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THE REGULATION OF MODERN BIOMEDICAL TECHNIQUES

Report Submitted by the American National Section, AIDP

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INTRODUCTION

The regulation of human biotechnology in the United States suffers from the lack of a cohesive policy and framework. Regulatory control is fragmented, both jurisdictionally and substantively. Additionally, serious social and ethical dilemmas frustrate the effort to regulate the area. As a result of this lack of cohesiveness, the controls employed to regulate modern biotechnology in the United States vary from suggested guidelines recommending voluntary compliance, to administrative and criminal sanctions for specific conduct.

This Report will begin by providing an overview of the jurisdictional interplay between state and federal government as it applies to the regulation of human biotechnology in the United States. The Report will then apply this overview, and examine the development of federal and state laws which regulate genetic therapy, human reproductive technologies, and preembryos treatment. Each of these three subcategories of human biomedical technology presents issues and problems not shared by the others. Accordingly, each will be addressed in a separate section.

I. JURISDICTIONAL OVERVIEW

The structure of federal and state government in the United States allows for both redundant and inconsistent health and safety laws. Therefore, in order to evaluate the United States' laws regulating human biomedical technology, one must first understand the relation between federal and state law. This section will examine how the power to regulate these matters is shared between the federal government and the states under our system of federalism.

The United States Constitution grants limited powers to the national government and reserves the remainder to the states. The Constitution does not expressly delegate the regulation of health and safety matters to the federal government. Consequently, health and safety has been primarily and

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historically a matter of local concern, with regulation being left to the states or their local subdivisions.¹ Because legislation varies from state to state, there are potentially fifty different regulations on any given issue.²

Nevertheless, due to the broad interpretation given to some provisions in the United States Constitution, the federal government has constitutionally enacted some health and safety regulations, and the potential for far more federal regulation exists. For example, among the delegated powers, is the power to regulate interstate commerce.³ Today, almost any action "affects" interstate commerce, and thus, is within the power of the federal government to regulate.⁴ In addition, under Congress' broad spending powers, whenever the federal government expends federal funds, it may regulate the institution which receives the funds.⁵ Given these broad general powers of the federal government, it is clear that Congress can pass laws covering the topics discussed in this report. Consequently, state laws, federal laws, or both may regulate the same or similar health and safety matters.⁶ The practitioner

1. See *infra* note 6 (discussing federal preemption of health and safety regulations).

2. The National Conference of Commissioners on Uniform State Laws, composed of commissioners from every state in the Union, regularly prepares and advocates the passage of uniform laws by the several states. For example, the Uniform Anatomical Gift Act ("UAGA"), in either its 1968 version, or the updated 1987 version, has been passed with minor amendments by every state in the Union. 8A U.L.A. 3, 22-23 (Supp. 1989) (listing states which have adopted the 1968 or the 1987 version). Such uniform adoption helps to regularize state laws. Where there is no model uniform act, however, or where the model act is not well-received, widespread differences and confusion may exist throughout the states. *E.g.*, UNIFORM DETERMINATION OF DEATH ACT § 1, 12 U.L.A. 310 (Supp. 1983) (definition of death).

3. U.S. CONST. art. I, cl. 8.

4. See, *e.g.*, *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528 (1985) (holding that Congress overstepped no constitutional limit on its commerce clause power by extending Fair Labor Standard Act's minimum wage and overtime protections to municipal mass-transit employees); *Wickard v. Filburn*, 317 U.S. 111 (1942) (finding congressional power under commerce clause to regulate single-farm crop productions). For an excellent and timely discussion of the scope of the modern commerce power, see Stern, *The Scope of the Phrase Interstate Commerce*, 41 A.B.A. J. 823, 871-72 (1955).

5. *North Carolina ex rel. Morrow v. Califano*, 435 U.S. 962 (1978).

6. Notwithstanding this general rule of concurrent regulatory power, there are limits. For example, under the preemption doctrine, a state or local regulation found to be in conflict with a federal law will be struck down by the supremacy clause of the United States Constitution. U.S. CONST. art. IV, cl. 2. Even in the absence of such direct conflict, a federal law can preempt a given area of law if the legislation so provides. Where only federal law is allowed to prevail, the area is considered preempted; otherwise, there is concurrent federal-state power to regulate.

In the biomedical area, a preemption issue arose in the Supreme Court decision, *Hillsborough County v. Automated Medical Laboratories*, 471 U.S. 707 (1985). In *Hillsborough*, the Food and Drug Administration had set federal standards for the collection of blood plasma, while a Florida County had passed further regulation on the same subject. A medical retailer challenged the local regulations as unconstitutional. The Court held preemption inappropriate, finding a lack of federal intention to preempt as well as a lack of actual conflict between the local and federal regulations. *Id.* at 716-23.

Hillsborough demonstrates that although the preemption doctrine exists as a theoretical

trying to determine what regulations govern any given area of human biomedical technology must check for federal statutes and regulations, as well as examine state and local law. However, the area is becoming increasingly federalized.⁷

This division of regulatory authority is further complicated by fragmentation in the congressional process. Over 100 committees and subcommittees of Congress are charged with overseeing science and technology.⁸ In addition, a burgeoning federal administrative bureaucracy is being created consisting of a multitude of agencies, divisions within agencies, boards, offices and committees, each with its own jealously guarded base of authority.⁹ Further, the areas of control overlap considerably.

International treaties and compacts with other nations, as well as membership in multinational conventions are also shaping federal policy. The United States, for example, is a signatory nation and participating member of the Organization for Economic Cooperation and Development (OECD).¹⁰ This is an organization of governments which, among other economic and social problems, has been reaching agreement as to the regulation of modern biotechnology. The implementation of agreements reached by the OECD has been facilitated by executive action at the federal level. The working of

limitation on the potential for biomedical regulatory fragmentation, it will not necessarily be effective in practice. First, Congress or a federal agency must have taken the initiative by enacting regulations in a given area in order for the Court to consider applying the doctrine. *Id.* at 714. Thus, federal preemption will do nothing to alleviate state-to-state conflicts in regulations in the absence of some federal law. Second, *Hillsborough* shows the narrow interpretation sometimes given to the preemption doctrine even when federal law exists on a certain topic. The doctrine will apply only where there is clear federal intention to preempt. *Id.* at 716-23.

7. See Bonk, *FDA Regulation of Biotechnology*, 43 *FOOD DRUG COSM. L.J.* 67 (1988).

8. See *N.Y. Times*, March 4, 1989, at 14 (letter from Frank H.T. Rhodes, President, Cornell University, calling on President Bush to appoint an Assistant to the President for Science and Technology).

9. See, e.g., *Genentech's Missteps and FDA Policy Shift Led to TPA Setback*, *Wall St. J.*, June 16, 1987, § 1, at 1, col. 6. The article presents a controversy between two FDA divisions, the Office of Drugs and the newer Office of Biologics. This clash illustrates the problems of such inter-agency conflict:

But Genentech also was a victim of an FDA policy shift on biotechnology products and of intra-agency maneuvering for control of them. Staff members in one FDA division accuse another of wresting away the review of TPA [a clot dissolving drug] in an effort to win authority over an expected slew of genetically engineered drugs. A result of the maneuvering was that the FDA changed the criteria Genentech had been trying to meet during more than two years of clinical testing, gave the company short notice of new demands, and coached a rival drug company whose competing clot dissolver was under review for wider use.

Id. See also Editorial and transcript in *Wall St. J.*, July 13, 1987, at 20, col 1-x.

10. The Economist describes the OECD as "the rich countries club." *THE ECONOMIST*, 1-7 July, 1989, at 9. In 1985, the United States Department of Commerce estimated that the worldwide market for genetically altered drugs could reach \$100 billion per year by the year 2000. Attanasio, *The Constitutionality of Regulating Human Genetic Engineering: Where Procreative Liberty and Equal Opportunity Collide*, 53 *U. CHI. L. REV.* 1274, 1279 n.28 (1986).

committees of the OECD prior to decision and recommendation are often confidential and unpublicized. Whether executive orders can directly implement such multinational agreements, as well as their binding effect, is unclear and beyond the scope of this article.¹¹ These and other jurisdictional conflicts in the United States must be dealt with and clear lines of authority determined if chaos is to be avoided in the regulation of modern biomedical techniques.

II. GENETIC PRODUCTS AND INTERFERENCE WITH HUMAN GENES

Advances in genetic engineering provide new systems applicable to a range of uses—from enhancing agriculture to the conquering of human diseases. Deoxyribonucleic Acid (“DNA”) is the chemical substance which contains the information that determines the characteristics a human cell will exhibit.¹² DNA is also the essential material in the transmission of genetic information in other organisms as well.¹³ It is now possible to manipulate and combine various segments of the DNA molecule from different sources.¹⁴ These “recombinant DNA” molecules can then be introduced into a vector such as a bacteria or viral-like agent known as plasmid.¹⁵ The vector can then multiply, replicating the recombinant DNA.¹⁶ This is commercially done through large-scale fermentation processes.¹⁷ The sought after recombinant DNA product is then retrieved and marketed.¹⁸ Other processes, including cell fusion, are also being utilized.¹⁹ Over the years there has been concern,

11. See *infra* notes 47-50 (discussing OECD).

12. See generally B. LEWIN, *GENES* 1 (3d ed. 1987); J. WATSON, *MOLECULAR BIOLOGY OF THE GENE* 1 (3d ed. 1976).

13. B. LEWIN, *supra* note 12, ch.2. See generally R. KRUEGER, N. GILLHAM & J. COGGIN, JR., *INTRODUCTION TO MICROBIOLOGY* 1 (1973).

14. B. LEWIN, *supra* note 12; Cohen, *The Manipulation of Genes*, 233 *SCI. AM.* 25 (1975); Crick & Watson, *A Structure for Deoxyribonucleic Acid*, 171 *NATURE* 737 (1953).

15. H. SUTTON, *AN INTRODUCTION TO HUMAN GENETICS* 93 (4th ed. 1988); B. LEWIN, *supra* note 12, at 350-353 (setting out methods of constructing the chimeric DNA).

16. H. SUTTON, *supra* note 15, at 93; B. LEWIN, *supra* note 12, at 350-53.

17. S. OLSON, *BIOTECHNOLOGY, AN INDUSTRY COMES OF AGE* 1 (1986).

18. S. OLSON, *supra* note 17, at 3.

19. Current Developments:

A. Application to individual human beings through correction of single-gene mutations. By recent count more than two thousand, of the three thousand human genetic disorders trace to single-gene mutations, that is, a point mutation, a single molecular change in the string of DNA. Sickle-cell anemia is caused, for example, by a change in the gene that directs synthesis of the protein molecule that is human hemoglobin. Judson, *Designer Genes*, *The New Republic*, September 19-26, 1983, at 12. Currently, genetic engineers are limited to transferring single genes, but this is expected to change as technology advances. Schneider, *Science Debates Using Tools to Redesign Life*, *N.Y. Times*, June 8, 1987, § 1, at 1, col. 2.

B. To date, six pharmaceuticals produced by genetically engineered bacteria have been approved by the FDA. Human genes have been inserted into bacteria to produce human insulin (for diabetes mellitus), human growth hormone (treatment of shortness from pituitary origin), two alpha-interferons (for treatment of hairy cell leukemia), Hepatitis B vaccine (for Hepatitis B) and Tissue Plasminogen Activator (TPA) (used for heart attacks). Letter from Frank E.

now sometimes considered overreactive, that molecules placed in living cells may be hazardous. For example, if DNA is placed in a bacteria it is possible that the bacteria will be disseminated into the environment and cause harmful or unpredictable results to plants, animals, and humans. This is especially feared where recombinant DNA includes a harmful gene used in experimentation.

Young, Commissioner of Food and Drugs, to NIH (51 Fed. Reg. 45,650-02, Dec 19, 1986) (discussion of containment issues). See also Pollack, *Gene-Splicing Payoff is Near*, N.Y. Times, June 10, 1987, at 29. Another major product, Interleukin-2, promising as a treatment for cancer, is expected to be approved by 1989. Pollack, *supra*, at 48 (there is also erythropoietin, or EPO, that helps in producing red blood cells, with hopes of treatment for anemia in patients undergoing kidney dialysis; colony-stimulating factors for treatment of cancer; a trial natriuretic factor, a potential treatment for hypertension; an epidermal growth factor for treating burn victims; and, superoxide dismutase, which helps prevent damage caused by the resumption of blood flow to an organ after a heart attack, etc.).

C. Applications for vaccines. Scientists, have transplanted foreign genes into the bacteria that make up the tuberculosis vaccine, an important preliminary step in adapting that vaccine for use against other diseases. Schmeck, *Genes Transplanted Into Vaccine for Tuberculosis*, N.Y. Times, Jan. 27, 1987, at 13-18. Similarly, a prototype vaccine against salmonella, produced through genetic engineering, is being carried out in mouse experiments. The Detroit Free Press, June 27, 1989 at 2.

