December 16, 2004

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

Dear Dr. Graham:

I am writing to follow up on public comments Regulatory Checkbook submitted on May 28, 2004, regarding OMB's Revised Draft Bulletin on peer review.[1] These comments supplemented comments submitted on OMB's Original Draft Bulletin.[2] The purpose of both the Original and Revised drafts is to "realize the benefits of meaningful peer review of the most important science disseminated by the Federal Government,"[3] and thereby assist federal agencies in the successful achievement of the pre-dissemination review requirements of OMB's government-wide Information Quality Guidelines implementing the Federal Data Quality Act.

CONTINUED CONCERNS ABOUT PROVISIONS OF THE REVISED DRAFT BULLETIN

In our comments we raised a number of concerns about provisions in the Revised Draft Bulletin that, our judgment, are individually sufficient to prevent it 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:[4]

1. The text would abdicate to unaccountable committees empanelled by The National Academies (NAS) the critical determination of whether influential scientific information satisfies the statutory criterion of objectivity as defined by OMB in its Information Quality Guidelines.

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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 Bulletin"). OMB has not posted on its website copies of public comments it received on the Revised Draft Bulletin. A copy of our comments is included as an attachment to this letter.

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

[3] 68 *Fed. Reg.* 54024 and 69 *Fed. Reg.* 23230.

[4] See Regulatory Checkbook comments on the Revised Draft Bulletin at footnote 9.

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2. The text would establish a new and non-rebuttable presumption that NAS reports, in whole or in part, inherently satisfy all applicable information quality standards in addition to the proposed scheme for governmental peer review.
3. The text juxtaposes requirements for transparency, objectivity and independence in peer reviewers with NAS procedures that are nontransparent, place little or no weight on objectivity as that term is defined by OMB, and consider only independence from private, for-profit interests while ignoring agency and nonprofit entanglements of equal or greater potential significance.
4. The text would abandon provisions in the Original Draft Bulletin that directed agencies to limit peer reviews to scientific matters and refrain from engaging in policy debates that are the purview of government officials.
5. The text would delegate to agencies unlimited discretion to decide which provisions of the peer review bulletin, if any, to incorporate into their own guidelines and procedures or to follow in practice.
6. The text would exempt from peer review requirements broad classes of influential information most deserving of objective, independent peer review, such as Regulatory Impact Analyses.

We highlighted only a few issues because our analysis of the Revised Draft Bulletin was severely time-constrained. First, OMB limited public comment to just 30 days despite the scope and scale of changes OMB made from the Original Draft Bulletin (on which the public comment period lasted four months). Second, OMB provided little information about comments that it had received from federal agencies—the parties whose conduct would be regulated by the Bulletin. Regulatory Checkbook petitioned OMB to extend the public comment period and, under the Freedom of Information Act, asked OMB to publicly disclose relevant comments received from federal agencies. OMB denied both requests.

Despite these setbacks, Regulatory Checkbook continues to research information quality issues, seeking to constructively assist the development of workable solutions that improve information quality without provoking unnecessary conflict. We strive to provide constructive input even when circumstances make this especially difficult.

RISING CONCERNS ABOUT THE UTILITY OF PEER REVIEW GENERALLY

Leaving aside our specific concerns about the Revised Draft Bulletin, we have recently been monitoring an incident that seems to expose weaknesses in peer review generally as a tool for ensuring effective pre-dissemination review of influential scientific information by federal agencies. As we understand it, OMB's goal for pre-dissemination review is to prevent, to the maximum extent practicable, the dissemination of information that does not meet applicable information quality standards. This would obviate the need for affected parties to submit error correction petitions and for agencies to divert scarce resources away from their core missions and toward corrective action. In short, pre-dissemination review serves the purpose of controlling scientific error at its source rather than trying to clean up mistakes after the fact. Further, OMB has stated that it believes peer review is an appropriate (if not the preferred) tool for ensuring adherence to applicable information quality standards prior to dissemination.

