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06/01/2004 06:22:13 AM

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Subject: Regulatory Checkbook comments on Revised Draft Peer Review Bulletin

My comments are attached in PDF form for your convenience.

040528 RegCheck comments on re...

- 040528 RegCheck comments on revised Bulletin FINAL.pdf

May 28, 2004

Dr. John D. Graham
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

Delivered by email to OMB_peer_review@omb.eop.gov

Dear Dr. Graham:

Pursuant to the Office of Management and Budget's *Federal Register* notice on April 28, 2004, Regulatory Checkbook hereby provides the following comments to OMB on its latest draft bulletin on peer review.[1]

Regulatory Checkbook has been an active participant in the debate over information quality, including guidelines proposed and issued by OMB and federal agencies. We provided comments to OMB on its August 2003 draft bulletin.[2] Regulatory Checkbook is a nonpartisan, nonprofit organization whose mission is to encourage the best available science and economics in regulatory policy and decision making. We are beholden to no interested party inside or outside of the federal government. These comments therefore do not necessarily reflect the views of any interested party or stakeholder in any regulatory matter, and they have not been authorized, vetted or approved by any such interest.

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[1] Office of Management and Budget, "Revised Information Quality Bulletin on Peer Review, 69 *Fed. Reg*. 23230-23242 (hereinafter, "Revised Draft").

[2] See Office of Management and Budget, "Proposed Bulletin on Peer Review and Information Quality," 68 *Fed. Reg.* 54023-54029 (hereinafter, "Proposed Draft"), and comments of Regulatory Checkbook, http://www.whitehouse.gov/omb/inforeg/2003iq/158.pdf.

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MATERIAL PROCEDURAL DEFECTS IN OMB'S ACTION

On or about August 29, 2003, OMB posted on its web site the Proposed Draft and sought public comment on or before October 28, 2003.[3] OMB did not provide any other public notice, such as notice in the *Federal Register*—the conventional federal practice OMB expects other federal agencies to follow—so many interested parties did not promptly learn of OMB's action. Subsequently, OMB re-published the Proposed Draft on September 15, 2003, and extended the public comment period until December 15, 2003.[4]

At a public meeting sponsored by OMB and held at the National Academy of Sciences, OMB announced that Federal agencies would have an additional month—until January 16, 2004—to file their comments. The justification for enabling federal interested parties to have more time than nonfederal interested parties was OMB's desire that federal interested parties "have the benefit of the [nonfederal] public comment[s] ... as they develop agency comments to OMB."[5] This is another highly unconventional administrative procedure. We are unaware of any other instance in which a federal agency has discriminated among interested parties with respect to applicable notice and comment deadlines.

On April 15, 2003, and also without normal public notice, OMB posted the Revised Draft on its website. OMB also posted a document titled "Summary of Public and Agency Comments on Proposed Bulletin on Information Quality and Peer Review, Including Responses by OMB."[6] Comments received from 187 *nonfederal* interested parties were previously posted to ensure transparency and facilitate public discussion of the issues raised by this action.[7] In the Revised Draft OMB stated that it had been substantially influenced by comments it received from *federal* interested parties. OMB did not post copies of these comments on its website, however, and nothing in the text suggested

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[3] *See* http://www.whitehouse.gov/omb/inforeg/peer_review_and_info_quality.pdf.

[4] The additional two months' delay might have been avoided if OMB had utilized the *Federal Register* at the outset.

[5] National Research Council, Policy and Global Affairs Division, Science, Technology, and Law Program, "Peer Review Standards for Regulatory Science and Technical Information," November 18, 2003, http://www7.nationalacademies.org/stl/Peer_ReviewTranscript.pdf at 27.

[6] http://www.whitehouse.gov/omb/inforeg/peer_review_comment.pdf.

[7] *See* http://www.whitehouse.gov/omb/inforeg/2003iq/iq_list.html.

that OMB would seek public comment on the Revised Draft Bulletin which for all intents and purposes appeared to be final.

