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"Nature is often hidden, sometimes
overcome, seldom extinguished."
-Francis Bacon (16th Century)

I. INTRODUCTION

Although recombinant DNA's effect on the future of mankind is unpredictable, its impact is certain to be monumental. Hailed by many as "a genie capable of transforming the world,"[1] others fear this new revolutionary technique may create Andromeda strains capable of destroying the human species.[2] Genetic manipulation[3] could

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1. Golden, *Shaping Life in the Lab*, TIME, Mar. 9, 1981, at 50. This genie-like characteristic has caused gene splicing to be viewed as "a new alchemy that may one day turn the basest of creatures into genetic gold." *Id.*

2. Zilinskas, *Recombinant DNA Research and the International System*, 51 CAL. L. REV. 1483 (1978). Zilinskas notes three broad categories under which such a situation might arise:

> (1) a life form with known detrimental properties might escape from a laboratory and enter the biosphere . . . (2) a life form, after being developed and used for a positive quality might manifest unplanned, detrimental side effects; or (3) life forms may be deliberately designed and developed for use in warfare, international terrorism, or blackmail.

Id. at 1483-84.

3. The terms—recombinant DNA, genetic manipulation and genetic engineering—will be used somewhat interchangeably in this article. What is being referred to is the process whereby the genetic material, containing hereditary instructions, is removed from a DNA molecule, and inserted into a host organism. This recombination may not occur in nature, which is why it is so revolutionary. The end result is that the host organism begins to take on the additional characteristics of the spliced DNA molecule, since the inserted material is replicated in the bacterium. For a detailed discussion of the structural aspects of DNA, see J. WATSON, THE DOUBLE HELIX (1968).

be to the 1980's what microcomputers were to the 1970's.[4] Possible uses are numerous and diverse, including the production of interferon, human insulin, human growth hormone, enzymes for food and animal feed, flavor and perfume additives, pesticides, lubricants, fertilizers to promote nitrogen-fixing in plants, and bacteria to convert coal into gas.[5] All nations must be concerned with biotechnology because of its ability to alter genetic structures, industrial processes, and possibly environmental balances. Regulatory schemes must be fashioned to anticipate, not merely react to, problems and complications which will arise as this new technology matures. Without a concerted and preventive approach by international groups, the world may discover that it has opened Pandora's box rather than rubbed Aladdin's lamp.

There are several countries which have formulated genetic engineering research guidelines.[6] Others rely on existing legislation which regulates related areas such as health-and-safety-at-work, the environment, and use of medical pharmaceutical products.[7] Although the biotechnologists themselves sounded the initial alert to the potential dangers of genetic manipulation,[8] many of these scientists now acknowledge that the original fears about DNA research were somewhat exaggerated.[9] This re-evaluation of the potential dangers of genetic engineering could result in a more relaxed attitude in many countries toward the necessity for regulation of scientific research.

This article provides an insight into the present status of the debate by analyzing the attitudes of nations which have established guidelines and/or legislation in this area. This article will also consider the feasibility of international cooperation in this field and identify current institutions, agreements and treaties. Finally, the strength

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4. Golden, *supra* note 1, at 51.

5. *Where Genetic Engineering Will Change Industry*, BUS. WK., Oct. 22, 1979, at 160, 172. In fact, expectations are that DNA may eventually "produce vaccines against hepatitis and malaria; miracle products like low calorie sugar; hardy self-fertilizing food crops that could usher in a new 'green revolution'; fuels, plastics and other industrial chemicals, out of civilization's wastes; mining and refining processes to relieve Malthusian anxieties about a future without sufficient raw materials." Golden, *supra* note 1, at 50.

6. Cripps, *A New Frontier for International Law*, 29 INT'L & COMP. L.Q. 1 & n.4 (1980).

7. *Id. See also infra* notes 17-97 and accompanying text.

8. Letter from Paul Berg, Chairman of the Committee on Recombinant DNA Molecules, to the Editor (June 1974) (warning of potential hazards of recombinant DNA molecules), *reprinted in* 71 PROC. NAT'L ACAD. SCI. 2593, 2593-94 (1974). *See also infra* notes 11-16 and accompanying text.

9. *See, e.g.*, Golden, *supra* note 1, at 59.

of the newly emerging genetic engineering industry[10] and its probable influence on the course of this debate are evaluated.

II. THE DEVELOPMENT OF GENETIC ENGINEERING

Although scientists have engaged in genetic research for decades, the development of new genetic engineering technologies began to make significant headway only in the late 1970's. Similar to the growth of computer technology, genetic engineering technology has advanced in quantum leaps. One scientist noted that approximately ninety-five percent of the projects on which his firm is working were not even conceived of two years ago.[11]

Stanford biochemist Paul Berg was the first scientist to question seriously the sufficiency of existing safeguards when he began to insert simian virus (SV40) genes into the bacterium *Escherichia coli* (*E. coli*), an organism normally found in the human intestine. Because of the uncertainty of what might ensue should the bacterium escape his laboratory, Berg voluntarily postponed his experiment. What followed led to numerous regulations and guidelines aimed at alleviating Berg's worst fears.

In 1974, a group of eleven scientists working in the genetic engineering field formed the National Academy of Sciences' Committee on Recombinant DNA Molecules and issued a warning to their peers patterned after Berg's concerns. Because of the Committee's efforts, many geneticists throughout the world have agreed that certain "high risk" genetic experiments should not be undertaken in the presently available facilities.[12] A significant result of the moratorium was the sponsorship of various conferences to discuss the potential hazards and ethical issues involved in genetic engineering research. Perhaps the most important meeting was the Asilomar Conference in 1973. This gathering of scientists issued recommendations to increase safety and decrease the risk of strange life forms escaping

10. Virtually nothing has been commercially marketed as a result of these discoveries. However, massive expenditures and investments have already been made in anticipation of what lies ahead. *See infra* notes 171-202 and accompanying text.

11. *Where Genetic Engineering Will Change Industry*, *supra* note 5, at 172.

12. Berg, Baltimore, Brenner, Roblin & Singer, *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 72 PROC. NAT'L ACAD. SCI., U.S.A. 1981 (1975), *reprinted in Genetic Engineering, Human Genetics, and Cell Biology: Evolution of Technological Issues: DNA Recombinant Research (Supplemental Report II): Report Prepared for the Subcomm. on Science, Research, and Technology of the House Comm. on Science and Technology*, 94th Cong., 2d Sess. 96 (1976) [hereinafter cited as *Supplemental Report II*].

from laboratories. National guidelines controlling genetic manipulation embodied many of these recommendations.[13]

Various efforts were made in the following years to develop and gather evidence relating to these early concerns about recombinant DNA. Most reports showed that certain strains of host[14] organisms had high safety ratings, particularly when inserted with specific plasmids[15] under special laboratory conditions. Some of the DNA recombinations were found to be no different than those naturally occurring in the atmosphere.[16]

The new data, in conjunction with the amazing advances and promised benefits from the industrial application of these techniques, led to a softening of criticism of genetic engineering research in some circles, particularly in the scientific community. Not all voices were silenced, however, as many people became aware of the potentially negative impact of genetic manipulation on public health, the environment and the evolutionary process.

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13. Over 100 top scientists met at Asilomar in Pacific Grove, California, to come to grips with this issue. Among the participants were James Watson, renowned for his decoding of DNA in the 1950's, and David Baltimore, a recent Nobel prize winner in the field. First, the group wanted the National Institute of Health (NIH), a source of most funding for work in this area, to formulate guidelines for future research activities. This major change in policy (outside control of scientific research was previously without precedent) was not as earth-shaking as the second request. Also sought was a complete worldwide moratorium until the potential hazards of recombinant research could be identified and addressed. The NIH's efforts which followed set the tone for much of the national activity by other countries. *See* Mays, *Tempest in a Test Tube*, STUDENT LAW., Mar. 1981, at 26, 28.

14. The "host" is the cell into which the recombinant molecule is introduced in order to determine how it will function or reproduce. Normally a microorganism, the host chosen, is one about which a great deal of genetic information is already known. The organism selected most frequently is *Escherichia coli* (*E. coli*), a common inhabitant of the human intestine. The non-pathogenic strain K-12 is the preferred host since it will not produce infections in the blood stream, a precautionary consideration in the event it escapes from the laboratory. *See Supplemental Report II*, *supra* note 12, at 9.

15. Plasmids are structures found in bacteria which contain DNA but, being smaller units, are more susceptible to manipulation. Capable of self-replication, these plasmids are extracted from the bacteria and reconstructed with different DNA materials. They are inserted into a host cell to complete the genetic engineering function. Much is still unknown about the behavior of plasmids in higher forms of organisms. *See id.* at 10-11.

16. This was used as a justification for continuing the work on recombinant DNA absent restrictions. The argument is weak, however, since the value of recombinant DNA emanates from the fact that it makes possible combinations which do *not* occur naturally. This has many people worried about the long-range potential to alter the evolutionary pattern of some classes of organisms, especially humans. *See generally* Rifkin, *Who Should Play God?*, *reprinted in Recombinant DNA Regulation Act, 1977. Hearing Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources*, 95th Cong., 1st Sess. 301 (1977).

III. NATIONAL REGULATORY RESPONSES

Not all nations have been actively involved in this debate because they do not currently sponsor genetic engineering research. It will be useful at this point, however, to examine the various ways in which some nations have responded to this dilemma, e.g., how their approaches have reflected a balancing of the uncertain risks and benefits generated by genetic engineering research.

A. United States

Reacting to the concerns expressed at Asilomar and in many parts of the country, the NIH in 1976 promulgated "Guidelines for Research Involving Recombinant DNA Molecules." These guidelines, drafted by the Recombinant DNA Molecule Program Advisory Committee (RAC), applied to all NIH-funded genetic manipulation research.[17] Prohibition of certain experiments and prescription of special procedures for other experiments were achieved through categorization of experiments by risk levels.[18] To prevent dangerous accidents, the guidelines sought to use physical[19] and biological

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17. Recombinant DNA Research Guidelines, 41 Fed. Reg. 27,902 (1976). These guidelines have been revised several times. The most current version was approved in November, 1980. On the issue of compliance, see Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines*, 35 FOOD & DRUG COSM. L.J. 633 (1980).

