LETTERS

Regulation of Biotechnology

Irving S. Johnson's editorial (20 Apr., p. 243) correctly praises the historical performance of the National Institutes of Health (NIH) Recombinant DNA Advisory Committee (RAC). Observers of the DNA discussions over the past decade cannot disagree with his conclusions about the expertise, competence, and service provided by the RAC.

The focus of the current debate, however, is not the RAC's past performance. The question of how to ensure a sufficient, timely, and publicly acceptable review of environmental, safety, and health questions consistent with existing federal statutes is what now needs thoughtful consideration as the products of biotechnology begin to be commercialized.

All of us share Johnson's opinion that the commercialization of biotechnology should not be unduly impeded. Utilizing the RAC as "a single and unified oversight system," as Johnson suggests, will not serve those goals. The implied extension of the RAC's mandate from laboratory research through market approval is neither appropriate, considering existing statutory mandates, nor widely supported.

Existing federal statutes and programs define in many circumstances which agency has the responsibility for review of laboratory research, for review of field or clinical research, and for approval for commercial use. The case of insulin produced by genetically engineered *Escherichia coli* is illustrative. The RAC was involved at the research level, and the Food and Drug Administration (FDA) became involved when commercialization was the primary issue. The product was examined and approved for use by the FDA, like any other drug, on criteria set forth in the Food, Drug and Cosmetic Act, such as clinical trials, product purity, and possible side effects. Similar cases are presented by the Environmental Protection Agency's (EPA's) review for commercial use of pesticides and probably chemicals, and for review by the U.S. Department of Agriculture (USDA) of products within its statutory responsibilities.

In a hearing before my Investigations and Oversight Subcommittee, the question of release into the environment of genetically engineered organisms was examined in great detail. At that hearing, EPA asserted (with the approval of the Office of Management and Budget) jurisdiction under the Toxic Substances Control Act (TSCA) over the release into the environment for *commercial purposes* of genetically engineered organisms, and jurisdiction over genetically engineered pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The RAC did not suggest that it had jurisdiction in this area. While not without question, EPA's interpretation of its TSCA authority has received support in Congress and in the genetic engineering industry.

The question of how to review releases into the environment on a limited scale for research purposes is less clear. For example, FIFRA gives EPA authority to control field-scale tests of pesticides by issuing experimental use permits. However, EPA's regulations generally exempt from permit requirements all experiments under 10 acres. Under TSCA, EPA can regulate chemicals used for research purposes, but it cannot require researchers to notify EPA before use in the laboratory. The parameters of USDA's jurisdiction are even cloudier.

For these reasons the recently released staff report of the Investigations and Oversight Subcommittee recommended that an interagency committee be established to sort out jurisdictional lines and to develop a reasonable road map for industry and the public. In such a process, it may well be that limited field studies could be exempt under appropriate EPA standards or that a RAC review could be used by EPA or others in reaching their decisions. The just-formed Cabinet Council under the direction of the President's Office of Science and Technology Policy could provide the mechanism to sort out the jurisdictional questions, but it will need to act quickly and decisively if it is to be successful in promoting the twin goals of rapid commercialization and appropriate review of public health and environmental considerations. Judge John J. Sirica's recent order (*1*) temporarily enjoining NIH's approval of release into the environment experiments funded by NIH reinforces the need for prompt development of an acceptable regulatory process.

There are several additional reasons why the RAC, as currently organized and constituted, cannot play the role suggested by Johnson. They include the lack of statutory authority to require submissions to the RAC and the lack of authority to make and enforce decisions outside its jurisdiction; by its charter, the RAC is limited to NIH-funded research (although, as Johnson correctly notes, the RAC has been reviewing some indus-

try laboratory research proposals for some time). The RAC also lacks the necessary procedures and the institutional capability to make timely reviews of large numbers of applications. The absence of statutory authority and regulatory procedures may have made the RAC an ideal process for review of laboratory research, as Johnson states. The rationale for an informal approach is less persuasive, however, when other agencies have statutory authority and when the statutes require a delicate balancing of science and public policy, such as the case of a clinical trial, field-scale test, or approval for commercial use.

An additional difficulty in extending RAC's jurisdiction is its focus. The RAC's orientation has been toward laboratory safety, and it has focused on containment procedures. While the RAC's expertise can be expanded to include an ecological perspective, the scope of the RAC's charter and expertise is limited to recombinant DNA, and it has specifically excluded many significant technologies, now or soon to be widely used, such as protoplast fusion and cell fusion.

To implement Johnson's proposal would require (in the light of the existing statutory authority of FDA, EPA, and potentially USDA) legislation to create a new organization that would of necessity need to greatly expand and codify the RAC. Indeed, the resulting agency would not be likely to have the attributes that make the RAC so attractive and well regarded. For all of these reasons, I prefer the approach my subcommittee has recommended.

ALBERT GORE, JR.
Subcommittee on Investigations and Oversight, Committee on Science and Technology, U.S. House of Representatives, Washington, D.C. 20515

References

1. *Foundation on Economic Trends* v. *Margaret M. Heckler* (Dist. Ct. D.C., Civil Action No. 83-2714; J. J. Sirica, *Memorandum and Order* (16 May 1984).

The main thrust of my editorial was that there was a unique benefit to be derived from a single and unified *scientific* oversight system. Because of the universality of recombinant DNA technology, information gained in one research area may be useful in another. The implication that the RAC's mandate should extend "from laboratory research through market approval" was not made nor intended. We agree that such a procedure would be inappropriate. We also agree that public safety is a primary concern. The safety of this research to date has been well documented. Mechanisms to evaluate the products of this research before they become available to the public are also well established under the regulatory authority of the appropriate government agencies. As Gore suggests, the RAC's oversight of genetically engineered human insulin and its approval and regulation by the FDA is a good case study and example of how the existing system has worked effectively from the outset.

However, jurisdiction over the release of genetically engineered organisms to the environment is made by claiming the novel DNA fragment as a chemical. This jurisdiction appears to be aimed at the research and development studies that precede the product. The imposition of unnecessary regulation at the research level would inhibit progress and limit our ability to maintain a competitive international position in biotechnology. It thus would not be in the public interest.

The subcommittee staff report has recommended creation of a special interagency committee to resolve jurisdictional problems. Although this is a sound objective, the Cabinet Council on Natural Resources and Environment has already created a Working Group on Biotechnology at the assistant secretary level. This Council has a charter broad enough to encompass almost all areas of potential regulatory concern or confusion.

I agree that the focus of the current debate is not the RAC's past performance. That has clearly been successful. The issue is more closely bound to environmental release of genetically engineered organisms and plants and statutory authority. Additional study may indeed be required on environmental release of genetically engineered microorganisms and plants; this should occur before any additional regulatory or legislative restrictions are placed on research. I believe these applications are assessable through liaison between the various working groups of the RAC, EPA, and USDA.

Let us maintain the RAC's oversight of the science and not invoke statutory regulation of research. Let us strengthen the liaison between the advisory role of the RAC and the appropriate regulatory agency for the product. I believe this is in the public interest and the best interest of science, biotechnology, and international competition. These various interests are not mutually exclusive.

IRVING S. JOHNSON
Lilly Research Laboratories, Indianapolis, Indiana 46285