On April 21, 2004, Regulatory Checkbook formally requested that, pursuant to the Freedom of Information Act,[8] OMB disclose covered communications with federal agencies related to the Proposed Draft. One week later, OMB published the April 15 draft Bulletin in the *Federal Register* for 30 days' public comment.

The information we sought through FOIA is critical for providing informed and constructive public comments on the Revised Draft. Therefore, on May 21, 2004, Regulatory Checkbook formally asked OMB to extend the public comment period "for at least 60 days subsequent to its fulfillment of legal responsibilities under FOIA." We clearly noted the significance of covered communications from *federal* interested parties in our extension request:

> Whereas the information we sought in our FOIA request might once have had only limited academic interest, it is now clear that its timely public disclosure is essential. Regulatory Checkbook is specifically interested in comparing and contrasting the views of non-federal and federal interested parties and evaluating how OMB balanced non-federal and federal views.

As of this date we have not received a response from OMB. Further, OMB rejected our request for an extension of the public comment period without acknowledgement of or reference to our outstanding FOIA petition despite the fact that it was the basis for our request. Finally, OMB has provided no evidence of a compelling public interest justifying only 30 days for the public to digest changes OMB proposes to make after several months to digest over 16 megabytes of comments submitted by *nonfederal* interested parties and an unknown amount of information provided by *federal* interested parties. OMB merely asserts without evidence or argument that "the current comment period provides sufficient time to prepare comments on this revised proposal."

Regulatory Checkbook believes OMB's assertion is untrue. Further, OMB's cavalier attitude raises grave concerns about the signal it sends concerning how other federal agencies would be expected to utilize the enormous discretion OMB grants them to design, shape, manage, and indeed control the peer review of influential scientific information they intend to disseminate. Material defects in OMB procedure also harm the public's capacity to provide informed and constructive public comment on the Revised Draft and undermine public confidence in both OMB's process and the processes other federal agencies likely would use to implement the Bulletin. Recognizing these defects, the

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[8] *See* 5 U.S.C. 552, and OMB's implementing regulations at 5 C.F.R. Part 1303.

comments below are limited to what we consider to be fatal flaws in the substance of the Revised Draft that imperil OMB's otherwise salutary efforts to use independent, external peer review as an effective tool for enhancing and maximizing the quality of federal information prior to its dissemination.[9]

OMB PROPOSES TO ABDICATE THE DETERMINATION OF DATA-QUALITY OBJECTIVITY TO COMMITTEES OF THE NATIONAL ACADEMIES

In its Revised Draft, OMB proposes to deem any process or work product of the National Academies as automatically meeting the information quality standard of objectivity. OMB would make this determination without regard for whether objectivity was the intended purpose or the actual result of the NAS work product. These determinations would be permanent, as OMB proposes not to provide a meaningful opportunity for rebuttal based on evidence. OMB would exempt NAS work products from any expectation of transparency and waive the normal procedural requirement that influential information be capable of being reproduced by competent third parties. In effect, OMB proposes to abdicate to standing and *ad hoc* committees of the NAS its statutory authority to determine what satisfies the standard of "objectivity".

In its Proposed Draft OMB liberally borrowed elements of the conflict of interest policy statement of the National Academies of Sciences. Numerous *nonfederal* interested parties commended OMB for this approach, most raising only issues at the margin with respect to the limited transparency of NAS procedures.[10] Indeed, OMB proposed to go further than NAS with respect to minimizing conflicts of interest and bias, especially with respect to potential panelists with deep and abiding financial or intellectual entanglements with agencies sponsoring review.

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[9] We consider a provision a "fatal flaw" if it is sufficient to prevent the Revised Draft from achieving OMB's stated purposes—to use peer review as an effective tool for pre-dissemination review as set forth in the Information Quality Law and OMB's Information Quality Guidelines.