18. This categorization has changed over time. Section I-D of the November, 1980 Guidelines prohibits those experiments which involve the formation of recombinant DNAs derived from various pathogenic organisms (listed in the annex to the guidelines), formation of recombinant DNAs containing genes for the biosynthesis of toxins potent for vertebrates, deliberate release into the environment of any organism containing recombinant DNA, deliberate transfer of drug resistance trait to microorganisms not known to acquire it naturally (if such acquisition could compromise the use of a drug to control disease agents in human or veterinary medicine or agriculture), and large-scale experiments (more than 10 liters of culture) containing recombinant DNAs. Guidelines for Research Involving Recombinant DNA Molecules, 45 Fed. Reg. 77,384 (1980) [hereinafter cited as 1980 NIH Guidelines].

19. These physical containment procedures, equipment, and laboratory installations, provide physical barriers, applied in varying degrees according to the relative anticipated biohazard. The objective is to "confine organisms containing recombinant DNA molecules and thus to reduce the potential for exposure of the laboratory worker, persons outside the laboratory, and the environment to organisms containing recombinant DNA molecules." *Id.* at 77,386 (§ II-B). Four levels of physical containment (P1, P2, P3 and P4) can be achieved by using different combinations of laboratory practices, containment equipment, and special laboratory design. These levels are based on existing containment approaches used by the Center for Disease Control and the National Cancer Institute. *Id.*

containment[20] in various combinations. While federal agencies adopted these guidelines as their working standards, private industry was not legally bound by the guidelines.[21] Nonetheless, the few private firms working with genetic manipulation have in large part adhered to the NIH Guidelines.[22]

Public debate over the merits of genetic engineering research and the sufficiency of the NIH scheme led to the establishment of guidelines at the community level in various states.[23] This public outpouring of concern did not prevent the NIH, however, from softening its tone in subsequent revisions of the Guidelines in 1978 and 1980.[24] Countless hearings were held by Congress, state legislatures, city councils and universities. Some of the most vocal participation took place during the Berkeley and Cambridge discussions.[25] Eventually, both Harvard and the University of California at

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20. Highly specific biological barriers are to be utilized to limit both the infectivity of a vector (plasmid or virus) for specific hosts and its dissemination and survival in the environment. HV levels (Host/Vector) are established, to which specific criteria apply. A further distinction is drawn between prokaryotes and eukaryotes, each designating different complexities of organisms used as hosts. Combinations of host and vector are chosen to minimize the following types of escape: (1) survival of the vector and its host outside the laboratory, and (2) transmission of the vector from the propagation host to other nonlaboratory hosts. *Id.* at 77,390 (§ II-D-2).

21. The Guidelines apply to all recombinant DNA research done within the United States or its territories which is sponsored by an institution that receives support for recombinant DNA research from the NIH. The Guidelines also apply to research done abroad if supported by NIH funds, unless the host country has established rules for recombinant DNA projects. In such a case, the NIH may waive compliance with the Guidelines. *Id.* at 77,398 (§ IV-B). In all other cases, compliance with the Guidelines, while encouraged, is merely voluntary. *Id.* at 77,404 (§ VI-A).

22. *See Recombinant DNA Research and its Applications: Oversight Report by the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science and Transportation*, 95th Cong., 2d Sess. 16-17 (1978) [hereinafter cited as *Oversight Report*].

23. *Id.* at 31.

24. This softening in tone effectively lifted restrictions on one-third of recombinant DNA work. The system still requires establishment of institutional biohazard committees and registration of projects, but the risk-assessment experiments performed after 1976 have led to decreased concern about certain classes of organisms. This is evidenced by the Exemptions list in the current Guidelines edition. *See* 1980 NIH Guidelines, *supra* note 18, at 77,385 (§ I-E).

25. In response to Harvard University's announcement that a new research facility was to be constructed for biological work, the Boston *Phoenix* published an article detailing the worst possible scenario involving escaped organisms spreading through Cambridge. This helped initiate a mass meeting on June 23, 1976, in conjunction with the city council meeting, attended by over 400 individuals. Testimony tended to condemn the NIH Guidelines (coincidentally released that day) as being too lenient for use in Cambridge. A moratorium on

Berkeley adopted even stricter standards than those of the NIH. Other universities followed suit, including Princeton and Amherst.[26]

A variety of legislation has been introduced in Congress addressing the biogenetic manipulation issue, but no bills have yet been passed.[27] During the most active legislative phase, the First Session of the 95th Congress, from January through December, 1977, sixteen recombinant DNA bills were placed in the mill.[28] Active lobbying by pharmaceutical manufacturers, scientists concerned about the potential loss of the United States' scientific edge, and patent lawyers anxious to capitalize on the United States Supreme Court decision allowing life forms to be patented,[29] contributed to the fact that no legislation resulted. Some legislators believed that it was possible to regulate potential recombinant DNA problems under existing legislation in related areas, at least until additional information was known about the technology and its genuine risks.[30] The statutes most frequently referred to in this context are the Public Health Service Act,[31] the Toxic Substances Control Act,[32] the Occupational Safety and Health Act,[33] the Hazardous Materials Transportation Act,[34] various Department of Agriculture quarantine laws,[35] and the Food, Drug and Cosmetic Act.[36]

However, none of the existing statutes deal with the unique characteristics of the recombinant DNA situation. The regulatory

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recombinant DNA work was agreed to until new guidelines, acceptable to the city, were established. This was completed by the end of the year. Mays, *supra* note 13, at 28. *See also* Krimsky, *A Comparative View of State and Municipal Laws Regulating the Use of Recombinant DNA Molecules Technology*, RECOMBINANT DNA TECHNICAL BULL., Nov. 1979, at 121.

26. Mays, *supra* note 13, at 51.

27. *Id.* Between 1977 and 1981, fifteen bills were introduced in Congress. *Id.*

28. For a recapitulation of the bills introduced during the Ninety-fifth Congress, see Hernandez, *Summary of Federal Recombinant DNA Legislation, 95th Congress First Session*, RECOMBINANT DNA TECHNICAL BULL., Nov. 1978, at 15.

29. Diamond v. Chakrabarty, 447 U.S. 303 (1980). *See infra* note 192 for a detailed discussion of this case.

30. *See generally Oversight Report, supra* note 22.

31. 42 U.S.C. § 264 (1978).

32. 15 U.S.C. §§ 2601-2629 (1982).

33. 29 U.S.C. §§ 651-678 (1982).

34. 18 U.S.C. §§ 831-836 (1979).

35. 21 U.S.C. §§ 111, 114, 114(b), 123, 134(a) (1972).

36. 21 U.S.C. §§ 301-364 (1972).

statutes[37] are not designed to prevent environmental damage or to eliminate health hazards of which little is known. Neither the pre-market testing statutes[38] nor the pollution control statutes[39] offer satisfactory aid because knowledge of the hazards is incomplete. The National Environmental Policy Act (NEPA)[40] is the only statute which can be utilized in spite of this information vacuum,[41] since it requires environmental impact statements (EISs) regardless of the industry's state of knowledge in an area. In sum, the existing statutory schemes do not add up to a stalwart preventive program. The key issues not addressed by existing statutes include licensing, mandatory disclosure of research, public participation in all phases of regulation, and establishment of civil liability for institutions whose activities lead to injury of individuals exposed to genetically manipulated organisms.[42]

Currently there is no great hope for passing any comprehensive legislation controlling recombinant DNA research and manufacturer use. Rather, as the genetic engineering firms grow and biotechnology

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37. These regulatory statutes include the Toxic Substances Control Act, the Occupational Safety Health Act, the Food, Drug and Cosmetic Act, and the Public Health Services Act. *Oversight Report, supra* note 22, at 94.

38. The pre-market testing statutes include, inter alia, the Toxic Substances Control Act and the Food, Drug and Cosmetic Act. *Id.*

39. The Occupational Safety and Health Act is one of the pollution control statutes. *Id.*

40. 42 U.S.C. §§ 4321-4370 (1982).

41. *Oversight Report, supra* note 22, at 94. The reason for this is that NEPA requires federal agencies to evaluate environmental impacts regardless of information gaps. *Id.*

42. *Id.* at 95. Eight goals were promulgated by the National Resources Defense Council as necessary for an effective regulatory program. This program must:

> 1. Apply uniformly to all persons and institutions engaged in recombinant activities.
>
> 2. Prevent release of organisms, rather than control emissions or remedy environmental damage after it has occurred. A preventive program is essential, because the consequences of recombinant technology are largely unknown, but likely to be irreversible. Licensing which requires containment facilities and regulates work practices is the most effective form of preventive legislation.
>
> 3. Protect the environment as well as human health.
>
> 4. Provide continuing evaluation of risks as more information becomes available.
>
> 5. Provide technology assessment of proposed uses of recombinant techniques and organisms.
>
> 6. Provide public participation in all phases of regulation.
>
> 7. Require full disclosure of all recombinant DNA research, development, manufacturing and use.
>
> 8. Establish civil liability of institutions engaged in recombinant DNA activities, for injury to individuals exposed to recombinant DNA organisms.

Id.

stocks continue to soar on Wall Street,[43] the prospects for national regulation are dim. Even though the recipients of NIH grants are still subject to a series of guidelines, private industry seems to have substantial freedom with which to conduct research. In fact, increased ties between private industry and universities are likely to result from attempts to avoid some of these restrictions. This is also an opportunity for universities to capitalize on the patent rush, in spite of academic fears that the integrity of pure research may be compromised.[44]

B. United Kingdom

Since the discussion of potential dangers of genetic engineering began, Great Britain has been a leader in exploring means of controlling and regulating the field. Great Britain's Ashby Working Party[45] and Williams Working Party[46] each produced data demonstrating the need for genetic engineering research to continue, but under carefully prescribed conditions. In addition to the Ashby Report of January 1975 and the Williams Report of 1976, the U.K. Health and Safety Commission (HSC) published draft regulations. These regulations conflicted philosophically and pragmatically with the two

43. *See* Golden, *supra* note 1, at 51-52.

