1-1-2002

Recognizing the Need for Uniform International Regulation of Developing Biotechnology: A Focus on Genetic Experimentation

Paul Hanna

RECOGNIZING THE NEED FOR UNIFORM INTERNATIONAL REGULATION OF DEVELOPING BIOTECHNOLOGY: A FOCUS ON GENETIC EXPERIMENTATION

I. INTRODUCTION

As new developments in the field of recombinant DNA technology become commonplace in the international arena, the need for a uniform system of regulatory laws that protect health and human safety becomes readily apparent. Genetic technology and its regulation pose a number of problematic issues.[1] These issues include: risk to health and the environment, choices made by patients and consumers, property rights, confidentiality and ethics, to name a few.[2] "Social, political and ethical controversy surrounds most of the recent advances in scientists' abilities to understand and manipulate genes on a molecular level."[3] "Like most modern technologies, [however,] biotechnology cannot be easily confined within the borders of a single state."[4] When people, animals and other organisms travel, they carry within them unique biotechnology products regulated by the laws of the region in which they are developed.[5] Thus, regardless of the strengths or weaknesses of the regulatory standards in any one region, those standards are routinely imposed upon the inhabitants of every region of the world when genetically modified individuals and organisms travel.[6]

Historical atrocities in Nazi Germany in the field of eugenics[7] experimentation on human subjects exemplify the failure of incon-

---

1. *See* Julia Black, *Regulation as Facilitation: Negotiating the Genetic Revolution*, 61 MOD. L. REV. 621 (1998).

2. *See id.*

3. Julie L. Gage, *Government Regulation of Human Gene Therapy*, 27 JURIMETRICS J. 200 (1987).

4. Thomas O. McGarity, *International Regulation of Deliberate Release Biotechnologies*, 26 TEX. INT'L. L.J. 423, 424 (1991).

5. *See id.*

6. *See id.*

7. Sir Francis Galton introduced the term eugenics and defined it as "the studies of the agencies under social control which may improve or impair the racial qualities of future generations physically or mentally." JOHN F. KILNER ET AL., GENETIC ETHICS: DO THE ENDS JUSTIFY THE GENES? 27 (1997).

sistent national regulation of genetic experimentation. The recurrence of such atrocities must be curbed by the creation and enforcement of uniform international regulatory standards for genetic experimentation. Furthermore, the emergence of widespread testing of gene therapy illustrates the importance of universal standards to prevent abuse in the application of this new technology. Such standards should also promote the changing direction of preventative medicine and human health care.

Part II of this comment discusses the practice of genetic experimentation and its impact on all human beings. It provides a brief overview of the basic elements of human genetics and genetic disease. It also introduces the practice of genetic experimentation as a therapeutic approach to disease control and prevention. It then focuses on the history of abuses in the field of genetics with a description of eugenics principles that gained international notoriety during the Second World War. Next, it discusses the reemergence of eugenics principles in modern applications of genetic research, specifically in the application of germ-line genetic experimentation. It further explores the prospect of enhancement gene alteration and the practice of selective reproduction. Finally, it discusses the biological disparities that would arise from unequal access to gene therapy treatments. Part III describes the current status of international and national regulation of the use of modern, often experimental, medical technology on humans. It describes how these regulations can and are applied to the practice of genetic experimentation. Part IV proposes a framework for uniform international regulation of human genetic experimentation and briefly examines the issue of enforcement of any such international framework.

II. UNIVERSAL NATURE OF GENETICS AND THE IMPACT OF GENETIC EXPERIMENTATION

A. Overview of Human Genetics and Disease

"When finally interpreted, the genetic messages encoded within our DNA molecules will provide the ultimate answers to the chemical underpinnings of human existence."[8] Deoxyribonu-

8. MAXWELL J. MEHLMAN & JEFFREY R. BOTKIN, ACCESS TO THE GENOME: THE CHALLENGE TO EQUALITY 14 (1998).

cleic acid (DNA) is the functional unit of biological inheritance.[9] The organization of DNA is fundamentally the same in all people.[10] This commonality of genetic composition is exemplified by the fact that the genetic "blueprint" may be understood by reference to a limited number of genetic models.[11]

Genes are composed of DNA, which control the synthesis of proteins.[12] Proteins, in turn, serve as structural components of various parts of the body, such as skin, bones, eyes and hair.[13] While "not every mutation causes disease"[14] or defects, mutations in critical portions of important genes result in genetic disease.[15] Genetic diseases may arise spontaneously or as a result of environmental influences.[16] In any event, genetic diseases are responsible for much human suffering.[17] The ability to interpret genetic messages would help explain not only how we function as healthy human beings, but also the role of genetic factors in a multitude of diseases "that diminish the lives of so many millions of people." [18]

B. Benefits of Human Genetic Experimentation: The Promise of Gene Therapy

The desire to find effective and permanent cures for genetic diseases that impact so many lives has been the driving force behind much of gene therapy research.[19] "Gene therapy is the intentional alteration of genes in cells or tissues in such a way as to treat or prevent an inherited disorder, or to make another pathological condition more amenable to treatment."[20] Gene therapy introduces one or more genes into cells to treat, diagnose or prevent

---

9. *See id.*
10. *Id.* at 15.
11. *See id.*
12. M. A. SANTOS, GENETICS AND MAN'S FUTURE: LEGAL, SOCIAL, AND MORAL IMPLICATIONS OF GENETIC ENGINEERING 9 (1981).
13. *Id.*
14. LEROY WALTERS & JULIE GAGE PALMER, THE ETHICS OF HUMAN GENE THERAPY 15 (1997).
15. *Id.*
16. *Id.*
17. *Id.*
18. MEHLMAN, *supra* note 8, at 14.
19. SANTOS, *supra* note 12, at 15.
20. THE REPORT OF THE CATHOLIC BISHOPS' JOINT COMMITTEE ON BIOETHICAL ISSUES, GENETIC INTERVENTION ON HUMAN SUBJECTS 6 (1996) [hereinafter BISHOP'S COMMITTEE].

