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OMB's Data Quality Policy: Significant Change or Codification of Existing Practice?

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The Office of Management and Budget (OMB) — part of the Executive Office of the President of the United States — has proposed peer review standards for scientific and technical information that significantly influences regulatory policies. See Proposed Bulletin Under Executive Order 12866 And Supplemental Information Quality Guidelines (Aug. 29, 2003) [hereinafter "OMB Proposal" or "Proposed Standards"].[1] The Proposed Standards — which are expected to take effect in the first quarter of 2004 — would supplement existing Information Quality Act (IQA) guidelines by mandating peer review for all scientific and technical studies, reports and other data that form the basis for important policy judgments made in the context of agency directives, guidance, procedures and regulations. For "especially significant" situations, the Proposed Standards would impose an enhanced peer review process that includes public comment, written agency certification of its adherence to a rigorous peer review process and peer review oversight by both OMB and the White House Office of Science & Technology Policy (OSTP).

Some government agency officials have downplayed the impact of the Proposed Standards on the grounds that their agency's existing peer review practices should satisfy the new criteria. Others fear, however, that the Proposed Standards could extend to many types of information not traditionally subject to peer review; could limit an agency's authority to act on a precautionary basis; and could establish an additional legal avenue to challenge agency action.

A key impact for industry and other private parties stems from the possibility that the Proposed Standards, when finalized, may result in greater scrutiny — and may even require peer review in some situations — for data developed and submitted to persuade or influence an agency. As a result, when designing research programs, private parties should keep IQA and peer review requirements in mind to avoid issues and problems down the road. Industry and other private parties also would be well-advised to begin evaluating ongoing and anticipated rulemakings and other regulatory activities for the potential impact of any peer review likely to be required when the Proposed Standards are finalized early next year and to adjust strategies and advocacy as necessary.

Discussion and Analysis

Most federal government agencies have extensive peer review policies; some laws also mandate peer review. Over the years, OMB has emphasized the importance of peer review as a means of ensuring information quality, but in 2001, Congress mandated a more active OMB role with the passage of the

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Information Quality Act ("IQA").[2] Pursuant to the IQA, OMB must issue guidelines requiring government agencies to ensure "the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency" and to "allow affected persons to seek and obtain correction of information maintained and disseminated by the agency."[3]

OMB issued IQA guidelines in January of 2002, and by October of 2002, all federal government agencies had developed parallel implementation guidelines.[4] These IQA guidelines recognize the value of peer review by creating a "presumption" that "data and analytic results . . . subject to formal, independent, external peer review [are] . . . of acceptable objectivity.[5]

In recent months, OMB has apparently examined peer review practices and determined that "[e]xisting agency peer review mechanisms have not always been sufficient to ensure the reliability of regulatory information disseminated or relied upon by federal agencies."[6] For example, despite the rigorous peer review policies prevailing at EPA under its Science Advisory Board and peer review handbook, OMB notes that the EPA Inspector General issued a report late last year finding that "[t]he critical science supporting [EPA's] rules was often not independently peer reviewed. Consequently, the quality of some science remains unknown."[7] In addition to the issue that the scientific and technical information undergirding many agency activities, including major rulemakings, does not always undergo peer review, OMB also has noted that even where peer review occurs, consistency does not reign across federal government agencies. For example, some agencies allow peer review by their own employees, while other agencies forbid such a practice.[8]

To address the matter of when peer review should occur and by what process, OMB has proposed to supplement its IQA guidelines with peer review standards that would apply across all federal government Executive Branch agencies. These Proposed Standards would require peer review for all "significant regulatory information" — with a broad definition of "regulatory information" to include "any scientific or technical study that is relevant to regulatory policy." The Proposed Standards also would impose enhanced peer review requirements for "especially significant regulatory information", which includes information that either is disseminated in support of a major regulatory action or is "determined [by OMB to be] . . . of significant interagency interest or is relevant to an Administration policy priority."

The potential ramifications of the OMB Proposal are still emerging, as the comment period on the Proposal did not end until October 29, 2003. Of the more than 170 viewpoints lodged during the comment period, reactions ranged on a continuum from strong support to strong concern. Early on, the U.S. EPA's science advisor, J. Paul Gilman, stated the OMB Proposal would not "create any new burdens" and largely codifies existing practices.[9] The National Academy of Sciences, however, has objected to what it calls the OMB Proposal's "highly prescriptive" approach that does not allow agencies to tailor peer review to each circumstance.[10] Industry groups have expressed support, with some noting that the OMB Proposal would create greater uniformity and rigor in peer review across agencies, and thereby, improve IQA compliance.[11] On the other hand, some organizations have questioned whether the OMB Proposal will politicize the peer review process and give industry greater leverage to gain acceptance of its own science.[12] Congressional members even have weighed in on the OMB Proposal, with a group of House Democrats led by Representative Henry Waxman (D-Calif) urging the Proposal's withdrawal, while others in the House, such as Representatives James Gibbons (R-Nev) and Chris Cannon (R-Utah), have

characterized the Proposal as a "good start at bringing sound and sensible science to the regulatory process."[13]

OMB has indicated that it will make "constructive revisions, as appropriate, based on the comments" received on the Proposal.[14] In the meantime, a careful reading of the OMB Proposal suggests the potential for significant impacts. These impacts will vary in scope and degree depending upon the interpretation and application in practice of the Proposal's central concepts — such as "influential"; "important public policies"; "important private sector decisions"; and "sufficient information" to name a few.

