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Cover Page Footnote

J.D., Candidate, 1999, Fordham University. This Note is dedicated to my parents, William and Louise Feiler, in gratitude for their constant love and support throughout my education. Special thanks to Gianfranco Arena for his untiring encouragement during the writing of this Note.

HUMAN EMBRYO EXPERIMENTATION: REGULATION AND RELATIVE RIGHTS

Christine L. Feiler*

INTRODUCTION

Reproductive rights and technologies have been at the forefront of politics and science in recent decades.¹ The development of contraception,² abortion,³ and—most recently—cloning⁴ have challenged the moral and ethical beliefs of many Americans. Human embryo⁵ research has likewise fueled ongoing debate within scientific, ethical, and legal circles.⁶

The development of *in vitro* fertilization (“IVF”), an assisted reproductive technique in which fertilization is accomplished outside the mother’s body,⁷ first made human embryos available for scientific re-

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1. See generally Robert Blank & Janna C. Merrick, *Human Reproduction, Emerging Technologies, and Conflicting Rights* (1995) (discussing medical advances, political responses, changing social values, and novel legal cases which currently challenge conventional notions of reproductive rights and create policy dilemmas).

2. “Contraception” refers to means or methods of preventing pregnancy and resulting birth. 1 Am. Jur. 2d *Abortion and Birth Control* § 2 (1994). Recent advances, however, have blurred the line between abortion and contraception. *Id.* For example, the controversial “abortion pill,” RU-486, induces abortion without surgical intervention, but is categorized as a form of contraception. *Id.*

3. The legal definition of “abortion” is the termination of a human pregnancy for a purpose other than production of a live birth or removal of a dead embryo or fetus. *Id.* § 1 (citing the Revised Uniform Abortion Act).

4. “Cloning” is a developing scientific technique which produces an exact copy of a molecule, cell, or individual plant or animal. National Bioethics Advisory Commission, *Cloning Human Beings Appendix-1* (1997) (discussing scientific, religious, legal, and public policy implications of human cloning) [hereinafter *Cloning Report*], available at <<http://bioethics.gov/bioethics/pubs.html>>. This technology dominated headlines in October of 1996, when Ian Wilmut reported the successful cloning and live birth of a sheep named “Dolly.” *Id.* at 1.

5. The term “embryo” signifies the developing human organism from the time of fertilization until the eighth week of gestation, when it becomes known as a “fetus.” National Institutes of Health, *Report of the Human Embryo Research Panel D-4* (1994) [hereinafter *NIH Panel Report*]. *But cf. infra* note 248 (discussing the inconsistent use of these terms in state statutes).

6. See, e.g., Jonathan Van Blerkom, *The History, Current Status and Future Direction of Research Involving Human Embryos*, in National Institutes of Health, *Papers Commissioned for the Human Embryo Research Panel 1*, 7 (1994) (discussing the controversy surrounding Peter Braude’s 1988 *Nature* study in which human embryos were created solely for the purpose of studying biochemical regulation of embryo development).

7. NIH Panel Report, *supra* note 5, at D-6. During the IVF medical protocol, a woman is treated with hormones to induce ovulation, her eggs are surgically retrieved and fertilized with sperm *in vitro*, and the resulting embryos are transferred to her uterus for implantation. Andrea L. Bonnicksen, *In Vitro Fertilization: Building Policy*

search purposes.⁸ In 1978, Patrick Steptoe and Robert Edwards reported the first live birth made possible by IVF technology.⁹ Four years later, they announced plans to freeze "spare" embryos leftover from these procedures for potential clinical or laboratory use.¹⁰

Embryos are currently utilized in two primary areas of investigation: (1) basic or laboratory research, which seeks to identify and explore the underlying biological principles and processes of embryological development; and (2) IVF development, which attempts to modify clinical or laboratory techniques used in assisted reproduction protocols.¹¹ Most work in the United States has focused on the latter, attempting to increase the frequency of pregnancy associated with laboratory-assisted conception.¹² Another growing area of research involves the embryo as "patient,"¹³ and includes techniques such as gene therapy¹⁴ and pre-implantation diagnosis.¹⁵

Researchers typically acquire embryos from couples who have undergone fertility treatment and voluntarily donate extra embryos that they do not wish to implant.¹⁶ An alternate source of these entities, however, is the deliberate fertilization and harvesting of embryos expressly for experimental use.¹⁷ In this age of scientific progress, purposeful production of embryos may be the only way to satisfy

