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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP

cc:
Subject: Comments on Draft Peer Review Guidelines

Ltr-OMB Peer Rev Guidelines.(

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Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street NW
New Executive Office Building
Room 10201
Washington DC 20503

RE: Comments on Draft Guidelines for Peer Review and Information Quality

Dear Dr. Schwab:

Personal Introduction: Having served from 1997-2001 as executive director of the National Assessment Coordination Office (NACO) under the interagency Office of the US Global Change Research Program (USGCRP), and as a research scientist and division leader with the University of California's Lawrence Livermore National Laboratory for over 30 years, the following comments are offered on the draft guidelines for Peer Review and Information Quality as published in the Federal Register. I would note that the NACO experience, which involved facilitating preparation of the US National Assessment by a federally appointed advisory panel, is particularly pertinent because the process of preparing this report involved a four-stage set of peer reviews; even this process, however, has not prevented the filing of lawsuits regarding both the process and the report's content by a group disenchanted with the results. During my 8 years with the Office of the USGCRP, I also had major responsibility for coordinating wide-ranging reviews of the periodic assessment reports of Intergovernmental Panel on Climate Change prior to the US Government officially accepting them at international meetings. I am presently retired, doing limited part-time consulting with various research-related groups, including helping with the review of the upcoming 8-nation Arctic Climate Impacts Assessment.

Importance of Review: First, let me say that I am strongly in favor of the review of scientific and technical reports generally, and of the assembly of such information into assessments, evaluations, and supporting materials for actions of all types, including development of regulations. I am deliberately choosing here not to use the term "peer review," however, because it is not at all clear how the term "peer" is or should be defined. My experience through overseeing reviews of the US National Assessment and of the IPCC reports (both processes of which involved seeking reviews by both technical experts and through an open Federal Register process) has been that useful and thoughtful comments can come from many sources (as can useless comments). Many of the issues that would come under the scope of the proposed guidelines are likely of the magnitude that they could affect wide sectors of the public and interested public and private organizations, and it is my view that a thorough review process needs to allow all potentially affected parties an opportunity to offer their comments. The government's objective and these rules should be written to ensure this.

Determining the Set of Reviewers: While the guidelines do suggest that alternative paths of commenting should be made available, I believe significant caution needs to be exercised in attempting the separation that is attempted in these guidelines. Although some view science as being wholly objective, potentially impaired by conflicts of interest of the particular scientist, I would argue that the traditions of various scientific disciplines in treating the concept of uncertainty introduce a value-based component that members of society have a right to be able to comment on. For example, some disciplines require achievement of a 95% or 99% or higher statistical level of confidence before a particular hypothesis may be considered to be sufficiently well established to be generally accepted—any lesser level is considered uncertain, independent of the importance of having an indication of likelihood due to unusual importance of the issue. This may well be defensible in constructing the proverbial "pyramid of knowledge," but this value-laden definition is not at all likely to be in tune with how most of those affected by a potential regulation may live their lives or run their businesses; in fact, there is not likely a single successful business that ever waited for such a level of confidence before being started.

In the area of climate change, the main disagreements are over how certain the research must be to reach various conclusions and findings, not so much in the substance of the science itself. For example, those who most highly value the benefits of fossil fuels want the science to be very certain before doing anything, so they look in every nook and cranny for something not completely explained; at the same time, however, these groups cite the worst case estimates of mitigation costs without even acknowledging that there are important uncertainties in these estimates. By contrast, those favoring actions to limit emissions are often most concerned about the risk of causing irreversible change to the environment, so raise every possible impact and change that is suggested; at the same time, however, these groups may not fully acknowledge the many benefits of fossil fuel use and the possible costs of switching to alternative energy technologies.

Through the National Assessment process, which focused on potential impacts rather than on mitigation, scientists and stakeholders of various perspectives were brought together, allowing the science to be discussed and the stakeholders to all decide for themselves what was certain enough for them. Through this process, there were many very good questions and interactions. These productive interactions, which involved stakeholders and scientist that some might say were conflicted in various ways, made clear to me that limiting the exchange of views only to assuredly unconflicted scientific experts would have been very sterile, sort of like a doctor providing copies of Institutes of Health laboratory studies on mice to the inquiring patient without allowing any questions about interpretation and significance of various possible treatments and their likelihood of success in a particular case.