44. This is the most controversial part of the debate. On the one hand, various people fear the inter-mixture of professor's duties and "moonlighting" for genetic engineering firms on the grounds that it will lead to compromises of integrity. The exchange of ideas and research among colleagues would dry up under this scenario, as researchers would want to protect potentially patentable, gold-laden ideas. On the other hand, many argue that commercialization in biology is past due. Commercialization of the chemicals industry has already been in effect for many years. The feeling of these advocates is that "[b]y treating biology as a sophisticated form of chemistry, the new techniques of manipulating genes are no more sacred and no less commercial than, say, the alloying of new metals or the production of new drugs." Mays, *supra* note 13, at 53. *See also A Firm, No: Research vs. Profit at Harvard*, TIME, Dec. 1, 1980, at 59.

45. Established by the Advisory Board for the Research Council in July, 1974, to assess the hazards and benefits of genetic engineering research, the Ashby Working Party concluded that, subject to stringent safety precautions, such work should continue and be encouraged. It suggested the formation of a national group to propound research principles and oversee research efforts. *First Report of the Genetic Manipulation Advisory Group (U.K.), reprinted in* RECOMBINANT DNA TECHNICAL BULL., June 1978, at 16-17.

46. On the basis of the Ashby Report's recommendations, another group, the Williams Working Party, was established in 1975. Its purpose was primarily to formulate guidelines. This study recommended that a genetic manipulation advisory body be commissioned, comprised of scientists and members of the public at large. The report also established four groups of experiments to be conducted under varying degrees of containment. Each institute which would conduct research was to have a biological safety officer and biohazard committee. *Id.*

reports.[47] Present regulations are slanted in favor of the Williams Report.

In response to the Williams Report, the Genetic Manipulation Advisory Group (GMAG) was formed in 1976, its principal duties being the review of genetic research proposals and the suggestion of safety precautions and laboratory procedures.[48] Unlike the United States' RAC, GMAG is structured to represent a broad range of interests in society, with members from the trade unions, scientific community, business community, universities, health services, and the public.[49] The need for consensus ensures that no single member can impose its views on the others.

GMAG makes recommendations as a technical advisory board, whereas HSC has authority to inspect university, industry and governmental laboratories. GMAG's legal bite derives, therefore, from HSC's administrative shield over the Health and Safety at Work Act.[50] In addition, GMAG's regulations apply to private industry as well as to public research, which pleases the public, but not industry.

As a result of GMAG's review of proposed industrial projects involving recombinant DNA, serious concerns over the possible loss of confidentiality exist among industrial cliques. The solution adopted to avoid compromising commercial secrecy is to ask all members of GMAG, some of whom either work for, or are consultants to, companies other than the one whose proposal might be under consideration, to voluntarily sign a confidentiality agreement.[51] Companies which have not signed the agreement, as well as those connected with the proposal in any way, do not participate in the deliberations. In

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47. Zilinskas, *supra* note 2, at 1487.

48. *Id.* at 1487-88.

49. In the establishment of the Group, the advice of the Trades Union Congress (TUC), the Confederation of British Industry (CBI) and the Committee of Vice-Chancellors and Principals (CVCP) was sought; the Group's membership now comprises 8 appointed as scientific and medical experts, 5—including our Chairman—able to represent the interests of employees, 4 nominated by the TUC to represent the interests of employees, and 2 (one nominated by the CBI, the other by the CVCP) to represent the interests of management.

First Report of the Genetic Manipulation Advisory Group (U.K.), supra note 45, at 17. *See also* Wolstenholme, *British Solution to Genetic Engineering*, 81 NEW SCIENTIST 1037 (1979).

50. *Report of the Sub-committee on Genetic Manipulation (Recombinant DNA Research, Application, and Regulation) [of the Scientific and Technical Committee of the North Atlantic Assembly]* in UNITED STATES DELEGATION TO THE TWENTY-FIFTH MEETING OF THE NORTH ATLANTIC ASSEMBLY, HELD AT OTTAWA, CANADA, OCTOBER 22 TO OCTOBER 27, 1979, 96TH CONG., 2D SESS., REPORT OF THE U.S. DELEGATION 206TH (Comm. Print 1980) [hereinafter cited as *Report of the Sub-committee on Genetic Manipulation*].

51. *GMAG Secrecy Worries MPs*, 81 NEW SCIENTIST 236 (1979).

general, this system has been relatively successful. The principal problem is that the committee is often left without experts when large numbers withdraw for fear of potential conflicts.[52] This frequently occurs since most members intend to communicate whatever they learn during the deliberations to their constituents.[53]

Although the First Report of GMAG, issued in May 1978, classified research proposals according to the organisms involved,[54] the approach of the group in 1979 was to adopt a "risk-assessment" system, taking into account the nature of the gene itself, rather than merely its source.[55] In this manner, experimentation with genes known to have pathogenic capacity in plants could be more highly restricted than harmless genes extracted from animals.[56] This approach would work only if previous research on the gene had been undertaken, i.e., how the genes behave in the test tube.

During late 1978 and early 1979, increasing reassessments of the GMAG structure were made. Particular questions arose as to why GMAG was not overseen by the Department of Health and Social Security (DHSS), but by the Department of Education and Science.[57] This concern over who should be regulating these activities is analogous to that present in the United States. The approach thus far has been for DHSS to take only a passing interest until the new products of genetic engineering arrive, or until the release of a genetically manipulated organism into the environment creates a disease or other disaster.[58]

The role of local safety or biohazard committees in the United Kingdom is significant. The Williams Working Party's report recommended that there be a safety committee at each institute where genetic research is being carried out. Moreover, GMAG has input into the composition of these local biohazard committees.[59] GMAG

52. *Select Committee Questions GMAG's Membership*, 81 NEW SCIENTIST 845 (1979).

53. *Id.*

54. Lewin, *New Guidelines for Britain's Genetic Engineers*, 81 NEW SCIENTIST 459 (1979).

55. *Id.*

56. *Id.* This sentiment and approach is reflected in the NIH Guidelines to an extent. *See* 1980 NIH Guidelines, *supra* note 18, at 77,384-85 (§§ I-D & I-E).

57. *A Cat's Cradle of Control for Genetic Manipulation*, 81 NEW SCIENTIST 557 (1979).

58. *Id.* This is also analogous to the attitude of U.S. agencies, many of which, rather than taking a preventive stance, prefer to postpone regulation until firms attempt to market genetically engineered products.

59. *Report of the Sub-committee on Genetic Manipulation*, *supra* note 50, at 206.

limits itself to safety considerations, while leaving to local committees the responsibilities of evaluating the ethical and scientific merits of proposals.[60]

However, even local committees began to feel the weight of top-level pressures to ease controls—pressures which were reflected in official policy statements by the House of Commons Select Committee on Science and Technology.[61] The tone of the report issued by this committee was one of concern lest stringent controls drive British researchers overseas and place indigenous scientists at a comparative disadvantage vis-á-vis foreign researchers.[62]

An offshoot of this concern was the outpouring of suggestions from various research councils that the government not only ease controls, but also support genetic research. The Advisory Council for Applied Research and Development (ACARD), the Royal Society, and the Advisory Board for the Research Councils (ABRC) issued a joint report imploring the government to ensure that some £10 million be spent from 1980 to 1985 on biotechnology research. Under the guidance of a Joint Committee for Biotechnology, the effort would seek to capture key industrial opportunities in the field.[63] The report also recommended establishing a national biotechnology firm similar to Genetech or Cetus, two private United States firms.[64]

Since the review of safety procedures in recent years is of less importance, GMAG's role is expected to change. Its members have suggested it give its expert attention to new issues such as pollution[65] and ethics[66] while remaining attentive to potential hazards if new research techniques develop.[67] In effect, GMAG is undergoing a face

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60. *GMAG Debates New Controls on Genetic Engineering*, 81 NEW SCIENTIST 4 (1979).

61. Lewin, *Genetic Engineering Under the Parliamentary Microscope*, 83 NEW SCIENTIST 430 (1979).

62. *Id.* A perfect example stems from the fact that interferon, although discovered in the United Kingdom, is being geared up for commercial production in the United States and Switzerland. *See infra* notes 194-202 and accompanying text.

63. Yanchinski, *Engineering the Future of Biotechnology*, 86 NEW SCIENTIST 3 (1980).

64. *Id. See also infra* notes 171-202 and accompanying text.

65. *Genetic Engineering: Watchdog Lives to Bite Again*, 89 NEW SCIENTIST 7 (1981). It has been suggested that particular emphasis should be placed on examination of the effects of genetically engineered pesticides and new plants or viruses that digest oil spills. *Id.*

66. *Id.*

67. *Id.*

lift. What form it ultimately takes also depends, in part, on the future effect of pressure exerted from the European Economic Community.[68]

C. Other OECD Nations' Approaches

Countries other than the United States and the United Kingdom which have established guidelines or considered legislation to regulate recombinant DNA research have adopted standards similar to those of the NIH or GMAG. Hence, no attempt shall be made to provide a detailed presentation of each country. Rather, brief descriptions of each will emphasize major differences and similarities.

1. Federal Republic of Germany

Voluntary guidelines were promulgated by the Federal Republic of Germany in mid-February, 1978.[69] Similar to the United States' guidelines, the German structure separates experiments according to risk factors, and outlines necessary physical and biological containment procedures. Overseeing the program is the Zentrale Kommission für die Biologische Sicherheit (ZKBS),[70] which is appointed by the Federal Minister for Research and Technology, in conjunction with several other ministers.[71] Each research body must have a project safety officer and a project leader. ZKBS is to assist each institution in appointing project coordinators and establishing containment procedures. Similar to GMAG and RAC, ZKBS's twelve members are to be drawn from a representative cross-section of German society.[72] Finally, the guidelines place great emphasis on monitoring the health of individuals engaged in genetic research.[73]

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68. *See infra* notes 98-111 and accompanying text.

