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12/15/2003 11:06:43 PM

Record Type: Record

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Subject: OMB Peer Review Bulletin

- K&H Comments on OMB Peer Review Proposal_rev.doc

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December 16, 2003

Electronic Submission

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
New Executive Office Building, Room 10201
Washington, DC 20503

Re: Proposed OMB Bulletin on Peer Review and Information Quality

Dear Dr. Schwab:

Keller and Heckman LLP appreciates the opportunity provided by the Office of Management and Budget (OMB) to comment on the referenced Information Quality Bulletin.¹ While we believe these comments generally reflect the views of our clients, we wish to make it clear that we have not had an opportunity to consult with all of them and, therefore, are submitting these comments in our name rather than as a representative of any particular client or clients. We welcome the thrust of this OMB proposal to substantially advance regulatory reform in this area. Our comments suggest modifications to the proposed bulletin that we believe will significantly enhance the effectiveness of this initiative.

¹ Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54023 (September 15, 2003).

INTRODUCTION

Decisions made by federal regulatory agencies that are likely to have a major impact on our economy, and on a significant number of its constituent businesses, must be well-supported by the best reasonably available information. For years, comprehensive regulatory reform efforts have been stymied by those whose bias for expanded regulation has permitted federal agencies to characterize anecdotes, pseudo science and leaps of faith as the best reasonably available information, allowing them to make critical regulatory policy decisions based on that type of information rather than sound scientific and economic analyses.

Based on the authority provided by Executive Order 12866, the Paperwork Reduction Act, and the Information Quality Act, OMB has appropriately issued a proposed bulletin for public comment, which would mandate that, "to the extent permitted by law", "significant regulatory information" be subjected to peer review and that certain "especially significant regulatory information" be subject to an INDEPENDENT, EXTERNAL peer review process. The term "especially significant regulatory information" would include information used to support a major regulatory action and information that could have a major impact on important public policies or important private sector decisions with a possible impact of \$100 million or more in any one year.

AN ILLUSTRATION OF THE CURRENT PROBLEM

We have closely observed at least one Federal agency –OSHA-- systematically circumvent the requirements and undermine the objectives of the Paperwork Reduction Act² and Executive Order 12866, and greet the new OMB Data Quality Guidelines³ with a business as

² This point is demonstrated by the enormous increases in the paperwork burden estimates approved by OMB over the last two review cycles in connection with, for example, OSHA's Lockout/Tagout and Personal Protective Equipment Standards, although the underlying rules have not changed.

³ 67 Fed. Reg. 8452 (February 22, 2002).

usual attitude⁴, and doubt that experience is unique to the Federal bureaucracy. Based on extensive experience, OSHA has been notorious for underestimating the economic impacts of regulatory requirements, using amortization schemes to spread out the substantially underestimated but still major initial and periodically recurring costs over several if not many years, and issuing unsubstantiated certifications that its actions will not have a significant economic impact on the U.S. economy, on small business, etc.

ADDRESSING THE PROBLEM

As a partial solution for reducing the potential for the aforementioned regulatory abuses, we believe there should be an OMB presumption that all “significant regulatory information” is “especially significant regulatory information” until proven otherwise. Furthermore, we believe any agency certification that information is not “significant regulatory information” or “especially significant regulatory information” should be signed by the head of the sponsoring agency under penalty of perjury. Having put lower level personnel at DOL/OSHA in the position of signing inaccurate Paperwork Reduction Act certifications (e.g., to the effect that a rule specifies the retention period for any required records when we have pointed out in written comments that no such no retention period is specified), we see the need for a change. Finally, in determining whether the possible impact of a regulatory initiative is \$100 million or more in

⁴ Appendix II of the Department of Labor’s (DOL’s) Information Quality Guidelines initially gives one the impression it plans to implement an effective peer review process along the lines of the EPA’s SAB. However, it is clear from experience that OSHA interprets the phrase “best available evidence” to mean the best of the readily available existing information, and whatever additional information OSHA decides is worth paying its consultants to produce, regardless of its quality. See, for example, “Technological Feasibility Study and Cost and Impact Analysis of the Draft Crystalline Silica Standard for Construction, Draft Final Report to OSHA, Prepared by ERG, August 19, 2003. According to the referenced Appendix II, “data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data), include[es] exposure data generated by [OSHA] enforcement activity, contained in published literature, and submitted to the rulemaking record.” The exposure data collected from OSHA enforcement inspections is hardly the unbiased, random data called for, and the fact that OSHA hires a contractor to memorialize that data in published literature gives new meaning to the concept of scientific analysis. For an example of this creative use of “literature”, see Technological Feasibility Study and Cost and Impact Analysis of the Draft Crystalline Silica Standard for Construction, Draft Final Report to OSHA, Prepared by ERG, August 19, 2003.

any one year, Federal agencies should not be permitted to play the amortization game in which they spread start-up and periodically recurring costs over 10-year periods.

