The Regulation of Recombinant DNA Research: The Alternative of Local Control

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I. INTRODUCTION

In a nation which prides itself on being a world leader in scientific, technological, and academic achievement, and embraces the concept of free speech and expression, the notion of prohibiting or restricting scientific inquiry is a discomfiting thought. However, the newest biological technology—recombinant DNA—has caused scientists and laymen alike to call for some degree of restriction over this field of research. This outcry has created a need to strike a balance between protecting the freedom of scientific inquiry and protecting public safety by regulating recombinant DNA research.

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1. G. Wald, quoted in Berger, Government Regulation of the Pursuit of Knowledge: Recombinant DNA Controversy, 3 VT. L. REV. 83, 84 (1978) [hereinafter cited as Berger]. Wald noted that our nation’s morality traditionally has encouraged scientific inquiry to proceed without restriction.

2. Simply speaking, recombinant DNA involves isolating and combining genes of one organism with those of another to form a new organism never before known to nature. For descriptions of the technology, see Galston, Here Come the Clones, 84 NAT. HIST. 72-77 (1975); Fox, Change of Genes, 49 CHEMISTRY 22-23 (1976); Science’s Newest “Magic”—A Blessing or a Curse, U.S. NEWS & WORLD REP., July 12, 1976, at 34-35; Shaping Life in the Lab, TIME, Mar. 9, 1981, at 50-59.

3. In an action described as “unprecedented in the history of science,” a group of noted scientists called for a moratorium on recombinant DNA research until the environmental hazards of the research were determined. Bennett & Gurin, Science that Frightens Scientists, ATLANTIC, Feb. 1971, at 43, 44.

4. The lay community’s response to recombinant DNA research is typified by events in Cambridge, Massachusetts where public hearings were held to discuss the advantages and hazards of the research in response to Harvard University’s plan to construct a new laboratory for high risk genetic experiments. See infra text at notes 237-41.
The debate over regulation of recombinant DNA has become vocal and controversial not only because of the first amendment tensions involved, but also because the potential benefits and risks associated with the technology are profound. Using recombinant techniques, researchers are developing therapeutic drugs such as human insulin—a growth hormone; and interferon—an antivirus drug which may lead to a cure for certain forms of cancer. Scientists are using the technology to develop improved processes in making antibiotics. Genetic recombinations also have wide applications in the chemical and energy industries. For example, through recombinant technology, researchers have created ethylene oxide, a compound used as the basis for making many chemicals, and yeast bacteria, which may enable producers of gasohol to eliminate the distillation process.

On the other hand, the potentially deleterious effects of recombinant research have alarmed researchers and the public and prompted a call for regulation. The major danger associated with recombinant DNA technology is that these new organisms will escape into the environment. Because these organisms have never existed before in nature, other living organisms have not had time to develop defenses and immunities to the new bacteria. As a result, some scientists have predicted that the release of recombinants—with

5. For a discussion of the first amendment right to freedom of scientific inquiry, see Berger, supra note 1, at 100-05. Berger describes the conflict as one between the freedom of experimentation and the police power of the state to protect the community from the hazards of the experimentation.


7. Wade, supra note 6.


9. Id.


Maryland and New York have adopted the NIH guidelines as state law. See MD. ANN. CODE art. 43, §§ 898-910 (1980); N.Y. PUB. HEALTH LAW § 3220 (McKinney Supp. 1981-82).

On the local level, Cambridge (discussed in text at notes 234-310 infra), Boston, Waltham, and Amherst, Massachusetts, and Berkeley, California have passed ordinances regulating the research.

Congress has considered bills in 1977 and 1978 for regulating the research; however, none made it to the floor of the House or Senate for a vote. H.R. 11192, 95th Cong. 2d Sess. (1978); H.R. 7897, 95th Cong., 1st Sess. (1977); S. 1217, 95th Cong., 1st Sess. (1978).


largely undetermined properties—will result in new animal and plant diseases, new forms of cancer, and novel epidemics. At present, there is no way of ascertaining how recombinant molecules will affect other forms of life or the ecosystem.

In the past year or so, the debate over the safety and regulation of recombinant DNA has assumed added significance. A problem once associated solely with the activities of the university research laboratory now involves industrial laboratories as well. Recombinant DNA experimentation is presently being carried out on a wide scale in at least a dozen private laboratories with the goal of manufacturing genetic products for profit. Private genetic engineering is now a highly competitive, multimillion dollar industry. The commercial future of private DNA engineering has been compared to the electronics industry of a decade ago.

In June, 1980, the Supreme Court added another factor to the DNA issue. In Diamond v. Chakrabarty, the Court held that the United States Patent Office can issue patents on man-made organisms. Presumably, researchers who manufacture a new organism through recombinant DNA techniques can now protect their proprietary interests in that organism with a government patent.

This article will discuss the regulation of recombinant DNA in light of recent developments in the recombinant DNA debate, namely, the Chakrabarty decision and the growth of the private genetic engineering industry. The article begins with a discussion of the issues in Chakrabarty and the factors which led the Court to decide as it did. Second, the growth of the private genetic industry and the likely impact of the Chakrabarty case on this growth will be documented. Third, the existing regulation of recombinant DNA research will be analyzed to see if it provides sufficient protection from the potential hazards of the research. Finally, the recombinant

13. Id. at 26. Scientists have been reluctant to identify the risks of the research with any more specificity. At present, the risks associated with recombinant DNA are purely hypothetical. There have been no recorded outbreaks of recombinant DNA molecules into the environment which would enable scientists to ascertain their deleterious effects more precisely.

14. Parisi, supra note 6. See also E.F. Hutton, BIOTECHNOLOGY, Nov. 1979, at 1. This is a magazine describing the development of industrial recombinant DNA laboratories and the attractiveness of investing in the technology.

15. Parisi, supra note 6.


17. Id.

DNA ordinance in Cambridge, Massachusetts will be discussed to demonstrate how it can serve as a model for states and localities desiring more control over recombinant DNA research being undertaken in their communities.

II. THE CHAKRABARTY CASE

A. Background

_Diamond v. Chakrabarty_19 involved the claim of General Electric scientist, Dr. Ananda M. Chakrabarty, to a patent for a _Pseudomonas_ bacterium, which he developed using genetic engineering techniques.20 The organism was developed in response to a significant social problem, oil spills in bodies of water. The _Pseudomonas_ bacteria are useful in cleaning up these spills. They break down and degrade crude oil into simpler substances and then ingest the substances. The bacteria, in turn, become food for other aquatic life.21

Dr. Chakrabarty sought patents for the process of producing the bacteria, for an inoculum composed of a carrier material capable of floating on water, and for the bacteria themselves.22 The Patent Examiner granted the claims to the process and the inoculum but denied the claim to the bacteria.23 The Examiner’s decision rested on the principle that bacteria are something occurring in nature and, therefore, unpatentable.24 The Board of Appeals of the Patent Office affirmed the Patent Examiner’s denial of the patent for the bacteria on a different ground25—that the bacteria are unpatentable because they are alive.26 The Board reasoned that section 101 of the Patent

19. Id.
20. The techniques used by Dr. Chakrabarty are explained in _The New Biology, NATIONAL GEOGRAPHIC_, 1976, at 374-75. See also Brief for Respondent at 6, _Diamond v. Chakrabarty_, 447 U.S. 303 (1980).
22. Id. at 6-7.
23. Id. at 7. Chakrabarty’s initial application was Serial No. 260,563 entitled “Microorganisms Having Multiple, Compatible Degradative Energy-Generating Plasmids and Preparation Thereof.”
24. Brief for Respondent at 7. See also id. App. 1-A (containing excerpts from the “Manual of Patent Examining Procedure,” which contains the statement that “a thing occurring in nature, which is substantially unaltered, is not a ‘manufacture’ ”).
25. The Board disagreed with the examiner’s conclusion that the bacteria were products of nature, finding that, because the _Pseudomonas_ contains two or more different energy-generating plasmids, they are not naturally occurring. 447 U.S. 303, 306 n.3.
Act,27 which permits patents for a "manufacture" and "composition of matter,"28 was not intended to include living organisms.29

The Court of Customs and Patent Appeals (CCPA), in Application of Chakrabarty,30 rejected this interpretation of section 101, holding that the bacteria cannot be excluded from patent protection solely because they are alive.31 The government appealed this decision to the Supreme Court and the Court granted certiorari on October 29, 1979.32 The issue in the Chakrabarty case was whether a living organism, made by man in a laboratory, can be considered as patentable subject matter within the meaning of section 101 of the Patent Act. The arguments before the Supreme Court rested mainly on congressional intent in enacting section 101, on public policy considerations in allowing patent protection for man-made organisms, and on the practice of the Patent Office in handling previous applica-

28. Section 101 provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."
29. This interpretation of the Patent Act was made by the government when the case was before the Supreme Court. See infra text at notes 51-52.
31. The court relied on its recent decision in Application of Bergy, 563 F.2d 1031 (C.C.P.A. 1977) in which the court approved a patent for a living bacteria discovered in the Arizona soil which is used in producing an antibiotic. At the time of the court's Chakrabarty decision, the government was in the process of appealing Bergy. The Supreme Court granted certiorari, 438 U.S. 902 (1978), vacated the court's Bergy ruling and remanded the Bergy case for further consideration in light of Parker v. Flook, 437 U.S. 584 (1978). The patents court also vacated its ruling in Chakrabarty and consolidated the two cases for review.
32. 444 U.S. 924 (1979). Certiorari was granted for the Bergy case as well which had been consolidated for review. While awaiting review by the Supreme Court, Bergy cancelled his claim to his bacterium and, on Jan. 14, 1980, the claim was dismissed by the Court as moot. 444 U.S. 1028 (1980). Chakrabarty's claim remained to be decided by the Court.
tions for patents on living organisms. The following subsections outline the major arguments of the parties and the reasoning of the Supreme Court in reaching its decision.

B. The Government’s Argument

The government began its argument by urging the Court to interpret the Patent Act narrowly and refrain from extending patent protection into new areas such as organisms made by genetic engineering not previously contemplated by Congress. The government urged that any expansion of patent protection should be done by Congress since Congress is best equipped to weigh the “difficult and controversial policy questions” involved in patenting living organisms and can “tailor the precise limits of the protections available and the statutory requirements for obtaining those protections to reflect the particular attributes of the forms protected.”

The government further argued that the denial of a patent was particularly appropriate in this case since Dr. Chakrabarty’s discovery involved genetic engineering which is closely related to recombinant DNA and, therefore, raised ethical and public safety questions concerning the desirability of permitting someone to own life forms produced through these techniques. This safety issue was also put forth in an amicus brief by the People’s Business Commission. They argued that the patentability of genetic products will increase incentives for development of the technology without proper consideration for safety.

