated procedures" for carrying out peer reviews, including procedures for panel selection and panel management, as well as various reporting requirements to inform the public about the substance of the peer reviewers' recommendations and the agency's responses.

OMB also deserves praise for fleshing out a critical part of the predissemination review process under OMB's Information Quality Act (IQA) Guidelines. This process should ultimately be more important than the administrative correction process, since it applies in all case, not only when a correction request is filed. Yet it has not received the attention from agencies that it deserves.

Before addressing issues related to the specific elements of the Bulletin, this Part of the Council's comments responds to several overall criticisms that have been directed to the fundamental concept of the Bulletin, and makes several recommendations about OMB's process of finalizing it.

#### **A. There Is a Problem**

At the workshop on the Bulletin hosted by the National Academy of Sciences (NAS) on November 18, a few speakers contended that the Bulletin was a solution in search of a problem and that no one had identified any examples where agency science would have benefited from being peer reviewed adequately. As the Appendix to these comments

documents, such examples are numerous and do in fact represent a problem that needs to be addressed.

#### B. OMB Has Ample Legal Authority

Some commenters have questioned whether OMB has legal authority to issue the Bulletin. There should be no question that the President has authority under Article II of the Constitution to issue the Bulletin as a means of guiding and limiting the discretion of agencies in his branch of the government, as he has done through Executive Order 12866.<sup>2</sup> And that Executive Order calls on agencies to base their decisions on “the best reasonably obtainable scientific, technical [and] economic . . . information.”<sup>3</sup> The Bulletin is thus a logical extension of that Order. The Council also endorses OMB’s citation of the IQA and the Paperwork Reduction Act. The IQA provides essential guidance for better federal regulations and, as such, implicitly endorses peer review as a mechanism to promote the use of objective information in regulatory analysis and decisions.<sup>4</sup> It also directs OMB to give guidance to agencies in maximizing the quality of information they disseminate. Given peer review’s vital role in identifying scientifically and technically deficient information, it is appropriate that OMB has singled out this aspect of federal information quality for stronger emphasis. OMB is demonstrating a clear, consistent commitment to high-quality science and to ensuring that federal agencies share this commitment.

#### C. The Bulletin Can Be Implemented

Some workshop participants questioned whether the Bulletin could be implemented without dramatically slowing down or diminishing the quality of agency work. ACC believes the answer to that question is yes:

- Administrator Graham’s case studies at the National Academy of Science workshop illustrated well the feasibility of implementing the Bulletin.
- Paul Gilman’s remarks there demonstrated that EPA is already managing an impressive throughput of peer reviews that meet Bulletin requirements in most respects.
- Implementing the Bulletin should result in more defensible rules, and to that extent will produce offsetting savings in agency resources.
- Implementation should also reduce the number of IQA correction requests submitted to agencies.
- The requirements of the Bulletin largely echo the recommendations of the National Research Council’s seminal report, *Science & Judgment in Risk*

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<sup>2</sup> See Opinion of the Office of Legal Counsel, U.S. Dep’t of Justice, “Additional Procedures Concerning OIRA Reviews Under Executive Order Nos. 12291 & 12498” (relying on the “take care” clause of the Constitution), reprinted in OMB, *Regulatory Program of the United States* 532-36 (1988-89).

<sup>3</sup> 58 Fed. Reg. 51735 (Oct. 4, 1993).

<sup>4</sup> In its guidelines under the IQA, OMB has already noted that formal, independent, external peer review creates a presumption of objectivity, 67 Fed. Reg. 8459 (Feb. 22, 2002).

*Assessment*<sup>5</sup> They will require some additional effort and resources on the part of agencies. So does compliance with the Administrative Procedure Act, or the Ethics in Government Act. We regard compliance with these latter enactments, and laws like them, as a reasonable cost of having a responsive and fair government. We should look at the Bulletin similarly, as embodying steps that are needed to produce agency science of requisite quality.

D. OMB Should Assess the Net Benefits of the Bulletin

ACC notes that OMB did ask agencies to comment on “the expected benefits and burdens of this proposed Bulletin.”<sup>6</sup> We believe this question is appropriate. We are confident that the conclusion will be one of net benefits, but we recommend that OMB address that issue in some rigorous fashion, as the Bulletin is implemented, in order to lay it to rest. In doing so, OMB should look (or direct agencies to look) to measure whether and how the Bulletin has produced better science than would otherwise have obtained, and how that has led to better agency action.

E. The Bulletin Will be Effective Upon Promulgation. Agencies Should Seek Comments on their Proposed Implementation of It

Because the Bulletin “supplement[s] th[e] requirements” of OMB’s IQA guidelines, and those guidelines are currently binding on agencies, once the Bulletin is issued in final form it will be effective immediately upon agencies. ACC supports such a result. We also support OMB’s requirement that agencies supplement or amend their existing IQA guidelines to incorporate it and to address a variety of agency-specific issues.<sup>7</sup> When OMB issued its IQA Guidelines, it required agencies to seek public comment on their own implementation of those Guidelines. This process worked well and resulted in significantly improved final agency guidelines. We recommend that OMB likewise require agencies to seek public comment on their proposed incorporation of the Bulletin.

F. OMB Should Post Comments It Receives

In the interest of promoting the openness and transparency by which the Bulletin is finalized, ACC recommends that OMB post comments it receives, from whatever source, on its website.

## II. Comments on Peer Review Issues

As OMB is aware, peer review of regulatory science has been the subject of significant controversy. Interested parties approach the process with deep suspicion that scientific information does not receive appropriately independent, objective, or meaningful review. In the often highly charged process of public policy making on environmental health, and

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<sup>5</sup> NRC, *Science & Judgment in Risk Assessment* (1994).

<sup>6</sup> 68 Fed. Reg. 54027.

<sup>7</sup> *Id.* at 54028.



safety issues, during which the validity and meaning of scientific information can become the target of intense controversy, it becomes exceptionally important to assure the quality of scientific information and the integrity of the policies and procedures for peer reviewing that information. OMB's Bulletin is an exceptionally well-crafted step in that direction. Below we comment on the principal issues raised by OMB or interested parties.

A. Scope

1. Procedures for Significant/Especially Significant Information

OMB was wise to define "regulatory information" to encompass information relevant to regulatory policy, and not just notice-and-comment rules. Also, it is practical for OMB to equate "significant" regulatory information with "influential" information under the IQA guidelines. (To cement the linkage with the IQA, and for simplicity's sake, we recommend that OMB drop the term "significant" and use "influential" in the final bulletin.)

The Council is concerned, however, that the Bulletin's proposed scope is not adequate to accomplish its praiseworthy objectives. In particular, we strongly believe that the proposed definition of "especially significant" information is too narrow. Under the proposal, agencies must provide "formal, independent, external peer review" for information that (i) has a "clear and substantial impact on important public policies or important private sector decisions with a possible impact of more than \$100 million in any year," (ii) the Administrator of OIRA deems of relevance to an Administration policy priority, or (iii) is of significant interagency interest. While there is little doubt that any document falling within this scope warrants independent, objective, and meaningful peer review, federal agencies routinely issue work products that do not in and of themselves have a cost impact of \$100 million a year and yet may possess other attributes that make them good candidates for additional scientific scrutiny. (Good examples include EPA's various cancer and noncancer risk assessment guidelines and IRIS files for widely-used chemicals.)<sup>8</sup>

We also question the utility of the generic peer review requirements proposed for merely "significant" information. These requirements are so minimal that they might not produce significant improvements over the current level of scientific quality. Or the improvements may not warrant the burden they necessitate.

