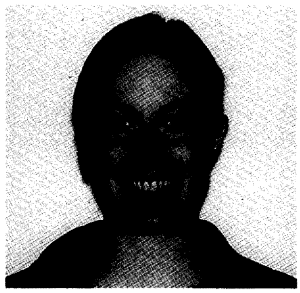

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CREATING HUMAN EMBRYOS FOR RESEARCH: A SCIENTIST'S PERSPECTIVE ON MANAGING THE LEGAL AND ETHICAL ISSUES

Emilie W. Clemmens, Ph.D.

INTRODUCTION

The use and creation of human embryos in the laboratory has generated considerable controversy for the past three decades. This debate has recently been reenergized by stem cell research, a marvel touted as perhaps "the most remarkable breakthrough since man walked on the moon."[1] Though stem cells are available from several sources, scientists believe embryonic stem cells, due to their unique capacities for self-renewal and differentiation into any human cell type, might be used to cure diseases, regenerate tissue, and change medicine as we know it.[2] Embryonic stem cell lines can be derived either through the destruction of spare human embryos donated from *in vitro* fertility (IVF) efforts or through human embryos created specifically for their use in stem cell research.[3] Though neither is currently eligible for federal funding,[4] the former is less ethically charged and has been recommended by all of the federal ethical boards addressing human embryo research thus far.[5] Nonetheless, scientists have expressed a desire to create human embryos exclusively for research purposes for a number of reasons including appropriate experimental controls, lesser quality and lack of available excess IVF embryos, and a desire to investigate cloning embryos for specifically non-reproductive, therapeutic

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1. *Stem Cell Research: Hearing Before the. Subcomm. on Labor, Health and Human Servs. and Educ. of the Senate Appropriations Comm*, 108th Cong. (2003) (statement of Senator Arlen Specter, Subcom. Chairman).

2. Thomas B. Okarma, *Human Embryonic Stem Cells: A Primer on the Technology and Its Medical Applications, in* THE HUMAN EMBRYONIC STEM CELL DEBATE 3 (Suzanne Holland et al. eds., 2001).

3. NAT'L INSTS. OF HEALTH, 1 REPORT OF THE HUMAN EMBRYO RESEARCH PANEL xi (Sept. 1994) [hereinafter HERP REPORT], *available at* http://ospp.od.nih.gov/pdf/VOLUME1_REVISED.PDF.

4. Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996); Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, Pub. L. No. 105-78, § 513, 111 Stat. 1467, 1517 (1997).

5. *See generally* HERP REPORT, *supra* note 3; ETHICS ADVISORY BD., DEP'T OF HEALTH, EDUC., & WELFARE, REPORT AND CONCLUSIONS: HEW SUPPORT OF RESEARCH INVOLVING HUMAN *IN VITRO* FERTILIZATION AND EMBRYO TRANSFER (May 4, 1979) [hereinafter EAB REPORT]; NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL ISSUES IN STEM CELL RESEARCH: EXECUTIVE SUMMARY (Sept. 1999) [hereinafter NBAC REPORT], *available at* http://www.georgetown.edu/research/nrcbl/nbac/execsumm.pdf.

purposes.[6] But a lack of federal funding will slow this nascent research, as the incentives for private investment are few at this stage and federal monies are needed to enhance the volume of high quality, peer-reviewed research for the development of this science as a clinical tool.[7]

Though the creation and use of human embryos *ex utero* would undoubtedly advance scientific achievements on multiple fronts, ethical and legal questions temper our rush to pursue this path. This Article will address the current United States legal situation regarding human embryo research and the creation of embryos, and will look to the legal history of human embryo research to investigate prevailing ethical notions of the creation of embryos *in vitro* and their effects on the development of policy. Finally, this Article will discuss the potential future ramifications of a lack of federal funding and, thus, oversight on embryo creation and use in research, while casting a cautious eye to Great Britain as a model for support and regulation of the use of human embryos in research.

I. CREATING LIFE OUTSIDE THE WOMB: THE SCIENCE OF IVF TECHNOLOGY

In vitro fertilization (IVF) includes the processes of ovulation induction, egg retrieval, fertilization, and embryo transfer. Drugs that manipulate hormones to promote ovulation are injected into the female.[8] After an appropriate interval to allow oocyte maturation, eggs are typically retrieved with ultrasound-guided aspiration through the vagina and cervix,[9] and are incubated with 50,000 to 1,000,000 sperm for 14-18 hours.[10] Following transfer to a new growth medium, the eggs are examined for the presence of two pronuclei, an

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6. RONALD M. GREEN, THE HUMAN EMBRYO RESEARCH DEBATES BIOETHICS IN THE VORTEX OF CONTROVERSY xi-xii, 15 (2001); James F. Childress, *An Ethical Defense of Federal Funding for Human Embryonic Stem Cell Research*, 2 YALE J. HEALTH POL'Y L. & ETHICS 157, 159-60 (2001); David I. Hoffman et al., *Cryopreserved Embryos in the United States and Their Availability for Research*, 79 FERTILITY & STERILITY 1063, 1068 (2003), *available at* http://www.asrm.org/Professionals/Fertility&Sterility/cryoembryos_may2003.pdf; Dr. John Gearhart, Medical Promise of Embryonic Stem Cell Research (Present and Projected), Address before The President's Council on Bioethics (Apr. 25, 2002), *available at* http://bioethics.gov/transcripts/apr02/apr25session1.html.

7. Audrey R. Chapman et al., American Association for the Advancement of Science & Institute for Civil Society, Stem Cell Research and Applications: Monitoring the Frontiers of Biomedical Research vi (Nov. 1999), *available at* http://www.aaas.org/spp/sfrl/projects/stem/report.pdf; *see also Stem Cell Research: the ethics of going it alone*, SITNFlash (Harvard Medical School, Boston, Mass.) Mar. 2004, *at* http://www.sitnboston.org/sitnflash/archives/sitnflash-200403.html (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review).

8. Resolve the National Infertility Association, Treatment: Assisted Reproductive Technology, *at* http://www.resolve.org/main/national/treatment/options/art/art.jsp?name=treatment&tag=options (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review) [hereinafter Resolve].

9. Infertility Counseling Associates, An Overview of the IVF Procedure, *at* http://www.mindspring.com/~yepstein/procivf.htm (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review).

