The Challenge of Biotechnology

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I. Introduction

Since recombinant DNA technology was first developed in the early 1970's, society has been faced with the immense task of overseeing its use and development. Scientists have been concerned with continuing their research free from burdensome regulations, while policy-makers have worried about the potential for a biotechnological disaster if such research remains unregulated. Accordingly, attempts to control the technology's potential dangers while encouraging exploration of its benefits have caused many conflicts, both within and between the scientific and regulatory communities.

The development of biotechnology has given society an awesome new power and an equally awesome responsibility to use it wisely. Unfortunately, the technology itself is developing so rapidly that our regulatory strategies seem to be chasing a moving target. Indeed, not since the discovery of atomic fission have we been presented with such a Pandora's box of issues. Unless we are prepared to deal rationally and competently with the implications of this new-found power, we will reap few of its benefits and will be left with many of its problems.¹

This article will discuss the history of the regulatory debate over biotechnology, the problems and choices it has created, and the principles that we as citizens and representatives must understand in order to formulate effective policy. The article will review current regulatory institutions and arrangements critically in order to illus-

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¹ One need only consider the current dilemma with nuclear weaponry to appreciate the hazards of a technology developed with neither planning nor foresight. It is important to note, however, that this analogy to the experience with atomic fission is not meant to imply that biotechnology presents the same risks or is doomed to follow the same pattern of development. Rather, it simply underscores the difficulty inherent in regulating an emerging technology and the absolute necessity that we do so in a timely fashion.
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trate the potential for new structures to succeed where old ones have proven inadequate. Although the article presents the perspective of the legislative branch, it will also emphasize the roles played by other vital participants in the process, namely scientists and the public at large.

II. Background

Advances in biotechnology in the mid-1970's created public concern over the safety of laboratory experiments. Because many such experiments involved the use of potentially infectious bacteria, some feared that a man-made "bug" could escape and spread a horrible disease throughout the population.²

Such a fear was not unfounded, and the prevalence of this concern resulted in the first attempt to create a regulatory framework for biotechnology. This early effort at oversight was the culmination of an ambitious self-regulatory push within the scientific community itself, with little prompting from the government. At a now famous conference held in Asilomar, California in 1975, many of the leading figures in this emerging science established guidelines for laboratory procedures and a process for the review of future experimental techniques.³

The Asilomar guidelines for research were widely accepted and implemented by the scientific community. In addition to substantive recommendations for proper laboratory methods, the guidelines called for the creation of a National Institutes of Health (NIH) advisory committee on recombinant DNA research. The recommendations of the Asilomar Conference were immediately adopted by the NIH, until such time as the new Recombinant DNA Advisory Committee (RAC) could formulate its own regulations.

Sixteen months later, the RAC and NIH produced a detailed series of regulations for recombinant DNA research.⁴ The Asilomar guidelines were used as the starting point for the development of regulations seeking to bind recipients of government grants for such research. A program of voluntary compliance by private research organizations was also instituted through the RAC which has been

². For a discussion of these early concerns see N. WADE, THE ULTIMATE EXPERIMENT 127-41 (1977).
generally successful to date.\textsuperscript{5} The swift response of the scientific community to the perceived dangers of early recombinant DNA research allowed the technology to develop for several years with a minimum of controversy. The original guidelines of the Asilomar Conference played a crucial role in the development of biotechnology. Their widespread acceptance by scientists calmed the public’s fear both of a biological accident and of the technology itself. In addition, the guidelines demonstrated that interim self-regulation by the scientific community was viable in the field of genetic engineering.

Public confidence in biotechnology was also enhanced by the creation of the RAC within the NIH (essentially as recommended at Asilomar). The RAC proved to be an effective forum for the discussion of any new experiments.\textsuperscript{6} Also, the safety of laboratory techniques for genetic experiments was quickly demonstrated; consequently, the regulations have been relaxed over time.\textsuperscript{7} Most government-sponsored genetic research is now exempted from compliance with the most stringent RAC regulations.\textsuperscript{8}

As a result of scientists’ excellent laboratory safety record, the public has grown less fearful of accidental disaster and has begun to appreciate the promising future of biotechnology. However, new and more complicated issues have arisen. If not handled properly, they could place that future in jeopardy.

Policy-makers today are more concerned with the control of purposeful applications of biological engineering and genetic “tinkering” than with the unintended release of organisms from laboratories.\textsuperscript{9} On a variety of fronts, genetic technology is advancing so rapidly that it may surpass the ability of our existing institutions to control it. It is presenting our society with new choices and decisions, and unlike earlier concerns, the problems presented now cannot be resolved by the scientific community alone. Because the decisions to be made involve moral and ethical issues, they must be discussed by all members of society, rather than any particular

\textsuperscript{5} See \textit{Splicing Life}, supra note 3, at 12-13. However, the lasting impact of the voluntary scheme remains to be seen. \textit{See infra} note 37.

\textsuperscript{6} See \textit{Human Genetic Engineering: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology, 97th Cong., 2d Sess. 182} (1982) (testimony of Alexander Capron, Executive Director, President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research) [hereinafter cited as \textit{Hearings: Human Genetic Engineering}].

\textsuperscript{7} \textit{See infra} note 35.

\textsuperscript{8} \textit{Splicing Life, supra} note 3, at 12-13.

\textsuperscript{9} \textit{Id.} at 5.
group or decision-making body. The government, particularly Congress, must play an increasingly active role to ensure widespread participation in the decision-making process, and it must attempt to build a true consensus by educating the public about genetic engineering. Otherwise, the momentum of the biotechnology industry may decide these issues for us.

