

Spring 1978

# DNA and the Congressional Prerogatives: Proposals for a Deliberate Legislative Approach to Genetic Research

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## Recommended Citation

English, Terry L. (1978) "DNA and the Congressional Prerogatives: Proposals for a Deliberate Legislative Approach to Genetic Research," *Indiana Law Journal*: Vol. 53 : Iss. 3 , Article 8.

Available at: <http://www.repository.law.indiana.edu/ilj/vol53/iss3/8>

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## DNA and the Congressional Prerogatives: Proposals for a Deliberate Legislative Approach to Genetic Research

The focus of recombinant DNA<sup>1</sup> research is the removal of a gene with a specific characteristic from one organism and the subsequent transplanting of it into another to produce a desired change. Despite the potential benefits envisioned by genetic engineers,<sup>2</sup> considerable public skepticism still surrounds DNA research.<sup>3</sup>

### Some DNA experiments

have a real streak of the macbre, if not the downright malevolent. It may be scientifically intriguing to grow a human baby in a test tube; it may be equally so to fuse a human and a gorilla cell to try to grow the resulting hybrid. Indeed, it may be very easy to justify this with cold logic or blithe irrationality. . . . But while these possibilities are wonderful to some, they are downright frightening to others.<sup>4</sup>

Since many members of the scientific community and the American public foresee the inevitable escape of deadly organisms from the laboratory<sup>5</sup> and their subsequent transmission across political boundaries, federal regulation is essential. This note proposes severe congressional circumscription of DNA experimentation until more is known about operational safeguards and the actual hazards associated with genetic engineering. Substantive proposals for permanent federal DNA legislation are suggested, as well as an alternative under which states would adopt their own regulatory safeguards.

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<sup>1</sup>Each living cell contains at least one chromosome whose essential component is DNA. This molecule is shaped like a double spiral and is composed of smaller segments called genes. These genes determine the organism's heredity properties. In addition, bacterial cells may also contain smaller DNA groupings called plasmids, which are relatively easy to handle in laboratories. They are also capable of entering other bacterial cells.

By using a substance called a restriction enzyme, scientists can split a plasmid into specific fragments, which have an important property: They will adhere to other DNA fragments with which they come in contact. Thus, if plasmids from two different organisms are split and the resulting fragments are mixed, they may "recombine" into a hybrid plasmid, bearing some of the characteristics of both original organisms.

To grow quantities of this hybrid, scientists can mix it with bacterial cells that will absorb the new plasmid and duplicate it at an enormous rate. Louisville Courier-Journal & Times, Nov. 14, 1976, Section D-E, at 1, col. 1.

<sup>2</sup>For an enumeration of the possible benefits of DNA research, see Recombinant DNA Research Guidelines, 41 Fed. Reg. 27902, at 27904 (1976) [hereinafter cited as NIH Guidelines].

<sup>3</sup>U.S. NEWS & WORLD REPORT, April 11, 1977, at 80 [hereinafter cited as U.S. NEWS].

<sup>4</sup>J. GOODFIELD, PLAYING GOD 70 (1977) [hereinafter cited as GOODFIELD].

<sup>5</sup>U.S. NEWS, *supra* note 3, at 80.

## THE RECOMBINANT DNA RESEARCH CONTROVERSY

After organisms mate, copies of the genetic material appear within a single cell. In most organisms, this genetic material is deoxyribonucleic acid (DNA). By natural processes, segments of the nucleic acid molecules from the two parental organisms are exchanged. This process is called genetic recombination since it leads to a reassortment of genetic material derived from the parental organisms by generating daughter organisms with new combinations of genes. In nature, recombination is restricted by mating and species boundaries.<sup>6</sup> However, within the last decade, biochemical methods have been developed which allow DNA molecules of completely unrelated species to be joined together. An integral, yet controversial, ingredient of the current research technique is the colon bacillus *Escherichia coli* (*E coli*), one of the Earth's most pervasive microorganisms. Scientists selected *E coli* as the research host cell because a great deal is known about the genetics of one of its strains, K-12, which was isolated 60 years ago and has been in continuous laboratory use ever since.<sup>7</sup> But while *E coli* is commonly used in DNA experimentation, scientists have not reached a consensus as to the relative safety of the microorganism. For example, noted biologist George Wald is troubled by the fact that *E coli* is a constant inhabitant of the human bowel,<sup>8</sup> subjecting man to potential attack by newly developed strains. By contrast, Mark Ptashne of Harvard's Biological Laboratories and a number of other scientists reject Wald's skepticism of *E coli* use.<sup>9</sup> Ptashne observes that no one has yet managed to transfer genes from pathogenic *E coli* K-12, which "is not surprising . . ." since "it is no easy matter to confer those multiple properties required for pathogenicity on a non-pathogenic bacterium grown for many generations in the laboratory."

## THE NIH GUIDELINES

On June 23, 1976, Donald S. Fredrickson, director of the National Institutes of Health (NIH), issued guidelines on recombinant DNA research.<sup>10</sup>

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<sup>6</sup>Report of the Second Meeting of the EMBO Standing Advisory Committee on Recombinant DNA, Memo NAR-68, at 11 (December 1976) [hereinafter cited as EMBO Standing Committee].

<sup>7</sup>Hubbard, *Gazing into the Crystal Ball*, 26 BIOSCIENCE 608 (1976) [hereinafter cited as Hubbard].

