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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP

cc:
Subject: Comments on Proposed Peer Review Bulletin

Attached please find my comments on OMB's Proposed Bulletin on Peer Review and Information Quality.

Thank you for your consideration.

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THE GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER
WASHINGTON DC

DEPARTMENT OF ENVIRONMENTAL AND OCCUPATIONAL HEALTH

December 15, 2003

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th St NW, NEOB, Room 10201
Washington, DC 20503
By email: OMB_peer_review@omb.eop.gov

Dear Dr. Schwab,

I am writing in response to the Office of Management and Budget's request for public comments on its "Proposed Bulletin on Peer Review and Information Quality." (68 *Federal Register* 178: September 15, 2003) Attached you will find the testimony I presented at the National Academy of Sciences' workshop entitled "Peer Review Standards for Regulatory Science and Technical Information" (Attachment 1). As my statement indicates, I believe OMB's proposed bulletin is fundamentally flawed; implementation will not appreciably improve the quality of science used in regulation. I strongly recommend it be withdrawn.

In addition to my testimony, I am attaching a proposal (Attachment 2) that would serve as an appropriate alternative to OMB's proposal; implementation of this alternative proposal would likely result in improving the quality and integrity of regulatory science. The proposal is also discussed in an article entitled "Disclosure in Regulatory Science", co-authored by Professor Wendy Wagner of the University of Texas Law School, that will appear in the December 19, 2003 issue (Vol. 302, #5653) of *Science Magazine*. I will forward a copy for the OMB docket once it is published.

Thank you for your consideration. Please do not hesitate to contact me if I can provide additional information.

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Attachments

Statement by David Michaels, PhD, MPH

Peer Review Standards for Regulatory Science and Technical Information Workshop
Science, Technology and Law Program
The National Academies
Washington, DC
November 18, 2003

Thank you Dr. Kennedy.

In my invitation to speak today, I was asked to base my comments in my experience in the complex and sometimes byzantine world promulgating regulation. I served as Assistant Secretary for Environment, Safety and Health, US Department of Energy, 1998-2001. As many of you know, the nuclear weapons complex is self-regulated. I headed the regulatory office. I also ran a nuclear safety enforcement program, and had a fairly significant research portfolio, so address these issues from a variety of perspectives.

I am also an epidemiologist. I've served on numerous federal advisory panels and I've peer reviewed quite a few journal submissions. I'm exactly the sort of person a regulatory agency might call on to review important scientific documents.

Like most scientists, Peer review plays a very important role in my professional life. In the world of publish or perish, you live or die by peer review. So I'm also speaking from the perspective of a scientist who might perform the proposed reviews.

I'll begin with my conclusion, so you have no doubt where I stand.

This proposed OMB Bulletin "Peer Review and Information Quality"[1] is fundamentally flawed. Implementation in its current form would serve little value; in the currency of the Office of Management and Budget, its costs will be substantial, and its benefit, at least to the public's health and environment will likely be negative: through delay and added costs, it will hurt rather than provide benefit.

It is not clear what problem this proposal is attempting to solve. In the Bulletin, and in Dr. Graham's talk today, we have not heard of widespread examples of inappropriate or flawed federal regulations being promulgated as a result of failure to peer review. In fact, we have not heard of a single example.

Yet we are today considering a proposal that has onerous and expensive requirements, but, and this is what I will primarily focus on, is unlikely to result in a system where important documents are reviewed by the best scientists.

I'll demonstrate this using examples from a regulatory process in which I was deeply involved – the DOE's Chronic Beryllium Disease prevention program.[2]

A little background. Beryllium important component in nuclear weapons – in the late 1940s, significant numbers of workers in the facilities manufacturing beryllium components for nuclear weapons were developing and sometimes dying from acute beryllium disease – even people living near the plant were getting it. Two Atomic Energy Commission scientists, literally in the back of a taxicab, came up with what seemed like a reasonable beryllium standard. That number became the AEC's standard in 1949; it was adopted by OSHA when that agency came into being. And it remained DOE's standard, since, being self-regulated; DOE sets its own standards.

This 1949 standard still survives today at OSHA. Although strengthening its beryllium standard was on OSHA's regulatory agendas for years, and I do not know a single scientist who believes it is an adequate standard, it has not changed it.

It became clear some years ago that workers exposed to levels far below the standard were developing CBD. By the early 1990s DOE started the process which resulted in DOE issuing a rule reducing the level at which workers could be exposed by a factor of 10 – from 2 to .2 micrograms per cubic meter.