Looking at the big picture, we agree with OMB that effective peer review is a “critical element in ensuring the reliability of scientific analyses” and believe that effective peer review is also a critical element in ensuring the reliability of economic analyses.⁵ We believe Congress came to recognize this fact as early as 1978, at least in the area of environmental regulation, when it established the Environmental Protection Agency’s (EPA’s) Science Advisory Board (SAB) under the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA). Subsequently introduced bi-partisan regulatory reform bills indicate that there is a broad understanding within the Congress that effective peer review is critical to all significant Federal regulatory initiatives. Unfortunately, prior to the Data Quality Act, the political environment had limited regulatory reform to the very important but inadequate changes contained in the Small Business Regulatory Enforcement and Fairness Act.⁶

GIVING PRACTICAL MEANING TO THE PHRASE "TO THE EXTENT PERMITTED BY LAW"

Given the exclusionary effect of the phrase "to the extent permitted by law", it is critical that OMB carefully interpret this phrase in a manner that is practical and consistent with existing statutory mandates. For example, the Occupational Safety and Health Act authorizes the Occupational Safety and Health Administration (OSHA) to adopt health standards based on the

⁵ According to DOL’s Information Quality Guidelines: “Peer review is an appropriate technique for reviewing scientific studies and economic analyses.”

⁶ SBREFA created a 60 day period to perform a limited review of draft EPA and OSHA rules. The review is conducted by a three agency panel (i.e., EPA or OSHA, OMB and SBA), is chaired by the sponsoring agency (i.e., EPA or OSHA), and is staffed primarily by the sponsoring agency (i.e., EPA or OSHA personnel). The SBREFA review provides for limited input from small entity representatives selected by the sponsoring agency (i.e., EPA or OSHA). In contrast, it took EPA’s independent SAB over one year to review EPA’s draft Trichloroethylene Health Risk Assessment.

best available evidence, but only to the extent that evidence would be considered persuasive by a reasonable individual rather than, for example, someone who is biased by a particular position or

ideology. We believe it to be consistent with the various authorizing statutes and inherent in the power of the Office of the President to make it clear to all executive branch agencies that:

- 1) Regulatory decisions must be based on sound scientific and economic analyses rather than anecdotes, pseudo science and leaps of faith;
- 2) OMB will serve as the internal gatekeeper;
- 3) The agency advancing a particular initiative (the sponsoring agency) has the burden of proving the initiative meets all legal and policy requirements; and
- 4) The positions of the sponsoring agency on each of the technical issues (as distinguished from policy issues) encompassed by that initiative and appropriately determined by scientific or economic analyses are presumed to be valid **to the extent** that the agency's positions **on each of the technical issues** are supported through an effective peer review process.

THE "EFFECTIVE PEER REVIEW"

Membership on the Peer Review Panel

Despite the reference to "independent peer review", we believe the appropriate phrase is "effective peer review," with the emphasis on: 1) necessary scientific and technical expertise; 2) panel balance; and 3) full disclosure. The proposal leaves open the possibility that employees of the sponsoring agency could serve on the peer review panel in certain circumstances. The appointment of employees of the sponsoring agency to review panels will always present, in the best of circumstances, the appearance of predisposition toward the agency's proposal, if not an actual conflict. On the other hand, requiring all peer reviewers to be independent of the agency

may deprive the panel of certain valuable (non-confidential) insights regarding the agency's thinking at a timely point in the review process and lead to an inefficient review.

The proposal also seems to suggest that it is possible to assemble a large pool of individuals with the necessary expertise and then whittle that pool down to eliminate those who are: 1) independent of the agency; 2) free of real or perceived conflicts of interest, including any financial interest in the matter; and 3) capable of approaching the matter in an open-minded and unbiased manner. While these criteria were no doubt developed with the best of intentions, they are not easily applied and, in any event, simply do not reflect the realities of the world in which we function.⁷ This approach would result in a panel of individuals who are not experts in the

⁷ As stated by Sheldon Krimsky, PhD and L. S. Rothenberg, JD in "Financial Interest and Its Disclosure in Scientific Publications", *JAMA*. 1998; 280:225-226:

An Institute of Medicine [Donaldson MS, Capron AM, eds. *Patient Outcomes Research Teams: Managing Conflict of Interest*. Washington, DC: National Academy Press; 1991:61-62.] report describes 2 competing models for the management of conflicts of interest: the "prohibition" model, which is "based on a presumption against any relationships that might present a conflict," and the "disclosure and peer review" model, which is "based on a presumption for such relationships with a provision for disclosure and review." A demonstration of "sufficient social benefit" (e.g., improved transfer of medical innovations to the bedside, creation of jobs, furtherance of economic development generally, and facilitation of private support of research programs and public universities) can override the prohibition model and outweigh the risk of bias. The disclosure and peer review model, by contrast, "holds that conflicts of interest are unavoidable and that financial conflicts are only the most visible and perhaps the least scientifically dangerous."

