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Law vs. Science: Legal Control of Genetic Research

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COMMENTS

LAW VS. SCIENCE: LEGAL CONTROL OF GENETIC RESEARCH

INTRODUCTION

A recent cartoon appearing in *Time* magazine[1] shows a delighted MIT scientist dancing into his laboratory which containes an assortment of genetic monsters. The scientist had just received news that the City Council of Cambridge had voted to permit recombinant DNA research at MIT. The same page in *Time* shows a photograph of an atomic bomb explosion. The message is obvious: permitting scientists to pursue such genetic research could create new forms of life which could ultimately lead to massive destruction of life on earth, and the need for legal control of such research is therefore imperative.

The new recombinant DNA techniques, which give scientists ability to alter the genetic structure of an organism, have elicited unparalleled response within the scientific community,[2] and the prospect of unprecedented legal control of such research has stirred an even greater response. Since the time of Galileo, scientists have struggled to achieve their treasured freedom of inquiry.[3] The real issue, then, is whether the legal system should impose controls on the traditionally unhampered pursuit of the truth. The question can only be resolved through an analysis of the rights and interests of the scientific community balanced against the rights and interests of society.

I. THE NATURE OF RECOMBINANT DNA RESEARCH

A. *The New Technique*

The controversial "gene splicing" technique involved in

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[1] Trippett, *Science: No Longer a Sacred Cow*, TIME, March 7, 1977, at 72.

[2] REPORT AND RECOMMENDATIONS OF THE NEW YORK STATE ATTORNEY GENERAL ON RECOMBINANT DNA RESEARCH (February 8, 1977), at i [hereinafter cited as REPORT OF THE NEW YORK STATE ATTORNEY GENERAL].

[3] Lederberg, *The Freedoms and the Control of Science: Notes from the Ivory Tower*, 45 S. CAL. L. REV. 596, 597 (1972).

recombinant DNA research was developed in 1972 and for the first time permitted researchers to manipulate genetic material, known as deoxyribonucleic acid (DNA), within the cells of certain lower organisms.[4] The technique involves utilizing a certain enzyme,[5] known as restriction endonuclease,[6] to cut the DNA isolated from another organism. By this method, a DNA molecule containing portions of DNA from two different types of organisms can be constructed.[7] The new molecule is then inserted inside a "host" cell, which multiplies into a "clone"[8] of cells, each containing identical sets of newly-constructed DNA.

DNA is the cellular substance that controls the biological make-up of all organisms. The difference among species, and even among members of the same species, is in large part due to differences in DNA. Thus, placing DNA segments from one organism into the DNA of another has the potential of permitting the "host" organism to produce some characteristics of the organism from which the foreign DNA was extracted. It is possible, then, that DNA from one species could be spliced into bacterial DNA, resulting in the creation of bacteria that could produce some characteristics of the other species.[9]

B. *Possible Benefits and Possible Dangers of Recombinant DNA Research*

Though such research is considered "pure science," that is, research performed in the quest for knowledge rather than for immediate practical application, certain benefits may be obtained from recombinant DNA research. The most immediate benefit is the advancement of scientific knowledge.[10] Bene-

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[4] *Recombinant DNA: Impacts and Advances,* 109 SCIENCE NEWS 389 (1976).

[5] An enzyme is a type of protein that promotes the chemical processes of life without itself being altered or destroyed. MCGRAW-HILL DICTIONARY OF THE LIFE SCIENCES 234 (D. Lapedes ed. 1976).

[6] *See Recombinant DNA: Impacts and Advances, supra* note 4, for a discussion of restriction endonuclease.

[7] 41 Fed. Reg. 38,428 (1976).

[8] A clone is a population of cells or organisms derived from a single cell or organism without sexual reproduction. R. RIEGER, A. MICHAELIS, & M. GREEN, GLOSSARY OF GENETICS AND CYTOGENETICS 109 (4th ed. 1976).