33. The government was relying on language in Deepsouth Packing Company v. Lastrom Corp., 406 U.S. 518, 530 (1972), in which the Court stated that because of the nation’s “historical antipathy to monopoly” the patent laws are strictly construed. Brief for Petitioner at 12, Diamond v. Chakrabarty, 447 U.S. 303 (1980).

34. In Parker v. Flook, the Court warned that the judiciary “must proceed cautiously when we are asked to tend patent rights into areas wholly unforeseen by Congress.” 437 U.S. 584, 596 (1978).


36. Id.

37. While Dr. Chakrabarty’s discovery was made using genetic engineering, the government did concede that he did not use recombinant DNA techniques. Brief for Petitioner at 17-18. Dr. Chakrabarty’s process involved migrating and fusing plasmids, a complete hereditary unit, from four cells to create a new bacteria. See Brief for Respondent at 4-5, 26. Unlike recombinant DNA processes, the splitting and recombining of genes outside the host organism does not take place. See infra text at notes 118-33 for discussion of how the Chakrabarty case will affect recombinant DNA research.

38. Brief for Petitioner at 18-20.


40. Id. at 2, 5.
The government next argued that Congress, in enacting section 101, did not intend to extend patent protection to living things. They adduced as proof the subsequent passage of the Plant Patent Act of 1930 and the Plant Variety Protection Act, which extended patent coverage to certain asexual and sexually reproduced plants. The government reasoned that if living organisms were already patentable subject matter then the Plant Patent Act and Plant Variety Protection Act would be redundant. It concluded that the only logical reason for these two acts was the extension of the patent laws into areas not previously covered. A letter from then Secretary of Agriculture Hyde appended to the House and Senate Committee reports on the Plant Patent Act supported this interpretation: “This purpose [encouraging the improvement of certain cultivated plants] is sought to be accomplished by bringing the reproduction of such newly bred or found plants under the patent laws which at the present time are understood to cover only inventions or discoveries in the field of inanimate nature.” The government also cited the Commissioner of Patents who supported amending the patent laws to permit protection for plants resulting “from human efforts,” as “the present patent law does not make it possible to grant patents” for them.

The government noted that, in these two instances, Congress has amended the Patent Act to provide for the patentability of certain living things—namely, various types of hybrid plants. Congress, however, despite the recommendations of the American Bar Association and various writers on patent law, had failed to pass legislation to broaden the scope of living things which may be

41. Brief for Petitioner at 21-37.
44. Brief for Petitioner at 22-24.
46. Id.
47. Hearings on H.R. 11372 Before the House Comm. on Patents, 71st Cong., 2d Sess. 6 (1930), cited in Brief for Petitioner at 35.
48. See supra text at notes 42-43.
49. Brief for Petitioner at 14 (citing the 1966 ABA PATENT, TRADEMARK, AND COPYRIGHT LAW SECTION, SUMMARY OF PROCEEDINGS 59, 74 (1967), and the 1969 ABA PATENT, TRADEMARK, AND COPYRIGHT LAW SECTION, COMMITTEE REPORTS 123 (1979)). The 1969 COMMITTEE REPORTS explicitly advocated the extension of patent protection to micro-organisms: “[t]here is growing concern by many that the micro-biological art is ready to enjoy the fruits of the patent system [and that] [t]here is also a growing belief that the micro-biological art needs stimulation of the kind offered by a patent system.”
patented beyond the coverage of those two acts. The government, therefore, argued that there is no "clear and certain signal from Congress"\(^{51}\) regarding the patentability of micro-organisms and, thus, the judiciary is foreclosed from extending patent protection into this area.\(^{52}\)

Finally, the government took issue with the CCPA which stated that the Patent Office regularly grants patents on living organisms.\(^{53}\) The government maintained that the patents on living organisms mentioned by the court and the respondent represented aberrations in the Office's policy with "minimal precedential significance, since they were only isolated actions of lower level employees [the 1,000-plus Examiners], made on applications neither contested nor reviewed."\(^{54}\) In a reply brief, the government stated that among the list of sixty-eight patents on living organisms alleged by the respondent, only three clearly involved claims to the organisms themselves.\(^{55}\)

\textbf{C. Dr. Chakrabarty's Argument}

Dr. Chakrabarty began his response by noting that the judiciary has consistently ruled in favor of patents on living organisms.\(^{56}\) He relied on \textit{Funk Bros. Co. v. Kalo Co.}\(^ {57}\) for judicial approval of the patentability of living things. In \textit{Funk}, the applicant sought a patent on a mixture of strains of bacteria useful in assisting the growth of leguminous plants. The Court denied the patent on the ground that the discovery was a natural phenomenon; a discovery of the fact that certain strains of naturally occurring bacteria can be mixed together

\(^{51}\) Brief for Petitioner at 21 (citing Parker v. Flook, 437 U.S. 584, 591 (1978), in which the Court referred to the principle enunciated in Deepsouth Packing Co. v. Lastrom Corp., 406 U.S. 518, 531: that judicial approval of extension of patent protection into a new field requires "a clear and certain signal from Congress").

\(^{52}\) Brief for the Petitioner at 21. As a further indication that Congress did not intend to permit patents for Dr. Chakrabarty's bacteria, the government relied on the language of the Plant Variety Protection Act which explicitly excludes bacteria from the coverage of the Act. The Act provides: "The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, . . . shall be entitled to plant variety protection therefore." 7 U.S.C. § 2402(a) (1976). The government found no explanation for this exclusion in the legislative history but did argue that "it cannot fairly be read as supporting the conclusion that the exemption was intended to preserve an assumed pre-existing patentability of bacteria under the general patent law." Brief for Petitioner at 27.

\(^{53}\) Brief for Petitioner at 38-39.

\(^{54}\) Id. at 39.

\(^{55}\) Reply Brief for Petitioner at 3.

\(^{56}\) Brief for Respondent at 12-16.

\(^{57}\) 333 U.S. 127 (1948).
for a specific beneficial use. Chakrabarty emphasized that nowhere in the opinion did the Court mention that the bacteria were unpatentable because they were alive; the opinion rested on the fact that the mixture was a natural phenomenon.

Similarly, in American Fruit Growers v. Brogdex Co. the Supreme Court denied a patent on fruit which contained a borax coating to retard spoilage. The Court found that the coating did not sufficiently change the form, quality, or property of the fruit to convert it from a product of nature to a manufacture. Again the Court did not contend that the fruit was unpatentable because it was alive.

Dr. Chakrabarty also argued that the policy and practice of the Patent Office has been to grant patents on living organisms. He noted that certain classifications of patents established by the office contain explicit reference to a host of living organisms which can be patented. Pursuant to these classifications, the Patent Office has granted patents on hundreds of living organisms. Further, Dr. Chakrabarty pointed out that, in the Patent Office's "Manual of Patent Examining Procedure," the subject matter considered unpatentable under section 101 includes "Printed Matter," "Naturally Occurring Article," "Method of Doing Business," and "Scientific Principle." The manual does not mention any proscription against living organisms.

Dr. Chakrabarty responded to the government's policy argument that patenting these types of organisms can only increase the hazards associated with recombinant DNA by pointing out that his process did not involve recombinant DNA. He concluded that the government's reliance on policy arguments against technology not

58. Id. at 131.
60. 283 U.S. 1 (1931).
61. Id. at 12.
63. Id. at 16-25.
64. Among the classes referred to by Dr. Chakrabarty were Class 424: "Whole Live Microorganism or Virus Containing"; Class 195: "Ferment containing products . . . , Living fungi-containing." Brief for Respondent at 16-17.
65. Id. at 18-22 (containing descriptions of some of the patents granted which include living organisms).
66. UNITED STATES PATENT OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE cited in Brief for Respondent at app. 1-A.
67. UNITED STATES PATENT OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE, § 706.03(j) cited in Brief for Respondent at app. 1-A.
68. Brief for Respondent at 17.
69. See supra text at notes 38-40.
used by him "demonstrates how far they must go to attempt to justify their policy change toward refusal of patents on living microorganisms." 70 Nevertheless, he noted that the dangers once associated with recombinant DNA research had diminished considerably 71 and stressed that the Court should not take any steps which might inhibit the development of such a beneficial technology. 72

Having argued that section 101 does not prohibit the patentability of living organisms, 73 Dr. Chakrabarty argued that his invention constituted a "manufacture" or "composition of matter" within the meaning of the section. 74 He relied mainly on American Fruit Growers 75 which accepted the definition of manufacture as "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." 76 Chakrabarty argued that his invention satisfied this test since the process used created an organism with a new name (Pseudomonas), with a new form (the fusion of four plasmids never before combined in an organism), and with new properties (the ability to degrade a variety of different components of crude oil). 77

In addition, Chakrabarty used the test provided by the Second Circuit Court of Appeals in P.E. Sharpless Co. v. Crawford Farms 78 to show that the Pseudomonas bacterium satisfied the requirements for a composition of matter. In Sharpless, the court stated that "a patentable composition of matter may well result or be formed by the intermixture of two or more ingredients, which develop a different or additional property or properties which the several ingredients individually do not possess in common." 79 Dr. Chakrabarty noted that the Pseudomonas bacterium is formed by combining two or more plasmids, creating a bacterium with a property possessed by none of the ingredients—namely, the capacity to degrade multiple components of crude oil. 80

71. Id. at 29-30. The respondent was mainly relying on the 1978 revision of the NIH Guidelines which significantly relaxed the restrictions on the research originally imposed in 1976. See infra text at notes 172-75.
73. See supra text at notes 56-68.
74. Brief for Respondent at 37-54.
75. 283 U.S. 1, 12 (1931). See supra text at notes 60-61.
76. 283 U.S. 1, 12 (1931). See also Brief for Respondent at 39 (citing 283 U.S. 1, 11 (1931)).
77. This test was also used in Steinfur Patents Corp. v. Beyer, 62 F.2d 238, 240 (2d Cir. 1932).
78. Brief for Respondent at 40.
79. 287 F. 655 (2d Cir. 1923).
80. Id. at 658, cited in Brief for Respondent at 41.
Chakrabarty concluded his argument by rejecting the government's position that the Plant Patent Act of 1930 indicates the general unpatentability of living organisms. First, he pointed out that the Plant Patent Act was passed to reverse the general perception that plants are products of nature, not man-made, and thus cannot qualify for patent protection. This perception was based largely on the Commissioner of Patent's decision in *Ex Parte Latimer* in which the Commissioner denied a patent application for parts of pine needles because the applicant's mere extraction of the components did not convert the discovery from a product of nature to a patentable manufacture. In that case, the Commissioner did note that if the applicant had processed the needles a step further and given them new properties or functions the invention would result in a patentable product. The respondents concluded that "[u]nder the rationale of Latimer, it appears that the work of the plant breeder did not qualify for a patent because there was insufficient change in the plant caused by man" and, thus, "it became an accepted tenet of patent law that plants were not patentable."

