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Biotechnology - Ethics, Safety and Regulation

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BIOTECHNOLOGY - ETHICS, SAFETY AND REGULATION

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INTRODUCTION

The term "biotechnology" is ambiguous, and the lack of consensus on what it means has been the source of much confusion. One of the broader definitions is "the application of biological systems and organisms to technical and industrial processes."[1] This definition includes processes as diverse as fish farming, beer fermentation, and recombinant DNA (rDNA), or "gene-splicing", techniques. Recombinant DNA is really an extension of the classical breeding techniques which have been used by plant and animal geneticists for decades. Classical breeding techniques involve the selective breeding of plants or animals, with the intent of producing offspring with the desired trait. Recombinant DNA technology furthers the specificity of the selection process by making it possible to add or delete specific genetic traits, permitting greater certainty that particular characteristics will be represented in the offspring.

The ethics and safety of biotechnology have been debated since scientists first began to investigate the new technology in the early 1970s. The concern expressed by molecular biologists about the safety of biotechnology research led first to a moratorium on certain research and then to the Asilomar Conference in 1974, a gathering of scientists sponsored by the United States government to discuss safety and ethical questions. As a result of this conference, the moratorium was lifted for most experiments and guidelines for conducting rDNA research were published by the National

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1. Miller & Young, *Biotechnology: A 'Scientific' Term in Name Only*, WALL ST. J., Jan. 13, 1987, at 28, col. 3.

Institutes of Health (NIH) Recombinant DNA Advisory Committee (RAC).[2] These guidelines specify how research should be conducted, particularly the degree of care to be taken to avoid unintentional release from the laboratory of experimental genetically-engineered organisms. Various levels of containment practices are required, depending on the nature of the organism.

I. BENEFITS OF BIOTECHNOLOGY

Despite the concerns expressed early on by scientists, and the fears which continue to be expressed by critics of biotechnology today, the development of the science continues. The potential benefits to be gained from biotechnology are too important to be ignored.

Exciting advances in human health care have already been made by use of this technology. Products of rDNA technology include interferon, which is used to treat a certain form of leukemia, human insulin used to treat diabetes, and human growth hormone used to help children with dwarfism to grow to normal size. Health care scientists also are using biotechnology to create new and safer vaccines to prevent diseases such as AIDS. Biotechnology will enable scientists to reduce greatly the risks of vaccination by making it possible to carefully select the genetic portions of the virus which causes the immune system response and omit that portion of the genetic material which causes the disease in making the vaccine. Scientists also are using biotechnology to develop techniques to diagnose, treat, and prevent genetic diseases such as Tay Sachs, Huntington's disease, and multiple sclerosis.

Biotechnology is being applied in agriculture to increase food production and to improve farming efficiency. Applications include the development of animal vaccines and drugs to treat animal diseases. The technology also is being applied to make growth hormones to help food producing animals to grow larger and faster, to decrease body fat, and to utilize feed more efficiently. Several companies are experimenting with bovine somatotropin, a growth hormone which greatly increases the feed efficiency of the cow, thus increasing the

2. Notice for Public Comment on Guidelines for Recombinant DNA Research, 41 Fed. Reg. 27,902 (1976) [hereinafter Guidelines for Recombinant DNA Research].

amount of milk produced without a proportionate intake in feed.

Scientists are working on adding new genetic traits to food and feed crops, such as disease resistance, pest resistance, and tolerance to drought, heat and cold. These advances would reduce the risks faced by farmers by extending the growing season and making crops less susceptible to varying weather conditions and disease. It may be possible one day to grow food crops in Third World countries where they cannot now be grown and are greatly needed to feed large populations.

Research is being conducted to genetically engineer microbes to protect plants from insects, to prevent injury to plants from frost, and to take nitrogen from the air and convert it to a form which can be used by plants.

Industrial applications of biotechnology include engineering of microbes which will be able to break down industrial waste into components which are not hazardous to health or the environment.

The economic potential of biotechnology is difficult to overestimate. Clearly, it will be significant. It can reduce farming costs through more efficient feed utilization by animals and the reduced use of fertilizers, herbicides and insecticides. By making farming more efficient, biotechnology can help American farm products become more competitive in world markets. Biotechnology can make industry more efficient as well, by providing new, cost effective methods for disposing of industrial wastes and by contributing to the development of more efficient manufacturing processes in some industries. By improving human health, costs of medical care, and economic losses caused by disease, government and community health support programs can be dramatically reduced with a corresponding benefit to all of society.