69. Guidelines for the Safe Handling of Recombinant Nucleic Acid (DNA) for the Federal Republic of Germany (approved by the Federal Cabinet in February, 1978), *translated in* RECOMBINANT DNA TECHNICAL BULL., Mar. 1978, at 11 [hereinafter cited as Federal Republic of Germany DNA Guidelines].

70. *Id.* at 16.

71. *Id.*

72. *Id.* at 17. Membership is based on:

(a) four experts working in the field of recombinant DNA research,

(b) four experts who, though not working in the field of recombinant DNA research, possess specific knowledge in the implementation of safety measures in biologic research work, particularly however in microbiology, cytobiology or hygiene, and in addition,

(c) four outstanding individuals, for example from the trade unions, industry and the research-promoting organization.

Id.

73. *Id.* Genetic manipulation laboratory staff members must undergo a series of checkups and blood tests. The serum from the blood tests is to be retained for at least two years from the end of employment. This would allow development of an extensive data base as well as reflect a concern for the immediate health of the worker. *Id.*

2. France

France's effort to regulate recombinant DNA research began in 1975, with the founding of the Ethical Review Group and Control Commission—two sub-groups of the Délégation Générale de la Recherche Scientifique et Technique (DGRST).[74] Adopted in 1977, the French guidelines are less stringent than many others in recognition of the perhaps conjectural hazards of DNA research. No effort to impose a statutory scheme over genetic manipulation research is presently anticipated.[75] Rather, the government is sponsoring diverse French industrial efforts, going so far as to set up the Groupe Genie Genetique, a specialized biotechnology firm.[76] In fact, official French comments indicate that biotechnology may receive the same special treatment already accorded the nuclear, space and information-processing industries, thus limiting the likelihood of strict controls.[77]

3. Canada

In Canada, the Medical Research Council guidelines were revised in December, 1978. These new guidelines are based on the revised NIH guidelines.[78] However, viruses are treated separately, and are assigned their own containment procedures. In addition, biological containment is preferred over physical containment in the Canadian scheme.[79] Further regulation of recombinant DNA activity is made possible under existing laws of the Health Protection Branch, whose powers include inspection of laboratories.[80] Thus far, the guidelines have been applied flexibly.

4. The Netherlands

Research regulation in the Netherlands has been under the control of the Royal Netherlands Academy of Arts and Sciences, a body

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74. *Report of the Sub-committee on Genetic Manipulation, supra* note 50, at 208.
75. *Id.*
76. *Challenging the U.S. Lead in Biotechnology*, BUS. WK., Aug. 4, 1980, at 30.
77. Lloyd, *French Come to Grips with Biotechnology*, 84 NEW SCIENTIST 677 (1979). A report requested by former President Valéry Giscard D'Estaing warns of the "risk to science's reputation as biology creates more and more opportunities for industrial activity under the guise of medical research." *Id.* The report also predicts that 30,000 jobs should develop over the next ten years in the biotechnology field in France. *Id.*
78. *Report of the Sub-committee on Genetic Manipulation, supra* note 50, at 207.
79. *Id.*
80. *Id.* at 208.

which favors legislation in conjunction with guidelines.[81] Despite its initial failure to include members of the public on its committee, the Dutch government has maintained a precautionary stance. But the revised guidelines have dropped some of the prohibited experiments from the NIH-patterned early guidelines. The deliberate introduction of any recombinant DNA material into the environment for testing purposes is still prohibited. All genetic manipulation experiments must be registered.[82]

5. Italy

An Italian group—the Society of Biophysics and Molecular Biologists—was patterned after Asilomar to study the implications of genetic research and the need for legislative responses.[83] A Ministry of Health advisory group recommended that a permanent committee be formed to analyze publicly funded research. Approval to continue work would then be granted or denied within three months of the application for consideration. While industry would not be bound by this scheme, effective regulation was virtually assured in the private sector by denying patents on those commercial products which might result from non-approved experiments.[84]

6. Norway

As late as 1979, there was very little recombinant DNA work being done in Norway. Thus, it is understandable that no special legislation has been passed. The existing Environment-at-Work laws are felt to be sufficient. Additionally, the Central Public Health Laboratory for Infectious Diseases operates with the National Committee on Recombinant DNA to screen all government-funded projects. Industry compliance is on a voluntary basis.[85]

7. Other European Countries

In both Belgium and Sweden, virtually no legislative attention has been paid to the genetic manipulation field. In Belgium, a

81. Cripps, *supra* note 6, at 1 & n.4 (citing Report of the Committee in Charge of the Control on Genetic Manipulation, Royal Netherlands Academy of Arts and Sciences, Mar. 1977).

82. *Report of the Sub-committee on Genetic Manipulation, supra* note 50, at 209-10.

83. Note, *Genetic Manipulation: Research Regulation and Legal Liability Under International Law*, 7 CAL. W. INT'L L.J. 203, 214 n.54 (1977).

84. *Report of the Sub-committee on Genetic Manipulation, supra* note 50, at 209.

85. *Id.* at 210.

sub-committee on recombinant DNA research, established by the National Foundation for Medical Research and the Committee for Medical Ethics, concluded that existing laws concerning work hazards provide adequate protection.[86] In Sweden, the only activity in the area has been the creation of a general toxicity committee by the Swedish Medical Research Council to study the implications of genetic research.[87]

8. Japan

Japan, a highly competitive country in complex technology industries, has yet to make significant inroads into biotechnology. Nevertheless, movement in this direction has been facilitated recently by the awarding of funds to private industry by the government's Research Development Corporation of Japan.[88] It is likely that the Japan Science Council guidelines will ultimately reflect the tone of the NIH regulations. These guidelines, according to the comments of the Council in 1977, should be based on the three principles of "independence," "democracy," and "openness to public scrutiny."[89] If public accountability is as great as it has been in other environmental contexts, the guidelines may have some teeth. Already these three principles supposedly guide Japanese atomic energy research.[90]

D. Non-OECD Nations' Approaches

1. Australia and New Zealand

Australia and New Zealand are involved in the recombinant DNA debate. New Zealand is considering legislation,[91] while the Australian Academy of Science (AAS) has passed guidelines for its microbiologists.[92] The University of Melbourne's interest in this topic

86. *Id.* at 207.

87. Note, *supra* note 83, at 214 n.54.

88. *Challenging the U.S. Lead In Biotechnology*, *supra* note 76, at 31.

89. Science Council of Japan, *Statement on the Security of the Recombinant DNA Research in Japan, translated in* RECOMBINANT DNA TECHNICAL BULL., Nov. 1978, at 18.

90. *Id.* For a comprehensive treatment of the development of environmental and safety standards in Japan, see L. GRESSER, K. FUJIKARA & A. MORISHIMA, ENVIRONMENTAL LAW IN JAPAN 252-59 (1981).

91. *See* Cripps, *supra* note 6, at 1 & n.4.

92. Maslen, *Genetic Engineering Debate Reaches Australia*, 82 NEW SCIENTIST 6 (1979).

has led to the formation of a special committee, comprised of a philosopher, a lawyer, a zoologist, an environmental designer and a biophysicist. This committee called for mandatory application of the AAS guidelines, establishment of a regulatory body, certification of institutions as suitable for carrying on genetic manipulation research, and development of legislation.[93] Despite the fact that voluntary compliance eventually breaks down, these recommendations for a mandatory scheme are likely to be dismissed, as they already have been by many Australian recombinant DNA researchers.[94]

2. Soviet Union

At the time of the Asilomar meeting, Soviet authorities had not established any official criteria for genetic manipulation research. The Soviet Ministry of Health stated that there were no restrictions on basic or applied DNA-related work.[95] Nevertheless, after the conference, provisional guidelines were issued. Drafted by the Recombinant DNA Commission at the Interagency Council on Scientific and Technical Problems of Molecular Biology and Molecular Genetics, these guidelines are compulsory for all Soviet activities in genetic engineering.[96] The distinction between publicly funded and private research, common to the countries considered above, is meaningless in the USSR since there is no truly private industry. The basic parameters of the guidelines are quite similar to the NIH pattern, although provisions have been inserted which make persons guilty of violations "legally answerable."[97] Neither the NIH nor the GMAG rules stipulate any particular liability, but rely on the sanction of cutting off funds for research to encourage compliance with the regulations.

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93. *Id.*

94. *Id.*

95. Note, *supra* note 83, at 214 n.54.

96. Provisional Guidelines on Recombinant DNA Manipulation (Union of Soviet Socialist Republics), *reprinted in* RECOMBINANT DNA TECHNICAL BULL., June 1978, at 9. Drafted by the Recombinant DNA Commission, the guidelines were approved by the State Sanitary Inspector-in-Chief of the Soviet Union and the All-Union Council of Trade Unions of the USSR. *Id.*

97. *Id.* at 10. No further elaboration is given as to what sanctions might attach to this type of violation.

IV. THE FEASIBILITY OF INTERNATIONAL COOPERATION

A. Existing International Bodies

The concern over genetic engineering research, which increased dramatically after the publication of the Berg Letter, sparked a series of international scientific conferences.[98] Many existing scientific bodies undertook to define the problems and propose solutions. New international and regional groups were created, specifically in response to the recombinant DNA debate. The most active bodies in this area have been the European Molecular Biology Organisation (EMBO), the European Scientific Foundation (ESF), the International Council of Scientific Unions (ICSU), the European Economic Community (EEC) and the World Health Organization (WHO).