diseases linked to genetic anomalies.[21] There are two types of gene therapy: 1) somatic-cell and 2) germ-line.[22]

1. Somatic-Cell Gene Therapy

Somatic-cell therapy involves manipulation of any cells that do not have the potential to contribute to the genetic material of offspring.[23] Many genetic disorders are treatable through somatic-cell gene therapy.[24] Various types of cancer and HIV infection/AIDS,[25] among other major diseases, are currently being targeted in somatic-cell gene therapy experiments.[26] Scientists anticipate using somatic-cell gene therapy in future treatments of hemoglobin diseases and muscular dystrophy.[27]

Critics of gene therapy contend that the use of somatic-cell gene therapy is too expensive, noting that applications of current techniques cost at least $100,000 per year per patient.[28] They also assert that alternative drug treatments for individuals with genetic diseases are improving, making costly somatic-cell gene therapy techniques unnecessary.[29]

Supporters of gene therapy theorize that it will someday be used to prevent disease as routinely as immunizations and antibiotics are used today.[30] One such visionary, Dr. W. French Anderson, has dreamed of the day when gene therapy will be used in a practical way to relieve human suffering, "I'd like to go to Africa with 10,000 vials and inject the gene to cure sickle-cell anemia."[31] These ideals have likely motivated the extensive financing used to advance somatic-cell gene therapy.

---

21. Charles F. De Jager, *The Development of Regulatory Standards for Gene Therapy in the European Union*, 18 FORDHAM INT'L L.J. 1303, 1307 (1995).
22. *Id.* at 1307-1308.
23. *Id.* at 1308.
24. *Id.* at 1310.
25. WALTERS, *supra* note 14, at 25.
26. *Id.* Other genetic diseases include: Cystic Fibrosis, Gaucher disease (type I), SCID, Familial hypercholesterolemia, Alpha 1-antitrypsin deficiency, Fanconi anemia, Hunter Syndrome (mild form), chronic granulomatous disease and purine nucleoside phosphorylase (PNP) deficiency. *Id.*
27. *Id.* at 35-36.
28. *Id.* at 53.
29. *Id.*
30. *Id.*
31. Daniel Glick, *A Genetic Road Map*, NEWSWEEK, Oct. 2, 1989, at 46.

2. Germ-Line Gene Therapy

Germ-line therapy involves manipulation of germ-line cells, including gametes, zygotes and undifferentiated cells of embryos in the early stages of development.[32] Germ-line gene therapy could potentially be performed in sperm or egg cells, although current studies involve only zygotes and pre-implantation embryos.[33] When an altered gene is added to a zygote or cells of a pre-implantation embryo, it reproduces into a healthy gene in the zygote or embryo.[34] Essentially, germ-line therapy serves the function of "reducing the incidence of certain inherited diseases in the human gene pool."[35] Ideally, the successful practice of germ-line therapy will treat genetic disease either before or shortly after conception of the "patients" who are to be treated.[36]

There are many reasons why germ-line therapy should be pursued. First, it may be the only way to reach developing brain cells or to prevent irreversible damage to the developing embryo.[37] Second, although more expensive to administer than traditional, and even somatic-cell gene therapy, the long-term benefits far outweigh the increased cost.[38] From a medical and public health perspective, if germ-line therapy is applied both to affected individuals, as well as those carriers of defective genes who do not manifest symptoms of disease, it would decrease the occurrence of genetic disease within the human gene pool.[39] In the long run, the benefit to the human race is immeasurable.

As illustrated above, the benefits of germ-line gene therapy are many. They suggest that the use of this type of genetic experimentation should remain a viable field of scientific research. The development of germ-line gene-therapy could be placed among the "[m]yriad biotechnology applications [with] the potential to alleviate some of the most pressing problems facing the global community, as well as to reduce dramatically human suffering and to improve the quality of life, particularly in the develop-

---

32. De Jager, *supra* note 21, at 1308.
33. WALTERS, *supra* note 14, at 62.
34. *Id.*
35. *Id.* at 63.
36. *Id.* at 74.
37. *Id.* at 80-81.
38. *Id.* at 81.
39. *See id.*

ing world."[40]

C. Potential Dangers of Human Genetic Experimentation

The great potential for benefit of germ-line therapy, however, must be balanced against the potential for abuse. "[T]he global community ought to coordinate and augment traditional treaty regimes"[41] to ensure the greatest degree of medical benefit with minimal risks of abuse in the experimental process.

1. History of Abuses in Genetics: The Principles of Eugenics

Experimentation in the field of genetics was introduced to the world through the reported atrocities of Nazi Germany's experimentation with eugenics.[42] In 1883, British biologist, Sir Francis Galton, introduced the term eugenics and defined it as "the studies of the agencies under social control which may improve or impair the racial qualities of future generations physically or mentally."[43] Galton sought to "maximize intelligence and prevent feeblemindedness. . .[by] advocat[ing] marital arrangements to breed a highly intelligent group of men for a number of generations."[44]

The Nazi practice of eugenics was termed "racial hygiene" by the German social Darwinist, Alfred Ploetz.[45] He attacked traditional medicine as "medical practice that helps the individual but endangers the race by allowing individuals, who would not have otherwise survived, to live and reproduce themselves."[46]

At the center of Hitler's policies were programs "aimed at ending racial deterioration."[47] The government passed the Sterilization Act, intending to prevent "hereditary taint."[48] The Act called for sterilization in cases of "'congenital mental deficiency,' schizophrenia, 'madness,' congenital epilepsy, Huntington's chorea, blindness, deafness,. . .serious disability. . .and 'chronic alco-

---

40. Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 1, 47 (2001).
41. *Id.* at 49.
42. *See* KILNER, *supra* note 7, at 27.
43. *Id.* at 25.
44. *Id.* at 26.
45. *See id.*
46. *Id.*
47. *Id.* at 27.
48. ARTHUR ROGERS & DENIS DURAND DE BOUSINGEN, BIOETHICS IN EUROPE 26 (1995).