ACC notes with approval the potentially much broader scope of EPA's *Peer Review Handbook*, which states that "all major scientific and technical work products used in

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<sup>8</sup> ACC does not agree with speakers at the NAS workshop who said that the \$100 million value should be adjusted for inflation. In our experience, relatively few rules fall into that category even now. Also, expectations regarding public involvement and Executive oversight have grown with inflation.

decision making will be peer reviewed.”<sup>9</sup> EPA’s *Handbook* provides the following list of attributes of a “major” work product:

- Establishes a significant precedent, model or methodology
- Addresses significant controversial issues
- Focuses on significant emerging issues
- Has significant cross-Agency /inter-agency implications
- Involves a significant investment of Agency resources
- Considers an innovative approach for a previously defined problem/process/methodology
- Satisfies a statutory or other legal mandate for peer review<sup>10</sup>

We also note with approval that EPA’s IQA guidelines include “major work products undergoing peer review” within the Agency’s definition of “influential information.”<sup>11</sup>

EPA’s *Handbook* adds that “[m]ajor work products intended to support the most important decisions, or that have special importance in their own right, *ordinarily should be the subject of external peer review.*”<sup>12</sup> The *Handbook* identifies some of the attributes just mentioned in its discussion of when external peer review is appropriate: “Generally, the more complex, novel and/or controversial the product, or the higher impact it has, the more the Decision Maker should consider implementing a large-scale peer review involving external experts.”<sup>13</sup>

Thus anything that EPA deems to be “influential” (i.e., “significant”) is “ordinarily” subject to external peer review if “supports the most important decisions” or “has special importance in [its] own right.” That scope is clearly broader than OMB’s current definition of “especially significant information.” ACC strongly recommends that OMB track the general approach of the EPA Handbook by requiring external peer review, not only for especially significant information, but also for all influential/significant regulatory information that is either:

- precedential or novel,
- particularly controversial, or
- highly complex.<sup>14</sup>

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<sup>9</sup> EPA Science Policy Council, *Peer Review Handbook* (EPA-100-B-00-001) (Dec. 2000) at 26 (emphasis in original).

<sup>10</sup> *Id.* at 26-27.

<sup>11</sup> See EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency* (EPA/260R-02-008) (Oct. 2002) at § 6.2 (pp. 19-20), available at [http://www.epa.gov/oei/qualityguidelines/EPA\\_OEI\\_IQG\\_FINAL\\_10-2002.pdf](http://www.epa.gov/oei/qualityguidelines/EPA_OEI_IQG_FINAL_10-2002.pdf).

<sup>12</sup> EPA *Peer Review Handbook* at 40 (emphasis added).

<sup>13</sup> *Id.*

<sup>14</sup> Further support for this proposal is found in the American Bar Association’s [Resolution on Risk Assessment](#) (October 1999), which recommends that the “nature, significance and complexity” of a risk assessment should govern whether and how it is peer reviewed. See <http://www.abanet.org/adminlaw/risk02.pdf>.

To lessen the increased burden on agencies this might impose, ACC would not object to the Bulletin dropping any peer review requirements for any other types of information. Thus, peer review would either have to meet the higher standard proposed now for “especially significant” information, or it would not have to occur at all.

At a bare minimum, OMB must require external peer review for the influential risk information that is currently subject to the Safe Drinking Water Act objectivity criteria established in OMB’s IQA Guidelines. Those Guidelines recognized that risk information is especially important, uncertain and contentious, and for those reasons imported the SDWA criteria. For the same reasons, OMB should ensure that this kind of information is subject to Section 3 of the Bulletin.<sup>15</sup>

If OMB adopts either of these last two approaches, it should require agencies, in their annual (or more frequent) reports summarizing their peer review plans, to state which “influential/significant” documents they propose to peer review under Section 3 procedures, allowing the public and OMB to weigh in on those proposed determinations.

## 2. Distinguishing between “science” and “policy”

ACC agrees with the Bulletin that peer reviews should focus on scientific questions and not address purely policy questions. ACC also recognizes that this distinction is often a difficult one to make in practice, but it is not impossible or immutable. For example, the existence and magnitude of *uncertainty* about something is a scientific judgment. Whether to use an uncertainty *factor*, and the size of that factor, has traditionally been regarded as a policy judgment. However, increasingly research is providing data that allow “data-driven” uncertainty factors that may be larger or smaller than the defaults they replace. As the amount and quality of those data increase, these kinds of determinations become less policy decisions and more matters of scientific judgment.<sup>16</sup>

*Science & Judgment in Risk Assessment* advises government risk assessors to address the scientific uncertainty justifying a default assumption, and not to wall off these questions as “policy.”<sup>17</sup> ACC has at times witnessed an inclination of agency science panels to duck questions that involve mixed judgments of science and policy. This is particularly problematic because, as Sheila Jasanoff observed at the NAS workshop, much if not most of the science being peer reviewed at agencies is not “normal” science where practitioners in the field all agree on methods and interpreting results, but “emergent” or

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<sup>15</sup> OMB should also clarify that “risk,” when used in its IQA Guidelines, includes components of risk such as hazard and exposure information. Some agencies have been attempting to evade the SDWA criteria by contending that they only apply to risk assessments that combine hazard and exposure data. ACC trusts that OMB does not share this view and hopes that it will clarify the issue.

<sup>16</sup> For a discussion of mixed science/policy judgments, see James W. Conrad, Jr., “The Reverse Science Charade,” 32 *Env’tl L. Rep.* 10306 (April 2003).

<sup>17</sup> *Science & Judgment in Risk Assessment*, *supra* note 5, at 89-91.

cross-disciplinary science.<sup>18</sup> As a general matter, ACC encourages OMB warn agencies - and reviewers -- against using the science/policy distinction too readily as a way for taking issues off the peer review table. To the extent issues of scientific judgment are involved, peer reviewers should be encouraged and authorized to opine on them, even if the ultimate decision is one that the agency will make by integrating those scientific judgments with policy choices.

B. Rebuttable Presumption for Journal Peer Review

ACC strongly believes that the final Bulletin should not establish any presumption, rebuttable or otherwise, for documents that have been subject to peer review by a scientific journal. We take this position, moreover, in full recognition of the importance of literature searches and journal studies in the development of environmental, health, and safety regulatory policy.

ACC has discussed this issue with numerous editors of scientific journals, who have uniformly insisted that journal peer review and government agency peer review are fundamentally different activities with fundamentally different goals. Those editors and other knowledgeable experts have made this point at numerous public meetings:

- At the September 4 meeting of the National Academy of Sciences Science, Technology and Law Program, Don Kennedy, Editor-in-Chief of *Science* magazine, stated [that journal peer review is inadequate for regulatory purposes]
- At the October 9 meeting of the American Bar Association's Section on Environment, Energy & Natural Resources, Dr. Gio Gori, Editor of the *Journal of Regulatory Toxicology & Pharmacology*, asserted that journal peer review is "a perfunctory process" that "is not nearly as thorough" as the type of peer review conducted, for example, by EPA's Science Advisory Board.

Any number of examples can be adduced to show that journal peer review cannot be presumed to guarantee the scientific validity of studies. For instance, in 1996, *Science* published a paper, "Synergistic Activation of Estrogen Receptor with Combinations of Environmental Chemicals,"<sup>19</sup> but after the study results proved irreproducible, the primary researcher admitted to falsifying data and the paper was retracted. More recently, *Science* published another study, "Severe dopaminergic neurotoxicity in primates after a common recreational dose regimen of MDMA ('Ecstasy'),"<sup>20</sup> that also had to be retracted after further experiments failed to reproduce the results (because the test subjects had actually been given methamphetamine, rather than 'Ecstasy').

Finally, ACC is concerned about the number of "scientific journals" being established by interest groups, especially those associated with the plaintiffs bar, as a means of giving

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<sup>18</sup> See transcript at 91, available at [http://www7.nationalacademies.org/stl/Peer\\_Review\\_Transcript.pdf](http://www7.nationalacademies.org/stl/Peer_Review_Transcript.pdf).

<sup>19</sup> S. Arnold *et al.*, "Synergistic Activation of Estrogen Receptor with Combinations of Environmental Chemicals," *Science*, Vol. 272, pp. 1489-1492.

<sup>20</sup> G.A. Ricaurte *et al.*, "Severe dopaminergic neurotoxicity in primates after a common recreational dose regimen of MDMA ('ecstasy')," *Science*, Vol. 297, pp. 2260-2263.

the appearance of credibility to theories advanced by those groups that have been unable to find acceptance in the scientific mainstream. Trial lawyers and others have created these journals as a means of overcoming the *Daubert* decision's requirement that expert testimony, to be admissible, must be reliable, as shown in part by the expert's theory being reflected in the journal articles in the relevant field.<sup>21</sup> Federal agencies should not be required or permitted to presume the validity of studies published in journals given the proliferation of these spurious "expert" journals.

