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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP

cc:
Subject: Public Citizen's Comments on Proposed Bulletin on Peer Review

Dear Dr. Schwab:
Attached and copied into the text below are Public Citizen's comments on the Proposed Bulletin on Peer Review and Information Quality.
Sincerely,
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- Public Citizen's Comments.doc
- Public Citizen Attachment.doc

Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

December 15, 2003

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB Room 10201
725 17th Street, NW
Washington, DC 20503
OMB_peer_review@omb.eop.gov

Re: Proposed Bulletin on Peer Review and Information Quality
68 FR 54023

Dear Dr. Schwab:

Public Citizen is a national non-profit consumer advocacy organization with over 150,000 members. We are writing in response to the September 15, 2003 notice in the Federal Register requesting comments on the Proposed Bulletin on Peer Review and Information Quality [”Proposed Bulletin”] issued by the Office of Information and Regulatory Affairs, Office of Management and Budget [“OMB/OIRA”]. These comments should be read in conjunction with the remarks made at the National Academy of Sciences Workshop[1] [“NAS Workshop”] on November 18, 2003, by Public Citizen Attorney Alan B. Morrison. Because the new procedures would create constraints on regulatory functioning that are unnecessary, improvident and costly, we urge that the Proposed Bulletin be withdrawn.

The essential issue presented by this proposal is not whether peer review should be expanded or improved; it is whether this particular proposal bears the hallmarks of a sincere interest in science or is instead an exercise in regulatory obstructionism. As our detailed comments below demonstrate, in this proposal OMB/OIRA has consistently taken the path that will predictably favor regulated industry and introduce potentially massive costs and delay, thus injecting paralysis by analysis into the regulatory process.

This highly unrealistic proposal would make OMB/OIRA, with its small staff and tiny

[1] “Peer Review Standards for Regulatory Science and Technical Information,” Science, Technology, and Law Program, The National Academies, November 18, 2003.

budget, responsible for the clearance of many hundreds of additional studies and documents, a task which OMB lacks both the staff and expertise to undertake. Moreover, such a task is far beyond OMB/OIRA's proper role. It is no overstatement that strict application of the proposal would bring many ordinary public functions to a grinding halt, including the government's obligation to present public health, environmental and other information on a timely basis.

Second, OMB/OIRA's proposed changes would most likely fail a *de minimus* review under its own standards, as no factual record is presented that could justify such changes. OMB/OIRA failed to identify a single regulatory action in which the lack of peer review, or inadequate peer review, has produced bad science, poor decision-making by agencies, unlawful regulations, or had other adverse effects on the public. Yet even in the absence of any demonstrated need, OMB/OIRA proposes to require significant diversion of public monies and staff effort toward increased use of peer review and, by so doing, to cause incalculable delays in the administrative process. If particular agency decisions have demonstrated a lack of scientific grounding or other competency problem, that problem should be addressed specifically, as a matter on the merits, and not with the broad procedural brush employed in the proposal.

Finally, even a cursory review of the scientific activities of different government agencies reveals that they have different peer review needs. OMB/OIRA lacks authority to implement its program, and moreover, should not be in the business of issuing a one-size-fits-all approach to peer review; instead, such decisions should be delegated to the individual agencies who best know their needs.

I. OMB/OIRA has made no attempt to assess either of the two types of "costs" its proposal would impose on agencies and the public - either in terms of the loss of health, safety and environmental protections that would have been provided by delayed or suppressed agency action or in terms of the use of public funds and staff time.

- *The Creation of Bureaucratic Obstacles to Regulation*

The Proposed Bulletin would apply to "any scientific or technical study (defined as "any research report, data, finding or other analysis") that is relevant to regulatory policy."[2] To the extent the new procedures would be construed as requiring peer review in those cases in which qualified agency staff believe the process will provide no benefit, time spent going through the motions of peer review is time lost to far more appropriate agency activities.