[9] 41 Fed. Reg. 38,426 (1976).

[10] Cohen, *Recombinant DNA: Fact and Fiction,* 195 SCIENCE 654, 655 (1977).

fits to society include the use of organisms containing recombinant DNA to produce substances of medical importance. For instance, human DNA segments which direct, or "code," the production of insulin could be spliced into bacterial DNA, and the bacterial hosts could be used to produce human insulin cheaply and efficiently, which would be a benefit to diabetics.[11] Other possible applications have been suggested, such as the use of recombinant organisms in the production of vitamins, antibiotics, and vaccines.[12] Pharmaceutical and chemical industries have already become aware of the potential benefits of such research, and these industries have considered initiating their own recombinant DNA research.[13]

Unfortunately, the very characteristics which give such research potential for beneficial application also confer potential for substantial risk. Organisms with the ability to produce some unnatural or unpredicted substance might escape from the laboratory and become serious pests.[14] Some critics have pointed out that the technique essentially creates new types of organisms, and therefore the natural barriers between organisms that have evolved to maintain the "balance of nature" could be broken. The result may potentially be "biological and social chaos."[15]

The potential for danger is enhanced by the fact that the organism best understood and most commonly used as a host in recombinant DNA research is *Escherichia coli (E. coli),* a type of bacterium that inhabits the human gut.[16] *E. coli* in its

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[11] Bennett & Gurin, *Science that Frightens Scientists,* 239 THE ATLANTIC, February 1977, at 44.

[12] Cohen, *supra* note 10, at 655-56. Researchers have successfully transferred genes which provide nitrogen-fixing ability in a certain bacterium into *E. coli,* which does not otherwise have the ability to fix nitrogen. This technique could lead to alternatives to chemical fertilizers. Brill, *Biological Nitrogen Fixation,* 236 SCIENTIFIC AMERICAN, March 1977, at 68.

[13] *See* REPORT OF THE NEW YORK STATE ATTORNEY GENERAL, *supra* note 2, at 7, for a discussion of potential pharmaceutical uses.

[14] *See* Bennett & Gurin, *supra* note 11, at 44, for a discussion of these dangers; 41 Fed. Reg. 38,430 (1976).

[15] Sinsheimer, *An Evolutionary Perspective for Genetic Engineering,* 73 NEW SCIENTIST 150, 150 (1977).

[16] The particular strain of *E. coli* generally used is known as K-12, which is a laboratory-developed strain that is a very poor colonizer of the human system. REPORT OF THE NEW YORK STATE ATTORNEY GENERAL, *supra* note 2, at 22.

natural state is relatively harmless. There is fear, though, that an escaped experimental *E. coli* strain containing recombinant DNA may colonize in the bowels of the human population and produce some undesired substance or become pathogenic.[17]

Though critics of recombinant DNA research have stated that the risks involved could lead to disaster,[18] the risks are merely potential and speculative, as they have never been demonstrated.[19] Other scientists have pointed out the overwhelming unlikelihood that such risks will be manifested and therefore have de-emphasized the dangers of recombinant DNA research.[20] The conclusion is inescapable, however, that the likelihood of danger resulting from recombinant DNA research is simply not known.

II. LEGAL DEVELOPMENTS IN THE CONTROL OF RECOMBINANT DNA RESEARCH

A. *The First Concerns of Scientists*

Shortly after the recombinant DNA technique was discovered, scientists involved with the technique became concerned with the potential for danger. At the Gordon Research Conference on Nucleic Acids in 1973, researchers in attendance confirmed their concern over the research, and recommended further study by the National Academy of Sciences and the consideration of establishing guidelines.[21] Scientists led by Paul Berg, who chaired the Committee on Recombinant DNA of the

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[17] 41 Fed. Reg. 38,430 (1976). Pathogenic organisms are those that are capable of producing disease. MCGRAW-HILL DICTIONARY OF THE LIFE SCIENCES 636 (D. Lapedes ed. 1976).