I want to go through the exercise of applying this proposed OMB peer review guidance to the multi-year process of promulgating a new standard.

The first question is what documents would have to undergo formal, external peer-review? The clear answer, as you know from reading the proposed Bulletin, is anything that relates to a major regulatory action, important public policy, or anything else that OMB thinks should be peer reviewed.

DOE started studying beryllium exposure and disease in the early 1990s. There were numerous workplace surveys and inspections, involving data collection and, here is the key word, as it links to the Information quality Act, dissemination. The studies looked at methods to measure exposure, methods to decontaminate buildings, the applicability of screening tests. All these reports were disseminated publicly, some in a widespread manner, some to small groups – like the workers involved. Some of these reports were distilled and synthesized in annual reports and other summary documents. Many are discussed in the regulation's preamble. We started a beryllium disease screening program, which also issued reports that were disseminated. These influenced the regulation as well. Should these ALL have been peer reviewed? They all fit the definition of significant regulatory information.

The Department was keenly aware of the need for outside review and comment– We issued a formal request for information in 1996, and convened an advisory committee, under FACA rules, that had numerous public meetings. And, of course, we had a notice of proposed rulemaking and a comment, actually several comment periods.

A few of our most important studies were submitted to scientific journals and received peer review, but certainly not all, and not necessarily in time for the rule-making process.

But this clearly wouldn't have been enough – under the proposed Bulletin, we'd have to have a different system for reviewing all the supporting studies.

Putting aside issues of cost, (at DOE, a contractor doesn't open a file cabinet without charging the agency) I have no idea who we could have chosen to peer review these documents, since every single beryllium disease expert in the country worked either full-time or as a consultant, for DOE, the beryllium industry, or, both.

Before addressing this issue, I want to make a brief parenthetical aside, and address the issue of deference to studies that have already had independent peer review, presumably through publication in the scientific literature. Again – I can use an example from beryllium, although the basic story will be familiar to many of you who work in other areas. There is little debate in the scientific community that beryllium is a carcinogen. There have been numerous animal studies demonstrating its carcinogenicity, as well as several well-conducted human studies, all published, needless to say, in peer reviewed journals. Beryllium has been designated as a "known human carcinogen" by the National Toxicology Program of the National Institute for Environmental Health Sciences (NIEHS) in the 10th Report on Carcinogens,[3] and is categorized by the International Agency for Research on Cancer (IARC) as a Group 1 "known human carcinogen." [4]

Earlier this year, scientists hired by the beryllium industry published a re-analysis of a study done by CDC scientists, in which, by changing some parameters, the statistically significant elevation of lung cancer in beryllium-exposed workers was no longer statistically significant. [5] It was published in a peer review journal – never mind this is not a journal that published much epidemiology. But it was peer reviewed, and has the opposite conclusion of other peer reviewed studies. The beryllium industry is now promoting this study as evidence that NIEHS and IARC are wrong.

While the beryllium industry's re-analysis was peer reviewed, the IARC monograph was not. Which one would DOE be allowed to rely on in standard setting?

This would be laughable, but you can imagine the mischief this could cause in the type of system proposed here, especially if the beryllium industry found a sympathetic ear at the Office of Management and Budget.

This is not an isolated example. There is now a whole industry that has sprung up that re-analyzes data to make results go away – Not surprisingly, these re-analyses, I don't like to call then studies, are commissioned when regulation appears on the horizon. The companies that do this work are hired guns working for dirty companies – they have the same relationship to epidemiology and toxicology as the Arthur Anderson Company has to accounting. Their work gets peer reviewed and published -- in 2nd rate journals, but still peer reviewed publications. It is clear that journal peer review doesn't make this task any easier; in fact, blind reliance on it might make it an agency's task more difficult, or at least more confused.

So who is going to review these reams of studies and reports my office at DOE was turning out?

Selection of which peers, which scientists, to do the reviewing will have a huge impact on the outcome.

The first issue here is the conflict of interest restrictions. It is outrageous to say, as OMB's proposed Bulletin appears to do, that if a university scientist get NIH funding, she can't be on a panel reviewing say, CDC on childhood lead poisoning, but you can be on it if your research funding is from a company that is directly impacted by the regulation, as long as you haven't taken a public positions on it. This component of the proposed Bulletin, which suggests that academic scientists are more beholden to public funding agencies than corporate funders is on face ludicrous

Most university-based scientists I know are public spirited and willing to devote a reasonable amount of time to assisting the government in issues of science, by serving on study sections or federal advisory committees. BUT, the job envisioned by these guidelines, peer reviewing reports many of which contain no new science, but consist of analyses and re-analyses of fairly mundane data, or which synthesize already published studies, is drudgery. Many university scientists, especially the more junior ones, are under pressure to publish and won't want to serve as reviewers, and unless they are paid very well (making this an expensive endeavor) couldn't afford to even if they wanted to.

