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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP
cc:
Subject: Comments on Proposed Bulletin on Peer Review

Hi:

Attached are my comments on your proposed bulletin on Peer Review and a copy of a recent resume. Please acknowledge receipt of my comments and I would like to receive information on OMB plans for follow up actions.

Peace,

Victor J. Kimm

- Comments on Peer Review.doc
- Resume-New.doc

Victor J. Kimm¹
December 15, 2003

OMB Peer Review Guidance

The Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) issued Draft Guidelines for Peer Review Standards for Regulatory Science dated August 29, 2003. As a long-time senior regulator at the Environmental Protection Agency, I wish to identify a number of areas within this proposal, which are likely to adversely impact the government's ability to promulgate regulations to protect the nation's environment, health and safety under existing legislation.

If promulgated as proposed, this action would create elaborate and expensive procedural requirements to enable OIRA and OSTP to control the early stages of regulation development, slow the ability of the regulatory agencies to respond to emerging problems, restrict the pool of qualified experts eligible to serve on peer review panels and potentially facilitate judicial challenges to future regulations.

To provide a context for these comments from a practitioner's perspective, the first part of this paper describes the nature of the regulatory task while the second section addresses the contribution that peer review procedures can make to regulatory decision making. The third section outlines the major features of the OIRA proposal, while the fourth section identifies specific concerns with the draft document. Finally, the last section offers specific recommendations for improving these guidelines.

I. Nature of the Regulatory Task

Economists use the term "externalities" to describe spillover effects that are not captured in prices established in the marketplace. A classic example of this phenomenon is pollution at industrial installations in that the product's price in the marketplace does not reflect conditions at the production facilities. Economists generally agree that market failures like these constitute a reasonable basis for governmental intervention through the establishment of regulatory programs. However, the degree of intervention is a value-laden political choice about which there can be significant differences of opinion (Weimer and Vining 1999, 74-115 and 134-194).

Controlling externalities is the rationale for most of the existing legislation designed to establish environmental, health and safety controls. Typically, these statutes identify the

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factors to be considered in setting specific requirements and provide broad discretion to the regulators about how much control is appropriate for designated classes of facilities. Specific requirements are developed through informal rulemaking procedures, which include proposals published in the *Federal Register*, a period for public comment and final promulgation, including responses to all of the major comments received.

These procedures include significant opportunities for interaction between the regulatory agency and the major stakeholders and typically take two to four years to complete. After promulgation, judicial challenges can further delay implementation of new requirements. Under the Administrative Procedures Act, final regulatory actions can be, and frequently are, challenged in court on the basis of the lack of clear legislative authority for the requirements and/or the absence of due process for interested stakeholders.

At their core, regulatory programs impose duties on the covered facilities to protect the public interest. By their nature, such programs encounter resistance from the regulated parties, which often view mandatory investments in such protections as unproductive in that they do not directly contribute to that firm's profitability. This opposition is often reflected in actions to avoid or delay regulation by focusing on uncertainties in the underlying risk assessments and overstating potential costs and impacts.

Finding effective means of promoting ongoing public interest and support to balance this inherent conflict with regulated entities is essential for effective program implementation. Professor Sparrow has captured these dynamics in a recent text on the subject (Sparrow 2000, 309-314). Among his major findings are the need for: (1) significant public participation in setting priorities and formulating requirements; (2) continuing citizen oversight in assessing implementation; and (3) the judicious use of enforcement powers against serious violations to promote high levels of compliance and avoid actions that the public is likely to see as abuses of discretionary powers.

In practice, the development of many regulatory initiatives begins with a number of small studies on toxicity and exposure levels that feed into a risk assessment of the uncontrolled situation. Typically, the next step is to look at the feasibility of potential interventions to reduce risks by lowering harmful exposures under existing legislative mandates. All of this takes place before specific regulatory initiatives are identified and more detailed assessments of the associated costs and economic consequences of potential regulatory actions are developed. For major regulations, those with annual compliance costs exceeding 100 million dollars, a regulatory impact assessment comparing the costs and benefits of specific proposed rules must be submitted to OIRA for review before publication in the *Federal Register*.

This general methodology is frequently referred to as risk analysis, which includes the interrelated concepts of risk assessment, risk management and risk communication. The risk analysis paradigm is designed to separate risk assessment, i.e., trying to quantify the magnitude of the risk posed by uncontrolled situations, from risk management, deciding what, if any, regulatory interventions are appropriate under existing legislation. This paradigm was postulated to promote a separation of the scientific issues about risk, which

virtually always include uncertainties, from the policy and political choices related to how much control is appropriate.