hol[ism].'"[49] An explanatory text attached to the Act states that "German people 'cannot afford the luxury of allowing the person concerned to choose whether or not to be sterilized.'"[50] Between 1934 and 1937, approximately 400,000 sterilizations took place in Germany.[51]

The practice of eugenics, however, was not limited to Nazi Germany.[52] Switzerland, for example, passed the first European sterilization law permitting sterilization of those likely to produce "degenerate offspring."[53] Before 1930, 15,000 individuals in the United States were sterilized in accordance with laws passed in twenty-eight states, which allowed for sterilization of the mentally ill and criminally insane to discourage "socially disadvantageous" breeding.[54] By 1939, 30,000 people in the United States were sterilized in the name of eugenics.[55] Towards the end of the Second World War, however, sterilization practices in the United States dropped significantly. Enforcement of sterilization laws was almost nonexistent in the 1950s.[56]

2. Resurgence of Eugenics Principles

Some critics argue that human beings have a right to inherit a genome that has not been artificially changed.[57] Critics of germline therapy, specifically human rights advocates, argue that "human beings have a moral right to receive from their parents a genetic patrimony that has not been subject to artificial tampering."[58] This is consistent with arguments against germ-line therapy that contend it invests in a small group of human beings too much control over the evolution of the human race in the reshaping of the genetic code.[59] These objections to germ-line therapy reflect a strong resistance to artificial manipulation of DNA that shapes the genetic traits of future generations.[60]

---

49. *Id.* at 27.
50. *Id.* at 26.
51. *See* KILNER, *supra* note 7, at 27.
52. *See id.*
53. *Id.*
54. *Id.*
55. *Id.*
56. *Id.* at 28.
57. BISHOP'S COMMITTEE, *supra* note 20, at 31.
58. WALTERS, *supra* note 14, at 84.
59. *Id.*
60. *See id.*

Others argue that germ-line therapy revives principles of Nazi racial hygiene programs that would allow government leaders to attempt to produce "a class of superior human beings."[61] The by-products of past eugenics abuses by the national socialist regime have "placed a permanent blot on the reputation of medical science, while providing irrefutable evidence of the consequences of a policy based on the selection of the fittest."[62] These criticisms, and the fear of future abuses, have obvious merit.[63] Fear of the powerful tool of gene therapy, however, should not stand in the way of its immense potential for disease control and prevention.[64] With appropriate, enforceable regulatory standards for the application of germ-line gene therapy, this developing technology may serve as one of the most positive, significant medical advances in history.

a. Enhancement Genetics

One highly criticized form of genetic experimentation does not involve correcting abnormal genes or curing disease.[65] Enhancement genetics works to "amplify 'normal' genes in order to make them 'better.'"[66] There are currently five types of enhancements that are products of genetic engineering.[67] These include: size (growth hormone therapy may take the form of germ-line or somatic-cell gene therapy),[68] sleep (gene therapy may be used to alter genes that encode for proteins that regulate the sleep-cycle),[69] aging (experiments have shown that mutating a single gene (the *age-1* gene) in non-human organisms has prolonged life by 40-60%), memory[70] and aggression.[71]

"Genetic enhancement raises a host of ethical, legal, and social questions."[72] Some contend that it is not enough to merely distinguish between genetic experimentation for therapy and for

---

61. *Id.*
62. ROGERS, *supra* note 48, at 30.
63. *See id.*
64. *Id.* at 85.
65. MEHLMAN, *supra* note 8, at 35.
66. *Id.*
67. WALTERS, *supra* note 14, at 101.
68. *Id.* at 101-102.
69. *Id.* at 102-103.
70. *Id.* at 104-106.
71. *Id.* at 106-107.
72. Maxwell J. Mehlman, *How Will We Regulate Genetic Enhancement?* 34 WAKE FOREST L. REV. 671, 673 (1999).

genetic enhancement in determining whether enhancement therapy is ethical.[73] Instead, the argument continues, where enhancement is involved, experimentation should be deemed "morally wrong if done with improper motives."[74] The fact that genetics may be used as a vehicle to advance improper motives, however, must not, in and of itself, render attempts at physical or mental enhancement altogether immoral.[75]

Individuals are constantly attempting to enhance their appearance and their minds through unnatural methods.[76] These methods are not more ethical simply because they do not employ genetics to achieve the desired results.[77] Accordingly, a focus on the intent of the therapy, the degree of voluntariness (or parental consent) and motivation are more appropriate factors for determining when enhancement therapy is ethically acceptable.[78] Using these criteria to determine the appropriateness of the gene therapy would better protect the public. For example, should a national leader seek to utilize genetic enhancement to create a uniform, "superior race," such motivation would be deemed unethical since it is motivated by eugenics principles.[79]

b. Unnatural Selection

Many worry that increased knowledge of genetic information increases the potential for abuses of the type that existed during the early days of eugenics practice.[80] "The power of the information to be gained from [genetic] mapping and sequencing projects raises concerns about how it will be used."[81] "The only way to ensure that history does not repeat itself is for the scientific and medical communities to remain constantly vigilant for abuses of genetics."[82]

Today, eugenics is practiced in a subtler manner. Such practices that reflect eugenics principles, absent the overtly unethical appearance of historical eugenics, include sperm and egg banks

---

73. KILNER, *supra* note 7, at 189.
74. *Id.*
75. *See id.*
76. *See id.*
77. *See id.*
78. *See id.* at 188.
79. *See id.* at 189.
80. *Id.* at 29.
81. *Id.* at 25.
82. *Id.*

such as the "Repository for Germinal Choice."[83] Established in the 1950s, the sperm bank "offer[ed] artificial insemination using sperm donated by 'superior' persons."[84] The ideal behind this particular bank was to "decrease the 'genetic load'. . .of potentially lethal genes in the human gene pool."[85]

Another example of applied modern eugenics principles is genetic counseling.[86] The goals of genetic counseling are not to create a uniform race or to specifically alter the gene pool in any particular manner.[87] Genetic counseling does, however, have the ultimate effect of influencing potential parents in their decision to have children based on the possibility of defective genetic traits in their offspring.[88] This form of eugenics is more properly described as laissez-faire eugenics.[89] This is an appropriate description for genetic counseling as one of the goals "is to enable families in which a genetic disorder exists to choose the courses of action that are best for them, and to make choices while taking into consideration their own values and beliefs in both reproductive decision-making and follow-up care."[90]