D. Chimera, half-mouse, half-human cells, for use as hybrid monoclonal antibodies to fight cancer have been developed through a process of cell fusion and are in experimental use. See S. OLSON, *supra* note 17, at 25-29; Schmeck, *Antibodies Redesigned as Potent New Tools*, N.Y. Times, Jan. 27, 1987, at 13-18. These cells are produced by a technique which brings together genetic material from two cells to produce a hybrid that can be reproduced through cloning. G. FJERMEDAL, *MAGIC BULLETS* 58-61 (1984). The chimeric antibodies solve two problems. It has been relatively easy to produce mouse monoclonal antibodies against a great many substances, but much more difficult to do this with human monoclonals. Using antibodies from mice in treating humans often leads to a damaging immune reaction because the antibody is foreign. By combining the target-seeking part of the mouse antibody with the other antibody part from a human, the risk of immune reaction may be much reduced. *Id.*

E. Diagnostic Tests. Predictive testing for Huntington's Chorea, a dominantly inherited, untreatable, progressive, and eventually lethal disease, is now possible through the finding of a genetically linked DNA marker. *BioLAW RPTR.* U:139. A technique developed through recombinant DNA research permits prenatal diagnosis of hereditary diseases such as phenylketonuria, Lesch-Nyhan disease and Thalassemia, and may soon be able to do so simply by taking a blood sample from the mother, since some fetal blood cells cross the placenta. See Gulley & Bird, *Regulation of Biomedical Applications of Recombinant DNA Research*, 19 U. RICH. L. REV. 1, 6-8 (1984); Francis, *Recent Developments in Genetic Diagnosis: Some Ethical and Legal Implications*, 1986 UTAH L. REV. 483-493 (1986). Medical researchers have also identified the genes that cause Duchenne Muscular Dystrophy, retinal cancer, and osteosarcoma. *BioLAW RPTR.* U:140.

F. Transgenic animals are currently being produced at the Department of Agriculture research center in Beltsville, Md. Schneider, *supra*, at 10. For example, pigs are being produced by injecting genes into fertilized animal eggs. Piercing cell walls kills between half and three quarters of the eggs. Thus, researchers are currently manipulating the primordial cells that produce sperm and eggs to enable breeders to select the characteristics of animals, including gender. See THE TRANSGENIC ANIMAL REGULATORY REFORM ACT, H.R. 4971, 100th Cong., 2d Sess. (1988) (which failed to become law).

On the other hand, use and development of these new techniques is resolving many severe health problems and may revolutionize agriculture. Applications of this aspect of genetic engineering include large scale production of products such as human insulin.²⁰ The prospect of human gene therapy²¹ is another potential benefit of recombinant DNA techniques. However, direct applications to humans heretofore have been limited.²²

This section of the Report will examine current regulation of genetic engineering, as well as concerns about the future course of genetic engineering. As federal regulation in this area is the most comprehensive to date, it will receive special attention.

A. Federal Regulation

Over the years, a number of federal statutes have been enacted which, while not designed specifically for this purpose, do regulate the products of recombinant DNA and modern biomedical techniques.²³ Also, Congress has established a Biomedical Ethics Board to report annually to Congress, but it has not functioned well.²⁴ There are over 100 committees and subcommittees of the Congress dedicated to science and technology.²⁵ It is clear that Congress has not regulated recombinant DNA or modern biomedical technology as a distinct field, but instead has left its regulation to laws which

20. See *supra* note 19, part B.

21. Gene therapy is the introduction of genes into a patient with a harmful genetic trait in order to effect a cure, without passing the cure onto offspring (somatic), or to affect future generations (germline). S. OLSON, *supra* note 17, at 7.

22. See discussion *infra* notes 71-99 and accompanying text; S. OLSON, *supra* note 17, at 43-53.

23. A matrix of laws that may be applicable to biotechnology products "at some point in research, development, marketing, shipment, use or disposal" has been assembled at 50 Fed. Reg. 47,174, beginning at 47,177 (Nov. 14, 1985). Statutes include: the Food, Drug and Cosmetic Act, 21 U.S.C. § 301-392; the Public Health Service Act, 42 U.S.C. § 262; the Virus-Serum-Toxin Act, 21 U.S.C. § 151-158; Toxic Substances Control Act, 5 U.S.C. § 2601-2929; the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136-136y; the Occupational Safety and Health Act, 29 U.S.C. § 651-678; the Comprehensive Environmental Response, Compensation, and Liability Act (Superfund Act), 42 U.S.C. § 9601-9657; the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6901-6987; Marine Protection, Research, and Sanctuaries Act (Ocean Dumping), 33 U.S.C. § 1404-1445; Federal Meat Inspection Act, 21 U.S.C. § 451-470; the Hazardous Materials Transportation Act, 49 U.S.C. § 1801-1812; the Federal Plant Pest Act, as amended, 7 U.S.C. § 150aa-jj; Animal Quarantine Laws (cites omitted); the Federal Noxious Weed Act of 1974, 7 U.S.C. § 2801-2813; the Clean Air Act, 42 U.S.C. § 7401-7642; the Clean Water Act, 33 U.S.C. § 1251-1376; the Safe Drinking Water Act (SDWA), 42 U.S.C. § 300f-300j-26; the National Environmental Policy Act (NEPA), 42 U.S.C. § 4321-4361; the Endangered Species Act of 1973, 16 U.S.C. § 1536; and others.

24. The Board has led a precarious life and has yet to produce a single report. Its current charge is to report on nutrition and hydration for the dying. See discussion *infra* in Section III, Reproduction Technology, on its earlier charge to report fetal research. Cf. Capron, *Bioethics on the Congressional Agenda*, 1989 HASTINGS CENTER REPORT 22 (March/April).

25. See *supra* note 8 and accompanying text.

govern both ordinary technology as well as the new technologies.²⁶

The existing system of oversight of these modern technologies has thus been left to the executive agencies and the President.²⁷ However, the executive machinery for regulating modern biomedical technology suffers from both inter and intra-agency rivalries, gaps in jurisdiction, and other inadequacies of oversight. This should be expected from agencies not designed to regulate this business, carrying out laws also not designed for that purpose.²⁸ Two issues have been at the forefront: safety concerns related to containment; and moral, safety and ethical concerns over use of recombinant DNA in treating individuals.²⁹ Each will be considered in turn.

I. Asilomar and the RAC

The first reaction to the possible dangers of recombinant DNA research was panic over safety concerns,³⁰ resulting in the International Conference on Recombinant DNA Molecules in 1975.³¹ The first federal guidelines soon followed in 1976.³² These early regulations called for strict containment procedures and completely prohibited certain experiments.³³ These guidelines set the jurisdiction for regulation within the National Institute of Health (NIH).³⁴ A Recombinant Advisory Board (the RAC) was established to advise the NIH.³⁵

26. See Barkstrom, *Recombinant DNA and the Regulation of Biotechnology: Reflections on the Asilomar Conference, Ten Years After*, 19 AKRON L. REV. 81, 93 (1985).

27. Gore & Owens, *The Challenge of Biotechnology*, 3 YALE L. & POL'Y REV. 336, 340 (1985).

28. "The central problems of the regulatory framework include its scattered authority, which has resulted in a 'balkanized' regime of biotechnology oversight, and the limited expertise of the agencies involved." Gore & Owens, *supra* note 27, at 343.

29. See *infra* text accompanying notes 102-114.

30. In 1971, attempts were made to join an animal tumor virus with a human virus and insert them into an E Coli bacteria. E Coli naturally lives in everyone's gut. Publicity about these experiments caused much public concern. See Areen, *Regulating Human Gene Therapy*, 88 W. VA. L. REV. 153, 155 (1985).

31. The initial anxiety was that genetic manipulation of E Coli could result in the creation of pathogenic bacterial strains that might cause mass epidemics or the spread of cancer. See Motulsky, *Impact of Genetic Manipulation on Society and Medicine*, 219 SCI. 135, 136 (Jan. 14, 1983) (citing D. JACKSON & S. STICH, *THE RECOMBINANT DNA DEBATE* (1979); J. WATSON & J. TOOZE, *THE DNA STORY, A DOCUMENTARY HISTORY OF GENE CLONING* (1981)).

32. 41 Fed. Reg. 27,902 (1976). The recommendations of the Asilomar Conference were adopted by the NIH until the new Recombinant DNA Advisory Committee (RAC) guidelines were developed. Gore & Owens, *supra* note 27, at 337.

33. For an extensive history of containment procedure regulations, see Barkstrom, *supra* note 26; 43 *Years of Advances in Altered Life Forms*, N.Y. Times, June 8, 1987, § 1, at 17, col. 1.

34. See Gore & Owens, *supra* note 27, at 337.

35. Originally, the RAC was composed of 12 scientists in the fields of molecular biology, virology, genetics, and microbiology. It was enlarged in 1978 to include nonscientists. Jaffe, *Inadequacies in the Federal Regulation of Biotechnology*, 11 HARV. ENVTL. L. REV. 491, 496 (1987); Areen, *supra* note 30, at 157.

Setting regulation within the NIH appears in retrospect an odd choice,³⁶ since the regulations applied only to projects funded by the NIH or directly undertaken by the NIH.³⁷ The only penalty for violating the guidelines was withdrawal of the grant money.³⁸ However, many private companies working with recombinant DNA adopted the guidelines, and even submitted research proposals to the RAC.³⁹ Other governmental agencies followed suit, as well as state and local governments.⁴⁰ The guidelines established the RAC of the NIH "as the primary point of regulatory oversight in the federal government."⁴¹

The strict containment guidelines were modified in 1978 to allow the forbidden categories to be excepted from the prohibitions with the express approval of the Director of NIH, and the advice of the RAC.⁴² However, the containment requirements were retained,⁴³ so that the RAC and the NIH typically conduct case-by-case determinations.

A number of problems developed to threaten the expansion of RAC jurisdiction. First, other agencies, such as the EPA, were beginning to challenge the RAC's expansive scope of responsibility over the release of genetically-modified organisms.⁴⁴ Second, the limited jurisdiction of the RAC and its lack of environmental experts caused criticism.⁴⁵ Finally, many experiments and, thus their related problems were now passing from the laboratory into the manufacturing realm. With this shift came the court's approval of the patenting of new life forms.⁴⁶

36. But probably apt, since the modern technologies were at that time primarily at the research stage, and were frequently federally funded.

37. Gore & Owens, *supra* note 27, at 337.

38. S. OLSON, *supra* note 17, at 69.

39. *Id.*

40. *Id.* See also Areen, *supra* note 30.

41. Areen, *supra* note 30, at 157.

42. 43 Fed. Reg. 60,108 § 1-D-6 (1978).

43. 51 Fed. Reg. 16,958, NIH Guidelines, May 7, 1986.

44. 49 Fed. Reg. 50,880-01. Notice of proposed policy. EPA plans to address certain microbial products of biotechnology under the Federal Insecticide, Fungicide & Rodenticide Act (FIFRA) and the Toxic Substance Containment Act (TSCA) (Dec. 31, 1984). The proposed policy states: "Inconsistent or duplicative domestic regulation will put U.S. producers at a competitive disadvantage."

45. On June 1, 1983, the NIH authorized release of a genetically engineered frost-inhibiting bacteria into a potato field. A group of environmentalists, led by Jeremy Rifkin, won an injunction in federal court against the release, with Judge Sirica stating: "[T]he Court must conclude that the 'standard' for granting a waiver can only be described as whatever it takes to win the confidence of, hopefully, at least a majority of the RAC and the subsequent approval of the Director of NIH." *Foundation on Economic Trends v. Heckler*, 587 F. Supp. 753, 760 (D.D.C. 1984). Although there is a "Risk Assessment Subcommittee" to advise the RAC, it appears that the NIH "may not be totally prepared to evaluate potential hazards." *Barkstrom*, *supra* note 26, at 105. See also, affirmation by the appeals court in *Foundation on Economic Trends v. Heckler*, 756 F.2d 143, 153 (D.C. Cir. 1985) where the Court stated: "RAC completely failed to consider the possible environmental impact from dispersion of genetically altered bacteria, however small the number and however subject to procedures limiting survival." *Id.*

46. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

2. The OECD & the Development of a New Regulatory Framework

In July, 1983, the OECD's Committee for Scientific and Technological Policy appointed an ad hoc group of government experts to study recombinant DNA safety considerations.⁴⁷ The restricted recommendations of the ad hoc group were made public on May 30, 1986, and adopted by the OECD Council on July 16, 1986.⁴⁸

The group's major recommendation was to limit regulation of the vast majority of industrial recombinant DNA large-scale applications to minimal containment. This could be achieved simply by following good industrial large-scale practice (GILSP).⁴⁹ The group also recognized that the technology of physical containment was well-known to industry and that recombinant DNA micro-organisms of higher risk could now be handled safely.⁵⁰ Finally, the group recommended that less developed agricultural and environmental applications of recombinant DNA could be approached by analogy to traditionally modified organisms.⁵¹ The major thrust of the recommendations was that there was no need for specific legislation for recombinant DNA products.⁵² The report stated: "Member countries should examine their existing oversight and review mechanisms to ensure that adequate review and control may be applied while avoiding any undue burdens that may hamper technological developments in this field."⁵³

During the same time that the OECD group was meeting to simplify and reduce the regulation of recombinant DNA products and other products of biotechnology, plans were being made in the United States to restructure existing laws and agencies into a comprehensive federal regulatory policy. This restructuring had the effect of decentralizing the role of the RAC of the NIH and diminishing the impact of its intensive regulation. In December, 1984, the Office of Science and Technology Policy, Executive Office of the President (OSTP), proposed a coordinated framework for the regulation of biotechnology.⁵⁴ The new regulatory body would have been housed within

47. Recombinant DNA Safety Considerations, Organization for Economic Co-Operation and Development, OECD 3 (1986) [hereinafter OECD-Safety]. There were 17 participants from the United States, including representatives from the EPA, the Office of Science and Technology Policy, the NIH, the Department of Agriculture, and the FDA, *Id.* at 64-65. No other country had more than five participants, except Japan, which had 13. There were seven participants from the Commission of the European Communities. Dr. R. Nourish from the United Kingdom was Chairman. *Id.* at 57-65.

