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Via email and fax

Office of Information and Regulatory Affairs
Office of Management and Budget
Attn: Mabel Echols
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Re: Request for comments on E.O. 12866; the need for OMB/OIRA's to continue to coordinate inter-agency review of scientific assessments likely to be used in regulations

The development of a regulatory proposal often begins with a scientific assessment in one of the many agencies with a scientific focus -- for example, HHS, EPA, NOAA, DOD/COE, DHS/ONL, DOI, USDA, DOT, CPSC, DOL/OSHA, or NRC. Such a scientific assessment can also have substantial impacts on government and private resources without ever becoming the basis for a federal regulation, through impacts on Superfund cleanups, State environmental standards, and international agreements.

Because scientific assessments underlie so many government operations and regulations, scientific expertise is widely distributed throughout federal agencies, not only in their headquarters offices, but in their research facilities. For example, EPA, HHS, DOE, DOD, NIST, and USDA all operate separate laboratory research facilities, and many of the federal laboratories are organized into the DHS Office of National Laboratories and the Federal Laboratory Consortium for Technology Transfer. It would be a waste not to utilize this distributed agency expertise when one agency conducts a scientific assessment involving science issues to which other agencies' scientists could contribute.

Because agency scientific assessments, as opposed to original research, are usually conducted for the purpose of providing input into policy and regulatory decisions, such

assessments must be conducted and presented in a way that will provide the type of input needed for those policy and regulatory decisions; therefore they cannot be conducted in complete isolation from policy concerns. Science must be kept objective and separate from policy; but it cannot be isolated from policy. Agency scientific assessments must address policy-relevant questions such as feasible alternatives and comparative benefits, the level of scientific uncertainty, and the feasibility and timeliness of new or ongoing research that would fill gaps in current knowledge.

To coordinate this distributed scientific expertise, and to ensure that scientific assessments are both objective and address the right policy-relevant questions, a federal coordinating entity is necessary. OMB's and OIRA's program and regulatory staff have the broad knowledge of agency programs and personnel needed to coordinate expert input into scientific assessments, while also maintaining a perspective of the policy questions that need to be addressed.

The White House Office of Science and Technology Policy ("OSTP") does not appear to be a practical alternative to OMB leadership in these matters. OSTP complements OMB in providing advice to the President, and implementing his policies, and has its own Congressional mandate; however, OSTP has a smaller staff than OMB and is more focused on basic research and international science cooperation, while OMB has more expertise on regulatory science practices and issues, the regulatory process and its requirements, and the full array of agency programs. OMB has very broad information oversight mandates from Congress, while OSTP has Congressional mandates focused more on basic science and R&D.

Some comments on E.O. 12866 have suggested formation of a new entity to provide advice to OMB/OIRA on scientific issues involved in regulations. It is not clear that a new independent entity is needed, and it is likely that insertion of a new entity into the scientific assessment and regulatory review process would result in new delays.

Regardless of the organizational structure for reviewing scientific input into regulatory and programmatic issues, it is clear that the principle currently enunciated in E.O. 12866 that

each agency "shall base its decisions on the best reasonably obtainable scientific . . . information . . " is manifestly sound and should be retained, and OMB should have a lead role in ensuring that principle is followed. How that principle is best addressed in the case of individual regulations or scientific assessments likely to lead to regulations is for the most part best left to OMB/OIRA; but to expedite consideration of regulatory issues, OMB coordination of inter-agency review of scientific assessments should begin as early as possible when it appears that a scientific assessment might lead to the development of a regulation.

To summarize: (1) OMB/OIRA should continue to play a central role in coordinating inter-agency expert input and oversight into scientific assessments involved in regulatory proposals, or that are likely to lead to regulatory proposals; and (2) such coordination of review should begin as soon as possible in the development of scientific assessments that are likely to lead to regulatory proposals in order to ensure that an assessment utilizes the best reasonably obtainable scientific information and focuses on issues that will be addressed during regulatory review.

Thank you for this opportunity to comment.

Respectfully,

William G. Kelly, Jr.