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* Nobel Laureate

December 12, 2003

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

Dear Dr. Schwab:

I am concerned that the Office of Management and Budget's proposal to use of peer review in the regulatory process, detailed in the Federal Register 2003; 68(178):54023-54029 is unnecessary. As proposed, it could interfere with and confuse the already difficult task Agencies face in developing technically sound regulations in a timely way.

I see the following problems with the proposal:

- The proposed system actually exacerbates the problem of reviewer conflict of interest and bias. As written, anyone who has received funding from the agency under review—that is, someone likely expert in the field—would be excluded from the peer review process, while individuals from affected *industries* would be allowed to serve as peer reviewers. Further, merely using panelists with opposite “bias” does not lead to balanced, meaningful reviews if panelists are not also experts in their field.
- While the scientists and engineers we represent are occasionally unhappy with the outcome of regulatory decisions, we have no evidence, and the OMB proposal does not provide any additional evidence, that the review process established by the agencies currently fails to consider the views of the scientific community.
- I am concerned, however, that increasing restrictions on the information from federal agencies makes review and evaluation of regulatory decisions by outside experts increasingly difficult. I would welcome an OMB decision to ensure that whatever information is needed for a full public review of any proposed regulation is available in a timely way.
- I am concerned that the proposed system will slow the process of completing new regulations without improving their quality. Absent the addition of new

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staffs and budgets, this proposal will either slow rulemaking or reduce the quality.

- The new rules are likely to provide new targets for litigation by anyone unhappy with regulatory decisions. This will further stress existing staff and resources and slow the process of putting needed regulations in place.

I urge you to withdraw the peer review proposal and enlist the assistance of the National Academies, the National Science Foundation, and other organizations with expertise in scientific peer review to formulate a system that would lead to genuine improvements in the regulatory process.

Sincerely,

A handwritten signature in black ink that reads "Henry Kelly". The signature is written in a cursive, flowing style with a long horizontal stroke at the end.

Henry Kelly, Ph.D.
President