[18] *See* Sinsheimer, *supra* note 15.

[19] Berg, *Potential Biohazards of Recombinant DNA Molecules*, 185 SCIENCE 303 (1974); Cohen, *supra* note 10, at 654-55. SCIENCE reported three incidents that were labeled "narrow escapes" which illustrate the possibility of potentially dangerous recombinant organisms being released into the environment and becoming nuisances. For example, at Stanford University an experiment was contemplated where a gene from the dangerous SV40 virus was to be inserted into *E. coli*. Wade, *Dicing with Nature: Three Narrow Escapes*, 195 SCIENCE 378 (1977).

[20] *See* Cohen, *supra* note 10, at 654-55. A British scientist used mathematical probabilities to illustrate the extreme unlikelihood of danger resulting from such research. Holliday, *Should Genetic Engineers Be Contained?*, 73 NEW SCIENTIST 399 (1977).

[21] Singer & Soll, *Guidelines for DNA Hybrid Molecules*, 181 SCIENCE 1114 (1973); *see* Bennett & Gurin, *supra* note 11, at 48.

National Academy of Sciences, called for an unprecedented moratorium on recombinant DNA research until more specific guidelines could be established.[22]

Prior to this action, the problems with recombinant DNA research were considered scientific problems to be worked out by scientists. The self-imposed "moratorium," however, was the event that precipitated public concern over the research.[23] Though the nature of the research and the risks involved tended to be misinterpreted by the public,[24] it was this initial concern which eventually led to public involvement and the development of governmental regulations.

B. *Asilomar Conference—Scientists Attempt Self-Regulation*

The first attempt at regulating recombinant DNA research came from the scientists themselves at an international conference which convened in February 1975 at Pacific Grove, California. The participants at the Asilomar Conference, as it is known, agreed that the research should proceed under a set of guidelines adopted by the Conference.[25] The guidelines banned certain experiments deemed potentially very dangerous, but allowed other experiments to proceed, provided that the experimental organisms were adequately "contained" in accordance with the potential risk of specific experiments. That is, the greater the risk involved, the more stringent the "containment" requirement.[26]

C. *The NIH Guidelines*

Although researchers in general conformed to the Asilomar regulations,[27] the regulations were internal only and not legally enforceable.[28] The Asilomar guidelines, however, served as the basis for the first controls imposed by the federal government

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[22] *See* Berg, *supra* note 19.

[23] *See* Bennett & Gurin, *supra* note 11, at 49.

[24] *Id.*

[25] SUMMARY STATEMENT OF THE ASILOMAR CONFERENCE ON RECOMBINANT DNA MOLECULES (May 20, 1975), *reprinted in* 188 SCIENCE 991 (1975).

[26] *Id.*

[27] Comment, *The Potential for Genetic Engineering: A Proposal for International Legal Control,* 16 VA. J. INT'L L. 403, 420 (1976).

[28] *Id.*

in the form of the Guidelines drafted by the National Institutes of Health.[29] The NIH Guidelines are more stringent and detailed than those adopted by the Asilomar Conference;[30] moreover, they ban certain extremely dangerous experiments[31] and require specific containment standards for permitted experiments, which are graded according to the risk involved.

Containment is provided by two methods: biological and physical. The minimal physical containment required is the "P1" level for experiments involving little or no risk.[32] Experiments involving low or moderate risks require "P2" or "P3" levels of containment. High risk experiments may be conducted only in "P4" containment facilities, which require complete isolation from the experimental area, shower rooms through which the experimenters must enter and leave, and other engineering features designed to prevent microorganisms from escaping into the environment.[33]

A graded series of "biological containment" requirements is also imposed on recombinant DNA research. The *E. coli* host strain used experimentally is much less likely to survive in the human system than the native *E. coli* strain. Therefore, some inherent biological containment is provided by the low likelihood of the experimental organisms' surviving outside the laboratory. Additional biological containment is required by the Guidelines; the minimal standard of containment required is titled "EK1."[34] Biological containment requiring the use of *E. coli* strains with even less likelihood of surviving outside the experimental area is tagged "EK2."[35] The highest level of biological containment requirements, "EK3,"[36] is imposed on certain high risk experiments.[37]

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[29] 41 Fed. Reg. 27,902 (1976).