Recombinant DNA research has been conducted for almost a decade now, and the catastrophes feared by some and predicted by a few have not occurred. Genetically-engineered organisms have not escaped from the laboratory and caused epidemics of new diseases nor persisted in the environment to destroy the ecological balance. Genetic scientists have not begun to "clone" individuals or eliminate individualism by selectively enhancing or deleting certain genetic traits.

The investigation and development of rDNA technology has proceeded very cautiously. It is unlikely that any new technology has ever before been so carefully studied and evaluated. As scientists have gained more knowledge about

biotechnology, they have discovered that many concerns expressed early in the development of the technology are without scientific basis. As a result, the RAC guidelines have been relaxed with respect to the number and degree of precautions and safeguards required for most experiments.

And yet, ethical and safety concerns persist, and government regulators, scientists, and members of the public continue to debate them. This is due in part to legitimate concerns which should be addressed and in part to the fact that the potential dangers and consequences of rDNA technology have been intentionally distorted and exaggerated by some critics and are often misunderstood by the general public.

Critics of biotechnology include the Foundation on Economic Trends, the Committee for Responsible Genetics, the Council on International and Public Affairs, The Humane Society, and the International Center for Law in Development. Perhaps the best known critic of the science is the founder and president of the Foundation on Economic Trends (FET), Jeremy Rifkin, a commentator on, and critic of, the potential social and environmental effects of the development and use of biotechnology. Mr. Rifkin and the FET have filed numerous lawsuits against universities, scientists, and government agencies, the effect of which has been the delay of advances in this new area of science. The following complaint is typical:

> Among the concerns of the Foundation are the potential for a "biohazard" or contamination of the planetary gene pool resulting from genetic engineering; the ethical, moral and philosophical implications of artificially controlled biological reproduction; the impact genetic engineering will have on the family and other social institutions; the legal issues surrounding genetic and biological research; the effects of low-level radiation and synthetic chemicals on human chromosomes and reproductive organs; environmental consequences of introducing new genetically modified life forms; and the economics of bioengineering—who will reap the benefits and who will pay the costs.[3]

Lately, Mr. Rifkin has been unsuccessful in his attempts to use the judicial system to halt the developments of biotechnology. Two recent lawsuits filed by Mr. Rifkin have been

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3. Complaint for Declaratory and Injunctive Relief at 4-5, Foundation on Economic Trends v. Thomas, 637 F.Supp. 25 (D.D.C. 1986) (first amended complaint dismissed).

dismissed by the courts.[4] However, there is no doubt that Mr. Rifkin and his supporters will continue to use the courts to delay the progress of the science. Most recently, the Foundation on Economic Trends has filed a lawsuit against the Department of Health and Human Services relating to the Food and Drug Administration's review of bovine somatotropin.[5]

II. Two Basic Concerns

Two of the most widely debated concerns about rDNA technology are the potential consequences of deliberate release of genetically-modified organisms into the environment, and the effect of such organisms on genetic diversity and biological integrity of plants and animals, including humans. A third less dramatic but also widely debated concern is the social and economic disruption resulting from the development of the science.

A. Uncontrolled Proliferation

Many genuine concerns have been expressed regarding the deliberate release of genetically-modified organisms into the environment. The fear is that the engineered organism may be more viable than the unengineered organism and may proliferate and damage or destroy the ecological balance, or that it may pass on genetic traits such as extraordinary susceptibility to a disease or resistance to a pesticide, and thus result in the creation of new pests which will spread disease or proliferate beyond control.

While such an occurrence is theoretically possible, the risk that it will actually materialize is very small for a number of reasons. First, the technology itself provides important safeguards. In classical breeding techniques, where genetic material from one organism is transferred to another organism, the breeder cannot always control the outcome. In trying to transfer a single genetic trait, which may be encompassed in a single gene, the breeder actually transfers hundreds or even thousands of genes, and cannot always predict the outcome of such a transfer. Genetic engineering using rDNA technology, on the other hand, permits the transfer of a single gene so that only the desired genetic trait is

4. *Id.*, and Foundation on Economic Trends v. Johnson, No. 86-1956 (D.D.C. 1986) (complaint dismissed Dec. 22, 1986).

5. Foundation on Economic Trends v. Department of Health and Human Services, No. 87-1009 (D.D.C. filed April 10, 1987).

transferred. As a result, the nature of the engineered organism is much more predictable.

The technology also enables scientists to engineer into the organism traits which will help to prevent proliferation. The organisms can be made weak so that they are unable to survive in the natural environment for more than a very short period of time. They can be engineered so that they cannot survive in the human body and thus cannot transmit disease to people. Genetic traits can be incorporated in such a way that they cannot be passed on to other organisms. Classical breeding techniques do not usually permit these characteristics to be incorporated.