III. Prospects and Problems

It is ironic that the dilemmas presented by biotechnology arise from its potential benefits to so many areas of our lives. The development of the technology has proceeded along two basic lines, each with its own set of promises and problems. The first broad line involves the commercial (i.e., agricultural and industrial) applications of the technology and the potential dangers presented by the deliberate release of new genetically engineered organisms into the environment. The second, and in many ways more significant, line encompasses the human applications of the technology and the awesome responsibility that accompanies the power to alter the genetic basis of human life.

A. Commercial Applications and their Environmental Implications

As the safety of recombinant DNA research in the laboratory was demonstrated over the years, commercial ventures rapidly began to develop applications of the technology; as a result research became concentrated along commercial lines. Major advancements in the ability to cleave and rejoin DNA and to insert recombinant DNA into new organisms gave scientists the means to alter organisms rapidly and effectively. Spurred by the 1980 Supreme Court decision in Diamond v. Chakrabarty, which permitted the patenting of new life forms, the biotechnology industry has burgeoned over the last few years. Recent research into the genetic modification of micro-


11. 447 U.S. 303 (1980). Chief Justice Burger, writing for the majority, emphasized the non-justiciable political nature of a decision to exempt new life forms from patent protection. 447 U.S. at 317. Accordingly, the majority refused to credit evidence preferred by scientists and environmental activists in opposition to Dr. Chakrabarty's patent application and held that the organism was patentable under a "plain reading" of the Patent Act. Justice Brennan, writing for the four dissenters (Justices Brennan, Powell, White, and Marshall), deemed the evidence worthy of note precisely because the patentability of new life-forms "uniquely implicates matters of public concern." 447 U.S. at 322.
organisms, plants, and animals appears to have wide potential appli-
cability to both agriculture and industry. In certain cases the
research has reached the point of field testing and commercial
application.

In June, 1983, the House Science and Technology Subcommittee
on Investigations and Oversight held hearings to explore the poten-
tial consequences of the deliberate release of genetically engineered
organisms into the environment. Concern existed, and continues
to exist, because of the development of many commercially lucrative
and socially beneficial uses of biotechnology that involve the release
of new organisms outside the laboratory. These concerns tend to
focus not on the ethical dilemmas presented by human applications,
but rather on the potential environmental impact and uncertain eco-
logical consequences presented by any biotechnological release.

Using biotechnology, scientists have created a host of new
organisms that could bring tremendous benefits to the world. For
example, researchers are rapidly developing new varieties of plants,
some of which can survive under even the most adverse conditions,
and others that produce yields many times greater than those that
are now possible. These stronger crops might be able to reduce

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12. Impacts of Applied Genetics, supra note 10, at 49-108; The Environmental Impli-
cations of Genetic Engineering: Hearings Before the Subcomm. on Investigations and Oversight of the
House Comm. on Science and Technology and the Subcomm. on Science, Research, and Technology of
the House Comm. on Science and Technology, 98th Cong., 1st Sess. 59-95 (1983) [hereinafter
cited as Hearings: Environmental Implications]. See also Cong. Research Service, Animal
Sciences: Advances in Reproductive and Health Technologies: Report Prepared
for the Subcomm. on Investigations and Oversight of the House Comm. on Science
and Technology, 98th Cong., 1st Sess. (1983); Cong. Research Service, Recent
Advances in the Plant Sciences: Applications to Agriculture and Agricultural
Products: Report Prepared for the Subcomm. on Investigations and Oversight of the

13. Three deliberate release requests for field testing of genetically engineered organ-
isms have been approved by the RAC, although none have been implemented. See 46
Fed. Reg. 40,331 (1981)(use of recombinant DNA to investigate transformation events);
48 Fed. Reg. 16,459 (1983)(use of recombinant bacterial and yeast DNA on tomato and
tobacco plants to investigate transformation events); 48 Fed. Reg. 24,549 (1983)(treat-
ing plants with recombinant bacterial DNA to study ice nucleation patterns). The first
two tests are not ready for final implementation. The commencement of the third test
was halted by preliminary injunction. Foundation on Economic Trends v. Heckler, 587

14. Hearings: Environmental Implications, supra note 12. As a member of the House of
Representatives, Senator Gore chaired the Subcommittee and conducted the hearings.
Steve Owens served as counsel to the Subcommittee.

15. This is not to say that ethical dilemmas may not arise from continued and ex-
panded use of commercial applications of biotechnology. They may arise in the future
from unforeseen developments within the range of commercial releases, or from the
interrelationships of agricultural, medical, industrial and zoological applications. It is
merely suggested that the present concern is not, and need not be, centered on ethical
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world hunger significantly at some point in the future.\textsuperscript{16}

Scientists are also working on the creation of new microorganisms that can prevent frost damage to crops,\textsuperscript{17} clean up oil spills,\textsuperscript{18} detoxify hazardous waste,\textsuperscript{19} enhance mineral recovery from the earth,\textsuperscript{20} and help convert biomass to energy,\textsuperscript{21} to name a few potential applications. It is easy to imagine the significant benefits to be derived from, for example, a microorganism that can break down hazardous waste into its non-toxic components. Our nation has a tremendous problem with toxic waste disposal, and existing technologies offer little hope for a long-term solution.\textsuperscript{22} The microorganisms now being contemplated would attack everything from dioxin to PCBs.\textsuperscript{23}

To date, work on these new plants and microorganisms has been limited to the laboratory. In fact, the research guidelines that emerged from the Asilomar Conference contained a ban on the release of new organisms into the environment.\textsuperscript{24} That ban has been honored until this time. Recently, however, such substantial progress has been made in the laboratory that researchers and their commercial backers are anxious to proceed with field tests of their creations.\textsuperscript{25} Without such experimentation it is difficult, if not impossible, to determine whether genetically altered organisms will both survive in the natural environment and perform on a commercial scale. Simply put, it does little good to have a "bug" that can eat hazardous waste if it is never released into a contaminated area.