<sup>8</sup>Wald, *The Case Against Genetic Engineering*, CURRENT, November 1976, at 27 [hereinafter cited as Wald].

<sup>9</sup>Ptashne, *The Defense Doesn't Rest*, CURRENT, November 1976, at 30 [hereinafter cited as Ptashne].

<sup>10</sup>NIH Guidelines, *supra* note 2 at 27904. The guidelines were issued as a result of an international meeting at the Asilomar Conference Center in Pacific Grove, California, in February 1975. Four lawyers spoke at the conference and laid bare a series of frightening possibilities, not involving human epidemics, but multimillion dollar lawsuits and injunctions against research that could descend on scientists and the owners of laboratories, whether or not they meant to do

The standards provide a framework for continuance of recombinant DNA experimentation. They affirm the view that the research is potentially of enormous benefit, but may involve unforeseen risks. "Recombinant DNA research offers great promise, particularly for improving the understanding and possibly the treatment of various diseases. There is also a potential risk—that microorganisms with transplanted genes may prove hazardous to men or other forms of life."<sup>11</sup>

Compliance with the guidelines is voluntary,<sup>12</sup> so that their effectiveness depends largely on the supervision of the NIH, a major federal funding agency.<sup>13</sup> The standards established by the guidelines regulate research directly sponsored through NIH grants<sup>14</sup> but do not limit the DNA experimentation of private industry, the sector most likely to have a marked impact on the general public.<sup>15</sup> The guidelines are comprehensive, especially with regard to establishing physical and biological containment safeguards. Physical containment procedures range from classification P1 to P4. P1 containment is that used in most routine bacteriological laboratories. P2 and P3 afford increasing isolation of the research from the environment while P4 represents the most extreme measures used for containing virulent pathogens and permits no escape of contaminated air, wastes or untreated materials.<sup>16</sup> Biological con-

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harm. The scientists were told that the research may very well fit into the legal category of "ultrahazardous activity." The scientists and their employers were told they might be responsible for subsequent damage and they would undoubtedly be liable if the microorganisms made by recombinant DNA were to escape.

In GOODFIELD, *supra* note 4, at 144, the author addresses the question of whether DNA experimentation involves abnormally dangerous conduct:

What constitutes "abnormally dangerous" is always a matter of debate, and in court a list of factors have to be examined to decide the degree of danger. These cover the severity of the risk; the gravity of the harm; the fact that even by being thoroughly reasonable, the risk could not be eliminated no matter how hard one tried; the question whether the conduct was common conduct; the appropriateness of the place where the work was going on; and the value of the activity to the community. In order to prove "abnormally dangerous conduct," however, not all the factors need to be present, and recombinant DNA research plainly qualifies as "abnormally dangerous conduct" on the first four counts.

<sup>11</sup>NIH Guidelines, *supra* note 2 at 27904.

<sup>12</sup>*Id.* at 27906.

<sup>13</sup>SCIENCE POLICY RESEARCH DIVISION, CONGRESSIONAL RESEARCH SERVICE, LIBRARY OF CONGRESS, GENETIC ENGINEERING, HUMAN GENETICS AND CELL BIOLOGY, 94th Cong., 2d Sess. 25 (1976) [hereinafter cited as HUMAN GENETICS].

<sup>14</sup>See Rifkin & Howard, *Taking Care of Business*, NEW TIMES, Jan. 21, 1977.

<sup>15</sup>See Wald, *supra* note 8, at 29.

Though there is nothing in the present legislation that imposes the guidelines on industry, there is strong moral pressure . . . In any case, they are at the moment restricted by certain bans, which prohibit release into the environment of materials or organisms made by these techniques. To say that industry is unhappy with this state of affairs is an understatement; they will certainly try to get these restrictions lifted by all means possible. The moment they have made a valuable product, like human insulin, and can see the possibility of full-scale commercial application, they will probably try and get a test case through the courts.

GOODFIELD, *supra* note 4, at 156-57.

<sup>16</sup>For the specific requirements of P1 containment, see NIH Guidelines, *supra* note 2, at 27912; for P2, see *id.* at 27913; for P3, see *id.*; and for P4, see *id.* at 27913-14.

tainment is the use of hosts and vectors<sup>17</sup> so that DNA is theoretically incapable of survival under natural conditions.

But while the guidelines, fairly characterized as moderate,<sup>18</sup> permit DNA research to continue with only the slightest infringement on scientific autonomy, many researchers have refused to acknowledge their urgency. "Half of the researchers . . . follow the guidelines fastidiously; others seem to care little . . . Among the young graduate students and post doctorates it [seems] almost chic not to know the NIH rules."<sup>19</sup>

With scientists themselves unable to agree on the magnitude of possible risks in DNA research,<sup>20</sup> Congress should opt for a cautious approach in implementing permanent regulatory legislation.

Arguably, the unlimited potential for prestige and profit-making has already dissuaded some scientists from making a dispassionate analysis of the biohazards inherent in genetic research. This is perhaps best demonstrated by the self-serving nature of the NIH guidelines themselves. "There is a conflict of interest when scientists, who stand to gain from this work—in terms of money and prestige—decide that it must be done. There is also a conflict of interest when NIH, which houses, promotes and sponsors the research, develops guidelines to regulate it."<sup>21</sup>

If Congress incorporates the NIH guidelines *in toto* in permanent legislation, it would be ratifying this scientific impropriety. But regardless of the manner in which it proceeds, Congress will meet with a groundswell of sentiment<sup>22</sup> against circumscription of research autonomy since scientists "have

<sup>17</sup>A vector is a virus-like entity known as a plasmid, which is used to carry genes of experimental interest in bacterial hosts. A host is an organism that harbors a parasite.