From Laboratories to Legislatures 147-51 (1989). For a full description of this technology, its history, and its public policy implications, see generally *id.*

8. Blank & Merrick, *supra* note 1, at 180.

9. *Id.*

10. *Id.* During IVF treatment, the physician may fertilize more embryos than will be implanted. Bonnie Steinbock, *Ethical Issues in Human Embryo Research*, in National Institutes of Health, Papers Commissioned for the Human Embryo Research Panel 27, 33-34 (1994). Such over-fertilization raises important choices for the individual or couple who has undergone treatment, including whether to destroy the "spare" embryos, donate them for research, or donate them to other couples. See Bonnicksen, *supra* note 7, at 37-38.

11. Van Blerkom, *supra* note 6, at 8; see *infra* Part II.B (providing a more extensive discussion of research areas).

12. Van Blerkom, *supra* note 6, at 8.

13. Steinbock, *supra* note 10, at 27-28.

14. Gene therapy is a developing technique that alters the genetic makeup of the subject, in an attempt to correct defects in the individual (somatic cell gene therapy) and perhaps even future offspring (germ-line gene therapy). *Id.* at 28. Somatic cell gene therapy could be used to treat an embryo with a defective gene, by replacing the abnormal cells with corrected stem cells. *Id.* While such treatment would not prevent the same disease in that embryo's future offspring, germ-line gene therapy introduces into the genetic makeup of an individual changes that are passed on to at least one generation. *Id.* (noting that germ-line gene therapy has never been attempted on human embryos due to unpredictable potential side effects).

15. Pre-implantation diagnosis involves the removal and biopsy of several cells from a developing embryo *in vitro* to identify the existence of genetic disease. *Id.* at 27-28. Such testing does not seek to treat the embryo; rather, it avoids the implantation of "defective" embryos simply by discarding them. *Id.* at 28, 38.

16. NIH Panel Report, *supra* note 5, at xiii.

17. *Id.* In other words, researchers fertilize embryos for their own use in experiments, not for individuals' use in becoming parents.

expanding research needs.¹⁸ Despite considerable public concern,¹⁹ however, there are currently no national standards to limit how scientists may acquire embryos for this type of experimentation, nor guidelines to govern how such research shall be conducted in the United States.²⁰

In response to this unresolved controversy, this Note advocates a uniform federal ban on the creation of human embryos for use in investigational embryo research.²¹ Part I considers the legal status of the embryo as it has been determined in other reproductive contexts, and ultimately distinguishes embryo research from those contexts. Further, it introduces the relative rights which must be considered in designing regulation of research embryo²² experimentation. Part II evaluates these competing rights from both sides of the embryo research debate and argues that the balancing of these interests requires that scientists be prevented from creating embryos solely for scientific use. Part III examines the manner and extent to which existing federal and state laws protect the interests outlined above and identifies

18. Blank & Merrick, *supra* note 1, at 180; see Part II.B (discussing research areas for which deliberately fertilized embryos are important).

19. See Meena Lal, *The Role of the Federal Government in Assisted Reproductive Technologies*, 13 Santa Clara Computer & High Tech. L.J. 517, 518 (1997) ("Lack of a national policy [regarding reproductive technologies] has resulted in . . . exploitation and commercialization of one of the most valued and personal aspects of our society."); Mary Cantwell, Editorial, *Should We Make Research Embryos? No, Humans Are Not Lettuces*, N.Y. Times, Nov. 25, 1994, at A36; David Walsh, *Benefits Don't Make it Ethical*, Wash. Post, Oct. 27, 1994, at A23.

20. Other countries, such as France, Germany, Spain, and the United Kingdom, subject human embryo research to strict oversight. See *Conceiving the Embryo: Ethics, Law and Practice in Human Embryology* 303-49 (Donald Evans ed., 1996). In the United Kingdom, for example, the Human Embryo Fertilisation and Embryology Act ("HFE Act") governs embryo experimentation. *Id.* at 303. The HFE Act requires licensing of all such research projects and limits the purpose for and the time frame in which embryos may be used. *Id.* at 308-09.

21. This Note uses the term "investigational embryo research" to mean tests, techniques, or procedures which are designed to increase the knowledge of the researcher or scientific discipline, but are not intended to diagnose or improve the life or health of the embryo or individual biological parent, and which result in the destruction of the embryo. This Note does not advocate restriction of "therapeutic research"—including gene therapy, *supra* note 14—performed on existing embryos, which is intended to benefit the embryo. See Blank & Merrick, *supra* note 1, at 177-78.

