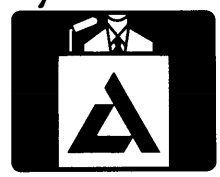
Policy Statement



Recombinant DNA Research

AD HOC COMMITTEE ON RECOMBINANT DNA, AMERICAN DIABETES ASSOCIATION

Diabetes mellitus is a complex metabolic disorder that accelerates the normal aging process, often leading to serious morbidity, disability, and premature death. In the United States alone, many millions of persons are afflicted with the disease, and between 1.5 and 2 million of these persons require daily injections of insulin, a protein hormone extracted from beef and pork pancreas glands derived as a by-product from the meat packing industry. Throughout the world about 2,000 kg. of insulin are produced annually, of which approximately half is used in North America. In recent years, questions have been raised as to the possible development of an insulin shortage through accelerated demands for the hormone in this country and with increasing availability of good medical care in underdeveloped countries and as supplies of pancreas glands from animal slaughter tend to plateau. Although the best available estimates do not indicate any immediate shortage, projections of the present flux of supply and demand factors suggest that an unfavorable balance could develop by the end of this century or even a few years earlier. In view of this impending problem it is imperative to explore alternative means for the production of insulin for therapeutic use.

The recent development of recombinant DNA technology has raised the possibility of transferring the genetic information for production of animal or human insulins to suitable microorganisms which could then be utilized through fermentative procedures as a supplemental source of the hormone. To make such methods practical, a considerable amount of additional research on fundamental aspects of recombinant DNA technology will be needed which will undoubtedly require minimally several years to accomplish. In view of the controversies that have surrounded this new experimental field the American Diabetes Association has selected a panel of distinguished scientists to carefully weigh the risks of such experiments and to assess their potential benefits for diabetics in this country and abroad. In consequence of their discussions and recommendations, the American Diabetes Association has adopted the following position of advocacy on recombinant DNA research:

(1) The American Diabetes Association, having carefully reviewed the published testimony regarding the issues of research with recombinant DNA molecules, believes that there is presently no indication that serious risks to the population or the environment will accrue from research activities of this kind if carried out within the safety precautions prescribed by the present NIH Guidelines for Recombinant DNA Research (Federal Register, vol. 41, no. 131, July 7, 1976).

Specifically, we concur with the belief expressed in the report of the Falmouth Workshop on Studies for the Assessment of Potential Risks Associated with Recombinant DNA Experimentation (S. Gorbach et al., Recombinant DNA Technical Bulletin, *1*: 19–27, 1977) that the host organism *E. coli* K12 could not be inadvertently converted to an epidemic pathogen by inserted foreign DNA molecules and that the possibility of transfer of genetic elements from *E. coli* K12 to other wild-type strains of bacteria in vivo is exceedingly low.

(2) Our assessment of the risk/benefit ratio of this research from the viewpoint of diabetes research and the diabetic patient indicates that the potential benefits to be derived from recombinant DNA research far outweigh any clearly identifiable hazards.

(3) Among important benefits that could accrue from recombinant DNA research is the production of human insulin in virtually unlimited quantities in microorganisms. However, many difficult technical problems, such as yields, purification, mass production and appropriate containment, remain to be solved and will demand extensive additional basic research and development. Although there is no acute or emergent need for additional sources of insulin at this time, most estimates indicate that, while there is no immediate cause for concern, shortages of insulin supply versus demand could occur before the end of this century (see references

and Appendixes A and B). Thus a comprehensive exploration of all potential alternative sources should be implemented as soon as possible.

(4) Microbially produced insulins and related molecules would also provide new research tools that would expand our knowledge of the basic mechanisms of action of insulin and, as well, improve its therapeutic administration.

(5) Potential further benefits of recombinant DNA research include the development of a better understanding of the genetic basis for the susceptibility to diabetes and related disorders which could ultimately lead to the development of wholly new means for the prevention and treatment of this disease. In addition, the exploration of these basic genetic mechanisms may yield information that will better our understanding of other medically important problems that face our society, such as malignancy, viral diseases, and birth defects and related developmental disorders.

(6) In view of the many potential benefits for diabetics and society as a whole from recombinant DNA research, the American Diabetes Association strongly advocates the continuation of this research activity under the guidance of the National Institutes of Health and without the imposition of any further restrictive measures beyond those already encompassed in the present NIH Guidelines for Recombinant DNA Research and any further modifications that may subsequently be adopted.*

Ad Hoc Committee on Recombinant DNA

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May 24, 1978

*** i.e., see *Recombinant DNA Technical Bulletin*, Summer 1977, draft version of Revised NIH Guidelines for Recombinant DNA Research.**

REFERENCES

[1] Insulin Supply and Requirements. Projections of the United States. Eli Lilly and Company, January 1978.

[2] Estimates of Insulin Supplies. OPE Study 39, by Jack E. Baer. April 1977.

[3] Comments of OPE Study; World production figures for slaughter animals 1961–75. Supplied by Novo (Copenhagen, March 30, 1977).

APPENDIX A

Correction of OPE report presented in testimony by Jack E. Baer on January 16, 1978, to Insulin Study Committee of the National Diabetes Advisory Board:

> Mr. Jack Baer, FDA, proceeded to explain to the Committee a formal modification of the findings of OPE Study 39. The original document stated in Estimating Procedure 1, that 16,000 pounds of pancreas glands would produce one pound of insulin, and that 1 pound would support 750 diabetics for one year. It has since been determined that the statment should have indicated that 16,000 pounds of glands yield one kilogram of insulin. The use of the figure requires Estimating Procedure 1 to read: "One kilogram of insulin obtained from 16,000 pounds of pancreas supplies 1650 diabetics for one year." This revision supports the conclusion that the danger of insulin use exceeding production may occur around 2006, not 1982.

APPENDIX B

Report of Insulin Study Committee on the National Diabetes Advisory Board (in press).