Scientists, as well as concerned citizens and Congress, are also concerned about how such releases may affect the delicate ecological balance of the natural environment. This potential disruption is

\textsuperscript{16} See Hearings: Environmental Implications, supra note 12, at 77-80 (statement of Dr. Ralph Hardy); IMPACTS OF APPLIED GENETICS, supra note 10, at 137-164.


\textsuperscript{18} Such an organism is described in Diamond v. Chakrabarty, 447 U.S. 303 (1980). See supra note 11.

\textsuperscript{19} See Hearings: Environmental Implications, supra note 12, at 59-61 (statement of Dr. Ananda Chakrabarty); IMPACTS OF APPLIED GENETICS, supra note 10, at 126-27.

\textsuperscript{20} See IMPACTS OF APPLIED GENETICS, supra note 10, at 117-19.

\textsuperscript{21} See id. at 293-303.


\textsuperscript{23} See supra note 13.


\textsuperscript{25} See supra note 13.
extraordinarily difficult to estimate. Predictions based on the effects of naturally arising organisms are of limited relevance because biotechnology is now producing many genetically engineered organisms with genotypes that did not previously exist.

The search for an accurate risk assessment methodology might be aided by an examination of natural analogues of biotechnological releases. For instance, human beings have adapted natural agricultural conditions to suit their needs throughout the history of civilization. The primary tools used in this adaptation have been crossbreeding and hybridization, which slowly develop and enhance desirable, naturally occurring mutations. Such techniques have made possible the “green revolution,” as well as the creation of new breeds of animals such as mules.

On the other hand, history is replete with examples of the problems created by the introduction of exotic organisms into environments to which they are not native and in which they have no natural enemies. For example, the gypsy moth was brought into this country in the nineteenth century as part of an effort to increase silk production; a few moths escaped and multiplied, and now gypsy moths destroy thousands of acres of American forests each year. The organisms that cause Dutch elm disease and chestnut blight entered the country accidentally; over the years, they have killed countless trees. Starlings were imported as pets; today, they travel in massive flocks, causing serious economic damage and posing a health hazard wherever they land. As a final example, kudzu was introduced into the southern United States in an attempt to control soil erosion. It may have helped prevent erosion, but it has spread dramatically throughout the South, often eliminating other forms of vegetation.

Considering all these factors, the Investigations Subcommittee concluded that while the possibility of any real harm resulting from a biotechnological release is small, the damage that could occur is great. In other words, any deliberate release presents a “low probability, high consequence” risk.

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26. IMPACTS OF APPLIED GENETICS, supra note 10, at 137.
29. STAFF OF SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT OF THE HOUSE COMM. ON
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All of the benefits and risks discussed here constitute only the roughest outline of factors to be evaluated during the risk assessment stage of an experiment. Unfortunately, testimony presented to the Subcommittee at the June 1983 hearings indicated that predicting the specific type, magnitude, or probability of environmental effects associated with a given release will be extremely difficult, if not impossible.\(^{30}\) As previously noted, this is primarily because no historical or scientific data reflects the behavioral characteristics of genetically engineered organisms outside the laboratory. Nevertheless, the testimony indicated that it is possible to devise procedures to produce generalized estimates of the probability of environmental damage.\(^{31}\) Clearly, these estimates must be used until better predictive methods are developed.

B. Governmental Oversight

1. The Current Regulatory Scheme

As long as the questions posed by biotechnology involved only matters of laboratory safety, the existing regulatory regime, largely consisting of NIH guidelines and RAC implementation, was sufficient. However, in the last few years, the expanding commercial potential of biotechnology has revived concerns about the adequacy of governmental oversight. As pressure increases to take genetically engineered organisms out of the laboratory and into the environment, Congress must determine how to ensure proper evaluation of the risks from deliberate release without unduly burdening the development of technology, and it must also decide whether the current regulatory scheme is adequate to perform this evaluation.

Extensive hearings by the Subcommittee on Investigations and Oversight in June 1983 made it clear that the current scheme of federal regulation does not guarantee that the potential environmental effects of a deliberate release will be adequately assessed.\(^{32}\) The central problems of the regulatory framework include its scattered authority, which has resulted in a “balkanized” regime of biotechnology oversight, and the limited expertise of the agencies involved. These flaws reveal the need to develop a comprehensive and centralized regulatory scheme. To respond to the difficult risk assess-

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\(^{30}\) Hearings: Environmental Implications, supra note 12, at 9-16 (statement of Dr. Martin Alexander, Cornell University); id. at 22-24 (statement of Dr. Frances Sharples, Oak Ridge National Laboratory); Staff Report, supra note 29, at 20-24.

\(^{31}\) Staff Report, supra note 29, at 20-24.

\(^{32}\) Id. at 24-25.
ment problems presented by biotechnology, governing agencies must possess both the expertise to evaluate properly the risks of release and the authority to enforce their decisions on uses and releases.33

The NIH guidelines, as overseen by the RAC, until recently constituted the only existing regulatory system governing deliberate biotechnological releases.34 The RAC was created, not primarily as a regulatory agency, but as an advisory body of experts to promulgate rules on safe laboratory practices and to prescribe physical and biological containment levels to protect against harmful environmental release.35 The deliberate release of any organism containing recombinant DNA requires the approval of the RAC, but only if such release is being conducted by an institution that receives support from the federal government.36 Privately funded biotechnology research cannot be controlled by these guidelines.37 Thus, although the RAC is the only federal entity that has had active responsibility for evaluating risks associated with biotechnology, its authority does not extend to the regulation of most commercial research.