The unfortunate lesson from the foregoing is that journal peer review should not be relied upon to screen out falsified data or poor quality studies. And it should not be expected to, even in the case of legitimate journals, since journal peer review is rather intended to ensure that the proper experimental procedures appear -- on the surface -- to have been followed. Journal peer reviewers are not provided with the data underlying a paper, and are not expected to seek or review it. As the Bulletin describes it, federal agency peer review, by contrast, is supposed to probe more deeply into underlying data and methods to make a more substantive determination regarding the ultimate validity of a paper's findings.

Given the essential differences between journal and agency peer review, and the resulting shortcomings of former from the perspective of the latter, it is absolutely essential that OMB's peer review requirement apply with equal force to journal articles. This will ensure that the science they present is subject to the requisite degree of scrutiny, and that members of the public have some ability to challenge the findings of a published study. It is not sufficient, moreover, to establish a presumption that is rebuttable "on a persuasive showing in a particular instance." In many if not most cases, the inadequacy of a particular paper may not be demonstrable until the underlying data can be obtained and reviewed. Thus it may be difficult to make a "persuasive" showing unless and until the paper undergoes agency peer review. The rebuttable presumption mechanism also would inexorably generate a new adjudicative process, with its own processes, precedents, timetables, and delays, all of which is contrary to the "common sense and workable manner" by which OMB intends the IQA process to operate.<sup>22</sup>

Abolishing this presumption would not work a significant hardship for agencies. Most government scientific documents are not articles that government (or someone else) has published in a peer-reviewed journal. In almost all cases, the agency (or contractor) develops a synthesis or meta-analysis document that reviews and summarizes available literature.<sup>23</sup> It is *this* document that should be peer reviewed. And ACC does not understand OMB to be saying that every published paper cited in a government document must *itself* be peer reviewed. Based on the Bulletin's scope provisions, the requirement for peer review would only apply where a published paper was itself "significant" -- i.e.,

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<sup>21</sup> *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

<sup>22</sup> 66 Fed. Reg. 49719.

<sup>23</sup> IRIS Toxicological Reviews are a good example. Other examples are NTP "Reports on Carcinogens," various "Background Information Documents" and "Technical Support Documents," reports developed under the National Environmental Policy Act or the Endangered Species Act, etc.

influential -- regulatory information. An example of such a rare article would be the ["Harvard Study" heavily relied upon by EPA in its most recent revision of the PM<sub>2.5</sub> NAAQS.<sup>24</sup>]

Nor would eliminating the proposed presumption denigrate the status or weight conventionally assigned to published work. Articles published in highly-regarded, influential journals will continue to enjoy greater prestige than not so published, and consciously or unconsciously will be accorded weight by agency decisionmakers in proportion to the reputation of the journals in which they are published. The only difference from the status quo will be that such papers, when significant to agency decisionmaking, will have to be peer reviewed like any other.

Finally, just as journals print retractions of papers that prove to be flawed, so OMB should require agencies that rely on scientific studies that later prove to be erroneous to inform the public about the rebutted studies and to review any agency decisions based on the refuted studies to assess their continued validity.

### C. Peer Review Panel Management

This section of our comments addresses a related set of greatly important issues: Who selects the peer reviewers? Who makes the decisions about qualifications, conflicts, and bias? Do the peer reviewers meet face-to-face? Who writes their report?

#### 1. Reviewer selection

In its Bulletin, OMB makes the following statement: "Simply put, the agency proposing or supporting a regulation or study may not always be the best entity to commission or supervise its own peer review."<sup>25</sup> The Council agrees -- an agency's supervising its own reviews is inherently problematic, arguably akin to a person on trial selecting his or her own jurors. Indeed, the Council is aware of at least one instance in which a peer reviewer whose scientific conclusions challenged EPA's conclusions was not invited to participate in a later contractor-managed review -- despite very high scientific qualifications -- while another scientist whose views comported with agency views was able to join in the later review. Without having conducted a formal study of the matter, the Council believes this practice is likely not confined to one instance and may perhaps be widespread or common practice. The incentives for an agency to select favorable reviewers are no different from the incentives facing any interested party.

The best way to achieve OMB's fundamental goal independent, objective, and meaningful peer review -- a goal shared by the Council and many others -- is for peer reviews to be managed by independent entities (e.g., for EPA, the Science Advisory Board, National Research Council, or other organizations with well-established and

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<sup>24</sup> Dockery, D., Pope, C.A., et al., "Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults," *Am. J. Respiratory & Critical Care Medicine* (March 1995).

<sup>25</sup> 68 Fed. Reg. 54025.

transparent peer review management policies and procedures), not by the agency itself. This is certainly how external peer reviews should be managed. As noted earlier, ACC recommends that OMB track the general approach of EPA's *Peer Review Handbook* and require external peer review of all significant regulatory information, or at least all significant regulatory information that is precedential or novel, particularly controversial, or highly complex. To the extent OMB continues to require internal peer review of other information, it is less important whether an independent entity selects the reviewers, so long as the persons responsible for developing a work product are not responsible for managing the peer review of that product.<sup>26</sup>

## 2. Interactive vs. letter reviews

ACC believes that face-to-face meetings between peer reviewers are by far the most productive and effective, and that conference calling and other real time or at least dialogic approaches are all superior to atomized letter reviews that involve no interaction among reviewers. At the NAS workshop, several speakers from different points on the political spectrum all agreed on this point.<sup>27</sup> ACC recommends that OMB promote the use of face-to-face or other interactive approaches to the maximum extent practicable. At a minimum, face-to-face reviews should be conducted for especially significant information, or in particularly controversial matters. As Gilbert Omenn noted, *Science & Judgment in Risk Assessment* emphasizes the use of standing panels like EPA's Science Advisory Board, instead of ad hoc, single-purpose entities, to promote collegiality in deliberations and to help reduce the transaction costs of convening face-to-face meetings.<sup>28</sup>

## 3. Report authorship

Finally, ACC strongly believes that OMB should clarify that the peer reviewers themselves, not the agency staff supporting them, should write the reviewers' report. There is simply too great a chance that reviewers' points will not be captured exactly, and too much temptation for staff to write what they would like to hear.

### D. Charge Issues

The Council supports OMB's proposal that agencies provide a comprehensive charge to peer reviewers. Rendering "a meaningful review of the work as a whole" is an essential peer review function. (Agencies should be free also to seek any more targeted review

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<sup>26</sup> On this point, EPA's Peer Review Handbook is half right. The Handbook (at 19) wisely declares that "[t]he Peer Review Leader [i.e., the person who chooses the peer reviewers] cannot be the Decision Maker [i.e., the person who decides what action the agency should take]." Perversely, however, it goes on to say that "[t]he Peer Review Leader can be the Project Manager [i.e., the person in charge of the work product being reviewed]." Id. ACC strongly disagrees with this notion. Peer reviewers should be chosen by someone not in the reporting chain of staff developing the document under review.

<sup>27</sup> See NAS transcript, *supra* note 18, at 247 (Gilbert Omenn), 281-82 (Sidney Shapiro).

<sup>28</sup> See *Science & Judgment in Risk Assessment*, *supra* note 5, at 8; see NAS transcript, *supra* note 18, at 259-60.

they might desire.) It is important for the peer review charge to be both broad and specific, and for it to encompass questions about “information quality, assumptions, hypotheses, methods, analytic results, and conclusions in the agency’s work product.”

Requiring reviewers to apply the standards of OMB’s and the relevant agency’s own Information Quality Guidelines -- as OMB proposes -- will also help ensure implementation of effective pre-dissemination review. Peer reviewers should particularly focus on the IQA elements of objectivity for influential risk information that are drawn from the Safe Drinking Water Act, so that they identify significant uncertainties and studies that would assist in reducing or eliminating those uncertainties. Reviewers’ suggestions should, in turn, inform agency research agendas, and OMB should monitor what agencies do to reduce uncertainties in a timely fashion.

