United States Senate

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

WASHINGTON, D.C. 20510

November 29, 1977

The Honorable Joseph A. Califano, Jr.
Secretary of Health, Education, and Welfare
Department of Health, Education, and Welfare
Washington, D.C. 20201

Dear Mr. Secretary:

The Subcommittee on Science, Technology, and Space recently concluded a series of hearings to examine the range of policy issues concerning recombinant DNA research and the applications of that research. As you know, several legislative solutions have been proposed to control the manner in which DNA research is conducted and to regulate other recombinant DNA activities.

Far less attention has been paid to insuring that the commercial products of recombinant DNA research, including the organisms themselves and any materials that may be produced, are properly controlled to avoid any undue risk to human health or the environment. The problem is particularly important since the potential exists to produce substances from organisms containing recombined DNA in the very near future. For example, Dr. Ronald E. Cape, President of the Cetus Corporation, testified on November 10 that, "Some non-medical products...probably could be made tomorrow." Dr. Cape was specifically referring to industrial enzymes produced from organisms containing recombined DNA. We are thus concerned with far more than a hypothetical problem.

Consequently, it would be very helpful to have your response to the following questions:

1. Section 361 of the Public Health Service Act authorizes the Surgeon General to prevent the introduction, transmission, or spread of communicable diseases. While this section appears to authorize the Surgeon General to control bacteria or other organisms containing recombinant DNA which may result in disease to human beings, it apparently does not relate to damage to the environment or to nonhuman animals that may occur from such organisms. Is this correct? In addition, is my understanding correct that section 361 of the Public Health Service Act is not applicable to the control of the products produced by microbial or other organisms which contain recombinant DNA since these products would not be considered "infectious" or "communicable"?

This should be answered by FDA.

2. Is there any other authority of the Secretary of HEW, or sub-units of the Department, that would be useful in controlling the commercial applications of recombinant DNA, organisms containing recombinant DNA, or materials which may be produced by such organisms? You may omit authorities of the Food and Drug Administration since a separate letter is being sent to the Commissioner of Food and Drugs.

3. As you may know, S. 1217 as reported by the Senate Human Resources Committee, effectively preempts all other federal authorities except the Occupational Safety and Health Act. Thus, with the exception of HEW responsibilities under the Occupational Safety and Health Act, your authority would be severely limited, if not preempted completely. Is it your position that any legislation to control recombinant DNA research should not preempt other federal statutes which may be applicable, not only to the recombinant DNA research, but to the control of commercial products derived therefrom?

So that we may consider your response well in advance of any action on recombinant DNA legislation by the Senate early next year, I would appreciate your response by December 9, 1977. Please contact Mike Brownlee at 224-9351 if you have any questions concerning this request.

With best wishes.

Sincerely yours,

ADLAI E. STEVENSON, Chairman
Subcommittee on Science, Technology, and Space