The recent incident in question involves certain studies disseminated by the Centers for Disease Control (CDC) concerning the relative mortality risks posed by obesity. These studies are clearly influential, as they are intended to reallocate the funding, research and public health priorities of the federal government and to significantly alter the behavior of

individuals, households, firms and other institutions. Based on publicly available information and news reports, which of course are necessarily incomplete and may not be entirely accurate, it appears that CDC's extensive pre-dissemination review procedures failed even though vigorous peer review is a core feature of these procedures and its commitment to peer review is perhaps the strongest among all agencies of the federal government.

This incident also seriously undermines OMB's longstanding deference to the presumptive objectivity of scientific information published in peer reviewed journals. The critical scientific paper supporting policy and programmatic positions of both CDC and its parent Department of Health and Human Services was peer reviewed and published by the *Journal of the American Medical Association (JAMA),* one of the top medical journals in the world.[5] Many peer reviewed journals have missions that are ideological or otherwise contrary to the statutory information quality standard of objectivity such that affected persons could be able to rebut, with little difficulty, the presumption that peer review by these journals was justified. However, there are a few scientific and professional journals whose peer review procedures would have been expected to easily fulfill OMB's expectations as an effective non-governmental arbiter of objectivity such that affected persons would have an extremely difficult job mounting a successful rebuttal. *JAMA* is clearly one such journal, but it appears that its peer reviewers and editors were unable to detect the errors discovered and apparently acknowledged by CDC. Indeed, the very mechanism by which these errors were detected and publicized suggests that peer review can inhibit or prevent, rather than enhance, the achievement of a high level of information quality in federal information dissemination.

This may seem counterintuitive, but fundamental differences in scholarly and governmental use of peer review may explain why. Consider first the authority of peer reviewers, which differs strikingly in scholarly and governmental applications. Journal editors, grant application reviewers, and dissertation advisors have substantial (and sometimes absolute) authority to reject scientific data, analyses or studies that they consider inaccurate or substandard. With real authority behind them, these peer reviewers' judgments must be accorded significant weight. Some reviewers may even abuse their authority so as to punish legitimate views with which they disagree or scientists they personally dislike. As long as there are many high-quality journals, multiple funding agencies and cycles with different peer reviewers, and myriad dissertation advisers, the damage wrought by abusive reviewers is necessarily limited. Monopoly power of review in a small number of hands is the main threat to scientific advancement and intellectual freedom.

In contrast, peer reviewers of governmental information products, such as those that would have been covered by OMB's Original Draft Bulletin, typically lack the authority to compel changes, or to reject data, analyses or studies that they consider substandard. When agency dissemination is perceived to be inevitable, securing any change at all may require peer reviewers to make unpalatable scientific compromises to achieve an ostensible consen-

[5] Mokdad AH, Marks JS, Stroup DF, Gerberding JL (2004). "Actual Causes of Death in the United States, 2000," 291*JAMA* 1238-1245.

sus. Indeed, government peer reviews often appear to be especially oriented toward securing consensus rather than performing aggressive critical review. [6]

A second critical variable affecting the quality of peer review is the depth of effort that reviewers are expected to devote to the task. It is a rare circumstance in which peer reviewers reproduce the authors' work to ensure that it meets the transparency standards that OMB established in its Information Quality Guidelines. Journal peer reviewers, such as those who reviewed the manuscript that became Mokdad et al. (2004), are not expected to perform this function. Hence, no one should be surprised that they missed the mathematical errors now acknowledged; it would have been rather startling if they had caught them. CDC's pre-dissemination review requirements (cited below) require extensive internal and external peer review, but do not explicitly include any provisions for reproducibility or for reproduction to occur as part of the peer review process.

A third variable that seems critical in this case is the prominence of authorship. In scholarly peer review, anonymity of both author and reviewer is generally desirable and may be actually achieved in practice. However, the degree of actual anonymity declines with the prominence of authorship. Reviewers should not be expected to devote the same attention to detail when they review manuscripts by prominent members of their fraternity as they do for unknown scholars. In addition, editors are never blind to author prominence and, wittingly or unwittingly, should be expected to give greater deference to prominent authors irrespective of the actual quality of scholarship in a manuscript. In the context of a federal agency, author prominence is similarly likely to result in systematically less intense peer review, and quite possibly, a high level of bureaucratic caution.