3. Inequitable Access to Medical Technology

a. Potential for Decline in Genetic Diversity

"There are long-term concerns about whether the widespread use of genetically modified products could accelerate the decline in global biological diversity."[91] In order for individuals to gain access to genetic technology, there must be an adequate supply, it must be affordable and individuals must be informed about it.[92] Access to traditional modes of health care, however, has historically been wealth-based.[93] This has caused inequities on both domestic and international levels.[94] Given the current social and

---

83. *Id.* at 29.
84. *Id.*
85. *Id.*
86. *Id.*
87. *See id.*
88. *See id.* at 147-148.
89. *See id.*
90. *Id.* at 148.
91. Murphy, *supra* note 40, at 48.
92. MEHLMAN, *supra* note 8, at 55.
93. *Id.* at 86.
94. *See, e.g.*, PHILIP KITCHER, THE LIVES TO COME 324 (1996).

economic disparities among social classes, creating unequal access to genetic experimentation may potentially create a greater separation between the rich and the poor.

b. Depletion of Resources for the Treatment of Other Diseases

A major concern for genetic research worldwide is prioritizing the allocation of limited medical resources.[95] "Everyone has the right to enjoy the benefits of scientific progress and its applications."[96] Essentially, the question is whether it is ethical to allocate medical research resources to treat diseases traceable to single genes, or whether those resources should be used to treat more serious conditions prevalent in third and fourth world nations.[97] Unfortunately, the global trend has been for affluent governments to provide large funding for research to treat relatively uncommon genetic disorders, while providing comparatively insufficient funds to nations where "millions of children die of malaria."[98] The disparity among nations in funding and the focus of genetic research should be considered as international regulation of genetic research develops.

III. THE CURRENT STATE OF REGULATORY LAW APPLICABLE TO GENETIC EXPERIMENTATION

Genetic research has a global impact. As such, "regulation has an important role to play . . . in facilitating the integration of the wide range of views as to the appropriate course that the technology and its regulation should take."[99] In an attempt to meet this goal, and to protect this technology from abuses, international guidelines have been established in the form of the Nuremberg Code[100] and the Helsinki Declaration.[101] These guidelines show

---

95. *See id.*

96. *Vienna Declaration and Programme of Action*, U.N. GAOR, 48th Sess., pt. I, 22d mtg. 21.7.1.(a)(i-vi), U.N. Doc. A/CONF.157/24 (1993).

97. *Id.*

98. *Id.*

99. *See* Black, *supra* note 1, at 621.

100. 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MIL. TRIBUNALS UNDER CONTROL COUNCIL Law No. 10, 181-182 (1949) *available at* http://ohsr.od.nih.gov/ Nuremberg.php3 [hereinafter *Nuremberg Code*].

101. World Medical Association, *Declaration of Helsinki, reprinted in* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 333-336 (George J. Annas & Michael A. Grodin eds., 1992) [hereinafter *Helsinki*].

an appreciation for "the need for human experimentation while accepting that this can only be accomplished at the expense of some of the subjects' right to self-determination."[102]

A number of nations that actively regulate the practice of human subject experimentation have implemented and attempted to expand the principles in the Helsinki Declaration.[103] This section discusses the focus and effect of international, European and U.S. regulatory standards for genetic experimentation on humans.

A. Scientific Experimentation on Humans: The Nuremberg Code and Helsinki Declaration

International declarations arose in response to abuses of scientific experimentation on human subjects.[104] These declarations set forth standards for maintaining respect for dignity and bodily autonomy in the practice of human subject experimentation.[105] The Nuremberg Code was the first set of international guidelines developed and implemented.[106] The Nuremberg Code is the product of the trials of twenty doctors who "knowingly agreed to dehumanize medicine by relegating individuals to the status of mere 'guinea pigs.'"[107]

During the Second World War, these doctors in Nazi Germany conducted countless experiments, many in the field of genetics, that resulted in the often violent, painful and dehumanizing deaths of millions of unwilling human test subjects.[108] After the Second World War, the realization of the grave potential of human rights violations in the name of scientific experimentation became evident.[109] This realization catalyzed the first major international debates on medical ethics.[110] The Nuremberg Code emphasized the importance of voluntary consent of the subject, the need for a beneficial purpose of the experiments on society, the limited risk

---

102. J. K. MANSON & R. A. MCCALL SMITH, LAW AND MEDICAL ETHICS 349, 350 (1994).

103. *See* JOHN ZIMAN ET AL., THE WORLD OF SCIENCE AND THE RULE OF LAW: A STUDY OF THE OBSERVANCE AND VIOLATIONS OF THE HUMAN RIGHTS OF SCIENTISTS IN THE PARTICIPATING STATES OF THE HELSINKI ACCORDS 1 (1986).

104. *Id.*

105. ROGERS, *supra* note 48, at 69.

106. *Id.*

107. *Id.*

108. *Id.* at 68.