10. Resolve, *supra* note 8.

indicator that normal fertilization has occurred.[11] Approximately three days later, the embryos are morphologically assessed for quality, and two to four embryos chosen by the embryologist are flushed into the uterus through a catheter.[12]

For the female, the IVF process is intricate, difficult, and potentially harmful. Frequent blood draws are performed to monitor estrogen levels.[13] The ovary-stimulating medications may cause pain, bloating, or in rare cases ovarian hyper-stimulation syndrome, which can cause kidney failure, thrombosis, and death.[14] Preliminary studies suggest a possible link between ovary-stimulating medications and ovarian cancer.[15] Injury during egg retrieval to adjacent organs and blood vessels has been reported in the literature.[16] Finally, the need to transfer multiple eggs to the uterus to improve the chances of implantation has led to a high incidence of multiple births, which can increase the "risk of complications or even miscarriage, as well as long-term disability, and they can cause considerable emotional and financial pressure," according to Ruth Deech, ex-chair of the Human Fertilisation and Embryology Authority (HFEA) in the United Kingdom.[17]

The current procedure of extracting and fertilizing multiple eggs respects a woman's health by lowering the number of times she may need to undergo the procedure, and respects a family's welfare by considering the high cost of the procedure. But the number of embryos transferred to the uterus must be limited to avoid multiple birth complications.[18] Thus through IVF, creation and cryopreservation of excess embryos have become the norm. According to a recent report, there are approximately 400,000 cryopreserved embryos in storage in the United States.[19] It seems unlikely that all these embryos will be used to attempt pregnancies and thus, given informed donor consent, they might be used in research rather than discarded. However, only 2.8 percent of those stored embryos are currently available for research.[20]

Beyond this, scientists argue that spare IVF embryos, which are typically of lesser quality than those used for implantation, may not be useful for

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11. *Id.*

12. *Id.*

13. *Id.*

14. PregnancyMD.org, Fact Sheets: Ovarian Hyperstimulation Syndrome (OHSS), *at* http://www.pregnancymd.org/ovarian-hyperstimulation-syndrome-ohss.htm (last updated Sept. 17, 2001) (on file with the Indiana Health Law Review).

15. AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, FACT SHEET: RISKS OF IN VITRO FERTILIZATION (IVF) (Dec. 1996), *available at* http://www.asrm.org/Patients/FactSheets/RisksIVF-Fact.pdf.

16. *Id.*

17. *Modern Fertility Techniques Boost Success Rates,* BBC NEWS, Dec. 15, 1998, *at* http:/news.bbc.co.uk/1/hi/health/235510.stm (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review).

18. *Id.*

19. Hoffman et al., *supra* note 6, at 1068.

20. *Id.*

developing stem cell lines of enough quantity and quality for therapeutic application,[21] and that embryo creation is critical to the advancement of therapeutic cloning, a novel technology that may transform medicine.[22] Also, creation of embryos not intended for IVF is necessary for appropriate controls for meaningful studies of embryonic development.[23] The development of IVF technology progressed over the years as all clinical research progresses—through the use and study of animal counterparts.[24] The media conditions, manipulation of sperm and egg, and even cryopreservation techniques were all attempted and optimized with animal gametes and embryos before attempts with human specimens were made.[25] Animal studies are typically undertaken so that large numbers of experiments may be performed to gather general information about the equivalent human system, with the hope that the same principles will apply and that few (and relatively non-invasive) human tests will be necessary to understand the human response to a drug or technology. Yet, scientists are continuously discovering important differences between animal and human systems. For example, though embryological studies with animal cells have yielded a wealth of information about early mammalian development, evidence suggests that human and other mammalian embryos are significantly different in form and function.[26] The science appears to have come to the point that studies with human embryos are necessary to acquire new information on human embryonic development.

Thus simply put, furthering our understanding of human embryonic development to the benefit of science and medicine (pediatric care in particular) will require research with human embryos. Yet both the use and creation of human embryos for basic science research and for therapeutic purposes demands a careful consideration of policy and ethics.

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21. Gearhart, *supra* note 6.

22. Sideny Altman et al., Statement by 40 Nobel Laureates Regarding Cloning (Apr. 10, 2002), *available at* http://www.ascb.org/publicpolicy/Nobelletter.html; AMERICAN SOCIETY FOR CELL BIOLOGY, POSITION PAPER ON CLONING: SOMATIC CELL NUCLEAR TRANSFER TECHNOLOGY IS JUSTIFIED AND ESSENTIAL FOR PRODUCING EMBRYONIC STEM CELLS FOR BASIC RESEARCH AND THERAPEUTIC APPLICATIONS (Dec. 3, 2001), *available at* http://www.ascb.org/publicpolicy/cloning.htm.

23. GREEN, *supra* note 6, at 7-10.

24. *Id.*

25. Jonathan Van Blerkom, *The History, Current Status and Future Direction of Research Involving Human Embryos*, *in* 2 PAPERS COMMISSIONED FOR THE HUMAN EMBRYO RESEARCH PANEL 1 (Nat'l Inst. of Health, Pub. No. 95-3916, Sept. 1994).

26. James A. Thomson, *Human Embryonic Stem Cells*, *in* THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 2, at 15, 20; Yves J.R. Menezo & Francois Herubel, *Mouse and Bovine Models for Human IVF*, 4 Reproductive Biomedicine Online 170, 170 (2002).

II. CURRENT HUMAN EMBRYO RESEARCH POLICY

A. Federal Law

Currently, there is no federal law criminalizing the creation of human embryos *in vitro*. The creation of embryos through *in vitro* fertilization (IVF) of human oocytes with human sperm is a medically accepted practice designed to assist infertile couples or individuals with childbearing.[27] Embryos created in this manner, referred to in this article as "preimplantation embryos," are ultimately either successfully implanted into a woman's womb, indefinitely cryogenically preserved, or destroyed through failure to implant, natural genetic destruction mechanisms, failure to survive the freezing process,[28] or by contractual enforcement to cease storage and destroy.[29] Some of these embryos, particularly those in the latter category, might be employed for scientific research purposes. Though there is no federal law prohibiting this use of human embryos, federal funding for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death" was banned in 1996 by Congress' passage of the Dickey Amendment to the Balanced Budget Downpayment Act of 1996.[30] Federal funding for the creation of embryos for research purposes was also banned by this Amendment.[31]

Current policy regarding the use of human embryos in the derivation of stem cell lines was established by President George W. Bush's pronouncement that federal funding for human embryonic stem cell research is limited to cell lines derived from embryos before August 9, 2001.[32] This policy is consistent with the Dickey Amendment, as it does not allow federal monies to be used in the destruction of human embryos,[33] but permits funding for research using stem cells derived from spare IVF embryos for which "the life-and-death decisions have already been made."[34] Nonetheless, both groups opposed to and in favor of the use of human embryos to create stem cells were unappeased

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27. AMERICAN MED. ASS'N., CODE OF MEDICAL ETHICS E-2.14 IN VITRO FERTILIZATION (June 1983), *available at* http://www.ama-assn.org/apps/pf_new/pf_online?f_n=resultLink&doc=policyfiles/HnE/E-2.14.HTM&s_t=in+vitro+fertilization&catg=AMA/HnE&catg=AMA/BnGnC&catg=AMA/DIR&&nth=1&&st_p=0&nth=2&.

28. John M. Baust, *Molecular Mechanisms of Cellular Demise Associated with Cryopreservation Failure*, 1 CELL PRESERVATION TECH. 17 (2002).

29. Litowitz v. Litowitz, 48 P.3d 261, 271 (Wash. 2002).

30. Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996).

31. *Id.*

32. *Remarks by the President on Stem Cell Research*, U.S. NEWSWIRE, Aug. 9, 2001, *at* National Desk [hereinafter *Remarks*].

33. Minutes, National Institutes of Health, Proceedings of the 78th Meeting of the Advisory Committee to the Director (June 3, 1999), *available at* http://www.nih.gov/about/director/minutes699.htm.

