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Subject: NRDC Proposed Bulletin on

Peer Review and Information Quality to Dr. Margo Schwab.

<<Peer Review ltr to Dr Schwab 12-11-03.pdf>>

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NRDC
THE EARTH'S BEST DEFENSE

NATURAL RESOURCES DEFENSE COUNCIL

December 11, 2003

BY ELECTRONIC MAIL

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

Re: Proposed Bulletin on Peer Review and Information Quality

Dear Dr. Schwab:

The Natural Resources Defense Council (NRDC) submits these comments regarding the Office of Management and Budget's (OMB) *Proposed Bulletin on Peer Review and Information Quality* (*Proposed Bulletin*).[1] NRDC uses law, science, and the support of more than 500,000 members nationwide to ensure a safe and healthy environment for all living things.

Summary and Overview

The *Proposed Bulletin* was written in response to the ostensible congressional mandate under the Information Quality Act (IQA)[2] that OMB police government-wide the production, assembly, management, use, and "truth" of any information that might influence an administrative decision. NRDC is increasingly troubled by OMB's expansive reading of its legal authority and mandate under the Act, passed as a rider to an appropriations bill that was neither debated nor explained by Congress. We have watched in alarm as OMB developed policies that actively encourage an unprecedented campaign by regulated industries to use the Act to accomplish the drastic reform of environmental rules that they could not accomplish through an appropriately democratic debate in Congress.[3] But these previous concerns pale in comparison to the blatant effort

[1] Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54023 (2003) [hereinafter *Proposed Bulletin*].
[2] Treasury and General Appropriations Act for Fiscal Year 2001, Pub. L. No. 106, § 515 (2001) [hereinafter Information Quality Act].
[3] See NRDC Comments on EPA Data Quality Act Guidelines, May 31, 2002.

to slant the playing field toward industry interests that would be accomplished if the *Proposed Bulletin* is put into effect.

The integrity of the science used to support regulatory decisions would be compromised, perhaps beyond repair, by OMB's effort to disqualify scientists who receive government funding from serving on peer review panels. Not only does OMB attack government-funded scientists without justification, it tacitly encourages the Environmental Protection Agency (EPA) and its sister agencies to ignore the serious problem of agency capture by regulated industries already documented with respect to high-stakes peer review panels by the General Accounting Office (GAO).[4] The broad application of mandatory peer review will further congeal the regulatory process, leaving threats to public health and the environment unaddressed.

When Dr. John Graham was appointed as the director of the Office of Information and Regulatory Affairs (OIRA), critics expressed deep concern about his ties to regulated industries. Dr. Graham assured Congress that, in essence, he was perfectly capable of overseeing government regulatory policy objectively and would not be unduly influenced by any industry group. While NRDC strongly disagrees with the ideology underlying this Administration's regulatory policies, we recognize that there is a difference between taking a conservative approach to such issues and serving as an in-house representative of regulated industries' direct economic interests. We still nurture a rapidly dwindling hope that the worst expectations regarding Dr. Graham's tenure can be avoided.

NRDC urges OMB to withdraw the Proposed Bulletin. Instead, OIRA should embark on a systematic effort to assemble panels of experts on peer review representing the full spectrum of stakeholders to, first, determine whether and how existing practices are a problem and, second, to explore what carefully targeted intervention OMB could undertake to address those discrete issues.

The remainder of these comments address NRDC's three chief concerns with OMB's unprecedented intrusion into the government's consideration of science: (1) inappropriate and groundless discrimination against publicly-funded scientists; (2) encouragement of industry capture of the peer review process; and (3) the use of peer review to magnify the crippling ossification of the rulemaking process.

Publicly-funded Scientists and the Peer Review Process

Article after article, empirical survey after empirical survey, and independent scientist after independent scientists have decried the overwhelming trend toward private funding of science.[5] At its most benign level, this trend ensures that only science

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[4] GENERAL ACCOUNTING OFFICE, EPA'S SCIENCE ADVISORY BOARD: IMPROVED PROCEDURES NEEDED TO ENSURE INDEPENDENCE AND BALANCE 18 (2001) (Report No. GAO-01-536) [hereinafter *GAO Peer Review Report]*.

[5] For a recent, incisive analysis of this research and its implications, see SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED BIOMEDICAL RESEARCH? 143-44 (2003).

expected to have a lucrative outcome is well-funded. At its most insidious, the trend means that self-interested private entities control not just study design and therefore outcome, but when and whether results will be released. The price we pay in terms of discoveries foregone is barely imaginable. As serious, the perception that science is bought and sold by the highest bidder will inevitably undermine the integrity not just of the academy, but of science itself.

The only counterweight to this seemingly irreversible trend is government funding of independent science. We stress independence because, unlike well-documented examples of consistent and ongoing efforts by industrial sponsors to suppress scientific results they do not like,[6] OMB points to *absolutely no evidence* that the government interferes with privately conducted research, punishes researchers who develop findings the sponsoring agency does not like, or retaliates against scientists who participate in peer reviews critical of agency work products or policies.

