GOVERNMENT REGULATION OF THE PURSUIT OF KNOWLEDGE: THE RECOMBINANT DNA CONTROVERSY

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For the past several years biologists have known how to transplant genetic material from one organism into another totally foreign organism. These transplants can leap across broad evolutionary distances, endowing an organism with new genetic information it could not possibly have acquired naturally. These experiments result in the creation of new and unique living things. The potential for this procedure cannot be underestimated; it is on a par with the splitting of the atom. Unfortunately, its consequences for mankind may be as devastating and as difficult to control.

As with many new technologies, recombinant DNA[1] research, as this technique is called, presents spectacular potential advantages to society as well as potential risks. Proponents claim that this research will lead to a profound new understanding of our genetic makeup, an easy method for producing scarce enzymes, heartier crops and possibly a cure for cancer and genetic diseases. Detractors point out that we know virtually nothing about the workings of genes. For all we know, they explain, an experiment could inadvertently create a new disease for which evolution has provided no defense. The word "create" is central to the debate. Underlying the technical dialogue is a concern that scientists will, through this research, assume the role of life-givers, creating modified or totally new living organisms and directing the course of evolution.

Inevitably, such a significant advance in technology poses potential consequences that are the legitimate concern of government. Federal, state and local legislators have responded by proposing, and in some instances imposing, strict controls on the conditions under which recombinant DNA experiments may be conducted.

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1. Deoxyribonucleic acid is the substance which transmits hereditary characteristics and controls cell functions.

Although not understood at the time, such regulations were precedent setting in that they regulated activities which were purely in pursuit of knowledge. Formerly, the threshold for regulation had been the proposed application of a new technology in society. Legislation controlling recombinant DNA research would, however, govern the development of the technology itself.

Amid public hearings and proposals for legislatively mandated controls, the biological research community has come under intense public scrutiny to which it is completely unaccustomed. Scientists have begun to protest that government control over the exploration for knowledge will stifle the creativity and technological progress that are hallmarks of our culture. They have asserted a right to freedom of scientific research and a right to decide for themselves what scientific activities are in the public's interest. In the recombinant DNA controversy, these issues have crystallized. It has become evident to an alarmed scientific community that the resolution of these issues will define boundary lines for increasingly frequent public intrusion into private scientific endeavors. It is equally evident to many laymen and legislators that important public policy questions exist in technological areas that heretofore have not been subject to the democratic process.

I. Recombinant DNA And Its Potential

Early man must have wondered what made the progeny of any species resemble their parents so closely, and why some differed. Since Mendel, the science of genetics has answered some of the basic questions of hereditary transfer, but the mechanism is still poorly understood. Scientists have long known that hereditary characteristics are carried on long chains of deoxyribonucleic acid (DNA) molecules called chromosomes. A discrete sequence of DNA molecules in a chain is called a gene. Genes code for the production of proteins which, in many combinations, make up the cell.[2] The particular combinations of proteins produced by an organism make it unique. Cells also may contain viruses and pieces of DNA not a

2. Some genes in higher organisms have other functions. A gene may direct other genes to start or stop the production of proteins, or the gene may be latent or unexpressed.

part of the chromosome.[3] It is these genetic segments which become the vehicle for the recombinant technique.

Researchers for many years have tried to decipher the genetic code contained in DNA molecules with limited success. DNA molecules are extremely small, too small to study their function in isolation. Even a simple bacterium contains at least several thousand genes. In order to study individual genes, a technique was needed to amplify a gene, to make its nature and function obvious. Artificial gene transplants provided a simple method.[4] It was discovered that enzymes produced by cells—called "restriction endonucleases" —split chains of DNA molecules at identifiable places. These enzymes could be used to split pieces of DNA or "vectors" that had been extracted from a single-celled bacterium. (See Figure I). DNA from any other organism could be isolated and split in precisely the same manner. When combined, pieces of DNA of one or more genes cut from the foreign organism will attach to the bacterial vector to form a hybrid "recombinant DNA" molecule. The vector can then be reinserted into the bacterium from which it came where it will reproduce itself each time the bacterium does. Each new generation will contain the recombinant DNA molecule. When grown in large quantities, the bacteria can easily be studied for any new properties it displays. The new properties should be the result of the new DNA, thereby unlocking the genetic code.[5]

A giant step has been taken, that of creating new life forms which have not occurred naturally. Understandably the consequences are largely unknown. The only certain product of this research will be an accelerated understanding of basic biological processes. Scientists hope that when enough information has been accumulated, they will know how genes are turned on and off in a cell,

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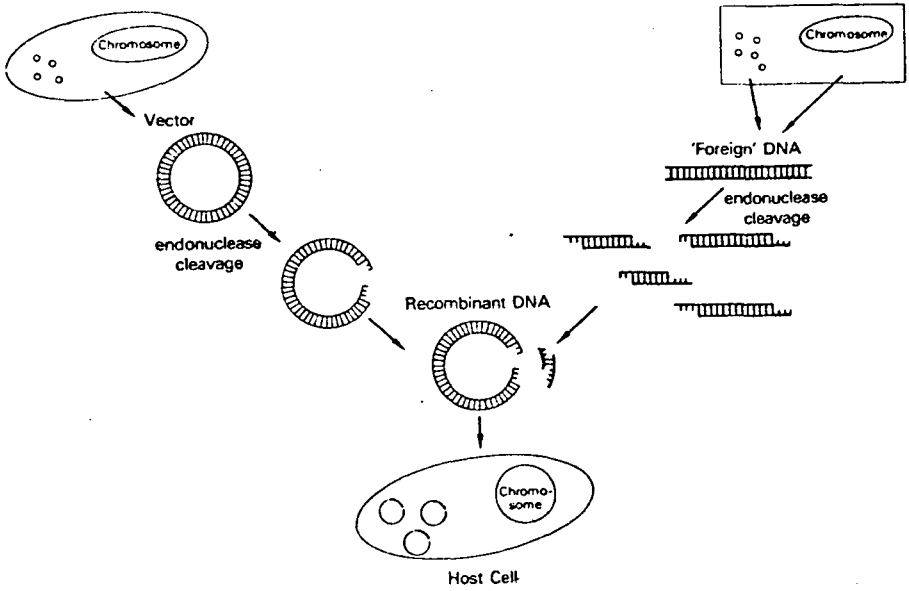
3. Extrachromosomal pieces of DNA used in recombinant DNA research are either plasmids, which are small circular pieces of DNA, or viruses, which are usually short, linear strands of DNA. Either can infect a cell. For a more complete discussion of cell biology, see J. WATSON, MOLECULAR BIOLOGY OF THE GENE (3d ed. 1976).

4. One observer pointed out that "[t]he technique requires a moderate degree of sophistication at present, [but] it will be a 'high school project within a few years.' " Wade, *Genetic Manipulation: Temporary Embargo Proposed on Research,* 185 SCIENCE 332, 332 (1974).