The technology also permits the genetically-engineered organism to be marked, so that it can be detected and destroyed if for some reason the organism appears to present a danger to health or the environment.

Government agencies will continue to thoroughly regulate to prevent harm to health and the environment. Government regulators are proceeding carefully and have created a regulatory system which will govern the development and testing of all biotechnology-derived products.

The principal federal agencies with authority to regulate biotechnology are the NIH, the Environmental Protection Agency (EPA), the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). Last year, the Office of Science and Technology Policy issued the Coordinated Framework for the Regulation of Biotechnology ("Framework").[6] The Framework sets out the regulatory policy of each of the federal agencies which regulate biotechnology.

The EPA regulates pesticides and toxic chemicals (defined to include genetically-engineered microorganisms and to exclude most products regulated by other federal agencies).[7] The FDA has jurisdiction over food, food additives, drugs, animal feed additives, animal drugs, medical devices, and cosmetics. The USDA has authority to regulate plants and plant products, animal biologics, plant pests, meat and poultry products, noxious weeds, and the importation and

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6. Coordinated Framework for the Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment, 51 Fed. Reg. 23,302-350 (1986) [hereinafter Framework].

7. Notice for Public Comment on Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,858 (1984).

interstate movement of animals, plants and seeds. The OSHA regulates worker health and safety.

The EPA and USDA are the two agencies which will be primarily responsible for regulating products comprised of genetically-engineered organisms to be used in the environment. Both agencies have established regulatory policies which will require review of these organisms before they are released into the environment, and have established procedures to fully assess and eliminate or limit the risk which may be presented.

The EPA has established a two-level reporting system. The agency will conduct limited review of certain organisms which, due to their very nature, present a very minimal risk of creating any adverse effect on health or the environment. Such organisms are, for example, those formed from genetic material of very similar organisms and those formed by genetic material from nonpathogenic organisms.[8] Other organisms will be reviewed more extensively.[9] In the course of both levels of review, the agency will require extensive greenhouse and laboratory tests designed to predict the viability of the organism, the likelihood of transfer of engineered genetic traits to other organisms, the effect of the engineered organism on other organisms in the environment (including insects, aquatic life, animals and plants), and other characteristics of the organism and the environment into which it will be released as deemed necessary by the agency. The EPA has established a Science Advisory Committee for Biotechnology which will provide peer review of the EPA's decision and will oversee its biotechnology policies and programs.[10] This committee will be made up of scientific and technical experts who are qualified to assess the hazards of exposure and the impact on the ecology.

The USDA has established a system whereby review is required before a genetically-engineered organism can legally be released into the environment.[11] Before a release will be

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8. "Pathogen" is defined in the Framework as "a virus or microorganism (including its viruses and plasmids, if any) that has the ability to cause disease in other living organisms (i.e., humans, animals, plants, microorganisms)." Framework, *supra* note 6, at 23,307. More simply, a pathogen is an organism which causes disease.

9. Notice of Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313, 23,320-321 (1986).

10. *Id.* at 23,318-319.

11. Final Policy Statement for Research and Regulation of Biotech-

permitted, the USDA will require laboratory and greenhouse tests designed to determine information similar to that required by the EPA. In addition, the USDA has established guidelines, very similar to NIH/RAC guidelines, to regulate laboratory and greenhouse research funded by the Department, and has expressed the hope that these guidelines will be voluntarily followed by industry in conducting its own research.[12] The USDA also has established the Agriculture Biotechnology Recombinant DNA Advisory Committee (ABRAC), which will function much like the NIH/RAC to oversee the implementation of the Department's guidelines.[13] Members of the ABRAC will provide scientific judgments on the safety of experiments they will review under the guidelines.

Government regulation of biotechnology, as currently established, is very extensive and begins at the earliest stage of product testing and development. It provides for public notice of decisions by the USDA and the EPA, and the regulations of both agencies provide for public participation in the regulatory decision making process. The regulations of both agencies also provide for review of agency decisions by experts qualified to assess the risks presented by the particular test, experiment, or product.

Each government agency will assess the risk of each test, experiment, or product, and decide whether it can be conducted or used safely. As when they review traditional products, the agencies use the knowledge and expertise of scientists and other experts along with quantitative risk assessment techniques, such as mathematical models, to assess the potential risks of the product.