A brief discussion of some key issues suggestive of the OMB Proposal's potential for significant impacts follows below.

The broad scope of the OMB Proposal's "regulatory information "definition suggests that all information relied upon or endorsed by a federal agency in connection with regulatory policy qualifies as "regulatory information", and hence, should be screened to determine whether the information further qualifies as "significant" or "especially significant" "regulatory information" subject to peer review.

The OMB Proposal indicates that "any research report, data, finding, or other analysis" constitutes a "study" and that any such "study" constitutes "relevant" "regulatory information" "if it might be used by local, state, regional, federal and/or international regulatory bodies." The breadth of this "regulatory information" definition suggests that nearly all forms of analysis that provide a basis for agency policy, regulation or other action could qualify as "regulatory information" if the federal agency has either prepared the analysis itself or has relied upon or endorsed an analysis prepared by others. To implement the OMB Proposal, therefore, an agency likely will need a screening process covering a wide array of information to identify that information which further qualifies as "significant" or "especially significant." This screening process also will need to address interpretative questions raised by the "regulatory information" definition.

In particular, when and how the agency has endorsed any analysis prepared by industry or other private parties sufficient to meet the "regulatory information" definition remains an open question. If, for example, the agency relies on industry-supplied data on emissions reductions to draw conclusions regarding environmental benefits or health impacts, does such reliance cause that industry-supplied data to qualify as "regulatory information" potentially subject to peer review? A related question is how does the "regulatory information" definition apply to "studies" that form the basis for analysis or conclusions in other "studies." For example, if an agency prepares a risk assessment for a health endpoint based on health and exposure studies, does only the risk assessment constitute the "regulatory information" potentially subject to peer review, or do any of the underlying studies ever also qualify as "regulatory information" potentially subject to peer review.

The "significant" versus "especially significant" regulatory information paradigm indicates that a greater scope of "regulatory information" may become subject to some form of peer review.

"Significant regulatory information" refers to any information "relevant to regulatory policies" that is "influential" — *i.e.*, "will have or does have a clear and substantial impact . . . on important public policies or private sector decisions." The common wisdom has been that this "influential" standard gives an agency substantial latitude to determine when "regulatory information" warrants peer review. To date, agencies, generally have reserved peer review for select, major activities. The OMB Proposal now would juxtapose this "influential" standard for "significant regulatory information" with three factors that will cause

"regulatory information" to qualify not just as "significant" but as "especially significant" — *i.e.*, "(i) the agency intends to disseminate the information in support of a major regulatory action, (ii) the dissemination of the information could otherwise have a clear and substantial impact on important public policies or important private sector decisions with a possible impact of more than $100 million in any year, *or* (iii) the Administrator determines that the information is of significant interagency interest or is relevant to an Administration policy priority." This juxtaposition would seem to erode some of the perceived agency latitude on when to conduct peer review in several respects.

In particular, the OMB Proposal would clearly elevate some of the "regulatory information" that agencies have regarded previously as "influential" to an "especially significant" status and mandate extensive peer review. This elevation means that the agency will lose discretion in certain situations, such as, for example, for information "in support of a major regulatory action,"[15] to define when peer review occurs and by what process. This elevation also suggests that other lesser types of regulatory information that an agency may not have previously have deemed "influential" now would so qualify under the OMB Proposal. Indeed, the Proposal's broad "regulatory information" definition, as discussed above, coupled with the "significant" versus "especially significant" juxtaposition, creates a paradigm under which information typically relied upon by agencies in promulgating regulations and policies that does not now undergo peer review — such as, for example, more routine analyses of benefits, costs, and paperwork burdens — could qualify as "significant" and require some form of peer review.

The peer review process for "especially significant regulatory information" may be consistent with most agency peer review policies, but the requirement for administrative record certification may force greater process rigor and the requirement to include peer review reports in the administrative record may bestow greater legal significance to the process.

The OMB Proposal would mandate a peer review process for "especially significant regulatory information" that includes many of the components already found in current agency policies, but some new requirements as well, including the requirement for the agency to certify for any major regulatory action how it "has complied with the requirements of [the OMB Proposal] . . . and the Information Quality Act with respect to the significant regulatory information at issue." This certification will require an agency to exercise diligence as to peer review components that may be found in current policies, but perhaps have been applied by the agency in the past with varying degrees of rigor, such as, for example, the Proposal's requirements for "public comments" "with ample time for consideration" by peer reviewers and for "sufficient information" access for peer reviewers. Strict application of these components — particularly in the context of major regulatory activities — could prolong the process; result in greater scrutiny of information submitted by industry and other private parties; and make achieving closure more difficult. Moreover, the OMB Proposal mandates that all peer review reports become part of the "administrative record for any related rulemakings" suggesting that these reports may carry greater legal significance in the context of any petition for reconsideration or judicial review of the rulemaking.