While OMB requires agencies to provide an opportunity for “other interested agencies and persons to submit comments” on “especially important” information, and to make those comments available to the peer reviewers, OMB should also require agencies to provide outside parties an opportunity to comment on the draft peer review charge. As OMB notes, “[i]n the past, some agencies have sought peer review of only narrow questions regarding a particular study or issue.”<sup>29</sup> Public review and input on a draft charge would help ensure that this did not occur. It should also help identify technical issues that may not have occurred to the sponsoring agency but that the public or other federal agencies deem important. This comment process could take place via the agency’s website, and could be limited to a short time.

#### E. Reporting to OMB

OMB’s proposal requires agencies to report to OIRA at least annually, summarizing any documents that the agency intends to disseminate in the coming year, and explaining the agency’s plan for conducting peer review of these studies. The Bulletin also implies that this report would be made public -- it describes this requirement as “permit[ting] the public . . . to monitor agency compliance throughout the peer review process.”<sup>30</sup> ACC strongly supports this requirement. The comprehensiveness of such lists, and the adequacy of planned peer reviews, will both benefit significantly if the public can review and comment on them. Such input might reveal that a major work product has been left out of the agency’s list, or that the peer review plan for a document is not commensurate with the document’s importance. Alan Morrison made this point at the NAS workshop, noting that public comment on agency peer review plans should streamline the process by ensuring that methodological issues were identified up front, not at the end.<sup>31</sup>

OMB states that this report could be included either in an agency’s annual report under the IQA or in one of its periodic reports under E.O. 12866. ACC suggests that OMB

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<sup>29</sup> 68 Fed. Reg. 54025.

<sup>30</sup> “These reporting requirements will permit *the public*, OMB, and OSTP to monitor agency compliance throughout the peer review process.” *Id.* at 54026 (emphasis added).

<sup>31</sup> Transcript, *supra* note 18, at 167.



require these reports to be included as part of the agencies' semiannual regulatory agendas. This will promote agency coordination of peer review with other aspects of regulatory development, and will ensure that the report is issued twice a year. (Once a year is too infrequent, in light of the speed with which events can occur.) And just as the regulatory agendas capture rulemakings from "prerule stage" to "completed actions," agency peer review reports should capture any documents that are planned for peer review, regardless of when they will be disseminated. EPA's "Information Products Bulletin"<sup>32</sup>, updated semiannually, is an excellent model for this concept. While it does not include peer review plans in detail, it does include peer review, where it is planned, under the heading "stakeholder/public involvement." With a few modifications, the IPB could satisfy ACC's proposed approach.

However, agencies can and should be encouraged to maintain a peer review inventory on their websites that is evergreen. Again, EPA operates an approximation of this idea in its "Science Inventory,"<sup>33</sup> a continuously updated website listing thousands of EPA "science activities." These entries can be sorted by whether they have been or will be peer reviewed, although again the level of detail provided is not what the Bulletin would require. These two EPA efforts show, however, how feasible OMB's (or ACC's) proposals are.<sup>34</sup>

#### F. Timing

The Bulletin does not discuss the timetables under which peer review would have to occur, particularly Section 3 peer reviews. The final Bulletin should establish reasonable but clear timelines for:

- agencies to issue revised IQA guidelines implementing it;
- ensuring that the public has adequate opportunity to comment on proposed reviewers and the draft charge;
- ensuring that the public has adequate opportunity to file comments on the document being peer reviewed (and supporting materials) early enough in the process that the peer reviewers can digest them;
- ensuring that the peer reviewers have adequate time to review the document being peer reviewed (and supporting materials) before their meeting or before their comments are due;
- the peer reviewers to file a report;
- the agency's response to the peer reviewers' report; and
- the agency's response to any public comments that invoke the IQA (*see* Part IV.A below) -- agencies need not respond to other public comments.

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<sup>32</sup> [www.epa.gov/ipbpages](http://www.epa.gov/ipbpages)

<sup>33</sup> <http://cfpub.epa.gov/si/>.

<sup>34</sup> OMB should note that ACC's comments on this issue are consistent with comments of the Coalition for Effective Environmental Information and the Styrene Research & Information Center.

The Bulletin should also make clear that the peer review materials, including the agency's response to the peer review report, must be included in the rulemaking docket at the time an agency publishes a proposed rule based on the document being peer reviewed. Finally, the Bulletin should also state OMB's intention to police these timelines under its various authorities, including its oversight of rulemaking under E.O. 12866.

#### G. Waivers

The Council agrees that occasions will arise when normal peer review requirements may need to be waived (e.g., emergencies, statutory deadlines), but OMB's waiver provisions are overly broad and should be revised to prevent abuse.

First, the Council believes the preambular reference to "court-imposed deadlines or other exigencies" is a too-lenient characterization of the reasons for waivers identified in the Bulletin itself.<sup>35</sup> In general, the Bulletin should establish a presumption that "significant" regulatory information should undergo peer review except in very unusual circumstances. In particular, OMB should reconsider its reference to court deadlines, especially since most of these are negotiated by agencies. Agencies that negotiate consent decrees should factor in sufficient time to conduct a peer review of information covered by the peer review standards. Otherwise, agencies may intentionally accept consent decrees with tight deadlines as a convenient basis for later seeking a waiver of the peer review requirement.<sup>36</sup>

Second, the Bulletin should make clear that a "waiver" is really an extension -- i.e., not a basis for evading the peer review requirement, but rather permission to wait until the basis for the waiver has passed. After that event, the information should be subjected to peer review, unless the issue is moot because the relevant decision cannot be revisited.

#### H. Certification Requirement

The Council supports OMB's requirement that agencies file a certification that they have complied with the OMB peer review standards and Information Quality Act when they rely on significant regulatory information. In other contexts, such as the Clean Air Act Title V permitting program, regulated entities have been required to file compliance certifications. It seems only fair that government agencies likewise certify they have met their responsibilities.

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<sup>35</sup> Those are: "an emergency, imminent health hazard, homeland security threat, or some other compelling rationale." 68 Fed. Reg. 54028.

<sup>36</sup> Relatedly, OMB should clarify that, in the event that an agency does negotiate a consent decree that governs a rulemaking or other agency action, this action should not fall under the "adjudication" exemption to the Bulletin on the theory that it arose from an adjudication.

### III. Peer Reviewer Selection -- Conflict and Bias

The Council strongly supports OMB's standard that "peer reviewers shall be selected primarily on the basis of necessary scientific and technical expertise."<sup>37</sup> Peer review quality largely hinges on peer reviewer qualifications. The touchstone of expertise is also emphasized in *Science & Judgment in Risk Assessment*,<sup>38</sup> and guides the procedures followed by the National Academies<sup>39</sup> and EPA's Science Advisory Board.<sup>40</sup>

At the same time, issues of potential conflicts of interest and bias must be effectively managed to ensure that debates about the role of peer review panels, and the results of their deliberations, are focused on scientific and technical issues, not political ones. Indeed, the legitimacy of peer review in the federal government ultimately depends in large measure on public agreement that the process is not tainted by hidden interests or domination by particular groups.

The Council and its members have consistently supported strong measures to ensure that prospective reviewers disclose their potential for conflicts of interest and bias. For instance, the Council supported the EPA Science Advisory Board in its development of revised panel formation guidelines, including an enhanced disclosure form, to ensure that sufficient – but not overly burdensome – financial and other information is available to peer review management staff responsible for establishing panels.<sup>41</sup>

OMB is right to draw attention to this issue, and to insist on high standards. ACC believes that the draft Bulletin's treatment of this issue could be significantly improved, however. Because of the importance and complexity of the issue, our comments address it separately and at length. We first lay out the way that existing federal laws and rules address the issue, which OMB may simply have omitted for brevity. We then apply the concepts inherent in current law to the various players in the peer review process, to lay the groundwork for the appropriate procedures for handling conflict and bias. Finally, we discuss what those procedures should look like. To summarize briefly at the outset, ACC recommends that the final Bulletin:

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<sup>37</sup> 68 Fed. Reg. 54027.

<sup>38</sup> See *Science & Judgment in Risk Assessment*, *supra* note 5, at 91, 105.