Primarily interested in disseminating technical information to genetic engineering research institutes, the EMBO works with the other scientific unions and has co-sponsored conferences with national groups.[99] It favors a single international gene pool for genetic engineering activities, as a means of minimizing risks associated with widespread cloning of materials needed for certain experiments.[100] Since EMBO has ties with the European Molecular Biology Laboratory (EMBL) in Heidelberg,[101] which operates a special containment facility that was designed for extremely high risk experiments, this goal could be readily accomplished with maximum safety.[102]

Sometimes considered the most active group, ESF promotes new scientific schemes, enhances communication between scientists, research councils and scholars, and investigates non-scientific aspects of recombinant DNA issues.[103] The latter purpose is achieved by the composition of the Working Group on Genetic Manipulation, which includes scientists, sociologists and lawyers.[104] This group favors the

98. Cripps, *supra* note 6, at 11 & n.64.

99. In addition to work done in association with the sixteen European nations (and Israel) which sponsor it, EMBO has also conducted risk-assessment experiments at the Microbiological Research Establishment in England. *Id.* at 11 & nn.65-66. *See also Regulation of Recombinant DNA Research: Hearings Before the Subcomm. on Science, Technology and Space of the Senate Comm. on Commerce, Science, and Transportation*, 95th Cong., 1st Sess. 427 (1977) [hereinafter cited as *Hearings on DNA Research*].

100. Cripps, *supra* note 6, at 11.

101. *Id.* at 11 n.67.

102. *Id.* at 11.

103. *See id.* at 12. *See also* Zilinskas, *supra* note 2, at 1488.

104. Cripps, *supra* note 6, at 12.

adoption of uniform international regulations, national registration of experiments and projects, the creation of national biohazard committees,[105] and enforcement structures at the domestic level.[106] Generally, the Foundation prefers the GMAG guidelines as a model for such a uniform system.

International scientific cooperation in the genetic engineering field is an aim of the European Economic Community (EEC).[107] This is consistent with that portion of the Treaty of Rome[108] which establishes the purposes of the group. EEC involvement has been particularly influential in efforts to bring both private and public research activities under the roof of a standardized regulatory household.[109] This harmonization attempt finally led to the issuance of an EEC Draft Directive calling for stricter controls in gene-splicing research.[110] Initial reactions to the Directive were not favorable, particularly in the United Kingdom where the Lords' Select Committee on the European Communities felt that the restrictions would inhibit European research in a highly competitive field and compromise business confidentiality by requiring prior authorization from a national authority before research could begin.[111]

The most active group on a truly international level is the ICSU, a body representing eighteen autonomous international scientific unions and over sixty national academies, research councils and similar institutions.[112] ICSU's involvement in the genetic engineering debate has been achieved through its Committee on Genetic Experimentation

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105. *Id.* These committees would be designed to have interpretive, advisory and supervisory responsibilities. *Id.*

106. *Id.* The ever-present dilemma, however, is the creation of "teeth" in the enforcement structure, such as the development of civil penalties. *Id.* (citing Recommendations of the European Science Foundation's Ad Hoc Committee on Genetic Manipulation (adopted by the ESF Assembly on Oct. 26, 1976)).

107. Cripps, *supra* note 6, at 12.

108. Treaty Establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 3.

109. *Cf. Select Committee Slams Directive on Gene Splicing*, 86 NEW SCIENTIST 71 (1980) (noting that the European Economic Community has proposed a draft directive on gene splicing which, if implemented, will have a significant impact on member states).

110. *Id.* This is particularly significant since the United States has just relaxed its controls.

111. *Id.* Prior authorization would apply to research, development, use and acquisition of recombinant material. *Id.*

112. *COGENE Reports*, *reprinted in* RECOMBINANT DNA TECHNICAL BULL., Apr. 1979, at 21.

(COGENE), a special committee formed in October, 1976, and supported by seven member unions.[113] Established as an interdisciplinary body, COGENE consists of representatives from various nations[114] and encourages observers from WHO, Food and Agriculture Organization (FAO), United Nations Economic, Social and Cultural Organization (UNESCO) and United Nations Environmental Program (UNEP) to attend its meetings.[115] COGENE's working groups—Recombinant DNA Guidelines, Training and Education, and Risk Assessment—enable it to contribute to the scientific literature on the state-of-the-art in genetic research and the various implications of such research.[116] It has sucessfully conducted numerous surveys, one of which showed that no less than 367 genetic engineering projects were in progress in 155 laboratories in 15 nations.[117] This report further indicated the levels of containment being utilized, the number of countries which had prepared their own guidelines,[118] and the nature of these guidelines.[119] Most have adopted the NIH guidelines, either wholesale or in large part.

COGENE has spoken out in favor of an international clone bank.[120] This contrasts with the EMBO's concern over a central bank for bacteria, plasmids and other recombinant DNA materials. In particular, the clone bank notion partially reflects COGENE's anxiety

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113. *Id.* These seven unions include: Pure and Applied Chemistry, Biological Sciences, Biochemistry, Pure and Applied Biophysics, Nutritional Sciences, Pharmacology, and the Immunological Societies. *Id.*

114. *Id.* at 21-22. These nations include the Soviet Union, the United States, Italy, Australia, France and West Germany. *Id.*

115. Cripps, *supra* note 6, at 13. The purposes of COGENE are:

(a) to review, evaluate and make available information on the practical and scientific benefits, safeguards, containment facilities and other technical matters,

(b) to consider environmental, health-related and other consequences of any disposal of biological agents constructed by recombinant DNA techniques,

(c) to foster opportunities for training and international exchange, and

(d) to provide a forum through which interested national, regional, and other international bodies may communicate.

COGENE Reports, supra note 112, at 21.

116. *Hearings on DNA Research, supra* note 99, at 426-27.

117. *COGENE Reports, supra* note 112, at 23.

118. *Id.* Seventeen nations have drawn up guidelines. Five of these have prepared their own; the remainder have based their regulations on either the United States' or British models. *Id.*

119. *Id.* Four nations' guidelines are reportedly voluntary; the guidelines of eight are enforceable through control over research funds; two countries have legally enforceable standards. *Id.*

120. Cripps, *supra* note 6, at 14 & n.81.

about the founding of plant genetic resource centers and the resultant trend toward genetic uniformity. COGENE members are concerned with the technological dependence on a specific feature of a crop that may result from this decrease in genetic diversity.[121]

COGENE, like other international bodies, has yet to propose a detailed regulatory scheme for genetic manipulation research. In fact, at its September, 1980 meeting in Paris, COGENE specifically reiterated that biological safety "would be a function of WHO and would not come within the ambit of COGENE."[122] This is one of the major criticisms of COGENE, despite its many contributions in other areas of the debate.

Based on these developments, the burden of forming a consensus on the genetic engineering research question has fallen upon WHO. As one author has already noted, WHO's involvement has caused a shift in emphasis "from agreement by the community of *scientists* to agreement by the community of *states*."[123]

Since the 1975 report from its Advisory Committee on Medical Research (ACMR) recommended the continuation of microbiological research under appropriate safeguards, WHO has promoted genetic engineering for its potential contribution to improving medical and public health.[124] Yet it has been equally concerned that safety regulations are promulgated, especially with respect to work with infectious materials.[125]

After co-sponsoring a conference on transportation and transfer of genetic research materials with the NIH, WHO established an Advisory Group for Safety Measures in Microbiology (AGSMM).[126] Moreover, four working sub-groups were created to coordinate research efforts in special areas: safe transfer of infectious materials, laboratory safety elements, maximum containment laboratories, and development of emergency services.[127] The latter sub-group's international contingency plans were specifically designed to deal with

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121. *Minutes of the Fourth Meeting of COGENE, reprinted in* RECOMBINANT DNA TECHNICAL BULL., Dec. 1980, at 215-16. COGENE had deferred to the International Board for Plant Genetic Resources (IBPGR) on this matter. *Id.*

122. *Id.* at 217.

123. Cripps, *supra* note 6, at 14 (emphasis added).

124. *Id.*

125. *Hearings on DNA Research, supra* note 99, at 426-27.

126. *Id.*

127. *Id.*

transportation-related accidents.[128]

Like COGENE, however, WHO has not promulgated research guidelines for recombinant DNA work. Nonetheless, WHO is perhaps in the best position to sponsor an international convention aimed at adopting uniform research standards.[129] This conclusion stems from the fact that WHO enjoys considerable prestige and possesses a wealth of experience in health matters affecting the international community, thus giving it the power base needed to unite diverse nations in support of a code. WHO may be able to enact an international code via its implied regulatory power from article 21 of the WHO Constitution.[130] In article 21, WHO is granted the authority to design regulations in pursuit of sanitation and quarantine goals and any others necessary to prevent the global spread of disease.[131] Preclusion of biological pollution is impliedly subsumed under this power. Limiting the feasibility of such an approach, however, is the fact that member nations are not bound by WHO regulations. By giving notice of a rejection or a reservation, members can exempt themselves from its jurisdiction.[132]

Although the lion's share of the scrutiny over genetic engineering research at the international level has been undertaken by the bodies discussed above, several other organizations have been involved as well. Substantial contributions have been made by the FAO, UNESCO, the Coalition for Responsible Genetic Research (CRGR), the Friends of the Earth, the International Association of Microbiological Societies (IAMS) and the World Intellectual Property Organization (WIPO).[133] In addition, several national bodies, such as NIH and GMAG, have sponsored international conferences and conducted on-going reviews of international regulatory efforts.

B. Existing Treaties, Conventions and Agreements

Various international agreements have already been formulated which may be applied to different aspects of the recombinant DNA

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128. Cripps, *supra* note 6, at 14-15.

129. *See* Note, *supra* note 83, at 214-15. For a discussion of the feasibility of such a code, see *infra* notes 155-70 and accompanying text.

130. Cripps, *supra* note 6, at 16.

131. *Id.* (citing Shubber, *The Role of WHO in Environmental Pollution Control*, 2 EARTH L.J. 363, 372 (1976)).