34. *Remarks*, *supra* note 32.

by the Bush Administration's policy, in part because the decision failed to address either the moral or legal status of the human embryo.[35]

Under federal constitutional law, a human embryo, either *in vitro* or *in utero*, does not qualify as a "person" entitled to the same rights as postnatal humans.[36] State courts have sanctioned this lack of personhood specifically for preimplantation embryos. In *York v. Jones*, the Eastern District Court of Virginia allowed a couple to transfer their IVF embryos to another clinic, finding that the embryos were the couple's property.[37] In *Litowitz*, the Supreme Court of Washington enforced an IVF contract requiring the destruction of cryogenically preserved embryos after five years of storage, implying the embryos had no particular right to life.[38] The Tennessee Supreme Court took a less strict view of the persons versus property debate in *Davis v. Davis* by finding that human embryos are neither "'persons' [nor] 'property,' but occupy an interim category that entitles them to special respect because of their potential for human life" but having no rights *per se*.[39] In addition, the *Davis* court upheld a father's right to avoid unwanted parenthood, a situation perhaps unique to the advent of IVF technology, as presumably this right could not be exercised post-implantation.[40] Thus, despite the continuing and often raging debates on the beginning of life and the rights of embryos, preimplantation embryos have been granted no particular legal rights by the federal government.

B. State Law

Due to the recent vintage of scientific advance (and subsequent debate) relevant to human embryo creation or use, few states have developed policy specifically directed at regulating human embryo research in the current context (*ex utero*). After the *Roe v. Wade* decision of 1973, however, several states passed laws designed to regulate research on fetuses or embryos *in utero*, and a number of these statutes may extend to affect *ex utero*, preimplantation embryos.[41]

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35. Carly Goldstein, Note, *Dipping Into Uncle Sam's Pockets: Federal Funding of Stem Cell Research: Is It Legal?*, 11 B.U. PUB. INT. L.J. 229, 240 (2002).

36. Roe v. Wade, 410 U.S. 113, 158 (1973); Davis v. Davis, 842 S.W.2d 588, 594-97 (Tenn. 1992); *see also* Goldstein, *supra* note 35, at 246-47.

37. York v. Jones, 717 F. Supp. 421, 426-27 (E.D.Va. 1989).

38. Litowitz v. Litowitz, 48 P.3d 261, 271 (Wash. 2002).

39. Davis v. Davis, 842 S.W.2d 588, 597 (Tenn. 1992).

40. *Id.* at 594-95.

41. Lori B. Andrews, *State Regulation of Embryo Research*, *in* 2 PAPERS COMMISSIONED FOR THE HUMAN EMBRYO RESEARCH PANEL, *supra* note 25, at 297.

Michigan,[42] South Dakota,[43] and Louisiana[44] have enacted laws prohibiting research that destroys or harms human embryos, defined by all three states to include IVF preimplantation embryos. Louisiana's law is particularly unusual, however, because it goes so far as to define a preimplantation embryo, or "in vitro fertilized human ovum," as a "juridical person" until implantation, at which time the embryo presumably loses its personhood and becomes subject to laws governing fetuses *in utero*.[45] Minnesota likewise prohibits nontherapeutic research on embryos "conceived either in the human body or produced in an artificial environment", but qualifies its ban to the "living human conceptus" defined by "evidence of life, such as movement, heart or respiratory activity, the presence of electroencephalographic or electrocardiographic activity."[46] As the preimplantation embryo inarguably has none of these indications of life, it is difficult to speculate if or how the statute might apply.

Kentucky permits public funds and facilities for "research into or the performance of in vitro fertilization" but prohibits the use of public medical facilities for procedures that "result in the intentional destruction of a human embryo."[47] The use of the term "intentional" here is presumably deliberate and implies an understanding that not all embryos created with IVF survive to be implanted or survive the implantation process. It is also significant that the Kentucky statute permits IVF research and public funding of that research, provided it does not *destroy* the embryo.[48] Finally, no mention of harm to the embryo is included in the statute, which begs the question: Are IVF procedures considered an acceptable risk of harm to human embryos? The South Dakota and Michigan statutes prohibit, respectively, research subjecting embryos to "substantial risk"[49] or research that "substantially jeopardizes the life or health of the embryo."[50] IVF, while generally considered a medical procedure, might easily be construed as research given the low success rates and lack of data or information regarding the effects of IVF on embryos.[51]

To support and facilitate stem cell research, California law has incorporated informed consent laws for the donation to research of embryos remaining after fertility treatments.[52] Creation of embryos for research is not

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42. MICH. COMP. LAWS §§ 333.2685, 333.16274 (2004).
43. S.D. CODIFIED LAWS §§ 34-14-16 to -20 (Michie 2004).
44. LA. REV. STAT. ANN. § 9:122 (West 2004).
45. *Id.* § 9:123
46. MINN. STAT. § 145.421-.422 (2004).
47. KY. REV. STAT. ANN. § 311.715 (Michie 2004).
48. *Id.*
49. S.D. CODIFIED LAWS § 34-14-17 (Michie 2004).
50. MICH. COMP. LAWS § 333.2685 (2004).
51. *See generally* Van Blerkom, *supra* note 25, at 1; DIV. OF REPRODUCTIVE HEALTH, DEP'T OF HEALTH & HUMAN SERVS., 2000 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS (Dec. 2002), *available at* hhttp://www.cdc.gov/reproductivehealth/ART/ArchivedARTPDFs/ART2000.pdf.
52. CAL. HEALTH & SAFETY CODE § 125315 (Deering 2004).

addressed. A New Hampshire statute regulates use of preimplantation embryos by disallowing *ex utero* growth longer than fourteen days and banning the transfer of embryos to the uterine cavity once they have been used for research purposes.[53] Iowa, Rhode Island, and Michigan have all enacted statutes prohibiting human cloning via somatic cell nuclear transfer,[54] while Missouri prohibits state funding of cloning procedures.[55] These statutes are currently the only laws directly addressing a form of embryo creation.

Twenty-five states have developed laws for experimentation on fetuses or unborn children.[56] However, those that might generally be construed to apply to embryos were not designed to account for preimplantation embryos. They refer to the "live human fetus"[57] or "unborn child,"[58] "before or after expulsion from its mother's womb," and define the term "fetus" to include an embryo, but do not further define embryo.[59] Maine's statute forbids the use of "any product of conception considered live born" for research purposes, but defines "live born" as "a product of conception after complete expulsion or extraction from its mother...," suggesting the statute would not apply to embryos created *ex utero*.[60] Considering the recent fate of similar state statutes held by state courts to be constitutionally vague,[61] it is unlikely that many of these statutes would pass muster should they be brought to court.

III. THE HISTORY OF HUMAN EMBRYO RESEARCH POLICY

The use of human embryonic cells in science dates back at least to the early twentieth century. In 1936, scientists used human embryonic brain tissue in attempts to culture the polio virus, and in 1954, the Nobel Prize in Medicine was awarded to three scientists who successfully cultured the virus in human embryonic kidney cells.[62] Scientific work with embryonic cells continued[63]

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53. N.H. REV. STAT. ANN. § 168-B:15 (2004).

