DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT OF

ANTHONY ROBBINS, M.D., DIRECTOR
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
CENTER FOR DISEASE CONTROL
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE
SUBCOMMITTEE ON SCIENCE, TECHNOLOGY AND SPACE
SENATE COMMITTEE ON COMMERCE, SCIENCE AND TRANSPORTATION

May 20, 1980

I am Dr. Anthony Robbins, Director of the National Institute for Occupational Safety and Health (NIOSH), administered by the Center for Disease Control (CDC). I am accompanied by a health scientist on my staff, Mr. Seth Pauker, who is coordinating NIOSH recombinant DNA activities. Under the Occupational Safety and Health Act of 1970, NIOSH is responsible for conducting research, recommending occupational safety and health standards, providing technical assistance to workers and employers, and conducting training and education programs. NIOSH has similar responsibilities to protect the health of miners under the Mine Safety and Health Act of 1977. I am pleased to have been invited to discuss our concerns about protecting the health of workers involved with industrial applications of recombinant DNA techniques.

As part of our mandated duties, NIOSH explores problems created by new technologies which may have associated occupational safety and health hazards. We pay particular attention to technologies which have high growth potential or which may have exposures of an uncharacterized nature. We are, for example, evaluating hazards associated with new energy technologies, such as synthetic fuel processes. By implementing recommendations for safeguarding health before costly capitalization occurs, industry avoids expensive retrofit and can install protective engineering controls in a cost effective manner.

The rapid growth potential of recombinant DNA technology, not only for pharmaceutical applications, but also in the chemical, agriculture, energy and food processing facets of our economy, indicates the necessity for careful evaluation of health risks. Our primary concern is the unknown. We don't know at this point whether risks increase or decrease and change in nature as we move from laboratory research to large-scale manufacturing operations. We don't know whether proposed fermentation equipment offers adequate safeguards

for the worker. We don't know how the worker's state of health may contribute to risks. We also don't know what risks may be associated with future host-vector systems other than E. coli K-12. Because of these unknowns we feel that NIOSH has a major responsibility to evaluate the commercial application of recombinant DNA technology.

Dr. Fredrickson's testimony describes a recent NIH sponsored workshop which addressed the question of risks related to E. coli K-12 production of insulin and human growth hormone. He indicated that the conclusion of most of those present was that the risks are minimal. We concur, but feel that the industry is too young to anticipate all future applications of recombinant DNA activity. We are concerned not only with the known end products but also with unanticipated byproducts. Such products may be biologically active compounds such as hormones or potentially hazardous organic chemicals which may be present in large quantities.

It is important to remember that those working with recombinant DNA will include not only scientists, but also technicians, maintenance and custodial workers. With many occupational diseases there is a 20 to 40 year latent period between exposure and onset of symptoms. We cannot assume that there are no potential health problems in working with recombinant DNA systems simply because no cases of illness have been observed in the laboratory. It is possible that evidence of illness has not been looked for in a rigorous and defined manner. As has been the case with known infectious agents, technicians in the laboratory and other auxiliary personnel may get sick and be treated, but the association with their working environment is not made.

Restrospective research on occupational health problems requires a determination of the individual, the substance or agent and the degree of

exposure. As we review the recombinant DNA field it seems important to assure that such data will be available. Any recommendation from NIOSH will include data collection and research proposals, to study any effects that are not prevented by early application of control technology.

NIOSH is conducting on-site studies of commercial facilities as they begin pilot operations and production. We will be assessing the control measures used in these facilities to determine which approaches best control exposures. We are evaluating physical containment design, engineering controls, work practices, validation procedures for ensuring containment, emergency procedures, medical surveillance, environmental monitoring, and worker education.

We also plan to evaluate the submissions from private companies on large-scale research or production made to the Recombinant DNA Advisory Committee which advises the Director of the National Institutes of Health. These submissions describe the biological systems and the physical facilities and work practices intended to ensure safe operation of the production process.

We will use this information to develop publications to minimize any identified risks to the workers as well as make recommendations to specific companies based on their proposals. This is similar to assessments of control technology that NIOSH has conducted in other industries.

In undertaking these activities, we are working closely with other programs in the Center for Disease Control and with the Occupational Safety and Health Administration (OSHA), who share our responsibility for protecting the health of workers and the general public.