OMB/OIRA's overly broad definition of materials requiring peer review is dubious in the

[2] 68 FR 54027. Although the definition does not mention economic analyses, John D. Graham, Administrator of OMB's Office of Information and Regulatory Affairs, stated at the NAS Workshop that information of this type was intended to be included. At the very least, the definitions must be rewritten so that the same kinds of information that are covered by the data quality guidelines are covered by the Bulletin; otherwise, the peer review requirement would appear to be biased against information designed to protect the public health, and in favor of industry data that opposes new regulations.

extreme. Many agency publications experience a *de facto* and remarkably thorough type of peer review as a part of the notice-and-comment process in rulemaking or less formal, but still highly effective, feedback and comment mechanisms. Many other publications, although they may involve "data," are the result of rather routine analysis by agencies, and not science in the truest sense. OMB/OIRA fails to consider whether peer review by exclusive panels is always, or even usually, preferable to the *public* peer review which all government publications already undergo.

Furthermore, additional mandatory requirements are to be imposed on "especially significant regulatory information," including "formal, independent, external peer review" and an opportunity for public comment before conclusion of the peer review. The definition of "especially significant regulatory information" includes a catch-all category - *i.e.*, anything determined by the OMB/OIRA Administrator to be of significant interagency interest or to be relevant to an Administration policy priority.[3] This could potentially reach <u>any</u> agency information, at the unfettered discretion of the OMB/OIRA Administrator.

The Proposed Bulletin makes no distinction between information used in rulemaking and other agency information. As written, the "additional" requirements of the Proposed Bulletin are supplemental to the existing opportunities for public input mandated by the Administrative Procedure Act,[4] creating the specter of serial freezes to the regulatory process and multiple opportunities for challenge by affected industry when (or perhaps if) a rule is eventually issued.

Viewed together, the absence of any case in which the public has been harmed by current procedures and the likelihood that the procedures will impair agency functioning lead Public Citizen and many others to conclude that decreased regulatory effectiveness is the actual intent of the proposal, and at the very least, the inevitable byproduct of this flawed effort to evaluate the quality of regulatory science. If the intent is not to divert resources and delay rulemaking, how can such complete disregard for the impact of the Proposed Bulletin be explained?

- *The Fiction of "Zero Cost"*

At the NAS Workshop, Administrator Graham presented a chart ascribing "zero cost" to some types of agency peer review, a highly dubious proposition that was disputed by everyone who addressed the point. Even in the unlikely event that a pool of qualified outside scientists could be assembled who would be willing to donate time to performing peer review in the greatly expanded number of situations that would be required under the Proposed Bulletin, there would inevitably be significant costs. There are always costs to develop plans and guidance, to provide mandated reports to OMB/OIRA, to hold required consultations with OMB/OIRA, to identify qualified scientists, to screen

[3] 68 FR 54027. "Especially significant regulatory information" is otherwise defined as significant regulatory information with a possible annual impact of over $100 million that the agency intends to disseminate in support of a major regulatory action.

[4] 5 U.S.C.A. §551, *et seq.*

potential panelists for technical expertise and conflict of interest, to educate panelists in OMB/OIRA's requirements, and to solicit and respond to public comments. To suggest that these functions could be performed at "zero cost" is not serious. Indeed, these are precisely the types of administrative costs that OMB/OIRA is so anxious to document when assessing the costs of proposed regulations to industry.

For other types of peer review, Administrator Graham conceded at the workshop that agency resources will have to be expended. However, OMB/OIRA appears to have made no assessment whatsoever of the amount of funds or staff time required or of the impact on current agency agendas of using existing funds and staff for this purpose. And, of course, there is no promise from OMB that the needed funding will be sought from Congress, let alone any assurance that the Bulletin will not simply create another unfunded mandate that will be paid for through reductions in other agency activities.

II. The Proposed Bulletin contains numerous procedural and substantive flaws and is likely to open agencies to protracted disputation.

The statutory and administrative provisions on which OMB/OIRA bases its Proposed Bulletin do not give it the authority to impose mandatory supplementary steps in the administrative process. Moreover, the Proposed Bulletin is so flawed that its implementation should and can be expected to result in additional legal challenges from both opponents and proponents of agency action. The Proposed Bulletin's deficits include the following:

- *Certain categories of information are arbitrarily excluded from the Proposed Bulletin's coverage.*

The Proposed Bulletin extends a blanket exemption to significant regulatory information that "relates to national defense or foreign affairs" or is disseminated in the course of "a proceeding on a permit application."[5] OMB/OIRA gives no rationale for treating these categories differently. If OMB/OIRA genuinely believed that the requirements of the Proposed Bulletin would enhance the quality of scientific and technical information used by agencies, it is difficult to understand on what basis information used in national defense would be excluded, particularly given the huge costs and tremendous harm that has and can occur with the technological and scientific mistakes that are well documented in defense work. Similarly, although "permit application" is not defined in the Proposed Bulletin, private sector activities for which official permission is a prerequisite often have significant health and safety implications.