<sup>39</sup> See "The National Academies Study Process" (available at <http://www4.nationalacademies.org/news.nsf/isbn/07302001?OpenDocument>) (describing how individuals with conflicts of interest may be appointed to Academy panels "if the Academies find that, after reasonable effort, they are unable to identify individuals with the required level and quality of specific expertise necessary for the study.").

<sup>40</sup> "At the SAB, a balanced panel is characterized by the inclusion of the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors can be influenced by work history and affiliation), and the collective breadth of experience to address the charge adequately. The SAB is a technical advisory body, not a committee designed to reflect stakeholder views." EPA SAB, "Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board," at 10 (EPA-SAB-EC-02-010) (September 2002).

<sup>41</sup> See May 1, 2002 letter from J. Solyst to A. Nugent.

- Carefully distinguish between conflict of interest and bias, recognizing that conflict of interest occurs in narrow circumstances, while bias is much more pervasive;
- Call for exclusion sparingly, and only in cases of true financial conflicts -- i.e., where the subject of the review is sufficiently narrow to constitute a “particular matter” affecting specific natural or legal persons, and where the prospective panel member actually holds some current financial interest in one of those persons (and even then, agencies should consider whether “the need for the individual’s services outweighs the potential for a conflict of interest”);
- In all other cases, instruct agencies to:
  - determine the necessary domains of knowledge
  - identify the most scientifically and technically qualified individuals within those domains as prospective panelists, and
  - from within that pool, choose panelists that represent the relevant scientific perspectives and the collective breadth of experience. Rather than attempting to match reviewers with “contrary bias,” agencies should strive to ensure the overall panel reflects a balance among competing scientific or technical perspectives.

The basis for these recommendations is explained below.

A. Conflict and Bias as Distinguished by Existing Law

In its discussion of reviewer selection, the draft Bulletin calls on agencies to find reviewers who “do not possess real or perceived conflicts of interest, and are capable of approaching the subject matter in an open-minded and unbiased manner.”<sup>42</sup> It also proposes as a remedy that, if a panel includes a reviewer who is or appears to be biased, the panel can be balanced by appointing another reviewer with a contrary bias.<sup>43</sup> ACC is deeply concerned that the language just quoted conflates two very different concepts -- conflict of interest and bias -- and that its proposed remedy would result in either of two results, both of which should be intolerable to OMB:

- The people most knowledgeable about a topic would typically be excluded – a concern raised repeatedly at the NAS workshop;<sup>44</sup> or
- Panels would be heavily orchestrated so that everyone was “contrary” to someone else along political dividing lines.

As discussed below, the Bulletin would do better to track existing federal law on this topic, which should be adequate for OMB’s purposes.

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<sup>42</sup> 68 Fed. Reg. 54027.

<sup>43</sup> *Id.*

<sup>44</sup> See transcript, *supra* note 18, at 201 (“[E]very single beryllium disease expert in this country works either full time or as a consultant for DOE, the beryllium industry or, in many cases, both.”) (statement of David Michaels). See also *id.* at 183 (James Mahoney), 188-89 (James Schaub).

Federal law on these concepts only applies to federal employees -- but these include “special government employees” like participants in panels organized under the Federal Advisory Committee Act (FACA).<sup>45</sup> So this law will always be applicable in cases where peer reviewers are government employees, or where the panels are conducted under FACA. Even in circumstances where this law is not literally applicable, for consistency OMB should require agencies to follow it.

## 1. Conflict of interest

The U.S. criminal code makes it a crime for a federal employee to “participate personally and substantially . . . through . . . the rendering of advice, investigation or otherwise, in a . . . particular matter in which, to his knowledge, he . . . has a financial interest.”<sup>46</sup> Exclusions are provided where the employee makes full disclosure to government and gets an advance written determination “that the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such . . . employee,”<sup>47</sup> or where government regulations have determined that such a financial interest is “too remote or too inconsequential” to affect the integrity of the employee’s services.<sup>48</sup> Also, an exclusion exists for special government employees serving on FACA panels where, after disclosure by the prospective panelist, the government official responsible for the appointment issues a waiver certifying that “the need for the individual’s services outweighs the potential for a conflict of interest created by the financial interest involved.”<sup>49</sup>

This statute and the Ethics in Government Act<sup>50</sup> have been implemented by regulations issued by the Office of Government Ethics (OGE).<sup>51</sup> These rules prohibit federal employees (including special government employees) from participating directly and substantially in a “particular matter” that will have “direct and predictable effect” on a “financial interest” of the employee (generally, employment or stock ownership) or on the employee’s employer, unless covered by an exclusion or issued a waiver as described above.<sup>52</sup> Generally speaking, government agencies have construed “particular matter” narrowly.

## 2. Bias

A separate subpart of the OGE rules addresses “impartiality,” which is essentially equivalent to bias. While this subpart also imposes prohibitions on federal employees

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<sup>45</sup> 5 U.S.C. App. 2.

<sup>46</sup> 18 U.S.C. § 208(a).

<sup>47</sup> *Id.* § 208(b)(1).

<sup>48</sup> *Id.* § 208(b)(2).

<sup>49</sup> *Id.* § 208(b)(3).

<sup>50</sup> 5 U.S.C. App. 4.

<sup>51</sup> 5 C.F.R. Part 2635.

<sup>52</sup> *Id.* Subpart D, esp. § 2635.402.

from participating in “particular matters,”<sup>53</sup> the kind of involvement that triggers applicability of the rules is much broader than the current “financial interests” that trigger the conflicts rules. Bias is implicated any time the matter at issue is likely to have a direct and predictable effect on a person with whom the employee has a “covered relationship,” which includes:

- an organization for which the person has served in the last year as officer, director, agent, attorney, consultant, contractor or employee; or
- an organization “in which the person is an active participant,”

where the employee (or the relevant agency) determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter.<sup>54</sup> As with conflicts of interest, the relevant agency can determine that the person’s impartiality is not likely to be questioned, or “that the interest of the government in the employee’s participation outweighs the concern that a reasonable person may question the integrity of the agency’s programs and operations.”<sup>55</sup>

### 3. Public participation statutes

While conflicts of interest and bias are legitimate sources of concern, OMB should also bear in mind that an entire body of federal law, including most administrative law statutes, embodies Congressional intent that agencies give interested or affected parties access to and input into the administrative process. Most prominent among these is the Administrative Procedure Act, which of course requires agencies to provide notice and “give interested persons an opportunity to participate in [a] rulemaking through the submission of written data, views, or arguments . . . .”<sup>56</sup> As the *Attorney General’s Manual on the Administrative Procedure Act* states, “[i]n general, the purpose of section [553] is to guarantee to the public an opportunity to participate in the rule making process.”<sup>57</sup> Numerous other statutes -- including many that OMB is charged with administering -- effectuate the goal of giving interested persons a voice in the regulatory process.<sup>58</sup> The point of these laws was perhaps made by Judge Patricia Wald, never known as a pushover for industry:

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<sup>53</sup> For purposes of both conflict of interest and bias, “particular matters” are those that involve “specific persons or a discrete and identifiable class of persons,” not “broad policy options directed to the interests of a large and diverse group of persons.” 5 C.F.R. § 2640.103(a)(1).

<sup>54</sup> *Id.* Subpart D, esp. § 2635.502.

<sup>55</sup> *Id.*

<sup>56</sup> 5 U.S.C. § 553(c).

<sup>57</sup> *Attorney General’s Manual on the Administrative Procedure Act* 26 (1947).