For governmental peer review to secure the benefits to information quality that OMB seeks, each of these problems (and others) must be addressed in the guidance issued to federal agencies. OMB's Revised Draft Bulletin is especially weak on these margins. Much more interesting in the case of the CDC's obesity reports, however, is the fact that relatively intense internal and external peer reviews, of the very kind OMB hopes for, failed to prevent the dissemination of influential information about obesity risks that was strikingly biased. These errors were discovered and exposed <u>despite</u> the existence of internal and external peer review procedures as vigorous and demanding as any that could reasonably be expected. As we note below, errors in the CDC obesity reports appear to have been discovered and exposed by scientifically and statistically competent stakeholders with a sharply divergent public health policy agenda. These stakeholders had the unusual added advantage of federal funding for their critical review, and by virtual of their location within CDC, complete access

[6] *See*, e.g., Environmental Protection Agency, *Peer Review Handbook* at 58 (EPA should not characterize as "collective" or "consensus" views the advice it receives from <u>individual</u> peer reviewers); *but see* 51 (contractor-led peer reviews need not avoid terms such as "collective" or "consensus") and 58 (balanced panels allow consensus building where consensus is the objective). Consensus is implicitly included as a goal in OMB's Revised Draft Bulletin at 23234 (peer reviewers "attempt to reach a consensus by weighing the accumulated evidence"), but not in the Original Draft Bulletin.

to the original data and analyses without the petty hindrances agencies routinely impose on outside parties.[7]

THE CDC OBESITY CASE

The publicly ascertainable facts in this case can be summarized as follows.[8] CDC researchers reviewed existing epidemiological studies and mortality data reported to CDC for the year 2000. The draft paper concluded that 400,000 fatalities per year were attributable to obesity, an increase of one-third since 1990 and less than 10 percent below the number attributable to tobacco.[9] This study is but the latest in a series of recent scientific studies by CDC scientists published in the peer reviewed literature[10], government reports[11], and stakeholder publications suggesting that obesity is an "epidemic" public health problem.[12] After it

[7] See, e.g., the error correction petition submitted to the Environmental Protection Agency by the Perchlorate Study Group seeking the disclosure of information within the Agency's possession that the petitioner believes is essential for reproducing EPA's work. EPA took nine months to respond and did not disclose the information the petitioners sought.

See www.epa.gov/quality/informationguidelines/documents/13679.pdf.

[8] We are not taking any position with respect to the substantive or presentational objectivity of the science in this case. Further, all "facts" reported herein are derived from press accounts, the accuracy of which is often in doubt. Our purpose in summarizing the case is limited to its illustrative value for showing the limited utility of peer review as a pre-dissemination review tool for "ensuring and maximizing the quality, objectivity, utility, and integrity of information."

[9] *Obesity* is arbitrarily (and almost universally) defined as having a Body Mass Index (BMI) exceeding 30, where BMI equals weight in kg divided by the square of height in meters. This definition ignores body type, level of physical fitness, and even percent body fat. Mokdad et al. (2004) did not actually estimate the number of deaths attributable to *obesity* per se. Rather, they assumed all deaths to persons with BMI exceeding 25 (the arbitrary upper bound commonly used for "normal" BMI) were "overweight-attributable deaths" irrespective of the proximate cause of death. They then categorized these deaths as being due to "poor diet and physical inactivity" without defining these terms or measuring them.