The OMB Proposal allows for political goals and considerations to impact when peer review occurs and by what process.

The OMB Proposal would deem "regulatory information" "especially significant" where "the [OMB] Administrator determines that the information is of significant interagency

interest or is relevant to an Administration policy priority." In this respect, the Proposal does allow for the political goals and considerations of the White House, through OMB, to trigger peer review. Moreover, the Proposal's requirement for consultation with OIRA "upon request" as to "how the agency plans to review a specific document . . . and whether such a plan is sufficient" affords an additional avenue for such political influence.

Conclusion

The OMB's Proposed Standards for peer review are scheduled to become effective in January 2004. A plain language reading indicates that the Proposed Standards would require federal agencies to evaluate a larger scope of information for possible peer review and would expand the scope of peer review that now occurs at federal agencies, particularly in connection with major regulatory actions. A more aggressive application of the Proposed Standards would increase the level of peer review profoundly, and thereby have a remarkable effect on the regulatory process.

Under the circumstances, industry and other private parties would be well-advised to begin evaluating ongoing and anticipated rulemakings and other regulatory activities now to assess the potential impact of any peer review likely to be required when the Proposed Standards are finalized and to adjust regulatory strategies and advocacy as necessary. In this context, it is important to recognize that the Standard's peer review requirement likely will result in greater scrutiny of studies, analyses and other data submitted by private parties in support of regulatory positions. Moreover, an agency may face constraints in relying significantly on such private party data as a basis for regulatory action absent some form of peer review. Thus, when designing research programs, private parties should keep IQA and peer review requirements in mind to avoid issues and problems down the road. Some general actions and issues to consider in this regard include:

In designing a non-routine study that falls outside of well-prescribed parameters, evaluate carefully how to ensure that the study satisfies the core IQA requirements of "quality, objectivity, utility and integrity." In this context, particular consideration should occur regarding how to limit extrapolations and other qualitative judgments more likely to trigger IQA insufficiency allegations. Depending upon circumstances, it may be useful to consult with government agency experts to obtain informal feedback prior to initiating the study. Also, serious consideration should be given to study management. For particularly important and/or costly studies, creating a management structure with some independence may offer an advantage.

In any study that will be used to support positions with respect to regulation, risk assessment or other government policy-making, consider carefully how to obtain sufficient "peer review" of the study. Notably, the OMB Proposal exempts "significant regulatory information" already subject to "adequate independent peer review" with "scientific journal" peer review presumed as adequate. To rely on this exemption, it may be useful to document the peer review process for a particular study to provide evidence later in the event of an adequacy challenge.

For any situation that may trigger the extensive "especially significant regulatory information" peer review process under the OMB Proposal, give due consideration to how you will approach this process. For example, will you argue against use of this process, and if so, on what grounds, when and to whom. If the process advances who will you nominate to serve as peer reviewers? Such selections should satisfy the dual prongs of sufficient expertise and lack of bias as determined under the OMB Proposal based on

factors such as financial interest in the subject matter, financial links to the agency, prior involvement in similar peer review processes for the same agency on the same "specific" matter, and prior advocacy. Also, how will you handle the public comment process, which likely will include both public meeting and written comment components, recognizing that this process — and how you handle it — ultimately may have special significance down the road in other venues, such as administrative challenges to a regulation supported by the process, in private party litigation relating to the subject matter of the process, and in the media.

Endnotes

[1] The OMB proposal is available at <http.//www.whitehouse.gov/omb/pubpress/2003-34.pdf> on the World Wide Web.

[2] Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554; H.R. 5658), known as the Information Quality Act [hereinafter "IQA"].

[3] IQA, § 515(b).

[4] OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (Jan. 3, 2003) [hereinafter "OMB IQA Guidelines"]. *See also* Memorandum from J. Graham regarding Executive Branch Implementation of the Information Quality Law (Oct. 4, 2002) (acknowledging completion by Executive Branch agencies of their parallel guidelines).

[5] OMB IQA Guidelines, Paragraph V.3.B.i.

[6] OMB Proposal, at 3.

[7] OMB Proposal, at 3; *see* U.S. Environmental Protection Agency Office of Inspector General, Science to Support Rulemaking, at ii (Nov. 15, 2002).

[8] *See* OMB Proposal, at 3.

[9] BNA Environment Report, "EPA Practice Said To Be Consistent With Draft OMB Guidance On Peer Review", A-4 (Sept. 4, 2003); Inside EPA, "EPA Science Advisor Downplays Impact of New OMB Peer Review Guide," (Sept. 5, 2003).

[10] *See* Inside EPA, "OMB Agrees To Share White House Peer Review Role Over EPA Analyses," (Jan. 2, 2004).

[11] *Id.*

[12] *Id.*

[13] BNA Environment Report, "Some Democrats, Advocates Urge Changes To Peer Review Guidance Proposed By OMB" (Jan. 6, 2004).

[14] *Id.*

[15] *See* Note xi *supra*.