Many agencies issue "permits," including the Nuclear Regulatory Commission, the Environmental Protection Agency ["EPA"], the Departments of Interior and Agriculture, as well as the Army Corps of Engineers, to name just a few. The drug and medical device approval system of the Food and Drug Administration ["FDA"] could be characterized as a "permit" process. But the science in support of "permit applications" of this type is provided mainly by industry. Surely, these decisions should also be made

[5] 68 FR 54027.

on the basis of sound, peer-reviewed science. Is OMB/OIRA proposing to exempt science from peer review when industry wants the government to act on its behalf but require peer review when industry does not want the government to be able to impose a particular regulatory requirement upon it? It certainly appears that this is the case.

- *The conflict of interest provisions lack transparency and are so one-sided as to betray the pro-industry bias of the Proposed Bulletin.*

In the section of the Proposed Bulletin that deals with "especially significant regulatory information," agencies are directed to consider the following factors in selecting peer reviewers: Whether the potential panelist (1) has any financial interest in the matter at issue; (2) has advocated a position on the specific matter at issue; (3) is currently receiving or seeking substantial funding from the agency (either directly or through another entity such as a university); or (4) has conducted multiple reviews, or review of the specific matter, for the agency. Incredibly, receipt of substantial funding from regulated industry is not a listed factor, and yet is the most patently obvious conflict.

OMB/OIRA attempts to justify its one-sidedness by claiming that "while some federal agencies are becoming more sensitive to peer reviewers' financial ties to private interests, most have not been as focused on reviewers' ties to the agency itself."[6] However, even an agency with extensive experience using peer review, EPA, was faulted by the General Accounting Office ["GAO"] in a 2001 report for failing to ensure the independence and balance of Science Advisory Board panels, as evidenced by, *inter alia*, the presence of two panelists who owned stock in companies that manufacture or distribute 1,3-Butadiene on a panel reviewing EPA's risk assessment of 1,3-Butadiene; and the presence of a panelist who had received substantial fees from a tobacco company and a research organization funded by the tobacco industry on a panel reviewing EPA's draft revised guidelines for assessing the health risks of carcinogens.[7]

As many persons in attendance at the NAS Workshop pointed out, application of the factors enumerated in the Proposed Bulletin could lead to the exclusion from peer review panels of both academic scientists whose universities receive agency funding and scientists employed by public interest organizations who have expressed opinions on the subject under review, while allowing the appointment of scientists who are employed by, or receive funding from, industries affected by the specific matter at issue.

Moreover, the conflict of interest provisions fail to meet minimal standards of transparency because sources of possible bias are to be disclosed only to the agency and not to the public, allowing agencies to secretly discount or make exception for many conflicts.[8]

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[6] 68 FR 54025.

[7] GAO, "EPA's Science Advisory Board Panels, Improved Policies and Procedures Needed to Ensure Independence and Balance," GAO-01-536, June 2001, pages 8 and 10.

[8] Potential public disclosure of a panelist's sources of personal and institutional funding is mentioned in the Proposed Bulletin only as one of several factors agencies are directed to "address" in their own guidelines. Section 4.b.; 68 FR 54028. See, by contrast, the FDA's Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory

- *The Proposed Bulletin creates a number of new opportunities for challenge that could fuel attempts to delay or derail agency action at the conclusion of the process.*

If an agency relies on "especially significant regulatory information," it is required to certify in the administrative record that it has complied with the Proposed Bulletin and with the Data Quality Act and to provide an explanation of the means of compliance. While this provision can be read as an open invitation for data quality "correction requests," OMB/OIRA cites no authority for this requirement.

In the case of "especially significant regulatory information," if the peer reviewers are expected to identify scientific uncertainties, they are to be asked to step outside their review function and "suggest ways to reduce or eliminate those uncertainties,"[9] thus laying the groundwork for a challenge to the adequacy of the data. It requires no stretch of the imagination to envision the attacks that will be launched if an agency attempts to act unless each of the outside panelists' suggestions has been fully implemented. The agency can expect to be charged with acting, at best, prematurely and, at worst, on the basis of "unsound science."