[10] OMB apparently ignores these concerns and inexplicably characterizes the NAS process as the very model of transparency: "[T]his revised Bulletin encourages agencies to consider using the panel selection criteria employed by the NAS. The use of a transparent process, coupled with the selection of objective and independent peer reviewers, should improve the quality of government science while promoting public confidence in the integrity of the government's scientific products." See Draft Revised Bulletin at 2.

In its public comments NAS supported these provisions with only small exceptions. NAS asked only that its reports be treated as meeting the same standard of peer review as which applies to publications in scientific journals:

> OMB should state explicitly that reports from the National Academies (National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council) are generally presumed to be adequately peer reviewed, *as the draft guidance has stated for publications in scientific journals*, as long as we comply with the special provisions of Section 15 of FACA.[11]

Under OMB's information quality guidelines, scientific information published in peer reviewed journals enjoys a presumption of objectivity that "is rebuttable based on a persuasive showing by the petitioner in a particular instance."[12] As OMB has acknowledged, peer review serves "diverse purposes" and "[e]ditors of scientific journals use reviewer comments to help determine whether a draft scientific article is of sufficient quality, importance, and interest to a field of study to justify publication."[13] Further, it is "editors of scientific journals (rather than the peer reviewers) [who] make final decisions about a manuscript's appropriateness for publication based on a variety of considerations"[14]. Objectivity, as that term is defined by OMB in its information quality guidelines, might not be as important as other criteria to a journal editor. Thus, a meaningful opportunity for rebutting the presumption of objectivity using consistent and procedures and a reasonable burden of proof is essential.

In its Revised Draft, however, OMB goes well beyond what NAS sought in its written comments. Instead, OMB would simply exempt the NAS entirely. OMB's Revised Draft Bulletin states:

> *As an alternative to complying with Sections II and III of this Bulletin*, an agency may instead … rely on a [sic] scientific information produced by the National Academy of Sciences [or] commission the National Academy

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[11] *See* http://www.whitehouse.gov/omb/inforeg/2003iq/115.pdf at 5, emphasis added.

[12] *See* OMB Information Quality Guidelines at Section V.3.b.i.

[13] Revised Draft at 3.

[14] Revised Draft at 4.

> of Sciences to peer review an agency draft scientific information product…

That is, agencies could utilize scientific information and reviews prepared by NAS *in lieu of adherence to applicable information quality standards*. NAS reports would enjoy much more than the same rebuttable presumption enjoyed by scientific information published in peer reviewed journals. Instead, NAS reports would be presumed to meet the presentational and substantive elements of the objectivity standard without regard for whether the information contained therein actually was substantively objective or presented in an objective manner.[15] NAS has not incorporated OMB's information quality standard of objectivity into its operations, and the standard was not derived from NAS policies or practices. Therefore, actual adherence by NAS to this standard would be only coincidental or serendipitous. OMB would allow agencies to treat NAS reports as adequately objective despite these obvious deficits. This would establish a bifurcated regime in which highly influential information must *either* meet the highest standard of objectivity *or* be published in a report by NAS.

OMB's approach has three additional practical consequences—each of which is highly undesirable.

First, the exemption for NAS would be permanent and immune to challenge irrespective of its actual merits in any given situation. There would be no effective, well-established, widely accepted and objectively applied procedures whereby a third party could rebut the presumption that a specific NAS report (or report element) met the applicable information quality standard. These procedures do not currently exist, and OMB's Revised Draft does not propose to create them. Second, agencies would be deterred from utilizing any peer review mechanism other than NAS, or other approaches to pre-dissemination review. OMB essentially invites federal agencies to abandon the demanding effort to ensure and maximize the quality of information they disseminate and instead simply rely on the revealed judgment of The National Academies. Third, agencies would be free to misuse or misapply NAS reports (or portions thereof) in support of their initiatives. The NAS cannot be expected to monitor what agencies do with their reports. OMB

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[15] The term "objectivity" entails both presentational and substantive elements of accuracy, completeness, reliability and unbiasedness. A specific NAS report might satisfy all of these criteria. However, no NAS project has included these requirements in its Charge; NAS panel members are unlikely to have seriously considered them and are not required to do so; and there is no evidence that peer reviewers of NAS reports take these factors into account. Further, NAS may not disclose enough information to make their reports "capable of being reproduced." See OMB's Information Quality Guidelines at sections V.3 ("objectivity") and V.10 ("reproducibility").