Despite this clear record – and equally clear absence of *any* empirical or conceptual support for the proposition that publicly-funded scientists are, by virtue of that funding, biased – OMB paints with a broad and reckless brush. In effect, the *Proposed Bulletin* accuses scientists who receive or would like to receive government funding of being agency puppets because they are not "truly independent" of an agency's "agenda" or are selected because an agency feels "comfortable" with them.[7] It goes so far as to establish public funding as a basis for disqualifying peer reviewer candidates in two of the four factors it instructs agencies to use in making such selections.[8] NRDC finds this unsupported view particularly ironic given the well-documented fact that this Administration's OMB has a relentless grip on regulatory output and thus seems to be chafing at the independence of agencies that perceive themselves to be completely under OMB's control.[9]

If OMB pursues its campaign to eliminate publicly-funded scientists from peer review, only one outcome is possible: ensuring that the only scientists available for peer review are privately funded. In the environmental, health, and safety regulatory arena, the source for such private funds -- more often than not -- will be regulated industry. OMB may choose to ignore that inconvenient reality, but it is incontrovertible. There is no significant private source of funding for scientific research regarding such issues other than regulated industries.

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[6] For a discussion of some of these episodes in the context of EPA's consideration of science, see Linda Greer and Rena Steinzor, *Bad Science*, ENVTL. FORUM 28 (Jan./Feb. 2002).

[7] *Proposed Bulletin*, supra note 1, at 54024 ("scientists employed or funded by an agency could be pressured to support what they perceive to be the agency's regulatory position") and 54025 (after observing that agencies often select the same peer reviewers for multiple panels, OMB alleges that this practice "could lead an observer to conclude that the agency continually selected the peer reviewers because of its comfort with them").

[8] Id. at 54027 (advising agencies to consider whether candidates are receiving or seeking agency funding and whether they have conducted multiple peer reviews for the same agency in recent years).

[9] See, e.g., GENERAL ACCOUNTING OFFICE, OMB'S ROLE IN REVIEWS OF AGENCIES' DRAFT RULES AND THE TRANSPARENCY OF THOSE REVIEWS (2003) (Report No. GAO-03-929).

As troubling, the *Proposed Bulletin* does not specifically identify receipt of private research funding as a possible source of bias, allowing agencies to ignore what may be "real or perceived conflicts of interest." Underscoring this double standard for industry-funded science, the *Proposed Bulletin* also does not deal appropriately with the situation presented by "significant regulatory information" that is produced by a private party rather than by an agency. In such cases, even though agency staff may have had nothing to do with the creation of the information, the *Bulletin* would discourage agency experts from peer reviewing it. Further, as discussed above, the *Bulletin* seems to encourage privately-funded scientists to become peer reviewers, leading to the possibility that industry-funded research could be reviewed by industry-funded scientists.

For the last three years, NRDC has received funding from the Beldon Foundation to monitor the composition of EPA peer review panels. Unlike comparable work conducted under the auspices of the National Academy of Sciences, service as a peer reviewer for EPA is not particularly prestigious. This work is compensated at a rate ($200-300/day) that does not provide nearly adequate value for a scientist's time. Because panels are too stacked with industry representatives and are sometimes poorly run, the work also requires enormous patience. Only a minority of available reviewers are primarily supported by public or foundation money. Eliminating those supported by government would narrow this universe to a handful.

A Nod and a Wink to Financial Conflicts of Interests

Compounding the drastic tilt of the peer review playing field toward regulated industries that would be accomplished by blackballing publicly-funded scientists is OMB's circular and ethically flaccid treatment of financial conflicts of interest in selecting peer reviewers from the candidate pool left standing. This outcome is accomplished in three overlapping, convoluted, but unmistakable steps:

1. OMB begins with the proposition that "[p]eer reviewers shall be selected primarily on the basis of necessary scientific and technical expertise." Standing alone, this statement is obviously valid, although without further ground rules, it may lead to the selection of experts with highly specific knowledge of the subject at hand, while overlooking competent, well-rounded scientists. This may be used as a convenient excuse to select technical experts from industry, in lieu of independent researchers.

2. OMB's next rule purports to deal with sources of bias:

   "When selecting reviewers from the pool of qualified external experts, the agency . . . *shall strive to* appoint experts who, in addition to possessing the necessary scientific and technical expertise, are *independent of the agency, do not possess real or perceived conflicts of interest*, and are

capable of approaching the subject matter in an open-minded and unbiased manner."[10]

The most obvious problem with this formulation is that it appears to be hortatory ("strive to" is a much looser instruction than "shall"). That shortcoming is compounded by the fact that the instruction places independence from the agency on the same footing as real conflicts of interest, such as working for the company that manufactures the chemical under review. This approach is especially disturbing because OMB does not acknowledge the legal prohibitions applicable to service by people who have real conflicts of interest on peer review panels, starting with the Ethics in Government Act and its voluminous implementing regulations. Of course, those laws allow waivers of these prohibitions under specific circumstances. Thus, it appears as if OMB is operating under the assumption that such waivers will be granted routinely and tacitly endorses that discredited approach. Last, but by no means least, the statement addresses the serious problem of bias and lack of balance identified by GAO and others by suggesting the unenforceable, impossible-to-administer approach of assessing whether the scientist can approach a matter in an "open-minded" and "unbiased" manner.

