

Scientific Priorities

The Office of Technology Assessment (OTA) report on federal research funding (1) is probably the most comprehensive and balanced analysis of federal R&D policy produced to date. Joseph Palca's characterization of the report as "heretical" (News & Comment, 29 Mar., p. 1555) underscores the difficulty of creating rational science policy in a culture that views federal funding for R&D as a divine right.

What the OTA report shows most clearly is that the health of the scientific research system is difficult to measure and that it may be influenced by many variables, both extrinsic (such as federal science funding and demographics) and intrinsic (such as research salaries and university publication policy). Palca states that the OTA report dares "to suggest that scientists may be better off now than they were a decade ago." Actually, the report suggests that *science* may be better off—more productive and more robust. The happiness of scientists as individuals was not a part of OTA's analysis.

Even if the federal government decides it is in the business of making scientists happy, the strategy for achieving this goal is by no means clear. For example, R&D funding for the National Institutes of Health (NIH) more than doubled, in real terms, during the 1980s. Nevertheless, there are continuing reports that NIH researchers are more frustrated and more discontent than ever (News & Comment, 1 Feb., p. 508). On the other hand, rapidly increasing federal funding for biomedical research has played a role in keeping the United States preeminent in the development and marketing of advanced biotechnologies. The point is that the happiness of scientists depends on more than just the level of federal funding. Publication pressure, tenure and promotion decisions, peer approval, institutional prestige, and other "quality of life" considerations may not be dictated by federal policy.

From the perspective of the federal government, perhaps the most important point made in the OTA report is that neither Congress nor the Administration has a consistent set of cross-cutting priorities and goals with which they can judge the potential value and ultimate success of federally funded research. Furthermore, OTA emphasizes that, even if these priorities and goals were well established, the data base for evaluating them rigorously does not exist.

This cripples the ability of Congress to forge rational science policy; it also prevents the federal agencies that fund R&D, and the scientists who conduct it, from discussing their programs in terms of explicit performance criteria or national goals.

As heretical as it may be, my view is that Congress must, in consultation with the Administration and the scientific community, set broad, cross-cutting federal R&D goals. Moreover, it must develop criteria for evaluating whether these goals are being achieved in a timely and cost-effective manner. Apparently unrelated programs—such as the Superconducting Super Collider, federally funded individual investigator research, and K-12 science education initiatives—should be evaluated as integrated components of an R&D system that contributes directly to the welfare of the nation, rather than as unrelated programs that are prioritized according to the potency of their individual political constituencies.

The House Committee on Science, Space, and Technology intends soon to begin a systemic and comprehensive long-term evaluation of federal R&D policy in an attempt to formulate rational guidelines for future decision-making. The OTA report represents a crucial first step in this process. If this be heresy, let's make the most of it.

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REFERENCES

1. Office of Technology Assessment, *Federally Funded Research: Decision for a Decade* (Government Printing Office, Washington, DC, 1991).

Biotechnology Regulation

Successful marketing of biotechnology products—especially agricultural ones—will require steady, deliberate efforts to address the health and safety concerns of the consuming public. Henry I. Miller *et al.* (Policy Forum, 26 Oct., p. 490) propose the principle of a "risk-based" paradigm for the oversight of field trials of any organism.

I see that paradigm as "too little too soon." It is "too little" because it minimizes consideration of ecological issues and overvalues the molecular biology approach to risk assessment of introduced organisms. Similarly, it does not take into account the considerable factual uncertainties regarding the effects of genetic modifications and the interaction between novel organisms and

the environment. It is "too soon" because it proposes a decentralized oversight of field trials before there is sufficient field trial data to support the model's assumptions and before the public has shown a willingness to accept self-regulation in the biotechnology industry.

One value of Miller *et al.*'s paradigm is that oversight criteria must be "scientifically defensible." Yet Miller *et al.* appear to limit what is "scientifically defensible" to the molecular biology view of the world as expressed by the National Academy of Sciences (NAS) (4) and the National Research Council (5).

But there is a conflict between molecular biologists and ecologists with respect to several crucial points. The NAS report finds that intergeneric organisms present "no unique hazards" and that "most" engineered organisms will be less fit than their parent organisms (4). Conversely, an Ecological Society of America (ESA) report predicts that "[o]rganisms with novel combinations of traits are more likely to play novel ecological roles" (6, p. 300). The ESA report notes that recent studies indicate that "fitness enhancing functions may inadvertently be transmitted along with an intended genetic alteration during molecular engineering" (6, p. 303). While genetic engineering may be precise, ecologists argue, the pleiotropic effects of even a single gene alteration "may be overlooked in focusing on intended primary effects. . ." (6, p. 302).