- *OMB/OIRA continues to extend its control over agency functioning.*

There are a number of provisions in the proposed procedures that would prevent agencies from acting without OMB/OIRA approval. For example, in the case of "especially significant regulatory information,"[10] agencies "shall" consult with OMB/OIRA (and the Office of Science and Technology Policy) concerning the sufficiency of their planned policies and, "upon request" (though whose request is not specified), "should" discuss the sufficiency of the planned review of specific documents with OMB/OIRA.[11] OMB/OIRA then suggests that an agency's failure to comply with these requirements is challengeable under the Data Quality Act.

This aspect of the proposal fails to reflect any concern for the realistic probability that OMB/OIRA will become a bottleneck blocking agencies' fulfillment of their statutory mandates and public information functions. It is unauthorized by Congress to play such a role. OMB/OIRA, while certainly ambitious, also utterly lacks the expertise or staff to address the incredible volume of information likely to be sent in its direction, and thus will only hinder the already difficult job of publishing important and timely research and completing the issuance of health, safety and environmental standards and other regulations.

Committees, which, though imperfect, does require public disclosure of panel members' financial conflicts. 67 FR 6545, February 12, 2002.

[9] Section 3; 68 FR 54028.

[10] As noted above, the category "especially significant regulatory information" can include any significant regulatory information, at the sole discretion of the OMB/OIRA Administrator.

[11] Section 3; 68 FR 54028.

Furthermore, even before the first annual reports are due under the Data Quality Act, OMB/OIRA is using the occasion of this Proposed Bulletin to impose still more data quality requirements that have nothing to do with peer review. Agencies are required to notify OMB/OIRA, or publicly post, all "non-frivolous"[12] correction requests and, upon the request of OMB/OIRA, are prevented from responding to a challenge until OMB/OIRA concludes its "consultation."[13] Again, OMB/OIRA fails to cite any authority and apparently fails to consider its own practical and inherent limitations.

- *OMB/OIRA's invitation to agencies to attempt to circumvent the Federal Advisory Committee Act [FACA] is misguided and likely to be unavailing.*

OMB/OIRA directs agencies to "assess" the treatment of peer review panels under FACA, points out that agencies may retain "outside firms" to oversee the process, and suggests that panels overseen by such firms would not be governed by FACA under the precedent of *Byrd v. EPA*, 174 F.3d 239 (D.C. Cir. 1999).[14] OMB/OIRA has misread the ruling of the *Byrd* case, which was premised on a finding that EPA had not "utilized" an advisory panel in the sense of that term that would bring it within the purview of FACA. However, the very mandatory nature of the procedures set out in the Proposed Bulletin supplies the element of "management or control" that establishes "utilization." Indeed, if an agency enters a contract with a third party, the sole purpose of which is to set up a group to review a study collectively, there is a strong argument that the agency has "established" that committee, which would also bring it under FACA. Moreover, any attempt by agencies to avoid the transparency and balance requirements of FACA will only further impair the independence and effectiveness of peer review panels and undermine the notion that better science, subject to full transparency, is the goal of the Bulletin.

- *There are a number of vague and undefined provisions that remain to be interpreted.*

In Section 2 of the Proposed Bulletin, which deals with other than "especially significant regulatory information," information that has already been subjected to adequate peer review is exempt from the new requirements. The Proposed Bulletin expressly creates a presumption in favor of the adequacy of peer review by a scientific journal. However, this presumption is rebuttable "based on a persuasive showing in a particular instance."[15] OMB/OIRA cites no specific criteria or procedures for evaluating a challenge to information that has undergone journal peer review and provides no guidance as to what it will find "persuasive" and by whom and at what stage such challenges can be made.

At the NAS Workshop, several questioners pointed out an internal inconsistency in the

[12] Agencies have seven days to decide whether a correction request is "non-frivolous," giving them the choice of posting - with the risk that they will be precluded from later labeling a request "frivolous;" or not posting - with the risk that their classification of a request as "frivolous" will itself be the subject of a "correction request."
[13] Section 7; 68 FR 54029.
[14] Section 4.a.; 68 FR 54028.
[15] 68 FR 54027.