The 1930 Plant Patent Act, according to Chakrabarty, merely amended the patent laws to give incentive to breeders by allowing these products of nature to receive patent protection. The respondent argued that the legislative history confirms that plants were previously unpatentable because they were perceived as products of nature. The Commissioner of Patents' testimony and Committee reports are devoid of reference to the living nature of plants. Chakrabarty argued that his invention bears no relation to the considerations which prompted the Plant Patent Act since it is a bacterium, not a plant, and was created solely through the work of man, not by nature. He supported his conclusion that the Plant Patent Act had no effect on the patentability of micro-organisms with evidence that, prior to and after 1930, the Patent Office did grant patents on a variety of micro-organisms.
D. Reasoning of the Court

In affirming the CCPA, the Court found Dr. Chakrabarty's work to be a "manufacture" within the meaning of section 101 of the Patent Act.92 The Court noted that the definition of manufacture is to be given wide scope including "anything under the sun which is made by man."93 The Court agreed with Chakrabarty's contention that his micro-organism satisfies the tests94 for a patentable manufacture: "the patentee has produced a new bacterium with markedly different characteristics from any found in nature . . . . His discovery is not nature's handiwork but his own; accordingly it is patentable subject matter under section 101."95

The Court rejected the government's argument that passage of the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act would have been unnecessary if living things were already patentable.96 Reviewing the patent history of plants,97 the Court found that the Acts were passed because of the common perception that plants, even those bred by man, were products of nature and, therefore, unpatentable.98 Another obstacle to patent protection prior to 1930 was the strict written description requirement in the Patent Act99 which was difficult to satisfy since plants cultivated by a breeder differed considerably in color and size. The 1930 Plant Patent Act resolved this difficulty by relaxing the requirement to "a description . . . as complete as it is reasonably possible."100

specifically excluded bacteria, thus indicating their patentability (this argument is discussed at note 52 supra), Chakrabarty argued that the explicit exclusion of bacteria merely reflected congressional recognition that bacteria were not considered plants under the 1930 Act. Brief for Respondent at 53. To establish that the 1970 Act was not intended to change the already existing patentability of bacteria, citation was made to the Senate Committee report which stated: "The Committee accordingly has examined S. 3070 and finds that it does not alter protection currently available within the patent system." S. REP. No. 1246, 91st Cong., 2d Sess. 3 (1970), cited in Brief for Respondent at 53.

92. 447 U.S. at 307-17.
93. Id. at 309. The Court was quoting the Committee reports accompanying the 1952 recodification of the Patent Act. S. REP. NO. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. No. 1923, 82d Cong., 2d Sess. 6 (1952).
94. The tests referred to are the American Fruit Growers test (see supra text at notes 60-61, 75-76; and a similar test proposed in Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887)).
95. 447 U.S. at 310.
96. Id. at 310-11. This argument advanced by the government is mentioned in text at notes 41-52 supra.
97. The Court was mainly relying on Ex Parte Latimer discussed in text at notes 83-87 supra.
98. 447 U.S. at 311.
100. Id. § 162 (1976), cited in 447 U.S. at 312.
The Court dismissed the government’s reference to Secretary Hyde’s letter, which stated that living organisms were unpatentable, on the ground that his comments were not controlling and were beyond his area of competence. On the contrary, the Court found mention in the Plant Patent Act’s Committee reports of the fact that the crucial distinction for section 101 patentability was not between living and inanimate inventions as urged by the government, but between products of nature, whether living or not, and human-made inventions. Applying this distinction to Chakrabarty, the Court found that Dr. Chakrabarty’s micro-organism was clearly made through human effort and ingenuity; the fact that it was also alive had no relevance for patenting purposes.

The majority also rejected the government’s argument that Dr. Chakrabarty’s patent would expand the patent laws into areas “wholly unforeseen by Congress” and that the Court should, therefore, defer to the legislature for a careful weighing of the issues involved in patenting genetic products. The Court found that the language in section 101 is broad yet wholly unambiguous. It reasoned that, once Congress has set the outer limits of patentability, it is the role of the judiciary to give content to the language by construing the meaning of the words employed. The Court concluded that to read section 101 as prohibiting patents on any invention not contemplated by Congress would frustrate the purpose of the patent laws since the most socially useful inventions are often those completely unforeseen by Congress—those which “push back the frontiers of chemistry, physics, and the like.”

101. See supra text at notes 45-46.
102. 447 U.S. at 312-13. The Court said that the Secretary’s comments were solicited on the administration of the new law, not on the overall scope of the patent laws.
104. 447 U.S. at 313 (citing S. REP. No. 315, 71st Cong., 2d Sess. 6 (1930); H.R. REP. No. 1129, 71st Cong., 2d Sess. 7 (1930)).
105. 447 U.S. at 313. The Court also agreed with Chakrabarty that the exclusion of bacteria in the 1970 Plant Variety Protection Act, see supra notes 43, 52 and accompanying text, either reflected the congressional consensus that bacteria were not considered plants under the 1930 Act or the fact that the Patent Office was already issuing patents on bacteria. The Court could find no support for the argument that the statute was enacted to change the plain meaning of the words of § 101, that manufactures are patentable subject matter. 447 U.S. at 314.
106. 447 U.S. at 314-16. The Court was referring to language in Parker v. Flook. See supra note 34.
107. 447 U.S. at 315.
108. Id.
109. Id. at 315 (quoting J. Douglas concurring in A. & P. Tea Co. v. Supermarket Corp., 340 U.S. 147, 154 (1950)).
fore, employed broad language in section 101 to enable the Patent Office to grant patents on these kinds of unforeseeable inventions.110

Finally, the Court refused to consider the effects of the decision on genetic research stating that "the grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks."111 The Court did recognize that the legislature is best equipped to weigh the complex issues associated with patenting genetic manufactures. It noted that Congress is still free to amend section 101 to prohibit the patenting of such inventions112 as it did in the field of nuclear research.113 The Court concluded, however, that, in the absence of any explicit prohibition, the scope of the Court’s inquiry is "a narrow one of determining what Congress meant by words it used in the statute."114

At the very least, the Chakrabarty case illustrates the difficulty in determining congressional intent. It appears that any patchwork of statements taken from the legislative history or the Patent Commissioner’s office could rationally support either proposition—that living organisms were or were not intended to be included within the scope of section 101 of the Patent Act.

In its opinion, the Court appears to have misestimated the importance of the decision on recombinant DNA development. While the majority is clearly correct in stating that "the grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks,"115 the Court overlooks the fact that the decision is likely to have a bearing on the pace at which the research is carried out and on the kind of individuals who will be attracted to conduct or invest in the research.116 These effects, discussed below, raise additional questions about the safety of the research and its regulations which, if considered by the Court, might have

110. 447 U.S. at 316.
111. Id. at 317.
112. Id. at 318.
113. Id. The Court was referring to 42 U.S.C. § 2181 (1976) which exempted from patent protection inventions "useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon."
114. 447 U.S. at 318. In a dissenting opinion, Justice Brennan (joined by J. White, J. Powell, and J. Marshall) agreed with the government that the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act demonstrated Congress’ recognition that § 101 does not include living organisms. Brennan’s examination of the legislative history led him to conclude that the Congress was doing something much more significant than correcting public perceptions about the patentability of plants; it was providing a carefully tailored list of animate objects which may be patented. 447 U.S. at 318-22.
115. 447 U.S. at 317.
116. These effects are discussed in text at notes 138-51 infra.
caused it to deny Chakrabarty’s application and thus foreclose patent protection for man-made living organisms until Congress provides a “clearer signal” on the issue.

**E. Relevance of Chakrabarty to Recombinant DNA Research**

Although Dr. Chakrabarty’s *Pseudomonas* bacteria were not produced through recombinant DNA techniques, the Court’s holding is broad enough to afford patentability for recombinant DNA microorganisms as well. The Court held that the crucial distinction for patent protection under section 101 is not whether the invention is alive, but whether it was made through human effort and ingenuity as opposed to “nature’s handiwork.” Recombinant DNA microorganisms satisfy this test since they are produced through human effort and ingenuity. The process of recombining genetic information from two cells to make a new organism would not take place in nature but for the ingenuity and labor of laboratory scientists. Recombinant DNA micro-organisms also satisfy the *American Fruit Growers* “new forms, qualities, and properties” test relied on by the Court in determining whether an invention is a manufacture within the meaning of section 101. The process of recombinant DNA results in organisms never before known to nature.

There is no question that both parties in *Chakrabarty* realized the potential impact of the case on recombinant DNA and other genetic research. The government argued that a finding in favor of Chakrabarty would compound the ethical and safety issues related to all genetic research by permitting individuals to own life forms. The government was supported by an amicus curiae brief from the People’s Business Commission. After detailing the environmental hazards of recombinant DNA research, the Commission concluded: “the technology of genetic engineering as a whole, is not in the public interest and should not be unduly encouraged by giving unwarranted economic incentive to corporations in the field of genetic research and development through the vehicle of awarding potentially lucrative patents on living organisms.”

