FINAL WORD

by Albert Gore, Jr.

TOWARD A NATIONAL POLICY ON HUMAN GENETIC ENGINEERING

The House of Representatives currently has before it legislation that could help direct the development of future public policy on biotechnology in this country. The legislation, which I introduced this past spring, establishes the President's Commission on the Human Applications of Genetic Engineering, a presidentially appointed advisory body that will monitor developments in human genetic engineering and examine the social, ethical, legal, and medical issues raised by them.

As its charge suggests, the purpose of the Commission is to help prepare our country to address the many complex issues raised by the application of the new genetic technology to human beings. Necessary to the formulation of public policy on any issue, especially one of this magnitude, is the development of a national consensus on the issues. Resolution of the difficult issues raised by human genetic engineering will be crucial as our nation moves toward a cohesive approach to biotechnology and its implications. How will the Commission help? First, the Commission will monitor developments in genetic technology that have implications for human genetic engineering. No one can dispute the fact that the new technology is developing far more rapidly than we had originally imagined. Development of this technology occurs almost exponentially, and the regularity of significant breakthroughs in laboratory research suggests that application of the technology to humans is not too far away. In fact, genetic experiments on human beings to treat disease were attempted three years ago, although they were unauthorized. The Commission will perform a much-needed function by monitoring the technology and keeping the President, the Congress, and the federal agencies informed of developments.

Second, the Commission will provide a mechanism to educate the public about genetic engineering. Many people are frightened or distrustful of the prospect of human genetic engineering in general, and an informed public is essential if our nation is to make reasoned decisions about the technology. The Commission will ensure that the public receives objective information about the possibilities and implications of human genetic engineering.

Third, and most important, the Commission will provide a forum for consideration of the tremendous ethical and societal issues that will be generated by human genetic engineering. The new genetic technology has the potential for tremendous benefit to our society. At the same time, however, it could be abhorrently misused. Our present system of bioethics is based on medical treatments and ideas vastly different from those that will be brought about by the new technology, and their advent raises a number of moral and ethical questions that are not easily answered. A new body of bioethics—"genethics"—must be constructed to enable us to come to grips with the technology. The Commission will facilitate that effort.

The need for the Commission was made very clear at a three-day hearing on human genetic engineering, held last November by the House Science and Technology Subcommittee on Investigations and Oversight. At that hearing, a number of eminent scientists, religious leaders, ethicists, and other individuals who have been involved in the genetic engineering debate offered their opinions on the possibility and implications of human genetic engineering in the near future. The overall conclusion from the hearing was that our society is ill-prepared to face the very difficult questions raised by the new technology.

The accuracy of this conclusion was emphasized recently by the controversy surrounding a resolution on genetic engineering, signed by a number of clergymen. The resolution called for a prohibition on genetic engineering of human germline cells and was based on a fear that the technology, if developed, could be severely misused. The sharp disagreements and debate that have resulted from the resolution emphasize the need for a mechanism to facilitate a reasoned and patient examination of the fundamental differences that exist within our society regarding the use of genetic engineering. The Commission that I have proposed is intended to address this need.

Because of the importance of biotechnology and the complexity of the issues raised by it, the Commission is designed to ensure that a broad and meaningful examination of the issues occurs. First, the Commission is an independent body: it is not housed within any federal agency, and its members are appointed by the President. Thus, the Commission will have freedom to consider issues and render objective advice. Presently, no independent group exists to review the technology. The only similarly independent body to consider genetic engineering, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, expired in March. Second, the Commission is interdisciplinary in its composition: it consists of representatives from a variety of areas, including the general public. A majority of the Commission members are nonscientists, to ensure that the Commission's focus is on ethical issues and not technical scientific concerns. Third, and finally, the Commission is nonregulatory: it is an advisory body with no regulatory power

Continued on page 706

Albert Gore, Jr.

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IN THE NOVEMBER ISSUE

- **RESEARCH PAPERS:** Novel cloning systems for gram negative bacteria. Lactate-acrylate interconversion in *Clostridium propionicum*. Induction of aflatoxin synthesis in *Aspergillus flavus* by cyclohexamide.
- **REVIEW ARTICLE:** Industrial applications of some new microbial polysaccharides.
- **FEATURE:** Microbes for pollution control.
- **TECHNOLOGY REPORTS:** The emerging role of the U.S. Environmental Protection Agency in regulation of rDNA technology. Biotechnology and Canadian agriculture. Computer conferencing as a tool for international communication in biotechnology.
- **NEWS:** International meeting reports on biotechnology in food and drink. Enzymes for human therapy. The BIO/TECHNOLOGY stock index.

BIO/TECHNOLOGY

COMMENTARY (Continued from page 676)
tactics such as higher cell density and lower product inhibition is even greater than would be the case for an extremely efficient conversion.

Between 1940 and 1978, the percentage of the world's organic chemicals derived from coal fell from 95 to 3. The figures for petroleum boomed accordingly. Such are the possible dimensions of the *next* revolution, with all its unsolved problems, now being spearheaded by a resource-favored land in Latin America.

FINAL WORD (Continued from page 718)
whatsoever. The Commission considers developments in genetic engineering and provides advice, in the form of written reports, to the President, the Congress, and appropriate federal agencies. These reports will present the Commission's conclusions, as well as any recommendations for regulatory or legislative action. Because it is a purely advisory body, the impact of the Commission's conclusions and recommendations will depend upon the force and quality of the reasoning behind them.

It is a primary responsibility of government not only to promote science but to attempt to foresee the future of technology and any problems it might present. As the new genetic technology develops, it will be essential for our nation to be informed about both the positive and negative implications of it. Particularly for those of us in Congress, it will be important that we base our reactions to and decisions about the technology on objective, reasoned consideration of the issues and not on misunderstandings or exaggerations of the technology's potential for either good or evil. Biotechnology will unquestionably have a tremendous effect on our society in the years ahead. The challenge we face is how to ensure that those benefits are realized and any misuses are avoided. Accomplishment of these objectives will require public education and thoughtful debate about the complex issues that will confront us. The Commission that I have proposed is a first step in that process.

CORRESPONDENCE (Continued from page 675)
the conventionally-derived version . . ." and "[T]he effect of the new policy seems to be to require full clinical testing of all rDNA drugs . . . [T]he obvious effect of this policy is to increase the cost of marketing rDNA products." The term "full clinical tests" is a buzz-word intended to be pejorative; in fact, full clinical tests may consist of brief trials on five patients or lengthy trials on five thousand, depending on the particular circumstances. The record time in which human insulin moved through the regulatory review process demonstrates that regulation by FDA of recombinant DNA-derived products need not be debilitating nor Draconian.

We reiterate that the FDA will regulate each product according to the relevant statutes and regulations, and, as important, will attempt to do so intelligently and responsibly.

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3. Miller, H. I. 1982. Recombinant DNA as a Paradigm of a New Technology: Its Impact on Regulation by the Food and Drug Administration. Journal of Parenteral Science and Technology **36**:248.