From a public policy perspective, the proposal of Miller *et al.* is deficient because it proposes a system for determining the degree of oversight that is neither consistent nor balanced. Miller *et al.* propose that "we" determine the level of concern according to "experts." Who is the "we" that picks these experts? From which areas of expertise? To whom are the experts responsible? Who pays them? Who reviews the review? Who learns about the review?

These are not rhetorical questions. Under the Coordinated Framework for Regulation of Biotechnology and the laws it cites, the government requires persons planning field releases of genetically modified organisms to at least notify the proper agency, either because the organism is a pesticide or a possible plant pest or because it is a "new" organism under the Toxic Substances Control Act. After notification, an agency can review the risks associated with the release, require additional data if needed, establish monitoring and reporting requirements, and invite public review of the proposal.

An alternative to Miller's privatization of the review process is the system envisioned in the Omnibus Biotechnology Act of 1990 (H.R. 5312) introduced in the 101st Congress. This bill proposed a uniform federal

system for the review and authorization of releases into the environment of genetically modified organisms and promoted research into, and collection of data regarding, the effects of such releases. The bill would have provided the Environmental Protection Agency (EPA) and the Department of Agriculture (USDA) with clear legal authority to review the environmental effects of genetically modified organisms before granting permits for their research or commercial use. The bill used the definition of "genetically modified organisms" adopted by the science advisory committees of EPA and USDA (7). Under the bill, the regulations would have expired in 7 years—a sufficient time for more to be learned about the risks involved and for public confidence in the biotechnology industry to be garnered.

Risk-based oversight has always been the goal of regulation, but it cannot be achieved through the decree of "experts." By advocating self-regulation that would limit the data available to regulators and the public, Miller *et al.* propose that we substitute assumptions for data and theory for experience. That is not the way to win the biotechnology race.

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2. S. Shapiro, *Ecology* 17, 1 (1990).
3. S. Krimsky, in *Biotechnology and the Environment, Risk, and Regulation. Proceedings of a Seminar Series Conducted by the American Association for the Advancement of Science for the U.S. Environmental Protection Agency*, A. H. Teich, M. A. Levin, J. H. Pace, Eds. (American Association for the Advancement of Science, Washington, DC, 1985), pp. 159-177; see also, *Survey of State Government Legislation on Biotechnology* (Industrial Biotechnology Association, Washington, DC, fall 1990).
4. National Academy of Sciences, "Introduction of recombinant DNA-engineered organisms into the environment: Key issues" (National Academy Press, Washington, DC, 1987).
5. National Research Council, "Field testing genetically modified organisms: Framework for decisions" (National Academy Press, Washington, DC, 1989).
6. Ecological Society of America, *Ecology* 70, 298 (1989).
7. A genetically modified organism was defined as an organism deliberately modified by the introduction of new genetic material into its genome, or the manipulation (including deletion) of the genetic material in its genome except by traditional methods such as selection of spontaneous mutants, and the breeding of plants, animals and other organisms by artificial insemination, hand pollination, or other methods designated as exceptions by the agencies.

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Westinghouse Winners

I read with great interest a recent piece about the statistics of recent winners of the Westinghouse Science Talent Search (STS) (Briefings, 22 Feb., p. 871). I was a 1969 STS winner. I did not fit the profile then, and I would not fit it now. I went to an ill-equipped Alabama high school (at the time I won, no one in the state could remember an Alabama winner; I do not know whether I was really the first). But I did have an enthusiastic science teacher always there pulling for me. Not only were neither one of my parents identified as "Doctor," neither had even a high school diploma. But they were also there encouraging, supporting. I sincerely believe that wherever an inquisitive, determined student is, there is a way of pursuing science, although it may mean literally knocking on doors in the pursuit. From my experiences as a Peace Corps Volunteer and a AAAS Science and Diplomacy Fellow, and now as a development professional working in India, I am indeed convinced that life is not fair. But science fair judges (and I have done some of this myself) can ferret out the understanding from the merely rote and the true pursuit of science from the merely

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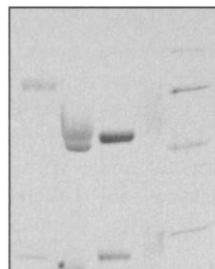
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