132. Cripps, *supra* note 6, at 16 n.94.

133. Many of these contributions have been in the form of conventions or agreements. *See infra* notes 134-54 and accompanying text.

research debate. For the most part, these deal with disease prevention and eradication, pollution, biological warfare, patent protection, liability for accidents and storage of genetic materials. Foremost among these agreements are the Declaration and Recommendations for Action formulated at the United Nations Conference on the Human Environment,[134] the International Covenant on Economic, Social and Cultural Rights,[135] the International Plant Protection Convention,[136] the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for Purposes of Patent Procedure,[137] the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction,[138] the Treaty Banning Nuclear Weapon Tests in the Atmosphere,[139] and the OECD Special Program on the Control of Chemicals.[140] Thus far, however, they represent only a piecemeal approach to controlling the production, storage, use and spread of genetically manipulated organisms.[141]

A significant goal of many of these agreements is protection of the environment. After the Stockholm meeting in 1972, world attention focused on the threat of international pollution. Principle 21 of the Conference on the Human Environment recognized state responsibility to avoid pollution across national borders; Principle 22 admonished states to further develop international law on liability and compensation of victims.[142] Although toxic or dangerous substances, rather than harmful organisms, are singled out for attention, it can be argued that damage caused by genetic engineering would fall under the protective umbrella of these precepts.[143]

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134. Cripps, *supra* note 6, at 6. The Conference was held in 1972 in Stockholm, Sweden. *See id.* at 6 n.41.

135. *Id.* at 7. In 1980, after being open for signature for fourteen years, it was not yet ratified. *See id.* at 7 n.48.

136. Dec. 6, 1951, 150 U.N.T.S. 67, *cited in* Cripps, *supra* note 6, at 8 n.52.

137. *Opened for signature* Apr. 28, 1977, W.I.P.O. Doc. BP/PCD/1 of May 31, 1977, *reprinted in* 17 I.L.M. 285 (1978)[hereinafter cited as Budapest Treaty]. *See infra* notes 150-54 and accompanying text for a discussion of this treaty.

138. Apr. 10, 1972, 26 U.S.T. 683, *cited in* Cripps, *supra* note 6, at 9 n.58.

139. Aug. 5, 1963, 14 U.S.T. 1313, *cited in* Cripps, *supra* note 6, at 1 n.1.

140. Organization for Economic Co-operation and Development (OECD): Documents from the High Level Meeting on Chemicals, May 19-21, 1980, *reprinted in* 19 I.L.M. 1025 (1980)[hereinafter cited as OECD Chemicals].

141. *See* Cripps, *supra* note 6, at 10.

142. Principles 21 and 22 are reprinted in Cripps, *supra* note 6, at 7.

143. Cripps, *supra* note 6, at 7.

This concern over pollution is present at a higher level in the Treaty Banning Nuclear Weapon Tests in the Atmosphere (Test Ban Treaty). Motivated by political and military reasons, the treaty was written to prevent fallout of radioactive waste material across national boundaries.[144] Genetic materials, under the worst scenario, similar to radioactive fallout, could also traverse national boundaries if a surviving host organism escaped the laboratory. Because of the replicative qualities of the bacteria, such an outbreak could be more dangerous than nuclear fallout. A ban on the release of all recombinant DNA organisms into the environment, therefore, is suggested by the Test Ban Treaty model.

Related to the problem of releasing organisms into the atmosphere is the problem of restraining biological warfare. Conventions dealing with biological warfare have repeatedly been construed as precluding the development of genetically produced organisms as biological weapons.[145]

A great number of agreements focus on the prevention and control of disease. By liberally construing the word "disease," genetic engineering-related incidents could fall within the jurisdiction of some of these agreements, such as the International Agreement for the Creation at Paris of an International Office of Epizootics[146] and the International Plant Protection Convention.

Chemicals are already heavily regulated in the international community, as evidenced by the OECD High Level Meeting on Chemicals and the Special Program on the Control of Chemicals. This effort is quite interesting since the nations involved in the Special Program agreed on test guidelines, good laboratory practices, the generation of pre-marketing data, updating mechanisms and mutual acceptance of data.[147] Additionally, the Special Program supported the future development of confidentiality of data proposals, promotion of information exchange and the sponsorship of studies on the economic and trade aspects of chemical regulation.[148] Billed as "a significant

144. The basis for this statement is a belief that the super powers saw the treaty as a means of preventing other nations from easily developing nuclear weapons, in particular the French, whose activities in the South Pacific were controversial throughout the 1960's.

145. *Hearings on DNA Research*, *supra* note 99, at 429 (statement of James Malone, General Counsel of the United States Arms Control and Disarmament Agency).

146. Jan. 25, 1924, 26 U.S.T. 1840, *cited in* Cripps, *supra* note 6, at 8 & n.49.

147. Bracken, *Introductory Note to OECD Documents from the High Level Meeting on Chemicals*, 19 I.L.M. 1023, 1023-24 (1980).

148. *Id.* at 1024.

breakthrough in the area of international cooperation for toxic substances control,"[149] the Special Program shows that agreement on technical procedures and precautionary standards dealing with scientific research and commercialization are both feasible and desirable at an international level.

Finally, the Budapest Treaty[150] and its importance to the patenting of genetically manipulated organisms should be mentioned. An essential purpose of the Treaty is to encourage all member states to recognize and accept patents granted by one member state. Member states, which require the deposit of micro-organisms for patent approval, are requested to recognize deposits made with various international depositories.[151] Nowhere, however, does the treaty address the question of what *kinds* of micro-organisms can be patented. Thus, it stops short of advocating the patentability of genetically engineered products. Read in association with the Patent Co-operation Treaty[152] and the European Patent Convention,[153] however, the Budapest Treaty represents a step toward greater uniformity regarding patent criteria.[154] This development reduces the chance of one nation rejecting a patent application which another nation has honored.

C. Prospects for a Special Agreement or Code

Despite the existence of scattered treaties, agreements and conventions, truly effective regulation of genetic engineering research at the international level is not likely to occur in the absence of a new specialized code or treaty squarely addressing the issues. Yet, past experience has shown that international conventions are often ill-suited to deal with rapidly changing technologies, and that the lengthy and painstakingly slow process of multilateral bargaining is insufficiently responsive.[155] But these problems have been rendered less

149. *Id. See generally Chairman's statement on the need for an international approach to the systematic control of chemicals*, OECD Chemicals, *supra* note 140, at 1028.

150. Budapest Treaty, *opened for signature* Apr. 28, 1977, *reprinted in* 17 I.L.M. 285 (1978). This treaty has been already subscribed to by 18 states. *See id.* at 285 n.*.

151. *Id.* art. 3(1)(a), *reprinted in* 17 I.L.M. at 287.

152. Patent Co-operation Treaty, June 19-Dec. 31, 1977, 1978 Gr. Brit. T.S. No. 78 (Cmd. 7340) (*entered into force* Jan. 24, 1978).

153. Convention on the Grant of European Patents, Oct. 5, 1973, 1978 Gr. Brit. T.S. No. 20 (Cmd. 7090).

154. Cripps, *supra* note 6, at 8. For a more detailed discussion of the patent situation, especially in the United States, see *infra* note 192.

155. Cripps, *supra* note 6, at 15 (citing Contini & Sand, *Methods to Expedite Environmental Protection: International Eco-Standards*, 66 AM. J. INT'L L. 38 (1972)).

troublesome by including special amendment procedures and provisions for on-going technical review by specialized standards committees in international conventions.[156]

The striking similarity of the aforementioned national guidelines[157] intimates that international agreement on safety measures for recombinant DNA activities would not be difficult to achieve. This effort would benefit from the work of regional bodies which have already advocated the adoption of either the NIH or GMAG guidelines.

A quick compromise on the issue of enforcing the guidelines, on the other hand, would be difficult to achieve. Most nations would be unwilling to surrender any of their sovereignty, thus reducing the enforceability of international regulations. Since certain prohibited activities might need to be curtailed or halted in the event of an emergency, this is problematic.[158]

One commentator proposes that an international board of inquiry be established for the purpose of entertaining complaints from any signatory state which feels it has been (or will be) injured by another state's genetic manipulation activities.[159] The board would suggest remedial measures. It would enjoin certain activities in the event of an emergency, and it would update member nations on the state-of-the-art in genetic research. But this would not give the body any "teeth." Consequently, this proposal has been accurately criticized for not allowing participation by members with legal or arbitral experience.[160] As an alternative, it has been insightfully recommended that a scientific advisory committee be formed to review regulations, conduct safety training courses and disseminate information on new genetic engineering developments. This advisory body would then work with the inquiry group, whose members would include legal experts. In the final analysis, however, both proposed solutions render the convention powerless. In these circumstances, arbitration seems the only realistic means to settle disputes. This conclusion is borne out by the almost universal adoption in contemporary

156. Cripps, *supra* note 6, at 16 (citing Shubber, *The Role of WHO in Environmental Pollution Control*, 2 EARTH L.J. 363, 371-72 (1976)).

157. *Hearings on DNA Research*, *supra* note 99, at 425-26 (Report of the Federal Interagency Committee on Recombinant DNA Research).

158. *See* Cripps, *supra* note 6, at 17.

159. Note, *supra* note 83, at 218. The suggestion draws upon the experience of United Nations' observer groups in India and Pakistan in 1948 and in the Middle East conflict and with respect to human rights in South Africa. *Id.* at 218 n.65.

160. Cripps, *supra* note 6, at 18.

multilateral agreements of arbitration as the preferred form of dispute resolution.

Liability for damages to one state (or its nationals) resulting from genetic manipulation activities of another state (or its nationals) is a matter of special concern. Existing theories of legal liability under international law fail to comfort those nations and individuals worried about the potential escape from a genetics laboratory of an Andromeda strain or its equivalent.[161] Because of the trend toward holding parties strictly liable[162] for damages resulting from "ultrahazardous activities,"[163] which some commentators feel includes genetic manipulation activities,[164] strict liability principles may be applied to this area. However, in order to achieve a consensus on a convention regulating research, it may prove propitious to draft principles pertaining to theories of liability as a separate convention or agreement.