5. *See generally* U.S. DEP'T OF HEW, ENVIRONMENTAL IMPACT STATEMENT ON NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (1977) [hereinafter cited as EIS].

FIGURE 1



what makes genes malfunction and ultimately, how to cure genetic diseases, possibly even cancer.[6]

It is difficult to predict the ultimate application of findings from basic research; often the rewards are in areas least expected. Recombinant research, however, has produced some tangible benefits already. In California, a team of researchers implanted a gene for the human growth hormone, somatostatin, into the bacteria.[7] By growing large quantities of the bacteria, they can artificially produce this medically valuable substance that has been in short supply. Through a similar process, it is hoped that bacterial cultures can become important manufacturers of organic substances. Industry is very interested in the chance to produce needed drugs inex-

6. *Id.* at 31-36.

7. Itakura, Hirose, Crea, Riggs, Heyneker, Bolivar & Boyer, *Expression in Escherichia coli of a Chemically Synthesized Gene for the Hormone Somatostatin*, 198 SCIENCE 1056 (1978).

pensively;[8] and it is believed that insulin may be next for production.[9] Other speculative applications of recombinant DNA research include the release of recombinant organisms directly into the environment. Research is being conducted on producing bacteria which would efficiently "eat-up" oil spills[10] and which could take nitrogen out of the atmosphere to enrich the soil.[11]

Some scientists have urged a cautious approach towards this research. They point out that new products or technologies often have unexpected environmental effects. Pesticides have proven toxic to wildlife and man, gases used in air conditioners and spray cans have been shown to deplete the earth's protective ozone layer, and many common substances are now known to be carcinogenic.[12] A new living organism could pose even greater problems. It is possible that an improved oil-eating bacteria would not confine itself to oil spills, but would digest hydrocarbons wherever they are found, in machinery, for instance.[13] A bacterium engineered to produce insulin could find its way into a human causing an oversupply of insulin or insulin shock.[14]

Of the many species that now inhabit our planet, we are quite certain that innumerable unsuccessful mutations of every species have occurred that did not survive. Evolution tells the story of those that did. The gene transplant technique allows scientists to blindly accelerate natural evolutionary processes in ways that could be dan-

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8. *Recombinant DNA Research: Hearings Before N.Y. State Att'y Gen.* 137 (Oct. 21, 1976) (statement of John G. Adams, Vice-President, Pharm. Mfg. Ass'n) [hereinafter cited as *Hearings Before N.Y. State Att'y Gen.*].

9. Wade, *Recombinant DNA: NIH Rules Broken in Insulin Gene Project*, 197 SCIENCE 1342 (1977).

10. *Hearing Before N.Y. State Att'y Gen., supra* note 8, at 339-40 (statement of Dr. Manuel Aven).

11. Marx, *Nitrogen Fixation: Prospects for Genetic Manipulation*, 196 SCIENCE 638 (1977).

12. *Recombinant DNA Research Act of 1977: Hearings on H.R. 4759, 4849, 3191, 5020, 4232 and H. Res. 131 Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 95th Cong., 1st Sess. 303 (1977) (statement of Pamela Lippe) [hereinafter cited as *House Hearings*].

13. Wald, *The Case Against Genetic Engineering*, THE SCIENCES, Sept./Oct., 1976, at 10 [hereinafter cited as Wald].

14. U.S. DEP'T OF HEW, National Institutes of Health, Decision of the Director, National Institutes of Health To Release Guidelines for Research on Recombinant DNA Molecules, 41 Fed. Reg. 27,902, 27,908 (1976) [hereinafter cited as Decision of the Director].

gerous. It is not understood at present how DNA molecules are expressed in an organism. A gene that functions benignly in one organism may, when transplanted, make another organism pathogenic (disease-causing). The organism most commonly used in recombinant DNA experiments in *Escherichia coli*, (*E. coli*) a ubiquitous organism that inhabits the soil, water, and the gut of all warm-blooded animals, including man. If *E. coli* were transformed into a pathogen, it would surely affect us. Even if a gene transplant only caused an organism to be slightly more competitive in nature, once out of a laboratory, the organism could multiply and displace other useful organisms, upsetting the normal ecological balance. Since a new organism has been created, it would have no natural enemies to limit its growth. And once a new living thing leaves the laboratory and enters our environment, it can never be destroyed or recalled.[15]

Genetic recombination of a different type has taken place naturally for a very long time: it is called sexual reproduction. Two members of the same or closely related species of the opposite sex each contribute half their genome to their offspring. The difference between sexual reproduction and artificial genetic recombination is that with the latter, the genes of any two organisms, even man and a bacterium, can be crossed. There is no necessity for evolutionary closeness. The evolutionary distance between primitive bacteria and man is enormous, and to our knowledge a barrier prohibiting genetic exchange between higher and lower organisms has never been crossed. That barrier may serve some special purpose of which we are not aware.[16]

Recombinant DNA research poses unique philosophical and theological questions which up until now have been the province of science fiction. As Nobel biologist George Wald has stated:

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15. For a detailed discussion of the risks of recombinant DNA research, see N.Y. ATT'Y GEN., REPORT AND RECOMMENDATIONS OF THE NEW YORK STATE ATTORNEY GENERAL ON RECOMBINANT DNA RESEARCH 14-32 (1977) [hereinafter cited as REPORT AND RECOMMENDATIONS]. This report was prepared by Deborah W. Feinberg, Environmental Scientist, and Richard G. Berger, Assistant Attorney General, under the supervision of Philip Weinberg, Bureau Chief of the N.Y. State Attorney General's Environmental Protection Bureau. *See also* EIS, *supra* note 5, at 23-25.

16. Primitive, single-celled organisms called prokaryotes have no defined nucleus to the cells. Higher organisms, or eukaryotes, have a nucleus. Scientists have not been able to show that genetic exchange between the two can occur.

> Recombinant DNA technology faces our society with problems unprecedented not only in the history of science, but of life on the Earth. It places in human hands the capacity to redesign living organisms, the products of some three billion years of evolution.[17]

The ultimate extension of the recombinant technique is the deliberate genetic engineering of human beings, replacing undesirable genes with desirable ones. While the "brave new world" of Huxley's nightmare is by no means yet at our disposal, the time when scientists can create test tube babies has been greatly hastened.[18] The power to design life according to man's intellect is repugnant to many people; it assumes omniscience too close to God for many to accept. Recombinant research may present man with another forbidden fruit decision—whether to place the course of all evolution into our own hands. As Wald put it:

> It presents probably the largest ethical problem that science has ever had to face. Our morality up to now has been to go ahead without restriction to learn all that we can about nature. Restructuring nature was not part of the bargain; nor was telling scientists not to venture further in certain directions. That comes hard.[19]

II. National Institutes of Health Guidelines

To its credit, the research community immediately grasped the significance and potential dangers of recombinant DNA.[20] At the Gordon Research Conference on Nucleic Acids in July 1973, participants voted to call for the establishment of a national scientific

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17. Wald, *supra* note 13, at 7.