54. IOWA CODE § 707B.4 (2003); MICH. COMP. LAWS § 333.16274 (2004); R.I. GEN LAWS § 23-16.4-2 (2004).

55. MO. REV. STAT. § 1.217 (2004).

56. Andrews, *supra* note 41, at 297.

57. ME. REV. STAT. ANN. tit. 22, § 1593 (West 2003); MASS. GEN. LAWS ch. 112, § 12J (2004); N.D. CENT. CODE § 14-02.2-01 (2003); R.I. GEN LAWS §11-54-1 (2004).

58. 18 PA. CONS. STAT. § 3216 (2003).

59. MASS. GEN. LAWS ch. 112, § 12J (2004); N.D. CENT. CODE § 14-02.2-01 (2003); R.I. GEN LAWS §11-54-1 (2004).

60. ME. REV. STAT. ANN. tit. 22, §§ 1593, 1595 (West 2003).

61. Forbes v. Napolitano 236 F.3d 1009 (9th Cir. 2000); Lifchez v. Hartigan, 735 F. Supp 1361 (N.D. Ill. 1990).

62. Professor S. Gard, Presentation speech for the Nobel Prize in Physiology or Medicine 1954 (Dec. 10, 1954), *in* NOBEL LECTURES, PHYSIOLOGY OR MEDICINE 1942-1962 (1964), http://www.nobel.se/medicine/laureates/1954/press.html (last modified June 27, 2003) (on file with the Indiana Health Law Review).

63. W. P. Luckett, *The Development of Primordial and Definitive Amniotic Cavities in Early Rhesus Monkey and Human Embryos,* 144 AM. J. ANATOMY. 149 (1975); J. F. Kennedy & B. R. Migeon, *Evidence for the Inactivation of an X Chromosome Early in the Development*

without controversy until the abortion debate reached a fever pitch with the *Roe v. Wade* Supreme Court decision in 1973.[64] Public concern with the use of aborted fetuses in research and the potential coercion of women to abort to donate to science led many states to enact laws governing the disposition of aborted fetal tissue.[65]

The controversy over *ex utero* embryos as research subjects intensified with the advent of IVF techniques.[66] In 1975, the Department of Health, Education and Welfare issued its guidelines for federal funding of research using fetal tissue.[67] Included in these guidelines was the provision that all grant applications for research using *ex utero* IVF embryos be approved by an Ethics Advisory Board (EAB).[68] The 1978 birth of Louise Brown, the first child born using IVF, led Congress to recognize both the imminent demand for this technology and the ethical challenges it would bear.[69] In response, an EAB was created to draft guidelines for funding research into the development of IVF and the use of human embryos in research in general.[70]

The EAB issued its recommendations in May 1979, which included support for funding research that would both use and create human embryos.[71] The public response to the EAB report was largely negative, particularly due to organized protests by religious groups, and the resignation of the Secretary of the Department of Health, Education and Welfare (HEW) in September of the same year.[72] The EAB's charter expired in 1979, effectively ending federal funding for research with human embryos as no board existed to approve requests for funding.[73] A new EAB was never convened, and challenges to the funding moratorium by NIH and Health and Human Services administrators went unheeded by the Reagan and Bush Administrations.[74]

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of the Human Female, 27 AM. J. HUM. GENETICS 233 (1975); Marvin S. Legator et al., *Aflatoxin: Effect on Cultured Heteroploid Human Embryonic Lung Cells,* 208 NATURE 345 (1965); P. A. Brunell, *Separation of Infectious Varicella-Zoster Virus from Human Embryonic Lung Fibroblasts,* 31 VIROLOGY 732 (1967); I.V. Sultanian & G. Freeman, *Enhanced Growth of Human Embryonic Cells Infected with Adenovirus 12,* 154 SCIENCE 665 (1966).

64. Andrews, *supra* note 41, at 297; John C. Fletcher, *The Stem Cell Debate in Historical Context, in* THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 2, at 27.

65. Andrews, *supra* note 41, at 297.

66. GREEN, *supra* note 6, at 2-3; Erin P. George, Comment, *The Stem Cell Debate: The Legal, Political and Ethical Issues Surrounding Federal Funding of Scientific Research on Human Embryos,* 12 ALB. L.J. SCI. & TECH. 747, 763 (2002).

67. Heather Boonstra, *Human Embryo and Fetal Research: Medical Support and Political Controversy,* GUTTMACHER REP. ON PUB. POL'Y, Feb. 2001, at 3, *available at* http://www.guttmacher.org/pubs/tgr/04/1/gr040103.pdf.

68. *Id.*

69. GREEN, *supra* note 6, at 2-3.

70. *Id.*

71. *Id.*; EAB REPORT, *supra* note 5.

72. GREEN, *supra* note 6, at 2-3.

73. *Id.*

74. *Id.*

In 1993, Congress passed the National Institutes of Health Revitalization Act, which eliminated the requirement of EAB approval for human embryo research funding.[75] The NIH then convened the Human Embryo Research Panel (HERP), to investigate and compile information on the ethics and science of the use of *ex utero* preimplantation human embryos in research and to recommend funding guidelines for such research. The panel consisted of scientists, physicians, bioethicists, lawyers, political scientists, a sociologist, and a representative of a sickle-cell anemia organization.[76] In 1994, HERP published its report, which, like the EAB reports before it, recommended federal funding for both the use and creation of human embryos for research purposes, provided a number of ethical principles were maintained.[77] These included informed donor consent, research of high medical significance for which other means of investigation were exhausted, prohibition of financial coercion for embryo donation, and "[o]ut of respect for the special character of the preimplantation human embryo", a fourteen-day limit on maintaining embryo growth.[78]

President Clinton, however, rejected HERP's recommendation that funding be permitted for the creation of embryos for research purposes, and in 1996, Congress correspondingly passed an appropriations bill containing an amendment, sponsored by Representatives Jay Dickey (R-AK) and Roger Wicker (R-MS), that banned federal funding of all human embryo research.[79] What was once a *de facto* moratorium became a legislated one.[80]

The Dickey Amendment did not end the human embryo research debate, however, as the medical promises of stem cell research and therapeutic cloning were too great to be ignored. In 1999, The Department of Health and Human Services (DHHS) concluded that the Dickey Amendment did not apply to embryonic stem cells directly, and that stem cell research is eligible for federal funding if the actual generation of the cells (through the destruction of a human embryo) was not accomplished with federal monies.[81] To establish responsible guidelines for funding stem cell research, the NIH subsequently assembled a stem cell working group, a team of ethicists, patients, advocates, lawyers, scientists, and physicians, who reported to the Advisory Committee

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75. National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 112 (1993).

76. HERP REPORT, *supra* note 3.

77. *Id.* at xi.

78. *Id.*

79. Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996).