Richard Horton, [Horton R. Conflict of interest in clinical research: opprobrium or obsession? *Lancet*. 1997;349:1112-1113.] editor of *The Lancet*, has argued that the case in favor of full disclosure rests on 3 fallacies: (1) scientific writing can be free from common prejudices; (2) financial conflicts of interest are of greater concern than academic, personal, and political rivalries and beliefs; and (3) disclosure can "heal the wound inflicted by financial conflict." An editorial writer in *Nature* suggests that, barring a demonstrated link between such financial interests and a lack of objectivity or other factors that weaken the credibility of a manuscript, disclosure should only be voluntary. [Avoid financial "correctness" [editorial]. *Nature*. 1997;385:469.]

Arguments favoring disclosure echo the conclusion reached by the American Medical Association, Chicago, Ill, that "the best mechanism available to assuage public (and professional) doubts about the propriety of a research arrangement is full disclosure" and that such disclosure "should be made to the journals that publish the results of the research." [Council on Scientific Affairs and Council on Ethical and Judicial Affairs. Conflicts of interest in medical center/industry research relationships. *JAMA*. 1990;263:2790-2793.]

material to be reviewed. We are also concerned that this approach could lead to panels dominated by academics with inadequate real world, hands-on experience and expertise. While the point is overstated as H. L. Menken's Law ("Those who can, do. Those who cannot, teach.")⁸ and our extension of that law ("Those who cannot teach, research."), we believe they reflect a legitimate concern.⁹ Those academics who do have adequate real world experience and expertise are likely to have the same problems satisfying the three criteria listed above as the rest of the private sector.

No Waiver of the Peer Review Requirement for Information Published in the "Standard" Peer Reviewed Journal Is Appropriate

Section 2 of the proposal states that the sponsoring agency need not arrange for a peer review if the information has already been subject to "adequate independent peer review" and then states that "peer review undertaken by a scientific journal may generally be presumed to be adequate", without describing what is meant by a "scientific journal." OMB's August 29, 2003 press release on this initiative refers to "a respected scientific journal." Regardless of how the term peer-reviewed scientific journal is defined, we believe this formulation reflects a fundamental misconception of what is required and fails to implement OMB's clearly stated intent that:

A "peer review", as used in this document for scientific and technical information [which should include economic analyses]

⁸ Bloch, Arthur, Murphy's Law 26th Anniversary Edition, Berkley Publishing, p. 115 (2003).

⁹ It appears that the peer review panel for the draft of OMB's Circular A-4 was limited entirely to individuals associated with academic institutions. We do not believe that all or even the majority of the most qualified individuals for that panel would be found at academic institutions. While they may be better prepared to intellectualize the issues, that is not necessarily the best mechanism for addressing them.

relevant to regulatory policies, is a **scientifically rigorous review and critique of a study's methods, results and findings** by others in the field with requisite training and expertise [emphasis added].

....

The charge should generally frame questions about information quality, assumptions, hypotheses, methods, analytic results and conclusions in the agency's work product.

We respectfully submit that the standard peer review practiced by scientific journals, even the respected journals are wholly inadequate to the task in issue. The review process that a journal article typically undergoes is not designed to be thorough or robust and, as such, should not be relied upon in support of "significant regulatory information". Such reviews do not have the opportunity or authority to examine the data upon which an article is based but serve as a limited screening process designed to increase the likelihood that the authors followed established scientific methods, that their conclusions appear to be supported by the study results, and that the article is within the scope of topics covered by the journal.

A recent study by Jefferson *et. al* concluded that "...there is little empirical evidence to support the use of editorial peer-review as a mechanisms to ensure quality of...research, despite its widespread use and costs."¹⁰ This is not to say that such publications do not support significant regulatory information, but that a study report that has gone through the standard "peer review" practiced by journals has not yet achieved the data quality level required of something that may be relied upon to establish an influential regulatory policy for this country. For example, a study recently published in *JAMA* examined the relationship between journal

¹⁰ Jefferson, T.O., Alderson P., Davidoff F., and Wager, E. Editorial peer-review for improving the quality of reports of biomedical studies. *The Cochrane Library*. Issue 4, 2003. Chichester, UK: John Wiley & Sons.

quality and methodological quality of clinical research articles and found that high citation rates, among other factors, appeared to be predictive of higher methodological quality.¹¹ Finally, the Bulletin should indicate that OMB, with the assistance of outside experts, if necessary, will make the final decision as to whether the information has been adequately peer-reviewed and, if so, whether any modification is necessary.