[30] 41 Fed. Reg. 38,434 (1976).

[31] One example of a banned experiment is transferring drug-resistant traits into microorganisms which are not naturally drug-resistant. 41 Fed. Reg. 27,914-15 (1976).

[32] Most laboratories used for microbial experiments satisfy this level of containment. 41 Fed. Reg. 27,912 (1976).

[33] 41 Fed. Reg. 27,913-14 (1976). The National Cancer Institute facilities at Fort Detrick, Maryland, are among the few laboratories presently satisfying P4 containment requirements. Culliton, *Recombinant DNA: Cambridge City Council Votes Moratorium*, 193 SCIENCE 300, 300 (1976).

[34] 41 Fed. Reg. 27,915-16 (1976).

[35] 41 Fed. Reg. 27,916-17 (1976).

[36] 41 Fed. Reg. 27,917 (1976).

[37] One example is an experiment involving the insertion of primate DNA into the

Compliance with the NIH Guidelines, though originally voluntary,[38] is now mandatory for all NIH-funded research.[39] However, compliance with the NIH Guidelines is still voluntary for non-federally-funded research, such as that conducted by pharmaceutical companies.[40] This shortcoming[41] and the belief by some critics that the Guidelines may be inadequate[42] have spawned additional concern at the local and federal levels.[43]

D. *Regulation at the Local Level*

Public interest evoked by recombinant DNA research has been unprecedented, as evidenced by the concern for regulating such research at the local level.[44] At the university level, regulation of the research was debated at the University of Michigan, the outcome being in favor of permitting the research.[45] Cities with major universities likely to conduct such research have considered establishing regulations. Ann Arbor, Michigan, and Bloomington, Indiana, have at least tentatively decided against restricting the research.[46] Madison, Wisconsin, is presently considering holding a public debate on the topic,[47] and a San Diego, California, study committee established by the Mayor has already heard debate and endorsed the NIH Guidelines, with minor qualifications, and has required the University of California at San Diego to refrain from conducting expe-

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host DNA, when the laboratory satisfies P3 but not P4 physical containment requirements. 41 Fed. Reg. 27,917 (1976). An EK3 host organism has yet to be developed. REPORT OF THE NEW YORK STATE ATTORNEY GENERAL, *supra* note 2, at 13.

[38] Wade, *NIH Seeks Law on Gene-Splice Research,* 195 SCIENCE 859 (1977).

[39] 41 Fed. Reg. 38,427 (1976). The NIH Guidelines, even where compliance is required, have been criticized for lacking an effective enforcement scheme. Wade, *Recombinant DNA: New York Ponders Action to Control Research,* 194 SCIENCE 705 (1976).

[40] *See* REPORT OF THE NEW YORK STATE ATTORNEY GENERAL, *supra* note 2, at 11.

[41] 41 Fed. Reg. 38,427 (1976). However, the mere establishment of the NIH Guidelines may influence compliance with the standards by all recombinant DNA researchers.

[42] Wade, *Gene-Splicing: At Grass-Roots Level a Hundred Flowers Bloom,* 195 SCIENCE 558 (1977).

[43] *See* Wade, *supra* note 38.

[44] *See* Wade, *supra* note 42.

[45] *Id.* at 559; Bennett & Gurin, *supra* note 11, at 59.

[46] *See* Wade, *supra* note 42, at 559.

