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To: Margo Schwab/OMB/EOP@EOP  
cc: Mabel E. Echols OMB\_Peer\_Review/OMB/EOP@EOP  
Subject: DaimlerChrysler Comments on OMB Peer Review and Information Quality Proposal

Dr. Schwab:

Attached are DaimlerChrysler's comments on OMB's Peer Review and Information Quality Proposal as published in the Federal Register on September 15, 2003, at 54023.

(See attached file: OMB Peer Review RFC 12-15-03.PDF)

Randy Edwards  
DaimlerChrysler Corporation  
Regulatory Affairs

- OMB Peer Review RFC 12-15-03.PDF

# DAIMLERCHRYSLER

December 15, 2003

DaimlerChrysler Corporation

Barry Felrice

Director

Washington Regulatory Affairs

Dr. Margo Schwab  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
725 17<sup>th</sup> Street N.W., Room 10201  
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Dear Dr. Schwab:

Re: DaimlerChrysler Comments on OMB Proposal on Peer Review and Information Quality, Published September 15, 2003 in the Federal Register at 54023

DaimlerChrysler Corporation is pleased to be invited to review and comment on the aforementioned proposal from the Office of Management and Budget. Where the safety and health of Americans and billions of dollars are frequently at stake, we believe that peer review of the foundation work is fundamental to good rulemaking and to the credibility of the regulatory process. DaimlerChrysler strongly supports the use of sound science as the basis for regulatory actions. We appreciate that, when predicting the future as regulatory actions must, that complete certainty is not possible. Nevertheless, given the effects that regulatory actions can have on consumers, the private sector, and the economy in general—including the goals toward which the regulation is aimed—as much certainty as possible for the basis of the action is in the public's interest. Our comments below are not aimed at any specific regulatory agency but are intended solely to help OMB produce guidelines that improve regulatory science. Overall, we believe OMB's Proposed Peer Review Standards for Regulatory Science *would* help to advance the science of regulatory activities. Consequently, DaimlerChrysler supports this effort and believes that OMB has done a thoughtful job of addressing a most difficult issue.

We support this effort because scientific analysis problems have long plagued research institutions in general, including regulatory research institutions, often leading to substantial errors in assessing the consequences—both pro and con—of regulations (e.g. demonstrated need, benefits, cost or root cause). Sometimes these errors may be the result of inadequate science but for the most part are the result of unintended, and unknown, biases that scientists often have. To the extent biases exist that peer review can rectify, we believe they are related to unconscious bias—regulatory inertia, escalation conditions, preexisting bias, temporal discounting, indeterminacy/ambiguity, and need for approval; terms found in the literature on this subject.

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## **DaimlerChrysler Comments on OMB Proposal on Peer Review and Information Quality, December 15, 2003**

Because of the often subjective nature of regulatory research, even the most meticulous and conscientious of researchers can unintentionally introduce errors that result in conclusions that may create a regulation that is less than optimal. This problem may not be amenable to resolution by internal changes within regulatory agencies, because of the nature of the regulatory process. It may only be resolved by external and independent unbiased analyses—such as peer review.

In general, the method chosen for addressing the possibility of preexisting or unconscious bias is the double blind study. However, the complexity and subjective nature of the regulatory process often makes that method intractable; thus, the need for peer review. However, achieving the common goal of improved regulatory science may require fundamental changes to the way regulatory results and conclusions are obtained and the peer review process will have to be effective, independent and rigorous. The process employed will need to embrace practices and procedures that recognize bias in regulatory research. We note that we do not use the term “bias” in a pejorative sense but only in terms of unintended and often unknown “leanings” in a particular direction.

OMB has approached elaborating on biases through a pragmatic delineation: the collection of anecdotal instances and observations of peer review being a critical element in ensuring the reliability of scientific analyses. In this process, OMB has cited numerous examples and testimonials of the value of peer review—all of which appear to be well founded and accurate. Through this process, the guidelines and required aspects of peer review are derived. A second possible approach to justifying and establishing the parameters of peer review is to address the fundamental problems that lead to the need for double blind studies and peer review. These problems are those of unconscious/ preexisting bias which can result in incorrect analyses and results.

As OMB has pointed out, there are environments, factors, and processes in which biases can strongly influence the outcome of a regulatory activity—with the risk of a negative outcome. For example, OMB has pointed out that the proposed peer reviewer should not be from the same institutions that receive funds from the regulatory agency, and that institutions should not use the same peer reviewers repeatedly. This sets guidelines as to how to help to reduce potentially historic and unconscious biases that may exist. The procedures outlined by OMB appear to address most of the areas of preexisting biases. Some of the standard identified areas of preexisting biases that OMB has addressed, and our thoughts on how they may be further addressed, follow.

**ESCALATION:** Without some type of external influence, individuals and organizations may become overly committed to “losing” courses of action; in a sense, “throwing good money after bad.” More than 10 years of research (1,2) on this escalation problem shows that, in many cases, persistence is associated with psychological variables, such as preexisting beliefs or unconscious biases. Cognitive studies show that people may slant data in the direction of their pre-existing beliefs and discredit information that conflicts with their opinions (3). Parallel effects in the escalation area have

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demonstrated that decision-makers tend to make use of positive and exonerating, support of pre-existing beliefs, and discount negative or contradictory data (4). Thus, it appears that once a direction or policy has been established, the accuracy of and inferences from any new data can be affected by past decisions—the data will not stand on its own (5,6). This theory can apply directly to the regulatory process. Once a regulation is established, subsequent data may not have any affect on whether the regulation is changed—it may be difficult for a regulatory agency to accept that any past analysis, no matter the nature of subsequent evidence, was flawed. As a result, “regulatory inertia” can have significant control on the scientific process’ outcomes.