NIOSH participates in the NIH Recombinant DNA Advisory Committee meetings and in conferences, such as that recently sponsored by the National Institute

of Allergy and Infectious Diseases. NIOSH and OSHA's interest lead to the creation of the Industrial Practices Subcommittee of the Federal Interagency Advisory Committee on Recombinant DNA Research. This group, chaired by Dr. Gilbert Omenn of the Office of Management and Budget will be discussing matters related to industrial application of recombinant DNA techniques and will be making recommendations to the larger Federal interagency committee chaired by Dr. Fredrickson. This Industrial Practices Subcommittee allows agencies most concerned with commercial applications the opportunity to discuss their responsibilities and activities. As NIOSH formulates its plans for a review of commercial development, we will be seeking expertise and counsel from the interagency group.

In March 1977, Dr. John F. Finklea, former director of NIOSH, made the following recommendations before the Subcommittee on Health and The Environment of the House Committee on Interstate and Foreign Commerce:

1. Establishment of a central registry of all workers engaged in recombinant DNA research, including the operation and maintenance of laboratories and pilot plants.

2. Provisions for a program of appropriate medical examinations for such workers prior to placement and periodically thereafter.

3. Assurance that all workers will be trained to perform their work safely and be adequately informed about the nature of their work and any potential health risks associated with recombinant DNA research.

4. Adequate labelling and posting in each work area so that workers entering these areas may be reminded of the precautions necessary to protect their health.

5. Provision to retain health records and all records detailing the configuration and operational history of each research facility.

6. Mandatory reporting of illness, injury, deaths, and provisions to facilitate medical follow-up of workers engaged or formerly engaged in recombinant DNA research.

7. Appropriate environmental and workplace monitoring systems to assure that inadvertent exposures to recombinant DNA organisms are not taking place

We are reviewing these recommendations in light of the continuing work of scientists and the NIH Recombinant DNA Advisory Committee. Finally we will advise OSHA on what should be incorporated in a program to protect workers as new recombinant DNA techniques and approaches move from the research laboratory to commercial application.

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. Recipient's Accession No. PB 90 192931/AS
4. Title and Subtitle NIOSH Testimony on Recombinant DNA by A. Robbins, May 20, 1980			5. Report Date 80/05/20
			6.
7. Author(s) NIOSH			8. Performing Organization Rept. No.
9. Performing Organization Name and Address NIOSH			10. Project/Task/Work Unit No.
			11. Contract (C) or Grant(G) No. (C) (G)
12. Sponsoring Organization Name and Address			13. Type of Report & Period Covered
			14.

15. Supplementary Notes

16. Abstract (Limit: 200 words) This testimony concerned the efforts of NIOSH to protect the health of workers involved with industrial applications of recombinant DNA techniques. The rapid growth of recombinant DNA technology in pharmaceutical, chemical, agricultural, energy and food processing facets of the economy indicated the need for careful evaluation of health risks to workers in these areas. A recent National Institutes of Health workshop addressed the question of risks related to Escherichia-coli-K-12 production of insulin and human growth hormone. Those possibly exposed to recombinant DNA will include not only scientists, but also technicians, maintenance and custodial personnel. As there often has been a long latency period with occupational diseases, there is no assurance that just because no problems have been identified among the workers as yet that there are no problems there. Retrospective research was underway. NIOSH was also conducting on site studies of commercial facilities as they begin pilot operations and production. NIOSH also planned to evaluate the submission from private companies on large scale research or production made to the Recombinant DNA Advisory Committee. All these undertakings were being made in close cooperation with the Center for Disease Control and the Occupational Safety and Health Administration. Recommendations which were made in 1977 to the Subcommittee on Health and the Environment were restated.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms NIOSH-Publication, NIOSH-Author, NIOSH-Testimony, Robbins-A, Laboratory-workers, Pharmaceutical-industry, Agricultural-industry, Food-processing-industry, Chemical-manufacturing-industry, Biomedical-engineering

c. COSATI Field/Group

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages 8
	22. Security Class (This Page)	22. Price A02

(See ANSI-Z39.18) *See Instructions on Reverse*

OPTIONAL FORM 272(4-77)
(Formerly NTIS-35)
Department of Commerce