Proposed Bulletin. Public comments on what we understand to be the draft regulatory study are to be provided to the peer reviewers for their consideration. However, if the peer review established by the Proposed Bulletin is a pre-dissemination requirement, what is the status of information disseminated for public comment prior to the conclusion of the peer review?

- *Centralization of peer review would neither enhance the quality of information nor increase public confidence in the process.*

OMB/OIRA requests comment on the advisability of centralizing agency peer review in a body that would select the reviewers or supervise the process. One of the more striking elements of the NAS Workshop was the widespread support for diversity and flexibility in the peer review process. Panelists and audience members alike described the benefits of adapting peer review to the particular circumstances and needs of the research at hand. Centralization of the function would lead in the opposite direction and widen even further the already too great gulf between oversight and control of information and the work of the agencies authorized by law to act on the information to promote public welfare.

III. The Proposed Bulletin attempts to blur the distinction between research science and regulatory science and ends up with a process suited to neither purpose.

OMB/OIRA begins the "Background" section of the Proposed Bulletin by referring to the role of peer review in scientific research, noting that "academic and scientific communities have withheld acknowledgement of scientific studies that have not been subject to rigorous independent peer review."[16]

However, as outlined by Donald Kennedy, Editor in Chief of *Science*,[17] at the NAS Workshop, the methods used by a scientific journal in determining whether to place its imprimatur on an article differ markedly from the type of peer review prescribed for "especially significant information" in the Proposed Bulletin. The scientific journal initially screens articles submitted to it internally and rejects approximately 50% of them. Articles that survive this process are sent out to two or three qualified scientists who give opinions on the basis of their own expertise. Journal reviewers operate at an Olympian remove. Their identities are not revealed to the authors and neither their identities nor their opinions are made public. Certain of their comments are withheld from the authors and provided only to the journal editors, who then decide whether to accept or reject the articles or request revisions based on the reviewers' comments.

By contrast, external peer review panel members for "especially significant regulatory information" under the Proposed Bulletin are to be constrained to follow a path charted by OMB/OIRA. Panelists are to be "ask[ed] to apply the standards of OMB's Information-Quality Guidelines and the agency's own information quality guidelines;" they "shall be informed of the reproducibility and other quality guidelines issued by

[16] 68 FR 54024.
[17] Dr. Kennedy is also Co-chair of the NAS Science, Technology, and Law Program.

OMB and federal agencies under the Information Quality Act;" and "should be briefed on the content of OMB's guidelines for regulatory analysis."[18] It is almost as if the purpose of the review is to have panelists police compliance with OMB/OIRA's guidelines rather than bring their own expertise to bear on the matter.

Moreover, it is instructive to consider the concept of rejecting or "withholding acknowledgement" of scientific studies in the context of regulatory, rather than research, science. Unlike scientific journals, government agencies are charged with the legal duty to promote the public welfare. Where research science is aimed at adding to the body of accepted truths, and journals and/or individual scientists can withhold acknowledgement until a threshold of incontrovertibility is reached, regulatory science is conducted for the purpose of enabling the government to carry out its functions. Agencies must continually assemble and assess information that bears on their regulatory function; it is necessary to their responsibility to determine whether and when to act. For public agencies in democratic societies, "withholding acknowledgement" of information – because it is not conclusive - is simply not an operative concept; neither sound public policy nor the law allows agencies to await scientific certainty before they must act.

In the case of health, safety and environmental regulation, lives literally are at stake, which is the reason that agencies acting in these areas are given authority to act on the best available science and technology rather than absolute certainty.

The disconnect between the control of information envisioned by OMB/OIRA and the use of information in the real world of regulatory activity is most starkly apparent in the waiver provisions of the Proposed Bulletin. In Section 4.c., the decision whether to bypass peer review in order to release information in the event of an emergency is taken away from the heads of health, safety and environmental agencies and given to the Administrator of OMB/OIRA. As the procedures are currently written, permission to notify the public of an imminent health hazard can be withhold by the OMB/OIRA Administrator even if the agency "makes a compelling case" for disclosure.[19] This hobbling of the regulatory agencies has nothing to do with ensuring the quality of scientific or technical information, the claimed purpose of the Proposed Bulletin, and likely violates many agency statutes.

Conclusion

The sole justification put forward by OMB/OIRA for the new procedures is that agency peer review is insufficiently similar to OMB/OIRA's conception of peer review in the scientific community. But the overwhelming majority of the scientific community, as represented at the NAS Workshop, found little benefit and much potential for mischief in

[18] 68 FR 54028.