Involving Stakeholders: In my view, the goal of the agencies should, therefore, be not only to involve a set of experts in the review process, but also to ensure that the wider set of stakeholders has an opportunity to comment on the underlying basis for interpreting the science and the clarity and assumptions in its presentation. It is my understanding that, for example, an adjustment to the standard of evidence was considered as an aspect in the review of some AIDS medications—faced with oncoming death, the notion of waiting until one has 100-1 odds assurance that a drug has a positive effect much greater than its side effects was replaced by one of a there likely to be a positive benefit. If those affected had not been able to comment on the criteria used by the scientists in their evaluation, asking, for example, for additional information, the information needed by the decision-makers to alter the standard might not have been included in the report.

Getting Good Comments from All Experts: In essence, what matters in reviews is the content of the comments, not from whom they come. The guidelines, to my reading, devote primary

attention to being concerned about the source of the comments. Indeed, conflicts of interest are potentially a concern, but it is quite likely that those with conflicts might also be the source of many useful comments. For example, through the Federal Register solicitation of review comments on the draft IPCC reports, there were quite a number of very pertinent and practical comments that came in from members of industry on the parts of the report dealing with issues such as what steps by industry could and could not accomplish. We actually received very few comments from industry (or any group) that were anything but constructive. It seems to me that rather than focus so much on ruling out those with possible conflicts (it would be like telling lawmakers to write all laws with no input from lobbyists of any stripe—one could well get quite uninformed legislation), a more effective review process might result if each reviewer disclosed conflicts of the types mentioned as potentially disqualifying (e.g., financial, advocacy, source of funding, etc.) and then submitted a signed statement of the form: "The review comments provided are based on my expert evaluation of the reviewed materials and, except as explained therein, are representative, in my view, of the prevailing scientific understanding about this issue." A statement of this general form would thus allow an industry expert to explain the prevailing practices or limitations in an industry (making clear that this is the case) and for a scientist funded by some agency to indicate that, although the prevailing wisdom is such and such, new findings hint at this or that. If the approach is to instead try to find experts who are all perfectly pure, I think the proposed approach will lead to endless battles (e.g., in the courts) over whether an expert is pure enough while, at the same time, preventing the gathering of pertinent and useful comments.

Futility of Trying to Balance Reviewers: I also think that the notion of trying to balance reviewers of different biases is totally unworkable. First, it makes the presumption that the agency knows how a particular person is biased, and, as importantly, can defend both their objective and subjective judgment to the person and more generally to the public. This seems to me highly dubious on both counts, given the level of contention over various issues. Basically, the approach necessitates a presumption that a person cannot be fair and objective, which will have the effect of really discouraging potential reviewers, especially if fringe groups can come in and say that so and so is biased against them, requiring the agency to ensure that they are also represented. Second, this whole notion seems to be based on the misperception that science is somehow two-sided; in reality, scientific views tend to be multi-dimensional and scientists often represent a wide range of views on an issue (distributed more like a Gaussian in many dimensions rather than a barbell). Third, likely matters have so many aspects that one person might be thought to be biased in some way on one aspect, and an opposite way on another (refer to the example above about how uncertainty is inconsistently applied)—achieving some sort of mythical balance would be virtually impossible. Fourth, it suggests that a person with some sort of perceived or actual slant would be expected to argue that position in the face of all discussion and input on a matter, rather than learning from the evidence and participating in reaching a panel consensus. Fifth, it assumes that each side will somehow be represented with equal force and effectiveness, as if that should be the criterion for decision—we'll end up with specialists in communication and power communicating on the panels. The main problem is that this whole approach focuses on the purity of the reviewer(s) rather than the merits of their comment—this is just not how science is supposed to work.

Dealing with the Review Comments: What needs to be sought through the review process is a range of perspectives on the strengths and weaknesses of the material (reviewers need to be asked to mention both aspects in order to minimize the possibility of changing well-supported explanations based on comments from a lone reviewer, for example). But that is only the start of

an effective review process. As critical an element is an assurance that the agency actually deals with the comments fairly and effectively. There is much too little discussion in these guidelines about this part of the process. In the climate area, the interagency group developing the new research strategy went through a very exhaustive process of gathering comments on the draft. Although many commenters and the National Academy of Sciences review committee urged attention be paid, for example, to the findings from the US National Assessment, the final draft has chosen to virtually totally exclude any consideration of it, all presumably at the direction of political level appointees who apparently do not want to mention it. The review process depends at least as much, if not more, on the agency response to it as on exactly how the review comments are solicited.