48. The Council recommendations are made by mutual agreement between the member nations. OECD-Safety, *supra* note 47, at 3.

49. OECD-Safety, *supra* note 47, at 41.

50. *Id.*

51. *Id.*

52. *Id.*

53. *Id.* (§ 1 (2)).

54. Office of Science and Technology Policy, Notice of Proposed Coordinated Framework for Regulation of Biotechnology, 49 Fed. Rep. 50,856 (Dec. 31, 1984) [hereinafter The Dec. 84 Notice].

the Department of Health and Human Services (DHHS), and the regulatory scheme would have required a two-tiered review of procedures and products. The idea of agency review, however, was rejected in favor of "an inter-agency coordinating committee composed of senior representatives from the involved agencies including NIH, NSF, Agriculture, EPA and FDA." This was viewed as providing "federal agency officials from different agencies a forum for discussing scientific questions raised in regulatory and research applications."⁵⁵ This change meant that public participation in an open review mechanism was being compromised in favor of a closed forum. This new coordinating committee, called the Biotechnology Science Coordinating Committee ("BSCC") was set up under the Federal Coordinating Council for Science, Engineering and Technology (FCCSET), rather than within the DHHS. The FCCSET falls within the ambit of the OSTP, which is within the Executive Office of the President.⁵⁶

Policy matters relating to agency jurisdiction, commercialization, and international biotechnology matters, which would include the OECD, were set up separately within a new Domestic Policy Council Working Group on Biotechnology. This working group, however, was at that time chaired by the Director of the OSTP, using the staff support of the OSTP.⁵⁷ The National Science Foundation's (NSF) Assistant Director for Biological, Behavioral and Social Sciences also assisted the director of the OSTP.⁵⁸ This coordination was done by the working group.⁵⁹

One immediate effect of the restructuring was a need to define the jurisdiction of competing agencies. Specific agencies were designated as responsible for a particular experiment, and, where there were multiple agencies with potential jurisdiction, one agency was designated as the lead agency.⁶⁰ Even with that modification, the RAC and NIH still maintained a notification and review function. However, on August 24, 1987, the NIH made two modifications to the NIH Guidelines, in which they relinquished review functions. Noting that large-scale fermentation was producing more than 2 billion dollars annually, the guidelines were modified to indicate that large-scale fermentation experiments, under all but the first containment level, needed no greater containment than that for the host organism.⁶¹ In other words, the products of recombinant DNA were not to be treated differently than other products. The NIH also modified its guidelines so that an

55. Office of Science and Technology Policy, Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174 (1985) [hereinafter Framework].

56. 50 Fed. Reg. 47,174, 47,176. For an excellent diagram see Jaffe, *supra* note 35, at Figure 3.

57. 50 Fed. Reg. 47,174, 47,175 (Nov. 14, 1985).

58. *Id.*

59. 51 Fed. Reg. 23,302, 23,306 (June 26, 1986).

60. *Id.* at 23,305.

61. 52 Fed. Reg. 31,848-02 (Aug. 24, 1987). However, the institutional biosafety committee, a local entity, can specify higher containment if it deems it necessary.

application may be sent to any other federal agency that has jurisdiction for review and approval, and that once approved all applicants could proceed without NIH review or approval.⁶²

The process of diffusion has now become almost complete. The other agencies in the BSCC have developed their own policies for governing recombinant DNA technology. These regulations, for the most part, are grounded in the premise that recombinant DNA technology is not to be treated as a distinct field, but rather, is more appropriately regulated by the agencies' pre-existing general policies. For example, it has been suggested that the federal legislative history of the Food, Drug, and Cosmetic Act "shows a clear intent by Congress not to regulate recombinant DNA research as a distinct technology."⁶³ This is the current policy.

For example, the federal Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (DHHS), approves new human drugs, biologics, food additives, medical devices and cosmetics.⁶⁴ In addition, the FDA regulates both federally funded and nonfederally funded products, including those produced by genetic engineering.⁶⁵ Consistent with the nonspeciality philosophy outlined above, the FDA has proposed no new procedures or requirements for the products of genetic engineering. Instead, the agency has reviewed on a case-by-case basis the intended use of each product, under its ordinary procedures.⁶⁶

62. 52 Fed. Reg. 31,848-02. However, the notice retained jurisdiction over gene therapy to human subjects.

63. Barkstrom, *supra* note 26, at 93.

64. See 21 U.S.C. § 348 (1988) (food additives); *id.* § 355 (new drugs).

65. FDA regulations prohibit shipment of any drug in interstate commerce until it establishes that the drug is safe and effective. 21 U.S.C. § 355(a) (1988).

66. Under FDA regulations, clinical investigations of human subjects that demonstrate a new drug is safe and effective, must be made by a qualified expert. Sponsors file a Notice of Claimed Investigational Exemption for a New Drug ("IND") to conduct clinical investigations on human subjects, including, for example, drug composition, manufacturing and control data, results of animal testing, training and experience of investigators, and a plan for clinical investigation. In addition, informed consent and protection of the rights and safety of human subjects is required. FDA, Final Policy Statement for Regulating Biotechnology Products, 51 Fed. Reg. 23,309, 23,310 (1986) [hereinafter Final Policy Statement]. The FDA evaluates IND submissions and reviews ongoing clinical investigations.

FDA approval of a New Drug Application or an abbreviated New Drug Application is required before a new drug can be marketed. This application must contain information about the composition of the drug, manufacturing and packaging procedures and controls, any clinical and nonclinical studies, and any pharmacological and toxicological effects.

Outside of human experimentation, the final policy statement of the FDA, in noting the adequacy of current standards, has concluded that differences in the structure of molecules through recombinant DNA might affect the immunogenicity of a drug. Immunogenicity is "the property that endows a substance with the capacity to provoke an immune response, or the degree to which a substance possesses that property." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (27th ed. 1988) [hereinafter DORLAND'S]. Thus for the FDA, this characteristic will affect the extent to which regulations and testing are deemed necessary.

The use of recombinant DNA technology to manufacture new drugs or biological

A second meeting of the OECD biotechnology committee was held in April, 1988, in Paris and chaired by NIH Director, Dr. James B. Wyngaarden. In this meeting it was recommended that a working group be formed to develop criteria for field testing of plants and microorganisms which fall into a low or minimal risk category.⁶⁷ One of the highest priorities set by the committee was the drafting of recommended standards and creating these standards will be the group's primary focus in the upcoming year. The working group on field testing will be working with restricted documents not available to the public.

The U.S. delegation to this working group, while appointed by the State Department, will be representing the OECD alone.⁶⁸ This raises two concerns. First, the lack of public input, and second, the imposition of secretly determined recommendations, no matter how laudable, from this organization of governments upon agencies of the United States federal government. The danger of this lack of public input is magnified when, as here, agreements are being made between member countries upon recommendations of experts who are high in the administration of these same agencies. There have been assurances that criteria agreed to by the member nations will not supersede this country's laws. However, the processes by which the first OECD recommendations were adopted are disquieting.⁶⁹

products may result in products that differ from similar products manufactured with conventional methods. . . . In some instances the molecular structure of the product may differ from the structure of the active molecule in nature. For example, the first human growth hormone manufactured using recombinant microorganisms has an extra amino acid . . . hence, it is an analogue of the native hormone. Such differences could affect the drug's activity or immunogenicity and, consequently, could affect the extent of testing required.

Final Policy Statement, *supra*, at 23,311.

The FDA policy also mandates quality control in the manufacture of new drugs or biological products produced by recombinant techniques. Manufacturers of new drugs and biologics must always operate in conformance with current good manufacturing practice regulations. *Id.* at 23,310. As with conventionally produced products, assurance of adequate processing techniques and controls is important in the manufacturing of any genetically-produced new drug or biological product. For example, the occurrence of mutations in the coding sequence of a cloned gene during fermentation could give rise to a subpopulation of molecules with an anomalous primary structure and altered activity. This is a potential problem inherent in the production of polypeptide in any fermentation process. The FDA has, therefore, prepared a series of "Points to Consider" for monoclonal antibodies, recombinant DNA technology, and the use of new cell substrate. However, the focus of the FDA is on the end product and good manufacturing processes, rather than on experimentation. Thus, "unless there is some factual basis for charging that recombinant DNA produces a deleterious substance, or that recombinant DNA manufacturing is not in conformance with good manufacturing practices, the FDA lacks a strong basis for regulation." Barkstrom, *supra* note 26, at 93.

67. Biotechnology Science Coordinating Committee Meeting Summary 3 [hereinafter BSCC report] (submitted to NIH by Walcoff & Associates, Inc. (703) 684-5588) (July 29, 1989).

68. BSCC report, *supra* note 67, at 8.

69. Such procedures are continuing right now with the field testing questions. It remains to be seen whether the EPA's authority under FIFRA and TSCA to regulate or prohibit the field

The early guidelines overestimated the potential hazards of recombinant DNA. What was applauded at the time as the exemplary behavior of the scientists in bringing to public attention the possible hazards of recombinant DNA, became in a few years the awkward realization that these restrictions were causing unnecessary impediments to the development of a multibillion dollar industry.⁷⁰ The current trend is to ease these restrictions.

3. Human Gene Therapy

After a seven month delay, the Human Gene Therapy Subcommittee of the Recombinant DNA Advisory Committee of the NIH (RAC) approved the performance of procedures which constituted a prelude to human gene therapy. This procedure was subsequently approved by the RAC and Dr. James B. Wyngaarden, Director of NIH in early 1989. Researchers are to be allowed to insert a marker gene into human tumor infiltrating lymphocytes (TILs), which will allow doctors to trace the TILs through patients receiving the treatment.⁷¹

The Working Group Subcommittee on Human Gene Therapy was created to advise the RAC and the NIH on guidelines for research on human applications of gene therapy.⁷² The group is composed of four physicians, two microbiologists, three lawyers, three ethicists, two public policy experts, and one lay member, appointed without public consultation.⁷³ The NIH and its committees lack significant public participation in both the development of policy and regulation.⁷⁴

testing of the products of biotechnology is eroded by any recommendations of the OECD. This is beyond the scope of this article. For a discussion of EPA jurisdiction, see Jaffe, *supra* note 35, at 510-17, 538-42.

70. "If one understands biology, the fundamental aspects of recombinant DNA experiments are not at all bothersome." Singer, *Genetics and the Law: A Scientist's View*, 3 YALE L. & POL'Y REV. 315, 325 (1985). This view is shared by Daniel Callahan, Director of the Hastings Center, a non-profit institute exploring the social implications of modern biomedical techniques: "It's very hard to sustain a great deal of worry about these things when, after ten years of pretty constant interest and attention, there have been no untoward events." *Concern Over Genetics Prompts a New Coalition of Critics*, N.Y. Times, June 9, 1987, § 3, at 1, col. 3 [hereinafter *Critics*].

71. BIO LAW REP. U:1279-80 (Minutes of the RAC are available from the Office of Recombinant DNA Activities, U.S. Dept. of Health and Human Services).

72. See OFFICE OF TECHNOLOGY ASSESSMENT, HUMAN GENE THERAPY: BACKGROUND PAPER 1 (1984).

73. Areen, *supra* note 30, at 153. The Working Group has passed this change in the definition of recombinant DNA: "In the context of these guidelines, recombinant DNA molecules are defined as either (i) molecules which are constructed outside living cells by joining foreign natural or foreign synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i) above." 51 Fed. Reg. 46,650-02 (Dec. 19, 1986). A footnote to "foreign" would state: "Rearrangements involving the introduction of DNA from different organisms or different strains of an organism will be considered recombinant DNA." See BIO LAW REP. U:235-236.

74. "[U]nfortunately, the members of the Working Group were chosen without public

There has been some criticism that the RAC is both promoting the new technology, and regulating it, and that these aims are conflicting. Similarly, the Working Group on Human Gene Therapy has been criticized on the one hand for not having enough scientists, and on the other hand for having too many scientists.⁷⁵

RAC regulation of human genetic engineering falls into two categories: first, the containment and approval requirements for research; second, the regulations specifically aimed at human gene therapy. Further, human gene therapy must also take into account germ line intervention.⁷⁶ These three categories will be discussed in turn.

a. Containment and approval

Four biosafety levels were established in the 1986 RAC Guidelines, and experiments involving human subjects were set at the III-A level. The III-A level requires that the local Institutional Review Board (IRB) review a proposal prior to submission to the RAC.⁷⁷ The review board is convened at the sponsoring institution. Any such proposal must then be published in the Federal Register for thirty days of comment.⁷⁸ Next, it is reviewed by the RAC and must have the specific approval of the NIH.⁷⁹ The III-A experiments also require the approval of a local Institutional Biosafety Committee (IBC).⁸⁰ This committee is also convened at the sponsoring institution. An IBC must have at least five members that have experience in recombinant DNA technology and have the ability to assess the safety and risks of experimentation with recombinant DNA. Additionally, an IBC must include two community members.

consultation. Consequently, the RAC and the Working Group should proceed only after consulting as widely as possible with interested experts and lay groups alike." Areen, *supra* note 30, at 166.

Currently, there is little consideration for public participation in the regulation hearings. The NIH has adopted the notice and comment requirements for rule-making found in the APA. 5 U.S.C. § 553 (1982). This allows the public to 'participate' only to the extent that written comments may be submitted to the NIH. The NIH is not obligated to pay heed to such comments. Therefore, public involvement is minimal.

Spaeth, *Genetic Engineering Research: An Analysis of the Government's Role in Regulation*, 7 UNIV. OF BRIDGEPORT L. REV. 71, 91 n.117 (1986).