<sup>58</sup> These include the Information Quality Act, 44 U.S.C. § 3516 note (allowing “affected persons” to seek and obtain correction of information disseminated by federal agencies that does not meet federal standards for quality), the Federal Register Act, 44 U.S.C. §§ 1501-11 (establishing a uniform system for publication of federal regulations, executive orders and other important documents; absence of such a publication “made it extremely difficult, and sometimes impossible, for interested persons to learn about rules and orders that had the force and effect of law.” ABA, *Federal Administrative Procedure Sourcebook* 445 (3d ed. 2000)), the Regulatory Flexibility Act, esp. 5 U.S.C. §§ 603, 604(a)(2) (requiring public notice of initial regulatory flexibility analyses and agency response to those comments), the Paperwork Reduction Act, esp. 44 U.S.C. § 3506(c)(2) (requiring public notice of proposed collections of information, solicitation of

Under our system of government, the very legitimacy of general policymaking performed by unelected administrators depends in no small part upon the openness, accessibility, and amenability of these officials to the needs of the public from which their ultimate authority derives, and upon whom their commands must fall. . . . Furthermore, the importance to effective regulation of continuing contact with a regulated industry, other affected groups, and the public cannot be underestimated. Informal contacts can . . . spur the provision of information which the agency needs.<sup>59</sup>

ACC's purpose in highlighting these laws is not to urge that agency peer review become a stakeholder process -- as EPA has wisely stated, "[t]he SAB is a technical advisory body, not a committee designed to reflect stakeholder views."<sup>60</sup> Rather, our goal is only to emphasize that the Bulletin should not too readily require or suggest that anyone with bias, or even a conflict of interest, be automatically or presumptively excluded from participation as a peer reviewer. As noted above, the criminal code and the Ethics in Government Act provide exceptions, in the cases of both conflict and bias, where:

- "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved"<sup>61</sup>; or
- "the interest of the government in the employee's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations."<sup>62</sup>

The Bulletin should retain these exclusions.

### C. Applying Existing Law to Agency Peer Review

#### 1. Conflict of interest law really has limited applicability

Under the conflict of interest rules discussed above, true conflicts of interest are limited to instances where the subject of a panel is sufficiently narrow to constitute a "particular matter" affecting specific natural or legal persons, and where the prospective panel member is currently employed by or has an ownership interest in one of those persons. A conflict might occur, for example, in the case of an employee of a business that generates significant revenues from a product, if that employee is tapped to review a government

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comments on the quality and utility of the information collected, and certification in light of comments), and FACA, esp. 5 U.S.C. App. 2, § 5(b)(2) (requiring "balance," which should equally prohibit exclusion of, as well as domination by, any interest).

<sup>59</sup> *Sierra Club v. Costle*, 657 F.2d 298, 400-01 (D.C Cir. 1981).

<sup>60</sup> EPA SAB, "Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board," at 10 (EPA-SAB-EC-02-010) (September 2002).

<sup>61</sup> 18 U.S.C. § 208(b)(3).

<sup>62</sup> 5 C.F.R. § 2635.502.

assessment of that product. (Even then, however, if the employee had sufficient expertise in the area, the agency could conclude that “the need for the individual’s services outweighs the potential for a conflict of interest.”) A conflict of interest could also occur in the case of a “public interest” representative, however, and in ACC’s view may have occurred in connection with several EPA peer review groups.<sup>63</sup> ACC cautions OMB, however, not to suggest that any past, present or future financial connection constitutes a “conflict of interest.” As Professor Lars Noah has observed, “critics suggest that [academic researchers who receive industry funding] will harbor biases because the industry funds their work, but, absent evidence of direct support of research relevant to the particular regulatory questions under review, this represents a fairly tenuous ‘taint’ at worst.”<sup>64</sup>

## 2. Bias is pervasive

In contrast to conflicts of interest, “partiality” (or bias) as defined under government rules is much more widespread. It could occur any time the subject of a peer review is likely to have a direct effect on an organization that a prospective consults for or is simply active in, or has been connected with in the recent past. And bias is conventionally understood to reach even more broadly than government rules describe. The National Academies believe that “[p]otential sources of bias relate to the points of view or positions that are largely intellectually motivated or that arise from the close identification or association of an individual with a point of view of a particular group.”<sup>65</sup> Similarly, an SAB committee has stated that, “[a]lthough it is possible to avoid conflict of interest, avoidance of bias is probably not possible. All scientists carry bias due, for example, to discipline, affiliation and experience.”<sup>66</sup> Fifteen past presidents of the Society of Toxicology have written that, “[o]f course, all scientists have biases; acknowledging this, we as a society must be aware of those biases and seek to ensure balance in the scientific panels whose task is to provide the best possible technical review of complex, important issues.”<sup>67</sup> Indeed, as a leading writer in this field has opined, “the greater his or her expertise, the more likely [a prospective peer reviewer] will appear to have at least some . . . biases, however mild, based on . . . prior publications, public

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<sup>63</sup> For example, Richard Clapp, a well-known expert witness for plaintiffs bar involved in the Anniston, Alabama PCB litigation, served as a consultant on the SAB Dioxin Reassessment Review Subcommittee. At an initial meeting of the Subcommittee, consultants were asked to disclose “sources of support” and “to state if they had identified any possible conflict of interest. . . .” “No such issues were identified,” according to the meeting minutes. Minutes at 2, <http://www.epa.gov/sab/pdf/dio11010m.pdf>. David Carpenter, another Anniston plaintiffs expert witness, is serving now on a National Academy of Sciences panel on implications for the food supply of dioxins & dioxin-like compounds (incl. some PCBs).

<sup>64</sup> Lars Noah, “Scientific ‘Republicanism’: Expert Peer Review and the Quest for Regulatory Deliberation,” 49 *Emory L.J.* 1033, 1066 (2000).

<sup>65</sup> The National Academies Study Process, available at <http://www4.nationalacademies.org/news.nsf/isbn/07302001?OpenDocument>

<sup>66</sup> EPA Science Advisory Board Env’tl Health Cmte, letter report re “Review of the Draft Report to Congress ‘Characterization of Date Uncertainty and Variability in IRIS Assessments, Pre-Pilot vs post-Pilot,’” EPA-SAB-EHC-LTR-00-007 (Sept. 26, 2000), available at <http://www.epa.gov/sab/pdf/ehcl007.pdf>.

<sup>67</sup> *Risk Policy Report* (Jan. 21, 2002).



statements, personal insights, and research agendas. No candidate is capable of a pure passion for dispassionate public service.<sup>68</sup>

Critics of involvement by regulated entities in the peer review process highlight the prospect that persons employed or retained by such entities will be biased toward them. Rather than dispute that contention, ACC only urges recognition, as explained below, that persons associated with government or nongovernmental organizations are equally likely to be biased.

a. Expert connections to federal agencies

The Council commends OMB for having the temerity to articulate the concern that peer reviewers' ties to an agency can undercut their independence. This issue, while apparently a sensitive one among agencies, has generally been neglected, perhaps due to that sensitivity. It is intuitive, however, that "scientists employed or funded by an agency could feel pressured to support what they perceive to be the agency's regulatory position, first in developing the science, and then in peer reviewing it."<sup>69</sup> As one leading scholar has observed, "most money, even so-called government money, comes with some strings related to expected results."<sup>70</sup> And with agencies like EPA charged with protecting the public, the expectation is likely to be precautionary. Protective statutes are generally oriented toward identification of toxic or hazardous substances, prevention of exposure, and forcing technology.<sup>71</sup> Institutional dynamics push the same way -- agencies generally are hailed for banning or restricting bad substances, and criticized if they fail to do so.

The Council thus strongly agrees that the issue of scientists' "agency ties" must be addressed during the panel selection process in the same manner that the potential sources of undue bias related to the private sector are managed. This is not to say that ties to an agency necessarily mean a potential reviewer has an undue bias, but it does point to the need for all prospective peer review candidates to undergo the same rigorous scrutiny on these matters. While the Confidential Disclosure Form used by some agencies to review potential conflicts of interest requires disclosure of research support and project funding from whatever source, this important standard should be adopted government-wide. The Council thus supports the Bulletin's proposed requirement that potential peer reviewers disclose whether they are "currently receiving or seeking substantial funding from the agency through a contract or research grant (either directly or indirectly through another entity, such as a university)" or "has conducted multiple peer reviews for the

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<sup>68</sup> Frederick Anderson, "Improving Scientific Advice to the Government," *Issues in Science & Technology* 34 (Spring 2003)

<sup>69</sup> 68 Fed. Reg. 54024.

<sup>70</sup> Robert W. Hahn, "Disclosing Conflicts of Interest: Some Personal Reflections," AEI-Brookings Joint Center for Regulatory Studies Working Paper 02-2 (Feb. 2002), at 8 n.25).

