United States Senate
COMMITTEE ON
LABOR AND PUBLIC WELFARE
WASHINGTON, D.C. 20510

July 19, 1976

The President
The White House
Washington, D.C.

Dear Mr. President:

For several years, the biomedical research community has been engaged in an extremely important debate over the safety of certain types of genetic research. The research involves combining genetic material from different organisms. The technology that permits this type of genetic experimentation, called recombinant DNA research, is revolutionary, and holds the promise of enormous benefits in our understanding of disease processes, and could lead us to ways of controlling or treating complex diseases such as cancer and hereditary defects. It could conceivably lead to improved ways of producing such important hormones as insulin, clotting factors, and enzymes important to treatment of many diseases. The technology also has conceivable applications in agriculture and industry. Clearly, it is a research area of enormous promise.

However, recombinant DNA research also entails unknown but potentially enormous risks due to the possibility that micro-organisms with transplanted genes might prove hazardous to human and other forms of life--and might escape from the laboratory. Indeed, scientists engaged in such research declared a voluntary moratorium on recombinant DNA research in 1974 when they foresaw the possibility, for example, of creating in the laboratory self-propagating infectious bacteria that contain genes from cancer-causing viruses. The moratorium was lifted in 1975, but maintained, again by the researchers themselves, for the specific types of experiment which might produce cancer-causing bacteria, raise the resistance of antibiotics of known bacteria, or have other dangerous results.

On June 23rd of this year, the National Institutes of Health issued comprehensive guidelines for recombinant DNA research which specify more stringent safety and containment measures than are currently required or practiced in many areas. They specifically prohibit the most potentially dangerous types of experiments. In addition, the guidelines prohibit the release into the air or water or environment of any of the genetic materials created by the research.

We appreciate the great care NIH has taken, in the formulation of these strict guidelines, in obtaining the best scientific advice as well as advice from experts in law and ethics. Opportunity was also given for the public to comment on the guidelines. The environmental impact assessment of the guidelines currently being prepared by NIH will offer further opportunities for such comment.

The guidelines will be widely discussed and debated with regard to their ultimate adequacy in safeguarding the public, and they will no doubt further evolve and develop during this debate and as our understanding of recombinant DNA advances. Based on the process by which NIH produced the present guidelines, we are confident they are a responsible and major step forward and reflect a sense of social responsibility on the part of the research community and the NIH.

However, we are gravely concerned that these relatively stringent guidelines may not be implemented in all sectors of the domestic and international research communities and that the public will therefore be subjected to undue risks. The National Institutes of Health has the authority to require adherence to the guidelines as a condition of their grants and contracts for research, but they cannot enforce the guidelines with respect to other Federal agencies, with respect to research in the private sector in this country, and with respect to research done in other nations.

In particular, it is clear that recombinant DNA research has great potential in the private sector, such as pharmaceutical manufacture, the oil industry and agricultural products. It is also clear that some elements of the guidelines, such as limitations on the size of experiments, public disclosure, and non-release of materials into the environment, may be contrary to the interest and practice of research in private industry, and may therefore be ignored. In addition, since private sector research will lead to industrial application, guidelines must be extended beyond research into application and production stages. If the NIH guidelines are necessary to protect the public in Federally funded research, it is clear they are necessary for privately funded research and application as well.

Given the high potential risks of this research, it seems imperative that every possible measure be explored for assuring that the NIH guidelines are adhered to in all sectors of the research community. We urge you to implement these guidelines immediately wherever possible by executive directive and/or rulemaking, and to explore every possible mechanism to assure compliance with the guidelines in all sectors of the research community, including the private sector and the international community. If legislation is required to these ends, we urge you to expedite proposals to Congress.

This is an unprecedented issue in the area of biomedical research. It has been likened in importance to the discovery of nuclear fission. In the interest of public safety, and in the interest of permitting this beneficial research to continue with the blessing of a reassured public, we must act expeditiously on these matters.

Sincerely,

Jacob K. Javits
Ranking Minority Member
Committee on Labor and
Public Welfare

Edward M. Kennedy
Chairman
Subcommittee on Health