75. See Areen, *supra* note 30, at 168 n.81.

76. For a more detailed discussion on germ line research, see *infra* notes 93-99 and accompanying text.

77. See Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 16,958, 16,960 (1986) [hereinafter DNA Research].

78. *Id.* at 16,960.

79. *Id.*

80. *Id.*

The responsibility of the sponsoring institution and each individual scientist is set out in the Guidelines.⁸¹ Once adopted, the sponsoring institution is required to report any significant problems to the NIH Office of Recombinant DNA Activities.⁸² This system, therefore, relies on the individual researcher to follow the guidelines; there are no mechanisms to monitor the researcher's laboratory work.

b. Human gene therapy

On September 29, 1986, the RAC adopted Human Somatic-Cell Gene Therapy Protocols including "Points to Consider."⁸³ Similar but updated "Points to Consider" are currently in the comment period.⁸⁴ The Protocols are guidelines which are adhered to when human genetic material is manipulated in order to diagnose and treat human disorders involving genetic defects.

Experiments in which recombinant DNA is introduced into cells of a human subject with the intent of stabilizing and modifying the subject's genome,⁸⁵ are required to be reviewed by the RAC and approved by the NIH prior to the experiments being carried out. The RAC will consider each proposal on a case-by-case basis. The RAC must (1) publish a precise proposal in the Federal Register, (2) allow an opportunity for public comment, and (3) review the proposal through a working group. RAC recommendations on each proposal are forwarded to the NIH Director for a decision which will then be published in the Federal Register. The NIH Director may approve proposals only if he finds that they present "[n]o significant risk to health or the environment."⁸⁶ In addition, a proposal will be considered by the RAC only after it has been approved by the local Institutional Biosafety Committee and by the local Institutional Review Board, in accordance with Department of Health and Human Services Regulations for the Protection of Human Subjects.⁸⁷ Moreover, if a proposal involves children, special attention is necessary.⁸⁸

81. *Id.* at 16,962. Other experiments using human pathogens as host-vector systems or cloning DNA from human pathogens in non-pathogenic prokaryotic or lower eukaryotic host-vector systems are set at a lower III-B level which requires approval only from the local IBC. *Id.*

82. *Id.*

83. 54 Fed. Reg. 10,956-02 (Jan. 1989). On January 30, 1989 the RAC appointed a "Points to Consider" subcommittee to review and update the "Points to Consider." NIH Points to Consider in the Design and Submission of Human Somatic-Cell Gene Therapy Protocols (Sept. 29, 1986).

84. 54 Fed. Reg. 26,660-02 (1986).

85. Genome is defined as "the complete gene compliment of an organism, contained in a set of chromosomes in eukaryotes, a single chromosome in bacteria, or a DNA or RNA molecule in viruses." DORLAND'S, *supra* note 66, at 687.

86. 54 Fed. Reg. 26,660-02 (June 23, 1989).

87. *Id.*

88. *Id.*

The standards to be applied are provided by the "Points to Consider" in the Design and Submission of Human Somatic-Cell Gene Therapy Protocols. This document provides, in pertinent part: "[i]n general, it is expected that somatic-cell gene therapy protocols will not present a risk to the environment as the recombinant DNA is expected to be confined to the human subject."⁸⁹ This issue, however, has yet to be addressed.⁹⁰ Two aspects of the clinical application of human gene therapy are considered in the document: the application of gene therapy to humans, and the social and ethical issues involved with human gene therapy.

The RAC has stated that it will consider somatic-cell therapy protocols in its approval process. The RAC requires that the design "offers adequate assurance that their consequences will not go beyond their purpose . . . namely, to benefit the health and well-being of the individual being treated while at the same time gathering generalizable knowledge."⁹¹ Finally, the Protocols require an examination of information from researchers on the unintentional vertical transmission to offspring, or horizontal transmission of viral infection to other persons with whom the individual comes in contact.⁹² Additionally, the Protocols require accurate information be made available to the public.

C. Germ line

The RAC does not at this time consider human germ line research.⁹³ However, the RAC Protocols do consider the possible long-term effects of applying knowledge gained in correcting gene defects in somatic cells to applications involving germ line intervention.⁹⁴ Nevertheless, the position of the "Points to Consider" is that germ line intervention will not follow immediately or inevitably from experiments with somatic-cell gene therapy.⁹⁵

Finally, the Protocols require applicants to disclose whether they intend to patent or to trademark their experiments.⁹⁶ It is important to note here

89. *Id.*

90. *Id.*

91. 54 Fed. Reg. 26,660-02 (June 23, 1989)

92. *Id.*

93. The Committee for Responsible Genetics of Boston, Mass., submitted a proposal which would have forbidden either review or approval of human genetic therapy or any such therapy that was not aimed solely at the relief of a life-threatening or severely disabling condition. In addition, the proposal asked for a similar prohibition on any *in vitro* recombinant DNA experiments that alter human germ line cells or early human embryos. Final Policy Statement, *supra* note 66, at 23,310. This proposal was rejected on the grounds that the RAC would not at present entertain proposals for germ-line alterations, and that an outright ban would harm research efforts in human reproductive biology.

94. Germ line intervention is manipulation of genetic material of an egg or sperm. Because manipulation is done at this early stage, the genetic change will be carried in all cells of the organism which is produced from those gametes. M.A. SANTOS, *GENETICS AND MAN'S FUTURE* 65-66 (1981).

95. 54 Fed. Reg. 26,660-02 (June 23, 1989).

96. *Id.*

that the United States Patent and Trademark Office decided in April, 1987, to allow inventors to patent animals produced by new biological technologies. The effect of this decision will be to accelerate the development of transgenic animals, which will almost certainly affect human gene research and development.⁹⁷ The OECD has been exploring the safety aspects of recombinant DNA productions in this realm, especially industrial mass production.⁹⁸ However, the OECD does not intend to become embroiled in the ethical problems of recombinant DNA research involving human subjects.⁹⁹

B. State Regulation

While the RAC guidelines apply to federally funded research, this does not prevent the states from regulating recombinant DNA genetic engineering. Thus, should someone be killed as a result of a catastrophe caused by the wrongful application of recombinant DNA, charges could be brought under the state laws of murder or manslaughter.

Some cities have adopted legislation which specifically regulates human gene therapy. Boston, for example, has enacted legislation adopting the NIH Guidelines for Research Involving Recombinant DNA Molecules.¹⁰⁰ This legislation also establishes a Boston Biohazard Committee and imposes a penalty in the form of a fine of \$200.00 per day for violations. Similar ordinances have been passed elsewhere.¹⁰¹

C. Emerging Social Problems

Approximately one out of every twenty babies is born with a discernible genetic deficiency, between twenty and twenty-five percent of all chronic

97. Hearings held on June 11, 1987, by the House Judiciary Subcommittee on Courts, Civil Liberties and the Administration of Justice, to assess this decision produced sharp clashes and reflect the intensifying debate over effects animal patents might have on the development of the biotechnology industry, particularly commercialization of the science and the patenting of human traits. N.Y. Times, June 12, 1987, § 1, at 12, col. 3. As of June 9, 1987, legislation had passed the Senate which would impose a moratorium on the patenting of animals until October 1, so that Congress would have time to consider the issues. This development followed naturally from the decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) in which the Court allowed genetically engineered bacteria to be patented.

An emerging problem related to the commercialization of gene research lies in the relationship between educational institutions, traditionally at the forefront of new technologies, and industry, with its problems of corporate control. There are currently a multiplicity of connections between universities and industry in the biotechnical field. See M. KENNEY, *BIO-TECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX* (1986); Motulsky, *supra* note 31, at 137.

98. See *supra* note 70.

99. Conversation with Dr. Solomon Wald, OECD's Science and Technology Policies, in Paris (July 8, 1988).

100. BOSTON, MASS., ORDINANCES ch. 9 (1986); BOSTON, MASS. ORDINANCES ch. 12 (1981).

101. Ordinances have been adopted in Berkeley, Cal., Emeryville, Cal., Amherst, Mass., Cambridge, Mass., Newton, Mass., Somerville, Mass., and Princeton, N.J. The State of New York has also passed a statute regulating recombinant DNA experiments. 44 N.Y. PUB. HEALTH LAW §§ 3221-3223 (McKinney 1985). See Spaeth, *supra* note 74, at 71 n.54.

diseases are of genetic origin, and at least half of the hospital beds in America are occupied by patients with problems of a genetic origin.¹⁰² There are, in fact, 3,000 such genetic diseases.¹⁰³

With the rapid advances in germ line research on animals, it is only a matter of time until the results are used in experiments involving the human germ line. This will almost certainly occur first in the area of negative alteration of the human germ line; that is, altering the human germ line to eliminate diseases inherited through single cell deficiencies.

Scientists and moralists are split as to whether or not to allow treatments to correct genetic disorders through manipulation of the human germ line. Such manipulation would occur by altering the egg or sperm cells passing the genetic material on to future generations. The main concern appears to be that if the line is not drawn at preventing germ line alteration, no other line will be able to be drawn. The potential result could be inadvertent changes which affect what it means to be human.

However, medicine already acts so as to allow negative engineering of the human germ line. Current medical treatments have kept alive persons with gene defects who would have previously died and these persons have had children who carry the defective gene.¹⁰⁴ Moreover, it is doubtful whether alteration of the human germ line can be stopped, given the research currently being conducted on animals. Finally, there is a serious question as to whether pure research in this area should be stopped,¹⁰⁵ or whether under the constitutional framework it can be stopped.¹⁰⁶

Assuming alteration of the human germ line begins by way of correcting life-threatening genetic conditions, the next question involves the correction of non-life threatening conditions. The gamut of possibilities ranges from changing the gene responsible for asthma or human baldness to altering genes for beauty, intelligence, memory or stamina. Indeed, "the line between positive and negative genetic engineering is perhaps too elusive for the law to pin down for regulation."¹⁰⁷

A primary area of concern is diagnostic testing of fetuses through recombinant DNA. Such prenatal testing can be done during the first trimester.¹⁰⁸

102. Smith, *Genetics, Eugenics, and Public Policy*, 1985 S. ILL. U.L.J. 435.

103. Schneider, *supra* note 19, at 1, col. 2.

104. Successful treatment of genetic diseases such as congenital heart disorders, diabetes, hemophilia, and immune deficiency allows the bearers of defective genes to live and have children. Motulsky, *supra* note 31, at 137.

105. *See Critics, supra* note 70, at 1, col. 3.

106. Even curbing preliminary research into genetic engineering involves potential first and fourteenth amendment difficulties, although whatever constitutional right to scientific research may exist certainly has limits. . . . To date, however, regulation of genetic research in the United States has been confined largely to containment of risks to health and safety. . . . Against this narrowly focused regulatory backdrop, genetic research is burgeoning.

Attanasio, *supra* note 10, at 1340-41.

107. *See* Judson, *supra* note 19, at 12-17.

108. Attanasio, *supra* note 10, at 1340.

While there may be some questions as to accuracy, the techniques appear to be increasingly more accurate. Furthermore, the procedures for obtaining the samples are generally safe and may someday be as noninvasive as obtaining a blood sample. Several questions are raised in relation to this technology.

First, should the government require prenatal testing for birth defects, under penalty of criminal sanctions? The specter of this type of legislation brings back images of the United States' eugenics sterilization movement of the 1920's.¹⁰⁹ Currently, federal legislation permits the use of public funds for voluntary genetic screening and counseling programs for carriers of sickle cell anemia, cooley's anemia, tay-sachs and other genetic diseases.¹¹⁰ The Supreme Court of the United States has found that there is a constitutionally protected right of privacy involved in making the decision of whether to have a child,¹¹¹ but whether that includes the right to refuse genetic prenatal testing has not been determined.

Second, upon determining that defects are present, may the government order abortion or prenatal gene therapy once such therapy is available, under penalty of criminal sanctions? It is clear that prenatal germ line gene therapy may never be widely practiced because treatment of abnormalities offers little advantage over the selection process. This viewpoint assumes the appropriateness of abortion, which some parents will reject for religious or ethical reasons. There remains the problem of whether the government may compel a parent carrying a defective fetus to engage in medical treatment of that fetus. This question may turn on whether the fetus is afflicted with a fatal disease or whether the fetus is merely the carrier of defective genes. The social goal of a treatment or abortion requirement would not only be to prevent the defective characteristic from crippling the child, but also from continuing in future generations. While this technology does not currently exist, these questions should not be discounted in view of the rapid development of this new technology.

Third, may the government restrict access to prenatal information when that information will be used to discriminate against the fetus on the basis of sex? This problem has already been confronted because of the availability of existing methods to identify the sex of a fetus. However, authorities have recommended against the practice of using such tests to help parents select the sex of a child. More discussion is required as to whether there should be governmental interference with this form of sex discrimination.

109. See Smith, *supra* note 102, at 438-40 (discussing rise and fall of the sterilization movement).

110. 42 U.S.C. § 300b-1 to 300b-6 (1988). Forty three states have limited neonatal screening laws for phenylketonuria (PKU), a single gene effect that produces severe mental retardation in children. See Smith, *supra* note 102, at 441 n.47.

111. See *infra* notes 115-126 and accompanying text (discussing constitutional rights of privacy surrounding decisions regarding procreation).