Specific Comments:

1. **Section 1: Definitions:** In that advisory committees are sponsored by agencies (and the draft suggests that review panels should be covered by FACA), would it not be the case that the reports of the review panels formed would have to also be reviewed because they are affecting the important matter at hand. If so, an endless chain could be created. In addition, it is not at all clear if advisory committees generally are or are not covered by the provisions of these guidelines. If they are reporting on an important matter, presumably they should be carefully checking the materials they use, but are their reports, which are nominally formed to get independent external advice, also then subject to having to be reviewed? Checking whether the definition of agency that is used in the guidelines will also include the review panels needs to be investigated.

2. **Section 2: Peer Review of Significant Regulatory Information:** The phrase "adequate independent peer review" is likely to be quite contentious. The assumption that review by any scientific journal is acceptable would seem likely to lead to establishment of a lot of marginal journals. At the very least, say "undertaken by a well-recognized and independent scientific journal," thus imposing the same sorts of requirements on the journal cited as for the expert reviewers. I would also note that I know of no outside organization that fully complies with the guidelines; namely, that make their reviews and responses available to the public, including with names attached. An attempt some years ago by the American Meteorological Society to ensure the purity of references cited also ran into the problem that the National Academy of Sciences chooses the reviewers for its own reports, thus potentially violating the independence rule even though they are considered quite authoritative.

3. **Section 3: Additional Peer Review Requirements (opening paragraph):** There are some fields of science where the scope indicated in the first paragraph will be very problematic: the issue of climate change is one of them. It would not be unreasonable to interpret the draft guidelines to mean that every report supported by an agency dealing with climate change needs to go through this entire process because, at some time, it may be used in decision-making by some entity somewhere in the world. This is especially the case if the Administrator can make a determination that some report or publication is covered because it may relate to some policy priority. At the very least, the language should be tightened here to indicate that such reviews would only be conducted for reports put together by the agency and when there is a close coupling of the report to the potential policy decision. The case of the US National Assessment illustrates the problem—the report had to do with potentially adapting to the ongoing and projected changes in the climate and associated impacts. However, the statements calling for further review are based on potential policies that have to

do with mitigation measures such as changing sources of energy, even though it is widely agreed that any such changes would have little influence on the rate of change of climate for many decades (and thus little effect on response strategies), even if there is concerted international action on the issue. There were many independent reasons to have this report widely reviewed, and it was indeed thoroughly reviewed. The requirements in these guidelines should only be operative when there is a quite close association between the report and the proposed policy, not when the association is nebulous or indirect.

It would also seem that the Administrator's decisions under this section, whether to insist on some report being reviewed or that some report not be reviewed, should be subject to comment and review, for example through a Federal Register process. At the very least, a periodic public explanation of decisions should be provided.

4. **Section 3: Additional Peer Review Requirements (selection of peer reviewers):** In addition to the problems created in trying to balance review panels, as was covered in the opening set of comments, strictly interpreting the four factors is likely to greatly limit the set of reviewers. In the climate change area, financial interests that were said by some to cause conflicts have been attributed to an entity paying for an airline ticket and other such mundane situations. More importantly, on contentious issues, groups are frequently charging other groups as having taken positions on matters, and so the charge of advocating a position could be easily made and virtually impossible to refute. One aspect of the problem involves determining what a position is (e.g., is it advocacy to agree with the international scientific assessments that the evidence indicates that the climate very likely changed during the 20th century—some would claim that it is). It might be more workable to modify the second factor to say received remuneration for advocacy on the matter before the agency. With respect to researchers at universities or laboratories, virtually all academics would be excluded unless a change were to be made to say that the term of one's employment depends on a contract or research grant from the agency (such a rephrasing would allow tenured professors to comment, at the very least).

5. **Section 3: Additional Peer Review Requirements (charge to peer reviewers):** Perhaps the major source of disagreement among scientists is in how uncertain or certain a finding might be. The charge should provide some guidance on how the issue of uncertainty or relative level of confidence in a result should be considered—e.g., asking reviewers to give some indication of relative likelihood of a finding (perhaps in terms of odds). The notion of leaving out all references to how the report will be related policy seems to me inappropriate. I believe it is vital for the reviewer to be aware of how important the consequences of their findings might be—will the agency be trying to avoid risks, evaluate future or past decisions, plan more research, etc. The key issue the agency report should be dealing with is whether the level of confidence in the science is adequate for some specific decision, and the reviewer should not be totally divorced from this consideration (and it is not clear this is possible). In being made aware of the coupling of the report to the decision, however, the reviewer has the obligation of explaining if and how it might have entered their decision-making process. In the climate change area, a key aspect of the issue is its time horizon—emissions being put in the atmosphere now will cause its composition to be altered for 100 years and more. It is all well and good to say that we do not have full quantitative understanding of the carbon cycle, etc., but is there sufficient understanding to justify the primarily qualitative statement about how long the atmosphere will be affected. By having a sense of the reasons the review is being undertaken, the reviewer can provide a response on the aspects of the issue that are relevant (in the case of understanding of the carbon cycle, we may not understand the

quantitative aspects well enough to immediately start a permit system for sequestration of carbon, but there may be enough understanding to justify an aggressive, broad-based policy for reducing emissions as much as possible as part of a broad-based program); expecting the reviewer to provide an appropriate review without any guidance seems to me likely to create serious problems.