also does not propose to undertake this function, perhaps because it would not have sufficient prestige to do so effectively.[16]

As for procedure, OMB's Revised Draft suffers similarly fatal defects in this regard. OMB invites agencies to "consider" the NAS conflict of interest policy and its "prevailing selection practices … concerning ties of a potential committee members to the sponsoring agency."[17] Yet, numerous commenters on the Proposed Draft cautioned OMB against adopting the NAS' approach to bias and conflict of interest because it is confusing, internally inconsistent and impossible to apply objectively.[18] In its response, OMB does not discuss any comments from nonfederal interested parties related to "bias". OMB also dropped the term from the Revised Draft and would direct agencies to "adopt or adapt" NAS policy and practices—despite this confusion and without any genuine guidance.

Even if NAS' policy is assumed to be the pinnacle of propriety in peer review, NAS' practices are not always consistent with this policy. For example, the NAS frequently appoints peer reviewers whose financial livelihood is entirely dependent on the sponsoring agency even in cases where equal expertise is available without such entanglements. Whereas OMB's Proposed Draft would have seriously discouraged the selec-

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[16] It is doubtful that *any* other institution has sufficient prestige.

[17] Draft Revised Bulletin at III.2(b-c).

[18] NAS provides a relatively cogent definition of *bias*: "Questions of lack of objectivity and bias ordinarily relate to views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group," but "are not necessarily disqualifying" as long as "a committee "represent[s] a balance of potentially biasing backgrounds or professional or organizational perspectives." At the same time, "[s]ome potential sources of bias, however, may be so substantial they preclude committee service," the example provided being "where one is totally committed to a particular point of view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary)."

NAS' definition of *conflict of interest* is less clear, however "[T]he term 'conflict of interest' means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization." The Academies insist that this definition is objective, and then identify subjective situations in which they interpret *bias* as *conflict of interest.*

tion of such highly conflicted reviewers,[19] its Revised Draft abandons this worthy reform and implicitly embraces the practice of placing much higher weight on avoiding financial interests with for-profit entities rather than similar interests with nonprofits or the sponsoring agency.

Should agencies extend OMB's deference to NAS even more broadly, the likely consequence is less, not more, transparency. Only Section 15 of the Federal Advisory Committee Act applies to NAS, which is largely entrusted with self-monitoring of its own compliance. NAS procedures are not transparent, nor does NAS (despite its technical and scientific superiority) operate a web site capable of "pushing" information to those who want to obtain it in order to stay informed. NAS provides 20 days of public comment on proposed committee members, but does not provide useful public notice that a public comment period has begun or adequate data to ensure that the public is equipped to provide informed comment. NAS routinely amends the limited biographical information it does disclose, but without effective notice that it has done so or explanation why modified disclosure was deemed necessary or appropriate.[20] NAS makes public access to documents unnecessarily difficult and time-consuming.[21]

NAS committees are often constructed with limited expertise in many areas and no expertise at all in others. Occasionally agency sponsors will specify required expertise

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[19] "Factors relevant to whether an individual satisfies [OMB's proposed conflict of interest] criteria include whether the individual … is currently receiving or seeking substantial funding from the agency through a contract or research grant (either directly or indirectly through another entity, such as a university)…" See Draft Proposed Bulletin at Section 3 ("Selection of Peer Reviewers"), emphasis added.

[20] In the case of the National Research Council's ongoing project to assess the human health risks posed by perchlorate ingestion, the committee's membership has changed three times; the effective dates for these changes was noted but no public explanation was provided. Some committee members' biographies were changed; the date these changes were made was noted but the specific nature of the changes was not. The scope of the review (i.e., the Charge) also has changed at least twice, but these changes have never been noted publicly and could only be discerned by comparing multiple, dated printed copies. See http://www4.nas.edu/webcr.nsf/CommitteeDisplay/BEST-K-03-05-A?OpenDocument.