<sup>18</sup>See Grobstein, *Recombinant DNA Research: Beyond the NIH Guidelines*, 194 SCIENCE 1133 (1976) [hereinafter cited as Grobstein].

<sup>19</sup>Hopson, *Recombinant lab for DNA and my 95 days in it*, 81 SMITHSONIAN 61 (1977) [hereinafter cited as Hopson].

<sup>20</sup>Even prior to implementation of the NIH guidelines:

Opinion differed on whether the proposed guidelines were an appropriate response to the potential benefits and hazards. Several scientists found the guidelines to so exaggerate the safety procedures that inquiry would be unnecessarily retarded, while others found the guidelines weighted toward promoting research. . . .

There was strong disagreement about the nature and level of the possible hazards of recombinant DNA research. . . .

Other commentators, however, found the guidelines to be adequate to the hazards posed. In their view, the guidelines struck an appropriate balance so that research could proceed cautiously.

NIH Guidelines, *supra* note 2, at 27904.

<sup>21</sup>Hubbard, *supra* note 7, at 611.

<sup>22</sup>Whether because of public apathy or the relative inaction of Congress to date on the DNA question, the noisy demonstrations on campuses and elsewhere which made headlines in the recent past have largely faded away, and about 300 research projects are believed to be underway right now.

"The clouds have gone, the sun is shining and politically, they are looking at other issues," said Daniel J. Hayes, chairman of the Cambridge Experimentation Review Board, in December 1977. He was in the midst of the controversy there over gene splicing research from the summer of 1976 through last winter.

held, and continue to hold, that there is no real external imperative upon them, no ethical core other than the ethics internal to the discipline. . . ."<sup>23</sup> This is all the more reason why Congress should ignore the scientific caterwauling and proceed to enact strict legislation during the formative years of DNA experimentation.

Such a government-supported diminution in scientific individualism in favor of safeguarding the public health was aptly demonstrated a decade ago in a similar situation where possible escape of pathogenic organisms was at issue.

Just prior to the launching of Apollo 11 on its historic lunar mission in 1969, scientists and government officials alike were as concerned about the possible escape of "moon germs"<sup>24</sup> as researchers are today about pathogenic DNA cells finding their way into the environment. In anticipation of the moon landing, however, scientific autonomy was effectively subordinated to the more pressing governmental concern of protection of the public as the National Aeronautics and Space Administration (NASA) proceeded with extreme caution in formulating plans for containment of microorganisms borne by "all NASA manned and unmanned space missions which land on or come within the atmospheric envelope of a celestial body and return to Earth."<sup>25</sup> Stringent regulations imposing containment requirements were promulgated and the returning Apollo 11 astronauts were even placed in isolation,<sup>26</sup> a measure intended to "protect the world against what was considered the unlikely possibility of contamination by lunar organisms."<sup>27</sup>

In addition to displaying the manner in which such cautious methodology can aid in the resolution of problems posed by potentially hazardous microorganisms, NASA has consistently demonstrated the benefits which can result from centralized supervision of scientific efforts<sup>28</sup> and from consistent

In spite of the current surface lull, many who have watched and tried to nudge the political process one way or another are convinced new legislation to set rules and regulations for genetic engineering will be enacted by the 95th Congress. Political lobbying, particularly on the part of the scientific community, is expected to be extensive.

<sup>23</sup>GOODFIELD, *supra* note 4, at 72.

<sup>24</sup>See the limited edition magazine APOLLO 11: ON THE MOON 54 (1969) [hereinafter cited as APOLLO 11].

<sup>25</sup>Extraterrestrial Exposure, 14 C.F.R. § 1211.101 (1977). The NASA administrator or his designee were empowered to promulgate this section under the provisions of the National Aeronautics and Space Act of 1958, 42 U.S.C. §§ 2455, 2456, 2473 (1971).

<sup>26</sup>34 Fed. Reg. 12305.

<sup>27</sup>APOLLO 11, *supra* note 24, at 56. This too is the intent of [1967] 18 U.S.T. 2416, Article IX, Outer Space Treaty, T.I.A.S. No. 6347:

States Parties to the Treaty shall pursue studies of outer space, including the moon and other celestial bodies, and conduct exploration of them so as to avoid their harmful contamination and also adverse changes in the environment of the Earth resulting from the introduction of extraterrestrial matter and, where necessary, shall adopt appropriate measures for this purpose.

<sup>28</sup>NASA, by regulation and certainly by administrative design, promotes the participation of the best qualified scientists in federal projects. The agency encourages researchers to conceive of specific projects, develop instrumentation for the investigations and participate actively,

enforcement of restrictive monitoring policies,<sup>29</sup> concerns which now face federal law-makers.<sup>30</sup>

wherever possible, in the actual conduct of the experiments. NASA also pushes scientists to publish their findings as soon as practicable and make their reduced data records available on a timely basis for use by others. *See* 14 C.F.R. §1205.101 (1977).