18. It was recently reported that a man had an exact replica of himself produced by cloning. It was claimed that the cell nucleus of a human egg cell was replaced by the nucleus of a cell from the "father." A 14 month-old son is claimed to be the product of this experiment. Although this incident is highly suspect, such experiments have been performed successfully with frogs. *See Author in Controversy on Cloning Asserts That He's Seen Lab Child*, N.Y. Times, Mar. 9, 1978, at 42, col. 3.

19. Wald, *supra* note 13, at 8.

20. In 1971, Dr. Paul Berg of Stanford University implanted a virus, SV40, which causes cancer in higher primates, into *E. coli* bacteria. Upon advice from Dr. Robert Pollack of the Cold Spring Harbor Laboratory, Berg destroyed his experiment. *See* Bennett & Gurin, *Science that Frightens Scientists*, The Atlantic Monthly, Feb. 1977, at 43.

committee to consider the new problems.[21] The committee in turn called for an international conference on recombinant DNA.[22] And for the first time in history, scientists engaged in research called for a voluntarily imposed moratorium upon certain of their own experiments.[23] The only conceivable precedent for this action was the recommendation to President Truman by the developers of the atom bomb not to use it.

The role of government, especially the federal government, in setting safety standards for recombinant DNA research has been a central issue of debate since the controversy arose. Government's involvement was understood to be a necessary part of the research process. The National Institutes of Health (NIH) had been directly involved with recombinant DNA research at the first through an extensive grant system. As a branch of the Department of Health, Education and Welfare, NIH was the natural agency to act as coordinator of research data and regulatory efforts. In 1974, at the behest of involved scientists, NIH established a Recombinant DNA Molecule Program Advisory Committee.[24] This committee, as others at NIH, was made up of members of the research community who were trusted to act responsibly toward their peers. Their efforts culminated in June 1976, in the publication of Guidelines for Research Involving Recombinant DNA Molecules.[25]

The NIH Guidelines established procedures for the conduct of recombinant DNA experiments and banned certain ultrahazardous experiments altogether. Prohibited were the implantation of DNA from a known pathogenic organism, from cancer causing viruses, and from organisms known to synthesize potent toxins (such as

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21. Singer & Soll, *Guidelines for DNA Hybrid Molecules*, 181 SCIENCE 1114 (1973) (letter to Philip Handler, president of the National Academy of Sciences, and to John R. Hogness, president of the National Institute of Medicine).

22. Berg, Baltimore, Boyer, Cohen, Davis, Hogness, Nathans, Roblin, Watson, Weissman, Zinder, *Potential Biohazards of Recombinant DNA Molecules*, 185 SCIENCE 303 (1974) (open letter from Committee on Recombinant DNA Molecules Assembly of Life Sciences, National Research Council, National Academy of Sciences).

23. *Id.* For a brief summary of the history of the recombinant DNA debate, see Decision of the Director, *supra* note 14, at 27,902.

24. Decision of the Director, *supra* note 14.

25. U.S. DEP'T OF HEW, NATIONAL INSTITUTES OF HEALTH, GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES, 41 Fed. Reg. 27,911 (1976) [hereinafter cited as GUIDELINES].

botulinium and diptheria toxins). Two security systems were proposed to minimize the risk in permitted experiments of a recombinant organism inadvertently escaping the laboratory. The first was a physical containment system of four categories ranging from a standard biological laboratory (P-1) to the type of laboratory used in biological warfare research (P-4). Experiments required one of the four types of facilities according to estimated risk. For example, in a P-4 facility all liquid and gaseous wastes are incinerated and personnel must shower and change clothes upon entering and leaving. The other containment system required the use of specially cultured bacteria which have difficulty surviving outside of specially controlled laboratory conditions.[26]

III. Government and Science

The NIH Guidelines, despite the fact that they were issued by an agency of government, were rules that were devised by scientists for scientists. As long as government regulation of scientific research was under the auspices of NIH, the research community felt secure. It was, in effect, a form of self-regulation. The NIH Guidelines apply only to NIH grantees, and their violation carries no legal sanction, only termination of the grant. NIH is not designed to be a regulatory

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26. Although the restrictions imposed upon those experiments classified as most hazardous are quite strict, they cannot guarantee the isolation of the experiment. A culture of bacteria contains many billions of organisms, only one of which has to escape the laboratory and survive. The NIH Guidelines in general have been the subject of severe criticism. They depend entirely for their effectiveness on the use of proper laboratory technique, which is often lacking in university labs. *See House Hearings, supra* note 12, at 296 (statement of Dr. Jonathan King). Moreover, the Guidelines impose only very loose requirements for experiments considered to be of lesser hazard. Prior history of such laboratories suggests that even under the best of conditions, laboratory workers still acquire infections and carry the quarantined organisms out of the laboratory with them. Kissling, *Laboratory Acquired Infections,* in Biohazards in Biological Research 70 (A. Hellman, M. Oxman, R. Pollack eds. 1973).

In this field filled with uncertainties, it should come as no surprise that the NIH Guidelines are basically the result of educated guesswork. Scientists do not yet know how foreign DNA will behave when inserted into a new organism. Moreover, it is often not known what the inserted DNA codes for, since finding that out is the purpose of many experiments. The Guidelines are based upon the assumption that the closer the organism which donates DNA (the foreign organism) is to man, the greater the potential biohazards, and thus the higher the assigned containment level. Decision of the Director, *supra* note 14, at 27,908. This assumption of being protective of man has no experimental validity. Moreover, it ignores the possibility of a recombinant organism becoming a blight to plants or animals upon which man depends for food.

agency and does not have the capability to conduct widespread inspections. Moreover, NIH's role as sponsor of research would make it difficult for it to assume the role of policeman.[27] There simply is not an arm's length relationship between scientists and the Institute—nor should there be.

The press and broadcast media reported the advent of recombinant DNA with interest and concern.[28] To some extent, the broad public exposure it received was due to the efforts of scientists themselves to inform the public of the nature and consequences of their work. Research scientists had always disclosed their work publicly to each other in scientific journals and at conferences. This time an effort to include the public was made. Members of the press, government and public interest groups were invited to an international conference called to discuss dangers of the research.[29] As the NIH Director noted:

> Public responsibility weighs heavily in this genetic research area. The scientific community must have the public's confidence that the goals of this profoundly important research accord respect to important ethical, legal and social values of our society. A key element in achieving and maintaining this public trust is for the scientific [*sic*] community to ensure an openness and candor in its proceedings.[30]

The wide publicity this issue received succeeded in arousing public concern and produced calls for mandatory controls to protect the public. Lawmakers in Congress, state legislatures and local governments responded with various proposals to license or otherwise regulate recombinant research. In the Senate, the Subcommittee on

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27. The Atomic Energy Commission formerly had dual responsibilities, to promote the peaceful uses of nuclear energy and to regulate the industries. Congress concluded that these two roles were inappropriate for one agency, and divided the duties between two new agencies, the Nuclear Regulatory Commission and the Energy Research and Development Administration. Energy Reorganization Act of 1974, Pub. L. No. 93-428, 88 Stat. 246 (codified in scattered sections of 5, 42 U.S.C.). See particularly, 42 U.S.C. § 5814(a) (Supp. V 1975).