[21] Unlike thousands of low-technology commercial web sites, the NAS does not allow members of the public to register to receive email alerts of new projects, announcements of provisional committee nominees, changes in committee members' biographies. Online access to documents other than final reports is generally not available.

that is unnecessarily narrow such that only a few scientists closely allied to the agency's scientific views or policy preferences qualify to serve. These problems are compounded when NAS panels are asked to review nearly completed, large, complex and multifaceted agency documents instead of narrowly focused works-in-progress with fundamental science issues that need early resolution before policy decisions have been made.

OMB's Proposed Draft would have seriously discouraged (but not prohibited) agencies from selecting peer reviewers who had previously advocated strong positions on major technical or policy issues related to the review.[22] The justification for excluding such experts is that their capacity for scientific open-mindedness is suspect if they have previously taken strong positions. Moreover, prospective peer reviewers of an agency's scientific information product who have strong *policy* views (such as what an agency's regulatory stance *ought* to be) may be unable to limit their review to the scientific issues before them. OMB struck the correct balance, permitting individuals with strong *scientific* views to serve as a last resort providing these views were balanced[23] and excluding policy matters from scientific peer review.[24]

In this regard OMB's Proposed Draft would have established a somewhat more (but appropriately) restrictive policy than that of The Academies. NAS does not exclude individuals from service who are "committed to a fixed position on a particular issue," but treats this as merely "a potential source of bias"[25] and apparently not something worthy of public disclosure.[26]

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[22] OMB considered this phenomenon a manifestation of *bias* or *conflict of interest*, terms which it unfortunately used interchangeably: "Factors relevant to whether an individual [has a conflict of interest] include whether the individual … has, in recent years, advocated a position on the *specific* matter at issue…" However, "[i]f it is necessary to select a reviewer who is or appears to be biased in order to obtain a panel with appropriate expertise, the agency shall ensure that another reviewer with a contrary bias is appointed to balance the panel." See Draft Proposed Bulletin at 10.

[23] "If it is necessary to select a reviewer who is or appears to be biased in order to obtain a panel with appropriate expertise, the agency shall ensure that another reviewer with a contrary bias is appointed to balance the panel." Id.

[24] As indicated below, the Revised Draft abandons OMB's attempt to limit scientific peer review to scientific matters. We consider this another fatal flaw of the Revised Draft.

[25] The National Academies, "Policy on Committee Composition and Balance and Conflicts of Interest," http://www.nationalacademies.org/coi/BI-COI_FORM-0.pdf, May

In combination with OMB's abandonment of the language in its Proposed Draft that would exclude policy matters from scientific peer review, backsliding on its proposed selection criteria poses a grave threat to the effectiveness of peer review in achieving the kind of pre-dissemination evidence of objectivity that OMB seeks. This concern is magnified by the extent to which NAS committees do not flinch when presented with the opportunity to opine on policy issues not within the scope of their expertise as scientists, such as the degree of policy-driven precaution that ought to be embedded in an ostensibly scientific risk assessment.

OMB PROPOSES TO ABANDON PROVISIONS IN ITS PROPOSED DRAFT THAT WOULD LIMIT SCIENTIFIC PEER REVIEW TO SCIENTIFIC ISSUES

In its Proposed Draft, OMB stated that scientific peer review should be focused on science and that peer review panels should not be asked (or accept a Charge) to review policy:

> Peer reviewers shall be asked to review scientific and technical matters, leaving policy determinations for the agency. This must be clearly stated and adhered to during the peer review process so the review is based solely on the science being evaluated.[27]

12, 2003. According to NAS, this form of bias might rise to the level of a conflict of interest, "where [for example] the individual is currently president of a professional society that espouses the same fixed position on the issue." The example cited is actually an odd one. It seems much more likely that an individual would hold a fixed position on an issue if he had authored several research papers upon which the sponsor relied or her research agenda supported the sponsoring agency's policy views. According to NAS, these would not be conflicts of interest unless "a critical review and evaluation of the individual's own work … is a central purpose" of the review.