80. George, *supra* note 66, at 765.

81. Minutes, National Institutes of Health, Proceedings of the 78th Meeting of the Advisory Committee to the Director (June 3, 1999), *available at* http://www.nih.gov/about/director/minutes699.htm.

to the Director.[82] President Clinton established the National Bioethics Advisory Commission (NBAC). After thorough review, the NBAC recommended that stem cell research using stem cells obtained from either cadaveric fetal tissue or excess IVF embryos be federally funded.[83] DHHS and NIH used these recommendations to establish guidelines (though later withdrawn) for the use of federal funds for stem cell research with IVF embryos that protected these embryos from commerce; induced donation, provided for informed consent, and required extensive procedural oversight.[84] NBAC recommendations did not, however, support federal funding of research engaged in the creation of embryos, basing its decision on the fact that, though there may be future compelling scientific reasons to do so, including "research into the process of human fertilization," currently "embryos remaining after infertility treatment provide an adequate supply of research resources."[85] They also cite "a morally relevant difference between generating an embryo for the sole purpose of creating a child and producing an embryo with no such goal."[86]

The election of George W. Bush to the White House expectedly begat winds of political change in the moral arena of embryos and research. Simultaneous with his decision to permit stem cell research only with cell lines existing prior to August 9, 2001, President Bush established his President's Council on Bioethics (PCB) to further research and debate the issue.[87] The PCB is still investigating the scientific and ethical issues of stem cell research but released a report on human cloning in July 2002.[88] The members of the Council were divided 10-7 against commencing federal funding for cloning for biomedical research (aka "therapeutic cloning"), with those opposed citing a belief that is it "immoral to create human embryos for purposes that are foreign to the embryos' own well-being and that necessarily require their destruction."[89]

IV. THE FUTURE OF HUMAN EMBRYO RESEARCH POLICY

The advent of *in vitro* fertilization (IVF) and other assisted reproductive technologies (ART) introduced a novel moral dilemma and legal challenge regarding the significance and rights of an embryo conceived by the union of

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82. Goldstein, *supra* note 35, at 238; Rich McManus, *Stem Cell Guidelines Still Pending Director's Advisors Bat 6 for 7*, NIH REC. (Nat'l Inst. of Health, Bethesda, M.D.), Jun. 29, 1999, *available at* http://www.nih.gov/news/NIH-Record/06_29_99/story02.htm.

83. NBAC REPORT, *supra* note 5.

84. National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (effective Aug. 25, 2001) (withdrawn on Nov. 14, 2001, 66 Fed. Reg. 220).

85. NBAC REPORT, *supra* note 5, at 5.

86. *Id.*

87. *Remarks*, *supra* note 32.

88. THE PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY (July 2002), *available at* http://www.bioethics.gov/reports/cloningreport/pcbe_cloning_report.pdf.

89. *Id.* at 201.

sperm and egg in a Petri dish that is not yet implanted into a woman's uterus and as such cannot become a human being. The medical potential of stem cell research seems to mitigate ethical concerns over embryo destruction in the minds of most, but the question of creating to destroy seems more disconcerting. Is it possible to permit and adequately regulate the creation of human embryos for research purposes only, with no intent to endeavor to create a human being? Does such an act violate an inflexible national moral code? In this part, I will attempt to address these questions.

A. Is The Creation of Human Embryos for Research Purposes Legal?

As discussed in Part III, current federal law does not criminalize the creation of embryos for research. Additionally, no provision currently qualifies preimplantation embryos as persons nor endows them with rights ensured to all humans under the Constitution, while state courts have held that preimplanted human embryos, though perhaps worthy of special moral consideration, have no specific legal rights.[90] Thus both the creation and use of preimplantation embryos in research is legally permissible under federal law, and consequently, privately funded, largely unregulated human embryo research continues here in the U.S.[91]

Individual state laws, where they exist, differ in their permitted treatment of human embryos. With the exception of Louisiana, no state laws proscribe the creation of embryos for research using traditional IVF technology (a few have banned the use of SCNT to create cloned embryos[92]). Thus the states have so far chosen not to prohibit creating embryos for research, perhaps to avoid overlap with creation of embryos for IVF and concerns that IVF procedures might be construed as experimental. Kentucky's statute, in particular, seems aware of this potential overlap and could even be interpreted to permit creation of embryos for research provided the research did not destroy the embryo.[93] A lack of prohibition of harm to the embryo in the Kentucky statute, contrasted with the conspicuous proscription of harm to the embryo in the Michigan, South Dakota, and Louisiana statutes[94] again provokes an inquiry into whether, in the latter three states, IVF procedures could be considered injurious to a preimplantation embryo. Relevant to the purpose of this

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90. York v. Jones, 717 F. Supp. 421, 426-27 (E.D.Va. 1989); Litowitz v. Litowitz, 48 P.3d 261, 271 (Wash. 2002); Davis v. Davis, 842 S.W.2d 588, 597 (Tenn. 1992).

91. For examples of American companies engaged in stem cell and therapeutic cloning research see Today's Stem Cell Research, Stem Cell Companies: Stem Cell Research Companies List, *at* http://www.stemnews.com/stem-cell-companies (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review).

92. IOWA CODE § 707B.4 (2003); MICH. COMP. LAWS § 333.16274 (2004); S.D. CODIFIED LAWS §§ 34-14-26 to -28 (Michie 2004); ARK. CODE §§ 20-16-1001 to -1003 (Michie 2003).

93. KY. REV. STAT. ANN. § 311.715 (Michie 2004).

94. LA. REV. STAT. ANN. § 9:129 (West 2004); MICH. COMP. LAWS §§ 333.2685, 333.16274 (2004); S.D. CODIFIED LAWS §§ 34-14-16 to -20 (Michie 2004).

discourse is the following question: Given the inherent risks and incomplete understanding of IVF mechanisms, is creation of an embryo itself injurious to the embryo, and thus illegal in at least three states? That is a question perhaps best answered by the courts. Still it is clear from the statutes that no state intends to interfere or hamper IVF as a practice, and so the creation of embryos by and large remains legal.

B. Is The Creation of Human Embryos for Research Purposes Ethical?

There currently seems to be no overriding pressure in this country to halt the creation of human embryos for treating infertility, despite the fact that the majority of these embryos will die. It appears that in the minds of the public, the benefits of IVF—the chance for an infertile couple to reproduce, a feat considered by most to be of fundamental value to human life—outweigh any moral reservations regarding the loss of excess embryos. This is not to suggest that there are no objections to IVF or the *in vitro* creation of embryos; on the contrary, several groups remain in objection, most notably the Catholic Church.[95] But in general, the widespread availability of IVF technologies suggests that the public accepts IVF as a scientific and medical achievement of merit, not science gone awry. It is also apparent, however, that the ethical objections to the destruction of embryos created *in vitro* is not as readily mitigated by the use of embryos for research purposes.[96] The willingness of the public (and thus the legislature and courts, inasmuch as they reflect the public moral fabric) to accept the use of such embryos for research may depend on the medical value that is assured from the research.

