

are not independent of the agencies, or are not perceived to be independent. Simply put, the agency proposing or supporting a regulation or study may not always be the best entity to commission or supervise its own peer review. Nonetheless, some agencies sometimes use their own employees to do peer reviews—a practice forbidden by other agencies' peer review manuals. See, e.g., Agency for Toxic Substances & Disease Registry Peer Review Policy (Mar. 1, 1996) (peer review is "by outside (not ATSDR) expert scientists"); DOJ, Office of Juvenile Justice & Delinquency Prevention, Peer Review Guideline at 1 ("Peer review is * * * by experts from outside the Department"). As the National Academies' National Research Council has explained:

External experts often can be more open, frank, and challenging to the status quo than internal reviewers, who may feel constrained by organizational concerns. Evaluation by external reviewers thus can enhance the credibility of the peer review process by avoiding both the reality and the appearance of conflict of interest.

Peer Review in Environmental Technology Development Programs: The Department of Energy's Office of Science and Technology 3 (1998) ("NRC Report").

The American Geophysical Union has likewise recognized that "real or perceived conflicts of interest" include the review of papers "from those in the same institution." AGU, Guidelines to Publication of Geophysical Research (Oct. 2000). Congress did the same in the Superfund legislation by providing that reviewers should not have "institutional ties with any person involved in the conduct of the study or research under review." 42 U.S.C. 9604(i)(13).

When an agency does initiate a program to select outside peer reviewers for regulatory science, it sometimes selects the same reviewers for all or nearly all of its peer reviews on a particular topic. While this may be appropriate in limited circumstances, more often it could lead an observer to conclude that the agency continually selected the peer reviewers because of its comfort with them. This hardly satisfies the purposes and principles underlying independent peer review. Thus, the National Academies' National Research Council has stressed that even "standing panels should have rotating membership terms to ensure that fresh perspectives are regularly replenished." NRC, Scientific Research in Education 138.

It is also important to understand the relationship of the peer reviewers with the agency, including their funding

history. A peer reviewer who is financially dependent on the agency, or at least hopes to profit financially from other dealings with the agency, may not always be completely independent, or appear truly independent. One agency's Inspector General has encouraged the agency to do a better job of "consistently inquir[ing] whether peer review candidates have any financial relationship with [the agency]." EPA OIG Report No. 1999-P-217, at 10 (1999). Medical journals have similarly recognized the possibility that the receipt of significant funding from an interested entity can lead to bias, or the perception of bias, on the part of a reviewer. See "Financial Associations of Authors," *New England Journal of Medicine*, vol. 346, 1901-02 (2002); Philip Campbell, "Declaration of Financial Interests," *Nature*, vol. 412, 751 (2001). But 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. See, e.g., Food & Drug Administration Guidance on Conflict of Interest for Advisory Committee Members, Consultants & Experts (Feb. 2000); National Institutes of Health Center for Scientific Review, Review Procedures for Scientific Review Group Meetings (Oct. 24, 2002).

In addition to selecting independent and qualified peer reviewers for regulatory science, it is also essential to grant the peer reviewers access to sufficient information and to provide them with an appropriately broad mandate. In the past, some agencies have sought peer review of only narrow questions regarding a particular study or issue. While the scope of peer reviewers' responsibilities will necessarily vary by context, peer reviewers must generally be able to render a meaningful review of the work as a whole. As one agency's peer review handbook explains, a good charge to the peer reviewers is ordinarily one that both "focuses the review by presenting specific questions and concerns" the agency is aware of, and also "invites general comments on the entire work product" so as to ensure that the peer review is not hemmed in by inappropriately narrow questions. EPA Science Policy Council, Peer Review Handbook, § 3.2.1 (2d ed. 2000).

Even when an agency solicits a comprehensive and independent peer review of regulatory science, the results are not always available for public scrutiny or comment. While a non-transparent peer review may be better than no peer review at all, public scrutiny of at least a summary of the

peer reviewers' analyses and conclusions helps to ensure that the peer review process is meaningful and that the agency has fairly considered the peer reviewers' conclusions. Simply put, openness enhances the credibility of the peer review of regulatory science.

For these reasons, the Fish and Wildlife Service and the National Oceanic and Atmospheric Administration have required that peer reviewers' reports and opinions be included in the administrative record for the regulatory action at issue. See Endangered & Threatened Wildlife and Plants: Notice of Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities, 59 FR 34,270 (July 1, 1994). The Agency for Toxic Substances and Disease Registry further requires that final research reports "consider all peer review comments," and that the "reasons for not adopting any peer reviewer's comment should be documented." Agency for Toxic Substances & Disease Registry Peer Review Policy at 5.

While the peer review policies described above promote independent and transparent peer review, experience has shown that they are not always followed by all of the federal agencies, and that actual practice has not always lived up to the ideals underlying the various agencies' manuals. In the National Science and Technology Policy, Organization, and Priorities Act of 1976 (Pub. L. 94-282), Congress called on OSTP to serve as a source of scientific and technological analysis and judgment for the President with respect to major policies, plans, and programs of the Federal Government. Pursuant to the 1976 Act, OSTP has evaluated the scale, quality, and effectiveness of the federal effort in science and technology, and has led interagency efforts to develop and to implement sound science and technology policies.

The President and the Congress have also granted OMB the authority and responsibility to address agency peer review practices. Executive Order 12866, issued in 1993 by President Clinton, specifies in section 1(b)(7) that "[e]ach agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, or other information concerning the need for, and consequences of, the intended regulation." The Executive Order further requires OMB to provide guidance to the agencies regarding regulatory planning. See *id.* section 2(b).

Similarly, the Paperwork Reduction Act requires the Director of OMB to "develop and oversee the implementation of policies, principles, standards, and guidelines to * * *