117. *See supra* note 37 and accompanying text.
118. 447 U.S. at 310.
120. *See supra* notes 60-61, 75-76 and accompanying text.
121. 447 U.S. at 310.
122. *See supra* note 2.
123. Brief for Petitioner at 20.
124. Amicus Curiae Brief for People’s Business Commission at 5.
Chakrabarty, while arguing that "[w]hether patents are to be granted on the recombinant DNA technique or its products is quite a different issue from whether Chakrabarty's different invention is patentable,"126 did concede that "a holding here that living bacteria cannot be patented would seriously impact upon recombinant DNA research."126 The potential impact of the case on recombinant DNA prompted Genentech, Inc., one of the nation's leading private recombinant DNA companies,127 to file an amicus brief in support of Chakrabarty. The brief attempted to minimize the dangers associated with recombinant DNA. As evidence of the diminishing hazards, it noted that the recombinant DNA guidelines promulgated by the National Institutes of Health128 have been "significantly relaxed."129

It is clear that, following Chakrabarty, recombinant DNA researchers can expect to receive patent protection for their inventions and processes, and, potentially, the financial benefits which can flow from that protection.130 At present, at least two applications have been filed in the Patent Office for patents on basic processes involved in recombinant DNA.131 Several more applications have been filed for patents on bacteria produced through recombinant DNA techniques.132 As a result of the Court's decision, the Patent Office is expected to approve these applications.133

Some commentators134 have observed that the most significant benefits from the Chakrabarty case may be experienced in the coming decade when scientists have sufficiently refined the technology to produce an organism worth patenting. At present, many private researchers may decide to forego patent applications and protect their proprietary secrets.135 At the very least, however, the case provides a psychological boost to the private genetic engineering in-

125. Brief for Respondent at 27.
126. Id.
127. See infra note 151 (describing Genentech's involvement on Wall Street).
128. See infra section IV of this article describing the guidelines in detail.
129. Amicus Curiae Brief for Genentech, Inc. at 11.
130. This statement assumes that Congress will not amend the Patent Act to exclude recombinant DNA organisms from patent protection.
132. Id. These bacteria are useful in producing products such as human insulin, human growth hormones, and interferon.
133. Id.
135. Wade, supra note 134.
dustry. Researchers now realize that, when their discoveries are sufficiently sophisticated to be used regularly in manufacturing products, their work can be protected with a government patent.\footnote{136}{Parisi, supra note 6; Wade, supra note 134.}

III. THE CHANGING GENETIC ENGINEERING INDUSTRY

The Chakrabarty decision has come at a time when a major shift in the field of recombinant DNA research from public to private concerns is taking place.\footnote{137}{See generally, Parisi, supra note 6; Wade, supra note 6; Amicus Curiae Brief for People's Business Commission; Powledge, Who Owns Life, NATION, Oct. 1979, at 326.} When initial reports of recombinant DNA technology were made available to the scientific community and the public in the mid-1970's, the government, under the auspices of the National Institutes of Health, began to provide financial support for much of the experimentation taking place in the United States.\footnote{138}{By the beginning of 1980, the NIH had funded 717 research projects at a cost of approximately $91.5 million. Amicus Curiae Brief for Genentech, Inc., at 11.} As the wide-ranging practical applications of recombinant DNA research have become apparent in recent years, more private firms are engaging in the research without government support.\footnote{139}{Parisi, supra at note 6.} The potential for creating useful products and earning substantial profits has transformed genetic research from a purely academic field into a highly competitive, rapidly growing industry.\footnote{140}{Id.} The growth of one recombinant DNA firm prompted one of its vice-presidents to remark, "[w]e're building another I.B.M. here."\footnote{141}{Powledge, supra note 137, at 326.} Nicholas Wade, editor of Science magazine, described the composition of the private genetic engineering industry:

Spearheading the gene-splicing industry are four small companies backed by venture capital and with leading molecular biologists among their founders and advisors. Next in the field were the large pharmaceutical companies [such as Upjohn, Miles Laboratories and Eli Lilly]. The latest arrivals on the scene are the giants of the oil and chemical industries, such as DuPont and Standard Oil of Indiana which are either recruiting in-house teams or establishing links with the small companies.\footnote{142}{Wade, supra note 6.}

One of the indicators of the growth potential for the private genetic engineering industry is its attractiveness to private and corporate investors and investment brokers. Wall Street analysts have
predicted that genetic engineering will eventually grow into a multi-
billion dollar industry,\textsuperscript{143} describing the industry as a "major new
profit opportunity"\textsuperscript{144} with the "most exciting investment
potential."\textsuperscript{145}

E.F. Hutton thought that the potential for recombinant DNA was
so lucrative that it devoted an entire issue of its monthly magazine to
the genetic engineering industry.\textsuperscript{146} The magazine contained a
status report on recombinant DNA development in the fields of
chemistry, energy, medicine, agriculture, and mining. To illustrate
the growth potential for the chemical industry, the magazine provid-
ed a market analysis by Genex Corporation, a company which
recently began a joint venture with Bristol Myers to produce in-
terferon.\textsuperscript{147} Genex estimated that recombinant DNA technology can
improve the synthesis of organic chemicals in products which
resulted in a sales volume of $32.4 billion in the United States in
1977.\textsuperscript{148} These estimates are necessarily conservative as they are
based on current technology assessments and do not take into ac-
count the likelihood that future advances in DNA technology will im-
prove the manufacturing processes on a wider range of products.\textsuperscript{149}

As Dr. J. Leslie Glick, President of Genex states: "[t]he possibilities
are so vast that it is impossible to predict the ultimate scope of the
impact of recombinant DNA technology. Suffice it to say that I
believe we have observed merely the tip of the iceberg."\textsuperscript{150}

Recombinant DNA technology has generated genuine excitement
in the investment world.\textsuperscript{151} Private venture capitalists are not the

\textsuperscript{144.} Amicus Curiae Brief for People's Business Commission at 17 (citing the comments of Nelson Schneider, a vice-president of E.F. Hutton).
\textsuperscript{145.} Id.
\textsuperscript{146.} E.F. Hutton Co., BIOTECHNOLOGY, Nov. 1979, at 1 [hereinafter cited as BIOTECHNOLOGY].
\textsuperscript{147.} Parisi, supra note 6.
\textsuperscript{148.} BIOTECHNOLOGY, supra note 146.
\textsuperscript{149.} Id.
\textsuperscript{150.} Id.
\textsuperscript{151.} This excitement is perhaps best illustrated by the experience involving Genentech, Inc., a small San Francisco-based genetic engineering firm which began operations in 1976. In
Sept., 1980, much to the delight of Wall Street investors, Genentech decided to become the
first venture capital DNA firm to offer its stock to the public. The public response to
Genentech's offering on Oct. 10, 1980, created what has been called by the Wall Street Journal
as "an historic day in the securities markets." The stock opened at $35 per share and rose to
$86 within 90 minutes. The price peaked at $88 before closing at $71\textsuperscript{\textfrac{1}{4}}. The opening day in-
crease represented the largest single daily increase for a new issue in 20 years. By the end of
the day, the market value of the company's shares had risen to approximately $530 million. See
Hot Reception Seen Today for Genentech As First Gene-Splicing Firm to Go Public, Wall
only ones who have been interested in this investment. In October, 1980, Harvard University announced that it was planning to become a minority shareholder in a private genetic engineering firm to raise revenues for the school. Ultimately, Harvard chose not to participate in the firm, deciding that such participation could conflict with its traditional academic role.

In summation, the shift of recombinant DNA research from the public to the private sector is evident. This trend is likely to continue in light of the attractiveness of investment and the potential for profits, a potential more likely to be realized as researchers are granted patent protection for their discoveries. It is with this transformation of the recombinant DNA industry in mind that the regulations controlling this research must be analyzed.

IV. THE NATIONAL INSTITUTES OF HEALTH’S GUIDELINES

A. Background

The federal government focused on the hazards presented by recombinant DNA in 1974. On October 7, 1974, the National Institutes of Health (NIH), an agency within the Department of Health, Education, and Welfare, formed a Recombinant DNA Program Advisory Committee to study the hazards of this research and to draft guidelines to be followed by recombinant DNA researchers. The guidelines were approved by the Director of NIH on July 7, 1976. They were made applicable to all recombinant DNA researchers engaged in NIH-supported work.


152. Commenting on the plan, Harvard President Derek Bok said: “If we are to continue to meet rising expenses and to maintain scientific research of high quality, we need to explore ways of sharing in the financial rewards that can come from the application of the new knowledge discovered in the university.” Cooke, Harvard to Decide Soon on DNA Business Venture, Boston Globe, Oct. 28, 1980, at 1, 18, col. 6.


154. 41 Fed. Reg. 27,902-03 (1976). This citation is for the “Guidelines for Research Involving Recombinant DNA Molecules.” They begin with an overview of the guidelines written by NIH Director Donald S. Fredrickson. His comments are followed by the formal provisions of the guidelines which begin at 27,911. As these are guidelines as opposed to regulations, there is no corresponding citation in the Code of Federal Regulations.

155. Id.

156. Id. at 27,911. The NIH is primarily responsible for conducting and awarding grants for research into man’s physical and mental diseases. The NIH administers research agencies for specific medical problems such as the National Cancer Institute. The various statutory provisions dealing with the function and management of the NIH do not confer authority to prom-
The purpose of the 1976 guidelines was to foster development of the technology and, at the same time, to advocate considerable caution and require adequate safeguards from the hazards of the research. Pursuant to this goal, the guidelines established a system for identifying all types of recombinant DNA experiments on the basis of risk. Six classifications of high-risk experiments were prohibited outright. The remaining types of experiments were grouped into classes and assigned corresponding levels of containment to prevent the possible escape of recombinant molecules into the environment.

The containment procedures which have been retained in the subsequent revisions of the guidelines provide a dual security system—both physical and biological. Physical containment requires special laboratory procedures and equipment that create physical barriers to an escaping organism. The containment levels are classified from P1 (lowest level of physical containment) to P4. Biological containment requires the use of experimental organisms which are biologically incapable of surviving outside the laboratory environment. This is accomplished by using weakened strains of host-vector systems—the organisms into which the DNA recombination is placed. The biological containment levels are classified from EK1 (lowest level of biological containment) to EK3.
Another important feature of the guidelines is the establishment of an institutional biohazards committee within each institution which receives NIH funds.\textsuperscript{164} This committee is responsible for advising the institution on recombinant DNA policies and monitoring all recombinant DNA activities within the institution. Specific responsibilities include: certifying to the NIH on all grant applications and annually thereafter that all DNA research and personnel have been approved by the committee; maintaining a central reference file with information on recombinant DNA technology and safety; developing a safety manual for any P4 laboratory; and making the minutes of its meetings available for public inspection.\textsuperscript{165}

The NIH staff is required to review all proposals for grants in order to assure compliance with the NIH guidelines. In reviewing the proposals for grants, the NIH assesses the judgment of the institution's "principal investigator"\textsuperscript{166} regarding the appropriate levels of containment and other safety precautions.\textsuperscript{167} The NIH will refuse to fund any proposals which do not comply with the guidelines.\textsuperscript{168} After the awarding of the grant, the NIH continues to fulfill its monitoring function by maintaining contact with the institutional biohazards committees through receipt of their annual reports and by responding to questions or problems submitted to them by the committees.\textsuperscript{169}

When the guidelines were promulgated, the NIH Director realized that they were based on insufficient data regarding the hazards of the research: "At present, the hazards may be guessed at, speculated about, or voted upon, but they cannot be known absolutely in the absence of firm experimental data—and unfortunately, the needed data were, more often than not, unavailable."\textsuperscript{170} As a result, the guidelines provided for a periodic revision so that current findings regarding the safety of the work could be incorporated into the regulatory framework.\textsuperscript{171}

Pursuant to the review provisions, the NIH revised the guidelines in December, 1978, based on an assessment by the scientific com-

\textsuperscript{165} Id.
\textsuperscript{166} The principle investigator is the individual who applies to the NIH for research funding.
\textsuperscript{167} Id. at 27,921.
\textsuperscript{168} Id.
\textsuperscript{169} Id. "NIH Staff has responsibility for: (i) Assuring that no NIH grants or contracts are awarded . . . unless they (a) conform to these guidelines."
\textsuperscript{170} Id. at 27,911.
\textsuperscript{171} Id. at 27,912.
munity that most of the hazards connected to the research were becoming more remote.\(^{172}\) This revision exempted five categories of experiments from the guidelines—amounting to approximately one-third of the experiments covered under the 1976 guidelines.\(^{173}\) The six classifications of prohibited experiments were continued with the Director retaining the authority to grant case-by-case exceptions to the prohibitions.\(^{174}\) The physical and biological containment levels were retained. Each classification of experiments, however, was downgraded at least one step in physical and/or biological containment.\(^{175}\) The guidelines were relaxed again in 1980.\(^{176}\) These revisions contained additional containment downgrading for certain types of experiments and exempted others completely from regulatory control.\(^{177}\)

**B. Analysis of the Guidelines**

The NIH guidelines represent virtually the only direct regulatory control over recombinant DNA in this country.\(^{178}\) There is evidence that no new regulations will be passed at the federal level.\(^{179}\) Many observers feel that the guidelines—as the sole regulatory control over recombinant DNA research—do not provide communities with sufficient protection from the hazards of the research.\(^{180}\) The insufficiencies pointed out by these critics relate to the scope of the guidelines, the nature of the promulgating agency, the substance of the provisions, and the lack of public involvement in the formation and implementation of the guidelines.