<sup>71</sup> OMB, "Informing Regulatory Decisions" 51-53, 57-60 (2003).

same agency in recent years, or has conducted a peer review for the same agency on the same specific matter in recent years.”<sup>72</sup>

b. “Public interest” science is biased, too

The final Bulletin should also recognize that persons associated with nonprofit advocacy groups can be biased. Indeed, it is arguable that such groups produce the most powerful biases. Fundamentally, NGOs are bureaucracies, too; with the same institutional dynamics as government, only more so. Their natural tendency will be not to publicize information that undercuts their agenda. Conversely, they are praised, and their grant and dues funding increases, to the extent they identify problems.

“Public interest” organizations, moreover, tend to define the public interest more narrowly than many others do, typically not including the social welfare costs of the policies they support (unemployment, reduced stock prices, etc.) or the availability and risks of substitutes. For example, Ralph Nader and Public Citizen trumpeted the virtues of air bags and derided the value of mandatory seat belt laws in the 1970s and 1980s. Evidence now shows that seat belts are far more effective at saving lives than air bags and that airbags pose risks.<sup>73</sup>

Last, but perhaps most important, “public interest” motivation is no guarantee of scientific merit, as is shown by the fact that a widely-publicized study that purported to show synergistic effects from pesticides ultimately had to be withdrawn after widespread failures to replicate its results<sup>74</sup> – but not until after it had played a major role in the enactment of the Food Quality Protection Act.

c. The solution to bias is disclosure and balance expert perspectives

The best way to address the issue of bias is to require adequate disclosure of potential sources of bias, and then to select a balanced slate of reviewers. In the latter connection, the Federal Advisory Committee Act requires federal advisory committees “to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee.”<sup>75</sup> The American Association for the Advancement of Science recently seconded this view, approving a resolution regarding membership on federal advisory committees that “calls on the federal government to ensure that the process of obtaining scientific, technical and medical advice follows the letter and spirit of [FACA]

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<sup>72</sup> 68 Fed. Reg. 54027.

<sup>73</sup> See Malcolm Gladwell, “Wrong Turn,” *The New Yorker* 50, 59-61 (June 11, 2001).

<sup>74</sup> See John McLachlan, “Synergistic Effect of Environmental Estrogens: Report Withdrawn,” *277 Science* 459-63 (July 25, 1997) (article withdrawn).

<sup>75</sup> 5 U.S.C. App. 2, § 5(b)(2)-(3).

and accords with democratic principles of governance.”<sup>76</sup> EPA’s Science Advisory Board also uses balance to remedy bias:

In addition to concerns about conflicts that may exist for individual members of a Panel, the SAB is also concerned about overall balance of the panel in terms of the points of view presented. . . . At the SAB, a balanced panel is characterized by the inclusion of the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors can be influenced by work history and affiliation), and the collective breadth of experience to address the charge adequately.<sup>77</sup>

Balance does not mean that every political perspective on an issue is entitled to a seat on a peer review panel. The statement just quoted continues: “The SAB is a technical advisory body, not a committee designed to reflect stakeholder views.”<sup>78</sup> As emphasized earlier, scientific and technical expertise must be primary, and balance ensures that different perspectives among the experts are represented.

#### D. Recommended Approach

In light of the foregoing, ACC recommends that the final Bulletin address peer reviewer selection as follows:

- It should state that federal laws and rules regarding conflict of interest and bias discussed above would of course apply whenever prospective peer reviewers are federal employees or “special government employees,” and that federal agencies should apply that authority as persuasive precedent in other cases. It should add that this authority would apply with equal force to all prospective panelists, including those associated with regulated entities, government and public interest groups.
- It should carefully distinguish between conflict of interest and bias, and recognize that conflict of interest occurs in narrow circumstances, while bias is much more pervasive.
- It should caution that exclusion should be applied sparingly, and only in cases of true conflicts -- i.e., instances where the subject of the panel is sufficiently narrow to constitute a “particular matter” affecting specific natural or legal persons, and where the prospective panel member actually holds some financial interest in one of those persons. Even then, however, the Bulletin should advise agencies to

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<sup>76</sup> AAAS, “AAAS Resolution Regarding Membership on Federal Advisory Committees” (2003), available at <http://www.aaas.org/news/releases/2003/0305fair2.shtml>.

<sup>77</sup> EPA SAB, “Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board” 10 (EPA-SAB-EC-02-010) (September 2002).

<sup>78</sup> *Id.*

consider whether “the need for the individual’s services outweighs the potential for a conflict of interest.”

- In all other cases, the Bulletin should instruct agencies to:
  - determine the necessary domains of knowledge;
  - identify the most scientifically and technically qualified individuals within those domains as prospective panelists, and
  - from within that pool, choose panelists that represent the relevant scientific perspectives and the collective breadth of experience. Rather than attempting to match reviewers with “contrary bias” agencies should strive to ensure the overall panel reflects a balance among competing scientific or technical perspectives.

As to the factors listed by OMB that agencies should consider, ACC recommends generally that OMB make clear that this list is non exhaustive, and that agencies should the relevant OGE regulations, which address which types of financial interests may potentially constitute a conflict of interest or cause a reasonable person to question the prospective panelist’s impartiality. ACC also has the following specific observations:

- “Has any financial interests in the matter at issue” -- Relevant to conflict of interest and bias, but which one is triggered depends on the facts. Reference OGE rules.
- “Has, in recent years, advocated a position on the specific matter at issue” -- An important question, relevant to potential bias.
- “Is currently receiving or seeking substantial funding from the agency through a contract or research grant (either directly or indirectly through an entity, such as a university)” -- Another important question relevant to bias, but should be generalized from “the agency” to “any interested party.”
- “Has conducted multiple peer reviews for the same agency in recent years, or has conducted a peer review for the same agency on the same specific matter in recent years.” -- Another important question relevant to bias, but again could be generalized from “the agency” to “any interested party.”

#### E. Burdens or Disincentives Created by Disclosure Requirements

Appropriately, OMB seeks comment on whether any of the peer review Bulletin’s provisions would “unnecessarily burden” or “discourage” qualified scientists from participating in agency peer reviews. Specifically, OMB seeks comment on whether disclosure requirements should be limited to a set number of years – for instance, activities occurring during the previous 5 or 10 years – rather than extending back indefinitely. To the Council’s knowledge, no current disclosure requirements extend back indefinitely, and imposing a burden of collecting personal data going back far into the

past would seem appropriate only for high-level national security concerns. Because an appropriate time frame is difficult to select on a strictly rational basis, the Council suggests that OMB review current disclosure practices of the federal government and base its choice on a reasonable extrapolation from current baseline practices.

As to the related question of how, more generally, agencies can encourage peer review participation by qualified scientists, the Council believes that it is important to ensure that the peer review process not be allowed to become a venue for political activism. While the public has a right to make its views known on significant technical matters, scientists participating in peer reviews have a right to expect that their public service as a peer reviewer does not create a venue in which detractors will abuse them. Unfortunately, this has not always been the case. In an extreme example, at the November 2000 meeting of EPA's Science Advisory Board's Dioxin Reassessment Review Committee, audience members dressed up in costumes handed out materials deriding several members of the panel as "cigarette scientists," held up bright yellow placards whenever they spoke, and photographed them.<sup>79</sup> No one from the Agency spoke up to stop this harassment. The final Bulletin should make the obvious point that peer review meetings must be conducted with appropriate decorum and be focused on matters of substance. Policy disagreements should be disputed in other, more appropriate venues. At bottom, qualified scientists must know that they will be judged on their qualifications and the quality of their scientific advice, not on extraneous political considerations.

#### **IV. Information Quality Act Issues**

As already indicated, the Council strongly supports issuance of the OMB peer review Bulletin under the Information Quality Act. While peer review is discussed in OMB's IQA guidelines, those guidelines do not set any standards for agency peer review. Thus, it is a logical next step for OMB to provide supplementary guidance on this highly important mechanism for assuring the objectivity of the most significant agency information. The Bulletin also spells out an important aspect of pre-dissemination review, a process that has not received sufficient attention to date. For these reasons, OMB's Bulletin supports Congress' intent for the IQA, as well as OMB's broader goals of smarter regulation supported by better analysis. This part of ACC's comments first addresses the overlap of the Bulletin's peer review process and the IQA, and then addresses the IQA-specific issues the Bulletin raises.