[47] *Id.*

riments requiring P4 facilities.[48]

Mayor Vellucci's attempt to ban much of the research in Cambridge, Massachusetts, has drawn the most attention. The Mayor was successful in persuading the City Council to impose a temporary moratorium on the research at Harvard and MIT until a review board of scientists and citizens investigated the research more thoroughly.[49] In spite of Mayor Vellucci's insistence that a ban on P3 and P4 experiments be imposed, the review board unanimously decided to recommend permitting the research to proceed.[50] In February 1977 the City Council rejected Mayor Vellucci's proposal and adopted the recommendations of the review board, permitting the research to proceed under the NIH Guidelines, with some minor additional restrictions.[51]

At the state level, New York, New Jersey, and California have considered regulation of the research. New Jersey Attorney General William Hyland is considering drafting regulations, but realizes that excessive regulation would only result in driving the research underground.[52] In California, two legislative committees are holding hearings concerning legislative regulation of the research, which may result in the adoption of the NIH Guidelines for all recombinant DNA research performed in the state.[53]

In New York, State Attorney General Louis Lefkowitz has held public hearings on the question of regulation.[54] In February of 1977, the Attorney General released his findings and recommendations[55] and submitted a bill[56] to the state legisla-

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[48] *Id.* Recombinant DNA research is being conducted at the University of Kentucky Medical Center by Dr. Robert Dickson. The research involves splicing a yeast gene which codes for beta-galactosidase, an enzyme involved in the digestion of milk sugar, into an *E. coli* host. The research is NIH-funded and requires P2 physical containment and EK1 biological containment. Compliance with the Guidelines will be assured by the Biohazards Committee established at the University. Though the research at the University of Kentucky may be expanded in the future, no other institution in Kentucky has current plans to conduct such research.

[49] *See* Culliton, *supra* note 33, at 300.

[50] Wade, *Gene-Splicing: Cambridge Citizens OK Research but Want More Safety,* 195 SCIENCE 268 (1977).

[51] Wade, *DNA: Laws, Patents, and a Proselyte,* 195 SCIENCE 762 (1977).

[52] *See* Wade, *supra* note 42.

[53] *Id.*

[54] Wade, *supra* note 39.

[55] *See* REPORT OF THE NEW YORK STATE ATTORNEY GENERAL, *supra* note 2.

ture requiring all recombinant DNA experimenters to be certified by the Commissioner of Public Health and allowing the Commissioner considerable discretion in permitting or prohibiting recombinant DNA experiments.[57] The New York bill differs from the NIH regulations in that it provides a means of enforcement of the regulations through suspension of certification,[58] while the NIH Guidelines have no enforcement scheme.

E. *Additional Regulation at the Federal Level*

Because the NIH Guidelines are imposed only on NIH-funded research and are difficult to enforce even at that level, NIH has sponsored legislation that would considerably broaden the application of the Guidelines.[59] On February 4, 1977, Senator Dale Bumpers introduced into the United States Senate the DNA Research Act of 1977,[60] which would make the NIH Guidelines apply to all research involving recombinant DNA.[61] In addition, the Bill provides means for enforcing the regulations. The Bill is now being considered by the Senate Subcommittee on Health and Scientific Research, and additional hearings will be held.[62]

Whether the DNA Research Act of 1977 is enacted or not, it is inevitable that federal regulations will be extended.[63] In

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[56] An Act to Amend the Public Health Law, in Relation to the Certification of Recombinant DNA Experiments, art. 32-A, §§ 3220-3223 (1977).

[57] *Id.* § 3222.

[58] *Id.* § 3223.

[59] *See* Wade, *supra* note 38. Guidelines Director Donald Fredrickson has voiced approval of the federal legislation. Louisville Courier-Journal, February 21, 1977, § A, at 1, col. 1.

[60] S. 621, 95th Cong., 1st Sess., 95 CONG. REC. 2274 (1977). Senator Bumpers was concerned specifically with pharmaceutical companies, who are not required to comply with the NIH Guidelines at present. 95 CONG. REC. 2274. A similar bill has been introduced into the House of Representatives by Rep. Richard Ottinger. H.R. 3591-92, 95th Cong., 1st Sess., 95 CONG. REC. 1117 (1977).