The RAC has developed a narrow regulatory focus and expertise as a consequence of the NIH guidelines. Originally, the deliberate release into the environment of any organism containing a recombinant DNA molecule was completely prohibited, but in 1978 the guidelines were modified to allow the RAC to approve releases on a

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35. Biological and physical containment refers to the need to confine certain classes of organisms to the laboratory because of their potential to become infectious or be destroyed once released. Special equipment, laboratory design, and procedures are designated by the regulations for each of four containment levels. See 48 Fed. Reg. 24,569 (1983). These restrictions have been steadily relaxed in recent years as it became apparent that the underlying risks had been overestimated. See McChesney and Adler, supra note 33, at 10,370 n.45.
36. The guidelines apply to all NIH-sponsored and other federally funded research. 48 Fed. Reg. 24,557 (1983). Failure to comply with the guidelines may result in revocation of funding. Id. at 24,563. These guidelines are limited, however, to genetic engineering techniques that involve "molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell." Id. at 24,557. Certain types of genetic research do not fall within this category. See McChesney and Adler, supra note 33, at 10,370 & n.50.
37. Individuals, corporations, and institutions that are not federally funded cannot be required to comply with the guidelines. 48 Fed. Reg. 24,563 (1983). Such private institutions are encouraged to comply and are assured of confidentiality if they do so, but they cannot be compelled to comply.
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case-by-case basis. Although the guidelines have not essentially changed since 1978, the role of the RAC has evolved from a containment-focused lab safety monitor to a regulator of proposals for deliberate release of genetically engineered organisms into the environment. The RAC has already received and approved release applications, although no biotechnology experiment has yet been conducted in the field. However, the RAC guidelines are not adequate to deal with this new regulatory role: they offer no risk-assessment procedure, nor are they binding upon commercial research. Because research has advanced to the point where commercial applications are imminent and field testing has become crucial, some of the highly competitive biotechnology firms may decide not to request RAC approval since the process can impose costly delays in the testing and marketing of products. Thus, the RAC, as conceived under the NIH guidelines, cannot fully address and resolve the problems posed by commercial release.

In addition to questions about the comprehensiveness and effectiveness of the RAC's authority, there are serious shortcomings in the review procedure employed by the RAC to evaluate release proposals. The procedure is surprisingly amorphous, with no standardized method for assessing the environmental risks of field testing, nor even any criteria for deciding what information is necessary for such an assessment.

38. 48 Fed. Reg. 24,548-49 (1983). The RAC was to work with a private commercial group proposing a release through an Institutional Biosafety Committee (IBC), set up by the private company and registered with the RAC. The RAC would assess the application for release presented by the IBC and determine whether it presented a "significant risk to health or to the environment." If so, no release was to be allowed. 43 Fed. Reg. 60,126 (1978). Unfortunately, no methodology was formulated to assess the risk of release in 1978, and no standards have been developed for risk assessment to date. 43 Fed. Reg. 60,083 (1978).


40. The Congressional Office of Technology Assessment found that the guidelines "do not address the full scope of the risks of genetic engineering. They cover one technique, albeit the most important; they do not address admittedly uncertain long-term cultural risks; they are not legally binding on researchers receiving funds from agencies other than NIH; and they are not binding on industry." IMPACTS OF APPLIED GENETICS, supra note 10, at 217.

41. While commercial firms have been complying voluntarily with the guidelines, there is no requirement that they continue to do so. Even now, only 52 of over 300 biotechnology firms in existence have IBCs registered with the RAC. STAFF REPORT, supra note 29, at 28.

42. Id. at 27. Moreover, the fact that the guidelines require extensive use of very expensive safety features reduces the incentives of private firms to comply voluntarily.

43. Id. at 44.

44. Id. at 29. Applications are often submitted with incomplete data because the RAC does not specify the type or comprehensiveness of material required. Currently, information does not have to be submitted until 30 days before consideration, and confidential information does not circulate prior to that time at all. Release requests have
Furthermore, the RAC's composition casts doubt on its ability to assess adequately the environmental impact data in release requests. At the time of the June 1983 hearings, the RAC included no member trained in ecological or environmental science, nor did it employ consultants to assess the environmental implications of deliberate release proposals.

The shortcomings of the RAC were highlighted when, at the urging of several environmental groups, a district court ruled that the RAC had violated the National Environmental Policy Act (NEPA) by failing to require an environmental impact statement for an approved release. This decision called into question the legality of the entire RAC review process. While the court of appeals later lifted the district court's injunction against RAC approval of any application for release, questions still remain as to the adequacy of the RAC's risk assessment capability.

2. The Environmental Protection Agency and the Department of Agriculture

Partly because of the problems of the RAC, other federal agencies have attempted to exert control over deliberate release. Doubts exist, however, about their ability to regulate these releases or even to coordinate regulation with the RAC. The Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA) arguably have both the statutory authority and the technical expertise to regulate the introduction of specific genetically engineered organisms into the environment by commercial groups. A number of environmentally related statutes provide each agency with authority over new substances and foreign organisms. None of these statutes, however, was designed specifically for genetically engi-

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45. The Director of NIH appointed Dr. Frances Sharples, a terrestrial ecologist, to the RAC at Senator Gore's suggestion after these hearings. Mr. David Pramer, a microbial ecologist, was recently named to the RAC as well.

46. STAFF REPORT, supra note 29, at 30 n.54.


49. Foundation on Economic Trends v. Heckler, 756 F.2d 143 (D.C. Cir. 1985). The Court of Appeals did find, however, that the District Court's injunction against the University of California's deliberate release experiment was "completely proper." Id. at 158.