The agencies with responsibility to regulate biotechnological products plan to create a data base of information which will eventually enable them to regulate these products more efficiently as more experience in this area of regulation is obtained. Even after this data base is established, regulatory decisions will be made to a great extent on a case by case evaluation of the risks presented by each individual product based on information derived from testing required by the agency as a prerequisite to approval of the product.

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nology Processes and Products, 51 Fed. Reg. 23,336, 23,342 (1986) [hereinafter Final Policy Statement].

12. Advanced Notice of Proposed USDA Guidelines for Biotechnology Research, 51 Fed. Reg. 23,367 (1986).

13. Final Policy Statement, *supra* note 11, at 23,336-337.

In addition to safeguards imposed by regulatory requirements, industry has voluntarily complied with the NIH/RAC guidelines since they were first promulgated. One of the requirements in the guidelines is that each organization conducting rDNA research establish an Institutional Biosafety Committee (IBC) to be composed of experts from within the organization, as well as outside experts who are not otherwise affiliated with the company and who are qualified to review the safety and ethics of each rDNA experiment or test.[14] The role of the IBC is important, because it provides for review of research programs by experts who have appropriate scientific knowledge and ability to objectively evaluate the safety of the experiment. IBC's also often include members with expertise and particular interest in protection of the environment and community standards. The IBC is designed to provide a thorough, multi-faceted review.[15]

Due to all of the safeguards that can be engineered into the organism itself, as well as the reviews conducted by the IBC and regulatory agencies, it is nearly impossible to conceive of an experiment that can go so wildly astray that catastrophic, or, for that matter, even lesser hazardous effects can occur which would result in harm to health or the environment.

B. Genetic Diversity

Another widely discussed perceived danger of rDNA technology is the effect on genetic diversity. The issues presented by this concern involve both safety and ethical considerations.

Critics of biotechnology express the fear that through engineering many genetic traits will eventually be eliminated from all species, thus reducing the genetic diversity of plants and animals. Some critics foresee certain catastrophe as the world is left with a small genetic pool of living organisms which succumb to some disease epidemic or insect plague.

Actually, the possibility of a disaster like this is more likely without the development of rDNA technology. For example, when many farmers grow a single strain of crop which is particularly susceptible to a disease, there is a realistic risk that the disease may take hold and destroy all of the crops in

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14. Guidelines for Recombinant DNA Research, *supra* note 2, at 27,920-921.

15. Guidelines for Research Involving Recombinant DNA Molecules, 49 Fed. Reg. 46,266, 46,270 (1984).

a large geographic area. The fact is, however, that rDNA technology can reduce or even eliminate this risk. By reducing the time needed to create new strains with characteristics such as resistance to certain diseases, and by making it possible to combine genetic traits from sexually incompatible species, biotechnology can be used to produce a wide diversity of crop varieties which can withstand not only disease, but also invasions by insects, drought, and extremes in temperature.

The potential that the technology will make it possible to overcome natural breeding barriers and transfer genes between species also will make it possible to increase genetic diversity. For example, someday it may be possible to transfer genes from bacteria into plants. A useful application of this development would be to transfer nitrogen fixation genes from bacteria to plants to reduce the need for nitrogen fertilizers, thus reducing the cost and increasing the efficiency of farming operations.

The very notion of transferring genes between species opens up many possibilities which raise obvious ethical concerns. Some critics fear that it is only a matter of time until human and animal traits will be transferred between species indiscriminately.

Ethical issues also are raised by so-called "human gene therapy," or the ability to eliminate or modify human genetic traits. There are really two categories of human gene therapy. Somatic therapy is the elimination or modification of the genes of the affected individual for the purpose of curing or preventing genetic diseases such as Downs Syndrome, muscular dystrophy, and Tay Sachs disease. The genetic change does not affect future generations. The other category of human gene therapy is germline therapy, which involves modification of the genetic pattern. Such modification would be passed on to future generations.

Critics fear that human gene therapy will be used to eliminate genetic traits and predetermine physical and other characteristics of future generations. They predict it will be used to standardize characteristics such as height, eye color and intelligence.

There are, no doubt, very legitimate questions about the extent to which gene transfer between species and human gene therapy should be practiced, such as which traits should be transferred between species, which traits are "bad" and should be eliminated through gene therapy, and who should decide. It is equally true that there are concerns which have been voiced by critics which are not valid. For example, crit-

ics have alleged that the transfer of human genes into animals is cruel and immoral because it somehow changes the nature of the animal. This is not a valid concern. A single gene does not determine the nature of an organism. The insertion of a human gene into an animal does not impart human characteristics to that animal.