[61] S. 621 purports to derive its power to institute such regulation from the commerce power. U.S. CONST. art. I, § 8, cl. 3; S.621, 95th Cong., 1st Sess. § 2, 95 CONG. REC. 2274 (1977).

[62] *See* Wade, *supra* note 38. A revised version of the Bill was introduced by Senator Kennedy in April, 1977. S.1217, 95th Cong., 1st Sess., 95 CONG. REC. 5335 (1977).

[63] See Wade, *supra* note 38. The Commerce Department is also involved in the recombinant DNA research issue because of the possibility that industry will patent certain recombinant DNA techniques that result in the manufacture of beneficial materials. *See* 42 Fed. Reg. 2712 (1977).

fact, federal regulations may be supported by scientists, in the hope that federal regulation may avoid the enactment of possibly overly-restrictive local regulations.[64]

F. *The Uniqueness of Recombinant DNA Research Regulations*

The regulation of recombinant DNA research is unprecedented in two aspects. First, science, not technology, is the subject of regulation. Technology involves the application of knowledge to a practical use. The regulation of nuclear energy constitues an example of extensive regulation of the technological application of atomic physics.[65] The regulation of recombinant DNA research is not such a technological regulation, as it is not the *use* of the research which is the immediate concern of the regulators, but the possible undesirable consequences of the research itself.

Second, though regulation of scientific research itself does exist, recombinant DNA research regulation differs with respect to the dangers sought to be prevented. Regulations designed to protect animals[66] or human subjects[67] used in research are examples of regulation of scientific research, but the dangers to be avoided are known and demonstrable. The dangers involved in recombitant DNA research are not yet known—they are still speculative.[68] Therefore, the recombinant DNA regulations differ from other scientific regulations in that the dangers involved with the research are unknown potential dangers rather than known and demonstrable dangers.

III. LIMITED RIGHT TO FREE INQUIRY

It is beyond the scope of this comment to discuss whether the present or proposed regulations will be effective in preventing disaster which may result from recombinant DNA research. The question here is whether the public, hence the government, should be involved in the control of pure scientific research at

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[64] *See* Wade, *supra* note 38.
[65] *See* 10 C.F.R. §§ 0-170 (1976).
[66] 3A C.J.S. *Animals* § 102 (1973).
[67] *See, e.g.*, 45 C.F.R. § 46 (1976).
[68] Berg, *supra* note 19.

all. The answer lies in a resolution of the conflict between the right of free scientific inquiry and the right of the public to be safe and secure.

A. *The Right to Free Inquiry*

Supporters of free scientific inquiry warn of the "dangers facing modern society if it chooses to foreclose avenues of knowledge and discovery which might lead to the emancipation of mankind from the chains of ignorance and disease."[69] Because pure research has traditionally been unregulated,[70] scientists are often fearful of any legal control.[71] Any threat of control of science is often equated with the Vatican's inquisition of Galileo.[72] According to this view, then, science should be left exclusively to the scientists.

Total scientific autonomy in the area of recombinant DNA research would imply that all restrictions on the research must be imposed only by the scientists involved.[73] Proponents of this view fear that once the public initiates monitoring and regulating of DNA experiments, the public will increase its demands that all scientific research meet its requirements for social desirability.[74] The result in the long run would be detrimental to both science and society.[75]

B. *The Public Interest*

On the other side of the conflict is the danger that recombinant DNA research may be harmful to the public, even though the precise risks have not yet been ascertained.[76] So-

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[69] Comment, *supra* note 27, at 416.

[70] *Id.* at 417.

[71] *See* Lederberg, *supra* note 3, at 596.