In short, NASA works as an informational clearinghouse, the same function which a newly authorized federal agency, or a subdivision thereof, could be called upon to serve in regards to DNA research.

<sup>29</sup>With centralized planning and consistent enforcement of monitoring policies, NASA has made strides toward balancing the scientific desire for autonomy with the national need for comprehensive knowledge concerning worrisome experimental projects. Federalization of genetic engineering efforts would not only result in a like balance but would also contribute to consistency of policy between jurisdictions.

With scientists currently conducting genetic engineering experiments at over 80 centers around the nation, the emergence of a quiltwork of local legislation was inevitable.

One of the most prominently mentioned feuds involving DNA research was fought in Cambridge, Massachusetts. The conflict was finally resolved on Feb. 7, 1977 when the Cambridge City Council passed a comprehensive city ordinance regulating research. Based on the report of the Cambridge Experimentation Review Board (CERB), the ordinance allows recombinant DNA research to proceed, but imposes more stringent safety precautions than those recommended by the NIH Guidelines. Under the new ordinance, all recombinant DNA research must be conducted in "strict adherence" to the NIH Guidelines. In addition, the ordinance requires that each institution conducting such research prepare a manual on safety procedures, train laboratory personnel in appropriate safeguards and procedures for minimizing potential accidents, and "monitor the survival and escape of the host organism or any component thereof in the lab worker." Researchers are required to test the host organism for purity and also to test new organisms generated by the experiments to determine their resistance to common antibodies. In an important expansion of the NIH Guidelines, the ordinance requires that the Institutional Biohazards Committees include a representative of the laboratory staff and at least one "community representative" unaffiliated with the institution. The City Council also acted upon the recommendation of the CERB in establishing a Cambridge Biohazards Committee (CBC) to ensure compliance with the ordinance, make on-site lab visits, and review reports of the Institutional Biohazards Committees. In what may be a point of future controversy, the CBC is to "review all proposals for recombinant DNA research to be conducted in the City of Cambridge for compliance with the current NIH Guidelines."

Besides eliminating the need for such piecemeal legal attempts at circumscription, uniformity of regulation would also eliminate the potential for experimental "site-shopping." No incentive would exist for scientists to search for those locales which afford the least restrictive DNA experimental standards.

Finally, foreign countries would arguably be more receptive to exchanging experimental information on a nation-to-nation basis than on a nation-to-scientist basis and such global cooperation might well yield unexpected benefits in the field of DNA. NASA certainly has borne out this theory in regards to space exploration. *See, e.g.,* SPACE WORLD, March 1972, at 35.

<sup>30</sup>Enactment of a transcendent body of federal law would permit scientists to know, at least constructively, the minimum safety standards with which their DNA experiments would have to comply. Currently, any one of a number of federal administrative agencies could arguably promulgate rules dealing with genetic engineering. They include the Department of Agriculture, the Department of Defense, the Department of Commerce, the Food and Drug Administration, the Occupational Safety and Health Administration and the Environmental Protection Agency.

The characteristics of an adequate legal response to recombinant DNA point to the need for new federal legislation with implementing regulations to control such research. The legislation could be relatively short and simple, merely expressing congressional concern and directing the Environmental Protection Agency to promulgate regulations.

7 ENVTL L. 308 (1977).

While new legislation and regulations would be a desirable response to the hazards of recombinant DNA research, an interim solution may be found in regulations adopted

## PROPOSED FEDERAL LEGISLATION

An analysis of the initial congressional response to the DNA dilemma indicates that broad-based legislative concerns about potential hazards do exist, even though no consensus opinion has emerged as to the most beneficial way to proceed legally. Law-makers introduced twelve bills<sup>31</sup> concerning recombinant DNA research during the first session of the 95th Congress. Only two of them, however, H.R. 7897<sup>32</sup> and S. 1217,<sup>33</sup> have received serious congressional attention.

Senate Bill 1217<sup>34</sup> proposes the creation of an eleven-member federal commission to control all recombinant DNA experiments, and an elaborate system of fines<sup>35</sup> and inspections.<sup>36</sup> As amended, the bill places full responsibility for the promulgation of regulations concerning DNA on the commission.<sup>37</sup> Initially, however, the NIH guidelines will serve as minimum standards to which genetic engineering experiments must conform,<sup>38</sup> at least until further study produces permanent legislation. Significantly, S. 1217 provides for crucial periodic reevaluation of all regulations governing DNA experiments.

[R]esearch with recombinant DNA may not require the same degree of safety regulation in the future as it does at the present. . . . As more becomes known about the potential hazards of recombinant DNA research, changes in the safety regulation of the activities may need to be made. It is certainly possible that as more is known there will be less concern about hazards and the need for any special safety regulation may disappear. On the other hand,

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pursuant to an existing federal statute. Section 361 of the Public Health Service Act of 1944 [42 U.S.C. §264 (1970)] gives the Secretary of Health, Education and Welfare (HEW) the power to make regulations which he judges necessary to "prevent the introduction, transmission, or spread of communicable diseases" into the country or between the states. Since one of the major risks of recombinant DNA research is that an organism might be released into the environment and cause an epidemic, regulations to prevent such an occurrence seem to come within the words of the statute.

*Id.* at 310-11.