Those who create a distinction, as did the NBAC, between creating embryos for implantation and creating embryos for research misinterpret the purpose of IVF technologies. IVF and other assisted reproductive technologies, not all of which involve the *ex utero* creation of an embryo, are designed to combat infertility, not to create life. Even when conception occurs in a Petri dish, a mother's womb is necessary to bring that embryo to term, to allow it to gestate and develop the organs, tissues, and sentience it needs to become a human child. This is not to suggest that the preimplantation embryo has no value; on the contrary, the existence of controversy reflects the moral significance and high regard that the public does, in fact, hold for these embryos. Yet arguably, IVF technology may never have come into being, or at least have become accepted practice, if it were not directed at the treatment of infertility. The purpose of IVF was never to create life *per se*, but to allow couples a chance at conception. And if it is ethical to create embryos to treat infertility, a purpose that is not therapeutic and can even be harmful to the

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95. AmericanCatholic.org, Web-Exclusives: Stem-cell Research and the Catholic Church, *at* http://www.americancatholic.org/News/StemCell/default.asp (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review).

96. HERP REPORT, *supra* note 3.

embryo itself, it ought to follow that it is ethical to create embryos to treat Parkinson's disease or other devastating illnesses. However, human embryos cannot be considered merely as a means to an end and, in all cases (including infertility treatments), are due some measure of respect for their potential to become human beings. Thus federal oversight of all human embryo research is not only wise scientifically speaking, but is also ethically necessary to uphold the respect due preimplantation embryos.

Furthermore, if IVF is to remain an accepted medical practice, then research into improving this technology is necessary to preserve not only the moral respect due human embryos, but also respect for human fertility and the process of childbirth, particularly considering the potential hazards imposed on a woman's body by current IVF methods. High quality, peer-reviewed research is required to advance this field in a clinically acceptable manner, and the creation of human embryos specifically for this research should be a compulsory component for adequate scientific controls.

The creation of human embryos *ex utero* currently requires the donation of human eggs, or oocytes.[97] Egg donation invokes both ethical and scientific issues. The current methods used to obtain eggs from the ovaries entail some risk and a great deal of discomfort, and arguably relatively few women would donate without some incentive, be it financial or a direct benefit to themselves or their loved ones. A dearth of oocytes then might induce scientists to coerce women to donate with larger financial compensation than ethically reasonable. However, local institutional review boards could manage such issues on a proposal-by-proposal basis, and there is no reason to suggest that they could not regulate appropriate monetary compensation for anonymous egg donation.

Directed or non-anonymous donation of oocytes may prove ethically more challenging. First, donation for the purpose of research avoids maternity issues provided the embryos are never transferred to a womb, and any legislation permitting the creation and subsequent use of human embryos in research should prohibit such transfer. There are legitimate concerns, however, that women might be unduly pressured or influenced by family, clinicians, or others to donate eggs to develop treatments for loved ones.[98] The risks imposed by egg stimulation and retrieval procedures warrant careful consideration of informed consent procedures, particularly if the egg donation is not intended to directly benefit the donor, as it is in IVF. Also, issues of ownership may arise if donors intend or wish to restrict the products of their gametes for a particular individual or group.

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97. A recent scientific report suggests that stem cells can be induced to become oocytes, potentially sidestepping donation, but the experiments were performed with mouse embryonic stem cells and no guarantee exists that the procedure would work with human embryonic stem cells. Karin. Hübner et al., *Derivation of Oocytes from Mouse Embryonic Stem Cells*, 300 SCIENCE 1251 (2003).

98. Suzanne Holland, *Beyond the Embryo: A Feminist Appraisal of the Embryonic Stem Cells*, *in* THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 2, at 73.

Yet, consider the case of Molly Nash.[99] In 2000, Jack and Lisa Nash gave birth to a baby boy, Adam, conceived through IVF. The embryo that became Adam was *chosen* using preimplantation genetic diagnosis to select for an embryo that was both a transplant match for and free from Fanconi Anemia, the genetic disease afflicting young Molly that results in bone marrow failure and often leukemia.[100] Stem cells from Adam's umbilical cord were transferred to Molly and have improved her condition.[101] Is it more ethical then to give birth to a baby and harvest its stem cells than to allow parents to create an embryo with IVF and use it to create stem cells to treat an ill child? If one considers the destruction of a preimplantation human embryo the moral equivalent of murder, the answer is simple. If not, it seems any measure of harm to a conscious, postnatal child is worse than disaggregating an embryo composed of a tiny cluster of cells.

Still there are those who object to the use of human embryos in research at all, regardless of how or why they are created, based on the belief that embryos are the moral equivalents of postnatal human beings.[102] However, the majority of Americans do not subscribe to this viewpoint;[103] and as bioethicist Erik Parens points out, this type of moral distinction typifies "a particular set of beliefs that citizens in a democracy are not obliged to accept."[104] Still it appears that Americans are not indifferent toward embryos but consider them with some deference.[105] The development of legislation concerning stem cell and therapeutic research, including the issues of embryo creation for research, should correspondingly reflect the diverse beliefs of U.S. citizens, rather than

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99. *Genetic Selection Gives Girl a Brother and a Second Chance,* CNN.COM, Oct. 3, 2000, *at* http://www.cnn.com/2000/HEALTH/10/03/testube.brother/index.html (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review).

100. Fanconi Anemia Research Fund, Inc., About Fanconi Anemia: What Is Fanconi Anemia?, *at* http://www.fanconi.org/aboutfa/FA.htm (last updated Aug. 1, 2004) (on file with the Indiana Health Law Review).

101. Rhonda Rowland, *Genetic Testing of Embryos Raises Ethical Issues*, CNN.COM, June 27, 2001, *at* http://www.cnn.com/2001/HEALTH/06/27/embryo.testing/ (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review).

102. A series of polls conducted on the topics of stem cell research and human cloning reveals that, while often a majority of respondents favor stem cell research using human embryos, typically 30-40 percent of respondents oppose this research outright. Furthermore, according to a Los Angeles Times Poll conducted from Jan. 30-Feb. 2, 2003, only 11 percent of respondents are in favor of eliminating all restrictions on human cloning research. PollingReport.com, American Scene: Science and Nature, *at* http://www.pollingreport.com/science.htm (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review).

103. Jeffrey M. Jones, *Update: Americans' Views on Stem Cell Research*, GALLUP POLL, August 14, 2001, *at* http://www.gallup.com/content/login.aspx?ci=4792 (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review).

104. Erik Parens, *On the Ethics and Politics of Embryonic Stem Cell Research, in* THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 2, at 37, 40.

105. *See generally* PollingReport.com, American Scene: Science and Nature, *at* http://www.pollingreport.com/science.htm (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review).

the more vocal and politically active religious interests or the silent but potentially profit-driven interests of infertility clinics.

Nonetheless, widespread public acceptance does not necessarily render a scientific technique *ethical*. Public demand for medical aid is capable of overshadowing ethical considerations. This has occurred with IVF and other assisted reproductive technologies, which undisputedly carry a measure of risk to the children born of these technologies[106] and, as discussed, engage in embryo creation with implicit understanding that many embryos will be destroyed. In fact, more careful consideration of the ethics of ART is most likely warranted and has been undertaken recently by the PCB in its March 2004 report.[107] Likewise, careful consideration of embryo creation for research purposes is necessary and should be *ongoing* as the science of stem cell research and therapeutic cloning advance because advance they will, either within or outside of the United States.