50. For an excellent discussion of these statutes and their implications for government oversight of commercial applications, see McGarity & Bayer, Federal Regulation of Emerging Genetic Technologies, 36 VAND. L. REV. 461 (1983); McChesney & Adler, supra note 33; and STAFF REPORT, supra note 29, at 24-51.
neered organisms, and none has been tested in the courts as a legitimate instrument for the regulation of biotechnology.

The EPA has claimed jurisdiction to regulate biotechnology under both the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). FIFRA suggests that the EPA has authority to regulate genetically engineered organisms in pesticides, but jurisdiction is limited to this narrow field. Similarly, because TSCA grants regulatory authority over "chemical substances," the EPA will be able to oversee the release of genetically engineered organisms only to the extent that the life forms themselves can be characterized as such. Such a characterization has yet to be examined by Congress or the courts.

Even if the EPA has clear jurisdiction to oversee deliberate release proposals of commercial entities, its technical ability to do so is questionable. The EPA has never been involved in regulating genetically engineered organisms and has no staff with the expertise to examine the risk assessment questions. The EPA has developed no methodologies to evaluate "environmental fate, human and experimental exposure, and potential environmental and health hazards of genetically engineered organisms." Moreover, the EPA review procedure under TSCA requires the agency to justify a rejection of a release proposal, unlike the RAC process which begins with a presumption against release.

The statutory authority of the USDA is even more problematic than that of the EPA. Several statutes arguably provide for USDA jurisdiction over genetically engineered organisms, but to date the agency has shown no real initiative in this area. Furthermore, the USDA also has limited expertise applicable to the regulation of biotechnology. Whether the USDA will become active in biotechnology remains to be seen. Should the agency seek to increase its role, as it was recently urged to do by a National Academy of Sciences

52. 15 U.S.C. §§2601-2629 (1982). FIFRA and TSCA are arguably the principal statutes defining EPA authority over biotechnology. Other statutes, such as the Clean Water Act, the Resource Conservation and Recovery Act, and the Clean Air Act, may also provide the EPA with authority to regulate various aspects of biotechnological release, but this mandate is unclear.
53. Staff Report, supra note 29, at 32-33.
55. Id. at 132.
56. Id. at 142 (statement of Dr. Edgar L. Kendrick, Acting Deputy Assistant Secretary for Science and Education, United States Department of Agriculture).
57. Staff Report, supra note 29, at 35-41.
58. Id. at 40.
The regulatory issues in this area would be further complicated. Because of the uncertainty surrounding USDA’s role, the General Accounting Office is currently reviewing the statutory authority of the agency over biotechnology.

3. Summary

The status of current federal oversight of deliberate commercial releases of genetically engineered organisms is uncertain, and the regulatory framework is riddled with gaps. No one statute gives any one agency complete and express jurisdiction over commercial biotechnology. The scope of agency activity is limited, with the result that the pressing concerns about the environmental implications of release are not properly addressed. No agency has enough expertise in both the scientific and the regulatory aspects of the problem to process a stream of applications for deliberate releases. There is also no formal mechanism by which the RAC, the EPA, and the USDA can coordinate their regulatory efforts. Indeed, what has resulted is a “balkanization” of regulatory responsibility and experience which could result in the inadequate assessment of release proposals.

C. Proposals for Reform

Because of the apparent regulatory vacuum, the Investigations Subcommittee recommended the formation of an inter-agency task force within the executive branch to review the jurisdiction of the various agencies with respect to the evaluation of release proposals and to begin the process of developing a risk assessment methodology. In response to this recommendation, the Administration formed the Cabinet Council Working Group on Biotechnology in April 1984. In December 1984 the working group issued a document which set forth the perspective of several agencies—the EPA, the USDA, and the Food and Drug Administration (FDA)—concerning their respective abilities to oversee aspects of biotechnology. The document contained policy statements from the three agencies outlining the regulatory steps each intends to take and the statutory authority under which each would act.

59. COMM. ON BIOSCIENCES RESEARCH IN AGRICULTURE OF THE NATIONAL RESEARCH COUNCIL, NEW DIRECTIONS FOR BIOSCIENCES RESEARCH IN AGRICULTURE 105-17 (1985).
60. The GAO review was initiated at the request of Senator Gore, who was then a member of the House of Representatives.
61. STAFF REPORT, supra note 29, at 41-42.
62. Id. at 43-51.
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Additionally, the document proposed the creation of an independent Biotechnology Science Board (BSB) to oversee activities pertaining to biotechnology within the executive branch. Five agencies (EPA, USDA, FDA, NIH, and the National Science Foundation) would form scientific advisory committees to provide technical expertise to the board. Each agency is to send a summary of any proposal it receives to its scientific advisory committee. The committee will then review the proposal and report to the agency's head on the proposal's acceptability. The BSB would also receive a copy of the proposal for comment and review.\(^\text{64}\)

The thrust of the Working Group's recommendation is to establish a RAC-like entity within each one of the relevant agencies (with the exception of NIH, in which the original RAC continues to operate). At first glance, this appears to be a step toward ensuring that an adequate risk assessment is made of every deliberate release of genetically engineered organisms. The plan, however, may not be all that it is promised to be. Indeed, while the plan aims to coordinate activities within the executive branch, the proliferation of RAC-like committees within the agencies could actually result in increased balkanization of those efforts.\(^\text{65}\) Thus, whether the proposal is either workable or desirable remains to be seen.

That the five agencies concerned might pursue their own particular interests is an unfortunate but realistic possibility, and to the extent that the "mini-RACs" escape the BSB's control and oversight, the goal of coordination will be thwarted. The most daunting problems for the government in regulating biotechnology have been the lack of much needed expertise within individual agencies and the divergent responsibilities of each agency. The EPA, for example, has considerable expertise with regard to environmental concerns but almost none concerning biotechnology. The NIH is the primary agency overseeing genetic engineering research, but it deals very little with environmental matters. Biotechnology is best treated as an interdisciplinary field, and the federal regulatory effort should recognize this fact. The agencies must, at a minimum, pool their resources and share their expertise.