\(^{173}\) Id.

\(^{174}\) Id.

\(^{175}\) Id.

\(^{176}\) Id.


\(^{178}\) Id.

\(^{179}\) At the present time, there are two state statutes and two local ordinances which also regulate the research. MD. ANN. CODE art. 43 §§ 898-910 (1980); N.Y. PUB. HEALTH LAW § 3220 (McKinney Supp. 1981-82); BERKELEY, CAL. ORDINANCE 5010, N.5 (1977); CAMBRIDGE, MASS. GENERAL ORDINANCES ch. 11, art. 2 (1977). The Cambridge ordinance is discussed in detail in text at section V infra. Other localities which have recently enacted ordinances include Amherst, Waltham, and Boston, Mass.

\(^{176}\) In 1977 and 1978 Congress held hearings and drafted bills regulating recombinant DNA work. However, none reached the floor of either house for a vote. H.R. 11192, 95th Cong., 2d Sess. (1978); H.R. 7897, 95th Cong., 1st Sess. (1977); S. 1217, 95th Cong., 1st Sess. (1978). No bills were considered in 1979 or 1980 and it is unlikely that the Reagan Administration will permit further regulations given the President's traditional aversion to regulating private industry. See Mayer & Kasindorf, Reagan on the Key Issues, NEWSWEEK, Mar. 31, 1980, at 26-27.

\(^{180}\) See generally Berger, supra note 1; English, DNA and the Congressional Prerogatives:
1. The Scope of the Guidelines

Perhaps the most glaring weakness in the NIH regulatory scheme is the fact that the guidelines are binding only on institutions receiving NIH funds.\textsuperscript{181} This leaves the burgeoning private DNA research industry\textsuperscript{182} wholly outside the regulatory framework. As a result, the guidelines control only a small fraction of the recombinant DNA activities taking place in this country.\textsuperscript{183} Clearly, as the shift toward private genetic research continues—a shift undoubtedly accelerated by the \textit{Chakrabarty} decision which allows patenting of genetic organisms\textsuperscript{184}—the fraction of projects under the control of the NIH will decrease.

When the NIH originally proposed its guidelines and solicited comments from the public, many commentators felt that the public could only be protected if regulatory control was asserted over the private sector.\textsuperscript{186} The NIH held meetings with representatives of twenty drug and chemical manufacturers in May, 1976 to discuss regulation of the private sector.\textsuperscript{186} The representatives did voice their general support for the guidelines and for voluntary compliance but expressed the fear that these guidelines might lead to enforceable regulations.\textsuperscript{187} They argued that mandatory control over their work would force them to reveal proprietary secrets which would jeopardize their competitive edge and that restrictions on large volume experiments would make their production processes less commercially feasible.\textsuperscript{188}

The NIH's response to the private sector was to initiate a voluntary program for private companies wishing to register their experiments with the NIH.\textsuperscript{189} The obvious weakness in this program is

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\textit{Proposals for a Deliberate Legislative Approach to Genetic Research}, 53 \textit{Ind. L.J.} 571 (1978);

181. This was a major criticism contained in the DNA REPORT at 7. It should be pointed out that this criticism is directed at the guidelines as a regulatory system and not at the NIH for failing to provide for private regulation. See supra note 156.

182. The growth of the private DNA industry is documented at section III supra.

183. DNA REPORT, supra note 180, at 7.

184. See supra text at notes 117-36.


186. \textit{Id.} at 27,906.


188. \textit{Id.}

the lack of power to enforce the guidelines. Since private companies which voluntarily submit receive no financial support from the NIH, the NIH cannot rely upon its sole enforcement mechanism—withdrawal of its funds.

Congress has recognized that exemption of the private sector represents a serious inadequacy in the regulation of recombinant DNA. In a report\footnote{DNA REPORT, supra note 180.} on the proposed Recombinant DNA Act,\footnote{H.R. 11192, 95th Cong., 2d Sess. (1978).} the House Committee on Science and Technology identified this weakness in the NIH guidelines and endorsed regulation of the private sector.

The question then can be asked, is it sensible or fair to require compliance with a set of standards by some researchers in this area and not by all? It is the considered belief of most who have studied the matter that all should proceed under the same rules or the 'guidelines' will be little more than a charade.\footnote{DNA REPORT, supra note 180.}

The proposed Act provided for extension of the guidelines to the private sector and empowered the Secretary of the Department of Health and Human Services to enforce the guidelines through fines and withdrawal of NIH funds.\footnote{Id. at 2-3.} The scientific community felt extremely threatened by such a legislative plan to regulate private research.\footnote{King, supra note 180, at 60.} Not surprisingly, the scientific lobby was instrumental in defeating the proposed Recombinant DNA Act.\footnote{Id.}

2. The Nature of the NIH

Another criticism directed at the guidelines concerns the nature of the NIH as the rule-making agency.\footnote{See generally English, supra note 180; Hubbard, Gazing into the Crystal Ball, 26 BIOSCIENCE 608 (1976); Berger, supra note 1, at 91-93.} The NIH is attempting to play a dual role in recombinant DNA research: it acts as promoter of the research by awarding millions of dollars in research grants; and, at the same time, as policeman by promulgating guidelines to safeguard the public from the research it sponsors.\footnote{Berger, supra note 1, at 92.} The potential for conflict between these seemingly contradictory roles is obvious.\footnote{An analogous situation in which a government agency was performing conflicting roles existed in the field of atomic energy when the Atomic Energy Commission had the dual roles of promoter and regulator.}
The potential for conflict of interest is magnified by the fact that the NIH's Recombinant DNA Advisory Committee which drafted the guidelines is comprised of DNA researchers. Thus, the job of regulating DNA researchers has largely been left to the researchers themselves. One author described the situation as follows:

[T]he 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 the NIH, the research community felt secure. It was, in effect, a form of self-regulation.

Having promulgated guidelines which amount to a form of "self-regulation," the NIH inspires little public confidence that it is capable of policing recombinant DNA work effectively. The NIH does not have the arm's length relationship with the scientific community necessary to monitor this research. As a result, it would appear desirable to remove the policing responsibilities from the NIH and establish a separate monitoring unit elsewhere within the Department of Health and Human Services, or within the NIH, provided it is staffed by laymen. Such a unit would have the responsibility for coapproving NIH grants, conducting site inspections in the field, and maintaining liaison with the institutional biohazards committees.

3. The Substantive Provisions

In light of the conflict of interest inherent in the NIH's responsibilities and the comfortable relationship the agency enjoys with the research community, the substantive provisions of the guidelines must be examined closely as well. The 1978 and 1980 revisions represent—to use former Secretary Califano's words—"a substantial relaxation" of the guidelines. Although the Secretary concluded that the 1978 revisions were based on new information regarding the safety of recombinant DNA technology, questions have been raised concerning the accuracy of the "new information" provided to the


199. Berger, supra note 1, at 90.
200. Id. at 91.
201. Id.
202. Id.
203. See supra text at notes 197-202.
204. 43 Fed. Reg. 60,080, 60,081 (1978).
Certainly the temptation for scientists to color their assessment of the technology is substantial considering the prestige and profits at stake.

According to Massachusetts Institute of Technology geneticist Dr. Jonathan King, the relaxation of the guidelines is directly related to misrepresentations about the safety of genetic technology by a group of scientists working for commercial interests. He concluded that, as a result of their efforts, "the guidelines have now been so weakened that, rather than protecting public health, they in fact protect those engaged in the technology from public inquiry and regulation." If this assessment of the substantive provisions of the guidelines is at all accurate, it is clear that the NIH has failed in its difficult, if not impossible, role of striking a balance between promoting this exciting technology and promulgating substantive controls to safeguard society from its potential hazards.

Another more specific deficiency in the substance of the guidelines is the monitoring system which it establishes. The guidelines only require on-site inspections of P4 facilities, of which there are only a handful in the entire country. After the initial review of a grant proposal by the NIH staff, in practice, the bulk of the responsibility for assuring compliance with the guidelines shifts to the project's principal investigator and his institution's biosafety committee. These individuals with vested interests in seeing their projects completed can hardly be characterized as neutral monitors. Under the present monitoring framework, it is possible for the local institutional biohazards committees to go a complete year without having any contact with the NIH office in Washington.

There is also evidence that in the present monitoring framework

205. King, supra note 180, at 60.
206. As with other new sciences, DNA research offers international recognition to its leaders. Dr. Walter Gilbert of Harvard was recently awarded the Nobel Prize for his work in recombinant DNA technology. See Five New Nobel Laureates, NEWSWEEK, Oct. 27, 1980, at 117.
207. See supra section III regarding the profitability of the private genetic engineering industry.
208. King, supra note 180, at 60.
209. Id.
211. "The principle functions of the IBC (Institutional Biosafety Committee) are to review and oversee all recombinant DNA projects with respect to compliance with the Guidelines and to advise the institution . . . whether the proposals and the research so comply." 43 Fed. Reg. 60,080, 60,093 (1980).
212. The guideline roles and responsibilities section mentions that the IBC must certify that research activities are in compliance with the guidelines in an annual report. 41 Fed. Reg. 27, 902, 27,920 (1978).
the guidelines are not taken seriously or are ignored completely.213 One science journalist who spent three months working in a California genetic engineering lab observed:

The high containment (P3) lab upstairs was shut down by the university's biohazard committee for a few days this week. I was dismayed to hear people joking about the closure and the messy conditions that precipitated it. Among the young graduate students and post doctorates it seemed almost chic not to know the NIH rules.214

It appears that tighter monitoring procedures would enhance the NIH's capacity to police recombinant DNA work and in the process provide better protection to society. These ends could be accomplished by requiring the NIH to remain in closer, more frequent contact with the local institutions after the grant has been awarded and by requiring NIH staff to conduct site inspections on all recombinant DNA labs (P1 through P4). These improvements, of course, would require increased funding and staffing of the NIH, measures unlikely to occur given the commitment of the Reagan Administration to reduce government spending.