The appropriate model for this peer review activity is something more akin to EPA's SAB, which is charged with providing EPA with advice and comments on the adequacy of the scientific and technical basis of the proposed regulatory action and any pertinent information in the SAB's possession.. For example, in the cover letter to EPA forwarding the 80 page report of the peer review panel on how EPA should proceed with the revision of its Draft Trichloroethylene Health Risk Assessment, the SAB stated:

The Board notes five key substantive areas for the Agency to address: a) the need to strengthen and expand the use of epidemiology data to update the uncertainty analysis, to incorporate new studies, and to focus on first tier studies and case-control studies that specifically address TCE exposure; b) the need to develop a more formal method for selecting and weighing evidence and communicating those decisions, when information comes from multiple lines of evidence; c) the need for a more detailed explanation for the Agency's treating cancer mode of action in a linear way, even as the Board notes that the Agency had provided clear criteria for the choice of a linear approach; d) the need to explain the derivation of the RfD and RfC study-by-study, endpoint-by-endpoint; e) the need to quantify and provide more explicit justification for the background exposures to be included in uncertainty factors and incorporated in the TCE assessment; and f) the need to be explicit about the assumptions underlying its analyses.

¹¹ Lee, K.P., Schotland, M., Bacchetti, P., and Bero, L.A. Association of journal quality indicators with methodological quality of clinical research articles. *JAMA*, June 5, 2002. Vol. 287, No. 21, pp : 2805 – 2808.

In addition, to strengthen and provide confidence in the Agency's assessment, the Board has identified several needs. There is the need for a summary paragraph in each section describing the Agency position/conclusion and a clear description in each section of the scientific basis for those choices and other alternatives considered. The Agency should develop a new children's chapter to discuss the pharmacokinetic, pharmacodynamic, and risk assessment conclusions in a comprehensive unified chapter focused on children's health. The new children's chapter should offer a model for other draft assessments to follow and would integrate information about specific aspects of risks to children's health as discussed in the other sections of the assessment. And finally, and most importantly, there is a need to enable others to reproduce the calculations and models on which the assessment's conclusions are based.

Therefore, we strongly advise the Agency to reference original papers on key issues, not only review articles, and to provide access to data, documentation, and results of intermediate calculations from which the Agency's results can be recreated.

A quick review of the foregoing illustrates the scope and depth of the required peer review for especially significant regulatory information and demonstrates the impact of applying the principles of effective peer review through a process that goes far beyond the standard peer review performed by any scientific journal.

OMB CIRCULAR A-4 SHOULD BE MODIFIED TO ENSURE IT IS CONSISTENT WITH THIS BULLETIN

Recently-issued OMB Circular A-4 appears to permit a lower standard of review for especially significant regulatory information than that required by the proposed bulletin. While we recognize that Circular A-4 addresses the analysis protocol for all regulatory information and not specifically 'significant regulatory information', we wish to draw your attention to the apparent inconsistency. Appendix D of the Circular states that regulatory analysis "...should rely on peer-reviewed literature, where available, ...". This standard is obviously less robust than a proposed mandatory peer-review requirement.

POTENTIAL BURDEN ON PARTICIPATING PANEL MEMBERS

OMB seeks comment on whether any of the provisions of this proposal would unnecessarily burden participating panel members or discourage qualified panel members from participating in agency peer reviews. The proposed guidelines would provide for disclosure of the identity of the members of the peer review panel and their affiliations. While there may be a concern is that a reviewer's ability to receive grants or funding from governmental agencies or other sources may somehow be jeopardized if he/she submits negative or unpopular comments, we believe the need for full disclosure outweighs that concern.

EFFECTIVE DATE

Given the passage of the Data Quality Act, the issuance of this proposal on August 29, 2003, and the fact that the Data Quality Guidelines have been in effect since October 2002, we support an effective date of January 1, 2004 for this bulletin, and believe it should be applied to all pending initiatives except where its application would impede compliance with a court order or comparable statutory deadline.

CONCLUSION

Adoption and implementation of the proposed bulletin, with appropriate modifications consistent with those advocated by these comments, would force Federal regulatory agencies to responsibly develop and evaluate the information necessary to the making of informed and responsible decisions that will affect the health, welfare, freedom, prosperity and quality of life for this and all future generations. This is a long overdue measure and we commend OMB for bringing about this fundamental change.

Dr. Margo Schwab
December 15, 2003
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LAW OFFICES

Thank you for your consideration of our comments. Should you have any questions, or if we can provide further information, please contact us.

Respectfully submitted,

Lawrence P. Halprin