[19] 68 FR 54028. OMB/OIRA here makes explicit an arrogation of power that it has reportedly already exercised. According to a December 29, 2002 article by Andrew Schneider in the *St. Louis Post-Dispatch*, "White House Office Blocked EPA's Asbestos Plan," OMB/OIRA prevented the EPA from declaring a public health emergency and issuing a national warning about Zonolite insulation, which contains highly carcinogenic asbestos fibers. See, January 8, 2003 letter from Joan Claybrook to Mitchell E. Daniels, Jr., Attachment 1.

the Proposed Bulletin. We repeat our request that the Proposed Bulletin be withdrawn.

If OMB/OIRA is serious about pursuing the idea of peer review guidelines, why hasn't it first funded an independent survey of agency staff, scientific and public interest organizations, universities, and others who participate in peer review in the regulatory context, to determine, among other issues: 1) the current uses of peer review in the various regulatory agencies; 2) the agencies' own perceptions of any deficits in current peer review practices; 3) the expenditure of funds and commitment of human resources that would be required to conduct peer review on such a vast scale; 4) the consequent delay in dissemination of information and development of policies and regulations; and 5) the potential impact of that delay on the health and well-being of the citizenry and the environment. The current proposal is neither workable nor consistent with the many public and agency comments that have pointed out its flaws. In sum, the OMB Peer Review Bulletin is demonstrably inadequate, over-reaching and *ultra vires*, and must be legally revisited as well as peer-reviewed.

Sincerely,

Joan Claybrook
President

Alan B. Morrison
Founder
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Peter Lurie, MD, MPH
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Winifred De Palma
Regulatory Affairs Counsel
Public Citizen's Congress Watch

Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

January 8, 2003

The Honorable Mitchell E. Daniels, Jr.
Director
Office of Management and Budget
Washington, D.C. 20050

Dear Director Daniels:

A recent *St. Louis Post-Dispatch* article, "White House Office Blocked EPA's Asbestos Cleanup Plan," by Pulitzer Prize winning reporter Andrew Schneider (12/29/02, p. A1), alleges that your office thwarted the Environmental Protection Agency's (EPA) plan to declare a public health emergency in Libby, Montana, and alert Americans nationwide regarding the dangers of Zonolite insulation, which contains highly cancerous fibers and is present in 15 to 35 million American homes.

This article – reportedly supported by nine file boxes of information received from the EPA under a Freedom of Information Act request – related the investigation, extensive internal debate, and tough questioning conducted by EPA Administrator Christine Todd Whitman and Marianne Horinko, head of the Superfund Program, prior to their decision to declare a public health emergency regarding Zonolite insulation in Libby on April 5, 2002. The "Libby Declaration" was to be accompanied by a nationwide alert regarding the presence and danger of Zonolite insulation in homes across the nation. The article claims that the EPA's intention to issue both the declaration and accompanying national alert were thwarted by the Office of Management and Budget (OMB) and by OMB's Office of Information and Regulatory Affairs (OIRA), headed by John Graham. When questioned by the reporter, both OMB and OIRA refused to provide an explanation for doing so.

Here are the disturbing facts, as we know them from this article:

- **Millions of households throughout the nation are contaminated with Zonolite.** Memos from the EPA and the Agency for Toxic Substances and Disease Registry repeatedly cite an estimate that between 15 and 35 million homes throughout America are insulated with Zonolite. Government extrapolations and interviews with former W.R. Grace Zonolite salesmen indicate that Zonolite insulation exists in 800,000 homes in Illinois, 700,000 in Michigan, and 380,000 in Missouri.

- **The asbestos in question is far more cancerous than "normal" asbestos.** Dr. Alan Whitehouse, a pulmonologist who has worked with NASA and the Air Force, has demonstrated that tremolite

- (the asbestos fiber found in Zonolite) is "10 times as carcinogenic as chrysotile (the more prevalent form of asbestos), and probably 100 times more likely to produce mesothelioma (a 'fast moving cancer of the lung's lining') than chrysotile." According to the article, the EPA has documented "how even minor disruptions of the material by moving boxes, sweeping the floor or doing repairs in attics can generate asbestos fibers." W.R. Grace, the company that provided the tremolite in Zonolite, has settled hundreds of suits that claimed death or illness from exposure to Zonolite.