Legitimate safety and ethical questions should and have been addressed.[16] Clearly the answer is not to stop the development of technology. The advancement of any science or technology poses many ethical questions which must be addressed by society. Advancement in medical technology, for example, has raised issues about the responsibility of physicians to take extraordinary measures to sustain life, and has created the question of the "right to die." One would not suggest that because of these issues the development of medical technology should cease. Rather, society must assess the issues and develop ethical codes and social institutions to address the problem and form a consensus about how it should be resolved. The same is true of the issues raised by biotechnology. In debating these issues, it is important that the risks presented be accurately defined and scientifically understood and that scientifically invalid criticisms and concerns be recognized and discounted. In order for legitimate ethical considerations to be rationally discussed and resolved, it is essential that unscientific rhetoric be separated from the facts and that science not be confused with ideology.

III. Social and Economic Disruption

Critics of biotechnology have predicted significant economic and social disruption as a result of some of the products derived from biotechnology which will soon be available. For example, such criticism has been directed at bovine somatotropin (BST), which research shows will be useful to increase milk production of dairy cows while reducing intake of feed per gallon of milk produced. Critics have predicted

16. In 1982 a Presidential Commission undertook to study the matter PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SPLICING LIFE: A REPORT ON THE SOCIAL AND ETHICAL ISSUES OF GENETIC ENGINEERING WITH HUMAN BEINGS (1982). This Report was the subject of Congressional hearings, e.g., *Human Genetic Engineering: Hearings Before the Subcommittee on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong. 2nd Sess. (1982) *See also* Singer, *Genetics and the Law: A Scientist's View*, 3 YALE LAW & POL'Y REV. 329-330 (1985)

that BST will cause increased milk production, requiring increased government support of the dairy industry and resulting in smaller dairy farmers going out of business.

In fact, BST should not have such an impact. It is unlikely that it will be used to produce more milk, but rather to produce the same amount of milk more efficiently, with fewer cows. The size of the farm should not affect the farmer's ability to use BST to increase the efficiency of his operation.

While the criticism leveled at BST is not legitimate, it cannot be denied that the development of any new technology is likely to change social and economic patterns to some extent. It will be important to anticipate the likely changes and prepare for them, but, as in the case of gene therapy, the answer is not to prohibit development of the technology.

IV. Risks of Over-Regulation

No one with an understanding of biotechnology will seriously argue that there are not important questions of safety and ethics which must be addressed. In some cases, regulation will be required. As has already been discussed, mechanisms are being developed and some are already in place, to address ethical considerations and to insure that tests and experiments involving biotechnology will be reviewed to prevent harm to health and the environment. While there is no doubt that there are issues that remain to be resolved, there is a real danger to the further development of the industry if they are not approached rationally.

Biotechnology presently is being regulated to a much greater extent than are most other industrial and scientific endeavors. Under the regulations published in the Framework, regulatory oversight begins much earlier in the process of product development than is true for most other products, such as pesticides and plant hybrids, manufactured or created by more traditional technologies. The possibility of over-regulation, brought about to a great extent by the failure of regulators and the public to understand the science, which is in part due to the rhetoric of many of its critics, may eventually stifle further development. The industry already is realizing that the extent of regulation of biotechnology results in the development of biotechnologically-derived products being much more time consuming and expensive than development of other products. Industry is having to face the fact that this may result in inability or unwillingness to develop some

potentially useful and beneficial products. Examples are vaccines and drugs which would be used to treat rare diseases and organisms which could be engineered to control rare but troublesome pests. Since the market for such products is relatively small, it is unlikely that industry would be able to recover the very large development, including regulatory, costs.

The high cost of development is only one problem which results from overly cautious regulation. Another is regulatory delay, which, though inherent in the regulatory process, may be prohibitive in the case of biotechnology. At the present time, the United States is far ahead of other countries in the development of biotechnology. But this lead will be lost if expense and delays associated with the development of new biotechnology products in the U.S. are excessive. The result will be that foreign companies will usurp the leadership position now enjoyed by U.S. industry. The way to prevent this loss is to approach regulation of biotechnology rationally, with a sound understanding of the scientific principles on which it is based, so that it is regulated adequately but not excessively.

The science of biotechnology holds the key to improving the quality of human life more dramatically than any previous scientific endeavor. This quest will continue. If the science is to be allowed to develop to its full potential, the public and the government must not be misled by ideologists predicting dire consequences which is not based on an understanding of the science. This new science holds the promise of eradicating many of society's worst problems, such as cancer, AIDS, and starvation. Failure to develop this technology will allow disease and hunger to continue when the science to alleviate much of it is at hand.