

Praise, for a Change

This page has occasionally been occupied with complaints about some new thing that the U.S. government is doing about science, so it's a welcome relief when there's something to commend. This time around, we offer praise to two institutions that have been targets of criticism from us: the Office of Management and Budget (OMB) and the Department of Health and Human Services (HHS).

The compliments arise from recent developments in the arcane process by which the government establishes rules based on legislative actions. In some cases, the law may require guidance that instructs, rather than rules that implement requirements. An agency will publish a draft Bulletin in the *Federal Register* and invite public comments; it may take these into account, but the result will be guidelines rather than rules. In cases where a regulation is the objective, a process of Notice and Comment Rulemaking is invoked. The agency proposes how it intends to proceed in a Notice, also published in the *Federal Register*. A period is then allowed for public comment, after which the issuing agency must take all comments into account and then either issue a final rule or allow another period for further comment. Two important government policies are now at midstream in these processes.

The first policy deals with information used by the government to formulate regulations or to provide information to citizens for their own guidance. Under the Information Quality Act, passed in 2002, OMB took the initiative to develop a Bulletin with guidelines for agency peer review to ensure quality. At *Science*, peer review is used to evaluate manuscripts; federal agencies would apply it to scientific information used, for example, in issuing a new air quality regulation or disseminating nutritional information. The first OMB Bulletin about how agencies should conduct peer review, issued in 2003, brought a storm of criticism. Comments pointed out that the draft failed to clarify the need for such a Bulletin, was vague about what information would be covered, and left agencies in doubt about their flexibility to develop review processes suited to particular needs. In the revision of April 2004, most of these concerns were answered, and some difficult questions about the transparency of the review process were resolved. The decision to make public the comments of identified reviewers may be questionable, but the comment period is still open until 28 May 2004 if that or any other draft measure concerns you. John D. Graham, head of the OMB unit responsible for this area, deserves credit for being a good listener.

The second policy involves an area that has long been of concern to the scientific community. Several charges of research misconduct in the biomedical sciences, beginning in the early 1980s, attracted congressional scrutiny and produced agony at the National Institutes of Health (NIH), which had funded the work. NIH established an office with the Orwellian name of the Office of Research Integrity (ORI). The office got off to a limping start, with severely flawed prosecutions of such high-profile cases as that of Theresa Imanishi-Kari, the coauthor of a paper with Nobel laureate David Baltimore. That one ground its way through a comedy of errors until it was finally heard by a three-person appeals court at HHS, which unceremoniously threw out the charges. In the meantime, however, she and Baltimore experienced years of unfair suspicion and harassment; some of it, sadly, from colleagues in the scientific community.

The processes at the ORI that preceded this reversal were notably ad hoc, giving little guidance to prospective defendants about what might happen to them. The procedures didn't experience much improvement until the Office of Science and Technology Policy in the Clinton White House took a hand in the matter. Since then, the ORI has undertaken a major revision, which is now open for comment until 15 June 2004. The new proposed rules not only clarify the definition of research misconduct but also provide a process for appeal to an administrative law judge rather than the three-lawyer panel formerly used. Full rights of legal representation, including cross-examination of witnesses, are retained, and either party may request that the judge appoint a scientist adviser. These changes should increase the confidence of the scientific community in the process, provided that the administrative law judges are taken from the top drawer of candidates. Otherwise, disappointed defendants may find themselves heading for their favorite federal district courthouse.

**We offer praise to
the Office of
Management and
Budget and the
Department of
Health and
Human Services.**

Donald Kennedy
Editor-in-Chief