- **EPA intended to declare a public health emergency and issue a national warning on Zonolite, but was thwarted by OMB/OIRA's directive from doing so.** EPA Administrator Whitman told her staff to move forward with the emergency declaration for Libby, Montana and national public notification. News releases were written and rewritten, lists of Governors to be contacted and politicians to notify were compiled. The White House acknowledged its active involvement in the issue, and opposed the declaration and public notification. Specifically, the article claims that "it was the White House budget office's Office of Information and Regulatory Affairs that derailed the Libby declaration."

- **OIRA refuses to explain the basis of its decision.** When contacted by the author regarding its role, the White House's Office of Management and Budget (OMB) spokesperson Amy Call referred questions to the EPA. Repeated requests by Mr. Schneider for interviews with you or anyone else involved in OMB's decision were denied. Both OMB and EPA refused Freedom of Information requests by the author for documents to and from OMB concerning the matter.

The allegations in this article deeply trouble Public Citizen. Beside the significant danger posed to the public's health by effectively blocking the EPA Zonolite warning, this incident illustrates the significance of the serious concerns we have raised in recent months and during John Graham's confirmation process regarding the willingness of the Administration to put the interests of industry over public safety and to bully federal agencies into actions contrary to their statutory obligations.

In light of these circumstances it would be best for you to reassure the public by providing an explanation about the following issues:

- Under what authority, if any, was OMB/OIRA acting to intercede in EPA's decision making process and to strongly recommend to EPA that it not issue the emergency declaration and public notification? Neither the emergency declaration nor the public notification appear to be matters subject to OMB/OIRA review under the Paperwork Reduction Act. Nor do they appear to be rulemaking matters, over which OMB/OIRA lacks statutory authority but has been given review powers by E.O. 12866.

- What scientific evidence did OMB/OIRA rely on in recommending to EPA not to make the emergency declaration and public notification? As you have long advocated, decision making on matters of public health should be science-based. Yet OMB/OIRA apparently challenged the scientific conclusions of the expert agency assigned by law to assess risks to public health. Decisions of this magnitude must be made in a manner that ensures transparency and accountability. OMB/OIRA's secret, behind-the-scenes intervention in this matter is especially troubling, and we call on you to make public the basis for OMB/OIRA's objections to notifying the public of this public health danger.

- The article strongly suggests that your office brought pressure to bear upon EPA not to make the emergency declaration and public notification. Do you deny that OMB/OIRA applied pressure to EPA to force it to change its planned course of action?

- Did you or your staff meet or consult with W.R. Grace or other insulation industry officials or representatives regarding this contemplated emergency declaration and public notification? Because in this instance a "rule" was not being contemplated, records of who OMB/OIRA officials met with when determining a course of action are not available. If you did meet, please provide a summary of those meetings, including with whom OMB/OIRA met.

- What role did the Administration's support for legislation to limit the liability of asbestos manufacturers play in OMB/OIRA deliberations on this matter? As you know, asbestos liability likely will be under consideration in Congress this year and news reports have indicated that the administration is trying to determine how to deal with the matter given Vice President Cheney's previous position as CEO at Halliburton, a company that is the subject of a large number asbestos liability claims.

We cannot overstate the gravity of our concern over this matter. Despite EPA's views to the contrary, OMB/OIRA has muzzled the responsible government agency, essentially forcing it to suppress information about a serious cancer problem that poses a risk to millions of American families. Graham's secret role in this decision is the antithesis of transparent, accountable, and responsible government, which he claims to support. We urge the Administration not to hide behind closed doors. Please answer these questions and let the American people know why OMB/OIRA interceded to stop EPA from declaring a public health emergency and warning the nation about the dangers of Zonolite.

More important, we urge you to authorize EPA to issue its intended public notification and discontinue your objections that serve to benefit asbestos companies. As William Ruckelshaus, former EPA Administrator under Presidents Nixon and Reagan, said when he learned of this problem, "Your first obligation is to tell the people living in these homes of the possible danger. They need the information so they can decide what actions are best for their family. What right does the government have to conceal these dangers?"

Sincerely,

Joan Claybrook
President

Frank Clemente
Director, Public Citizen's Congress Watch

cc: John Graham, Adminstrator, Office of Information and Regulatory Affairs