Which peers will actually do the reviewing? – I predict 2 types of scientists will predominate, and both are problematic:

First, scientists whose employers see it worthwhile to pay their salaries for the time spent reviewing. Needless to say, if an employer thinks they are deriving a benefit for their employee's work in peer review government publications, we are probably facing a conflict of interest issue here that should preclude that employee's participation as a peer reviewer. These guidelines, however, fail to address this issue, and this is one of its fatal flaws.

The second category of reviewer is the contractor – once agencies start using some of the usual contractors for peer review, putting peer review into the support services budget, paying at the same rate they pay for other services, there will be no shortage of contractor scientists willing to take this on. We'll start seeing full time peer reviewers – probably people incapable of supporting themselves actually doing science. Are these the peers we're going to rely on? A scientist whose primary work is peer review probably no longer qualifies as a peer.

Further, there is no reason to think that there will be any consistency in the peer reviews, especially if you have many documents under review by many different reviewers (and you need to have many reviewers because you don't want to have one set of scientific biases replicated over and over).

As every scientist who has had a submission turned down by one scientific journal and then accepted by another knows, success in a peer review system peer review has a lot to do with luck of the draw. Whoever gets the paper to review has a huge influence on its fate. Scientific peer review is not a perfect system. We just don't have a better one.

Finally, I have to say the obvious. I am a strong supporter of peer review. But this proposal provides far too many opportunities for mischief.

I am troubled by OIRA's attempt to define itself as the arbiter of what is good science, and how peer review is performed. Outside of certain defense and intelligence agencies, there are few offices more opaque than OMB. Let me be clear this is not a criticism of this administration alone – I believe that under Dr. Graham, OMB has become less opaque than in the past. But it is still the black hole of regulation.

I call your attention to a report recently issued by The GAO entitled OMB's Role in Reviews of Agencies Draft Rules and the Transparency of Those Reviews. One example is telling – EPA proposed listing manganese in a rule on hazardous waste reporting. The steel industry, among others, filed comments with EPA. EPA considered those comments and decided to maintain the listing of manganese. The same industry representatives then went to OMB and behind the scenes, got manganese delisted. There was no public process here, no transparency. No discussion of how the decision was made. It may have been for budget reasons – but we don't know and OMB has stated that they do not have to tell. Unfortunately, OMB is historically the place where regulated parties go for a second third or fourth bite at the apple – the place to kill regulation without leaving fingerprints.

Again this is not a partisan criticism. I would say the exact same thing if it were a Democratic Administration's proposal: OMB is NOT a science agency, and it should not be the arbiter of regulatory science.

Peer review is an important process. It's too important to be addressed in a poorly conceived proposal that will be finalized behind closed doors.

It is no surprise that we are sitting here in the auditorium of the National Academy of Sciences. For the last 150 years, when the federal government needed help on tough science issues, it engaged the scientific community, through the NAS.

This proposal is badly flawed and potentially dangerous and wasteful. The issue is too important and too complex to attempt to fix through public notice and comment.

Though the National Academies, the scientific community can help you.

The scientific community can help determine what problems, if any, exist, and which need to be fixed.

We can help define the scientific threshold for which peer review is appropriate.

We can help construct a system that can identify those cases in which new science or new ideas are deserving of peer review, the cases for which the accompanied delay and costs are justified.

We can help design a system that doesn't dumb down peer review by making it attractive only to scientists who shouldn't be doing the peer review.

This issue isn't new to the Academies. In the past, when issues around peer review at EPA arose, the NAS provided useful analyses and solutions.

Twenty years ago, the NAS conducted a study of science in regulation and issued the famous red book – Risk Assessment in the Federal Government: Managing the Process. What was the purpose of the study? "(t)o strengthen the reliability and objectivity of scientific assessment that forms the basis for federal regulatory policies."[6]

It clearly is time for the NAS to revisit this issue.

Dr. Graham, declare victory – you've raised the issue of peer review by the agencies. Now, in the interest of protecting our system of protecting the public's health and environment, please, withdraw the proposed Bulletin and engage the scientific community and the agencies in an open, transparent process. Let us help you resolve it in a way that actually will work.

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[1] Office of Management and Budget. Proposed Bulletin on Peer Review and Information Quality. Federal Register 2003;68(178):54023-54029.