[72] *Id.* Such fears may also explain the attitude of the scientific community towards lawyers. *See* Curlin, *Mutatis Mutandis: Congress, Science, and Law,* 190 SCIENCE 839 (1975).

[73] *See* Wade, *supra* note 39, for a discussion of self-imposed regulations; Culliton, *Public Participation in Science: Still in Need of Definition,* 192 SCIENCE 451, 452 (1976).

[74] *See* Trippett, *supra* note 1, at 73.

[75] *Id.*

[76] Another aspect of the issue of public control of recombinant DNA research is the ethical considerations of "genetic engineering." Particularly objectionable to some critics is the possible future application of the techniques to the genetic make-up of

ciety has the right to be secure from threats to the general health and welfare, and society, through government, can invoke its police power to protect that interest. Indeed, among the most legitimate uses of the police power is its use in the protection of the health and safety of society.[77] It is this interest in the public's safety which is the basis for the "public participation in science" movement.[78]

Advocates of regulation have taken the position that the public should maintain strict control over scientific inquiry.[79] MIT biologist Jonathan King has stated that scientists are less than objective in assessing the impact of their own research on society.[80] Cal Tech biologist Robert Sinsheimer explains that the reason for this lack of objectivity is the intense dedication to one's research that is required to do productive science.[81] This view, simply stated, asserts that science is too important to be left to the scientists.[82]

Those who favor the "public control" position insist on a moratorium on recombinant DNA research, at least until there is more substantial public investigation.[83] Even the Guidelines imposed on NIH-funded research are felt by some critics to be insufficient controls on the researchers.[84] Such was the position of Mayor Vellucci of Cambridge in his effort to ban much of the recombinant DNA research at Harvard and MIT.[85]

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human beings. This objection differs from the objection based on public safety in that it is not a potential danger to human health, but a threat to human integrity, dignity, and individuality. Edsall, *Scientific Freedom and Responsibility,* 188 SCIENCE 687, 688 (1975). *See generally,* SCIENTIFIC FREEDOM AND RESPONSIBILITY (M. Lipkin & P. Rowley ed. 1974); P. RAMSEY, FABRICATED MAN (1970).

[77] 16 AM. JUR. 2d *Constitutional Law* § 308 (1964).

[78] Culliton, *supra* note 73, at 452.

[79] *Id.*; Culliton, *Kennedy: Pushing for More Public Input in Research,* 188 SCIENCE 1187, 1189 (1975).

[80] *See* Wade, *supra* note 39.

[81] Wade, *Recombinant DNA: A Critic Questions the Right to Free Inquiry,* 194 SCIENCE 303, 305 (1976).

[82] *See* Trippett, *supra* note 1, at 73; Sinsheimer, *The Right to Free Inquiry,* 190 SCIENCE 768 (1975).

[83] Wade, *supra* note 42, at 560.

[84] *See* Wade, *supra* note 81, at 303; *see also* Wade, *supra* note 39.

[85] Wade, *supra* note 50.

C. *The Need for a Moderate Approach to Public Involvement in the Control of Genetic Research*

Both the rights of scientists to free inquiry and the rights of the public to protection of its health and welfare are rights valuable to society in the long run. Therefore, the approach taken should satisfy the interests of each group while infringing as little as possible on the rights of the other group. Even members of the scientific community have realized that freedom from restraint on research is unrealistic and maybe even undesirable.[86] Dr. John Edsall, reporting for the American Association for the Advancement of Science Committee on Scientific Freedom and Responsibility,[87] stated that the pursuit of knowledge through research is limited by the risk involved in pursuing that knowledge.[88] The fact that the scientists themselves were the first to "expose" the possibility of danger of recombinant DNA research and voluntarily undertook to establish their own regulations shows that the scientific community feels the need for control, even if only internally-imposed control. But some degree of public involvement in the regulation of scientific research is the only way society can assure itself that its rights will be protected. Furthermore, though scientific research, including research involving recombinant DNA, is often sophisticated and complicated, members of the non-scientific public can make sense out of it and arrive at a rational decision concerning its potential impact.[89]

But the involvement of the public in the regulation of science must be restrained if the scientists' right to free inquiry is to be protected. There must be a limit on the magnitude of public control so that the pursuit of knowledge through scientific research is not unnecessarily stifled. The scientific community itself can do much to limit public control by gaining public trust. Scientists can attain public confidence by ensur-

[86] *See* Comment, *supra* note 27, at 417, for a discussion of the desirability of subjecting scientists to the pressures of the political process.