C. *Missed Opportunities: Federal Funding of Human Embryo Research*

Federal oversight of human embryo research and its application should be mandated for several reasons. First, given the rapid development of novel technologies, a lack of regulation and oversight may well lead to unexpected scientific consequences. Concerns with human cloning were rightly intensified by scientific evidence that Dolly the sheep and other animal clones may have health problems related to the cloning process.[108] The effects of IVF on embryos have not been fully studied,[109] and as neither somatic cell nuclear transfer nor *in vitro* fertilization to create embryos qualify as treatments on a living patient, they are not currently subject to review by the Food and Drug Administration or other regulatory agency.[110] Federal funding will ensure these technologies undergo peer review to evaluate their scientific quality and value and should dramatically increase the number of studies undertaken to assess whether these technologies adversely affect embryos. Such knowledge would enhance both the practice of treating infertility and our understanding

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106. For example, the higher incidence of multiple gestation leads to greater probability of newborn health problems. DEP'T OF HEALTH & HUMAN SERVS., 2001 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 20 (Dec. 2003), *available at* http://www.cdc.gov/reproductivehealth/ART01/PDF/ART2001.pdf.

107. THE PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY THE REGULATION OF NEW BIOTECHNOLOGIES (Mar. 2004), *available at* http://www.bioethics.gov/reports/reproductionandresponsibility/index.html.

108. Bridget M. Kuehn, *Goodbye, Dolly: First Cloned Sheep Dies at Six Years Old,* JAVMANEWS, Apr. 15, 2003, *at* http://www.avma.org/onlnews/javma/apr03/030415f.asp (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review).

109. Van Blerkom, *supra* note 25, at 1.

110. AM. ASS'N FOR THE ADVANCEMENT OF SCI., REGULATING HUMAN CLONING (Apr. 3, 2003), *available at* http://www.aaas.org/spp/cstc/issues/cloningreport.pdf.

of embryonic development, and by improving IVF technology, might well lead to a decreased number of embryos needed for both the clinic and in research.

Secondly, federal oversight ensures that the ethics of both using and creating human embryos are always carefully considered. Though their recommendations were subsequently discarded, the various national boards appointed to review the ethics of emerging technologies reflect this effort.[111] And as discussed in the next section, a glance *across the pond* at the U.K.'s Human Fertilisation and Embryology Authority reveals a unique regulatory agency that endeavors to maintain ethical standards while permitting embryo creation.

Lastly, with federal funding of human embryo research, the United States can maintain its status as a leader in scientific and medical advances. Federal monies will both allow these rapidly developing and potentially revolutionary technologies to bloom here at home and allow the U.S. system of scientific peer-review to shine as a model for careful and deliberate consideration of both scientific merit and ethical concerns. Without federal funding, the next decade may witness talented U.S. scientists who are dedicated to infertility or stem cell research departing for other countries; the continued use of non-peer-reviewed, potentially lesser quality research in our clinics; and the absence of recourse to hinder those who would violate ethical principles due human embryo research by, for example, attempting human reproductive cloning. Furthermore, private investors in this research may be difficult to find, as the promise of the medical technologies that may develop are too far down the road to warrant capitalization.[112] This too, will dramatically slow the progress of human embryo research in the United States, and we can only watch as other nations become the world's new scientific leaders.

All of the recommendations published by federally commissioned ethics groups clearly outlined mechanisms for maintaining the respect due preimplantation human embryos during their use in scientific research.[113] These groups were diverse in their opinions and interests and presumably approached their task as impartially as possible. Though their recommendations differed somewhat, arguably due to changes in the political climate, their valuable expertise and concerted efforts to develop appropriate regulations appear to have been consistently ignored by politicians bowing to pressures from an unyielding minority. For this reason, the efforts of these ethics review groups represent multiple missed opportunities for the United States to enact legislation concordant with our historical and current legal treatment and moral consideration of preimplantation human embryos.

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111. HERP REPORT, *supra* note 3; EAB REPORT, *supra* note 5; NBAC REPORT, *supra* note 5.

112. Luke Timmerman, *A Puzzling Investment Stem-Cell Research is Exciting, But Not to Investors, Who See Ethical Risks, An Expensive, Unpredictable Product and a Sketchy Business Model with an Unknown Future*, SEATTLE TIMES, Feb. 22, 2004, at E1.

113. HERP REPORT, *supra* note 3, at 100-14; NBAC REPORT, *supra* note 5, at 65-74.

D. The HFEA and the United Kingdom Example

A survey of eleven democratic nations, including Australia, Canada, and nine European countries, revealed that only one, Norway, has banned all human embryo research.[114] Great Britain, a nation typically politically allied with the United States, is one of the most liberal nations in terms of permitting the use of human embryos in research. Approximately seventy percent of U.K. citizens support the use of human embryos "for medical research to find treatments for serious diseases and for fertility research",[115] and the government's policy reflects this position. What, then, is different about their approach?

In 1990, the United Kingdom established the Human Fertilisation and Embryology Authority (HFEA) to oversee and regulate all scientific and medical use of human embryos.[116] All human embryo research proposals, regardless of their source of funding, must be approved and licensed by the HFEA.[117] Approval is contingent on both the purpose and the necessity of the research; only proposals that the HFEA deems necessary to advance one of its purposes eligible for licensing will be authorized.[118] These purposes include promoting advances in infertility treatment, increasing knowledge of causes of congenital disease and miscarriage, developing more effective techniques for contraception, developing methods for detection of genetic or chromosomal abnormalities in preimplantation embryos, advancing understanding of embryonic development, increasing knowledge of serious disease, and enabling such knowledge to be applied in developing treatments for these diseases.[119]

From this list, it is apparent that the original goals of the HFEA were to facilitate human embryo research that would improve infertility treatment, enhance family planning, and increase our understanding of embryological disorders. The latter three purposes, added in 2001, were enacted to facilitate stem cell research[120] and imply that this use of human embryos is ethically acceptable in the United Kingdom. However, researchers wishing to derive stem cells from human embryos must justify why embryonic stem cells are to

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114. Andrews, *supra* note 41, at 297.

115. *Seven In Ten Members Of The Public Support The Use Of Embryos For Medical Research*, MORI, Apr. 8, 2003, *at* http://www.mori.com/polls/2003/amrc.shtml (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review).

116. Press Release, Human Fertilisation and Embryology Authority, Suzi Leather, Chair of the Human Fertilisation and Embryology Authority clarifies the Authority's role in regulating stem cell research (Sept. 11, 2002), *at* http://www.hfea.gov.uk/PressOffice/Archive/85775462 (last visited Apr. 17, 2005) (on file with the Indiana Health Law Review).

117. Human Fertilisation and Embryology Act, 1990, c. 37 (Eng.), *available at* http://www.legislation.hmso.gov.uk/acts/acts1990/.