[10] See, e.g., Mokdad AH, Bowman BA, Ford ES, Vinicor F, Marks JS, Koplan JP (2001), "The Continuing Epidemics of Obesity and Diabetes in the United States," 286 *JAMA* 1195-1200; Mokdad AH, Serdula MK, Dietz WH, Bowman BA, Marks JS, Koplan JP (1999), "The spread of the obesity epidemic in the United States, 1991-1998," 282 *JAMA* 1519-1522; and Must A, Spadano J, Coakley EH, Field AE, Colditz G, Dietz WH (1999), "The disease burden associated with overweight and obesity," 282 *JAMA* 1523-1529. *JAMA* has provided extensive space to obesity research since at least 1998 when its editor issued a call for papers on the subject, calling obesity a "global epidemic" responsible for 300,000 deaths per year in the United States alone. See Fontanarosa PB (1998), "Health Promotion and Obesity Research: Call for Papers," 280 *JAMA* 1866.

[11] Department of Health and Human Services, Office of the Surgeon General (2001), The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity.

[12] American Council for Fitness and Nutrition (2004), *Tipping the Scales on Obesity: Meeting the Challenges of Today for a Healthier Tomorrow*. Mokdad et al. (2004) is cited as the source for the statistic that in 2000 "more than 400,000 deaths in the United States were attributed, in part, to people being overweight." The qualifying caveat "in part" that renders the statement quantitatively meaningless is not found in the Mokdad et al. study ("We estimate that 400 000 deaths were attributable to poor diet and physical inactivity…") but belongs to the Council, though its report does not again mention its significance. The word "epidemic" appears 17 times in the report.

was published by *JAMA,* CDC promoted the study[13] and offered specific policy conclusions based on it.[14]

According to press accounts, CDC and its researcher-authors admit to have overstated the number of annual fatalities from obesity by at least 80,000 cases due to a "statistical" or "computational" error[15] or the failure to properly apply "a statistical correction factor"[16]. Instead of a 33% increase in deaths from obesity between 1990 and 2000, the ten-year increase now appears to be no greater than 7% before increases in the U.S. population are taken into account. CDC is said to be conducting an internal inquiry directed by Assistant Director for Science Dr. Dixie Snider, after which the agency will submit an erratum to *JAMA*. CDC Director Dr. Julie Gerberding, a co-author of the study, is reported to have acknowledged this math error but does not believe that it affects the study's conclusions or its policy import: "The bottom line is that obesity is a leading cause of death." In addition, Dr. Gerberding is quoted downplaying the significance of this article, reportedly stating, "This paper in and of itself is a very minor contributor to our knowledge of obesity."

While perhaps nontrivial, a 7% increase in an uncertain quantity is not likely to have provided a persuasive basis for the dramatic increase in attention devoted to obesity relative to other public health risks such as tobacco use. Moreover, as the CDC authors point out, total deaths increased 10% from 1990 to 2000 "due largely to population growth and increasing age."[17] Therefore, the population-adjusted incidence of deaths from obesity might actually have declined.

In addition to the acknowledged math error, scientists both within and outside CDC say that the methods the authors used to estimate deaths from obesity are upwardly biased when compared to the methods used to estimate deaths from tobacco, do not account for genetic factors, and thus imply that deaths from overweight and obesity are behavioral.[18] Other scientists say they are "puzzled" by the authors' statistical methods,[19] which appear to

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[13] Centers for Disease Control (2004), *Press Release: Physical Inactivity and Poor Nutrition Catching up to Tobacco as Actual Cause of Death.* Online at http://www.cdc.gov/od/oc/media/pressrel/fs040309.htm.

[14] Centers for Disease Control (2004), *Press Release: CDC's Prevention Activities that Target Actual Causes of Death.* Online at http://www.cdc.gov/od/oc/media/pressrel/fs040309b.htm; *See also* Centers for Disease Control and Merck Institute of Aging and Health (2004), *The State of Aging and Health in America, 2004* (almost 35 percent of deaths in the U.S. in 2000—those attributable to smoking, poor diet and physical inactivity—were behavioral, implying among other things that obesity and overweight are never genetic).

[15] McKay B (2004a), "CDC Study Overstated Obesity as a Cause of Death," *Wall Street Journal* (November 23) at 1. Typical of most press accounts, this article characterizes the Mokdad et al. (2004) study as having estimated deaths from "obesity," not the more convoluted locutions identified in footnote 9.