Nor does this Note address research conducted on "spare" or "surplus" embryos, which are embryos left over from IVF procedures and voluntarily donated by parents for experimental use. Different constitutional issues and ethical arguments arise with respect to experiments conducted with these embryos. See NIH Panel Report, *supra* note 5, at 42 (observing that many who oppose the creation of research embryos tolerate research conducted with spare embryos, because the latter may be justified as the byproduct of otherwise well-intentioned attempts to conceive healthy children); Steinbock, *supra* note 10, at 29 (suggesting that, under certain conditions, even those who believe that the unborn have equal status with children might not object to experimenting on, as opposed to discarding, spare embryos); *infra* note 97 (noting potential reproductive autonomy implications of research with spare embryos).

22. This Note uses the term "research embryo" to refer to an embryo created solely for use in investigational embryo research.

their limitations and inadequacies. Part IV then proposes a federal statute to prohibit the creation and exploitation of research embryos and correct the problems identified in existing legislation.

I. THE LEGAL STATUS OF THE EMBRYO

The embryo itself is the necessary starting point for any discussion of research regulation: What is it and why should (or shouldn't) it be protected? Answers to these difficult questions have elicited both condemnation and endorsement of human embryo research.²³ The scholarly disagreement over the moral worth and legal status of the embryo is mirrored in our nation's courts, which currently afford disparate treatment to embryos in a variety of reproductive contexts.²⁴ These treatments necessarily influence both attitudes toward, and regulation of, human embryo research.²⁵

This Part introduces some of the recent federal and state decisions which have considered the legal status of the embryo in the context of abortion and IVF disputes. As a problem separate and distinct from both abortion and IVF, however, research involving deliberately fertilized embryos implicates different legal issues and requires independent analysis. This discussion proceeds to introduce the rights and interests that must be considered in designing regulation of this complex area of scientific activity.

A. Abortion Law

The legal status of the unborn was most notably evaluated in *Roe v. Wade*.²⁶ In *Roe*, the United States Supreme Court struck down a Texas statute that criminalized abortion except in life-threatening circumstances.²⁷ The majority held that the right to privacy, arising from the Due Process Clause of the Fourteenth Amendment, protected a woman's interest in obtaining an abortion.²⁸ Writing for the majority,

23. Compare, e.g., Hadley Arkes et al., *The Inhuman Use of Human Beings: A Statement on Embryo Research by the Ramsey Colloquium*, 49 *First Things* 17 (January 1995) <<http://www.firstthings.com/ftissues/ft9501/ramsey.html>> [hereinafter *The Ramsey Colloquium*] (outlining pro-life opposition to human embryo research and critiquing the Human Embryo Research Panel Report), with John A. Robertson, *In the Beginning: The Legal Status of Early Embryos*, 76 *Va. L. Rev.* 437, 444-47 & n.30 (1990) (outlining the viewpoint that supports embryo research).

24. See Lal, *supra* note 19, at 526; *infra* note 37.

25. See *infra* text accompanying note 33; see also George J. Annas et al., *The Politics of Human-Embryo Research — Avoiding Ethical Gridlock*, 334 *New Eng. J. Med.* 1329, 1329 (1996) (observing that medical ethics are held "hostage" by the unresolved abortion debate and arguing that embryo research must be disentangled from this divisive political issue to achieve much-needed compromise).

26. 410 U.S. 113 (1973); see generally John A. Robertson, *Gestational Burdens and Fetal Status: Justifying Roe v. Wade*, 13 *Am. J.L. & Med.* 189 (1987) (discussing the impact of *Roe*).

27. *Roe*, 410 U.S. at 164.

28. *Id.* at 153.

Justice Blackmun denied that the unborn were "persons" within the meaning of the Constitution,²⁹ but acknowledged that the State's interest in protecting fetal life was sufficiently compelling to limit the right to abortion under certain conditions.³⁰ Protection of unborn life can never be absolute, however, because of the competing Constitutional rights of women. *Roe's* holding was later affirmed in *Planned Parenthood v. Casey*,³¹ where the Court established an "undue burden" test to determine whether state regulation of abortion is permissible.³²

Roe and its progeny "loom[] heavily in the background of any discussion of policies regarding research on conceptuses [embryos and fetuses]." ³³ These cases do not, however, dispose of the embryo research debate. The Supreme Court's abortion jurisprudence does not

29. *Id.* at 156-58. Although the Constitution does not define "person" in so many words, its usage of the term

has application only postnatally. None [of the Constitutional references to person] indicates, with any assurance, that [person] has any possible prenatal application.