28. Bennett & Gurin, *Science that Frightens Scientists, supra* note 20; Cavalieri, *New Strains of Life—or Death,* N.Y. Times, Aug. 22, 1976, § 6 (Magazine) at 8; *Tinkering With Life,* TIME, Apr. 18, 1977, at 32.

29. U.S. DEP'T OF HEW, I Documents Relating to "NIH Guidelines for Research Involving Recombinant DNA Molecules" 140 (1976) (Proceedings of a Conference for Research on Recombinant DNA Molecules in Recombinant DNA Research, Feb. 1975-June 1976).

30. Decision of the Director, *supra* note 14, at 27,903.

Health held hearings as early as 1975 on problems presented by this new research.[31] In 1976 the subcommittee proposed legislation which would have imposed comprehensive regulations upon all persons conducting recombinant DNA research, including industry and others who received no NIH funding.[32] A key concept in the bill was the mandatory participation of nonscientists in a National Recombinant DNA Safety Commission which would set regulations and oversee licensing. The bill also required that members of the lay public sit on biohazards committees, to be established at each licensed institution.[33]

Involved scientists, who at first had been eager to inform the public of their exciting new discoveries, began to reconsider the implications of their position. They saw themselves losing control of regulatory efforts to laymen who would not understand the technically complex issues and who might not have the same good will towards the research profession as one of their own.[34]

Legislative activity was not limited to the Senate. In the House, the Subcommittee on Health and the Environment held hearings on several of its own legislative proposals.[35] Although the House bills were as extensive as the Senate bill, they were more to the liking of the scientific community because they mandated no lay involvement.[36]

Several states began to consider the adequacy of the NIH Guidelines and the need for state legislation. The New York Attorney General's office held a public hearing in October 1976, and concluded that New York should devise its own, possibly more re-

31. *Hearings on Genetic Engineering, Examination of the Relationship of Free Society and its Scientific Community, Before the Senate Subcomm. on Health of the Comm. on Labor and Public Welfare*, 94th Cong., 1st Sess. (1975).

32. S. 1217, 95th Cong., 1st Sess. (1976) (as amended, July 22, 1977) S. 1217 established a National Recombinant DNA Safety Committee within HEW to study new data, promulgate updated safety regulations, review license applications and to invoke sanctions in cases of violation. One of the Commission's charges was to analyze the ethical implications of potential application of recombinant DNA technology.

33. S. REP. No. 95-359, 95th Cong., 1st Sess. 35 (1977).

34. Culliton, *Recombinant DNA Bills Derailed: Congress Still Trying to Pass a Law*, 199 SCIENCE 274, 275 (1978) [hereinafter cited as Culliton].

35. *House Hearings, supra* note 12.

36. Culliton, *supra* note 34, at 275.

strictive, regulations to protect its citizens.[37] A bill proposed by the Attorney General was in fact passed by the legislature that would have licensed recombinant DNA experiments and production of recombinant organisms and required minimum qualifications to be set for persons conducting the research.[38] The bill was vetoed by the governor after strong lobbying by the scientific-academic community.[39]

In California, a comprehensive law was proposed to regulate all hazardous biological research including, specifically, recombinant DNA research.[40] The argument had been presented that many kinds of biological research were known to be extremely hazardous, as opposed to recombinant research which only carried that potential. Scientists had for some time worried that recombinant DNA regulation would act as a first precedent for total regulation of their work. The California bill confirmed their worst fears.[41]

In Maryland, a much simpler bill which merely adopted the NIH Guidelines as state law passed the legislature and was signed by the governor.[42] Maryland is now the only state where all researchers must comply with the Guidelines.

It was in Cambridge, Massachusetts, however, the home of Harvard and Massachusetts Institute of Technology, that lay participation in the standard-setting process for scientific research was actually practiced. In July of 1976 the City Council of Cambridge imposed a moratorium on all recombinant DNA experiments which were in the two most hazardous classifications for permissible experiments under the NIH Guidelines.[43] A citizens' committee was established to review the adequacy of the Guidelines. It recommended finally that the research continue under strict adherence to the Guidelines with certain additional regulations, including a com-

37. REPORT AND RECOMMENDATIONS, *supra* note 15.

38. N.Y., S. 4009-D, A. 6740-D (1977-1978 Sess.).

39. N.Y. LEGIS. RECORD AND INDEX, Memo 45, at S408 (1977)(vetoed Aug. 5,1977). The bill was opposed by the American Association of University Professors and several medical research institutions.

40. Cal., A. 757 (1977-1978 Sess.).

41. *See* Wade, *Gene Splicing: Senate Bill Draws Charges of Lysenkoism* 197 SCIENCE 348, 350 (1977).

42. MD. ANN. CODE art. 43, §§ 889-910 (1977).

43. *House Hearings, supra* note 14, at 209 (statement of David Clem).

munity representative on institutional biohazards committees. In February 1977, the City Council passed an ordinance adopting the recommendations.[44]

IV. Who Shall Decide What is Hazardous

Faced with the possibility of multiple requirements being placed upon their research by various levels of government, scientists closed ranks in defense of their profession. A strong lobbying effort was launched to defeat any congressional legislation.[45] They argued that new evidence demonstrated that hazardous recombinant organisms were more difficult to create and had less chance of surviving than formerly feared.[46] To some extent, these lobbying efforts were based upon scientific judgment that recombinant research did not present an imminent threat to mankind. Scientists did not want burdensome requirements imposed upon them which might ultimately prove unwarranted. But in part, objections to legislation were based upon a belief that only scientists were competent to judge what research constitutes a public hazard.

William McGill, president of Columbia University and a leading critic of government intrusions into university affairs, stated the argument quite clearly:

> Scientific questions simply cannot be settled by persuasive argument. The only effective method for resolving safety questions in nuclear or biological research is the objective analysis of experimental results by our best scientific minds.[47]

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44. Balmer, *Recombinant DNA: Legal Responses to a New Biohazard*, 7 Envt'l L. 293, 300-04 (1977); Wade, *Gene-Splicing: Cambridge Citizens OK Research but Want More Safety*, 195 Science 268 (1977).

45. Culliton, *supra* note 34, at 276.

46. *Id.* at 275. Roy Curtis, III, a prominent expert on *E. coli*, claimed that the laboratory strain of bacteria used in more hazardous recombinant experiments had a statistically small possibility of surviving and could not transfer its DNA to normal bacteria which could survive. A recent conference at Falmouth, Massachusetts, reviewed recent experiments, and found that risks from recombinant DNA were still speculative. Another researcher, Dr. Stanley Cohen, claimed that genetic recombinations between bacteria and higher organisms occur in nature and are not unique to the laboratory.

47. Address by William J. McGill to the Guild of Catholic Lawyers of the Archdiocese of N.Y., *reprinted in McGill Warns vs. Adversary Method*, 198 Science 275 (1977).