[16] Stein R, "CDC Study Overestimated Deaths from Obesity," *Washington Post* (November 24) at A11. Stein notes that the acknowledged 80,000-case error is 20 percent of the 400,000-case total estimate but fails to point out that it is 80 percent of the reported 100,000-case increase since 1990.

[17] Mokdad et al. (2004) at 1239.

[18] McKay (2004a) (citing concerns raised internally by CDC scientists but not resolved); Barnoya J, Glantz SA (2004), "Letters: Modifiable Behavioral Factors as Causes of Death," 291 *JAMA* 2941-2942; and McKay B (2004b), "Obesity's Toll Is Even Murkier than Reported," *Wall Street Journal* (December 3) at A15.

[19] Blair SN, LaMonte MJ, Nichaman MZ (2004), "Letters: Modifiable Behavioral Factors as Causes of Death," 291 *JAMA* 2942.

overstate obesity as a risk factor by relying excessively on estimates derived from deaths among the obese at younger ages.[20] In other words, the methods used appear to be designed to yield "reasonable upper bounds" for the number of deaths attributable to overweight and obesity.[21] Press accounts indicate that CDC has contracted with the Institute of Medicine to hold a workshop to sort out these methodological issues, and not incidentally, rescue the agency from a serious loss of public credibility resulting from this episode.[22] Press reports also suggest that the death toll from obesity could be cut by more than half by the application of correct methods.[23] A downward revision of this magnitude could undermine or destroy the legitimacy of the massive CDC-led public health campaign against fat that has been based on this study and previous literature using similar methods.

Press accounts report that the CDC researchers' work was subjected to normal internal peer review procedures. These procedures are described in detail in CDC's Information Quality Guidelines[24] as well as those of its parent, the Department of Health and Human Services (DHHS).[25] CDC pre-dissemination review procedures are extensive and appear to capture precisely the objectives of the OMB Information Quality Guidelines and OMB's desire for peer review to play a dominant role in pre-dissemination review:

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[20] McKay (2004b).

[21] "Reasonable upper bounds" are popular elsewhere in the federal government even though they are clearly biased when disseminated as representing central tendency estimates of risk, prevalence or incidence. At one federal agency, the professional staff asserts that risk estimates should be biased so as to yield values that are "not underestimated" but also "not appreciably overestimated". See Environmental Protection Agency, Office of the Science Advisor, *Staff Paper: An Examination of EPA Risk Assessment Principles and Practices*, March 2004 at 141 (online at http://www.epa.gov/osa/ratf-final.pdf). Because systematic, policy-driven bias of this sort is viewed by all parties in the CDC obesity case as scientifically unacceptable and inappropriate, the effectiveness of peer review, not whether scientific inquiry should be overtly or covertly biased by policy considerations, is the only issue at hand.

[22] A news account in *Science* (10 December 2004 at 1875) says this workshop was scheduled for December 13-14, 2004. McKay (2004b) reported that this workshop would include "scientists from inside CDC and out." The extent to which the workshop will include (and respond to) scientific critics of the Mokdad et al. methodology is unknown. However, the speed of this schedule may be unprecedented. The math error became public only in mid-November 2004 and the initial press accounts did not mention the methodological debate that IOM presumably would resolve. Hasty schedules for scientific review inhibit the quality of scientific debate. We find no reference to the IOM workshop on either the IOM or CDC websites, so we infer that CDC intended to limit public participation and is more interested in political damage control than genuine dispute resolution.

In our May 28, 2004, public comment on OMB's Revised Draft Bulletin, we noted significant areas in which NAS review procedures deterred lacked transparency, such as the delayed posting of the barest of information and the routine exclusion of the public, and argued that these procedures made NAS a very poor procedural model for federal agencies to follow. The available evidence in this case seems to support our general inference.

[23] McKay (2004b).

[24] Centers for Disease Control, Management Analysis and Services Office, *Guidelines for Ensuring the Quality of Information Disseminated to the Public,* online at http://www.cdc.gov/maso/qualitycontrol/Guidelines.htm.