Moreover, the Working Group's plan is premised on the assumption that existing statutes provide the agencies with authority to regulate biotechnology. As noted earlier, questions remain about the


jurisdictional scope of several statutes. As the RAC’s litigation experience has shown, little can be taken for granted in this area. At present, however, a wait-and-see approach seems best. Congress should allow the current Administration effort to proceed for now, if only because it reflects the agencies’ intention to do something rather than nothing. The challenge facing Congress as a result of this latest regulatory proposal is to determine where the executive branch’s efforts are proceeding effectively and where they are not.

Subsequent to the Science Investigations Subcommittee hearing in June 1983, two other congressional committees examined the deliberate release issue. Neither committee issued a report on its review, but it is clear that each was likewise concerned that adequate steps be taken to protect the environment. Additional hearings will inevitably be held on the subject.

It is too early to conclude that new legislation is needed to address the problem of deliberate releases. As long as the Administration’s effort proceeds smoothly, there is no real need for a legislative counter-effort. Of course, in the event that the current regulatory scheme is invalidated by the courts or is otherwise rendered inadequate, Congress will have to decide how best to guard against the potential hazards of deliberate releases without unduly burdening the development of socially beneficial technology. It should be recognized that throughout this regulatory process, Congress’ role will be primarily one of oversight and review. Congress has neither the desire nor the technical expertise to become enmeshed in the scientific minutiae that characterize the field of biotechnology. Moreover, that is not its purpose. It is the role of Congress to ensure that the right questions are being asked and to make certain that a process is established whereby the answers to those questions can be found. This is the case with all legislation involving health, the environment, science and related issues. Congress must look to “outsiders” such as scientists, industrialists, environmentalists, and concerned citizens for assistance in defining the questions and outlining the parameters for a regulatory approach. Once a regulatory approach has been defined, the task of developing specific regulations is delegated to the executive branch.

66. See supra text accompanying notes 50-60.
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gress then reviews the actions of the executive branch to ensure that it is fulfilling the legislative mandate, but it tries to avoid involvement in the actual regulation writing. In short, governmental oversight in the field of biotechnology must be a cooperative venture; the regulatory scheme must account for the respective roles of Congress and federal agencies and appropriately utilize the capabilities of each.

IV. Human Applications—Gene Therapy

A. Issues Involved

Gene therapy presents the greatest challenge of biotechnology for our society, if not for all of civilization. Biotechnology is providing us with vast amounts of information about the genetic basis of life, and scientists are beginning to understand how to intervene directly in the human genome to affect dramatically the fundamental characteristics of human beings.

Human gene therapy can be divided into two broad categories: somatic therapy and germline therapy. Somatic therapy affects only the cells of the individual being treated, while germline therapy affects the germ cells and thus the offspring of the individual. The most immediate use of either type of gene therapy would be in

68. One example of the dynamic character of biotechnology is the expanding use of genetic screening in the workplace. Such testing allows employers to determine whether a particular employee or job candidate is especially susceptible to some ailment based on an examination of his or her genetic make-up. While workplace genetic screening may seem to be a blessing in that it allows the employer to shield high-risk individuals from potentially life-threatening environments, the discriminatory potential of such screening is obvious. If employment decisions are based on such hypersusceptibility, and these traits have a disproportionate incidence among economically disadvantaged minorities, screening may become yet another invidious form of constitutionally impermissible discrimination. Thus the apparent boon brings with it a sobering bane. These issues were examined in depth during hearings of the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology. Senator Gore was chairman of this subcommittee when he served in the House of Representatives. See Genetic Screening and the Handling of High Risk Groups in the Workplace, Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology, 97th Cong., 1st Sess. (1981); Genetic Screening of Workers, Hearing Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology, 97th Cong., 2d Sess. (1982).

69. "Germ" or "germline" refers to those cells which are passed through the generations as part of the reproductive process.

70. See SPlicing Life, supra note 3, at 46. Scientists have already achieved the ability to make changes in the inherited physical characteristics of animals. In one experiment, the eye-color gene of fruit flies was altered, and the change in eye color was passed on to the offspring. See Spradling & Rubin, Genetic Transformation of Drosophila with Transposable Element Vectors, 218 SCIENCE 348 (1982). In the other experiment, a rat growth gene was spliced into the germline cells of several mice. The offspring of the mice inherited the growth trait, and in maturity were twice the size of normal mice. See Building Bigger Mice Through Gene Transfer, 218 SCIENCE 1298 (1982).
the treatment of certain diseases. Scientists already know that many serious diseases such as sickle-cell anemia, Tay-Sachs disease, and Lesch-Nyhan syndrome have genetic-based causes. They also believe that many others, including cystic fibrosis, muscular dystrophy, hemophilia, and some forms of cancer, similarly result from genetic disorders.\(^7\) By correcting defects through somatic gene therapy, an individual could be cured of an illness. Gene therapy performed on the germline cells of individuals could prevent the defective genes from being passed on to future generations, thus allowing for the total eradication of some diseases.

There seems to be almost universal agreement that somatic gene therapy ought to be used to cure genetically based diseases in individuals. However, there is a fine line between altering a gene to cure a disease and altering a gene to “enhance” a physical trait. Traits such as eye color and hair color are known to be genetically based. Other characteristics, such as personality, memory, and intelligence, are also thought by some to be derived from genes or gene clusters.\(^7\)\(^2\) Using somatic gene therapy to enhance physical traits is not as clearly desirable as using it to cure diseases. Most people involved in the debate do not think trait enhancement is advisable, but some find it acceptable.