[26] The National Academies, "Background Information and Confidential Conflict Of Interest Disclosure for General Scientific and Technical Studies and Assistance," http://www.nationalacademies.org/coi/BI-COI_FORM-3.pdf. NAS interprets conflict of interest narrowly to mean "ordinarily financial" matters "that could be *directly* affected by the work of the committee" (emphasis added). However severe, indirect conflicts (such as potentially ruinous financial effects on one's academic research; strong positions on relevant scientific, technical or policy issues) are generally not *disqualifying* conflicts.

[27] Proposed Draft at 10 ("Charge to Peer Reviewers").

We indicated support for this language in our comments on the Proposed Draft. We also expressed concern that it "seems inadequate, however, to deal with agencies and institutions that have active peer review programs but routinely ask reviewers to address policy matters or impose policy-driven constraints on scientific review."[28]

We recommended amending the Proposed Draft to explicit direct agencies to ensure that scientific information distributed for the purpose of peer review of data quality should be as free as possible of policy content. We offered the example of risk characterization as something which out to be delayed pending peer review of important underlying scientific issues.[29] In our view, the logical first step toward achieving policy-neutral reviews of scientific information and assessments by scientists is the removal of embedded or intertwined nonscientific policy judgment.

In its Revised Draft, OMB has abandoned this worthy reform. In its place are nebulous musings about uncertainty and hortatory admonitions to agencies that maybe they should do something to distinguish facts from uncertainties and science from policy in crafting the scope of the review:

> Specialists attempt to reach a consensus by weighing the accumulated evidence. As such, *it is important that peer reviewers be asked* to ensure that scientific uncertainties are clearly identified and characterized. Furthermore, since not all uncertainties will have an equal effect on the conclusions drawn, *reviewers can be asked* to ensure that the potential implications of the uncertainties for the technical conclusions drawn are clear. Within this context, peer reviewers *can make an important contribution* by distinguishing scientific facts from professional judgments. Reviewers

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[28] See http://www.whitehouse.gov/omb/inforeg/2003iq/158.pdf at 2. We said that ostensibly scientific peer reviews quickly become exercises in policy deliberation: "An obvious and commonplace example is an agency request that peer reviewers opine as to whether the agency's *interpretation* of the science is *reasonable* given a litany of so-called *science policy* defaults." We believe that scientist-reviewers should be free of policy-driven constrains on their work, and in return they should limit their reviews to scientific matters.

[29] "Risk characterizations are vital, but they incorporate substantial policy judgments. The validity of these policy judgments often depends crucially on whether the underlying scientific information satisfies applicable information quality standards. Publishing the risk characterization *before* ensuring and maximizing the quality of underlying scientific information has the effect of placing a very large policy thumb on the scale." See http://www.whitehouse.gov/omb/inforeg/2003iq/158.pdf at 3.

> *might be asked* to provide advice on reasonable judgments that can be made from the scientific evidence, but the charge *should make clear* that the reviewers are not to provide advice on the policy (e.g., the amount of uncertainty that is acceptable or the amount of precaution that should be embedded in an analysis). Such considerations are the purview of the government.[30]

These musings and admonitions aside, the actual text of the Revised Draft contains little or no guidance on the subject of uncertainty or the need to limit scientific peer review to scientific issues. It's as if a critical subsection of the Revised Draft had been deleted at the last minute.

OMB PROPOSES TO EXPRESSLY PERMIT AGENCIES THE DISCRETION TO CHOOSE WHICH PROVISIONS OF THE REVISED BULLETIN (IF ANY) TO IMPLEMENT AND DENY AFFECTED PARTIES ANY MEANS TO CONTEST THESE DECISIONS.