[25] Department of Health and Human Services, HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, online at http://aspe.hhs.gov/infoquality/Guidelines/index.shtml.

> Publication of scientific information by individual employees must undergo a formal review and clearance process by the CIO ADS [CDC Assistant Director for Science] or designee before dissemination. This review includes the evaluation of data collection measures for completeness, accuracy and timeliness, data management and analysis, clarity and accuracy of presentation, and validity of interpretation of findings.
>
> Oral presentations undergo appropriate supervisory review. Laboratory data are reviewed to assure that good laboratory data practice was followed for sampling, methodology, instrumentation and analysis.
>
> Intramural research programs will be subject to review and monitoring by external, objective peer review through an advisory committee or board of scientific counselors. Scientific research studies submitted to journals are subject to peer review of methods and findings by the journal prior to publication. ATSDR has a mandated policy for external peer review of all intramural and extramural research study protocols and findings prior to public dissemination.[26]

It is unclear whether CDC's review procedures were followed to the letter in this case. Co-author Dr. Gerberding is reported as having conceded that agency procedures were followed but that these procedures were insufficiently rigorous.[27] She says that CDC procedures need to be tightened, but news reports do not divulge what changes she believes are needed. CDC scientists not affiliated with the study seem to disagree, suggesting that CDC's peer review procedures were skewed perhaps because of Dr. Gerberding's prominence (she is CDC's Director) or because of a strong, high-level policy-level commitment to elevate the relative importance of obesity as a public health hazard.[28]

Looking at this incident from the outside, it would appear that both positions are likely to be true. CDC's internal peer review procedures, however stringent and effective in routine cases, are probably inadequate to ensure the quality of influential scientific information, especially when it directly impacts a critical agency initiative or it involves a senior agency official or scientist.

CDC's internal review procedures require clearance by the agency's Assistant Director for Science, an individual who in this case is inferior in rank to a co-author of the study. No internal peer review procedure should be expected to be successful under these conditions. Hence, Dr. Gerberding's suggestion that CDC's existing procedures are inadequate appears valid. But this problem was surely predictable given Dr. Gerberding's involvement. Moreover, the absence of direct involvement via authorship by senior officials or scientists, whether career or political, in no way assures that internal peer review procedures would escape real or perceived pressure to accommodate, compromise and force consensus.[29] The

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[26] HHS Information Quality Guidelines at V.B.a.1.

[27] McKay (2004a).

[28] McKay (2004a, b).

[29] We have found no evidence from press accounts suggesting that Dr. Gerberding did anything inappropriate that would compromise the effectiveness of internal CDC peer review. Rather, our position is that there is nothing she could have done to assure effective peer review by scientists who are her subordinates. The failure of internal peer review as a tool for pre-dissemination review is inherent to both her supervisory

previous obesity studies by Mokdad et al. (1999) and Mokdad et al. (2001) were co-authored by then-CDC Director Dr. Jeffrey Koplan, so author prominence also may have affected internal CDC review of these studies as well. Internal scientific criticism also may be muted to avoid compromising significant public health policy positions and programs of various CDC divisions. This may further attenuate the effectiveness of internal peer review, especially for projects that are led or endorsed by senior agency officials such as Dr. Gerberding or her predecessor, Dr. Koplan.[30]

Regulatory Checkbook is now researching the second-order question of whether peer review procedures at *JAMA* actually satisfy the objectivity tests set forth in OMB's Information Quality Guidelines. *JAMA* is well regarded for its concern about the quality of peer review, having published numerous scientific and review articles and editorials on the subject over the years. Still, it is not obvious that the specific information quality concerns in OMB's guidelines are manifest in *JAMA's* publication criteria. A more troubling concern is the unusually close working relationship *JAMA* has with CDC and its scientists.[31] It is easy to see how this relationship could result in the application of weaker peer review procedures for CDC-initiated or –authored research papers than for scientific manuscripts in general.[32]

STAKEHOLDER COMPETITION, NOT PRE-DISSEMINATION PEER REVIEW, WAS KEY TO IDENTIFYING AND EXPOSING ERRORS IN CDC'S OBESITY STUDY