Even more difficult ethical questions are raised by germline gene therapy. The human genetic structure is the result of a long process that scientists do not fully understand. The effects that would be triggered if the genetic pattern were altered are unknown. A commonly cited example of the problems that could arise if certain genetic defects were completely eliminated from the gene pool is the connection between sickle-cell anemia and malaria immunity.\(^7\)\(^3\) Sickle-cell anemia carriers have a high resistance to malaria. If the sickle-cell gene were eliminated from the gene pool, no more carriers would exist. Other things being equal, tropical zone populations would, as a statistical matter, be much more susceptible to malaria. While this problem might be controlled through a vaccination program, the costs of eliminating sickle-cell anemia might outweigh the benefits. One way suggested to deal with the kind of problem posed by links between genetic disorders and disease protection is to create “gene banks” in which genes could be stored and

\(^7\)\(^1\) See, e.g., Hearings: Human Genetic Engineering, supra note 6, at 275-76 (statement of Dr. Theodore Friedmann) (discussion of genetically based diseases).
\(^7\)\(^2\) Id. at 288 (statement of Dr. W. French Anderson).
\(^7\)\(^3\) See id. at 508 (statement of Dr. Bernard D. Davis) (discussion of sickle-cell anemia/malaria connection).
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remain available for future generations. While this idea may have merit, it raises a host of new questions such as which genes would be stored, what they would be used for, and who would make these decisions.

Another ethical question raised by germline therapy is that of consent. Future generations are unable to give their informed consent to genetic manipulation. The decision to alter germline cells has an impact far beyond the generation initially receiving the treatment. In such a case, society would in effect be acting as the agent not only of the child, but of all future generations as well. In some instances, such as Tay-Sachs disease, the benefits of eliminating the disease seem to be so immense that the consent of future generations may be taken for granted. Not all cases, however, will be so clear.

The problems raised by somatic therapy pale in comparison to the ethical conundrums raised by germline therapy. The same technology that may allow the eradication of crippling diseases could open the door to the Huxleyan possibility of predetermining the physical traits of future generations. The root of the problem lies in the fact that some genetic variations, such as the XYY chromosome abnormality, are not as clearly in need of correction as is Tay-Sachs disease. As an extreme example, societies could come to view certain physical characteristics, such as blue eyes and blond hair, to be so desirable that differing traits should be forever eliminated. At the core of the dilemma is the question of who would decide what is a disease and what is not. This is fundamentally a question of power within a society. It is likely that the people who would be classified as being diseased and in need of “correction” would not be the people who would be making the decisions. Genetic engineering thus could become a tool of social control. Is there a way to shield society from potential abuses without negating the unprecedented ben-

74. See id. at 388-89 (statement of Dr. LeRoy Walters).
75. The troublesome ethical questions presented by human gene therapy are discussed in Fletcher, Moral Problems and Ethical Issues in Prospective Human Gene Therapy, 69 VA. L. REV. 515 (1983). See also Hearings: Human Genetic Engineering, supra note 6, at 156-57 (statement of Dr. Alexander Capron)(ability to change genes implicates fundamental ethical values); id. at 388 (statement of Dr. LeRoy Walters)(as we move to more complex cases, the burden of moral justification becomes greater).
76. It is claimed that the higher representation of “super males” with the XYY chromosome configuration (as opposed to the normal XY configuration) in prisons “proves” that XYY males are prone to anti-social behavior. The question then arises whether society should opt for genetic screening to prevent the birth of XYY males, use genetic therapy to “correct” the XYY configuration, or simply do nothing at all. See Hearings: Human Genetic Engineering, supra note 6, at 478 (statement of Prof. Troy Duster).
benefits promised by gene therapy? We believe there is, but achieving that result will require a serious and thoughtful effort by our society.

These questions have already prompted a great deal of debate. For instance, in June of 1983, a number of religious leaders from Protestant, Catholic, and Jewish groups signed a "Theological Letter Concerning the Arguments Against Genetic Engineering of the Human Germline Cells." The letter called explicitly for a ban on research into germline engineering. It also expressed the fear that continuation of genetic research could lead to unthinkable applications of the technology. While the letter obviously did not halt the research, it emphasized the widespread societal concern about the ethical ramifications of the application of biotechnology to humans.

In November 1982, the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology held three days of hearings on the subject of human genetic engineering. There was no unanimity among the witnesses on the answers to the questions raised at those hearings. Every witness, however, expressed the sentiment that we must begin to examine the issues now while the technology is still in its earliest stages.

It is becoming clear that the technology to perform gene therapy may be upon us sooner than originally imagined. The first gene therapy experiments could occur within a year. Although these experiments will entail only an elementary application of the tech-

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77. On July 22, 1982, the New York Times published an editorial entitled "Whether to Make Perfect Humans." The Times believed the dangers of germline engineering to be so grave that it suggested serious consideration of "whether the human germline should be declared inviolable." Calling deliberate manipulation of the human germline a "watershed in history, perhaps in evolution," the editorial stated that although declaring the human germline inviolable would probably prove unnecessary, the question should be thoroughly debated in order to reach a full understanding of the issues. "The remaking of man," said the Times, "deserves a little discussion." N.Y. Times, July 22, 1982, at A22, col. 1.

78. This letter was subsequently placed in the Congressional Record by Senator Mark Hatfield. See 129 Cong. Rec. S.8202 (daily ed. June 10, 1983)(remarks of Senator Hatfield).