109. *See id.*

110. *Id.* at 69.

of harm to the research subject and the freedom of the subject to bring the experiment to an end.[111]

The Helsinki Declaration was another result of the abuses discovered after World War II.[112] Part of the larger Helsinki Accord, the Helsinki Declaration was drafted by the World Medical Association in 1964 and signed as part of the Accord by the leaders of thirty-five nations in 1975.[113] The Helsinki Declaration, much like the Nuremberg Code, attempts to protect human subjects of biomedical research.[114] It goes further than the Nuremberg Code, however, by establishing guidelines for non-therapeutic clinical research,[115] providing additional protection for subjects who would not receive any direct therapeutic benefit from the experiments.[116]

Similarly, neither the Nuremberg Code nor the Helsinki Declaration imposes legal obligation on the signatory nations.[117] The Helsinki Accord specifically states that "the text 'is not eligible for registration under article 102 of the Charter of the United Nations'" indicating that "it is not a binding international treaty."[118] Nevertheless, while the two documents do not directly carry with them the full force of law, their very existence represents world leaders' recognition of the need for ubiquitous standards of biomedical research that serve to protect individuals on an international level.[119]

B. National Law On Genetic Experimentation

Most nations currently regulate human genetic experimentation by defining acceptable practices for human subject experimentation.[120] This approach seems appropriate since, to date, all practices of genetic experimentation on humans are in the experimental phase.[121] The European Communities and United States draw their regulations and the policies behind them from the prin-

---

111. *Nuremberg Code*, *supra* note 100.
112. *See Helsinki*, *supra* note 101, at 336.
113. ZIMAN, *supra* note 103, at 1.
114. *Helsinki*, *supra* note 101, at 336.
115. *Id.*
116. *Id.*
117. ZIMAN, *supra* note 103, at 1-2.
118. *Id.*
119. *See id.*
120. *Id.* at 10.
121. *Id.*

ciples of the Nuremberg Code and the Helsinki Declaration. Another similarity between the European and U.S. laws is that neither expressly addresses the practice of germ-line gene therapy.[122] U.S. and European Communities laws differ, however, in that "the trend in the United States has been to ease the regulatory burden, [whereas] the emphasis in the European Communi[ties]. . .has been to tighten and harmonize regulatory standards."[123]

1. Regulation of Genetic Experimentation in the European Communities

The strongest gene therapy regulations in the European Communities involve good clinical practice for medical drug trials on human subjects.[124] These regulations take the form of a Council Directive on "the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use."[125] Based primarily on the Helsinki Declaration, the regulations passed by the Commission of European Communities seek to protect human rights and the dignity of the human being during research in biology and medicine.[126] The regulations serve several distinct functions, each of which are designed to protect the human subject from different sources of harm.[127]

First, the regulations protect the subject from adverse effects of experimental treatment by requiring toxicology tests prior to clinical trials.[128] Accordingly, any new drug, including gene therapy drugs, must be tested for toxicity on live subjects (i.e., animals)

---

122. *See id.* at 40.

123. Colleen K. Ottoson, Comment, *Regulation of Biotechnology in the European Community: How Twelve Nations Are Transforming a Global Industry*, 16 MD. J. INT'L L. & TRADE 255, 257 (1992); *See FDA Head of Biologics Will Accelerate Review Time Table*, BIOTECHNOLOGY NEWSWATCH, Mar. 16, 1992, at 1; AUDREY WINTER ET AL., BUREAU OF NATIONAL AFFAIRS, EUROPE WITHOUT FRONTIERS: A LAWYER'S GUIDE 272-77 (1989).

124. *See* Council Directive 2001/20/EC, 2001 O.J. (L 121) 34.

125. *Id.*

126. The text specifically states, "Whereas . . . (2) [t]he accepted basis for the conduct of clinical trials in humans is founded in the current revision of the Declaration of Helsinki and the Council of Europe Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine." *Id.*

127. *Id.*

128. *Id.*

prior to human exposure at the clinical trial.[129] This requirement is consistent with the spirit of the Helsinki Declaration. [130] Like the Declaration, it balances the protection of individual health with the interest in immediate advancement of medical technology.[131]

Second, ethics committees must screen clinical trials before they may be initiated.[132] This screening process essentially promotes the principles of the Nuremberg Code[133] and the Helsinki Declaration.[134] The committees are comprised of disinterested individuals who can assess the benefit to both the individual patient and society and the risks of subjecting a human being to the clinical trials.[135] This committee evaluation is particularly significant in light of prior abuses of genetic experimentation, and specifically to avoid an unchecked reemergence of eugenics practices.[136]

Finally, the European laws provide for the protection of personal data.[137] Ideally, this protection prevents the release of private medical information about the human subject involved in the trials. Maintaining the anonymity of the subjects prevents potential insurance or employment discrimination associated with genetic disease.[138]

Unfortunately, while these regulations focus primarily on the impact of experimentation on the individual, they do not address the problem of equal access to experimental procedures.[139] They also fail to encourage innovations in developing biotechnology, as evidenced by the European Communities' opposition to the development of germ-line therapy, whose long-term impact is unknown.[140] These deficiencies, however, are not unique to Euro-

---

129. *Id.*
130. *See Helsinki*, *supra* note 101, at 333.
131. *See* Council Directive 2001/20/EC, 2001 O.J. (L 121) 34.
132. *See id.*
133. *See Nuremberg Code*, *supra* note 100.
134. *See Helsinki*, *supra* note 101.
135. *See id.*
136. *See* KILNER, *supra* note 7, at 27.
137. Council Directive 2001/20/EC, 2001 O.J. (L 121) 34.
138. *See id.*
139. *See id.*
140. *Id.* In particular, the European Parliament's Commission on Civil Liberties and Internal Affaires explicitly states, "Fearful of the dangers of a new eugenics movement, [the European Union and its Member States oppose] any moves to permit experiments which could result either directly or indirectly in the modification of heritable genetic characteristics (germ-line genetic engineering) or in the production of genetically-enhanced human beings or human research models by cloning or other equivalent tech-

pean law. National regulations patently fail to address the far-reaching and long-term impacts of modern research techniques. These deficiencies are equally prevalent in U.S. medical research law.[141]

2. Regulation of Genetic Experimentation in The United States

a. Federal Regulations

U.S. regulations[142] seek to protect human autonomy and dignity as suggested by the Nuremberg Code[143] and the Helsinki Declaration.[144] The U.S. Code of Federal Regulations (Federal Code) emphasizes the importance of patient safety and bodily autonomy.[145] These regulations are primarily enforced by Institutional Review Boards (IRBs).[146] IRBs are established by research institutes and are comprised of scientists, ethicists and members of the general public to evaluate the specific experimental protocol for institutes conducting research to ensure that the intent of the Federal Code is met.[147] The IRB has the power to amend or even to seek the termination of a particular protocol if it fails to comport with the Federal Code.[148]

The Federal Code protects bodily autonomy through the requirement of informed consent.[149] "An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117."[150] Informed consent means that the

---

niques." Resolution on Respect for Human Rights in the European Union (1997), A4-0468/98, 1999 O.J. (C 98) 279.