[T]his, together with our observation . . . that throughout the major portion of the 19th century prevailing legal abortion practices were far freer than they are today, persuades us that the word "person," as used in the Fourteenth Amendment, does not include the unborn.

Id. at 157-58.

30. *Id.* at 163-64. Justice Blackmun acknowledged that the State has two "separate and distinct" interests: preserving and protecting the health of pregnant women, and protecting the potentiality of human life. *Id.* at 162. The former interest becomes compelling at the end of the first trimester, at which point the State may regulate abortion to the extent it "reasonably relates to the preservation and protection of maternal health." *Id.* at 163. The State's interest in unborn life, however, becomes compelling only at the point of viability, when the fetus is "presumably" capable of "meaningful" life outside the mother's body. *Id.* The State may pursue this interest even to the point of proscribing abortion after viability, except where abortion is necessary to preserve the life or health of the mother. *Id.* at 163-64.

Planned Parenthood v. Casey, the Supreme Court affirmed that "the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus . . ." 505 U.S. 833, 846 (1992) (plurality opinion) (emphasis added). The Court retained viability as the point before which a woman has the right to terminate her pregnancy. *Id.* at 870-71. The Court abandoned *Roe's* trimester framework, however, and held that the State's interest in protecting fetal life justifies [e]ven in the earliest stages of pregnancy . . . rules and regulations designed to encourage [a woman] to know that there are philosophic and social arguments of great weight that can be brought to bear in favor of continuing the pregnancy to full term and that there are procedures and institutions to allow adoption of unwanted children as well as a certain degree of State assistance if the mother chooses to raise the child herself.

Id. at 872. *Roe's* rigid structure was deemed "incompatible with the recognition that there is a substantial state interest in potential life throughout pregnancy." *Id.* at 876 (emphasis added).

31. 505 U.S. 833 (1992) (plurality opinion).

32. *Id.* at 878-79. "A finding of an undue burden is a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." *Id.* at 877.

33. Blank & Merrick, *supra* note 1, at 176 (quoting Lori B. Andrews, one of the advisors to the NIH Panel, *see infra* note 248).

prohibit the government from granting rights to fetuses or embryos; it merely holds that the Constitution does not obligate the government to do so.³⁴ Such rights, however, must not unduly interfere with constitutionally protected interests, such as a woman's right to abortion.³⁵ As one commentator has noted:

[Blackmun's] opinion did not try to assign a precise moral or legal status to fetal life. It merely identified the upper bounds of that status (i.e., it is not protected by the equal protection clause), which was sufficient for cases that balanced clearly protected rights of pregnant women against fetal interests. This is precisely why the 1973 *Roe* decision . . . still leave[s] it to the legislative branch to determine whether embryos can be killed in the name of scientific progress.³⁶

Thus, the Court's abortion jurisprudence does not limit the legislatures' power to define the scope and permissibility of investigational embryo research in years to come.

B. IVF Law

Recent disputes have also given the courts an opportunity to consider the legal status of the embryo in the IVF context. Federal and state courts have given differing treatment to embryos that were subjects of IVF controversies.³⁷

In *York v. Jones*,³⁸ a couple sued for the return of a single frozen embryo held in storage by their Virginia IVF clinic after the clinic refused to transfer it to the couple's California fertility specialist.³⁹ At the start of their IVF treatment, the Joneses signed a "Cryopreservation Agreement" with the fertility clinic that detailed their respective rights to the excess embryos.⁴⁰ The Eastern District of Virginia held

34. R. Alta Charo, *The Hunting of the Snark: The Moral Status of the Embryos, Right-to-Lifers, and Third World Women*, 6:2 Stan. L. & Pol'y Rev. 11, 20 (1995).

35. *Id.* But see *Casey*, 505 U.S. at 980 (Scalia, J., dissenting) (voicing the opinion of four Justices that the Constitution does not, in fact, guarantee a right to abortion); *Roe*, 410 U.S. at 171-78 (Rehnquist, J., dissenting) (rejecting the majority's result as unfounded in the Constitution). This Note recognizes that the right to abortion is protected as fundamental under the current majority's abortion jurisprudence and attempts to operate within the constraints of that holding. It does not, however, endorse that premise or presume that the issue is immune from future consideration by the Court.