In addition to diagnosis of the genetic makeup of a fetus, genetic testing might be used in employment. Diagnostic tests of workers are possible to detect, not only abnormalities, but also the potential for such abnormalities. This raises the possibility of using the tests to rid the workplace of the susceptible as a cheaper alternative to creating a safe working place and also as a means of reducing insurance costs.¹¹² Currently, some states have laws prohibiting employment discrimination based upon discovery of the sickle cell trait, or other atypical hereditary cellular or blood traits.¹¹³

Finally, it is possible to introduce human genes into an animal or animal genes into a human. This is referred to as a transgenic process. Two developments leave the future containment of transgenic processes uncertain. The first is that half-human, half-animal cells have been fused together into one entity which has been cloned. These half-human, half-mouse hybrid antibodies may be used to treat multiple sclerosis and colon cancer.¹¹⁴ The second is that agricultural researchers are rapidly developing techniques for creating new transgenic animals, which may be patentable.¹¹⁵ It is entirely possible that, in the future, new partly human life forms could be developed from which valuable organs or parts may be harvested. Once the technology is in place, it would be difficult to prevent the mass production of such entities.

III. NEW HUMAN REPRODUCTIVE TECHNOLOGIES

In the United States, infertility among couples of child-bearing years is a serious problem. Due to long waiting periods, adoption is frequently not the answer. As a result, infertile couples seek alternative methods to conceive or to acquire a child. These methods range from private adoption, to artificial insemination, to in vitro fertilization ("IVF"), to surrogacy. Regulation of these reproductive technologies exists at four levels: (1) regulation of research on preembryos; (2) regulation of physicians who perform the new procedures; (3) regulation of what kind of family relationships will be allowed in parenting a child; and (4) regulation of any third party donor or surrogate. This section will examine the latter three categories, while regulation of preembryo research will be examined separately in Part IV of this Report. But before proceeding to the actual regulations, it is necessary to examine

112. See, e.g., Murray, *Warning: Screening Workers for Genetic Risk*, 13 HASTINGS CENTER REP. 5 (1983); Smith, *supra* note 102, at 443 n.54.

113. Gully & Bird, *supra* note 19, at 18-19.

114. See *infra* note 19, part D and accompanying text.

115. So far, genetic engineers are largely limited to transferring single genes into animals, but a transgenic animal has been created. Recently, a boar has inherited the gene that scientists inserted into its father, and the gene has expressed itself. The research was conducted at the Department of Agriculture research center in Beltsville, Maryland. See Schneider, *supra* note 19, at 1, col. 2. Also, "supermice" were developed in 1982 by injecting rat growth genes into mouse embryos, producing mice roughly twice the normal size. Attanasio, *supra* note 10, at 1282 n.46

potential federal constitutional restraints on the regulation of reproductive technologies.

A. *Constitutional Restraints on the Regulation of Reproductive Technology*

The United States Constitution constrains both federal and state regulatory power and has been interpreted to include a "right to privacy." The right to privacy has been articulated most frequently in cases which protect marriage and the family relationship and has been described, in part, as an individual's right to make important decisions regarding marriage and procreation without interference from government.¹¹⁶ For example, the right to privacy has been held to include the right to marry,¹¹⁷ the right to divorce,¹¹⁸ the right to abort a fetus,¹¹⁹ and the right to use contraception.¹²⁰ In *Skinner v. Oklahoma*,¹²¹ the Supreme Court explained the significance of these particular areas of privacy and the reason for singling them out for special protection when it stated: "Marriage and procreation are fundamental to the very existence and survival of the race."¹²² Thus, although not explicitly

116. See *Whalen v. Roe*, 429 U.S. 589, 599-601 (1977). The Court in *Whalen* described the federal privacy right as consisting of two main branches: 1) the right to make certain kinds of important decisions without governmental interference; and 2) the right to be free of governmental disclosure of highly personal matters. *Id.*

117. See, e.g., *Zablocki v. Redhail*, 434 U.S. 374, 386 (1978) (recognizing right to marry as an aspect of right to privacy, stating that "the decision to marry has been placed on the same level of importance as decisions relating to procreation, childbirth, childrearing, and family relationships."); *Loving v. Virginia*, 388 U.S. 1, 12 (1967) (striking down as violative of equal protection a Virginia miscegenation statute and referring to marriage as a "fundamental freedom [which has] long been recognized as one of the vital personal rights essential to the orderly pursuit of happiness by free men."). See generally Goodman, *In Sickness or in Health: The Right to Marry and the Case of HIV Antibody Testing*, 38 DEPAUL L. REV. 87, 88-95 (1988) (discussing history of right to marry).

118. See, e.g., *Sosna v. Iowa*, 419 U.S. 393, 407 (1975) (upholding one-year residency requirement to file for divorce based on state's important interests in "avoiding officious intermeddling in matters in which another State has a paramount interest, and in minimizing the susceptibility of its own divorce decrees to collateral attack"); *Boddie v. Connecticut*, 401 U.S. 371 (1971) (sustaining indigents' challenge to a Connecticut law requiring court fees and costs averaging \$60 in order to sue for divorce, and reasoning that, because unlike other contractual arrangements, marriage could only be covenanted for or dissolved with state approval, state could not interfere with an individual's access to these procedures).

119. See, e.g., *Roe v. Wade*, 410 U.S. 113 (1973) (striking down as violative of due process Texas statute banning abortions in the first trimester). The *Roe* Court stated that the fundamental privacy right was "broad enough to encompass a woman's decision whether or not to terminate her pregnancy." *Id.* at 153.

120. See, e.g., *Eisenstadt v. Baird*, 405 U.S. 438 (1972) (striking down Massachusetts law making it a felony to distribute contraceptive materials, except in the case of registered physicians and pharmacists furnishing materials to married persons); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (seminal case delineating reproduction privacy right; Court struck down state statute banning sale and use of contraceptive devices).

121. 316 U.S. 535 (1942).

122. *Id.* at 541.

stated in the Constitution, the right of privacy clearly extends to the right of couples to bear their own child by sexual intercourse. Privacy rights, moreover, are "fundamental" rights. Under current constitutional doctrine, neither the federal nor state government can regulate activities in a manner which abridges these rights absent a compelling state interest that is effectuated through the least restrictive means available.¹²³ Notwithstanding these theoretical limitations, exactly what constitutes a compelling state interest and how far the government can go in regulating reproductive technology is unclear, as the case law deciding these issues has been meager.

One notable exception to this general dearth of constitutional precedent is a Michigan appellate court's decision in *Doe v. Kelly*.¹²⁴ In *Kelly*, parties to a surrogacy agreement brought an action to seek a declaratory judgment that the Michigan Adoption Code unconstitutionally infringed their federal right to privacy because it prohibited payment in connection with adoption and thus outlawed their surrogate contract. The plaintiffs argued that the adoption code provision as applied prohibited them from having children, because under the code they could not pay a surrogate to bear a child. The court, however, reasoned that the statute did not prevent the parties, John Doe and Mary Roe, from having a child: it simply prevented them from using the adoption code to change the legal status of the child.¹²⁵ The right to change the legal status of a child, moreover, was found to be a non-fundamental right.¹²⁶ Having characterized the interference in this way, the court had no trouble in refusing to declare the statute an unconstitutional infringement of the federal privacy right.¹²⁷

B. Federal and State Regulation

1. Federal Regulation

Unless federal funds are involved, the federal government has ordinarily not regulated reproductive technologies.¹²⁸ Congress, however, clearly has the authority to regulate surrogacy under the commerce clause.¹²⁹ Moreover, Congress has addressed ethical issues regarding surrogacy in a report of the Ethical Advisory Board of the United States Department of Health, Edu-

123. See, e.g., *Roe*, 410 U.S. at 155 (defining strict scrutiny).

124. 106 Mich. App. 169, 307 N.W.2d 438 (1981), cert. denied, 459 U.S. 1183 (1983).

125. *Id.* at 174, 307 N.W.2d at 441.

126. *Id.* at 173-74, 307 N.W.2d at 441.

127. *Id.*

128. See *infra* notes 182-84 and accompanying text.

129. See *supra* notes 3-6 (discussing federal government's power to regulate under the commerce clause). The United States Congress has considered, but not adopted, measures to regulate surrogacy. See Surrogacy Arrangements Act of 1987, H.R. 2433, 100th Cong., 1st Sess. (1987).

cation and Welfare.¹³⁰ Thus, federal activity in this area may increase in the near future.

2. State Regulation

As a result of the lack of federal activity in the area, most regulation of human reproductive techniques occurs at the state level. State regulation covers each of the three types of reproductive techniques examined in this section of the Report, although to varying degrees.

a. Artificial insemination

The majority of laws which regulate reproductive techniques concern artificial insemination by a sperm donor (AID). Most of these laws establish the paternity of the infant conceived through AID. In fact, over fifty percent of the states have laws which establish the paternity of the infant.¹³¹ In fifteen of the twenty-eight states with such laws, the law provides that the man who donates the sperm is not the father of the resulting child. Rather, the legal parents are the biological mother and her husband, provided that the sperm donor consented to insemination.¹³² Pursuant to these provisions courts have ordered the husband who consented to his wife's insemination to pay child support.¹³³ Although unclear, the AID principles should also apply to women who donate ova.

b. Surrogacy

Another area of reproductive technology that has been the source of much state-law litigation is surrogacy. Unlike artificial insemination, however, very little state law exists that is specifically applicable to surrogate contracts. The one exception is the state of Michigan, which has adopted legislation

130. Protection of Human Subjects: HEW Support of Human in Vitro Fertilization and Embryo Transfer; Report of the Ethics Advisory Board, 44 Fed. Reg. 35,033 (1979) [hereinafter Human Subjects].

131. See 46 FERTILITY & STERILITY 14S n.28 (Supp. 1986) [hereinafter FERTILITY] (citing state law provisions).

132. ALA. CODE § 26-17-21(b) (Supp. 1984); CAL. CIV. CODE § 7005(b) (West 1983); COLO. REV. STAT. § 19-6-106(2) (1978); CONN. GEN. STAT. ANN. § 45-69j (West 1981); ILL. REV. STAT. ch. 40, para. 1453(b) (1987); MINN. STAT. ANN. § 257.56(2) (1982); MONT. CODE ANN. § 40-6-106(2) (1983); NEV. REV. STAT. § 126.061(2) (1983); N.J. STAT. ANN. § 9:17-44 (West Supp. 1985) (unless woman and donor have entered into a written contract to contrary); OR. REV. STAT. § 109.239(1)(2) (1983); TEX. FAM. CODE ANN. § 12.03(b) (Vernon 1975); WASH. REV. CODE ANN. § 26.26.05(2) (Supp. 1985) (unless woman and donor have agreed in writing to contrary); WIS. STAT. ANN. § 891.40(2) (West Supp. 1983); WYO. STAT. § 14-2-103(b) (1978).

133. FERTILITY, *supra* note 131, at 11S (citing cases).

forbidding surrogate contracts.¹³⁴ Moreover, AID principles, which may be applicable by analogy to women who donate ova, will not generally apply to surrogacy contracts. This is because most AID laws presume that the biological mother intends to raise the child. On the other hand, in the typical surrogacy situation, a woman is artificially inseminated with the sperm of the man who intends to raise the child. The woman agrees before conception to give up all legal rights to the child and to allow the wife of the biological father to adopt the child. Thus, the situation is the reverse of the AID situation, because the man whose sperm is used intends to raise the child, while the biological mother does not.

Nonetheless, a multitude of more general state laws already in existence may be applied to the surrogacy situation. Two examples of this phenomenon are provisions found in state adoption¹³⁵ and custody statutes.¹³⁶ For example, state adoption laws preventing the sale of a child might be construed to regulate surrogacy contracts. This use of adoption code principles was accepted by a Michigan intermediate appellate court in *Doe v. Kelly*,¹³⁷ and resulted in the unenforceability of a surrogate contract.¹³⁸ Antibabyselling provisions in state adoption codes are but one example of such interpretations. In addition to statutory adoption and custody limitations, one state's Paternity Act has also been held applicable to surrogate contracts.¹³⁹

Perhaps the most comprehensive analysis of using pre-existing state statutory provisions to regulate surrogate contracts is the New Jersey Supreme Court's decision in *In re Baby M*.¹⁴⁰ The *Baby M* litigation grew out of a surrogate mother's desire to avoid her contractual obligation to give up her child to the biological father and adoptive mother. The New Jersey Supreme

134. In 1988 Michigan declared surrogacy contracts as against public policy and made participation in a surrogacy contract, involving the payment of compensation, a felony punishable by up to five years imprisonment and a fine of \$50,000. In the Act, a surrogacy contract is defined as one in which a woman agrees to relinquish her parental rights upon birth. The American Civil Liberties Union, representing three couples who wished to enter into surrogacy arrangements, sued the Attorney General and challenged the constitutionality of the Act. Wayne County Circuit Court, No. 88-819032-CZ (Mich. 1988). The circuit court held that the Act was valid but only after the Attorney General agreed that he would enforce the law only if the contract required the mother to give up the baby. It was the position of the ACLU that the mother should have the right to change her mind if unable to relinquish the child. Both sides hailed the decision as a victory, but the issue is once again before the Michigan legislature as to whether the law should be more narrowly drafted. See 1988 MICH. LEGIS. SERV. 199, § 5 (West).

135. KY. REV. STAT. ANN. § 199.500(5) (Michie/Bobbs-Merrill 1984).

136. In determining custody, courts usually give consideration to "the best interests of the child." See, e.g., KY. REV. STAT. ANN. § 403.270(1) (Michie/Bobbs-Merrill 1984).

137. 106 Mich. App. 169, 307 N.W.2d 438 (1981), cert. denied, 459 U.S. 1183 (1983). See *supra* notes 124-27 and accompanying text (discussing *Doe* in greater detail).

138. *Id.* at 170-72, 307 N.W.2d at 439-40.