<sup>31</sup>H.R. Res. 131, 95th Cong. 1st Sess. (1977); H.R. 3191, 95th Cong. 1st Sess (1977); H.R. 3591, 95th Cong. 1st Sess. (1977); H.R. 3592, 95th Cong. 1st Sess. (1977); H.R. 4759, 95th Cong. 1st Sess. (1977); H.R. 4848, 95th Cong. 1st Sess. (1977); H.R. 5020, 95th Cong. 1st Sess. (1977); H.R. 6158, 95th Cong. 1st Sess. (1977); H.R. 7418, 95th Cong. 1st Sess. (1977); H.R. 7897, 95th Cong. 1st Sess. (1977); S. 621, 95th Cong. 1st Sess. (1977); S. 1217, 95th Cong. 1st Sess. (1977).

In addition to these measures, a group of scientists and administrators at Harvard University and other institutions in early 1978 were reported to be drafting a bill for regulation of DNA research in the hope that one of the congressional committees would use it as a working draft.

<sup>32</sup>H.R. 7897, 95th Cong. 1st Sess. (1977) [hereinafter cited as H.R. 7897].

<sup>33</sup>S. 1217, 95th Cong., 1st Sess. (1977) [hereinafter cited as S. 1217].

<sup>34</sup>As amended by the Senate Human Resources Committee. See S. REP. NO. 359, 95th Cong. 1st Sess. (1977) [hereinafter cited as Resources Committee Report].

<sup>35</sup>The amount is not to exceed \$10,000 for each violation of rules regarding safety precautions. S. 1217, *supra* note 33, at 45.

<sup>36</sup>*Id.* at 30.

<sup>37</sup>Resources Committee Report, *supra* note 34, at 10.

<sup>38</sup>*Id.*



it is also conceivable that the need for more stringent safety regulation will become evident.<sup>39</sup>

House bill 7897 relegates the task of regulating DNA experimentation to "local biohazards committees"<sup>40</sup> which will operate under the guidance of the Secretary of Health, Education and Welfare.<sup>41</sup> Like S. 1217, H.R. 7897 calls for federal licensing of research facilities<sup>42</sup> and provides for the assessment of fines for statutory violations.<sup>43</sup> It too makes reference to the NIH guidelines, mandating that all recombinant DNA experiments undertaken within 18 months of the date of promulgation of the act must be done in compliance with the guidelines.<sup>44</sup>

Sponsors of the two measures do not contemplate that congressional entry into the field of genetic engineering will necessarily pre-empt all state authority. Under S. 1217, officials of a state or one of its political subdivisions may ask the federal commission to waive certain rules concerning DNA research. The commission may do so if the state's applicable regulation "is, and will be administered so as to be, as stringent as, or more stringent than" the federal requirement.<sup>45</sup> A similar provision in H.R. 7897<sup>46</sup> permits the secretary to grant the exemption only after notice and opportunity for an oral hearing.

S. 1217 and H.R. 7897 can be characterized only as interim measures.<sup>47</sup> Rather than propose permanent standards, they defer many relevant and difficult decisions until a later time. Such a deliberate congressional approach is admirable, but law-makers must mandate that scientists comply with strin-

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<sup>39</sup>Resources Committee Report, *supra* note 34, at 11.

<sup>40</sup>These committees, while local in constitution, have only limited authority. See H.R. 7897, *supra* note 32, at 21. They are subject to regulations prescribed by the Secretary of Health, Education and Welfare. And, committee action in regards to the issuance, amendment or renewal of a license can be reviewed by the secretary upon the written request of any member of the group.

<sup>41</sup>*Id.* at 20.

<sup>42</sup>*Id.* at 10.

<sup>43</sup>The amount is not to exceed \$5,000 for each violation. *Id.* at 28.

<sup>44</sup>*Id.* at 5.

<sup>45</sup>S. 1217, *supra* note 33, at 48. In the normal situation, the "police power," the sovereign authority to legislate in areas touching on the health and welfare of the citizenry, is reserved to the states. However, as is noted in 16 C.J.S. CONSTITUTIONAL LAW § 177 (1956), "When the United States exerts any of the powers conferred upon it by the Constitution, no valid objection can be made based on the fact that such exercise may be attended by the same incident which attends an exercise by the state of its police power." In regard to DNA research, both S. 1217 and H.R. 7897 cite the provisions of the commerce clause, U.S. CONST. art. I, § 8, as extending rights of intervention to the federal government. The contention is that DNA molecules could conceivably escape from the laboratory and ultimately harm commerce among the states.

<sup>46</sup>H.R. 7897, *supra* note 32, at 42.

<sup>47</sup>Under H.R. 7897, the Secretary of Health, Education and Welfare is merely empowered to promulgate regulations to implement requirements for interim control. H.R. 7897, *supra* note 32, at 5; for licensing, *id.* at 11; and for establishment of local biohazards committees, *id.* at 21.

Under S. 1217, the federal commission must prescribe physical and biological containment requirements for DNA activities within 180 days of the enactment of the statute. S. 1217, *supra* note 33, at 30.

gent standards in the meantime, thereby allowing Congress sufficient time to make an informed assesment of the scope of permanent legislation required and permitting a margin of safety for future action.