141. *See* 45 C.F.R. §§ 46.101-46.409 (2000).

142. *See id.*

143. *See Nuremberg Code*, *supra* note 100.

144. *See Helsinki*, *supra* note 101, at 333-336.

145. *See* §§ 46.101-46.409.

146. *See id.*

147. *See id.*

148. § 46.109. This section specifically calls for an IRB that "shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy." *Id.*

149. *Id.*

150. *Id.* at § 46.109(c). § 46.117 provides for waiver of informed consent if the IRB finds "(1)That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context." *Id.* at §

potential human subject is informed of the risks involved in taking part in the trial.[151] It also requires the subjects to be informed of his or her freedom to suspend or halt the trial at any time.[152] Informed consent helps guarantee that the human subject is in control of personal health decisions.[153] The emphasis on informed consent arose out of past eugenics abuses, such as mandatory, nonconsensual sterilizations of individuals considered not worthy to breed.[154] The hope is that informed consent will lessen the risk of future abuses in the experimental process, and, in particular, in the manipulation of the human genome.[155]

The Federal Code also emphasizes that research practices must minimize the health risk to the test subject.[156] It provides that subjects may participate in experimental drug trials only when it poses minimal risk to the health and safety of the subject.[157] For a test to receive IRB approval it must minimize "[r]isks to subjects . . . [by] (i) using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes."[158] Non-beneficial treatment is also allowed under both the Federal Code[159] and the Helsinki Declaration.[160] The question remains, however, whether the current regulations are sufficiently effective to regulate the newer experimental gene therapy trials.[161]

b. Diminished Authority of United States Regulatory Agencies

In October of 1974, the National Institutes of Health (NIH) established the Recombinant DNA Technology Committee (RAC) "in response to public concerns regarding the safety of

---

46.117(c).

151. *See id.* at § 46.117.

152. *See id.* at § 46.116.

153. *See id.*

154. *See* KILNER, *supra* note 7, at 27.

155. *See id.*

156. *See* 45 C.F.R. § 46.116(d)(1) (2000).

157. *See id.*

158. *Id.* at § 46.111(1).

159. *See id.*

160. The Helsinki Declaration provides a separate four-part section of guidelines entitled "Non-therapeutic biomedical research involving human subjects (non-clinical biomedical research)." *Helsinki, supra* note 101.

161. *See* YVONNE M. CRIPPS, CONTROLLING TECHNOLOGY: GENETIC ENGINEERING AND THE LAW 81 (Praeger Publishers 1980).

manipulation of genetic material through the use of recombinant deoxyribonucleic acid (DNA) techniques."[162] Regulatory control over human biotechnology, however, has since become "fragmented, both jurisdictionally and substantively."[163]

Since its inception, the RAC, "which includes scientists, lawyers, ethicists, and consumers," has lost much of its regulatory potency.[164] For example, RAC membership has been reduced from twenty-five members to only fifteen, and it no longer has the authority to approve or block recombinant DNA experiments involving gene transfer.[165] Rather, the Food and Drug Administration (FDA) retains statutory authority to approve or disapprove gene transfer experiments;[166] however, "the FDA cannot regulate nor directly oversee all the innovative work being carried out in academic institutions."[167] Thus, when researchers submit a proposed human gene transfer protocol to the NIH, they must simultaneously submit an application for investigational new drugs to the FDA for approval.[168] These rigorous and often duplicative standards are necessary due to "concerns that the FDA [alone] cannot adequately address the ethical implications of novel gene therapy investigational new drugs."[169]

The Federal Code,[170] like the European Communities regulations,[171] focuses primarily on the protection of human life. The IRBs, who are ultimately responsible for deciding whether or not an experiment may go forward, do not inquire into the societal or cultural impact of performing new experiments.[172] Rather than

---

162. Judith E. Beach, *The New RAC: Restructuring of the National Institutes of Health: Recombinant DNA Advisory Committee*, 54 FOOD & DRUG L.J. 1, 49 (1999).

163. Dorean M. Koenig, *The Regulation of Modern Biomedical Techniques*, 38 DEPAUL L. REV. 1013 (1989).

164. Beach, *supra* note 162, at 49.

165. *See id.*

166. *See id.*; *See also* Federal Food, Drug and Cosmetic Act, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052 (1938) (codified as amended at 21 U.S.C. § 355 (1994)); 21 C.F.R. pt. 312 (1998).

167. Phillip D. Noguchi, *From Jim to Gene and Beyond: An Odyssey of Biologics Regulation*, 51 FOOD & DRUG L.J. 367, 372 (1996).

168. *See* Beach, *supra* note 162, at 51.

169. *Id.* at 50.

170. *See* 45 C.F.R. §§ 46.101-46.409 (2000).

171. *See* Council Directive 2001/20/EC, 2001 O.J. (L 121) 34.

172. In fact, § 46.111 specifically states, "The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. § 46.111(a)(2).

protecting the general population, the Federal Code regulates the impact of experimental procedures on individuals.[173]

These efforts, however, should not be too harshly criticized. Regulatory agencies are placed in the competing role of both regulator and promoter of developing genetic technologies.[174] As promoters, these agencies seek "to maximize successful projects and scientific breakthroughs" leaving them "no incentive to enforce any regulation that might prevent the science from moving forward."[175] As regulators, however, the agencies "are supposed to be careful and conservative," erring on the side of safety.[176] Where one agency serves these dual functions "doing both satisfactorily may be impossible."[177]

IV. A FRAMEWORK FOR INTERNATIONAL REGULATION OF THE SCIENCE OF GENETIC EXPERIMENTATION

Because human gene therapy has such far-reaching potential benefits for preservation and maintenance of human health, the practice must be both protected and guarded against.[178] "The possibility of widespread industrial application of genetic engineering is not remote."[179] Furthermore, biotechnology as a whole is a "strategic industry" with significant regulatory deficiencies.[180] Therefore, "instead of attempting to fit regulation of gene therapy into the existing framework, it may be better to . . . ask what regulatory framework would be best now, yet be flexible enough to change as the industry grows."[181]

The regulation of gene therapy must be as broad as the practices of science and technology. Because science and technology can potentially reach anywhere in the world, regulations must be equally expansive.[182] They must encourage responsible develop-

---

173. *See* §§ 46.101-46.409.