Agency pre-dissemination review procedures, even when buttressed by an exceptional commitment to both internal and external peer review, had no discernable effect on quality control. Peer review did not detect and correct the math error in the CDC-authored study, nor did it identify and resolve the methodological issues now before the IOM. What happened is that competing financially and intellectually competent stakeholders disagreed. Some of these stakeholders resided within the CDC. They invested the time and resources to re-analyze the data, uncover significant errors, and cause these errors to be exposed on Page One of the *Wall Street Journal*. Scientists in CDC's Office on Smoking and Health apparently took the lead, motivated by twin concerns about scientific accuracy and the threat that newly fashionable concerns about obesity posed to their public health agenda. Without taking any position on the relative strength or propriety of these motives, it seems clear that each of these factors was essential. Concern about significant scientific error is necessary but insufficient to motivate competent parties to investigate, detect and seek to correct scientific error.

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position and the conviction among high-level officials within CDC and HHS that obesity is an epidemic public health problem.

[30] McKay (2004a) reports that then-CDC Director Koplan initiated the series of studies in 2001.

[31] Two of the authors of Mokdad et al. (2004) regularly serve as peer reviewers for JAMA. Conflicts of interest could arise if they were asked to review manuscripts authored by other CDC scientists.

[32] Of related concern is the extent to which the American Medical Association, the publisher of *JAMA* and several other prominent and highly regarded peer reviewed medical journals, may be unable to ensure objectivity because of the organization's prominent role in the public health campaign against obesity. A search of AMA journals yields 15 recent articles (seven in *JAMA* alone) in which obesity in the United States is characterized as an "epidemic" in the title or the abstract. A downward revision by half or more in the number of deaths legitimately attributable to overweight and obesity undermines the AMA's position on this public health issue.

Stakeholders willing to bear these costs are essential, and almost always they will have competing economic or policy views.[33]

Ironically, the competitive model OMB devised for error correction procedures is very similar to what appears to have happened in the CDC obesity case. OMB Information quality Guidelines enable stakeholders of any stripe (i.e., "affected parties" loosely defined) to challenge information they believe to be inaccurate or otherwise deficient according to the standards set forth in OMB's and the disseminating agency's information quality guidelines. Errors that lack stakeholder support for correction are likely to never be challenged, but on average resources will be devoted to correcting material errors of highly influential information. OMB's error correction model envisages extensive, active, persistent and perhaps relentless stakeholder competition to sort out competing claims and to ensure that the highest quality information survives. The contrast between this competitive model for addressing erroneous information *ex post* contrasts starkly with the agency monopoly model OMB initially established for addressing erroneous information *ex ante*. This contrast would intensify if OMB's Revised Draft Bulletin on peer review were finalized, precisely because it strengthens the agency monopoly model rather than promotes scientific competition.

HOW RELYING ON PEER REVIEW AS A TOOL FOR PRE-DISSEMINATION REVIEW RETARDS ADVANCEMENTS IN INFORMATION QUALITY

From this case study (combined with other analyses we have performed) we believe it is necessary but not sufficient to restructure agency monopolistic pre-dissemination review to be more similar to OMB's competitive model for error correction. At the same time, OMB's competitive model for error correction needs serious improvement. OMB's Information Quality Guidelines create some of the institutional foundation for scientific competition, but then undermine it by delegating excessive discretion to the agencies to determine when correction is "appropriate." There is no external oversight or genuinely neutral appeal mechanism, such as what OMB could provide using its existing statutory authority under the Paperwork Reduction Act.

The effectiveness of error correction procedures has been held hostage to agencies' willingness to admit error, which thus far has proved to be among the rarest of commodities. It is instructive that, in this case, the challenging stakeholders resided within CDC and did not utilize the agency's administrative error correction procedures. The fact that they went to

[33] Much obesity research has been funded by for-profit firms promoting weight loss through exercise, diet or pharmaceuticals. Mokdad et al. (2004) states that its methods were based on those used in the 1999 study that generated the figure of 300,000 deaths from obesity in 1990. Sources of funding for that study are not clearly revealed in the paper, but substantial financial relationships between such firms and the authors are disclosed. See Allison DB, Fontaine KR, Manson JE, Stevens J, VanItallie TB (1999), "Annual Deaths Attributable to Obesity in the United States, 282 *JAMA* 1530-1538.