Finally, as one author poignantly observes, no convention would

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161. As has been pointed out by various commentators, the existing body of international law is not necessarily structured to handle an international recombinant DNA hazard. No nation is to use its territory in a way which will harm the territory of another nation. *See* The Trail Smelter Arbitration (U.S. v. Can.), 3 R. Int'l Arb. Awards 1901, 1965, 9 Ann. Dig. 315, 317, 35 AM. J. INT'L L. 684, 716 (1941). *See also* Rubin, *Pollution by Analogy: The Trail Smelter Arbitration*, 50 OR. L. REV. 259 (1971). Special liability for environmental damage has been provided in various conventions, yet no precise parallels exist between recombinant DNA material damage and common spoliants such as oil spills. Nonetheless, parallels might be drawn to nuclear accidents. *See* Convention on Third Party Liability in the Field of Nuclear Energy, July 29, 1960, *reprinted in* 55 AM. J. INT'L L. 1082 (1961) ; and Handl, *Territorial Sovereignty and the Problem of Transnational Pollution*, 69 AM. J. INT'L L. 50 (1975). *See generally* G. SCHWARZENBERGER & E. BROWN, A MANUAL OF INTERNATIONAL LAW 141-47 (6th ed. 1976).

162. This principle gives cognizance to the notion of risk rather than fault. It is not yet a codified principle of international law, but several conventions have included it as a basis for assigning liability. Most recently, the principle has been adopted for use regarding activities in outer space. *See* Convention on International Liability for Damage Caused by Space Objects, Mar. 29, 1972, 24 U.S.T. 2389, T.I.A.S. No. 7762. *See also* Wiewiorowska, *Some Problems of State Responsibility in Outer Space Law*, 7 J. SPACE L. 23 (1979); and Mossinghoff, *Managing Tort Liability Risks in the Era of the Space Shuttle*, 7 J. SPACE L. 121 (1979).

163. These high-risk activities merit special treatment since it would be inequitable to require proof of fault by those injured. This inequity derives from the fact that the "risk of serious harm" cannot be eliminated through the acting party's "exercise of the utmost care." In return for allowing the activity to continue, the acting party assumes greater responsibility. Note, *supra* note 83, at 222 (citing RESTATEMENT OF TORTS § 520 (1938)).

164. Note, *supra* note 83, at 222. *See also* Mays, *supra* note 13, at 51. Through proper use of containment procedures (physical and biological) it is possible to substantially minimize this high-risk of genetic engineering activities. However, if an organism *did* escape and survive, few methods exist by which it could be detected and observed. There are no "biological geiger counters" with which one might trace its path. This fact lends support to the "ultrahazardous" label.

be truly complete absent a provision for some form of accident compensation.[165] Thus, an international fund patterned after the Brussels Convention on Third Party Liability in the Field of Nuclear Energy[166] has been suggested.[167] The Brussels plan, which includes a compensation limit, is based on the use of domestic insurance plans and proportional contributions from member states to a special fund.[168] However, the proposal that these contributions be based on "the classification and measure of genetic engineering projects"[169] is vague. A more precise means of assigning value to the relative stakes each state has in genetic engineering research should recognize, in some manner, each state's research and development, number of patents in the field, international market position[170] and past safety record. This seems to be a more viable method of determining proportional contribution levels. As the industry grows, the variables should be re-evaluated and others included.

V. PRIVATE INDUSTRY

Fundamental to any consideration of international regulation of genetic engineering research is an understanding of the newly emerging recombinant DNA industry. Commercialization of these scientific breakthroughs has begun. Stock market analysts and industry experts predict that the market for recombinant DNA pharmaceutical products will be $3 billion annually by 1990.[171] Speculation in

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165. Cripps, *supra* note 6, at 19-20.

166. Jan. 31, 1963, *reprinted in* 2 I.L.M. 685 (1963). This treaty is supplementary to the Paris Convention on Third Party Liability in the Field of Nuclear Energy, July 29, 1960, *reprinted in* 55 AM. J. INT'L L. 1082 (1961).

167. Cripps, *supra* note 6, at 19-20.

168. Compensation up to $120 million per nuclear accident is provided. The domestic insurance scheme accounts for $5 million (laboratory or factory operator's insurance). The nation on whose property the nuclear facility is located provides $65 million in public funds. Finally, $50 million is contributed from public funds on a proportional basis, according to a formula reflecting each member state's gross national product and nuclear thermal power total. *See id.*

169. *Id.* at 20.

170. Even though few patents have been issued and commercialization of genetically engineered products is only now beginning, markets will develop swiftly in the next few years. Thus, this criteria will be valid by the time any agreement is reached on a convention or code.

171. Study by International Resource Development, Inc., a Connecticut research firm, *cited in* Golden, *supra* note 1, at 49.

companies going public has been frenzied.[172] Investment by pharmaceutical firms and chemical companies in specialized plants has proceeded even though many of the hopeful products have yet to be tested and approved.[173] Intensive lobbying by the industry and by the individual scientists, all eager to capitalize on these new opportunities, has reduced legislative concern over regulation of genetic engineering research.

A. The "Big Four"

Several biotechnology firms have sprouted within the past three years. Four mainstream companies, however, have captured the early lead in the race to become the Xerox or Polaroid of genetic manipulation. These four are Genetech, Cetus, Biogen and Genex. Genetech was founded in 1976 by a former Citibank venture capitalist, Robert Swanson, and Herbert Boyer, a biochemist at the University of California at San Francisco. Clearly the leader in the field, it has signed several research agreements with large pharmaceutical firms and already offers a variety of products.[174] In particular, Genetech has developed a brain hormone called somatostatin, is mass-producing human insulin, and is perfecting production of interferon, a drug to cure many cancers.[175] As an indication of success, gross revenues of $856,335 in 1978 rose to $3.5 million for the first half of 1980 alone.[176] But success has not come without controversy. Genetech's close relationship with the University of California has been threatened by accusations that Genetech stole university research results and put them to commercial use. In one such incident, Genetech eventually agreed to pay $350,000 to the University

172. Not only has Genetech benefited from the speculation, but smaller companies have enjoyed the new investor mood. Enzo Biochem, which went public at $7 a share in July, 1980, hit $14 by mid-August and $26 by mid-September. This took place without any products being sold. Mays, *supra* note 13, at 53.

173. Eli Lilly, a mammoth pharmaceuticals firm, committed funds for a $40 million insulin production complex before the insulin was proven effective in humans. *Id.* at 54. Merck and Company equipped its laboratory with an additional $23 million in improvements for recombinant DNA work. Upjohn and General Electric are also gearing up. Clark, Begley & Hager, *The Miracles of Spliced Genes*, NEWSWEEK, Mar. 17, 1980, at 62, 71.

174. These agreements are with companies such as Hoffman-La Roche, A.B. Dabi and Eli Lilly.

175. *See Genetic Engineers Plug Brain Genes Into Bacteria*, 76 NEW SCIENTIST 333 (1977); *How Genetech Made Human Insulin*, 79 NEW SCIENTIST 926 (1978); *Malaria Vaccine Engineered Genetically*, 89 NEW SCIENTIST 131 (1981).

176. *Investors Dream of Genes*, TIME, Oct. 20, 1980, at 72.

of California.[177] Yet this did not hamper the firm's subsequent 36 million over-the-counter stock offering in the fall of 1980.

Cetus Corporation was founded in 1971 by a biochemist, a Nobel prize-winning physicist and a physician. The largest of the "Big Four" companies, Cetus has received much of its support from two sources—Schering-Plough and National Distillers & Chemical Corporation.[178] In addition, Standard Oil of California and Indiana Standard have bought substantial shares. As of late 1979, some $30 million of the firm's $35 million institutional capital came from the latter three firms.[179] Many of these funds go toward producing ethylene oxide and ethylene glycol.[180]

Biogen S.A., a research-oriented firm founded in 1978, and based in Geneva, is the only foreign member of this group. The first to develop bacterial interferon,[181] this multinational firm[182] is also heavily tied to outside industrial interests. Schering-Plough paid $8 million for a 16 percent interest in Biogen in return for various exclusive manufacturing and sales rights.[183] International Nickel Company, Ltd., a mammoth metals company, obtained a 23 percent interest to promote the use of bacteria to leach metals from mineral ores.[184] Biogen is also working toward cures for foot-and-mouth disease, hepatitis and malaria.[185]

Operating out of Rockville, Maryland, Genex Corporation was started by a molecular biologist, J. Leslie Glick, in 1977.[186] By using recombinant DNA techniques to manufacture enzymes and industrial

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177. *Id.* This is one of the reasons university officials and academics are concerned about violations of the integrity of research at academic institutions. It also becomes a matter of economics, since schools could be precluded from capitalizing on discoveries if researchers patent them on behalf of companies instead. *See supra* note 44 and accompanying text.

178. *Investors Dream of Genes, supra* note 176, at 72 .

179. *Where Genetic Engineering Will Change Industry, supra* note 5, at 160.

180. Golden, *supra* note 1, at 51.

181. *Id.* at 52. Bacterial interferon was produced in 1980 after sifting through 20,000 different genetic fragments. *Id.*

182. Its board of directors includes individuals from the U.K., U.S., West Germany, Canada, Belgium and the Netherlands. Incorporated in the Netherlands-Antilles in 1978, Biogen operates from its Geneva-Swiss operating subsidiary. Despite its cross-section of scientists and capital sources, it is still essentially a company supported through U.S. financing. *See DNA Can Build Companies, Too,* FORTUNE, June 16, 1980, at 144-53.

183. *Investors Dream of Genes, supra* note 176, at 72.

184. *Where Genetic Engineering Will Change Industry, supra* note 5, at 160.

185. *Investors Dream of Genes, supra* note 176, at 72.

186. Golden, *supra* note 1, at 52.

chemicals, the firm grew rapidly. Its estimated worth in early 1980 approached $75 million.[187] Koppers Company invested $2 million in Genex. Smaller commitments were made by Emerson Electric, Monsanto and Aetna Insurance.[188] Glick has identified an existing market of $12.4 billion annually in which bacteria could be used more efficiently and economically to produce synthetic organic chemicals. Also, subject to penetration is a group of markets such as plastics, synthetic rubber and pesticides worth $20 billion.[189]

In addition to the activities of these four firms, various large corporations with diversified product lines have begun developing in-house biotechnology programs. Drug companies, energy corporations, chemical firms and agribusiness concerns have all realized the vast untapped potential of these scientific advances.[190] But the new technology will have to be learned and incorporated gradually. Few of these firms have experience in culturing living organisms.[191] Yet, the recent trend toward protecting patents for living organisms[192] will

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187. This estimation was made by Glick himself. *See* Clark, Begley & Hager, *supra* note 173, at 70.