118. *Id.*

119. *Id.*

120. *Id.*

be used, rather than other types of stem cells, provide detailed information on what happens to the stem cells throughout the project, and place a sample of all cell lines established in the MRC Stem Cell Bank.[121] Scientists also are prohibited from transferring stem cell lines to third parties, so that the HFEA may maintain a complete inventory and research trail.[122]

Prior to granting new licenses or allowing a change in an existing license, the HFEA inspects all research facilities to ensure appropriate facilities, security, and mechanisms for informed consent without coercion and confidentiality are in place. The HFEA also regulates the separation of embryos for research and for treatment, methods for obtaining embryos, the length of time such embryos may be maintained in culture (fourteen days), and the proper procedures for embryo destruction. Further, for a license to be granted, the proposal must pass a local Research Ethics Committee review and be peer-reviewed to determine the following:[123]

1. Whether the research fulfills the categories for which embryo research is permitted;
2. The importance of the research in the field;
3. Whether the research has been done before;
4. Whether the use of human embryos is justified;
5. The suitability of the methods to be used;
6. The proposed length of the study;
7. The applicant's qualifications.[124]

In short, the use of human embryos in the United Kingdom is not taken lightly. The rigorous process of review and licensing endeavors to maintain a level of integrity in the science and respect for the embryo by limiting its use.

The unique and most controversial feature of the HFEA regulations, though, is the authorization of the creation of human embryos for research purposes.[125] Yet within its extensive oversight framework, the HFEA can ensure medical and ethical standards are maintained in the creation of embryos, whether for research or for infertility treatment. It has established mechanisms to ensure informed consent before gamete donation and before use or storage of embryos.[126] It currently mandates anonymous egg donation and requires that donors be informed they relinquish all control over future use of the embryos and any products (stem cells) derived from these embryos.[127] As Ruth Deech points out, "[i]n this area of medicine [sic] for, it is vital that

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121. *Id.*

122. *Id.*

123. Human Fertilisation and Embryology Act, 1990, c. 37 (Eng.), *available at* http://www.legislation.hmso.gov.uk/acts/acts1990/.

124. *Id.*

125. *Id.*; *See also* Peter Moore, *Are Stem Cells the Answer? A Global Struggle to Deal with Human ES Cells*, HHMI BULLETIN, Mar. 2002, at 16.

126. Human Fertilisation and Embryology Act, 1990, c. 37 (Eng.), *available at* http://www.legislation.hmso.gov.uk/acts/acts1990/.

127. *Id.*

patients understand the implications of their treatments, the ethical and emotional sensitivities . . . [t]he Code of Practice requires clinics to give such information to patients."[128] Though United States' clinics typically provide some measure of informed consent, patients, relevant lawsuits, and the disparate decisions of the courts[129] suggest that a federally organized uniform code of informed consent might benefit both IVF patients and research embryo donors.

The HFEA also endeavors to protect patients by certifying that clinics "undertake research and sufficient training before treating patients with a new technique."[130] Though certainly the United States' judicial system offers a mechanism to redress medical malpractice, the HFEA's proactive stance offers a better protection of patients, and one that is not obviously present in U.S. clinics dealing with desperate would-be parents. The opportunity exists for clinics to unintentionally put patients at risk when they are eager to try a new technology for the sake of science or if medical personnel become emotionally invested in helping an infertile couple conceive. With oversight, however, the development of new techniques, such as the creation of embryos to harvest stem cells for directed donation, can be restricted to the research phase until deemed ready for clinical practice. In addition, the strict data reporting and collection methods employed by the HFEA may also prove valuable in assessing the impact of such technologies on the health of women and children involved.[131]

Despite the freedoms in human embryo research granted scientists and clinicians in the United Kingdom, even the HFEA has been criticized as "a barrier to progress."[132] Perhaps some scientists will never be satisfied when their actions are regulated in some form. Yet the sensitive nature of embryo research, particularly the creation of embryos for research, compels careful ethical and scientific contemplation, the employment of guidelines and regulations that protect ethical standards, and an impartial body outside the clinical setting to make sure those standards are upheld. In the United Kingdom, the HFEA serves as this *impartial body* for all human embryo use and creation and thus far appears to have served it well. Time will tell if the permitted and funded creation of embryos bears the promised medical fruits and renders Great Britain the international leader of scientific research in human embryology, therapeutic cloning, and stem cell research, but their open-minded, non-ideological but respectful approach certainly will grant them a head-

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128. Ruth Deech, *A Fine Conception: the Experience of the Human Fertilisation and Embryology Authority* (HFEA), 85 EURO. J. OBST. & GYN. & REPROD. BIOL. 3, 5 (1999).

129. York v. Jones, 717 F. Supp. 421 (E.D.Va 1989); Davis v. Davis, 842 S.W.2d 588 (Tenn. 1992); Litowitz v. Litowitz, 48 P.3d 261, 271 (Wash. 2002).

130. Deech, *supra* note 128, at 5.

131. P. Doyle, *The U.K. Human Fertilisation and Embryology Authority. How it has Contributed to the Evaluation of Assisted Reproduction Technology*, 15(1) INT. J. TECH. ASSESS. HEALTH CARE 3 (1999).

132. Deech, *supra* note 128, at 5.

start. Meanwhile, as Ruth Deech observes, "[t]he experience of the HFEA is that it is possible to provide effective controls, as long as close co-operation is maintained with licensed clinics, professional and patient groups."[133]

The regulation of human embryo research, however, does not require a unique regulatory body like the HFEA. The current system in the United States for managing and regulating scientific research is highly effective and collaborative. We might look to the future successes of the HFEA, however, and realize that the ethical and regulatory issues of human embryo research, including the creation of embryos solely for research purposes, are manageable and, due to the need to respect human life in all its forms, best under the public microscope rather than under the influence of the profit-driven private sector. Nonetheless, due to the public interest and media frenzy currently surrounding the sensitive issues of cloning and stem cell research, a centralized national review board under the auspices of the NIH and the DHHS might be prudent at this time to maintain public awareness until the benefits of this research can be clearly delineated and effective ethical management demonstrated. Once accomplished, review of human embryo research might be then relegated to local IRBs. The medical significance of the research ought to preclude a repeat of the failed EAB of the late 1970s.

V. CONCLUSIONS

Widespread public medical demand for the medical benefits of embryonic stem cells and therapeutic cloning, like IVF and ART, may lead to a general acceptance of the creation of embryos *in vitro* with the intent to disaggregate them and end their potential to become fully nascent human beings. Thus to allow the opinions of all U.S. citizens on this highly controversial issue to be heard and represented, to maintain respect for the human embryo, and to avoid inappropriate use and creation of embryos, federal funding and oversight of human embryonic research should be undertaken. It is important to consider and carefully weigh the medical and ethical significances of creating embryos to pursue research. It is perhaps unethical *not* to pursue this research in terms of both scientific standards and advancing medicine to treat ravaging diseases affecting millions. It is also plausible that unmeasured embryo creation could profoundly diminish our cultural regard for the significance of human individuality. Yet the experience of the United Kingdom's Human Fertilisation and Embryology Authority demonstrates that the ethics of embryo creation are manageable, and the HFEA provides a rudimentary framework that might be adapted in the United States under the auspices of the NIH and DHHS.

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133. *Id.*