3. OMB's final rule misses the opportunity to make the *Bulletin's* rules respectable, if not workable. The provision specifies the "relevant factors" that should be considered when an agency strives to satisfy these criteria. One of those four factors is whether the individual "has any financial interests in the matter at issue."[11] OMB thereby relegates the complex web of real and perceived financial conflicts of interests to a factor that should be weighed but not necessarily considered disqualifying. Read in context of its pronounced insensitivity to the implications of such interests contained in the second phase of the selection process described above, this approach not only fails to deal with the serious threat to the scientific integrity of peer review documented by GAO, [12] it could be read to encourage the continuation of such behavior.

Lastly, we note that the guidance leaves to another day, and to individual agencies' discretion, whether and how to disclose information to the public about reviewers' potential biases.[13] The important goal of assuring the public that agency peer reviews are not undermined by blatant conflicts of interest and that peer review panels are balanced for bias can only be achieved by a transparent process. For all its ostensible commitment to transparency, OMB has omitted this crucial safeguard where it is essential to the credibility of such reviews.

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[10] *Proposed Bulletin*, supra note 1, at 54027 (emphasis added).
[11] Id.
[12] *GAO Peer Review Report*, supra note 4.
[13] Id. at 54028.

Ossification Magnified

The *Proposed Bulletin* requires peer review with respect to every piece of "significant regulatory information" that an agency might wish to consider, either in the context of rulemaking or otherwise.[14] Since peer review can be a time-consuming and expensive process, especially given the sharp reductions in the pool of potential candidates that would be produced by the *Proposed Bulletin*, agencies would presumably be compelled to identify information likely to prove influential far in advance of formulating a final rule. OMB does not acknowledge the burden on agency resources that would be imposed by this broad new initiative. Nor does it spend any energy considering whether yet another layer of analysis is really necessary in all contexts where an agency might conceivably rely on a piece of information in issuing a new rule.

For reasons explained very well in comments submitted by the Center for Progressive Regulation with respect to the *Proposed Bulletin*, NRDC believes that OMB has exceeded its legal authority under the Information Quality Act by applying peer review requirements to rulemaking. The Act does not apply to rulemaking because, although Congress did not explicitly consider any of the implications of its passage, the statute states plainly that it applies only to proceedings where agencies did not already have in place a process for vetting information quality.[15] If OMB persists in using the Act to throw such a broad and needlessly expensive net over rulemaking, it will magnify the excessive delays that already plague the rulemaking process.

While the simple prospect of rulemaking delayed and denied may not trouble OMB, an equally inevitable byproduct of that result will be the widespread public perception that peer review, far from guaranteeing excellence in science, is primarily motivated by the desire of regulated industries to throw yet another roadblock in the path of government action to protect the environment. If OMB is at all sincere in its wish to strengthen public perceptions about the validity of government science, as opposed to serving industry interests in further complicating the regulatory process, it will curtail the *Proposed Bulletin's* applicability substantially. Developing a framework for narrowing the proposal's application will take some time and thought. Consequently, withdrawing it for further deliberation is OMB's wisest course.

Conclusion

In the last several months, the number of industry challenges to information under the IQA have climbed steadily. (These requests are catalogued and discussed on the web site maintained by OMBWatch at http://www.ombwatch.org/article/archive/171/.) OMB has sat on its hands as this trend escalated, and the *Proposed Bulletin* announces that it expects agencies to report the status of all future challenges, allowing it to second-guess

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[14] *Proposed Bulletin*, supra note 1, at 54027.

[15] Information Quality Act, supra note 2, §515(b)(2).

agency responses to industry critics.[16] This misguided proposal takes OMB off the fence, propelling it into the center of the action and making it the primary driver of the industry effort to discredit regulatory activity.

NRDC deplores these blatant efforts to achieve what could not be achieved through the intense campaigns to lobby regulatory reform legislation through Congress. We have made a conscious decision to refrain from using the IQA to challenge the vast quantities of information used to suppress regulation, including and especially the discredited, outdated data used by OMB itself in evaluating the costs and benefits of regulation. We can only hope that with the benefit of historical hindsight, the IQA is seen for what it really is: a vague, aspirational fragment of a law that was exploited by corporate interests to accomplish what our democratic system of government denied them. We urge OMB to retreat from its posture as the chief sponsor of these efforts.

Sincerely,

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Health and Environment Program

Jennifer Sass
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Health and Environment Program

[16] *Proposed Bulletin*, supra note 1, at 54029.