174. Gregory A. Jaffe, *Inadequacies in the Federal Regulation of Biotechnology*, 11 HARV. ENVTL. L. REV. 491, 529 (1987).

175. *Id.*

176. *Id.*

177. *Id.*

178. *See e.g.*, CRIPPS, *supra* note 161, at 9-19.

179. Stevan M. Pepa, *International Trade and Emerging Genetic Regulatory Regimes*, 29 LAW & POL'Y INT'L BUS. 415, 418 (1998).

180. Judith A. Cregan, *Light, Fast, and Flexible: A New Approach to Regulation of Human Gene Therapy*, 32 MCGEORGE L. REV. 261, 284 (2000).

181. *Id.*

182. *See id.*

ment of technologies without significantly detracting resources from traditional and more accessible forms of disease treatment and prevention.[183] Ultimately, the task of regulating genetic experimentation falls on the international community. It is only through international regulation that these technologies will reach their potential while imposing minimal adverse consequences for the world community.[184]

A. A Proposed Framework for International Regulation of Genetic Research

1. General Concepts of International Regulation of Medical Technology

Any law passed "specifically for the purpose of controlling genetic [experimentation] should aim toward the establishment of a unified system that would, to the fullest extent possible, govern every facet of the technology."[185] For international law to be universally accepted and effective, however, it must be narrowly tailored to address only those issues that are common to all individuals impacted by the research.[186] Since social norms differ from nation to nation, international regulation must focus on preventing negative global impact, while respecting preexisting national laws that reflect values and ideals unique to each society.[187] This approach would serve the dual function of creating uniform standards for the common protection of all human beings while, at the same time, allowing nations to protect their sovereignty by preserving local regulations. This would also encourage the application and enforcement of both the international and domestic regulations.[188]

2. International Cooperation

"In spite of the fact that all states are dependent on a shared environment, the international community has, in the past, been slow to recognize the need to regulate the harmful effects of new

183. *See id.*
184. *See id.*
185. CRIPPS, *supra* note 161, at 81.
186. *See id.* at 81.
187. *See id.* at 126.
188. *See id.* at 125.

technologies."[189] The formation of a "transnational forum on biotechnology [such as genetic experimentation] . . . could . . . be instrumental in achieving consensus on a coherent and effective legal regime that addresses concerns with transnational biotechnology and balances the tremendous opportunities of biotechnology against its potentially severe and adverse transnational effects."[190] These international committees should be formed out of different interest groups "in order to balance interests with regard to [genetic] biotechnology."[191] The committees would consist of representatives, such as scientists, lawmakers and ethicists that monitor and enforce the laws of each nation or region that practice genetic experimentation on humans.[192]

The national representatives would have a number of reporting duties. First, they would report to the World Heath Organization (WHO) and to each other on the current status of genetic research and "information on the physical and mental health" of the nation's population.[193] Furthermore, national representatives would provide information focusing on the current state of research in human genetics to reduce risks of delaying notification of "perceived dangers" until after their manifestation.[194] Free disclosure of such information would also prevent any one nation from falling significantly behind in the advancement of, and potential access to, genetic technology.[195]

Second, information provided to the WHO and each of the represented nations would include proposals for new innovations in human genetic experimentation.[196] Disclosure of new proposals would serve two necessary functions. First, disclosure would educate less technologically advanced populations in the latest tech-

---

189. *Id.* at 124.

190. Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 49 (2001).

191. Valerie Szczepanik, *Regulation of Biotechnology in the European Community*, 24 LAW & POL'Y INT'L BUS. 617, 642 (1993).

192. *See, e.g.*, 45 C.F.R. §§ 46.101-46.409 (2000).

193. These reporting guidelines are similar to those proposed in the Guidelines Regarding the Format and Contents of Reports to be Submitted States Parties under Articles 16 and 17 of the International Convention on Economic, Social, and Cultural Rights. *See* BRIGIT C.A. TOEBES, THE RIGHT TO HEALTH AS A HUMAN RIGHT IN INTERNATIONAL LAW 367 (Intersentia-Hart 1999).

194. *See* CRIPPS, *supra* note 161, at 124.

195. *See* MEHLMAN, *supra* note 8, at 55, 87.

196. *See* CRIPPS, *supra* note 161, at 82.

nologies.[197] Knowledge of the existence of such technologies is essential if developing nations are to be given an opportunity to utilize them.[198] Second, disclosure would provide a more thorough evaluation of the global implications of the new technologies.[199]

Finally, the representatives would be required to include reports on the efficacy of current domestic regulation, as well as recommendations for more effective implementation and enforcement of national laws.[200] Shared information on the efficacy of domestic health law would encourage consistency in the application of these laws worldwide.[201]

3. New Proposals

Before new gene therapy protocols can be approved, the organization seeking to implement the protocol would have to submit a report to local domestic regulatory bodies.[202] The report would outline the risks and benefits of the experiments and show that the protocol adheres to national guidelines.[203]

If the proposal involves novel forms of genetic experimentation, it is submitted to the international committee for review.[204] The proposal would be reviewed to insure it is consistent with international regulations.[205] Presentation to the international committee would provide an additional safety net; protecting against domestic laws or regulations that may fail to recognize that "all

---

197. *See* MEHLMAN, *supra* note 8, at 55, 87.

198. *See id.*

199. *See id.*

200. *See* CRIPPS, *supra* note 161, at 125.

201. *See* TOEBES, *supra* note 193, at 154.

202. *See* CRIPPS, *supra* note 161, at 82.