4. The Role of the Public

A final deficiency in the NIH guidelines is that the public has played little role in their formulation and administration. The guidelines were originally based on the discussions conducted at a conference of microbiologists in Aslomar, California in 1975.215 The original drafting body, the Recombinant DNA Advisory Committee, was comprised entirely of scientists.216 The extensive 1978 revision of the guidelines was drafted by a Recombinant DNA Advisory Committee which had two laymen among its sixteen members.217 On the local level the lack of public involvement is evidenced by the fact that the 1976 guidelines did not require any laymen unconnected to the institution as members of the local institutional biohazards committees.218

Clearly, in regulating this research, which is complex and constantly changing, government must rely substantially on input from

214. Id.
216. See King, supra note 180, at 56.
218. The Secretary did identify this problem and the 1978 guidelines require 20 percent of the IBC members to be laymen with no ties to the institution. Id. at 60,081.
the scientists to define the risks involved. It does not follow, however, that the public should be foreclosed completely from the regulating process, or play an insignificant role. As Harold P. Green has pointed out, it is inappropriate and antithetical to the democratic process to rely solely upon scientists to assess the cost and benefits of public safety issues and permit them to make decisions based on those assessments.\footnote{219} According to Green, constructing a cost/benefit analysis on public safety issues always involves making value judgments. Since risks and benefits mean different things to different people,\footnote{220} scientists are simply incapable of accurately reflecting those judgments in their cost/benefit analyses.\footnote{221} "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."\footnote{222} Of course, in determining acceptable levels of risk, the scientific community must be called upon to identify and quantify the scientific risks and benefits of the issue.\footnote{223} It is, however, the lay community which, by virtue of its ability to incorporate a broad spectrum of value judgments into its cost/benefit analyses, is most appropriate to make the ultimate decision regarding what levels of risk society is willing to bear. The resulting decision, therefore, should reflect a partnership between the scientific and lay communities.\footnote{224}

It is clear that the NIH has not allowed the public to assume this type of role. One possible explanation for this result is the common perception within the scientific community that the public is simply too ignorant to make intelligent assessments and decisions regarding the hazards of complicated scientific technology such as recombinant DNA.\footnote{225} For adherents of this view, self-regulation by scientists, therefore, becomes a necessity. This view is illustrated by the remarks of William McGill, president of Columbia University: "Scientific questions simply cannot be settled by persuasive argu-

\footnote{220}{Green uses the example of a nuclear power plant. To some, the benefits of the increased energy production outweigh the hazards of the undertaking. To those living in the neighborhood of the proposed plant, however, the cost benefit calculation might come out the other way. \textit{Id.} at 792 n.3.}
\footnote{221}{\textit{Id.} at 792.}
\footnote{222}{\textit{Id.}}
\footnote{223}{\textit{Id.}}
\footnote{225}{Berger, \textit{supra} note 1, at 95.}
ment. 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."\textsuperscript{226}

Despite this attitude, there is ample evidence to suggest that laymen are capable of making intelligent decisions on issues with a scientific basis after the risks and benefits have been identified by experts. For example, legislators at all levels of government commonly hear testimony from experts before enacting legislation addressed to problems of a complex and scientific nature such as air and water pollution, nuclear energy, and hazardous waste control.\textsuperscript{227} In procuring medical service under the doctrine of "informed consent," a patient has a right to decide what treatment he will receive, after his physician has identified the risks and benefits associated with each procedure.\textsuperscript{228} Juries are commonly asked to decide complex issues after the complexities have been explained by experts and argued by adversaries.\textsuperscript{229}

In light of the above examples, it appears that the public could move to the forefront in deciding levels of risks regarding recombinant DNA research after the risks have been identified by scientists. Such an evaluation of the public role would eliminate the self-regulating aspect of the guidelines and permit a weighing of risks more reflective of the attitudes of the American public in regard to this controversial research.

It does appear that the NIH is at least moving toward the goal of fostering public participation. In promulgating the December, 1978 guidelines, former Secretary Califano recognized the need for more public participation in the regulation of genetic research.\textsuperscript{230} The Secretary announced that he would expand the base of the Recombinant DNA Advisory Committee, which is responsible for drafting the guidelines, to include representatives from the fields of law, public health, ethics, and the environment.\textsuperscript{231} Furthermore, on the local level, the 1978 guidelines require that 20 percent of the Institutional Biohazards Committee be comprised of individuals who represent the general public with no ties to the institution.\textsuperscript{232} The guidelines

\begin{footnotesize}
\begin{itemize}
\item[226.] Id. (quoting an address reprinted in 198 Science 275 (1977)).
\item[227.] Berger, supra note 1, at 97.
\item[228.] See Karp v. Cooley, 493 F.2d 408, 419 (5th Cir. 1974); Annot., 88 A.L.R. 3d 1008 (1978).
\item[229.] Berger, supra note 1, at 96-97.
\item[230.] 43 Fed. Reg. 60,080, 60,081 (1978).
\item[231.] Id.
\item[232.] Id.
\end{itemize}
\end{footnotesize}
also require the bulk of the Institutional Biohazards Committee records to be made available for public inspection.\textsuperscript{233}

These steps clearly afford more public participation and scrutiny over recombinant DNA research. At the same time, they appear to fall far short of allowing the public to play a significant role in determining what risks society is willing to tolerate in regard to this research. As a result, a few local communities have, on their own initiative, established controls over recombinant DNA research. The final portion of this article discusses the action taken by one community, Cambridge, Massachusetts, in regard to recombinant DNA.

V. THE CAMBRIDGE RECOMBINANT DNA ORDINANCE

Since the NIH guidelines represent the sole form of direct federal regulation over this research, the weaknesses in the guidelines\textsuperscript{234} raise serious questions as to whether communities are sufficiently protected from the potential hazards of recombinant DNA. States and localities may consider enacting further control over this developing technology particularly in light of the \textit{Chakrabarty} case which provides additional incentives to the growing genetic engineering industry. One community which has responded to the hazards of recombinant DNA is Cambridge, Massachusetts, which in 1977 enacted an ordinance controlling the research.\textsuperscript{235}

The following discussion considers the Cambridge ordinance as a potential model for other communities desiring more control over recombinant DNA research. The provisions of the ordinance and their application in Cambridge will be analyzed mainly in terms of the ways in which they address the major inadequacies in the NIH guidelines: the scope of the regulation; the conflict of roles within the monitoring agency; and the degree of public participation afforded in the regulation process. Weaknesses in the ordinance and suggestions for improvement will be discussed as well.

A. Background

Public concern over recombinant DNA research is no more evident than in Cambridge, Massachusetts; a city in which a substantial amount of recombinant DNA research is carried out at the Massachusetts Institute of Technology (M.I.T.) and Harvard Univer-

\textsuperscript{233} \textit{Id.} at 60,080.
\textsuperscript{234} See \textit{supra} text at section IV.
\textsuperscript{235} \textit{CAMBRIDGE, MASS. ORDINANCES} ch. 11, art. 2 (1981).
The volatility of the issue was demonstrated in the summer of 1976 when a public uproar resulted in response to a story in a Boston weekly newspaper describing Harvard's plan to build a P3 lab for recombinant DNA experiments. Mayor Albert Vellucci responded to the community's concern by sponsoring public hearings. These hearings, which drew overflow audiences and received considerable media attention, provided Cambridge residents with an opportunity to discuss the research. Witnesses from Harvard and the NIH testified, explaining the benefits and risks associated with recombinant DNA. After the hearings, the City Council imposed a three-week moratorium on all recombinant DNA research and began to consider an ordinance to regulate all DNA experimentation in the city. The ordinance was passed unanimously on February 7, 1977.

B. Analysis of the Ordinance

1. Scope of the Ordinance

One of the crucial differences between the ordinance and the NIH guidelines is that the ordinance controls all recombinant DNA experimentation in the City of Cambridge. In other words, all institutions and private research labs are legally required to comply with the ordinance regardless of whether they are receiving financial support from the NIH. By asserting control over private research, the ordinance has successfully addressed what has been described as the most critical inadequacy in the federal regulation of the recombinant DNA research.

236. Harvard and MIT have active recombinant DNA laboratories. Cambridge has been described as one of the birthplaces of recombinant DNA since many of the initial discoveries regarding this technology were made at these institutions. Interview with Dr. Robert Neer, chairman of the Cambridge Biohazards Committee in Boston, Jan. 19, 1981 [hereinafter cited as Neer Interview].


238. Neer Interview, supra note 236.

239. Id. The transcripts of these proceedings are available at the Cambridge City Hall and the Cambridge Public Library [hereinafter cited as DNA Transcripts].

240. DNA Transcripts, supra note 239.

241. CAMBRIDGE, MASS. ORDINANCES ch. 11, art. 2, § 11-9 (1977). A revision of the ordinance was passed on Apr. 27, 1981, in response to the possibility of commercial DNA firms locating in Cambridge. Most of the provisions in the two versions are similar. The following discussion does refer and cite to the revised ordinance and, where appropriate how these provisions improve upon the prior ordinance.

242. Section 11-7(II) provides: "All use of recombinant DNA experiments by institutions in the City of Cambridge shall be undertaken only in strict conformity with the 'Guidelines.'"

243. DNA REPORT, supra note 180, at 7.
Prior to 1980, this distinction between the NIH guidelines and the ordinance was not as crucial since all research in Cambridge was being conducted at Harvard and M.I.T. These institutions receive support from the NIH, and, thus, their experiments are already controlled by the NIH guidelines. In the fall of 1980, however, Biogen, Inc.—a private, Swiss genetic engineering firm, considered locating a research facility in Cambridge. Aware of the ordinance and its control over private research, Biogen met with the City Council and the Cambridge Biohazards Committee (CBC) to discuss their work and any difficulties they might have in complying with the ordinance. Presumably, more private firms will be established to take advantage of the potential in genetic research, and they too will be governed by the Cambridge ordinance.

2. The Substantive Provisions

The Cambridge ordinance draws upon the work of the NIH by incorporating the 1976 guidelines and subsequent revisions. In addition, the ordinance mandates safety precautions beyond those required by the guidelines. For example, the ordinance requires all institutions proposing recombinant DNA work to prepare a detailed safety manual for research conducted at all levels of containment. The NIH guidelines require the manual only in regard to P4 experiments. The Cambridge ordinance also prohibits experiments classified by the NIH as potentially more hazardous than P3-EK2 containment without prior approval of the CBC and completely prohibits P4 experiments. In contrast, the NIH guidelines permit experiments classified up to P4 physical containment and EK3 biological containment. The ordinance also grants authority to the Commissioner of Health and Hospitals to issue additional health regulations to achieve the purpose of the ordinance, although, to date, the Commissioner has not used this authority.