Because only scientists are capable of defining what is dangerous with regard to their own activities, they believe that they must be essentially self-regulating.[48]

The argument that experts must make technical safety decisions has some attraction. For lay legislators to recognize that a potential public hazard exists, some member of the scientific community must identify the problem. If there is complete unanimity in the scientific community that a particular technology presents no danger, laymen would not be aware of such danger until the damage has occurred. Even when problems have already become manifest, experts are needed to define the causes. Society here depends upon the conscientious scientist to warn it despite the fact that the scientist's self-interest may be adversely affected. Moreover, the duty continues, because in any developing field of knowledge, new data will constantly develop which might modify initial judgments. Experts must honestly interpret this new data for their representatives.

The ability to define risk situations, however, does not give scientists the duty to decide what level of risk society will bear. That decision must be made by the representatives of those who bear the risk—the public. Professor Harold Green commented in regard to the making of public safety determinations:

> Scientists and engineers have an important role to play in the making of safety determinations. Representatives of these disciplines are obviously better equipped than others to identify and quantify potential risks and identify potential benefits. It is questionable, however, whether they have any special competence to quantify benefits in a manner that can be regarded as authoritative in the formulation of public policy. No elite group of experts, no matter how broadly constituted, has the ability to make an objective and valid determination with respect to what benefits people want and what risks people are willing to assume in order to have these benefits.[49]

The ability of laymen to understand and judge the merits of

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48. This argument was forwarded by Nobel Laureate David Baltimore. *Hearings Before N.Y. State Att'y Gen.*, *supra* note 8, at 43.

49. Green, *The Risk-Benefit Calculus in Safety Determinations*, 43 GEO. WASH. L. REV. 791, 792 (1975).

issues when presented with arguments from all sides is the basis of the jury system. Indeed, legislators have always made judgments upon technical issues when legislating on behalf of public safety. Traditional subjects of legislation, such as sewer regulations, are perhaps less complex, but in principle are no different from the issues posed by recombinant research. In the past few decades, legislators have worked with difficult technical problems of air and water pollution, toxic substance control, and nuclear power, without being overwhelmed.

When experts disagree about a particular issue, they most often concur on factual issues but differ in their underlying assumptions about that which is unknown and subject to speculation. Joshua Lederberg, a Nobel prizewinning biologist, aptly states this in evaluating the risk to the public from environmental radiation:

> [C]onscientious men . . . had no difficulty in finding the common boundary of their knowledge of the hazards of a given dose of radiation. They could make rough estimates of the expected number of deaths and other miseries—but this was all they were competent to do.[50]

The rest of the inquiry, that of determining what level of radiation is acceptable to society, is for government to decide.

With increasing frequency, detailed risk analyses are being used to help guide policymakers in making critical decisions on technological issues. They are used most often to predict the possibility of a certain undesirable event from occurring. Incredibly sophisticated mathematical models have been developed to predict the catastrophic failure of a nuclear power plant,[51] the risk of a supertanker spilling a large quantity of liquefied natural gas in a harbor collision[52] and of other instances of the implementation of a new technology. But in almost all cases the model of the probability of a particular event is subject to attack due to the many assump-

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50. Lederberg, *The Freedoms And The Control of Science: Notes From The Ivory Tower*, 45 S. CAL. L. REV. 596, 610 (1972).

51. U.S. NUCLEAR REGULATORY COMM'N, REACTOR SAFETY STUDY, WASH. 1400 (1975).

52. *See* Application of Distrigas Corp., Docket No. CP73-132 (Fed. Power Comm'n, filed Nov. 17, 1972); Eascogas LNG, Inc., Docket No. CP73-47 (Fed. Power Comm'n, Filed Aug. 14, 1972).

tions made at each stage of the model. The unpredictable factor of human error must be considered as well.

In the recombinant DNA controversy, the possible risk scenarios are so varied and the available information is so scant that no risk analysis can even be attempted. As in most cases, scientists are in agreement about the known facts. The dispute thus revolves around philosophical differences. Basically, proponents believe that the benefits of recombinant DNA research are needed by society, that scientific inquiry should not be limited, and that research should continue until hazards can be demonstrated.[53] Opponents point to unacceptable potential hazards in arguing that the research should be deferred or severely restricted until it can be proven safe.[54] The debate seen in this light resembles disputes in more conventional environmental issues, such as whether to begin drilling for oil in a virgin area of the continental shelf.

Despite the deference sometimes accorded scientists by our society, their opinions about matters within their chosen fields may be colored by self-interest. Scientists are no different from any other group in this regard. In the biological research field there is intense competition to produce experimental results and to obtain grant money.[55] Under these pressures, laboratory rules are often carelessly disregarded, in the interest of saving time.[56] Biologists often work with known disease-causing organisms, and tend to accept the risks of their work for themselves, risks the public would not voluntarily bear. It is thus easy to understand why the judgment of acceptable societal risk by a practicing biologist might differ greatly from that of an average person.

Balancing the needs of society against threats of the public

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53. *Hearings Before N.Y. State Att'y Gen., supra* note 8, at 94-95 (statement of Dr. James D. Watson).

54. *Id.* at 67-75 (statement of Dr. Erwin Chargoff).

55. *House Hearings, supra* note 12, at 296 (statement of Dr. Jonathan King).

56. *Id.* George Wald testified that the Harvard biology laboratories are infested by red ants which have proven immune to pesticides. One researcher left flasks of radioactive materials unwashed. The ants devoured the medium and spread radioactivity throughout the laboratory. *Hearings Before N.Y. State Att'y Gen., supra* note 8, at 111-12.

Already, there have been two reported violations of the NIH Guidelines. *See* Wade, *Harvard Gene Splicer Told to Halt,* 199 SCIENCE 31 (1978); Wade, *Recombinant DNA: NIH Rules Broken in Insulin Gene Project,* 197 SCIENCE 1342 (1977).

health, welfare and safety is the particular province of elected representatives. These decisions are essentially moral decisions. For example, in the case of air pollution laws, it is understood that even if all of the imposed air quality standards are met, a certain number of susceptible people will become ill or die from the effects of pollution. Legislators weigh those factors against the high costs of eliminating pollution from automobiles, industry and other sources to arrive at acceptable standards. Those standards might be quite different from industry or medical society recommendations. In much legislation dealing with technological problems, the regulatory task is assigned to administrative agencies which develop expertise in a particular field. But the basic balancing is a nondelegable legislative function.

In an age of startling technological advance, the public has come to see scientific issues as political questions involving matters of proper administration of government and distribution of goods and services. The phenomenon can be seen in the debate over nuclear power alternatives, including reliance on fission-powered reactors, funding and development of plutonium-breeding reactors, and plans for the reprocessing of spent nuclear fuel for the extraction of plutonium.[57] In many states populist referendums were placed on ballots proposing moratoriums on construction of nuclear power plants.[58] Similarly, the proposal to land supersonic passenger aircraft in the United States has caused intense debate. People have begun to realize that these seemingly abstract issues may have a profound impact upon their lives. Most importantly, they are demanding that technical decisions be made subject to democratic institutions and majority rule.