[87] Edsall, *Scientific Freedom and Responsibility,* 188 SCIENCE 687, at 687 (1975). Earl Warren, former Chief Justice of the United States Supreme Court, was a member of the AAAS Committee on Scientific Freedom and Responsibility. *Id.*

[88] For example, there are limits on the use of human subjects in experiments. *Id.* at 688.

[89] *See* Culliton, *supra* note 73, at 453.

ing openness and candor in their proceedings.[90] Gaining public trust through such means could reduce the present spirit of skepticism toward science and the feelings that science needs to be tightly controlled.[91]

Public input into scientific decision-making, however, should be limited to just that—input, not absolute control. Regulation of science by some means is certainly a proper method of achieving public input into scientific decision-making. But whatever committees,[92] agencies,[93] courts,[94] commissions,[95] or commissioners[96] are established to regulate scientific research, the regulators have the responsibility to protect the rights of the scientists as well as the interests of the public. It is imperative that the regulators consciously prevent themselves from becoming vehicles of public demands that all research meet the test of social desirability.[97] But where a clear risk to the welfare of the public is involved, the regulators have the responsibility of protecting the public's interest.

CONCLUSION

The only statement that can be made with certainty concerning the risks to public welfare involved in recombinant DNA research is that the risks are not precisely known. But the mere possibility that such risks exist and that the risks may be

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[90] Wade, *Gene-Splicing: Critics of Research Get More Brickbats than Bouquets*, 195 SCIENCE 466, 469 (1977).

[91] *See* Trippett, *supra* note 1, at 73.

[92] *See, e.g.*, the Review Board established by Mayor Vellucci in Cambridge.

[93] *See, e.g.*, the National Institutes of Health, which established the NIH Guidelines.

[94] "Science Courts" have been suggested as a way to safeguard the public's interest in scientific research. Letter from John C. Cobb, in 194 SCIENCE 674 (1976). Such courts would not actually render verdicts but would attempt to determine the probability of harmful effects or results of certain types of experiments or technological innovations. Simpson, *Science Court: Good Idea*, 43 THINK, January/February, 1977, at 28.

[95] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which is involved in the development of guidelines on fetal experimentation, has been discussed as a successful example of the commission approach to achieving public input. Culliton, *supra* note 73, at 453.

[96] *See, e.g.*, the New York Attorney General's proposal to use the Commissioner of Public Health as a licensing agent. REPORT OF THE NEW YORK STATE ATTORNEY GENERAL, *supra* note 2.

[97] *See* Trippett, *supra* note 1, at 73.

substantial gives the public the right to regulate recombinant DNA research. The public's interest in its health and welfare must be protected. The public cannot be assured that this interest will be protected if scientists are left to regulate themselves.

Government, as the agent of the public, has the responsibility to assure public input into control of recombinant DNA research, as well as any other scientific pursuits which could threaten the welfare of society. But such input and control must be limited. The rights of scientists freely to conduct research is a cherished right and one that serves society in the long run. Recombinant DNA research may eventually result in the development of new technologies which may be beneficial to society. But if the research is unnecessarily hampered by overzealous regulation, such benefits may never be realized. Thus the recombinant DNA research controversy represents a situation where regulation must establish a crucial balance between protecting the rights of the public and protecting the rights of the scientific community. If the regulations or lack of regulations tip the balance to either side, society will eventually be the loser.

Frank Becker