139. *Skyrowski v. Appleyard*, 122 Mich. App. 506, 333 N.W.2d 90 (1983), rev'd, 420 Mich. 367, 362 N.W.2d 211 (1985) (allowing use of Paternity Act in surrogate arrangement, even where surrogate mother was married).

140. 109 N.J. 396, 537 A.2d 1227 (1988).

Court found the surrogacy contract conflicted with three statutory provisions. First, New Jersey forbids persons from paying or accepting money in connection with adoption.¹⁴¹ The court found that the parties to the surrogacy contract, as well as the Fertility Center, violated this provision because they used money in connection with adoption, thus, rendering the contract void.¹⁴²

Second, New Jersey only recognizes irrevocable termination of parental rights when the child is voluntarily surrendered to an approved agency or to the Division of Youth and Family Services accompanied by a written acknowledgment of termination of parental rights.¹⁴³ The surrogate mother had not surrendered the child to any such agency.¹⁴⁴ The court reasoned that because the state only provided for irrevocable termination of parental rights if the child was surrendered to an approved agency, it followed that a private placement adoption which circumvented appropriate agencies was always revocable. The surrogacy contract, however, called for an irrevocable surrender of parental rights. Therefore, the court concluded that the contract conflicted with New Jersey law and was void on this ground as well.¹⁴⁵

Finally, in addition to statutory conflict, the New Jersey Supreme Court found the statute void as against public policy.¹⁴⁶ The state's policy is to keep children with both of their natural parents to the greatest extent possible. Since the surrogacy contract at issue guaranteed permanent separation from one of the child's natural parents, Ms. Whitehead, the contract violated the state's policy.

However, not all states have been supportive of this use of more general statutory provisions to ban surrogate contracts in the absence of specific state legislative action. Perhaps the best example of this hesitancy is the trial court decision in *In re Baby M.*¹⁴⁷ The New Jersey Superior Court, in answer to the argument that the child born into a surrogacy arrangement will not be protected, stated:

141. N.J. STAT. ANN. 9:3-54a (West 1976). The statute provides:

No person, form, partnership, corporation, association or agency shall make, offer to make or assist or participate in any placement for adoption and in connection therewith (1) pay, give or agree to give any money or any valuable consideration, or assume or discharge any financial obligation; or (2) take, receive, accept or agree to accept any money or any valuable consideration.

142. 109 N.J. at 422, 537 A.2d at 1240.

143. See N.J. STAT. ANN. §§ 9:2-16 to-17 (West 1976); (voluntary surrender of child); *id.* § 9:3-41 (West Supp. 1988)(surrender must be by signed instrument); *id.* § 30:4C-23 (West 1976)(Bureau of Children's Services responsible).

144. 109 N.J. at 422, 537 A.2d at 1243. The State of New Jersey will terminate parental rights only where there is a finding of "intentional abandonment or a very substantial neglect of parental duties without a reasonable expectation of reversal of that conduct in the future." N.J. STAT. ANN. 9:3-48(c)(1) (West 1976).

145. 109 N.J. at 423-34, 537 A.2d at 1240-46.

146. *Id.* at 434-44, 537 A.2d at 1247-50. The state's policy is to keep children with both of their natural parents to the greatest extent possible. Because the surrogacy contract at issue guaranteed permanent separation from one of the child's natural parents, Ms. Whitehead, the contract violated the state's policy. *Id.*

147. *In re Baby M.*, 217 N.J. Super. 313, 525 A.2d 1128, (N.J. Super. Ct. Ch. Div. 1987).

So long as there is no legislation and some court action in surrogacy arrangements is required, the child born of surrogacy will be protected in New Jersey. If there is compliance with the contract terms, adoption will be necessary; hence, court inquiry about best interests must take place. If there is non-compliance with the contract, as in this case, best interests is still litigated with protection to the child, with its own guardian and experts retained to aid the court in its best interests determination.¹⁴⁸

The court also rejected the argument that a surrogate contract constitutes payment to purchase a child, as the father "cannot purchase what is already his;" consequently, it found that surrogacy did not fall within the state's laws of adoption.¹⁴⁹ Rather, the court looked to *parens patriae* concepts, which concern the best interests of the child, and contract law principles.¹⁵⁰ These considerations led the court to reject arguments that surrogacy would undermine traditional notions of family or exploit women of lower economic status.¹⁵¹ Finally, the court rejected the rule developed in Kentucky that the mother should have a time period after birth to change her mind, stating:

To wait for birth, to plan, pray and dream of the joy it will bring and then be told that the child will not come home, that a new set of rules applies and to ask a court to approve such a result deeply offends the conscience of this court. A person who has promised is entitled to rely on the concomitant promise of the other promisor. . . . Once conception has occurred the parties rights are fixed, the terms of the contract are firm and performance will be anticipated with the joy that only a newborn can bring.¹⁵²

Another example of the hesitancy to ban surrogate contracts in the absence of specific legislation is the Kentucky Supreme Court's decision in *Surrogate Parenting Association, Inc. v. Commonwealth ex. rel. Armstrong*.¹⁵³ In *Armstrong*, Kentucky's Attorney General instituted an action against Surrogate Parenting Association, Inc., (Association) in order to revoke its corporate charter. The Attorney General alleged that, by promoting surrogate contracts, the Association had misused and abused its corporate power in a manner which was detrimental to the state and its citizens.¹⁵⁴ The Association allegedly violated Kentucky's prohibition of the sale of children¹⁵⁵ and the

148. *Id.* at 371, 525 A.2d at 1157.

149. *Id.* at 372, 525 A.2d at 1157.

150. *Id.* at 372-73, 525 A.2d at 1157-58. The court relied on these concepts after it determined that surrogacy was unknown and unthought of when adoption statutes were drafted. Because adoption statutes were to be strictly construed, and surrogacy was not explicitly addressed by the statutes, the court relied on the concept of *parens patriae* and contract principles. *Id.*

151. *Id.* at 373, 525 A.2d at 1158. The court found that the "intense desire to propagate the species is fundamental." *Id.* Therefore, the notion that a wealthy upper class would use a poorer lower class to bear its children was considered "insensitive and offensive to the intense drive to procreate naturally" which is "within the soul of all men and women regardless of economic status." *Id.*

152. *Id.* at 375, 525 A.2d at 1157.

153. 704 S.W.2d 209 (Ky. 1986).

154. *Id.* at 210.

155. KY. REV. STAT. ANN. § 199.590(2) (Michie/Bobbs-Merrill 1984).

giving up of children for adoption prior to five days after their birth.¹⁵⁶

The Kentucky high court, however, refused to ban surrogate contracts under Kentucky's antibabyselling statute.¹⁵⁷ The court reasoned that the Kentucky statute was enacted to keep baby brokers from exerting pressure on expectant mothers to give their babies up for adoption to the highest bidder. In the surrogacy situation, these concerns were not present because the agreement was reached before the child was conceived. In response to arguments based on social and ethical considerations, the court added that these should be left to the legislature. Thus, the court found no outright ban on surrogate contracts.¹⁵⁸

Nonetheless, even the courts which have not banned surrogacy contracts under pre-existing state statutes have applied state law to limit their scope. For example, the trial court in the *Baby M* litigation determined that it must first decide what was in the best interests of the child, and that this interest was paramount over the contract rights of either party.¹⁵⁹ The standards set forth in the New Jersey child custody statute were, therefore, applicable to surrogate contracts.¹⁶⁰ After thoroughly reviewing the evidence, the court determined that the best interest standard dictated that the child be placed with the father.¹⁶¹ Only then did the trial court order specific enforcement of the surrogacy contract and terminate the surrogate mother's parental rights. The *Baby M* trial court's response is typical.

The courts have not yet considered the scenario of the gestational mother who does not wish to relinquish her nonbiologic child. In this area, however, the use of pre-existing regulations will be much more difficult. First, the adoption laws seem inappropriate because the biological parents would not be adopting the child. Second, the custody statutes are similarly inapposite because the natural parents are not opposing each other. Resolution of this question would appear to call for a novel application of existing principles.

c. In vitro fertilization

Of the three reproductive techniques discussed in this section, in vitro fertilization (IVF) is subject to the least regulation. Indeed, only a few states, including Louisiana and Pennsylvania, have attempted to regulate IVF or to prohibit the techniques.¹⁶² As a result of this lack of specific regulation, courts, as in the surrogacy area, have reasoned by analogy from existing state law to impose a degree of regulation upon the technique. Moreover,

156. *Id.* at § 199.601(2).

157. 704 S.W.2d at 211.

158. *Id.* at 214.

159. 217 N.J. Super. at 323, 525 A.2d at 1132.

160. *Id.* at 390-91, 525 A.2d at 1166-67.

161. *Id.* at 398, 525 A.2d at 1170.

162. LA. REV. STAT. ANN. § 9:121-133 (West Supp. 1989); PA. STAT. ANN., tit. 18, § 3213(e) (Purdon Supp. 1985). The Michigan legislature has considered such legislation. See H.B. 4554, 83d Leg. (1986).

because IVF is a newer phenomenon than surrogacy, but related to it, the analogies that have already been developed in surrogacy contracts are often applied directly to the IVF technique. For example, laws prohibiting the sale of a child for the purpose of adoption, where only the biological father makes the contract, have been construed to regulate IVF.¹⁶³

In addition to the limitations grounded in surrogacy doctrine, the organ transplant statutes as written in a few states may prohibit payment for eggs or sperm.¹⁶⁴ Moreover, some statutes, whose enactment was triggered by religious and moral concerns, prohibit the sale or transfer of embryos.¹⁶⁵ These statutes could also be construed to prohibit both payments to preembryo donors and the transfer of embryos in the IVF process.

C. *Emerging Social Policy Choices*

Neither the courts nor the legislature has clearly enunciated a social policy for the emerging reproductive technologies. It is clear, however, that the argument over proper policy in this area of biomedical technology must take into account the federal constitutional right to privacy. Under the federal Constitution, the most protected choices lie with the couple who wish to conceive their own biological child.¹⁶⁶ When a couple is unable to conceive, and consults with medical personnel, under current doctrine, the couple's privacy right as joined with the doctor-patient privilege can be invoked in order to constitutionally protect the use of noncoital techniques.¹⁶⁷ This application of the privacy right almost certainly would be upheld even by a conservative Supreme Court.

Furthermore, extension of this right beyond its present scope is possible, although doubtful. If the privacy right were extended beyond the couple's right to conceive their own biological child, the couple would then have the fundamental right to create, store, and have transferred to them extracorporeal preembryos created by their egg and sperm.¹⁶⁸ They would also have the right to determine whether their gametes would be used for reproduction and to determine the disposition of preembryos created with their gametes,

163. *Surrogate Parenting v. Commonwealth ex rel. Armstrong*, 704 S.W.2d 209 (Ky. 1986).

164. ALA. CODE § 367 [c][1] (1989); MD. HEALTH-GEN. CODE ANN. § 3.5 408(a)(3) (Supp. 1982); VA. CODE ANN. § 32.1-289 (1985).

165. ME. REV. STAT. ANN. tit. 22, § 1593 (1980); MASS. ANN. LAWS ch. 112, § 12 J(a) IV (Law. Co-op. Supp. 1982); MICH. COMP. LAWS ANN. § 333.2690 (West 1980); NEB. REV. STAT. § 28-342 (1979); N.D. CENT. CODE § 1-735A (Supp. 1982-83); R.I. GEN. LAWS § 11-54-1(f) (Supp. 1982); UTAH CODE ANN. § 76-7-311 (1978); WYO. STAT. § 35-6-115 (1977).

166. See *supra* notes 116-127 and accompanying text (discussing constitutional right to privacy in making decisions about procreation).

167. Such a scenario, when applied to a biological child of a couple, avoids the invocation of adoption procedures and, accordingly, the fatal analogy drawn by the Michigan court in *Doe v. Kelly*, 106 Mich. App. 169, 307 N.W.2d 438, (1981), *cert. denied*, 459 U.S. 1183 (1983), to a change in legal status. See *supra* notes 124-134 and accompanying text.

168. See *supra* notes 116-127 and accompanying text (discussing development of right to privacy under United States Constitution).

which would include a right to donate preembryos to other couples. Indeed, the right might also be found to extend to posthumous reproduction, which might occur with stored sperm or preembryos after the death of a spouse.

The problems have been addressed by a number of prominent legal organizations. At its February, 1989 mid-year meeting in Denver, the American Bar Association House of Delegates, in a vigorous exchange, approved the Uniform Status of Children of Assisted Conception Act promulgated by the National Conference of Commissioners on Uniform State Laws.¹⁶⁹ The report, noting that in 1987 a billion dollars was spent by Americans on infertility,¹⁷⁰ states: "[w]hat technology holds for the future is uncertain, but the law must provide clear rules of legal parentage for those children born through assisted conception."¹⁷¹ The report addresses surrogacy, invitro fertilization, artificial insemination, and all other artificial forms of procreation.¹⁷²

IV. STATUS OF THE PREEMBRYO, AND CRYOPRESERVATION OF PREEMBRYOS

In addition to concern over the safety of new reproductive techniques and the parentage of the newborn infant, there is much concern over treatment of the products of procreation, especially the result of noncoital reproduction—the preembryo.¹⁷³ This section will focus on laws regulating the treatment of the preembryo.

In IVF, if the sperm successfully fertilizes the egg, a "preembryo" results. A preembryo differs from an embryo in that only the outer cells which will form the extra-embryonic (feeding) sac are developed while the inner cells which form the embryo are undeveloped. Additionally, an embryo is imbedded in the wall of the uterus, a preembryo is not. Furthermore, the preembryo has only a moderate chance to successfully implant in the uterus and to come to term.