#### RECOMMENDATIONS

Congressional caution in preparing DNA research regulations is crucial.<sup>48</sup> The time constraints and self-interest pervading the drafting of the NIH guidelines,<sup>49</sup> around which legislative attempts now center, argue against their future use to control experimentation where "more is unknown than known [and] the repertoire of the techniques are [sic] incomplete."<sup>50</sup>

More effective regulation demands implementation of five procedural restrictions: (1) Development of safer hosts and vectors, (2) Surveillance of each facility by a full-time medical officer, (3) Institution of P3 containment as the minimum requirement for future DNA experimentation, (4) Confinement of P4 experiments to a single national laboratory, and (5) Proscription of the intentional release of mutant cells.

The federal government, through enactment of rigorous permanent legislation, must promote development of safer hosts and vectors for use in DNA experimentation. Although the K-12 strain of E coli is environmentally feeble,<sup>51</sup> the eventual escape of a significant number of potentially deadly pathogens is likely.<sup>52</sup> Once these microorganisms escape into the environment,

<sup>48</sup>Senator Edward Kennedy, the sponsor of S. 1217, might now question whether congressional intervention is merited at all. Kennedy has retreated from his earlier hard-line position on DNA research, voicing the opinion that he is concerned about "the fluctuating scientific data and the emotional atmosphere of the debate." Kennedy has withdrawn support for his own bill and is now proposing instead compromise legislation to extend the current NIH guidelines for one year to all parties conducting recombinant DNA research and to establish a national recombinant DNA study commission to recommend, after nine months, whether permanent legislation is necessary. Kennedy cites new work by Stanley Cohen of Stanford University as challenging the belief that recombinant DNA research can produce novel organisms. See Halvorson, *Recombinant DNA Legislation—What Next?*, 198 *Science* 357 (1977).

<sup>49</sup>See Grobstein, *supra* note 18, at 1134.

<sup>50</sup>GOODFIELD, *supra* note 4, at 4.

<sup>51</sup>See TIME, Aug. 15, 1977, at 56.

<sup>52</sup>R. CURTISS, GENETIC MANIPULATION OF MICROORGANISMS: POTENTIAL BENEFITS AND BIOHAZARDS 37 (1976) [hereinafter cited as CURTISS].

Estimating the number of virus vectors or hosts that might escape per day per investigation for a properly operated P1 facility is difficult, but let me guess at a value of  $10^5$ . If we then assume 1,000 investigators working on 300 days per year, then  $3 \times 10^{10}$  will escape from P1 facilities,  $3 \times 10^7$  from P2 facilities and  $3 \times 10^4$  from P3 facilities. These routes of escape will be by contamination of the investigator (on clothing or by breathing or ingestion), by discharge through the ventilation system, by removal of floor sweepings and by accidental disposal down the drain.

*Id.*

A member of the NIH committee which drafted the guidelines, Curtiss only recently changed his position on the possible health hazards of DNA from one of greater to lesser concern. In a widely circulated letter to the director of NIH, Curtiss wrote: "I have gradually come to the realization that the introduction of foreign DNA sequences into certain host-vectors offers no danger whatsoever to any human being," except in very special circumstances. "The arrival at

they cannot be recalled; "[b]y the time a sufficient number of people get sick to make one suspect trouble, the organism[s] will have spread far and wide."<sup>53</sup>

Calculation of escape probabilities presumes that investigators and other personnel understand the operation of the containment devices sufficiently well to minimize mistakes. But many microbiologists, either purposely<sup>54</sup> or from lack of knowledge, will not utilize the laboratory facilities and procedures properly.<sup>55</sup> As a consequence, even more potentially dangerous altered cells could escape undetected into the environment, though the microorganisms would have to overcome nearly insurmountable obstacles in order to pose a disease threat.<sup>56</sup> A myriad of human errors will undoubtedly occur as the scope of genetic research widens and only stringent safety precautions will minimize the ecological impact of laboratory mistakes. So as to forestall even the remote possibility of a scientifically produced epidemic, Congress must establish a mandatory cut-off date after which *E coli* and its laboratory strains cannot be used in federally licensed DNA facilities.<sup>57</sup> Legislation should empower the government to revoke the operating license of

this conclusion has been somewhat painful and with reluctance since it is contrary to my past 'feelings' about the biohazards of recombinant DNA research." *Gene Splicing: Senate Bill Draws Charges of Lysenkoism*, 197 *SCIENCE* 348 (1977).

<sup>53</sup>Hubbard, *supra* note 7, at 611.

<sup>54</sup>A questionable breach of NIH rules on gene splicing occurred in 1977 in the Department of Biochemistry and Biophysics at the University of California, San Francisco, one of the leading centers for the practice of the DNA technique. No hazard resulted, but the episode underlines some of the difficulties experienced by research laboratories in adapting to the new rules.

The breach was the use of a biological component before it had been certified by the NIH director. Another incident demonstrating that some workers still lag behind their new public accountability was pointed out:

One Ph.D. candidate visited from another university this week and did experiments with a disease-causing bacterial strain. These experiments would seem to require a higher level of physical containment than our P1 lab affords—probably a costly type of ventilation hood. When asked what level was specified by the guidelines, he replied, "Damned if I know." Someone else asked, "Well, what containment level do you use at your own lab?" He shrugged, "I never looked it up."

Hopson, *supra* note 19, at 61.

<sup>55</sup>CURTISS, *supra* note 52, at 38.