188. *Where Genetic Engineering Will Change Industry, supra* note 5, at 160.

189. *Id.*

190. These companies include Eli Lilly, DuPont, General Electric, Monsanto, Exxon, Hoffman-La Roche, Upjohn, G.D. Searle, Merck, Standard Oil of California, and Lubrizol.

191. Monsanto's commercial development manager, Bernard Gruber, commented that "[w]e're looking at this upside down . . . . The chemical industry has started with small molecules [and built larger, more complex ones] . . . [while] nature makes the large molecule first and processes things down." *Where Genetic Engineering Will Change Industry, supra* note 5, at 172.

192. Diamond v. Chakrabarty, 447 U.S. 303 (1980). Ananda Chakrabarty, a microbiologist working for General Electric, filed a patent application in 1972 for his invention of a bacterium capable of breaking down crude oil. The invention involved the transfer of four different plasmids to a *Pseudomonas* bacteria, which then had the capacity to degrade oil. This made possible the biological control of oil spills. The issue before the Supreme Court was "whether a live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101." *Id.* at 305. The application survived the Court's scrutiny: "[R]espondent's micro-organism plainly qualifies as patentable subject matter. His claim is not a hither to unknown natural phenomenon, but [is] a *nonnaturally occurring manufacture or composition of matter*—a product of human ingenuity . . . ." *Id.* at 309 (emphasis added).

The decision is limited, however, for a variety of reasons. First, it did not deal with recombinant DNA because Chakrabarty's invention essentially involved cross-breeding. *Cf. id.* at 308. Second, the Court continuously reiterated that Congress must address the ethical and philosophical questions raised by genetic engineering, perhaps even constructing a special statute to deal with patents. *See, e.g., id.* at 316-18. Third, by not addressing the question of whether progeny of man-made organisms are covered by the patent, the Court has perhaps

stimulate more aggressive recruitment of scientists, and a far greater willingness to commit funds to the basic research and development of specialized facilities.[193]

B. National Support for Biotechnology Firms

Government support has made many of these scientific discoveries possible, particularly through basic research grants to university scientists and by specialized funding for scientific foundations and government research institutes. Although the United States has been the leader in terms of public support—primarily for NIH activities[194]—other nations have become increasingly active. This trend has accelerated recently for two reasons. First, pressures to regulate genetic engineering activities have been relaxed. Second, more nations have discovered the potential contribution of genetic engineering to the health of their respective national economies.

Private genetic engineering firms are supported less in the United States than elsewhere. In fact, such support is virtually non-existent in the United States. Foreign governments, on the other hand, particularly in Europe and Japan, have been actively subsidizing companies involved in recombinant DNA research. Some governments have even established their own national entities to develop and commercialize genetically engineered products.

British industry has entered the industry somewhat late, even

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weakened its value. Fourth, the high rate of technological change in this burgeoning field will decrease the relative value of patents by outdating the processes being protected. Fifth, as Chief Justice Burger noted in the majority opinion, "legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides." *Id.* at 317.

Although not holding that either gene-splicing or organisms created by the process are patentable, the *Chakrabarty* decision gives the proverbial green light to further scientific and industrial efforts. *See* Yanchinski, *Patenting Life is No Guarantee of Success*, 86 NEW SCIENTIST 373 (1980); Mays, *supra* note 13, at 52-54; *The Right to Patent Life*, NEWSWEEK, June 30, 1980, at 74. How significant a qualitative effect this will have on the development of genetic engineering depends, in large part, on Congress' response to the Court's challenge for it to fashion a special patent law. *Cf. Genetic Patents: Less than Meets the Eye*, BUS. WK., June 30, 1980, at 48 (stating that the *Chakrabarty* decision left many questions unanswered and that their resolution has been placed in the hands of Congress). Congressional inaction, thus far, would indicate guarded pro-industry sympathies.

For an elaboration on Europe's inability to fashion a solid position on the patent issue, see *What's Bugging the European Patent Office?*, 81 NEW SCIENTIST 845 (1979).

193. Nelson Schneider, a vice-president at E.F. Hutton, expects private capital for these activities to hit almost $2 billion by 1985. *Genetic Patents: Less than Meets the Eye*, BUS. WK., June 30, 1980, at 48.

194. The level of NIH funding at the end of 1979, for example, was $91.5 million. *A Flood of Federal Funds for Genetic Engineering*, BUS. WK., Oct. 22, 1979, at 164.

though interferon was discovered there in 1957. British Petroleum Company and Imperial Chemical Industries Limited have created in-house laboratory facilities and are sponsoring recombinant DNA research. The British government, after following the stringent GMAG guidelines for many years, eventually decided it could not afford to allow its talented scientists to work overseas for foreign firms. In July, 1980, the National Enterprise Board (NEB) made public its plans to establish a British biotechnology firm—Celltech. Capitalized with $28.5 million, Celltech was to receive between 40 and 49 percent of its initial capitalization from the NEB with the remainder coming from four large British investment houses.[195]

On the Continent, France has launched a massive program to build a national biotechnology industry. Acting upon the assumption that annual sales of inteferon and genetically produced human insulin could reach $3 billion and $30 billion respectively,[196] France set up the Groupe Genie Genetique (known as G3)—a conglomerate of state-run genetic research institutes, which works with the Pasteur Institute.[197] Private industrial activities include research by Société Nationale Elf Aquitaine—the French national oil company—into production of energy from cellulose, research by a multi-firm enterprise called Transgene,[198] and extensive work with insulin production by the Merieux Institute, a subsidiary of France's largest chemical company, Rhone-Poulenc.[199]

Japanese efforts have centered around governmental support for private genetic research activities. In early 1980, Toray Industries and Green Cross Corporation were each awarded $4 million annually for five years by the government's Research Development Corporation of Japan. The goal of these grants is to produce interferon on a mass scale.[200] Mocida Pharmaceutical Company has agreed on a joint venture with G.D. Searle of Chicago to produce interferon[201] and even Kirin Brewery has thrown its hat into the interferon ring.

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195. *Challenging the U.S. Lead in Biotechnology, supra* note 76, at 30.

196. *Id.*

197. *Id.*

198. It is comprised of Roussel Uclaf, BSN-Gervais Danone, L'Air Liquide, Möet-Hennessy and Elf. Plans were to spend $20 million in research between 1980 and 1985. *Id.*

199. Merieux's insulin already received U.S. Food and Drug Administration approval for public sales. *Id.*

200. *Id.* at 31.

201. A $9 million to $14 million plant was to be built in Shizuoka by late 1981. Seven other firms were also doing interferon research and development in Japan by 1980. *Id.*

One must conclude that foreign governments, anxious not to lose their share of what promises to be a burgeoning economic opportunity, are still concerned about public pressures for some regulatory structures. The technological complexities of the issues alone are reason enough for exercising caution in proceeding to formulate policy. One means of balancing these two competing concerns is to continue funding basic research, but not to be overly generous in granting patents or in approving products for mass marketing and public sales. As one observer has noted, the likely result of this juggling is that "[t]he biotechnological contest in the U.S., Japan and Europe may be decided as much by government policy as by corporate initiative."[202]

VI. CONCLUSION

In the past decade the world has witnessed the growth of a phenomenal new technology. Ironically, as with so many recently heralded discoveries, this technology simultaneously possesses the ability to either significantly improve the quality of human life or to eradicate the species. National efforts to regulate recombinant DNA have aimed, thus far, at preventing the latter event from occurring. Primarily patterned after the NIH and GMAG guidelines, these regulations have been most effective when applied to publicly funded research activities. Voluntary compliance by the private sector has been substantial, but not complete.

Various regional and international bodies have focused their attention and resources on the recombinant DNA research debate. At present, however, most of these groups' contributions have centered on gathering and disseminating information, conducting risk-assessment experiments, and sponsoring conferences and workshops. They have pointed out the inadequacies of current regulatory schemes and have detailed the need for greater multilateral cooperation but have not recommended a comprehensive set of standards for adoption.

Despite a plethora of treaties, conventions and agreements potentially applicable to isolated aspects of the recombinant DNA controversy, none adequately tackles the entire problem. This has caused many observers to conclude that a separate convention or agreement on recombinant DNA is necessary. The recent success of the OECD High Level Meeting on Chemicals in establishing standards for chemical regulation indicates that international agreement on recombinant

202. *Id.*

DNA research safety is possible. Relevant issues, such as legal liability for injury from recombinant DNA activities, compensation for such injuries and dispute settlement mechanisms, may have to be left for separate agreements in order to reach a minimal consensus on the research safety issue.

The ultradynamic growth of the genetic engineering industry limits these national and international intentions for regulatory control. While many nations' initial reaction to the recombinant DNA debate in the mid-1970's was one of extreme caution, the overwhelming potential economic and health benefits to be derived from this nascent technology have altered their perspective. Fearful of promoting an exodus of their indigenous scientists, researchers, industries and venture capital, these countries have not only softened restrictions and halted national legislative efforts, but they have also actively begun subsidizing national biotechnology research. This technology is seen by some nations as a means to revitalize national industrial health.

Even though the pendulum has swung almost completely to the opposite side in a decade, it is not too late to prevent catastrophic accidents. Sufficient public concern still exists. Nations are not blind to this fact; rather, they are somewhat stunned by the rapidity of change in this area and by the visions of wealth seen by industrial entrepreneurs. Consequently, nations do not share a common perception of the *threat* of potentially disastrous recombinant DNA accidents, and meaningful international standards are not likely to be promulgated until the world witnesses its first genetic "Three Mile Island" incident. It seems there is no turning back, but we have been warned.