36. Charo, *supra* note 34, at 20.

37. See *York v. Jones*, 717 F. Supp. 421 (E.D. Va. 1989) (construing embryos as property); *Davis v. Davis*, No. E-14496, 1989 WL 140495 (Tenn. Cir. Ct. Sept. 21, 1989) (treating embryos as children), *rev'd*, No. 180, 1990 WL 130807 (Tenn. Ct. App. Sept. 13, 1990), *aff'd*, 842 S.W.2d 588 (Tenn. 1992) (holding that embryos occupy an "interim category" with symbolic value as potential life), *cert. denied*, 507 U.S. 911 (1993).

38. 717 F. Supp. 421 (E.D. Va. 1989).

39. *Id.* at 424.

40. *Id.* at 424-25. The contract stated that if the Joneses no longer wished to attempt pregnancy, their embryos could be "1) donated to another infertile couple, . . .

that the contract created a valid bailment relationship between the couple and the clinic.⁴¹ Furthermore, the court acknowledged that embryos were properly considered "property" for the purposes of such contracts.⁴² The couple's property and "possessory interest[s]" in the embryo—rather than any rights or interests of the embryos themselves—were the controlling considerations in the court's decision to return the embryo to the Yorks.⁴³

The Tennessee Supreme Court criticized this treatment of the embryo as property in *Davis v. Davis*.⁴⁴ *Davis* began as a divorce action, in which the parties were able to agree on all terms of dissolution, except one: who was to have "custody" of the seven frozen embryos that the couple had deposited with a fertility clinic during earlier attempts to conceive a child.⁴⁵ Mary Sue Davis originally requested control of the embryos so that she might have them implanted in her own uterus, in "a post-divorce effort to become pregnant."⁴⁶ Her husband objected, desiring that the embryos remain in their frozen state until he decided whether he wanted to become a parent outside of their marriage.⁴⁷

The trial court held that the embryos should be treated as children for the purposes of this custody dispute,⁴⁸ and awarded them to Mrs. Davis.⁴⁹ The judge further instructed that Mrs. Davis "be permitted the opportunity to bring [these children] to term through implantation."⁵⁰ The appellate court reversed and awarded "joint control . . . [and] equal voice over [the embryos'] disposition" to both spouses.⁵¹

2) donated for approved research investigation, [or] 3) thawed but not allowed to undergo further development." *Id.* at 424. The clinic argued that the Jones' proprietary right to the embryos were limited to those "three fates" enumerated in the agreement and did not include inter-institutional transfer of the embryos. *Id.* at 425.

41. *Id.* at 425. A bailment relationship exists under Virginia law wherever there "is the element of lawful possession however created, and duty to account for the thing as the property of another . . ." *Id.* (citing *Crandall v. Woodward*, 143 S.E.2d 923, 927 (Va. 1965)). When the purpose of the bailment has terminated, the bailee is under an absolute obligation to return the subject matter of the bailment to the bailor—a duty implied from the fact of lawful possession of another's personal property. *Id.* at 425.

42. *Id.* at 424-25.

43. *Id.* at 425-27.

44. 842 S.W.2d 588 (Tenn. 1992), *cert. denied* 507 U.S. 911 (1993).

45. *Id.* at 589.

46. *Id.*

47. *Id.*

48. *Davis v. Davis*, No. E-14496, 1989 WL 140495, at *1 (Tenn. Cir. Ct. Sept. 21, 1989), *rev'd*, No. 180, 1990 WL 130807 (Tenn. Ct. App. Sept. 13, 1990), *aff'd*, 842 S.W.2d 588 (Tenn. 1992) (holding that embryos occupy an "interim category" with symbolic value as potential life), *cert. denied*, 507 U.S. 911 (1993).

49. *Id.*

50. *Id.*

51. *Davis v. Davis*, No. 180, 1990 WL 130807 at *3 (Tenn. App. Sept. 13, 1990), *aff'd*, 842 S.W.2d 588 (Tenn. 1992) (holding that embryos occupy an "interim category" with symbolic value as potential life), *cert. denied*, 507 U.S. 911 (1993).