203. CRIPPS, *supra* note 161, at 82-83. This system of national approval was recommended by the working party of New Zealand which proposed that a national committee adjudicate on novel genetic techniques including: "(a) any procedures involving the combination of DNA or RNA [Ribonucleic Acid] molecules of different biological origin by means that overcome natural barriers in mating and recombination, to yield molecules that can be propagated in some host cell and the subsequent study of such molecules; (b) any procedures involving the combination of chemically or enzymatically prepared copies of DNA or RNA molecules . . . that can be propagated in some host cell, and the subsequent study of such molecules; (c) with the specific exceptions. . .the fusion of animal, plant, fungal, or bacterial cells inter-specifically by whatever means, leading to the formation of cells or complete organisms with novel genetic constitution." *Id.*

204. TOEBES, *supra* note 193, at 154. This model is based on reporting practices for the ESC wherein "[n]ational reports are. . .sent to the Secretary General of the Council of Europe at two-yearly intervals concerning the application of the provisions. . .that the State party has 'accepted.'" *Id.*

205. *See* CRIPPS, *supra* note 161, at 82-83.

states are dependent on a shared environment."[206] It would standardize the research consistent with the Nuremberg Code[207] and Helsinki Declaration.[208]

Since the human gene pool "represents the collection of genes carried by all humans alive in a given population,"[209] any new proposal would also have to include an analysis of the impact of the protocol on the current model of the human genome to determine the negative consequences of the therapy for future generations.[210] "Even proponents of germ-line manipulation recognize that a number of safeguards must be in place before germ-line technology will be ready for use in humans."[211] The current model of the human genome serves as the basis not only for genetic equality, but also of the human species.[212] The impact of altering the model would disrupt research efforts that are based on the current model.

New therapeutic protocols for genetic experiments impose potentially unpredictable, and possibly detrimental, consequences to the human race when an altered genome reacts to the natural, global environment.[213] One precaution that has been proposed would require researchers to "post bonds and prepare plans for cleanup in the event of inadvertent dispersal" of genetically altered materials into the environment.[214] This measure may be implemented on an international scale requiring regional sponsors of proposed research to post bonds.[215] Analysis of the impact of genetic experimentation is likely the most complicated function of the international committees.

4. Approval of the New Proposals

After assessing the impact of the protocol on the human genome, the international committee would approve, disapprove or seek modification of the protocol.[216] A unanimous approval

---

206. *See* CRIPPS, *supra* note 161, at 124.
207. *See Nuremberg*, *supra* note 100.
208. *See Helsinki*, *supra* note 101.
209. Robert B. Wilson, *Environmental Regulation of the Human Gene Pool as a Genetic Commons*, 5 N.Y.U. ENVTL. L.J. 833, 833 (1996).
210. *Id.* at 842.
211. *Id.*
212. *See* MEHLMAN, *supra* note 8, at 15.
213. *See, e.g.*, Wilson, *supra* note 209, at 842.
214. Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 ENVTL L. 183, 269 (1987).
215. *See* CRIPPS, *supra* note 161, at 84.
216. *See id.*

would be highly unlikely.[217] Therefore, in order to advance gene-therapy technology, a unanimous approval should not be required. Rather, a supermajority should suffice to assure protection of the human genome, while encouraging genetic research through new experimental technologies.[218]

The adverse consequences of inadequate medical resources would suggest that the international conference should provide equitable access to the technologies.[219] Knowledge of the existence of the technologies is a starting point.[220] This knowledge would be facilitated by the reports of the representatives at the international conference. The committee would also have to find a way to equally distribute approved genetic experimentation technology to different regions of the world.[221] This equal access to genetic experiments and technology would ensure that "products of the technology of genetic [experimentation do not] traverse national boundaries and. . .upset the ecological balance in distant states."[222]

B. Enforcement

The enforcement of any international regulation has been historically difficult.[223] "The difficulties involved in enforcing judgments increase geometrically when the legal systems of two or more countries are implicated."[224] Difficulties in implementation, however, cannot hinder efforts to protect individual human dignity and autonomy. Hopefully, avoiding the atrocities of Nazi Germany's eugenics practices is a goal of national leaders. Such awareness of and protection against eugenics and uninformed consent are integral to maintaining the dignity and autonomy of individuals around the world.[225]

V. CONCLUSION

Human genetic experimentation's potential for both benefit

---

217. *See id.* at 85.
218. *See id.* at 81.
219. *See* MEHLMAN, *supra* note 8, at 55.
220. *See id.*
221. *See id.*
222. CRIPPS, *supra* note 161, at 124.
223. *See* Maryellen Fullerton, *Enforcing Judicial Judgments Abroad: The Global Challenge*, 24 BROOK. J. INT'L L. 1 (1998).
224. *Id.* at 1.
225. *See* TOEBES, *supra* note 193, at 154.

and harm is seemingly immeasurable. It holds the promise of rooting out disease before it has a chance to manifest itself, while at the same time, carrying with it the inevitable stigma of eugenic practice. Human gene therapy is far too valuable a means of disease control and prevention to be suppressed by fears of abuse. It is inescapable, however, that genetic experimentation has the potential to go unchecked and become a source of significant, long-term human rights violations. Moreover, genetic experimentation, while capable of discovering new ways to treat and prevent disease, inherently alters the human genetic make-up.

On a large scale, inequitable application of this type of therapy carries with it the risk of creating genetically divergent evolutionary cultures. Surprisingly, given the global implications of this experimental technology, there are currently no enforceable international regulations to protect against widespread abuses or significant alterations to the genetic code.

While this comment suggests specific methods for regulating the application of human genetic technologies, it is by no means comprehensive. It does, however, seek to address the nonexistent state of effective international regulation of human genetic experimentation.

*Paul Hanna**

* J.D candidate, Loyola Law School, Los Angeles, 2002; B.S., (Physiological Science and Neuroscience), University of California at Los Angeles, 1997. To my family who showed me that the most important thing is for people to take care of one another. And to my friends. Thanks to the editors and staff of the *Loyola of Los Angeles International and Comparative Law Review* who worked very hard helping me put this comment together.