The way in which our society addresses problems of new technology has been altered. Formerly, a new product was tested in the marketplace. If it satisfied a need and if it did not cause detectable harm, it would continue to be sold and distributed. This process of using society as guinea pigs has become unacceptable. New technological advances are fundamentally different in that they can inflict

57. *See* Shea, *New Nuclear Policy Under The National Energy Plan*, 29 BAYLOR L. REV. 689 (1977).

58. *See, e.g., California County Votes 2 to 1 to Bar Nuclear Plant, N.Y. Times*, Mar. 9, 1978, col. 4 at 57.

massive damage on humanity. When a case is in question, the burden of proof is now upon the developer of a technology to show that it will not be harmful. This is the practical effect of the Toxic Substances Control Act[59] and the National Environmental Policy Act.[60] The latter Act has been interpreted to require a thorough investigation of the environmental consequences of a new technology during development stages, before an irreversible commitment is made which bars other alternatives.[61]

Recombinant DNA research is somewhat different from nuclear power plants, supersonic aircraft or pesticides. No one has suggested that harmful technologies can be deliberately inflicted upon society against its will. Recombinant DNA research, however, involves no deliberate introduction of its product into society. In the future, it may be proposed to use recombinant organisms, such as oil-eating bacteria, outside the laboratory. At this point it is predominantly pure research, and only inadvertently might society be adversely affected. The questions posed are thus different from those involved in prior technologies. Can society regulate and possibly restrict the mere development of a new technology? Is there a first amendment protection for scientific research which requires that society bear certain risks to foster free inquiry? These novel questions will now be considered.

V. Scientific Research and the First Amendment

Amid public calls for strict regulation, scientists have asserted in their own defense a right to pursue their work free from outward controls.[62] Dr. David Baltimore of Massachusetts Institute of Technology, a Nobel prizewinning biologist, stated the argument in these terms:

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59. 15 U.S.C. §§ 2601-2629 (Supp. V 1975).

60. 42 U.S.C. §§ 4321-4347 (Supp. V 1975).

61. Scientists Inst. for Public Information v. Atomic Energy Comm'n, 481 F.2d 1079 (D.C. Cir. 1973) (regarding the liquid metal fast breeder reactor).

62. The editor of *Science*, Philip Abelson, commented in a recent editorial on the unsuccessful attempts in Congress to impose mandatory controls on recombinant DNA research. He began: "During 1977 the scientific community escaped a threat to the freedom of inquiry in the form of harsh legislation." Abelson, *Recombinant DNA Legislation*, 199 Science 135 (1978).

> The new biology has become the new politics in a very concrete manner: biologists are spending their time in the halls of Congress trying to prevent the establishment of the first commission to be appointed to control basic research. I believe that our success or failure will determine whether America continues to have a tradition of free inquiry into matters of science or falls under the fist of orthodoxy.[63]

Columbia's president, William McGill, became even more impassioned. With respect to the recombinant DNA debate, he recently stated: "To those of us raised in the traditions of academic freedom the atmosphere is reminiscent of the days of Galileo and the Inquisition."[64]

To these and many other scientists, the public reaction to dramatic press reports of potential biohazards is frightening. They are worried that if the public can regulate the conditions for their work because of public health dangers, their work can also be banned. And if it can be proscribed for scientific reasons, it can also be proscribed because it is unpopular. As Galileo and Darwin have demonstrated, new discoveries can result in new hypotheses which contradict strongly held societal beliefs, making the exponent seem heretical. Scientists seem to be asking that their freedom to pursue new avenues of knowledge not be blocked for nonscientific reasons.

If protected by the Constitution, freedom of scientific inquiry must find its shelter under the first amendment. The question of whether there is a first amendment freedom of scientific inquiry has never been the subject of judicial review. An argument might be made that scientific research is a type of speech, and even if unpopular, is constitutionally protected.

The subject of academic freedom, which encompasses the subject of freedom of scientific inquiry, has been discussed in dicta by the United States Supreme Court in *Keyishian v. Board of Regents*.[65] The Court there struck down a New York law which required teachers to certify that they were not communists. Al-

63. Address by Dr. David Baltimore, University of Missouri (May 6, 1977), *quoted in* Culliton, *supra* note 34, at 274.

64. McGill, *Adversary Legal Process—Scientific Research*, COLUM. TODAY, Winter, 1977, at 24.

65. 385 U.S. 589 (1967).

though not resting on academic freedom, the Court's opinion outlined strong support for this right.

> Our Nation is deeply committed to safeguarding academic freedom, which is of transcendent value to all of us and not merely to the teachers concerned. That freedom is therefore a special concern of the First Amendment, which does not tolerate laws that cast a pall of orthodoxy over the class room.[66]
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> . . . To impose any strait jacket upon the intellectual leaders in our colleges and universities would imperil the future of our Nation. No field of education is so thoroughly comprehended by man that new discoveries cannot yet be made.[67]

As government proceeds toward regulation of intellectual activities which are probing outer frontiers of our knowledge, the issue of constitutional protections must be faced. There are, however, many distinctions between recombinant DNA research and the advocacy of communism. The activity of conducting an experiment which may cause physical harm is traditionally something which state governments have regulated under their police powers. Advocacy of communism is definitionally only a type of speech. When divorced from activities which directly would undermine our government by extraconstitutional means, it is mere advocacy of an alternative socio-economic system and hence beyond regulation under the police powers.

Almost any activity engaged in can take on an aspect of speech. Recombinant research, for example, can have the attributes of speech in two ways. First, the mere advocacy of recombinant research is pure speech. Second, an experiment may be objectionable not because it endangers anyone, but because, as with the practice of communism, it offends community ethical values.[68] The latter is an example of symbolic speech.

Courts have long found justification in limiting speech when its consequences cause public harm. Justice Holmes, in *Schenck v. United States*,[69] first used the analogy of a man shouting fire in a

66. *Id.* at 603.

67. *Id.* (quoting Sweezy v. New Hampshire, 354 U.S. 234, 250 (1957)).

68. Recombinant research, because it may lead to human engineering, has already been so criticized. *See* Wald, *supra* note 13.

69. 249 U.S. 47, 52 (1919).

crowded theater as an example of limitations on free speech. That was an example of conduct which involved both speech and action. Obviously, the word "fire" is not normally seditious. It was the act of shouting in a theater, thereby provoking panic, that the Court said could be proscribed, and not the content of the words.

In *United States v. O'Brien,*[70] the Supreme Court considered the problem of what protection was afforded symbolic speech by the first amendment. In that case the symbolic speech was the burning of a draft card as an act of protest against the Vietnam War. The Court, in upholding the conviction, noted:

> [W]hen "speech" and "nonspeech" elements are combined in the same course of conduct, a sufficiently important governmental interest in regulating the nonspeech element can justify incidental limitations on First Amendment freedoms.[71]

In other cases where conduct or symbolic speech was even more drastic, such as destroying Selective Service files[72] and refusing to pay taxes in protest against the Vietnam war,[73] courts have also placed limits on the manner of expression of ideas.