244. Neer Interview, supra note 236.
245. Id. The Biogen plan is discussed further in the text at notes 306-09 infra.
246. Some investors and scientists have predicted that Massachusetts will become the research center of the world for recombinant DNA research with strong inducements to come to the area such as the proximity of Harvard and MIT. Cooke, Genetic Engineers: From Labs to Riches, Boston Sunday Globe, Sept. 13, 1981, p. 1, col. 1-4.
248. Id. § 11-7(IV)(a)(4).
250. CAMBRIDGE, MASS. ORDINANCES ch. 11, art. 2, § 11-10 (1981). The Cambridge Biohazards Committee is discussed in detail in text at notes 253-98 infra.
Another significant component of the Cambridge ordinance is the provision of a system for enforcing the safety regulations beyond that provided by the NIH guidelines. The ordinance provides for the formation of the CBC "for the purpose of overseeing all use of R[ecombinant] DNA in the City of Cambridge." This committee adds an additional tier of policing to the NIH guideline monitoring system. In the NIH framework, the principle investigator is responsible to his institution's biohazards committee which, in turn, reports directly to the NIH. The CBC provides an intermediate level of monitoring between the institutional biohazards committees and the NIH, as the institutional biohazards committees must report regularly to the CBC as well as to the NIH. The specific responsibilities of the CBC include: maintaining liaison with the institutional biohazards committees (at Harvard and M.I.T.); reviewing all proposals for recombinant DNA research; conducting site visits to institutional laboratories; and approving all revisions and amendments of the NIH guidelines.

One feature recently amended to the ordinance is a requirement that all institutions proposing to use recombinant DNA must first obtain a permit from the Commissioner of Health and Hospitals with the approval of the CBC. The permit application must include a written statement agreeing to: abide by the approved NIH guidelines and other ordinance provisions; allow site and record inspections by the CBC; prepare a health and safety manual; and establish a safety training program for research personnel. Additional permit requirements are mandated for those institutions engaging in "large-scale" uses of recombinant DNA. For example, their permits must contain a statement that researchers will ob-

253. Id. at § 11-7(III). The nature of the CBC is discussed in text at notes 279-92 infra.
254. See supra note 166.
255. See supra text at notes 164-69.
256. CAMBRIDGE, MASS. ORDINANCES ch. 11, art. 2, § 11-7(V) (1981).
257. Id. § 11-9(I)(c).
258. Id. § 11-9(I)(e).
259. Id. § 11-9(I)(b). The ordinance incorporates the NIH guidelines and its revisions. See supra note 242 and accompanying text. The ordinance also provides that, if the guidelines are discontinued or abolished by the NIH, "those guidelines in effect at the time of such discontinuance shall remain in effect in the City of Cambridge." Id. § 11-9(I)(b).
260. The amendments were approved by the City Council on Apr. 27, 1981.
261. CAMBRIDGE, MASS. ORDINANCES ch. 11, art. 2, § 11-7(IV)(a) (1981).
262. Id.
263. "Large-scale" experiments are those defined by the NIH Guidelines as those involving cultures over 10 liters. These experiments are regulated by the NIH Guidelines found in 45 Fed. Reg. 77,384 (1980). These regulations are directed at commercial institutions concerned with profitability, whose economies of scale necessitate larger-scale experiments.
tain advance approval for uses of recombinant DNA requiring P2 or P3 physical containment.264

To date, there has been no record of the effect of the permit requirements on the monitoring of recombinant DNA research. When commercial enterprises do begin their operation in Cambridge, the permit system should facilitate the CBC’s efforts to monitor their activity.

The ordinance also contains stricter sanctions for violation of the regulations than those provided by the NIH guidelines. The penalties for violating the ordinance are a $200 fine per day and the possibility of closure of the facility by the Cambridge Commission of Health and Hospitals.265 In addition, the Commissioner may revoke the institution’s operating permit for material violations of the ordinance or the permit agreements.266 In contrast, the sanctions available to the NIH under the guidelines are limited to withdrawal of NIH funds.267

A review of records maintained by the CBC shows that, in practice, the committee is actively fulfilling monitoring responsibilities imposed by the ordinance.268 The bulk of the monitoring function is carried out through correspondence between the CBC and the institutional biohazards committees at Harvard and M.I.T. Copies of all research proposals at the institutions are forwarded to the CBC for review. The institutional biohazards committees also forward all minutes of their meetings to the CBC to keep them informed of developments at their institution.269

As required by the ordinance,270 the CBC has met and approved the revisions of the NIH guidelines which contain a downscaling of containment levels.271 CBC records also reveal that the Committee

265. Id. § 11-11(I).
266. Id. § 11-11(I)(a) (1981).
268. These records are available for public inspection in the CBC staff office located at the Cambridge City Hospital.
269. These minutes and proposals are kept on file at the CBC office and are available for public inspection.
271. The Dec., 1978 guidelines were approved by the Committee on Jan. 24, 1979. See Minutes of CBC Meeting of Jan. 24, 1979. The July 29, 1980, revisions were approved on Sept. 18, 1980, see Minutes of CBC Meeting of Sept. 18, 1980. In regard to the July 29, 1980, revision (proposed in Apr., 1980) a delay in approval by the CBC did have an impact on research at Harvard. In a letter sent by CBC Chairman Dr. Robert Neer to the biological safety officers at MIT and Harvard, Chairman Neer noted:

I understand from Dr. Lieberman that two experiments at Harvard have been delayed because we had not formally approved the April revisions of the rules for
has visited the recombinant DNA laboratory sites at Harvard and M.I.T. The last visits were made on March 20, 1980, and April 17, 1980.\textsuperscript{272} Dr. Robert Neer, chairman of the CBC, contemplates that site visits will take place on a once-a-year basis unless there are exigent circumstances indicating that an immediate inspection is required.\textsuperscript{273} An additional role which the CBC has assumed is to provide a public forum for the discussion of particularly controversial aspects of recombinant DNA regulation. For example, on October 28, 1980, the CBC sponsored a public hearing in regard to Biogen's plan to construct a research facility in East Cambridge.\textsuperscript{274}

One indication of the efficacy of the monitoring system is the willingness of the research community to assist the CBC in their policing function. They have submitted descriptions of their research and forwarded copies of the institutional biohazards committees meetings to the CBC.\textsuperscript{275} Furthermore, a letter sent by Dr. Neer to M.I.T. and Harvard,\textsuperscript{276} indicating that researchers delayed experiments until the guidelines were approved by the CBC, is further evidence that the recombinant DNA researchers respect the authority of the CBC and are willing to operate within the regulatory framework created by the ordinance. Dr. Neer commented that the institutional biohazards committees’ practice of communicating and assisting the CBC in their monitoring function stems mainly from the CBC’s power to approve or reject NIH guideline revisions:

\textit{They [the institutional biohazards committees] come to see us on a regular basis because we have to approve any changes in the NIH guidelines, and that brings them continuously back. That makes it not only in our interest, but in their interest, that there be an open flow of communication going on, because anytime that we get dissatisfied with something that they are doing we can just refuse to approve the latest revision in the NIH guidelines and then they have every investigator [preparing to conduct research pursuant to these revisions] in the university ... complaining to them. That’s a tremendous power embedded in the last article of the ordinance.}\textsuperscript{277}

\textsuperscript{272} See Minutes of CBC Meeting of Mar. 20, 1980, and Apr. 17, 1980.
\textsuperscript{273} Neer Interview, supra note 236.
\textsuperscript{274} See supra text at note 245.
\textsuperscript{275} See supra note 269 and accompanying text.
\textsuperscript{276} See supra note 271.
\textsuperscript{277} Neer Interview, supra note 236.
3. The Nature of the CBC

The nature of the Cambridge Biohazards Committee has a significant impact on the efficacy of the committee in both positive and negative ways. The four members of the CBC\textsuperscript{278} are representatives from the lay community without any ties to facilities undertaking recombinant DNA research.\textsuperscript{279} Although their contact with the two institutional biohazards committees has educated them about recombinant DNA, they lack expertise or experience in the field of genetic research.\textsuperscript{280} One distinct advantage inherent in this type of monitoring committee is that, unlike the members of the NIH's Recombinant DNA Advisory Committee who are mainly DNA researchers,\textsuperscript{281} the CBC members are free from potential conflicts of interest in fulfilling their policing responsibilities. In other words, there is no danger that the assessments of individual CBC members will be colored by considerations of how their decisions will affect their colleagues researching in the field. The potential for unbiased assessments of safety hazards, therefore, is at a maximum.

Another improvement in this monitoring system over the NIH framework is that the function of the CBC is solely regulatory. By contrast, under the NIH guidelines, the NIH is attempting to fulfill the contradictory roles of sponsoring and policing recombinant DNA research.\textsuperscript{282} By concentrating its efforts on monitoring, the CBC does not have to consider promotion of the research in its decisions.

On the negative side, the nature of the CBC does raise questions concerning the competence of the committee to monitor the research. There is some evidence that the committee is hampered by a lack of technical expertise in uncovering the more subtle problems raised by the research. For example, while approving the revision of the NIH guidelines is one of the committee's most important functions,\textsuperscript{283} it appears that the CBC has accepted the NIH reassessment of the potential hazards of recombinant DNA without much independent review.

\textsuperscript{278} The ordinance provides for five members: three appointed by the City Manager; one to represent the Chairperson of the Health Policy Board; and one to represent the Commissioner of Public Health. CAMBRIDGE, MASS. ORDINANCES ch. 11, art. 2, § 11-7 (III)(a)(1981). As of this writing, there was no Commissioner of Public Health and no one was designated to represent that office.

\textsuperscript{279} The occupations of the members are: endocrinologist; chemist; employee of the Cambridge Rent Control Board; and a retired nutritionist. Neer Interview, supra note 236.

\textsuperscript{280} Neer Interview, supra note 236.

\textsuperscript{281} See supra text at notes 199-200.

\textsuperscript{282} See supra text at notes 197-98.

\textsuperscript{283} See supra text at note 277.
The initial approval of the July 29, 1980 guidelines was conducted through a telephone poll of the committee members. Dr. Neer admits that the committee lacks the expertise to make a comprehensive investigation of the NIH downscaling of containment levels: “When it comes to the question of whether experiment A is appropriately classified under the guidelines, those evaluations involved judgments that we are totally incapable of making.” As a result, the CBC “rubber stamps” the technical revisions of the guidelines. Dr. Neer does point out that major nontechnical issues contained in the revisions do receive considerable discussion and evaluation. It would appear that placement of a geneticist on the committee would provide the committee with enough technical expertise to comprehend the technical aspects of the guidelines without risking the threat of self-regulation as exemplified by the NIH guidelines.