##### **A. Need to Explain the Overlap Between the Bulletin and the IQA**

Administrator Graham made clear at the NAS workshop that he regards the peer review process described in the Bulletin as part of the pre-dissemination review that the IQA Guidelines require agencies to institute.<sup>80</sup> Consistent with that view, the Bulletin talks about agencies' plans for peer reviewing documents that "constitute or support . . .

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<sup>79</sup> See Nov. 17, 2000 letter to D. Barnes, SAB from C. Howlett, Chlorine Chemistry Council.

<sup>80</sup> Transcript, *supra* note 18, at 10.

information that the agency intends to disseminate.” By that reasoning, one could conclude that when documents are released for peer review, they have – in some sense – not been “disseminated” yet. If that were true, they would not yet be subject to correction requests under the IQA. But in plain English, of course, they would have been “disseminated,” and could cause adverse effects to affected parties, or be used by agencies in ways that harm such parties. And, absent enforceable deadlines, the peer review could in some cases drag on for years. (The diesel engine emissions peer review used as a case study by Administrator Graham spanned a 10-year period.) This is not a hypothetical problem -- see Appendix A, Example #2. It is something OMB needs to address: how to limit the harm potentially caused by documents being peer reviewed without disrupting the peer review process.

One solution would be for OMB to instruct agencies that they may not, in any fashion, rely on a document being peer reviewed, until the conclusion of the peer review. The sanction for noncompliance if an agency did so rely would be that the IQA correction process would attach and be available to affected parties. ACC urges OMB to consider this approach, but notes that it may unduly restrict agencies in cases where the document being peer reviewed clearly represents a scientific advance over earlier versions.

In response to a question about this problem asked at the NAS workshop, Administrator Graham ventured an alternative approach: the peer review public comment period would provide the “appropriate forum” for addressing an IQA concern.<sup>81</sup> This approach would be consistent with the OMB’s IQA approach to rulemakings and other administrative processes that currently include a correction process of some sort. This approach may also be workable, so long as the Bulletin were revised to provide that in the case of comments that referenced the IQA (as opposed to other public comments), the agency would have to respond by a date certain.<sup>82</sup>

#### B. Comments on Generic IQA Proposals

In addition to supporting OMB’s issuance of the peer review standards under the IQA, the Council strongly supports OMB’s proposed non-peer review-related IQA requirements; i.e., that agencies:

- post all non-frivolous IQA correction requests on their websites (or else provide such documents to OMB) within seven days of receipt; and
- upon request from OMB, provide draft responses at least seven days prior to issuance.

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<sup>81</sup> Transcript, *supra* note 18, at 29.

<sup>82</sup> Administrator Graham also noted that the issue became “much more difficult” if an agency allowed the peer review process to continue “indefinitely,” *id.*, another reason to impose time limits on the activities covered by the Bulletin. Also, OMB should provide that more timely correction would be appropriate in cases involving reasonable likelihood of actual harm where correction would not cause undue delay. See Sept. 5, 2002 OMB Memorandum.

With respect to the first of these requirements, ACC urges OMB simply to require all agencies to place their entire IQA dockets on line, for the following reasons:

- EPA, DOT and the U.S. Forest Service (at least) have all done so, and deserve credit for taking the initiative to support an open IQA implementation process.
- It is becoming clear that the IQA is not generating a flood of correction requests, and so it should be easy and not expensive for other agencies to follow these three pioneers.
- Placing IQA dockets on the web is consistent with the E-Government Act,<sup>83</sup> the APA and other statutes, as well as with the Administration's E-Government Strategy.<sup>84</sup> The APA was enacted to end "secret law," and yet an important new statute -- IQA -- is being implemented in secret at most agencies. Affected persons (and the general public) need access to information on how the act is being implemented.
- The IQA is all about information dissemination. It is thus ironic for government agencies not to disseminate information on their implementation of the IQA

The Council also supports OMB's proposal to take a more active role in the IQA correction process, especially in commenting on draft agency responses to IQA petitions for corrections. In the main, agencies are reflexively denying correction requests, and without OMB involvement to ensure these denials have merit, the Act's ability to advance its goals of much-improved government information will suffer.

Finally, and as also noted earlier, the Council supports requiring peer review charges to include the IQA standards, so that agencies and reviewers will routinely address those issues. This provision will help foster improved pre-dissemination review, which is currently languishing at EPA and perhaps at other agencies.

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Once again, ACC appreciates the opportunity to submit these comments. If you have any questions, please contact one of the undersigned at 703-741-5000.

Sincerely,

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Science Policy Team Leader

James W. Conrad, Jr.  
Science Policy Team Counsel

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<sup>83</sup> 44 U.S.C. § 3506 note.

<sup>84</sup> See [http://www.whitehouse.gov/omb/egov/2003egov\\_strat.pdf](http://www.whitehouse.gov/omb/egov/2003egov_strat.pdf)

**Appendix A -- Examples drawn from EPA  
Supporting the Need for the OMB Peer Review Bulletin**

The following examples are drawn only from EPA, and thus arise from an agency that is at the forefront of federal agencies in terms of the extent and sophistication of its peer review practices. This would suggest that such a list drawn from experience with other agencies would only be longer. Clearly there is need for the Bulletin.

1. **Metal Products and Machinery.** Kevin Bromberg of the SBA's Office of Advocacy spoke at the NAS workshop regarding the very poor quality of the analysis underlying this proposed rule, which ultimately EPA reconsidered.<sup>85</sup> Timely peer review could have identified those flaws much earlier and saved both EPA and the private sector significant resources and time.

2. **Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities.** A draft of this document was sent out for peer review in 1998. *Simultaneously*, it was used by the EPA and state agencies for risk assessments that they were requiring to be conducted following the protocol. The peer review identified many problems with the guidance, but EPA has never made changes to correct those problems, and continues to require the use of this guidance. See <http://www.epa.gov/epaoswer/hazwaste/combust/risk.html>.

3. **Screening-level Ecological Risk Assessment Protocol for Hazardous Waste Combustion.** Presents the same issues noted for the human health risk assessment protocol. See <http://www.epa.gov/epaoswer/hazwaste/combust/ecorisk.html>.

4. **EPA Total Maximum Daily Loads (TMDLs) regulations.** This 2000 regulation requires states to develop TMDLs for impaired water bodies. States do not have sufficient (or in many cases any) data to support EPA's assertion that the approximately 40,000 water bodies identified (thus far) are, in fact, "impaired." The scientific basis for this rule was peer reviewed after the fact by the NAS. The review identified this and other significant scientific problems with the TMDL program. The cautions identified by the peer reviewers have not to date been heeded. See <http://www.house.gov/transportation/press/press2001/release80.html>.

5. **Diisononyl phthalate (DINP) TRI listing.** In Sept 2000, EPA proposed to list DINP under EPCRA Section 313. The technical support document for this proposal was deficient in a number of respects. It ignored the primate data indicating that the effects seen at high doses in rodents do not occur in primates. Also, EPA's conclusion that DINP could reasonably be anticipated to cause adverse health effects in humans was at variance with the conclusions of other reviewing bodies (e.g., NTP, IARC, EU). A peer review of EPA's scientific support for the proposal may well have

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<sup>85</sup> Transcript, *supra* note 18, at 225-27.



led the agency to conclude that the petition to list should be denied rather than granted.

**6. EPA Persistent, Bioaccumulative, and Toxic (PBT) list.** In 1998, EPA proposed a draft list of RCRA chemicals that are PBTs. Three phthalates were included. ACC submitted comments, and when EPA finally published a Waste Minimization Priority Chemicals list in 2002, phthalates had been removed from the list. However, the four years that they were proposed to be listed (1998-2002) have led many to believe that phthalates are PBTs -- a misconception that still haunts the Internet. A peer review of the supporting science in 1998 could have shown that phthalates do not meet the PBT criteria and thus would have prevented the misconception from ever arising.