In his article, *Duties of Science,*[74] Julius Stone challenged the notion of the inviolable freedom of inquiry. He argued that scientists themselves must desist from a line of inquiry "as soon as it becomes clear that it is likely to bring about a mankind-endangering situation, which no one has any foreseeable capacity to handle—in that sense a 'limit-situation for mankind.' "[75] Stone's prime example of such a "limit-situation" was recombinant DNA and other genetic research which in 1973 was in the very first stages of development. He asserted that this duty to desist calls into question "the absoluteness of the scientist's supposed liberty to pursue knowledge for

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70. 391 U.S. 367 (1968).

71. *Id.* at 376.

72. United States v. Donner, 497 F.2d 184 (7th Cir. 1974), *cert. denied,* 419 U.S. 1047 (1974); United States v. Moylan, 417 F.2d 1002 (4th Cir. 1969), *cert. denied,* 397 U.S. 910 (1970); United States v. Berrigan, 283 F. Supp. 336 (D. Md. 1968), *aff'd sub nom.* United States v. Eberhardt, 417 F.2d 1009 (4th Cir. 1969), *cert. denied,* 397 U.S. 909 (1970).

73. United States v. Malinowski, 472 F.2d 850 (3d Cir. 1973), *cert. denied,* 411 U.S. 970 (1973).

74. Stone, *Knowledge, Survival, and the Duties of Science,* 23 AM. U.L. REV. 231 (1973).

75. *Id.* at 234.

its own sake, wherever it may lead, leaving the consequences for society to deal with."[76]

Legislation is not the only possible form of government intrusion into scientific research activities. The funding of research is potentially dangerous to scientific freedom in that it determines what ideas are to be pursued. The federal government is now responsible for the funding of most basic and applied research in the United States. Harold Green noted in a 1968 article discussing government involvement in assessing technological change:

> Government expenditures on scientific research and development are presently at the level of about 16 billion dollars annually, representing about two-thirds of all money spent in research and development in the United States. In many areas, the availability of federal support is the *sine qua non* of research and development.[77]

In the health field, the figures for research funding clearly show the control of the federal government. In 1975, 3 billion of a total 4.6 billion dollars for health research came from the federal government.[78] Half of the federal funds went to universities, one-quarter to federal research facilities and one-eighth to other nonprofit research institutions.[79] As of May 1977, NIH had outstanding grant awards involving use of recombinant DNA technology totalling 23.1 million dollars with additional in-house expenditures.[80] Most academic research in this field is entirely dependent on federal grant money.

By controlling the purse strings, government officials could effectively determine what research is pursued and what is not—a most effective tool of censorship. The strength of a department at a university or of a research institution often depends on the ability

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76. *Id.* at 234-35.

77. Green, *Technology Assessment and the Law: Introduction and Perspective*, 36 GEO. WASH. L. REV. 1033 (1968).

78. U.S. DEP'T OF HEW, BASIC DATA RELATING TO THE NATIONAL INSTITUTES OF HEALTH 2-3 (1977).

79. *Id.* at 3. Of the 1.3 billion dollars spent by industry on health research, nearly all of it (83%) went to industrial research facilities.

80. EIS, *supra* note 5, at 62. This figure does not include grants to support recombinant research made by other federal agencies.

to secure these funds. NIH believes that the threat to terminate grants to an institution that violates its Guidelines is quite potent.

> The importance of this threat is enormous. Adequate funding for research efforts is pivotal to independent investigators. Worthwhile scientific achievement is the main relevant currency—the single most important criterion for reputation, for institutional advancement, and for personal satisfaction—in the scientific community, and achievement is totally dependent on funds to purchase equipment and supplies and to support assistants. Because alternative sources of funds are very limited, NIH funding is of primary importance.[81]

It is likely that legislation affecting recombinant DNA research would have much less impact on free scientific inquiry than funding decisions. Proposed federal and state legislation would not dictate which experiments are worthwhile, but would prescribe special requirements for the conduct of such experiments designed to ensure a reasonable level of public safety and worker safety. All proposals call for licensing and for measures similar to the NIH Guidelines or the imposition of the Guidelines themselves as mandatory on all researchers. Any legislative body, be it muncipal, state or federal, could impose more stringent conditions or even ban the research, but such power is not likely to be exercised unless a major mishap or disaster arises. No governmental body in this country has shown an inclination to stifle basic research and the example of the Cambridge City Council bodes well for moderation.

There are a few precedents for regulation of basic research. In nuclear research, the federal government monopolizes the right to possess fissionable[82] or other radioactive materials.[83] The Nuclear Regulatory Commission is empowered to issue licenses to persons for use of radioactive materials in medical and other research projects[84] "to promote the common defense and security and to protect the health and safety of the public."[85] Thus by controlling the sup-

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81. *Id.* at 62.

82. Atomic Energy Act, 42 U.S.C. § 2077 (1970 & Supp. V 1975).

83. 42 U.S.C. § 2111 (Supp. V. 1975).

84. Pursuant to 42 U.S.C. §§ 2011, 2093 (1970), the NRC can license the possession of radioactive materials for research purposes and pursuant to 42 U.S.C. § 2134 (1970), it can license "utilization and production facilities" for medical and other research.

85. 42 U.S.C. § 2134(a) (1970).

ply of materials, the Commission can regulate research. This approach is not applicable to recombinant research, because no one component of the research is either scarce or harmful.

In New York, research with human subjects is now regulated, and researchers are required to obtain the "informed consent" of their subjects.[86] The United States Department of Health, Education and Welfare has similar requirements which apply to its grantees.[87] Most states also limit those persons who may conduct research on pathogenic microorganisms to medical doctors and other certified researchers.[88] None of the above described measures would be as drastic an intrusion into the field of basic research, however, as would be the proposed recombinant DNA legislation which would specifically limit the conditions under which an experiment may take place and would ban certain experiments altogether.[89]

VI. Problems in Drafting Technical Legislation

If scientific research is to be accorded first amendment protection, it seems quite clear that the protection will not be absolute. The value of free scientific research must be balanced against the public's need to protect itself and its environment. The Supreme Court set forth criteria for balancing these interests in the *O'Brien* case, stating:

> [W]e think it clear that a government regulation is sufficiently justified if it is within the constitutional power of the Government; if it furthers an important or substantial governmental interest; if the governmental interest is unrelated to the suppression of free expression; and if the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest.[90]

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86. N.Y. Pub. Health Law §§ 2440-2446 (McKinney 1977).

87. 45 C.F.R. §§ 46.101-.301 (1976).

88. *See* N.Y. Pub. Health Law §§ 3200-3203 (McKinney 1977), which limits possession of such organisms without a certificate to doctors, dentists, and veterinarians. Query whether an unfortunate person afflicted with a communicable disease is guilty of violating this statute.