It is difficult to successfully fertilize an egg outside the human body, and it is even more difficult for a preembryo to successfully implant and carry itself to term. Consequently, when a couple undergoes IVF several gametes are fertilized. Of those gametes which successfully develop into preembryos, usually the three "best" are transferred to the woman. In some circumstances more than three preembryos might result. The additional preembryos would not be transferred to the woman. There is much controversy over the status

169. Uniform Status of Children of Assisted Conception Act (1989) (USCACA) drafted by the National Conference of Commissioners on Uniform Laws and approved and recommended for enactment in all states at the Annual Conference Meeting, Washington, D.C. (Aug. 5, 1988).

170. *Id.*

171. Report to the House of Delegates of the National Conference of Commissioners on Uniform State Laws I (1989).

172. *Id.*

173. Pre-embryo is defined as "[a] fertilized ov[um] not more than 14 days after fertilization." 1986-90 REPORTER ON HUMAN REPRODUCTION AND THE LAW 38.

of the preembryo and what to do with it if it is not going to be transferred to the woman.

If a preembryo is not going to be transferred to the woman, several possibilities exist. First, the couple undergoing IVF might choose to donate the preembryo to another couple. Second, the couple might choose to have the preembryo frozen, so that they could use it at a latter date. This is referred to as cryopreservation. Third, the couple might choose simply to dispose of the preembryo. There are moral and legal difficulties inherent in all of these choices.

If a couple chooses to donate the preembryo, they may have trouble finding a capable recipient. The preembryo must be transferred to a woman quickly and that woman must be at the appropriate stage in her menstrual cycle to receive the preembryo.

If a couple chooses to freeze the preembryo, ownership, as well as moral, dilemmas arise. First, if the couple divorces or one partner dies, who gets custody of the preembryo? Who has the power to say at what point the preembryo should be destroyed? Second, it is unclear whether frozen preembryos can successfully be defrosted, implanted in a woman, and come to term.¹⁷⁴ Finally, what is the preembryo? Is it human? What rights does it have?

Similar issues arise if the couple decides to dispose of the preembryo. The rights in this area are analogous to abortion rights. Moreover, if a couple wants to dispose of a preembryo, should a research institution be able to use the preembryo for research? This is currently the dispute in a lawsuit in Maryville, Tennessee. Another dispute in the Federal District Court in Norfolk, Virginia involves a lawsuit seeking the release from a medical institution of frozen embryos to the parents.¹⁷⁵ If so, how does this affect a woman who chooses an abortion? Should researchers also be able to take the fetus for use in research? As in the last section, this section of the Report will examine the potential constitutional restraints on regulation of the treatment of preembryos, as well as the current regulation and status of preembryos.

A. Constitutional Restraints on the Regulation of Preembryos

As was the case with the regulations examined in Part III, treatment of the preembryo also potentially implicates the federal Constitution. In concluding that the right of personal privacy includes the abortion decision, the Supreme Court has held, that "the unborn have never been recognized in the law as persons in the whole sense," and that "conception is a 'process' over time, rather than an event."¹⁷⁶ Applying these principles, it would appear that, in the IVF procedure, the couple whose genetic material was involved might have a constitutionally protected right to destroy any re-

174. See FERTILITY, *supra* note 131, at 53S-54S.

175. See Curriden, *Frozen Embryos The New Frontier*, 1989 A.B.A. J. 68 (August).

176. *Roe v. Wade*, 410 U.S. 113, 147 (1973).

maintaining fertilized ova which are not implanted into a woman.¹⁷⁷ In connection with this view, the Ethics Advisory Board unanimously agreed in 1979 that although a preembryo is entitled to profound respect, it is not entitled to the full legal and moral rights attributed to persons.¹⁷⁸

Nonetheless, a counterargument remains that *Roe v. Wade* was concerned solely with the right of a mother to carry a child and grounded in a woman's privacy rights in her own body. A preembryo, on the other hand, is conceived in a petri dish; the mother is not "carrying" it as she is an embryo. Under this interpretation, the Supreme Court's decision in *Roe* might not protect the decision to destroy a preembryo. Indeed, under this rationale, the right of the mother to destroy an extracorporeal embryo might not be constitutionally protected at all. A further result of this narrow reading of *Roe* would be that, because cryopreservation is still considered experimental, physicians could constitutionally be required to transfer all fertilized ova to the woman undergoing IVF. Requiring such a procedure, however, is dangerous and could inhibit the successful birth of a child through IVF.

B. Federal Regulation

Beginning in 1973, the Secretary of the Department of Health, Education and Welfare began to formulate a policy with respect to the protection of human subjects of research activities.¹⁷⁹ The final regulations, in 1975, concluded that the government would not fund any IVF, embryonic or fetal research until the Ethical Advisory Board (Board) reviewed the proposal and declared the procedure ethical.¹⁸⁰ The Board, however, ceased to exist in 1980, without ever having reached any conclusions and, accordingly, the department has never funded any such research. In the Health Research Extension Act of 1985, a Biomedical Ethics Board (BEB) and a Biomedical Ethics Advisory Committee (BEAC) were created with one charge—to report on fetal research. No report ensued, but Congress has reauthorized the BEB and BEAC in the Omnibus Health Extension Act of 1988.¹⁸¹

Even if the federal government allocated funds for such research, federal regulations require that an Institutional Review Board (IRB) approve all research involving humans.¹⁸² These IRBs must consider whether the research

177. When they choose to destroy remaining fertilized ova, a couple could rely on their constitutionally protected right of privacy in making decisions regarding procreation. See *supra* notes 116-127 and accompanying text (discussing right to privacy).

178. Human Subjects, *supra* note 130, at 35,056.

179. Dep't of HEW, Protection of Human Subjects, Policies and Procedures, 39 Fed. Reg. 30,648 (1974). Informed consent was the critical concern, particularly where a subject's capability of providing informed consent is absent or limited.

180. Dep't. of HEW, Rules and Regulations, Protection of Human Subjects, Fetuses, Pregnant Women, In Vitro Fertilization, 40 Fed. Reg. 33,526, 33,529 (1975) [hereinafter Human Subjects Rules].

181. See *supra* note 24 and accompanying text. The moratorium on federally funded research thus continues until October 31, 1990 or until the BEAC has reported.

182. As stated in Fanta, *Legal Issues Raised by In Vitro Fertilization and Embryo Transfer*

will be conducted in a manner that will minimize risks, whether the risks are reasonable in comparison to the anticipated benefits, and whether participants have been sufficiently informed to consent to the research. Additionally, the IRBs monitor data to insure the safety and privacy of the human subjects. Although no research on noncoital reproduction is currently being federally funded, most university medical centers receive other federal funds for research on humans, which requires IRB approval. Thus, most hospitals which practice IVF already have IRBs even without federal funding of IVF. While private IVF centers generally do not have IRBs, they may have advisory committees.¹⁸³ Additionally, some states require that IRBs be established.¹⁸⁴

C. State Regulation

As seen in Part III of this Report, the United States Constitution and case law protects the right of the woman to obtain an abortion, at least during the first two trimesters, prior to viability.¹⁸⁵ However, increasingly, embryos have gained protection in state statutes.

At early common law, a conviction for murder of a fetus could only be obtained if the fetus was born alive and subsequently died.¹⁸⁶ One reaction to this common law limitation has been to criminalize the destruction of a

in the United States, 2 J. OF IN VITRO FERTILIZATION AND EMBRYO TRANSFER 65, 67 (1985):

The regulations established the following criteria for IRB approval: (i) that the risks to subjects be minimized; (ii) that the risks to subjects be reasonable in relation to the anticipated benefits (but the IRBs were directed not to consider 'possible long range effects of applying knowledge gained in the research, for example, the possible effects of the research on public policy'); (iii) that the selection of subjects be equitable; (iv) that informed consent be sought from each prospective subject (the regulations established extremely detailed requirements for the method of procuring informed consent and the elements thereof); (v) that informed consent be appropriately documented (again, extremely detailed requirements were established); and (vi) that adequate provisions be made for (a) monitoring the data collected, (b) protecting the privacy of the subjects, and (c) maintaining the confidentiality of data.

Id. at 67.

183. However, it should be noted that the AID procedures, including surrogate mother arrangements, are usually carried out in a doctor's office, without any official scrutiny or screening of surrogate mothers. Many of the problems which result may be the result of an inadequately informed consent procedure in these private situations.

184. See FERTILITY, *supra* note 131, at 9S.

185. *Roe v. Wade*, 410 U.S. 113 (1973). See *supra* notes 146-156 and accompanying text for an analysis of the federal privacy right.

186. See, e.g., *Keeler v. Superior Court of Amador County*, 2 Cal. 3d 619, 627, 470 P.2d 617, 621, 87 Cal. Rptr. 481, 485 (1970) (husband beat wife after stating, "I'm going to stomp it out of you"; no liability under murder statute). *Accord* *People v. Greer*, 79 Ill. 2d 103, 402 N.E.2d 203 (1980); *State v. Gyles*, 313 So. 2d 799 (La. 1975).

fetus.¹⁸⁷ In Florida, for instance, it is manslaughter to willfully destroy a fetus.¹⁸⁸ Fetus is defined as an "unborn quick child."¹⁸⁹ But such laws would not apply to an extracorporeal embryo, because it is not "quick."

Louisiana, however, directly protects the preembryo. That state's statute considers "an in vitro fertilized human ovum . . . as a juridical person until such time as the in vitro fertilized ovum is implanted in the womb"¹⁹⁰ The statute creates a "high duty of care"¹⁹¹ for the donors, and the physician is directly responsible for the safekeeping of the fertilized ovum.¹⁹² Anyone who intentionally terminates an in vitro preembryo can be charged with homicide.

Similar to the Louisiana statute, an Illinois statute refers to the preembryo as a human being and entrusts the physician who performs IVF with the care and custody of the "child."¹⁹³ Furthermore, Illinois has a child abuse statute which makes it unlawful to permit a child to be endangered.¹⁹⁴ Thus, a physician may be guilty of child abuse if he destroys a preembryo. However, in response to a lawsuit involving this issue, the Illinois legislature amended the child abuse statute to except in vitro fertilization.¹⁹⁵ Notwithstanding this limitation with respect to in vitro fertilization, one commentator has noted that the statute could still be used to prosecute physicians or patients "who engage in embryo lavage¹⁹⁶ or cryopreservation."¹⁹⁷

Another approach to regulation is that taken by Pennsylvania. Pennsylvania monitors IVF by requiring that quarterly reports be filed on any IVF

187. FLA. STAT. ANN. § 782.09 (West 1983); GA. CODE ANN. § 26-1105 (Harrison 1983); MICH. COMP. LAWS § 750.322 (1975); MISS. CODE ANN. § 97-3-37 (1972); NEV. REV. STAT. § 200.210 (1985); OKLA. STAT. ANN. tit. 21, §§ 713-714 (West 1983). For further discussion of criminal statutes which include the fetus, see Andrews, *The Legal Status of the Embryo*, 32 LOY. L. REV. 357, 376 (1986).

188. FLA. STAT. ANN. § 782.09 (West 1976).

189. "The willful killing of an unborn quick child, by any injury to the mother of such child which would be murder if it resulted in the death of such mother, shall be deemed manslaughter." *Id.*

190. LA. REV. STAT. ANN. § 9:123 (West Supp. 1988).

191. *Id.* § 9:127.

192. *Id.* Further, the statute provides: "[A] viable in vitro fertilized ovum is a juridical person which shall not be intentionally destroyed" *Id.* § 9:129. As this author reads the statute, it could be interpreted to create a criminal case for homicide ("destruction" of a "juridical person"), though on its face, the statute is not clear.

193. ILL. REV. STAT. ch. 38, para. 81-26 (Smith-Hurd Supp. 1989).

194. ILL. REV. STAT. ch. 23, para. 2354 (1987).

195. *Smith v. Hartigan*, 556 F. Supp. 157 (N.D. Ill. 1983) (holding Illinois' in vitro fertilization statute did not absolutely prohibit in vitro fertilization).

196. Embryo lavage is an experimental procedure in which an ovum is fertilized in the mother's uterus, then washed out for transfer to the uterus of a surrogate who carries the embryo to term. This technique holds promise for women who can conceive but who cannot carry a child to term; the technique could allow them to have a child of their own.

197. Andrews, *supra* note 187, at 399.

procedure. The reports must include the number of fertilized ova,¹⁹⁸ the number of embryos destroyed, and the number of women in whom embryos are implanted.¹⁹⁹ A fine of \$50.00 per day for noncompliance is mandated.²⁰⁰

In a related area, many states have reacted to the federal abortion right by passing laws which ban embryo research with aborted fetuses.²⁰¹ The statutes carry criminal penalties.²⁰² At least six states specifically prohibit research on embryos,²⁰³ another six prohibit research on any product of conception,²⁰⁴ and six more states prohibit research on living preembryos

198. Superovulation may create as many as 17 eggs per laparoscopy, and if all fertilized, the record keeping may become burdensome, a point to be kept in mind in determining the constitutionality of such procedures. *See* Andrews, *supra* note 187, at 400.