By insuring that peer reviewers are not from the regulatory agency and have no stake in the past regulatory actions, this issue can be addressed. In addition, the guidelines suggest that the reviewers have no financial interest in the matter at issue, have not in recent years advocated a position on the specific matter at issue, and are currently not receiving or seeking substantial funding from the agency. These criteria can also help to address this area.

**INDETERMINCY/AMBIGUITY:** Bias exists wherever and whenever there is the possibility of interpreting information/data/analysis in different ways—people tend to reach decisions controlled by unconscious or preexisting beliefs (or “biases”) whenever ambiguity surrounds a piece of evidence. While it is true that some analysis decisions are cut-and-dried, most others in the regulatory environment require interpretations that use subjective judgments. This is because verification and validation of the estimation procedure used to estimate the response of complex physical systems--such as the human body, the environment, transportation accidents--is impossible. Testing is never complete, experimental along with system identification errors are always unknown, the physical systems evaluated are never closed and test results are always non-unique. One hundred percent confirmation can never be attained due to incomplete access to the physical phenomena. The results can only be evaluated in relative terms, and their predictive value is always open to some degree of uncertainty. In the end, there are often many possible results and final conclusions are therefore somewhat subjective. This problem of ambiguity extends to a wide range of regulatory activity. In the end, benefit analysis, regulatory justification, and regulation effectiveness studies are not absolute science but somewhat of an art, with subjective judgments sprinkled liberally about.

The draft guidelines address issues suggesting that there be independent and qualified peer reviewers with an appropriately broad mandate. In addition, by ensuring that the peer review group receives sufficient information to enable them to understand the data analysis methods, analytic results and conclusions of the regulatory agency, as well as those of interested parties, any biases generated through ambiguity may be minimized.

**APPROVAL:** Research shows that biases may become even stronger when researchers are unknowingly endorsing others’ biased judgment—providing those judgments align with their own—than when they are making original judgments

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themselves (7). A benefit analysis, analysis on the effect of a regulation or justification for a regulation may be an unknown, or known, endorsement of judgments that others in the agency may have already made. If the analysis, benefit, effect or justification represents a position that is inconsistent with the broad goals of the regulatory body, it may place the individual doing the analysis in a negative light, providing a potential conflict of interest. Should this type of situation exist in an organization, then analyses may not be as truly independent as they could be.

The OMB proposal addresses approval by suggesting the peer review process be as independent as possible including financial independence. However, OMB might wish to consider having a group outside the agency conducting the peer review. Independency is probably the most important aspect of the guidelines for the peer-review process.

**TEMPROAL DISCOUNTING:** People tend to be far more responsive to immediate consequences than delayed ones, especially when the delayed outcomes involve uncertainty. Many human “vices”—especially those related to personal health and safety--spring from this reflex. In the same way, regulators may unknowingly and incorrectly value near-term positive regulatory effects more so than longer-term potentially negative effects, especially if the latter are uncertain in their magnitude.

Temporal discounting is a difficult area to address. To some degree it is addressed in the draft guidelines by having the reviewers be as independent as possible and by advocating that the reviewers see alternate analyses from the public comments. However, improvement might be possible by not only ensuring that the peer review group has all the information available with respect to the scientific area under study but additional information that reflects how this information is to be used by the regulatory agency, and the overall goals of the regulatory agency with respect to the area under investigation.

**Conclusion:** We believe the key to improving the scientific foundations of regulatory analysis is a process that follows the philosophy of the double blind study. This means that influence on the scientists which affects any unconscious biases that may exist, should be eliminated or minimized to the extent possible. Consequently, to enhance the science of regulations to come, it is desirable and helpful to regulators to provide independent confirmation, or refutation, via peer review, of their analyses. Independence of the peer-review process will help to minimize biases.

### **Response to Additional Request for Comment:**

With respect to agency employees serving on the peer-review panel: As stated above, independency of the peer-reviewers is crucial to the integrity of the process. Although it is important that the relevant technical, and scientific knowledge be applied by the peer reviewers, if there is not independency those skills may not yield the intended results. We recognize the dilemma this results in for regulatory agencies and have no firm

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guidance to resolve it. However, we do offer the observation that we believe it is not always necessary to find an expert in the exact field; rather, an expert in a related field with a sound, broad fundamental scientific knowledge, can have sufficient technical background to review the subject matter with adequate common sense, technical and scientific skills while maintaining independency. OMB's concern of inability to find qualified independent experts may therefore not be an issue in all cases.

One additional comment: The scope of peer review and the effort required from the qualified scientists might be beyond the extent to which the scientists would be willing to donate their time. To address this issue, a procedure of compensation might need to be set-up to support the system.

We hope these comments are helpful. Please contact Guy Nusholtz, at 248-576-5622, if you desire clarification on these suggestions.

Respectfully,



Barry Felice  
Director, Washington Regulatory Affairs

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