89. Guidelines, *supra* note 25, at 27,914.

90. 391 U.S. 367, 377 (1967).

The proper approach, therefore, as suggested in *O'Brien,* is to design a statute to control the dangers of recombinant DNA research which minimizes impacts upon free scientific inquiry.[91] This may be a difficult task indeed for legislators who are not versed in the complexities of microbiology. Knowledgeable scientists have a duty to honestly inform legislators of the nature of their work, of what conditions would make it impossible to proceed, and of what reasonable regulations would be workable. For instance, one possibility for regulation is to confine all recombinant research to a few remote centers like Fort Detrick, the former biological warfare research facility.[92] In order to decide whether to choose this option or to apply it only to certain experiments or reject the alternative, legislators must have a sophisticated idea of the relative hazards and the effect this restriction would have on biomedical research.

In New York and in Congress, legislation for recombinant DNA research was prepared which utilized specific technical language. Legislators had difficulty in defining what was to be regulated and what activities were to be proscribed. An early Senate bill prohibited "possession" of recombinant DNA without a license.[93] This concept would have been totally unworkable. Since billions of bacteria are grown in any one experiment, often under minimal containment conditions, it is possible, even likely, that a researcher will carry one or more away from the laboratory with him and transmit the recombinant organism to someone else. Moreover, possession of a recombinant organism is almost impossible to detect unless the investigator knows what he is searching for. Unlike radioactivity, there is no biological Geiger counter to differentiate a recombinant organism from others.[94]

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91. To minimize the impact on free scientific inquiry, the statute must clearly define the proscribed activity. In Keyishian v. Board of Regents, 385 U.S. 589, 604 (1966), the Supreme Court explained that the vagueness of the law prohibiting communist teachers tended to have an adverse effect upon free expression in universities:

> The danger of that chilling effect upon the exercise of vital First Amendment rights must be guarded against by sensitive tools which clearly inform teachers what is being proscribed.

92. Confinement was considered an alternative in the EIS, *supra* note 5, at 69. Fort Detrick now houses the nation's first level P-4 laboratory for research with recombinant DNA. *DNA Lab: Fort Detrick Room Set For Genetic Engineering,* Wash. Post, Mar. 18, 1978, at B1, Col. 1.

93. S. 1217, 95th Cong., 1st Sess. (1976).

94. *Hearings Before N.Y. State Att'y Gen., supra* note 8, at 97 (statement of Dr. Robert Pollack).

In New York, a bill which purported to deal only with recombinant DNA research contained an overly broad definition of what was to be regulated. An earlier version had correctly defined a regulated activity to be an experiment "which attempts to artificially combine different segments of genetic material into one molecule, in a cell free environment, that is inserted into a living organism . . . ."[95] The final version omitted the phrase "in a cell free environment."[96] The omission could have had the effect of including other types of genetic research which utilized natural gene exchanges between organisms and not just recombinant DNA experiments.

In drafting technical legislation, legislatures often assign the task of specifically defining that which is to be regulated to an administrative agency. The bill proposed by the California Assembly to regulate all hazardous biological research was of this kind.[97] Under this bill, a state commission would decide what research was potentially hazardous, and thus would require regulation.[98]

Such sweeping legislation could offend the precept of *O'Brien* to use the narrowest means possible to regulate a protected activity. It confers broad powers on an administrative agency with very few guidelines as to what can be regulated and what regulations to adopt. This kind of statute, however, has certain advantages. Delegation of authority to an administrative agency may provide the necessary flexibility to a regulatory scheme which would limit its effect upon free scientific inquiry. By delegating to an agency the power to decide which research is hazardous, the legislature provides for a more efficient accommodation of new information. Such new information might modify past judgments as to which experiments and activities are dangerous. It is much more difficult for a legislature to change a law than for an agency to change its regula-

95. N.Y., S. 4009-A, A. 6740-A (1977-1978 Sess.).

96. N.Y., S. 4009-D, A. 6740-D (1977-1978 Sess.).

97. Cal., A. 757 (1977-1978 Sess.). In the Federal Toxic Substances Control Act, 15 U.S.C. §§ 2601-2629 (Supp 1977), Congress assigned to the Environmental Protection Agency the task of deciding what substances were toxic. This legal action does not affect the development of new substances, however, but only their introduction into the marketplace. Its impact on scientific inquiry is thus insubstantial.

98. Such broad delegations of legislative authority to an administrative agency are often looked upon unfavorably by state courts. *See, e.g.*, Darweger v. Staats, 267 N.Y. 290, 196 N.E. 61 (1935).

tions. Legislation which too rigidly defines the manner and scope of regulations could become outmoded quickly.

A model statute for regulation of scientific research should combine elements of both the administrative delegation and standard-setting types of legislation. Many tasks can be left to administrative agencies, including defining the relative hazard and appropriate controls for different hazardous activities. But legislation should provide clear guidance as to what activities in general are to be regulated and what form that regulation should take. The basic balancing of societal interests must in the first instance be made by legislators.

VII. In Defense of Legislating Morality

The discovery that allowed scientists to unlock the genetic code has also significantly altered the political environment of scientific research. Recombinant DNA technology presents society with new problems of extending its protective regulations. As outlined above, we must decide whether to restrict an activity which has only been shown to be potentially hazardous, which involves a quest for new scientific knowledge, and which gives man the capability to design new life forms and ultimately, perhaps, to design future generations of himself.

One can only assume that future scientific advancements will increasingly present us with discoveries whose ramifications to all mankind are as far-reaching as those of recombinant DNA research. Each new breakthrough could affect our physical environment and alter the way in which we live and reproduce ourselves. The average citizen has an enormous stake in these issues. The public and its representatives will have to educate themselves in the new technologies in order to make rational choices. Whether to accept a new technology, and under what conditions, will always be a difficult moral decision. Society must rate potential effects as harmful or beneficial according to its value structure, and decide what level of risk it should bear.

It is imperative that society not shirk its duty to defend its values in the face of technological change. Too often scientific advances are seen as inevitable and irresistible events to which we

must adapt. Americans have in the past equated new technologies with progress and have blindly trusted that science will provide remedies for adverse side effects. If a new technology, such as human genetic engineering, enabled man to perform acts which offended common moral standards, society would have a duty and a right to proscribe that activity.

Implicit in society's right to restrict a technology is the right to legislate a moral code. All laws are the expression of commonly held moral values, reflecting a consensus of what conduct should be encouraged or proscribed. The first amendment protects an individual's right to advocate the adoption of his own values. In a free society, there should be robust and uninhibited discussion of the potential effects of a new technology leading to an informed consensus of opinion. The first amendment, however, does not restrict society's right to prohibit conduct which it considers immoral.

It may be difficult to reject the lure of a new technology. It may be characterized as a modern attempt to keep Adam from eating the forbidden fruit. But if man is truly to use the faculties given him, if he strives to be the master of his own destiny, he has a duty to decide what his diet shall be.