The National Academy of Sciences in its seminal report (NAS 1983, 1) emphasized the need to have “mechanisms to ensure that government regulations rest on the best available scientific knowledge and to preserve the integrity of scientific data and judgments in the unavoidable collision of the contending interests that accompany most important regulatory decisions.” This principle is as important today as it was twenty years ago, if not more so, in that stakeholders with deep pockets and/or political influence are devoting increased attention to the early stages of regulatory development.

In their first recommendation (NAS 1983,151), they indicate: “Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessment of risks and the consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic and technical considerations that influence the design and choice of regulatory strategies.” And, in the next sentence, they qualify these findings by noting: “Although the committee concludes that risk assessments cannot be made completely free of policy considerations, it also believes that policy associated with specific risk management decisions should not influence risk assessment unduly.”

Numerous NAS panels have reaffirmed this need to assure that risk management policy not be allowed to control risk assessment policy. More recently, an independent commission mandated by the Clean Air Act (Presidential/Congressional Commission on Risk Assessment and Risk Management 1999) has generally reaffirmed belief in the risk analysis paradigm outlined above.

II. Nature of Peer Review

The scientific community has long required peer review, an independent assessment by experts within the relevant disciplines of significant scientific, technological and economic analyses before such findings are published in professional journals. Regulatory agencies already embrace this principle for scientific information relied upon in the regulatory context. For this reason, substantive peer review of the scientific underpinnings for major regulations have been in place at EPA and other regulatory bodies for the past decade or more.

However, the procedures employed range from soliciting written comments from a few independent experts to formal meetings of larger panels with elaborate public participation. The procedures selected are tailored to: the significance of the study to related public policy or regulatory decisions; the complexity of the specific issues being addressed; and the relevant statutes, many of which mandate reviews of critical activities by independent advisory bodies.

In practice, peer reviews, while often costly and time-consuming, add value to regulatory decision making by ensuring that:

- (1) Analyses are consistent with mainstream thinking in the relevant disciplines;
- (2) Computations and modeling follow accepted norms;
- (3) Uncertainties in the analyses are clearly identified; and
- (4) Conclusions are supported by “weight of the evidence” findings that explain why the reported conclusions are likely to be appropriate or inappropriate.

However, peer review is no panacea. It does not remove all underlying scientific uncertainties, nor is it likely to extend the data being assessed or uncover intentionally biased data or analyses. Nevertheless, knowledgeable regulators have strongly supported these reviews related to significant regulatory actions as a way to ensure the application of mainstream science, avoid computational errors, clarify uncertainties in findings and enhance the public credibility of the conclusions of the related studies.

III. OIRA Proposal

As proposed, the draft bulletin does not clearly define the problem it is intended to address nor does it include any analysis of its potential impacts. It is, therefore, difficult to assess the significance of the proposal in that its coverage is unclear, as are the number of transactions impacted, or the resources needed for implementation by OIRA and by the regulatory agencies.

1. Coverage

The proposal differentiates between “significant regulatory information,” described in section 2 and “especially significant regulatory information,” addressed in section 3. For the former category, studies that contain significant regulatory information that the agency intends to disseminate, the sponsoring agencies are granted broad discretion to tailor peer review requirements to the novelty and complexity of the related studies.

On the other hand, the definition triggering the more elaborate section 3 requirements includes: (i) the agency intends to disseminate the information to support major regulations; (ii) the information could have impacts on important public policies or private sector decisions with an impact above 100 million per year (the threshold for “major regulations” in current OMB jargon); or (iii) that OMB determines that the information raises significant interagency concerns or relates to an Administration policy priority. In practice, this last criterion enables OMB to impose the more elaborate procedures on any topic they so desire.

2. Detailed Requirements

For “especially significant regulatory information,” the proposed bulletin would require the agencies to:

- (1) Conduct an appropriate scientifically-rigorous peer review and prepare a report of all “especially significant regulatory information” that meet the full requirements outlined below (section 3);
- (2) Update existing agency guidance reflecting OMB and agency requirements initiated under the Information Quality Act to include compliance with this bulletin (section 4 b);
- (3) Develop written conflict-of-interest guidelines on relationships that would preclude individuals’ participation in peer review panels as well as provisions for the protection of confidential business information (section 4 b);
- (4) Develop written guidance on the types of information about panel members that should be publicly released in the peer review report (section 4 b);
- (5) Prepare an annual plan identifying all specific studies that may, in whole or in part, constitute “significant regulatory information” covered by sections 2 and 3 of this bulletin (section 6);
- (6) Provide a detailed plan for peer review for each of the studies identified above (section 6);
- (7) Consult with OIRA and OSTP on the adequacy of the plans and, upon request, discuss with OIRA the proposed procedures for peer review of any specific documents prior to dissemination (section 3);
- (8) Notify the public of intended peer review of specific documents and solicit public comments on the charge to the panel (section 3);
- (9) Ensure that stakeholder comments are delivered to the panel prior to its deliberations (section 3);
- (10) Include in the charge to the panel the specific and general questions they are asked to address, including a specific request to identify the uncertainties in the analyses and how these uncertainties might be reduced or eliminated (section 3);
- (11) Inform panel members of OMB and agency guidance on data quality and regulatory impact analyses (section 3);
- (12) Require a written panel report of their findings and conclusions, including majority and minority views as well as information on panel members’ qualifications and potential conflict-of-interest relationships (section 3)
- (13) Prepare an agency response to the panel report describing areas of agreement or disagreement with their findings, identify any actions the agency plans in response to the report, and how such actions respond to the concerns identified in the report (section 3);
- (14) Disseminate to the public the agency’s responses to the panel findings (section 3);
- (15) Certify in the administrative record for related major regulations how the agency complied with the requirements of this bulletin (section 3)
- (16) Notify OIRA within 7 days after receipt of any information correction requests under the Information Quality Act and add such notification to the agency’s Web site (section 7);
- (17) Submit to OIRA, when requested, a draft response to such requests and not issue it until OIRA, and possibly OSTP, have concluded their reviews (section 7); and

- (18) Respond to any interagency comments on peer reviews, which may be initiated by OIRA (section 8).

A number of these activities might be initiated by the agencies without the bulletin, such as soliciting public input on planned peer review panels related to major rulemaking or drafting guidance on conflict-of-interest requirements for panel members. However, if promulgated as drafted, the bulletin would require that all of the above activities become mandatory for each covered transaction and would give OIRA and OSTP major new roles in the early stages of future regulatory development.

The bulletin also allows the regulatory agencies to request a waiver from these requirements from OMB if the needed information is necessitated by an emergency, imminent health hazard, homeland security threat or other compelling rationale. OMB may consult with OSTP in deciding how to respond to the requested waiver (section 3). Thus key decision authority of responses to important health and safety issues would migrate to OMB from the implementing agencies designated in existing legislation

IV. General Comments

Promulgation of the bulletin as drafted raises concerns in four major areas.

- (1) **Absence of Any Impact Analysis**—The proposal creates a complex set of new and expensive procedures through which OIRA and OSTP will control the early stages of regulatory development without addressing the anticipated impacts of the proposal.
- (2) **Delay Regulatory Responses to Emerging Problems**—Creating an additional and redundant round of notice, public comment and response to comments on all related studies will greatly delay the government’s ability to respond to newly-identified problems.
- (3) **Impact on Academic Peer Review Members**—Proposed changes in assessing potential conflict of interest of panel members appear overly simplistic and could significantly reduce the pool of qualified panelists drawn from the academic community.
- (4) **Potential Impacts on Litigation by the Regulated Community**—Requirements to add all materials related to peer review to the official record of related rulemaking might be interpreted as opening new avenues for legal challenges to subsequent rulemaking actions.

These concerns are developed more fully in the remainder of this paper as well ways to modify the draft bulletin to retain the benefits of peer review while reducing the potential adverse consequences of the proposal.

1. The Lack of Impact Analyses

The proposed bulletin lacks any clear definition of the problem it is intended to solve, how OIRA intends to implement its discretionary authorities, the number of studies likely to be impacted, and the added resources in the agencies and OIRA necessary to conduct

the mandated new procedures. Without such information, there is no rational basis for assessing the wisdom of the proposed initiative and little basis for public comment requested in the draft bulletin. This seems especially important in that these new procedures lack any specific Congressional mandate and, yet, may have large impacts on the implementation of existing legislation.

2. Potential to Delay Regulation of Emerging Problems

Requiring public participation in peer reviews of virtually all studies in the early stages of rulemaking will give the regulated community new opportunities to slow or derail the regulatory process by focusing vast resources on exploiting all of the scientific uncertainties that typify the early stages of assessing emerging issues. Consider the lengths that the cigarette manufacturing companies undertook to discredit the early studies and the associated researchers purporting to show links between smoking and adverse health effects.

The new procedures are redundant with the mandated due process provisions of existing rulemaking procedures and provide stakeholders with two sequential opportunities to slow future regulations. Such interventions are also likely to undermine the risk analysis paradigm described earlier in this paper, which seeks to separate the consideration of scientific issues associated with risk assessment from the policy or political choices considered in making risk management decisions.

The specific concern here is not with well-established procedures for public comment on the underpinning for major rulemaking, but with the extension of the process to cover the initial studies conducted to assess emerging problems. If adopted, these changes seem certain to slow the development of regulations and further undermine public confidence in government's ability to impose duties on the regulated communities and fulfill the requirements of existing legislation.