<sup>56</sup>Helling & Allen, *Freedom of Inquiry and Scientific Responsibility*, 26 *BIOSCIENCE* 610 (1976) [hereinafter cited as Helling & Allen].

First, the [cells] would have to survive and grow in competition with other cells. . . . Second, the cells would have to be ingested. Third, the ingested cells would have to survive passage to the bowel. Fourth, the cells would have to multiply in the intestine or pass the potentially hazardous genes to another resident cell. In the latter case, the genes would have to confer a growth advantage on the new cell or maintain themselves by rapid replication and frequent transfer to new cells. Fifth, the gene must produce its product. Sixth, the product must be released in active form at physiological concentration. And finally, the product must either attack the intestinal lining or pass into internal fluids at physiological concentration.

*Id.*

<sup>57</sup>Even the NIH Guidelines, *supra* note 2, at 27915, concede that serious attempts need to be made to find another host-vector system. It was noted: "[W]hile proceeding cautiously with *E coli*, serious efforts should be made toward developing alternative host-vector systems."

any violating facility and withhold public funds from laboratories continuing to use E coli. To alleviate the impact of such a prohibition, Congress should appropriate adequate funds for discovery and testing of alternative hosts and vectors. The federal government should direct scientific interest toward testing of the polyoma virus, which holds promise as a potential vector.<sup>58</sup> Initial testing has shown that the virus probably will not infect humans, even though it is detectable in mice.<sup>59</sup>

But even as the government succeeds in mandating the use of safer host-vector systems in DNA research, improvement in medical supervision of laboratories will still be required. The NIH guidelines now vest in a principal facility investigator<sup>60</sup> the responsibility for implementing precautionary medical procedures, a system wholly inadequate to the safety challenges presented. While the facility investigator exercises a broad oversight function, he apparently does not have to engage in strictly routine experimental operations on a regular basis; as a consequence, scientists could conceivably conduct hazardous experiments without restrictive supervision and thereby expose themselves to hazards for which immediate medical help is unavailable.

Instead of adopting the NIH approach to oversight, permanent DNA legislation should make provisions for placement of all laboratory personnel under the surveillance of a facility medical officer whose duties are clearly delineated.<sup>61</sup> This officer would work in conjunction with the facility's biological safety officer, another legislatively created position. The safety officer would (1) enforce a facility code of practice (based upon the national regulations when are they promulgated),<sup>62</sup> (2) conduct all aspects of training, (3) investigate and report accidents, (4) make provisions for the safe storage and transportation of materials, (5) maintain an inventory, (6) provide laboratory security and (7) oversee the maintenance of laboratory equipment.<sup>63</sup> The safety officer would also formulate an appropriate plan of action which would become operational in the event of an accidental spill of recombinant DNA or a viral vector containing it.

The initial uncertainty surrounding genetic engineering makes the implementation of such safety procedures necessary. But these measures, even when coupled with the physical and biological safeguards set forth in the NIH guidelines, may not afford adequate protection to the American public.

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<sup>58</sup>See *id.* at 27919.

<sup>59</sup>See *id.* at 27924.

<sup>60</sup>EMBO Standing Committee, *supra* note 6, at 8.

<sup>61</sup>See *id.*

<sup>62</sup>In issuing a facility license, government officials (or their designated representatives) presumably will mandate minimum safety standards which must be met by researchers.

The safety officer, as envisioned, would oversee laboratory work and, theoretically, his presence would discourage deviation from legislatively authorized experimental practices. Under the proposal made here retention of the government-granted license would depend, to a significant degree, upon the integrity of the safety officer and the vigor with which he pursues his responsibilities.

<sup>63</sup>Many of these responsibilities are vested currently in the principal investigator.

As a consequence, Congress should set "P3 containment" as the minimum level under which scientists can conduct future DNA experiments, at least until testing establishes conclusively that no major health hazards exist. Use of P3 laboratories, which are technically more sophisticated than other facilities<sup>64</sup> and highly effective in containment of microorganisms, would generally permit closer government scrutiny and analysis of existing projects during the crucial early days of DNA experimentation.

Congress should also recognize the necessity of confining all inherently dangerous P4 experiments to a single national laboratory.<sup>65</sup> This would include all recombinant DNA research involving transgression of species boundaries.<sup>66</sup> Notwithstanding predictable protest by members of the scientific community, Congress should designate the center as a top security facility, primarily because terrorists could conceivably use the DNA technology in preparation of military weapons. Opponents of such security procedures might well argue that any terrorist able to use the sophisticated DNA procedures would opt instead for proven agents from nature's arsenal, such as smallpox or plague, rather than spending years attempting to develop a biological weapon of dubious effectiveness. But terrorists would not only obtain the ingredients to produce disease of incomprehensible scope but the mode by which to incite world calamity; fear of the unknown is precisely the element making DNA-produced diseases so formidable.

Congress should also take steps to proscribe the intentional release of genetically altered cells into the environment.<sup>67</sup> Commercial developers have

<sup>64</sup>It is estimated that the number of escaped viral vectors is reduced about 1,000-fold for each increasing level of containment starting at P1. W. Emmett Barkley, in his capacity as director of research safety of the National Cancer Institute, has even gone on record as saying that the most highly contagious biological agents may be used in P3 laboratories with minimal risk. Barkley estimates that, on the average, workers in P3 laboratories incur about two infections for every 100 person-years of work—and this is with the most highly infectious agents known. Ptashne, *supra* note 9, at 31.

