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Coalition for Responsible Genetic Research

January 21, 1980

The Honorable Patricia Roberts Harris
Secretary
Department of Health, Education and Welfare
Washington, D.C. 20201

Dear Secretary Harris:

Responding to the request for comment on large-scale recombinant DNA projects, we wish to register the following points:

1. The upper limit of 10 liters of culture of recombinant DNA organisms has prevailed in NIH Recombinant DNA Guidelines since June 23, 1976. Great pressure for exemptions from this limit is being brought to bear by those whose interest lies mainly in the industrial application of this controversial technology.

2. Recent NIH risk assessment experimentation indicates greater hazard than previously thought:

   a. recombinant DNA molecules survive for four days in sewage and the human gut[1]

   b. naked polyoma DNA can cause infection in sterile mice[2]

   c. gene-splice products can cause tumors in experimental animals[3]

3. Risk assessment of large-scale projects has not been pursued although industrial scale-up would involve volume-oriented production of recombinants carrying hormones (insulin, somatostatin, etc.) and other human substances (e.g. interferon). The impact on human and other populations is not known (i.e. anaphylaxis, autoimmune diseases, etc.) and investigation has yet to be initiated.

4. Expanding the volume of production sharply increases the chance for biologic mishap.

Before exemptions from the 10 liter limit can be considered, experimentation to assess the risks of large-scale production must be

1. S. Levy and B. Marshall, "Survival of E. coli Host-Vector Systems in the Human Intestinal Tract", Recombinant DNA Bulletin 2/7/79
2. B. Rosenberg and L. Simon, "Recombinant DNA:Have Recent Experiments Assessed All the Risks?", NATURE, 282, December 20-7, 1979.
3. "Molecular Cloning of Polyoma Virus DNA in Escherichia coli; Oncogenicity Testing in Hamsters", SCIENCE, 205, March 2, 1979.

carried out. Such investigation needs, at minimum, to include the following:

1. assessment of the disposal of large quantities of recombinant organisms into effluent systems

2. pharmacologically-active proteins produced by gene-splicing in large quantities should be adequately pre-tested for effects on humans and the environment.

3. experimentation to include anaerobic bacteria and wild strains of E. coli.

If the data derived from these investigations indicate that, with specified safeguards, it would not be premature to proceed, then the following should be included among those requirements for projects exceeding the 10 liter limit:

1. sufficient evidence to demonstrate that the subjects for cloning would not be harmful

2. prohibition of release of recombinant organisms into the environment (drains, effluent, waste, etc.) without meticulous testing to ensure that all organisms are inactivated

3. ongoing health surveillance and maintenance of health records of employees

It seems to us patently clear that protection of the public health requires that industry comply with NIH regulations. Historically, industrial self-policing has never worked. It is not likely that there is any reason to suspect a change in this area, nor can we permit ourselves the luxury of experimentation with voluntary compliance; the technology of recombinant DNA does not allow much margin for error. We wish, therefore, to underline our unequivocal support for required compliance with regulation by industry, which was voted for by the NIH Recombinant DNA Advisory Committee.[5]

We need to keep in mind the tragic failures of the nuclear energy industry: only by open, full disclosure of facts and data, regulation of public and private sectors, and a cautious approach will we be able to avoid a biological Three Mile Island.

Reducing laboratory containment standards and permitting exemptions without supporting data constitute neither a cautious nor a scientific approach. We hope that your tenure in office will be marked by a change from current NIH philosophy and practice to one of caution that would be more appropriate to an agency whose "mission is to improve the health of the American people".[4]

Yours very truly,

Francine Robinson

Francine Robinson
Executive Director

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4. U. S. Government Organizational Manual

5. S. Krimsky and D. Ozonoff, "Recombinant DNA:Scope and Limits of Regulation", American Journal of Public Health, December 1979.