3. Conflict-of-Interest Requirements

As outlined earlier, the proposal focuses attention on limiting potential conflict-of-interest and bias problems among the members of peer review panels. Toward this end, the new procedures require that the sponsoring agencies develop criteria that would preclude panel membership for classes of individuals and that future panel reports include information on the qualifications and potential conflict problems of members. While the goal of independent reviews is well recognized, the draft bulletin is overly simplistic, will not produce a level playing field and could result in greatly limiting the pool of well-qualified participants in future peer review panels.

Because of the large pool of potential candidates, it is relatively easy to avoid real or perceived conflicts of interests or prior biases among panel members for studies where general expertise in disciplines, like statistics or chemistry, is necessary to conduct the reviews. However, in selecting panels to review more specialized issues, which typify many contentious regulatory issues, the task is more complex. It is often difficult or

impossible to identify leading experts who have not had prior involvement with interested parties or taken clear positions on underlying issues. In such circumstances, the agencies and independent organizations like the National Academy of Sciences try to choose panels that represent a balance of expert views based on full disclosure by panel members. The International Life Sciences Institute has prepared a Model Peer Review Policies and Procedures (ILSI ,2002) that includes the type of information that panel members should provide to promote full disclosure.

Although not addressed in the bulletin, identifying pro-industry biases is becoming more difficult, since the private sector has begun devoting added attention to emerging science through well-funded, pro-business think tanks and financial support for friendly researchers. Including panel members dependent on ongoing industry support makes the likelihood of independent review problematic. These potential biases and conflicts need further attention and should be addressed in the final bulletin.

More troubling, however, is the suggestion in the draft bulletin that past, present or future research funding of a researcher by a regulatory agency implies inordinate agency control and should disqualify future participation. These suggestions seem unfounded, since participation in agency-funded research is largely driven by outside expert panels, which are generally insulated from agency regulatory interests. Similar prohibitions of past panel membership would preclude participation by many of the nation's leading academic scientists. Nevertheless, strong biases can be expected from some academic researchers, whether funded by the agencies of the business community, which need to be publicly disclosed and considered by the sponsoring agencies on a case-by-case basis.

The difficult task of ensuring independence of these reviewers ought to be left to the sponsoring agencies with appropriate public, professional association and stakeholder oversight. Any suggestion that OIRA or OSTP play a central role in future selections, as contained in the introduction to the proposal, is inappropriate in that they lack the relevant expertise and, in view of the widely perceived pro-business track record of this Administration, will never escape the perception that their primary function is to further politicize the regulatory process.

4. Potential Legal Challenges

The inclusion in the record of all materials related to peer review might appear to create new bases for legal challenges to future rulemaking. As drafted, the bulletin includes a number of self-imposed Executive Branch procedural practices lacking any specific legislative mandate and do not alter the existing legislation establishing regulatory programs. Therefore, the bulletin should clearly state that these requirements are procedural in nature like other executive orders and are not intended to create any new or extended bases for challenging existing or future regulations under the Administrative Procedures Act.

V. Recommended Changes

Unless associated with clear benefits in regulatory decision making, practitioners can be expected to express concern about any mandatory changes in existing peer review procedures that are likely to place further demands on scarce resources, slow the regulatory process on emerging issues, or reduce flexibility to tailor reviews to the significance of the related findings. It is also important to avoid actions likely to further politicize the difficult task of sorting out scientific and technological uncertainties on emerging issues and create additional opportunities for the regulated community to delay the implementation of thoughtful regulations.

More specially, it is recommended that the draft bulletin be modified to:

- (1) **Include an impact assessment**—to clarify the coverage and identify the costs and benefits (discussing uncertainties) of the proposed changes, which should be subject to another round of public comment before promulgation;
- (2) **Phase implementation**—so that its full impacts can be assessed over time (for example, the procedures might be initially limited to major regulatory initiatives costing more than 100 million dollars per year, which constituted about 30 transactions in 2002);
- (3) **Preserve the integrity of the risk analysis paradigm**—to separate risk assessment and risk management to the extent feasible by greatly limiting coverage of initial studies of emerging problems or regulations that are already subject to peer review procedures under existing legislation;
- (4) **Revise the conflict-of-interest guidance**—to grant added flexibility to the Agencies in selecting well-qualified and balanced experts panelists based on full disclosure by participants and include clearer limits on the participation of experts whose activities are largely supported by the business community; and
- (5) **Clarifying legal implications of the new procedures**—to include explicit language noting that these requirements are Executive Branch procedural matters and are not intended to provide any new legal bases for judicial challenges to new or existing regulations; and
- (6) **Develop procedures to better mesh peer review and regulatory development procedures**—to obtain the benefits of peer review without significantly delaying the ability of regulators to deal with emerging issues.

References:

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