



James P. Vondale, Director
Automotive Safety Office
Environmental & Safety Engineering

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VIA FACSIMILE TO (202) 395-7245

John D. Graham, Ph.D.
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
c/o Dr. Margo Schwab
725 17th Street, N.W.
New Executive Office Building, Room 10201
Washington, D.C. 20503

Dear Dr. Graham,

Ford Motor Company ("Ford") appreciates the opportunity you have provided for public comment on the Office of Management and Budget's (OMB) proposed bulletin on peer review and information quality. Ford strongly supports the concept and use of peer review of scientific and related studies. In particular, government agencies' decisions on regulatory issues need to be based on sound assessments of benefits, costs, and other related issues. Independent, objective peer reviews of agencies' studies and analyses can enhance the quality of such work, and, thus, enhance the quality of regulatory decision making, leading to increased benefits to the American public.

Ford offers the following specific comments on OMB's draft bulletin:

Scope of Applicability – Section 1 of the draft bulletin defines "regulatory information" as "any scientific or technical study that is relevant to regulatory policy. Information is relevant to regulatory policy if it might be used by local, state, regional, federal, and/or international regulatory bodies." Ford believes this definition should be broadened to include information that may significantly affect private sector, as well as public sector, decision making. In many cases, Federal agency studies may significantly affect private sector behavior, even if these studies ultimately are not used for regulatory purposes. For example, statistical analyses performed by the National Highway Traffic Safety Administration (NHTSA) of real-world crash statistics for 15-passenger vans have resulted in some colleges and universities banning or restricting the use of 15-passenger vans, and some insurance companies refusing to cover these vehicles, even though a more in-depth analysis of the crash data demonstrates that these vehicles are as safe as, or safer than, substitute vehicles. These studies have not led to government regulatory action, yet they are substantially affecting private sector decision-making. In addition, as a consequence of private sector misinterpretation of these studies, NHTSA has had to repeatedly state publicly that 15-passenger vans are not unsafe. An objective, independent, peer review of these studies prior to their completion could have averted these problems in the first place.



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Reviewer Independence and Scope of Review – Ford strongly supports the use of external reviewers, who are truly independent of the agencies. The company believes the bulletin should clearly discourage the use of agency employees for peer review, but should nevertheless encourage agencies to adopt internal quality control standards that may include intra-agency review in addition to external peer review. Ford also supports the concept of rotating peer reviewers, to assure fresh perspectives on agency work and to address the perception that agencies are choosing peer reviewers with which they are most comfortable. In addition, Ford concurs with OMB's view that peer reviewers should be charged by agencies to look at studies as a whole, rather than being limited by the agency to examining narrow issues. For example, in the case of NHTSA's analysis of crash data involving 15-passenger vans, the agency's narrow statistical analysis was basically correct and would have been confirmed by peer reviewers asked to review just that analysis. But NHTSA's conclusions were misleading because the analysis failed to consider important questions, such as whether the findings were unique to 15-passenger vans and the causes of the accidents reflected in the data. For peer review to be meaningful, the reviewers must be able to ask these types of probing questions, which may not be apparent from the face of an agency's paper. In many instances, therefore, the peer review should examine comments from affected entities in addition to the agency draft.

Ford believes OMB should consider encouraging agencies to use an independent organization, such as the National Research Council, to develop and select individual peer reviewers or panels of peer reviewers. We have concerns about agencies continually needing to "reinvent the wheel" if they need to establish an individual peer review mechanism for each instance of significant regulatory information. If an agency needs to establish an individual review mechanism for each study, it is likely to unduly prolong the regulatory process. OMB should consider encouraging multiple regulatory agencies to work together to establish a common agreement with an independent organization to organize and perform peer reviews.

Section 4(b) of the proposed bulletin says, "Agencies should have specific guidelines as to what entanglements with agencies or affected businesses are so significant as to preclude an individual's participation as a peer reviewer." Ford believes that OMB should consider either developing model guidelines or selecting one particular agency's guidelines as a model, to avoid a patchwork of differing and inconsistent agency guidelines in this area.

Process Transparency and Public Participation – Ford believes that peer reviewers need to have access to public comments on an agency study and the public should have access to, and be able to comment on, peer reviewer comments on an agency study. To enhance public trust in the peer review process and to ensure agency accountability, a rulemaking's administrative record needs to include the document in its original form, peer reviewers' comments, subsequent agency changes to documents, and documented reasons for the agency not adopting peer reviewers' comments. In general, for regulatory decision-making that involves the typical notice and public comment process before a final decision, Ford believes that opportunity for public comment on peer reviewer comments should be provided at the notice of proposed rulemaking (NPRM) stage. Peer reviewers should develop a draft report that the agency would release concurrently with an NPRM and a final peer review report should be issued simultaneously with a final rule. For agency studies that are not tied to a particular regulatory action, a similar opportunity for public comment also should be mandated by OMB.

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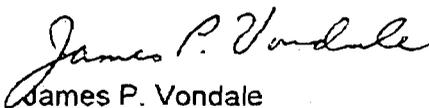
OMB also should consider mandating a minimum 90-day public comment period on agency studies and draft peer reviewer comments. The complexity of many agency analyses, which may have been under development for a year or more, preclude adequate opportunity for thorough public review in the 30- to 60-day comment periods often provided on agency proposals.

Ford strongly supports proposed Section 6, which would mandate an annual report by each agency on existing, ongoing, or contemplated studies that might constitute or support significant regulatory information the agency intends to disseminate in the upcoming year. We believe that agencies should be required to publish this report in the Federal Register for public comment. In addition, Ford believes agencies should be required to identify in this report forthcoming studies the agency believes do not constitute or support significant regulatory information, so that the public can comment as to whether they should be covered by the peer review process.

Timeliness – Ford believes that OMB should structure its final bulletin in a form that encourages agencies to integrate peer reviews into their regulatory processes without extending rulemaking time frames. This could be accomplished, for example, by agencies providing peer reviewers with copies of their studies in early-draft stages, when these studies may still be undergoing internal agency review. To the extent feasible, agencies should be encouraged to have peer reviews performed in parallel with existing steps in the rulemaking process to avoid rulemaking delays. Ford is particularly concerned that agencies faced with Congressionally- or judicially-mandated rulemaking deadlines may feel they do not have the time for peer reviews. Ford believes that such rulemakings have a particular need to be based on good, peer-reviewed science, so that Congress or the judicial branch are fully aware of the costs, benefits, and other impacts of mandated rulemaking deadlines.

Thank you again for this opportunity for public comment on this important issue.

Sincerely,



James P. Vondale
Office phone: (313) 845-4320
Email address: jvondale@ford.com