199. PA. STAT. ANN. tit. 18, § 3213(e) (Purdon 1983).

200. *Id.*

201. ARIZ. REV. STAT ANN. § 36-2302 (1986); ARK. STAT. ANN. § 20-17-802 (1987); FLA. STAT. ANN. § 390.001(6),(7) (West 1986); IND. CODE ANN. § 35-1-58.5-6 (Burns 1985); LA. REV. STAT. ANN. § 14:87.2 (West 1986); ME. REV. STAT. ANN. tit. 22, § 1593 (1980); MASS. ANN. LAWS ch. 112, § 125 (Law. Co-op. 1985); MICH. COMP. LAWS ANN. §§ 333.2685-.2692 (West 1980); MO. ANN. STAT. § 188.037 (Vernon 1983); MONT. CODE ANN. § 50-20-108 (3)(1987); NEB. REV. STAT § 28-342, -346 (1979); N.D. CENT. CODE § 14-02.2-01 to -02 (1981); OHIO REV. CODE ANN. § 2919.14 (Baldwin 1982); OKLA. STAT. ANN. tit. 63, § 1-735 (West 1984); 18 PA. CONS. STAT. ANN. § 3216 (Purdon 1983); R.I. GEN. LAWS § 11-54-1 (Supp. 1985); UTAH CODE ANN. § 76-7-310 (1978); WYO. STAT. § 35-6-115 (1977).

202. ARIZ. REV. STAT. ANN. § 36-2303 (1987)(violator guilty of class 5 felony); FLA. STAT. ANN. § 390.001(10) (West 1986) (violator guilty of class A misdemeanor); LA. REV. STAT. ANN. § 14:87.2 (West 1986) (person committing crime of human experimentation imprisoned at hard labor for not less than five nor more than 20 years, or fined not more than ten thousand dollars, or both); ME. REV. STAT. ANN. tit. 22, § 1593 (1980) (punishable by a fine of not more than \$5,000 and by imprisonment for not more than 5 years); MASS. ANN. LAWS ch. 112, § 12J(a) V (Law. Co-op. 1985) (punished by imprisonment for not less than one year nor more than two and one-half years in jail or house of correction, imprisonment for not more than five years in state prison and fine of up to \$10,000); MICH. COMP. LAWS ANN. § 333.2691 (West 1980) (imprisonment for not more than five years); MO. ANN. STAT. § 188.075 (Vernon 1983) (violator guilty of class A misdemeanor); § 50-20-108 (4) (1987) (violator guilty of a felony); NEB. REV. STAT. § 28-344 (1979) (violation is class II misdemeanor); N.D. CENT. CODE § 14-02.2-02 (1981) (violation is class C felony); OHIO REV. CODE ANN. § 2919.14 (guilty of abortion trafficking, a first degree misdemeanor); 18 PA. CONS. STAT. ANN. § 3216 (Purdon 1983) (commits first degree misdemeanor); R.I. GEN. LAWS § 11-54-2 (Supp. 1985) (guilty of felony and fined at least \$1,000, or imprisoned for not less than one year nor more than 14 years).

203. ARIZ. REV. STAT. ANN. § 36-2302 (Supp. 1982-83); MASS. ANN. LAWS ch. 112, § 12(a)IV (Law. Co-op. Supp. 1984); MICH. COMP. LAWS ANN. § 333.2685 (West 1980); N.D. CENT. CODE § 14-02.02 (1981); OHIO REV. CODE ANN. § 2919.14 (Baldwin 1982); R.I. GEN. LAWS § 11-54-1(f) (Supp. 1982).

204. KY. REV. STAT. ANN. § 436.026 (Michie/Bobbs-Merrill 1975), § 311.720(5),(6) (Michie/Bobbs-Merrill 1983); LA. REV. STAT. ANN. § 14:878.2 (West 1974), § 40:1299.35.1(2), to .35.13 (West Supp. 1984); MASS. ANN. LAWS ch. 112, § 12J(a)IV, K (Law. Co-op. Supp. 1984); MO. ANN. STAT. §§ 188.037, 188.015(5) (Vernon 1983); OKLA. STAT. ANN. tit. 63, §§ 1-735, §§ 1-730(2) (West 1984); PA. STAT. ANN. tit. 18, §§ 3216, 3203 (1983).

that are not the products of abortion.²⁰⁵ Eighteen states prohibit embryo research, but they specifically limit this prohibition to abortion procedures.²⁰⁶ These statutes, therefore, are not relevant to cryopreservation or IVF where no abortion has occurred. Nonetheless, one commentator has noted: "[E]mbryo transfer after in vitro fertilization might be banned since the definition of abortion is broad enough to encompass the flushing technique used in uterine lavage."²⁰⁷ Thus, it appears possible that these statutes may be interpreted to extend to experimentation on preembryos which result from noncoital reproduction.²⁰⁸

In addition, half of the states have fetal research laws which prohibit nontherapeutic research with fetuses and embryos. These statutes also apply to IVF preembryos which are not implanted.²⁰⁹ The language and range of the statutes varies.²¹⁰ Those experimental reproductive techniques which risk loss of embryos, such as cryopreservation or embryo donation, or which involve use of less than all of the fertilized ovum might be prohibited under such laws.²¹¹ At best, they create an area of uncertainty for medical personnel.

Other statutes prohibit the donation of fetuses for research or experimentation.²¹² Seven states with this prohibition potentially prohibit a woman who conceives a preembryo from donating it,²¹³ and five of these might prohibit a woman from having some of her preembryos frozen for use by a second woman.²¹⁴ State statutes regarding ownership and disposition of unused embryos and gametes have also been considered.²¹⁵ For example, one Illinois statute, since repealed, allowed a woman to terminate an extracorporeal embryo.²¹⁶

205. ME. REV. STAT. ANN. tit. 22, § 1593 (1980); MASS. ANN. LAWS ch. 112, § 12J (Law. Co-op. Supp. 1983); MICH. COMP. LAWS §§ 333.2685-333.2692 (West 1980); N.D. CENT. CODE §§ 14-02.01, 14.02-02 (1981); R.I. GEN. LAWS § 11-54-1 (Supp. 1982); UTAH CODE ANN. § 76-7-310 (1978).

206. See *supra* note 201 (listing states).

207. Andrews, *supra* note 187, at 397.

208. *Id.* at 397 n.228.

209. ME. REV. STAT. ANN. tit. 22, § 1593 (1980); MASS. ANN. LAWS ch. 112, § 12J (Law. Co-op. 1985); MICH. COMP. LAWS ANN. § 333.2685 to .2692 (West 1980); N.D. CENT. CODE §§ 14-02.2-01, 2-02 (1981); R.I. GEN. LAWS § 11-54-1 (Supp. 1985); UTAH CODE ANN. § 76-7-310 (1978).

210. See *supra* note 209 (sampling of statutes).

211. Andrews, *supra* note 187, at 397.

212. See FERTILITY, *supra* note 131, at 9S.

213. ME. REV. STAT. ANN. tit. 22, § 1593 (1980); MASS. ANN. LAWS ch. 112, § 12J(a)IV (Law. Co-op. Supp. 1982); MICH. COMP. LAWS ANN. § 333.2690 (West 1980); NEB. REV. STAT. § 28-342 (1979); N.D. CENT. CODE § 14-02.2-02 (1981); R.I. GEN. LAWS § 11-54-2(f) (Supp. 1982); WYO. STAT. § 35-6-115 (1977).

214. ME. REV. STAT. ANN. tit. 22, § 1593 (1980); MASS. ANN. LAWS ch. 112, § 12J(a)IV (Law. Co-op. Supp. 1982); MICH. COMP. LAWS ANN. § 333.2690 (West 1980); N.D. CENT. CODE § 14-02.2-02 (1981); R.I. GEN. LAWS § 11-54-2 (f) (Supp. 1982).

215. ANDREWS, *supra* note 187 at 403.

216. ILL. REV. STAT. ch. 38, para. 81-6(7) (1987).

*Del Zio v. Columbia Presbyterian Medical Center*²¹⁷ exemplifies the confusion and emotional underpinnings surrounding the status of the preembryo. In 1973, a physician at Columbia-Presbyterian Hospital incubated a test tube preembryo without prior authorization. The Chief of Obstetrics and Gynecology removed the tube from incubation, thus, destroying the preembryo. He stated that the basis for the destruction was that the procedure was unethical and immoral and needed the prior approval of the hospital's human experimentation committee. The plaintiffs argued that through the destruction of the preembryo the doctor had intentionally inflicted emotional distress on the plaintiff and had wrongfully converted someone else's property. The jury awarded damages for emotional distress, but rejected the conversion claim.²¹⁸

D. Social Policy Choices

The ethical and policy issues generated by new reproductive techniques have been addressed by various ethical, medical, and governmental groups. In 1979, the Ethics Advisory Board reported that it is ethically acceptable to research IVF and embryo transfer,²¹⁹ provided certain conditions are met.²²⁰ The report advocated a model or uniform law to clarify the rights and responsibilities of donors and recipients of offspring resulting from IVF.²²¹

Perhaps the most comprehensive statement of social policy has come from the American Fertility Society Committee. In a report, the Committee stated the preembryo was not a person but should be treated with profound respect. Furthermore, if implantation is possible, the preembryo deserves more respect, because it is a potential person. Moreover, research on a preembryo which can survive embryo transfer requires an obligation not to harm the potential offspring.²²² However, the question of whether all preembryos must

217. No. 74-3558 slip op. (S.D.N.Y. Nov. 14, 1978).

218. *Id.* See Sweeny & Goldsmith, *Test Tube Babies: Medical and Legal Considerations*, 2 J. OF LEGAL MED. 9 (1980).

219. Human Subjects, *supra* note 130, at 35,057.

220. These conditions consisted of (a) "that the research compl[y] with . . . regulations governing research with human subjects," i.e., the regulations respecting risk and informed consent; (b) that [t]he research [be] designed primarily to establish the safety and efficacy of embryo transfer and to obtain important scientific information toward that end not reasonably attainable by any other means; (c) that the "gametes used be obtained exclusively from persons who have been informed" of their proposed use and who "have specifically consented to such use"; (d) that "[n]o embryos will be sustained *in vitro* beyond the stage normally associated with the completion of implantation (14 days after fertilization)"; (e) "[a]ll interested parties and the general public will be advised if evidence begins to show that the procedure entails risks of abnormal offspring higher than those associated with natural human reproduction" and (f) that embryo transfer "be attempted only with gametes obtained from lawfully married couples." Fanta, *supra* note 182, at 67.

221. Human Subjects, *supra* note 130, at 33,058.

222. [W]e find a widespread consensus that the preembryo is not a person but is to be treated with special respect because it is a genetically unique, living human entity

be transferred to a uterus and whether research can be done with nontransferred preembryos is less clear.²²³

With respect to cryopreservation of preembryos, the Committee reviewed the advantages for screening preembryos for disease or deformities and preserving them for later use, or donating them to other infertile couples; against the risk of preembryo injury and extension of the normal reproductive span. The Committee concluded that research on cryopreservation should be pursued, but carefully monitored.²²⁴ Nonetheless, the Committee further concluded that cryopreservation should not be used as a clinical technique; rather, it should continue to be viewed as strictly experimental.²²⁵

With respect to preembryo research, the Committee concluded that research on human gametes prior to fertilization is of less concern than research on fertilized gametes.²²⁶ Fertilized gametes, on the other hand, should not even be maintained beyond the fourteenth day of postfertilization development.²²⁷ Although this time limitation is somewhat arbitrary, it recognizes, that beyond this time, the definitive embryo and placenta may be structurally discriminated, individuality seems assured, and anatomic differentiation of the embryonic corpus begins. Moreover, because of the high moral value accorded to each human preembryo, any requests to do research on human preembryos requires strong justification. Indeed, the matter is of such grave public importance that approval of preembryo research should require conformity with guidelines established at the national level.

that might become a person. In cases in which transfer to a uterus is possible, special respect is necessary to protect the welfare of potential offspring. In that case, the preembryo deserves respect because it might come into existence as a person. This viewpoint imposes the traditional duty of reasonable prenatal care when actions risk harm to prospective offspring. Research on or intervention with a preembryo, followed by transfer, thus creates obligations not to hurt or injure the offspring who might be born after transfer.

FERTILITY, *supra* note 131, at 30S.

223. *Id.*

224. *Id.* at 55S.

225. The Committee therefore believes that research using cryopreservation techniques should be pursued, with careful oversight, in those centers that perform this type of research. It appears at present that a general clinical application of freezing human preembryos is inappropriate. The use of human preembryo material for cryopreservation therefore should be viewed as a clinical experiment until such time as the success rate and preembryo risks are clearly defined.

Id. at 55S.

226. The Committee finds that in research with the use of human preembryos, the following guidelines should apply. Gametes, before fertilization are of lesser concern than their postfertilization products. Accordingly, unfertilized eggs are not accorded comparable worth to human preembryos at any postfertilization stage; this view recognizes that some preembryos can progress to the development of children.

Id. at 57S.

227. Several committees have reached this conclusion, including the Ethics Committee of the American Fertility Society in 1984, Great Britain's Warnock Committee also in 1984, and Australia's Waller Commission in 1983.

CONCLUSION

It is generally agreed that the public needs more information about the process, limitations, and effects of the new biomedical technology, and that the present federal structure has allowed for this only in a limited way.²²⁸ The congressional technology office published a survey of 1,273 adults in May, 1987, and found that a majority of those interviewed believed that the potential benefits of genetic engineering outweighed its risks, although they were disturbed by manipulations in human embryos among other things. As one commentator has succinctly stated: "The challenge facing the law is to develop mechanisms that will provide adequate protection for the public from unreasonably dangerous advances in biotechnology without fettering progress."²²⁹

228. Cowen, *In the Rear and Limping a Little: Some Reflections on Medicine, Biotechnology and the Law: The Roscoe Pound Lectures*, 64 *N.B. L. REV.* 548, 555 (1985).

229. Permut, *Biotechnology Law: Public Protection or Stifled Progress*, 1986 *Del. Law.* 26 (Summer).