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Role of the Recombinant Advisory Committee

Recombinant DNA technology has been developing in an unprecedented scientific–public forum atmosphere in which the transfer of new basic scientific knowledge to the realm of practical commercial use has been extremely rapid. During this time, the scientific community has turned to the National Institutes of Health for help in organizing a Recombinant Advisory Committee (RAC) with the expertise to deal with the scientific and technical questions raised by the research as well as to ensure that the public interest is responsibly represented. In its several years of existence, RAC has established expertise among its members, advisers, and consultants that is unparalleled in its ability to deal with the complex problems in recombinant DNA technology.

The high level of public service rendered by the committee in its consideration of recombinant DNA applications has provided for protection of the public health and the environment. In addition, current public policy which blends scientific oversight through RAC with voluntary adherence by industry and other non-NIH funded parties has fostered technological innovation and U.S. leadership in genetic research. Starting in 1979, RAC reviewed complex industrial submissions in closed sessions, much as NIH continues to do with research grant proposals. This practice has decreased since most recombinant DNA research no longer falls under the guidelines as they have evolved. This diminished requirement for RAC oversight hardly justifies a need for redundant statutory regulation. Furthermore, deemphasizing the contribution of NIH and RAC in oversight and review could create public concern and lead to controls inconsistent with public health needs, scientific progress, and the national interest.

A number of firms and all regulatory agencies and Cabinet-level departments have commented in support of the current activities of RAC; so, too, has the American Society for Microbiology, which probably includes the majority of the individual practitioners of the technology. Too frequently, government and industry become adversaries. RAC's review procedures enable industry, government, and academia to work together effectively and to produce fruitful research without encumbering those involved in the research with a regulatory process that is not needed to preserve public safety. This, too, is in the public and national interest.

If a significant concern is the need for more direct input from the regulatory federal agencies, their nonvoting representatives on the committee could be charged with submitting formal comments on proposals whose implementation would fall within the jurisdiction of their agencies. Duplication of the functions of RAC among several federal agencies has thus far been avoided. The public interest is well served by continuing to have a single review group with the demonstrated capability to deal with the complex but assessable problems presented by recombinant DNA research.

Because of the universal applicability of the basic concepts of recombinant DNA, the activities of RAC should not be confined to the biomedical field. Members to the committee with expertise in areas such as epidemiology and microbial ecology could be added to the committee as needed. To create additional independent committees would simply increase communication difficulties; the organizational redundancy would place further strain on our available intellectual resources. Additional structures would only create delays in a scientific endeavor that requires a highly efficient review process to keep up with the expanding knowledge base as well as to maintain a fragile competitive advantage internationally.

The track record of the RAC clearly shows its usefulness to the scientific community and to the public. Moreover, the universality of recombinant DNA research—like that of the genetic code upon which it is based—argues for a single and unified oversight system. RAC's oversight should continue until that time in the not too distant future when there will be little left for it to oversee.—IRVING S. JOHNSON, *Lilly Research Laboratories, Indianapolis, Indiana 46285*