In its Proposed Draft OMB frequently used "shall" to convey the idea that, although agencies had substantial discretion to craft peer review procedures to fit their needs, their adherence to broad peer-review principles was not optional. Few of these imperatives remain in the Revised Draft.

Perhaps the most subtle aspect of OMB's backsliding is new language permitting agencies to ignore almost any element of the Revised Draft that they wish. In addition to the substitution of "shoulds" for "shalls" (and the emasculation of many of the remaining "shalls"[31]), OMB expressly permits agencies to cherry-pick provisions as they see fit:

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[30] Revised Bulletin at 13 (footnotes omitted, emphasis added).

[31] For example, in several places OMB says that agencies "shall consider" various things: Agencies "shall … consider the conflict of interest policy used by the National Academy of Sciences; "Agencies shall consider the comments of the reviewers"; agencies shall … consider requesting the nomination of potential reviewers based on expertise and objectivity from the public, including scientific and professional societies"; agencies "shall … consider the prevailing selection practices of the National Academy of Sciences concerning ties of a potential committee members to the sponsoring agency"; agencies "shall consider establishing a public comment period for a draft report and sponsoring a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public"; "Agencies must consider public comments on peer review plans." In this formulation, "shall" (or "must") has no practical effect.

> To be considered "adequate" for purposes of [influential scientific information], a peer review need not comply with all of the requirements of this Bulletin.[32]

Virtually all influential scientific information potentially subject to peer review would be governed by this permissive language. Only a handful of instances involve "highly" influential scientific information that would be subject to the (slightly) more stringent provisions of Section III after OMB raises the threshold from $100 million to $500 million in annual effects.[33]

OMB also would delegate to the agencies complete discretion to determine how much peer review is enough. In addition to enjoying the discretion to decide what form of peer review to sponsor,

> An agency may deem a prior peer review adequate if it determines that the peer review was sufficiently rigorous in light of the novelty and complexity of the science to be reviewed and the benefit and cost implications.

All discretion is left to agencies to make these determinations, and OMB provides no mechanism for affected parties to contest their adequacy. What little content remained in the Revised Draft is now fully drained away.

OMB PROPOSES TO EXEMPT FROM PEER REVIEW BROAD CLASSES OF INFLUENTIAL INFORMATION FOR WHICH EXTERNAL, INDEPENDENT PEER REVIEW IS LEAST FREQENTLY PERFORMED: \SCIENTIFIC ASSESSMENTS CRITICAL FOR ADJUDICATIONS AND PERMITTING DECISIONS AND \REGULATORY IMPACT ANALYSES.

In Section 4(c) of its Proposed Draft, OMB retained the authority to waive

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[32] Revised Draft at II(2).

[33] "Highly" influential scientific information is generally limited to that which could have effects exceeding $500 million in any one year. For an inkling of how rare these actions might be, only three regulations reviewed by OMB in 2003 appear to meet this threshold—the U.S. Coast Guard's Facility Security rule, and the Department of Transportation's Truck Driver Hours of Service and Light Truck CAFÉ rules. *See* Office of Management and Budget, "Informing Regulatory Decisions: 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities," February 13, 2004, http://www.whitehouse.gov/omb/inforeg/draft_2004_cbreport.pdf.

> some or all of the peer review requirements … of this Bulletin if an agency makes a compelling case that waiver is necessitated for specific information by an emergency, imminent health hazard, homeland security threat, or some other compelling rationale.[34]

In the preamble OMB gave more examples where waivers might be necessary, "such as when court-imposed deadlines or other exigencies make full compliance with this Bulletin impractical."[35] Generally, however, anything that was covered within the definition of information in OMB's information quality guidelines was subject to the Proposed Draft. Because agencies bore the burden of proof that specific information (or classes thereof) ought to be exempt, a fair reading of the Proposed Draft is that peer review appropriate for the scale and scope of the information would become the norm rather than the exception.