We do not raise the matter of for-profit financial support of science to criticize that practice, for we believe that the quality of science should be judged solely on its scientific merit and not on its source of funding. Rather, our point is that effective error correction depends on the existence of stakeholders with significant interests—whether policy or economic—to justify the expense of preparing challenges. We believe that effective error prevention depends on the same phenomena, not on the mystical virtues of peer review.

the press instead suggests further that they had no more confidence in the agency's error correction procedures than they had in its internal peer review. It appears that they also believed exposure through public embarrassment was necessary to secure the acknowledgement that error had occurred. This belief appears to have been warranted. CDC has retreated only in part. Its director continues to assert that obesity is a top public health hazard in the United States irrespective of the magnitude of downward quantitative revision that proves to be necessary. And the agency has not even acknowledged on its website that corrections are necessary and will be forthcoming. These are all signs of institutional and official resistance, not repentance.

As a model for effective pre-dissemination review, peer review seems to have limited utility when compared to the vibrant interplay of stakeholders that could be associated with competitive error correction procedures. This is not an argument for abandoning peer review. However, it is a solid basis for caution concerning what peer review can be reasonably expected to achieve. For routine scientific information that is not influential, does not involve senior agency scientists or officials, and does not impact significant agency programs or priorities, independent and external peer review may well be the ideal pre-dissemination tool. But if any of these three conditions arises—and each of them arose in the CDC obesity case—peer review seems assured of being an ineffective tool for pre-dissemination review. Ironically, OMB would direct agencies to utilize peer review in only those instances where it is likely to be least effective.

The CDC obesity case also illustrates the dire risk of trusting in peer review as an overarching pre-dissemination review strategy whose outputs are presumptively "objective" and cannot be contested by affected persons. Under OMB's Revised Draft Bulletin, affected persons would be helpless to challenge influential information such as the CDC obesity reports if they had passed internal and external peer reviews that are among the most rigorous of any federal agency and scholarly journal. Worse, if any part of that peer review was conducted by NAS, or any part of the information in question was derived from NAS sources, then the information in question would be immune to challenge irrespective of quality. As it happens, the erroneous figure of 400,000 deaths from Mokdad et al. (2004) is cited authoritatively in an upcoming Institute of Medicine report on childhood obesity.[34] If finalized, OMB's Revised Draft Bulletin would memorialize this error, perhaps for all time, by allowing federal agencies (including CDC!) to rely on it merely because it had been published by The National Academies.

Unwittingly, OMB's Revised Draft Bulletin authorizes federal agencies to use peer review not as a tool for ensuring and maximizing information quality, but rather as a shield to protect themselves from information quality challenges. In any case where they can rely on work products of The National Academies, agencies would have an easy, affirmative defense to any and all such challenges. Indeed, the Revised Draft Bulletin would permit CDC to continue disseminating its estimate of 400,000 annual deaths from obesity even if all scientists agreed, and the agency conceded, that it was a gross overestimate. Clearly, these are

[34] Institute of Medicine (2005). *Preventing Childhood Obesity: Health in the Balance.* National Academy Press (at 77).

consequences OMB did not intend and which it would like to avoid. Finalizing the Revised Draft Bulletin, however, practically ensures that these unintended consequences will occur.

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We appreciate the opportunity to continue the dialogue on these important issues. We hope that our comments and insights are helpful as you work to improve the pre-dissemination review process, and we will continue to strive to provide constructive, nonpartisan and policy-neutral advice.

Sincerely,

Richard B. Belzer PhD
President

Belzer@RegulatoryCheckbook.org

Attachment: Regulatory Checkbook comments on OMB Revised Draft bulletin on peer review, May 28, 2004.

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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