<sup>65</sup>But as is noted in Helling & Allen, *supra* note 56, at 611, [P4] is known from long experience at Fort Detrick to offer no absolute barriers against the escape of pathogenic organisms. Microbiological techniques were devised to keep contaminating organisms *out* of one's experiments, not to keep organisms one works with *in*, for that cannot be done in an absolute sense.

Further, HUMAN GENETICS, *supra* note 13, at 40, stated:

Studies have been made to determine the extent of accidental infection within such highly secure and tightly controlled facilities as the former biological warfare research laboratory at Ft. Detrick, Maryland. These studies have shown that while the incidence of infection leading to either morbidity or mortality has been relatively low, it has occurred frequently enough to demonstrate that the best of the systems is not one hundred percent fail-safe. In these instances, a large portion of the infections were the result of human failure to comply with safety requirements.

<sup>66</sup>The nub of the new technology is to move genes back and forth, not only across species lines, but across any boundaries that now divide living organisms, particularly the most fundamental such boundary, that which divides prokaryotes (bacteria and bluegreen algae) from eukaryotes (those cells with a distinct nucleus in higher plants and animals).

<sup>67</sup>See CURTISS, *supra* note 52, at 53, where the researcher notes: "I consider such release anytime in the near future to be potentially quite hazardous."

already begun expansive testing of a variety of marketable organisms which could ultimately have a substantial impact on the eco-system.<sup>68</sup>

In formulating controls over the intentional release of bacterial mutants with unpredictable capabilities, Congress should also recognize the international import of freeing genetically altered cells; release in the United States is a de facto release in all other countries.

If Congress fails to pass DNA legislation,<sup>69</sup> the individual states should proceed with the drafting and promulgation of rigorous regulatory standards. State guidelines are imperative and appropriate because universities, which now house most DNA research projects, generally must account solely to the legislature. Universities owe little, if any, statutory allegiance to the communities in which they operate.<sup>70</sup>

In the absence of more objectively formulated standards, a state seeking to resolve the agonizing technical problems posed by DNA experimentation should build its regulatory framework around the NIH guidelines. Most state governments lack both the technical input and the requisite available financing to draft independent DNA safeguards even approaching those laid down by the NIH. However, in formulating a state regulatory system, officials should view the NIH guidelines as minimum, not maximum, regulatory standards. Further, the state legislature should augment the NIH provisions by insistence upon extensive training of laboratory employees; by mandating periodic, yet unscheduled, inspections of DNA facilities by independent analysts familiar with microorganic containment procedures; and by requiring strict accountability by genetic researchers to top officials of the state health board.

#### CONCLUSION

Since the inception of genetic research, scientists and legal theorists have pondered the technical<sup>71</sup> and ethical questions posed by this new technology.

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<sup>68</sup>General Electric, for example, is reportedly trying to patent a newly assembled strain of pseudomonas bacteria that can wholly digest crude oil, such as might result from an oceanic spill. It was developed by GE researchers by transferring plasmids from several strains, each of which would digest oil partially, into a single strain that can do the whole job. But how will the strain attack oil that has not spilled—petroleum still in the ground or in storage? Can this organism be kept from destroying oil we want to use?

<sup>69</sup>In the absence of a statutory remedy for injury, a plaintiff could arguably sue in tort for DNA-related injuries. In *Rylands v. Fletcher*, L.R. 3 H.L. 330 (1868), Judge Blackburn established a basis for judgments in similar cases in both Britain and American ever since. The ruling states that if for your own purposes you collect any material on your land that might damage people if the material escaped, and if it does escape and cause damage, then you are liable—even though it was not your negligence that led to its escape in the first place.

<sup>70</sup>In Indiana, for example, local personal property taxes cannot be levied on state-owned lands, *i.e.*, public university property. See 1944 ATTY GEN. ANN. REP. 11. See also *Russell v. Trustees of Purdue University*, 201 Ind. 367, 374, 168 N.E. 529, 531 (1929), where it was said that when incorporated universities exist which are founded and supported by the state, they are generally treated by the courts as public rather than private corporations.

<sup>71</sup>In the case of the DNA issue, the research is moving so fast that it is difficult to maintain an awareness of the status of the development. The rewards and . . . incentives

But while the initial regulatory response to the problem has been well-intentioned, Congress now has a moral responsibility to impose circumscriptive experimental standards to safeguard the public health.

Federal law-makers will likely refuse, however, to transform their theoretical concerns about DNA hazards into restrictive legislative policies and will succumb instead to the lobbying efforts of financially interested corporations and the organized scientific community. Such government inaction would further erode public confidence in Congress as a concerned legal institution and needlessly expose the population to the potentiality of genetic disaster.

Should Congress fail to act, the individual state legislatures must proceed to adopt their own regulatory safeguards, using the NIH guidelines as minimum safety standards.

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for success in research in this area are extremely high for commercial developers and researchers alike. The risk in some instances can be partially defined but in most cases are highly speculative. Since most of the research is being supported by Federal funds, there is a considerable political challenge to maintain an awareness sufficient to exercise control over policy. At the same time, there has always been considerable resistance, from the basic research community, against any infringement upon the historic rights of academic freedom and the search for basic knowledge. HUMAN GENETICS, *supra* note 13, at 19.