79. These hearings may be found in Hearings: Human Genetic Engineering, supra note 6.

80. Proposals for two gene therapy experiments are currently being prepared. One experiment will involve treatment of a child with Lesch-Nyhan disease. The other will involve children with a severe immunological disorder. See Baskin, Doctoring Genes, Science '84, Dec. 1984, at 53-54. A previous, albeit unsuccessful, attempt at human gene therapy was made in 1980 by Dr. Martin Cline of the University of California at Los Angeles. Dr. Cline attempted to use gene therapy to treat two girls who suffered from a blood disorder. Because Dr. Cline failed to receive permission to conduct the experiments from both the university and the NIH, he was severely reprimanded and stripped of his research grants. Hearings: Human Genetic Engineering, supra note 6, at 442-462 (statement of Dr. Martin J. Cline, University of California School of Medicine, Los Angeles); id. at 541-45 (statement of Dr. Bernard Talbot, Deputy Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health).
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ology, they represent the first step on a journey to an unknown destination. The earlier in the journey that society develops guidelines for dealing with gene therapy, the smoother the trip will be.

B. The Need for Consensus

Because of the enormous potential impact of biotechnology on society, answers to the fundamental questions it raises must be the product of social, not just scientific, consensus. We must acknowledge that biotechnology presents both benefits and risks. A broad national consensus concerning both the benefits we seek and the risks we will accept is necessary before technological momentum and rapid commercial exploitation effectively foreclose the opportunity to ask crucial ethical questions.

It is clear that we have far more to learn about the benefits and the dangers of human genetic engineering. Unless we achieve a better understanding of all its implications, we cannot hope to make reasoned decisions about the uses of the technology. If a consensus is not achieved regarding the crucial issue of where to draw the line between acceptable and unacceptable uses, the pressure of scientific advancement will severely test the ethical and political framework of our society.

The demands created by rapid scientific advancement must be counter-balanced by procedural safeguards to ensure that the ethical questions are adequately addressed. Instead of leaving the crucial decisions concerning the use of gene therapy to any one group or segment of society, we must formulate democratic processes to address the anxieties surrounding a technology which has the potential to alter fundamental aspects of human life.

Given the tremendous issues raised by the prospect of human genetic engineering, there is a critical need for review by some established forum. While many private and public studies of human genetic engineering have been conducted, and the Congressional Office of Technology Assessment has prepared comprehensive analyses of biotechnological issues, as yet no institution exists to monitor developments on an ongoing basis.

There is widespread agreement that some formal mechanism

82. See Id. at 91-105.

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should be established to address these issues. This sentiment was perhaps best expressed in November 1982 in testimony before the Investigations Subcommittee, when the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research called for the creation of a formal oversight body.\textsuperscript{84} Because it is so vital that we anticipate the consequences of human gene therapy in advance of the technology’s development and application, legislation was introduced in the Ninety-eighth Congress to establish a national commission on human genetic engineering.\textsuperscript{85} The commission proposal was approved by both the House of Representatives and the Senate. Unfortunately, it never became law.\textsuperscript{86} Similar legislation has been introduced in the Ninety-ninth Congress.\textsuperscript{87}

The proposed commission would have three functions. First, it would monitor developments in genetic technology that have implications for human genetic engineering. Second, it would provide a mechanism for public education about genetic engineering. Third, and most important, it would provide a forum for considering the ethical and social issues generated by human genetic engineering.

Additionally, because of the importance of biotechnology and the complexity of issues raised by it, the commission is designed to ensure that a broad and meaningful examination of the issues occurs. First, the commission would be an independent body. It would not be housed within any executive agency and would thus have maximum freedom to consider issues and render reasoned, objective advice. Furthermore, the commission would be interdisciplinary in its composition. It would consist of representatives from a variety of areas, including the general public. A majority of the commission’s members would be nonscientists, to ensure that it focuses on ethical issues and not on technical scientific concerns. Finally, the commission would be nonregulatory. It would be a purely advisory body with no regulatory power whatsoever. The commission would consider developments in genetic engineering and provide advice, in

\textsuperscript{84} Hearings: Human Genetic Engineering, supra note 6, at 114-21 (statement from President’s Commission for the Study of Ethical Problems in Medicine and Biomedical Research); \textit{id.} at 176-80 (statement of Alexander Capron).


\textsuperscript{86} The commission proposal eventually was incorporated as a provision in a larger piece of legislation reauthorizing the National Institutes of Health. The NIH bill, however, eventually was vetoed by the President for reasons unrelated to the commission. \textit{See Conference Rep. on H.R. 2350, 98th Cong., 2d Sess.} (1984).

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the form of written reports to Congress. Acceptance of the commission’s conclusions and recommendations will, of course, depend upon the force and quality of the reasoning behind them.

V. Conclusion

It is the responsibility of government not only to promote science but to consider the future path of technology and to anticipate any problems that technology might present. As biotechnology develops, it is essential that our nation be informed about its positive and negative potential. It is especially important that those of us in Congress base our reactions to and decisions about this technology on objective, reasoned consideration of the issues, and not on misunderstandings or exaggerations of its potential for either use or abuse.

Biotechnology will unquestionably have a tremendous impact on our society in the years ahead. The challenge we face is how to ensure that its benefits are realized while its misuses and dangers are avoided. Accomplishing this objective requires public education and reasoned debate over the complex issues that confront us. Legislators have a particular responsibility to ensure that the necessary discussion takes place and that we anticipate the questions which must be answered before events answer them for us. This will require diligence and continued foresight. The ever-changing nature of the technology and the emotionally charged atmosphere generated by the inevitable ethical dilemmas will not make this an easy task. However, “great powers imply great responsibility.”88 Congress must meet the challenge of this responsibility with timely vigor.

88. Hearings: Human Genetic Engineering, supra note 6, at 10 (statement from President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research).