Another illustration of the need for more technical expertise within the committee or more consultation with experts relates to the site monitoring conducted at Harvard and M.I.T. in March and April of 1980. The committee records describe these events as “tours” and “visits” in which the CBC was given an opportunity to see the facilities and ask questions. These descriptions hardly suggest the meticulous inspection seemingly contemplated by the ordinance. On the other hand, Dr. Neer has stated that the site visits were far from cosmetic, as certain practices were readily apparent to the committee, such as whether the facilities were clean and free of insects, and whether the biological waste was stored in special containers. Commenting on the value of these visits, Dr. Neer concluded: “You can’t tell whether they [the guidelines] are being observed successfully . . . to the letter . . . but you can get a very

284. See Minutes of CBC Meeting of July 17, 1980.
285. Neer Interview, supra note 236.
286. To illustrate the level of scrutiny for nontechnical revisions, Dr. Neer noted that certain classes of P1 experiments were exempted by the 1978 guidelines; therefore, the possibility existed that investigators involved in those exempted experiments could proceed without approval from their institution’s biohazards committee. The Committee noted this possibility and ordered the IBC to continue to approve all P1 experiments. This was done to guarantee that someone other than the investigator would be reviewing P1 experiments. Neer Interview, supra note 236.
287. See supra text at note 272.
289. Although § 11-8(IV)(a)(3) authorizes the CBC to carry out site visits to institutional facilities, it is hard to imagine how anything less than a careful inspection of laboratories would further the purpose of the ordinance. CAMBRIDGE, MASS. ORDINANCES ch. 11, art. 2, § 11-8(IV)(a)(3) (1981).
290. Neer Interview, supra at 236.
good sense of whether people are serious or not, and, I think they are seriously followed."  

Whether this level of scrutiny is desirable for site visits, of course, depends on the perception of the individual community. The mere presence of a government committee walking through a recombinant DNA lab is bound to have some effect on the conduct of researchers.  

The City Council apparently was concerned by the lack of technical expertise available to the CBC in fulfilling its responsibilities. Under the 1981 revised ordinance, the CBC has the express authority to hire "competent professional assistance in carrying out their duties." In the case of site inspections on "large-scale" institutions, the institution must reimburse the city for the expense involved. Whether the CBC will use this power effectively in calling on experts whenever important technical matters arise remains to be seen.  

The negative aspects of the lay composition of the CBC, however, could be addressed more directly by placing one expert on the committee. Placement of one geneticist on the CBC would increase the overall efficacy of the committee, since the expert could explain the technical aspects of the research to his fellow committee members. The need to call in outside experts would be obviated in most situations. These explanations would aid the committee in their evaluations of the revised NIH guidelines, which are currently "rubber stamped," and help in conducting site visitations which, to date, are mainly cosmetic. Since the geneticist would represent a distinct minority on the committee (one out of five), there would be little chance of his dominating the committee and turning the ordinance into a form of self-regulation. In seeking such an expert, the committee would be advised to find an individual with no special bias or financial interest in recombinant DNA research so that the information they receive from the geneticist is as objective as possible.  

291. Id.  
292. Id.  
294. See supra note 263.  
296. See supra text at note 286.  
297. See supra text at notes 287-92.  
298. Admittedly, finding such an individual would be difficult, particularly in a university town where most scientists would be working for the university and interested in contributing to this technological advancement.
4. The Role of the Public

In the House report on the Recombinant DNA Act, the Interstate Commerce Committee recognized the authority of localities to respond to public safety issues, such as those raised by recombinant DNA research. The Committee noted: "[I]t is an important Constitutional prerogative for State and local governments to be able to deal legally with issues which are primarily local in nature." Living in one of the nation’s centers for recombinant DNA research, the residents of Cambridge have acted pursuant to their constitutional prerogatives and mobilized to control what they have perceived as a threat to public safety. In both the formulation and implementation of the Cambridge ordinance, the public has played an active role.

In the formulation process, the ordinance resulted from well-attended public hearings in which members of the community voiced their concerns about recombinant DNA and heard testimony from experts in the field describing the risks. The way in which the ordinance was conceived closely parallels the scenario endorsed by Green and Halvorsen who proposed a regulation process in which representatives of the community (in this case the Cambridge City Council) determine what level of risk their community is willing to bear after having heard the risks spelled out for them by technicians in the field. Contrary to the NIH guidelines, in which risk assessments were conducted by scientists without lay participation, the Cambridge ordinance reflects the lay community’s perception of the level of risk they are willing to bear.

The public continues to play an active role in the regulation of recombinant DNA work in Cambridge. As discussed previously, the monitoring component established by the ordinance is comprised of laymen. On October 28, 1980, the CBC sponsored a public hearing to consider the plan of Biogen, Inc., a private recombinant DNA firm, to establish a commercial headquarters in East Cambridge. At the hearing, Dr. Andre Muller, Biogen’s director of United States

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300. Id. pt. 1 at 27.
301. See supra text at notes 237-40.
302. See supra notes 219-24 and accompanying text.
303. See supra text at notes 219-23.
304. See supra text at notes 199-200.
305. See supra text at notes 278-79.
operations, was questioned at length by the CBC members as to the risk of their work and whether they contemplated any difficulty in complying with the ordinance.\textsuperscript{307} Area residents also testified, including one East Cambridge woman who voiced strong opposition to, and fear of, Biogen's intentions to locate in her neighborhood.\textsuperscript{308} Following the hearing, the City Council recalled a special citizens committee to study the problem of private DNA firms locating in the city and asked them to submit policy recommendations to the City Manager.\textsuperscript{309} This study resulted in a revision of the ordinance tailored to the problems raised by the influx of private institutions.

It is clear that the Cambridge ordinance has and continues to allow the public to participate in the regulation process in a meaningful way by enabling them to make their own assessments of the degree of risk they are willing to tolerate and by giving them responsibility for monitoring the research. These roles were denied to the public in the NIH guideline process.\textsuperscript{310} The residents of Cambridge should feel some psychological comfort in knowing that as the field of genetic research continues to expand, a mechanism is in place—a mechanism resulting from their own efforts—which affords them an opportunity to respond directly to potential or actual hazards presented by the technology.

\textbf{C. Summary of the Cambridge Ordinance}

A comparison of the NIH guidelines and the Cambridge ordinance indicates that the ordinance does successfully address many of the weaknesses in the guidelines. The ordinance brings all researchers—public and private—under the scope of regulation.\textsuperscript{311} The monitoring of the ordinance is carried out by laymen,\textsuperscript{312} thus avoiding the conflict of interest inherent in the NIH framework in which scientists are asked to sponsor and police their colleagues.\textsuperscript{313} Unlike the NIH system, the ordinance's monitoring agency (the Cambridge Biohazards Committee) maintains frequent contact with the institu-

\textsuperscript{307} Dr. Muller responded that only P1 experiments were contemplated at present and that he envisioned no problems in conforming to the requirements of the ordinance. Hearing at Cambridge City Hall, Oct. 28, 1980.
\textsuperscript{308} The speaker was Mrs. Mary Nicoloro.
\textsuperscript{309} The Committee recalled was the Cambridge Experimentation Review Board which assisted in the original drafting of the Cambridge Ordinance in 1976 and 1977.
\textsuperscript{310} See supra text at notes 215-18.
\textsuperscript{311} See supra text at notes 242-44.
\textsuperscript{312} See supra text at notes 278-79.
\textsuperscript{313} See supra text at notes 197-200.
tional biohazards committees. The passage and implementation of
the ordinance has been characterized by active participation from
the lay community. These improvements would seem to indicate
that the Cambridge ordinance provides considerably more protection
to its citizens from the hazards of recombinant DNA than that af­
forded by the NIH guidelines.

At the same time, however, the ordinance in its application ap­
ppears to exclude meaningful participation by the scientific com­
munity whose opinions are useful in identifying and quantifying
recombinant DNA risks and in detecting violations of technical
safety requirements. Additional participation by geneticists would
result in more accurate assessments of the degree of regulation ap­
propriate to address the potential hazards and in more meticulous
monitoring of the research.

VI. CONCLUSION

Recombinant DNA technology represents one of science’s most ex­
citing and potentially useful discoveries. It offers the promise of the
development of products and drugs to cure or control a variety of
medical and social problems such as cancer, diabetes, and the energy
shortage. The growth of the technology has been further enhanced
by the Supreme Court’s decision in Diamond v. Chakrabarty which
will permit researchers to obtain patent protection for the forms of
life they create in the laboratory through recombinant DNA tech­
niques.

This research, however, can introduce serious hazards to society as
well. There is widespread concern that recombinant DNA molecules
will escape into the environment and, given the extent of the scien­
tific community’s understanding of the technology at this time, there
is no way of knowing how these molecules will react. Some scientists
have predicted that the molecules will cause new diseases, new forms
of cancer, and/or novel epidemics.

The federal government’s response to the potential hazards of the
technology has been to promulgate research guidelines through the

314. See supra text at notes 275-77.
315. See supra text at notes 301-09.
316. See supra text at notes 278-80.
317. See supra text at note 223.
318. A minority role is being advocated here, such as the placement of one geneticist among
the CBC’s five members, or contracting with scientists to conduct site inspections. See supra
text at notes 296-98.
National Institutes of Health. These guidelines, however, do not provide communities with adequate protection. They do not apply to the private sector—where the vast majority of dollars are being spent to develop this new technology. Furthermore, the guidelines are hampered by a lack of public involvement and by a clear conflict of interest within the NIH which is attempting to promote and police the research at the same time.

Given the fact that recent congressional bills attempting to regulate the research have died before reaching the floor of Congress and given President Reagan's traditional aversion to additional regulation over the private sector, it appears unlikely that the federal government will enact additional controls over the research in the near future. States and localities, therefore, who perceive that the hazards of recombinant DNA research are of concern to their communities will have to take the initiative in addressing the weaknesses in the NIH's regulatory framework.

In considering local regulation, states and localities should consider modeling their legislation after the Cambridge, Massachusetts recombinant DNA ordinance. The ordinance addresses the major inadequacies in the NIH guidelines by eliminating undesirable conflicts of interest within the monitoring process and by affording maximum public participation. Local legislators would be advised to increase the role of experts in genetic research to insure informed decision making in carrying out the legislation. In sum, the Cambridge ordinance provides a good foundation for states and localities to build upon as they incorporate their own perception of what level of risk their communities are willing to bear in regard to recombinant DNA technology.