[2] 10 Code of Federal Regulations, Part 850. Federal Register 1999; 64(235):68854-68914.

[3] National Toxicology Program. Tenth Report on Carcinogens, 2002.

[4] International Agency for Research on Cancer. Monograph: beryllium, cadmium, mercury and exposures in the glass manufacturing industry, 1994.

[5] Levy PS, Roth HD, Hwang PMT, Powers TE. Beryllium and cancer: A reanalysis of a NIOSH cohort mortality study. Inhalation Toxicology 2002; 14:1003-1015.

[6] National Research Council. Risk Assessment in the Federal Government: Managing the Process. National Academy Press, 1982.

RESEARCH INTEGRITY IN REGULATORY SCIENCE: A PROPOSAL

Summary: To protect the health of the public from misleading or incomplete conclusions, the leading biomedical journals now only publish studies done under contracts in which the investigators had the unfettered right to publish. Federal regulatory agencies, charged with protecting the public's health and environment, have no requirements for "research integrity" comparable to those of medical journals. To ensure the integrity of data used by regulatory agencies, parties who submit scientific materials for agency consideration should be required to disclose conflicts of interest that might bias the work and whether the data were produced by scientists who had the contractual right to publish their findings without influence and without obtaining consent of the sponsor.

Background: Following a series of alarming instances in which the sponsor of research used their financial control to the detriment of the public's health, the leading biomedical journals in the US and abroad have established policies that make their published articles transparent to commercial bias and that require authors to accept full control and responsibility for their work. The editors of thirteen of the world's leading biomedical journals, including *The New England Journal of Medicine* and *The Journal of the American Medical Association*, recently declared that they will only publish studies done under contracts in which the investigators had the right to publish the findings without the consent or control of the sponsor. In a joint statement, the editors of these journals asserted that contractual arrangements that allow sponsor control of publication "not only erode the fabric of intellectual inquiry that has fostered so much high-quality clinical research but also make medical journals party to potential misrepresentation, since the published manuscript may not reveal the extent to which the authors were powerless to control the conduct of a study that bears their names."

The academic community generally shares the biomedical community's commitment to research independence. With the increased involvement of universities in commercial enterprises and collaborations, many academic institutions require that faculty members who enter into contractual agreements for sponsored research retain full rights to publish and to otherwise disclose information developed in the research.

The Problem: Federal regulatory agencies, charged with protecting the public's health and environment, have no requirements for "research integrity" comparable to those of medical journals. These agencies rely on scientific evidence to determine, for example, the allowable level of arsenic in drinking water, pesticide residue in food, and particulate matter in air. Given the central role science plays in shaping public health and environmental protection programs, regulatory science should be subject to quality controls at least as rigorous as those employed by biomedical journals. However, federal regulatory policies ensuring research integrity have not kept pace with developments in the academic and biomedical communities.

The need to ensure the integrity of research used for environmental and health regulation is made all the more imperative by the regulators' dependence on regulated parties for much of the scientific information used to formulate regulations, a dependence made necessary by limited federal research funding.

Compounding concerns about conflicts is the fact that much of this mandated private research is subject to considerably less oversight by the scientific community than federally funded research and research published in biomedical journals. Once a sponsor claims that a study is protected as a trade secret, the data and research are immediately classified unless a Freedom of Information Request is filed and the agency determines that the trade secret claim is unjustified.

The Data Quality Act requires agencies to develop more formal procedures "for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies," but the implementing regulations promulgated by federal agencies uniformly neglect to require any disclosures of conflicts of interest. Even more problematic, the Data Quality Act regulations explicitly exempt most industry-sponsored science from the "good science" requirements.

Our Proposal: Under the current regulatory system, sponsors with clear conflicts of interest have no incentive to relinquish control over sponsored research governing their products and activities. Federal agencies should therefore adopt, at a minimum, requirements for "research integrity" comparable to those used by biomedical journals:

- Scientists who submit comments or other materials for consideration by government agencies should be required to disclose financial and other conflicts of interest that might bias their work. They should also disclose whether they had the contractual right to publish their findings without influence and without obtaining consent of the sponsor. If their work was reviewed by a party affected, prior to either publication or submission to the regulatory agency, that should be disclosed as well.

- Parties that submit data from research they have sponsored must disclose if the investigators had the contractual right to publish their findings without the consent or influence of the sponsor.

- Other parties (i.e. trade associations, unions, public interest groups) who submit scientific results to regulatory agencies should disclose all known financial and other conflicts of interests of the scientists conducting the studies.

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