6. **Section 3: Additional Peer Review Requirements (opportunity for public comment):** The number and quality of comments submitted as part of public comment processes can vary widely. For example, in the Federal Register review process for the climate assessment we received many comments that were the same or very similar, two draft books on a subject irrelevant to the matter, etc. The phrase should be changed to "such substantive comments" so that reviewers will not be inundated with junk comments, which would tend to discourage participation.

7. **Section 3: Additional Peer Review Requirements (peer review comments):** The text does not make clear if compilations of comments will retain the attribution of each comment to each reviewer. For a number of reasons, I would advocate ensuring that comments be individually attributed to the reviewer, rather than to just have a list of comments and a separate list of reviewers. As an additional comment, there should be an opportunity for comment made to the responses that an agency provides so that, for example, a researcher whose research might be questioned or an industry representative whose comment might be overridden can have an opportunity to respond to how the agency dealt with the comment. As noted earlier, how review comments are dealt with is as critical as the choosing of the reviewers to make the comments.

8. **Section 4a: Federal Advisory Committee Act:** The wording is not clear—what does "an agency should assess the treatment of such a panel" mean?

<u>Other Matters and Points</u>

A. **International Reports:** There are a number of assessment reports that come up as a result of international evaluations. For example, the Intergovernmental Panel on Climate Change provides governments the opportunity to review their reports. At the stage this happens, these reports have already gone through an initial technical review. Later in the process the US representative to an international meeting is expected to accept the technical chapters of the report and negotiate an overview of the report (summary for policymakers). It is not at all clear how the proposed guidelines might apply to this process, which is governed separately. It might be useful to indicate that for such reports, US agencies should encourage a process that meets the objectives of those in the guidelines and then to explicitly exclude them having to work within these guidelines (e.g., so that claims could not be filed in the US to derail an international assessment process—for were this to happen, the US would end up disrupting the very type of international consensus process that it has urged be created).

B. **Multi-stage Reviews:** At least for the US National Assessment, we went through a multi-stage review process. The first stage involved technical reviewers selected by the facilitating group (so equivalent to an agency selecting its own reviewers). In addition, a process was set up so interested groups could recommend technical reviewers for this stage of the review. This first stage of the review process allowed close scrutiny of the various parts of a quite lengthy report. The second stage involved review of the entire document (though a bit less

thoroughly) by a set of experts selected by OSTP (so independent of the agency sponsoring the panel of authors). The third stage involved a Federal Register review with comments from the public and various interested parties. The fourth and final stage involved a subpanel of the President's Council of Advisers on Science and Technology plus some external participants they invited. It would have been totally impractical to apply all of the suggested guidelines for reviewers at all stages of this review—only perhaps at the last level were the requirements reasonably met. It would be appropriate for the guidelines to have a provision allowing for multiple review stages and for only enforcing all of the guidelines, for example, at the final stage even though the earlier stages would be a useful part of the overall process.

C. Encouraging Participation of Reviewers: The most important way to encourage independent external reviewers to participate is to make sure that their comments make a difference. As indicated in the general comments, how the agencies deal with the comments is as important as what the comments are. If comments are only dealt with in a pro forma or casual way, the interest of being a reviewer will drop significantly; having these guidelines indicate that comments need to be seriously addressed is vital.

The next most important aspect is to rid these guidelines of the presumption that everyone is likely to be biased in some way and that any sort of conflict of the type mentioned can create uncorrectable problems. What matters is the content of the comment, not where it came from—science is not a vote, it is about really good reasoning, so what matters is the strength and validity of the comment, not its source. Thus, the guidelines should worry less about the issues of conflicts and much more about how agencies actually deal with them, and their capabilities for sorting out the wheat from the chaff and making a convincing documentation that this has been done for the right reasons.

I hope that these comments will prove useful in your consideration of how to revise the draft guidelines.

Sincerely yours,

Michael C. MacCracken