LETTERS

A Scientist-Senator on Recombinant DNA Research

I wish to express great concern about the broad implications for scientific research in this country if the regulation of recombinant DNA research is expanded in the manner proposed by Senator Edward Kennedy and others (News and Comment, 23 June, p. 1368). As a scientist as well as a Senator, I feel obligated to offer views on the desirability of legislative or executive action which would restrict recombinant DNA research activities more severely than do the current National Institutes of Health (NIH) guidelines.

For the past 2 years Congress has debated the need for and ramifications of the regulation of recombinant DNA activities. This has been an enlightening and worthwhile experience which has assisted Congress and the public in understanding the nature of scientific research and the benefits of a new field of scientific inquiry. After Senator Stevenson and I took the procedural steps necessary to postpone Senate consideration of hastily conceived DNA legislation, we jointly agreed to hold 3 days of oversight hearings on this issue by the science, technology, and space subcommittee during November 1977. These hearings were particularly useful in establishing the scientific basis for calculating the conjectured risk of recombinant DNA research.

The use of recombinant techniques to modify genetic codes in DNA offers great promise for all of mankind through improved understanding of biological processes and varied applications in such fields as medicine, industry, and agriculture. Nevertheless, as with any new field of scientific research, it is impossible at this stage to say with absolute certainty that there is no future hazard from such research. On the other hand, our understanding of natural recombinant processes, evolutionary processes, bacterial genetics and ecology, and pathogenicity all indicate very strongly that there is little to fear. The situation is very similar to the extremely remote possibility of pathogenic organisms being returned to Earth by the Apollo missions. Reasonable safeguards were imposed then without regulatory or legislative action.

There have been recombinant processes occurring in nature since life began, and nature has built-in defenses against

aberrant DNA strains. There have been no illnesses or any other harm associated with recombinant DNA research. However, we cannot ignore the theoretical risks, nor can we ignore the necessity to assure the public that its health and safety and that of the environment are not reduced from that which exists naturally.

The general thrust of testimony from the more than 20 witnesses who appeared at the subcommittee hearings was that, if there is determined to be a need for legislation, it should be directed toward extending the NIH guidelines to nonfederally funded research on recombinant DNA. I generally agree with that conclusion. However, I am concerned that any action more restrictive than the NIH guidelines might initiate unnecessary and unreasonable restrictions on the conduct of basic scientific research in this country.

The initial fears of potential harm raised by concerned scientists led to what many consider to be premature legislative proposals which would, if enacted into law, unduly restrict the conduct of this valuable research. Subsequently, more broadly based analysis and review of advancements in knowledge about recombinant techniques led to a reassessment of the need for formal government regulation. Many of the scientists who originally raised concerns about the safety of such research have since modified their position in light of more complete information and have concluded that there is little, if any, hazard resulting from recombinant DNA research, particularly when performed under the NIH guidelines. Their assessments of the practical benefits from such research continue to be more and more favorable.

Faced with the continuing controversy over the need for legislation regulating recombinant DNA research, Senator Kennedy and others have suggested that it might be preferable to encourage action by the Executive Branch under the presumption that statutory authority exists, specifically Section 361 of the Public Health Service Act (42 U.S. Code 264). This section authorized the Secretary of Health, Education, and Welfare (HEW) to regulate activities related to the spread of "communicable disease." While the delegation of authority to the Secretary under this section is admittedly broad, there are numerous legal uncertainties and scientific inadequacies associated with its application to recombinant DNA research.

HEW Secretary Joseph Califano has

indicated on several occasions that he feels the use of Section 361 to regulate recombinant DNA research is inappropriate and inadequate. On 4 May, I wrote to Secretary Califano asking for his specific legal views on the application of Section 361 to recombinant DNA activities. Although I have yet to receive a response from him, I have acquired information from HEW which strongly suggests that application of Section 361 to recombinant DNA research would be inappropriate and ill-advised.

Some of my personal concerns with Section 361 are as follows:

• Application of Section 361 would serve as a bad precedent for Congress by encouraging unilateral and unauthorized action by the Executive Branch to regulate an area of basic scientific research.

• Section 361 would give the Secretary unbridled discretion to promulgate and enforce regulations controlling basic research without adequate safeguards against regulations which would be unnecessarily restrictive. In an 18 May letter replying to my request for his views on the use of Section 361 for regulating DNA research, Frank Press, director of the Office of Science and Technology Policy, said, "Section 361, of course, was not written to regulate research. Its use in this regard may provide precedent for broad intrusions into the research environment. . . ."

• The Congressional Research Service, responding to my request for an analysis of Section 361, agreed with the conclusions of the Federal Interagency Committee on Recombinant DNA Research that ". . . no single legal authority or combination of authorities currently exist that would clearly reach all research and other uses of recombinant DNA techniques. . . ."

• Under Section 361, there would be no preemption of local law regulating recombinant DNA research, a condition thought to be necessary by many researchers; I am personally uncertain whether preemption is a critical factor.

• Use of Section 361 is likely to lead to much litigation and delay in U.S. research and applications in the recombinant DNA area.

• Section 361 would authorize the Secretary to impose sanctions of up to $1000 in fines and 1 year's imprisonment, which is wholly unreasonable in view of the purely hypothetical nature of the suggested risks of recombinant DNA research.

Precipitous action such as that proposed by my Senate colleagues could seriously damage basic scientific research in this country at a time when the rest of the world is moving rapidly to reap its benefits. Premature regulation of scientific research based on hypothetical risk assessments would have vast implications for all of science and technology. We must move cautiously and, at the same time, fully explore all of the alternatives to and ramifications of such regulation before embarking on this course.

Until we fully understand the implications of stretching Section 361 to include recombinant DNA activities, it would be imprudent to recommend or allow its application. If we are not more far-seeing and more cautious in our use of regulatory authority, we may find the United States becoming irrelevant, first in the advance of science, then in the advance of technology, and, finally, in the advance of the best of human civilization and freedom.

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