This clarity of purpose vanished in the Revised Draft. As indicated above, OMB first narrowed the scope and significance of Section III requirements for "highly" influential scientific information and dramatically weakened Section II requirements for all other influential information. Then OMB established extraordinarily broad exemptions for entire classes of influential information—most notably, information "disseminated in the course of an individual agency adjudication or permit proceeding (including a registration, approval, licensing, site-specific determination)" and "agency regulatory impact analysis or regulatory flexibility analysis subject to interagency review under Executive Order 12866".

Neither of these exemptions is justified. In 2002 OMB exempted adjudicatory proceedings from government-wide information quality guidelines. Thus, no additional language was needed to exempt influential information narrowly related to such proceedings. The practical effect of this exemption is to insulate site-specific risk assessments from critical review and oversight. Ironically, it may be this very category of influential scientific information that would be most improved by consistent and rigorously applied peer review.

As for Regulatory Impact Analyses, it is an intriguing concept that OMB might exclude such documents on the implicit ground that its own review is equivalent to inde-

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[34] See Draft Bulletin at 12.

[35] Ibid. at 6.

pendent and external peer review.[36] OMB's review procedures are clearly independent and external to the agency "sponsoring" the review, and "sponsoring agencies" have no control over the selection of "peer reviewers." These reviewers are demonstrably without conflict of interest and are likely to have biases contrary to those of the "sponsoring agency" rather than coincident with it. The "charge" to these reviewers is transparent—to ensure that Regulatory Impact Analyses conform methodologically to OMB Circular A-4 and honestly portray the likely consequences of each regulatory alternative.

At the same time, OMB review does not currently follow the OMB peer review model in a number of important respects. OMB reviewers do not publish peer review reports such as those that would be required by Section III(5). OMB reviewers do not describe "the nature of their review and their findings and conclusions," nor do they "summarize the views of individual reviewers" or provide "the credentials and relevant experiences of each peer reviewer." The "sponsoring agency" does not "prepare a written response to the peer review report explaining: the agency's agreement or disagreement; any actions the agency has undertaken or will undertake in response to the report; and (if applicable) the reasons the agency believes those actions satisfy any key concerns or recommendations in the report," nor does it "disseminate the final [OMB] peer review report and the agency's written statement of response on the agency's web site" or include "all the materials related to the peer review (charge statement, peer review report, and agency response) … in the administrative record."[37]

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[36] OMB appears to adopt this logic in justifying this exemption: "This Bulletin covers original data and formal analytic models used by agencies in Regulatory Impact Analyses (RIAs). However, *the RIA documents themselves are already reviewed through an interagency review process* under EO 12866 that involves application of the principles and methods defined in OMB Circular A-4. *In that respect, RIAs are excluded from coverage by this Bulletin,* although agencies are encouraged to have RIAs reviewed by peers within the government for adequacy and completeness." See Revised Draft at 27 (emphasis added)..

[37] The Revised Draft makes all these requirements of peer review to ensure transparency and "process integrity," which OMB says "includes such issues as 'transparency and openness, avoidance of real or perceived conflicts of interest, a workable process for public comment and involvement,' as well as adhering to defined procedures." See Revised Draft at 11.

Making OMB review more like external and independent peer review is an intriguing idea, and it is one that could be readily justified by the common objective of ensuring and maximizing the quality of information disseminated by the federal government. Still, there is no credible evidence from the Revised Draft that OMB proposes to exempt RIAs from peer review in order to make its own review more like peer review. Rather, the logic behind the exemption is best characterized as missing.

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These brief comments have highlighted just four issues raised by OMB's Revised Draft bulletin on peer review. We believe that each one exposes a fatal flaw in the Revised Draft—a flaw so great that it is sufficient by itself to undermine OMB's stated objective to use peer review as a tool for securing effective pre-dissemination review. OMB may have made these changes in response to concerns raised by *federal* interested parties; we are unable to examine that hypothesis because OMB has not yet responded to our FOIA request for the disclosure of covered interagency communications. If indeed this is the case, however, OMB has so fully accommodated the concerns of federal agencies that its most recent foray into peer review as a tool for pre-dissemination review is doomed to fail.

Sincerely,

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