United States Senate

WASHINGTON, DC 20510
June 26, 1996

Dr. Harold Varmus
Director
National Institutes of Health
9000 Rockville Pike, Building One
Rockville, Maryland 20892

Dear Dr. Varmus:

We are writing to express our concerns over the proposed abolition of the National Institutes of Health (NIH) Recombinant DNA Advisory Committee, known as the RAC.

The tremendous progress in genetic research and the dramatic growth of the biotechnology industry in the past 20 years can be attributed significantly to the rigor, flexibility and credibility of this regulatory structure. Unlike many other developed countries, the United States has been exceptionally successful in maintaining an appropriate balance between academic freedom, commercial requirements and broad social considerations in our pursuit of knowledge and our search for new therapies. It is our concern that abolition of the RAC would be widely perceived both here and abroad as a step backward from this successful balance.

According to your staff, there are two policy reasons for abolishing the RAC. We believe neither of them would outweigh the potential damage caused by such a step. Indeed, there are alternatives which would address your agency's concerns without jeopardizing a vital component of our country's oversight of genetic research.

The first reason cited was the potential of RAC review to delay gene therapy research. Yet only a year ago, the NIH and the Food and Drug Administration (FDA) acted on the recommendations of the National Task Force on AIDS Drug Development and adopted an interagency "consolidated review" process to streamline the review of human gene transfer experiments. The consolidated review process ensures that only novel protocols are referred to the RAC for review. Today, the vast majority of protocols are exempt from RAC review.

Nor are we convinced that institutional review boards (IRBs) are capable of taking on the primary responsibility of reviewing novel gene therapy protocols. In March 1996, the General Accounting Office (GAO) issued a report titled, "Scientific Research: Continued Vigilance Critical to Protecting Human Subjects." The GAO concluded that "workload and other demands" currently "impair IRB oversight" of clinical trials. It is our concern that abolishing the RAC could abruptly add new and unfamiliar responsibilities to the workloads of IRBs across the country.

The second reason cited was a desire to address broad policy issues relating to genetic research which are beyond the RAC's mandate. We have been informed that the RAC is to be replaced by *ad hoc* gene therapy policy conferences and a smaller ORDA advisory group. We applaud your plans for policy conferences, which may address broad issues in an open and participatory manner, but such conferences should not be viewed as a substitute for the RAC's activities. Moreover, if the ORDA advisory group is intended to have a comparable membership to the RAC, it is questionable whether any significant savings or efficiencies will result from abolishing the RAC. Indeed, there is a strong argument to be made that retaining the RAC would ensure the continuity of valuable expertise.

Most significant, in our view, is the importance you have placed on the public accountability and oversight which are integral to the RAC. On April 27, you emphasized in approving the consolidated review process that "public review and access to submission, review and follow-up information is critical to the safe and focused advancement of human gene therapy research." The RAC agreed, voting unanimously to endorse the consolidated review process and emphasizing their collective concern for maintaining the "comprehensive overview [of gene therapy protocols] in a public forum."

Finally, the *ad hoc* review committee you convened to review the RAC's activities concluded, "Review of protocols by the RAC in an open public forum should continue in several areas of concern in which a particular protocol or new technology represents a significant degree of departure from familiar practices... [or] could lead to the formulation of significant new policy." The committee also recommended that "[T]he RAC should continue to provide advice on policy matters revolving around gene therapy and other recombinant DNA issues to the NIH director, individual members of the research community, institutional review boards, and the public."

We urge you to embrace the recommendations of your *ad hoc* review committee, by retaining the RAC and expanding its mandate to address broader policy issues. In light of the remarkable changes anticipated in genetic research, the need for a trusted and proven advisory body to the Director of NIH will only grow in the next century.

Sincerely,