The court cited *York* in support of its holding,⁵² but failed to explicitly define the Davis' interest in the embryos.⁵³

Dissatisfied with both lower court conclusions, the Tennessee Supreme Court set out to clarify the legal status of the embryo.⁵⁴ The court looked to the American Fertility Society's Ethics Committee Report, which outlined three interpretations of the embryo's legal status: the embryo as "a human subject after fertilization, which requires that it be accorded the rights of a person,"⁵⁵ 2) "no different from any other human tissue";⁵⁶ and 3) "an intermediate [entity, which] . . . deserves respect greater than that accorded to human tissues but not the respect accorded to actual persons."⁵⁷

The court rejected the first option, noting that embryos did not enjoy the status of "persons" under state tort law⁵⁸ or federal abortion jurisprudence.⁵⁹ The court also denied that embryos were "property."⁶⁰ Rather, the court concluded that embryos "occupy an interim category that entitles them to special respect because of their potential for human life."⁶¹ Both spouses were held to have equivalent "decision-making authority" over the disposition of the embryos.⁶² The court further commented that any proposed state interest in preserving the life of the embryos "is at best slight When weighed against the interests of the individuals and the burdens inherent in parenthood, the state's interest in [] potential life . . . is not sufficient to justify any infringement upon the freedom of these individuals to make their own decisions as to whether to . . . becom[e] parents."⁶³

52. *Id.*

53. *Davis v. Davis*, 842 S.W.2d 588, 596 (Tenn. 1992) (observing the appellate court's lack of further analysis), *cert. denied*, 507 U.S. 911 (1993).

54. *See id.* at 596-97.

55. *Id.* at 596 (citing the Report of the Ethics Committee of The American Fertility Society).

56. *Id.*

57. *Id.*

58. The court referred to the Tennessee Wrongful Death statute, which did not allow such actions for death of a fetus unless it was first born alive. *Id.* at 594.

59. *Id.* at 595.

60. *Id.* at 597.

61. *Id.*

62. *Id.* The court then balanced the parties' relative interests: Mrs. Davis's right to procreate versus Mr. Davis's right to avoid procreation. *Id.* at 603.

Ordinarily, the party wishing to avoid procreation should prevail, assuming that the other party has a reasonable possibility of achieving parenthood by means other than use of the preembryos in question. If no other reasonable alternatives exist, then the argument in favor of using the preembryos to achieve pregnancy should be considered. However, if the party seeking control of the preembryos intends merely to donate them to another couple, the objecting party obviously has the greater interest and should prevail.

Id. at 604. Because Mrs. Davis had later decided that she wanted to donate the embryos, rather than implant them in herself, Mr. Davis's right to avoid genetic parenthood controlled. *Id.*

63. *Id.* at 602.

The New York state appellate division recently considered a similar controversy in *Kass v. Kass*.⁶⁴ After unsuccessful IVF treatments and a failed marriage, the parties were left with surplus embryos,⁶⁵ as in the *Davis* dispute.⁶⁶ Mrs. Kass wanted possession to attempt future pregnancy and Mr. Kass objected.⁶⁷ Unlike the Davises,⁶⁸ however, the Kasses had signed an informed consent agreement at the time of the fertility treatments.⁶⁹ This document effectively donated the disputed embryos to the IVF clinic for use in approved research activities.⁷⁰

The trial court held that the agreement was not controlling and awarded the embryos to Mrs. Kass with the "exclusive right to determine [their] fate"—including their use in another attempt to achieve pregnancy.⁷¹ The Appellate Division reversed.⁷² The court held that the parents' *mutual* intent regarding the disposition of the embryos, as evidenced by the informed consent document, should be given effect.⁷³ While the trial court endorsed the view of the *Davis* court that the embryos were something more than property but less than persons,⁷⁴ the Appellate Division did not reconsider the legal status of the embryos themselves.⁷⁵ Rather, the parents' joint decisional authority over these entities was the paramount and controlling consideration.⁷⁶

In light of these differing conceptions of the embryo, some commentators have called for federal legislation to clarify the embryo's

64. 663 N.Y.S.2d 581 (App. Div. 1997).

65. *Id.* at 583.

66. *Davis*, 842 S.W.2d at 589.

67. *Kass*, 663 N.Y.S.2d at 583.

68. *Davis*, 842 S.W.2d at 590.

At the outset, it is important to note the absence of [a] critical factor[] that might otherwise influence or control the result of this litigation: [the Davises] did not execute a written agreement specifying what disposition should be made of any unused embryos that might result from [their IVF treatment].

Id.

69. *Kass*, 663 N.Y.S.2d at 583. The informed consent document provided that if the couple disagreed over the disposition of the remaining embryos, the IVF clinic would use them for approved research and investigation. *Id.* at 588. It explicitly stated that, "[o]ur frozen [embryos] will not be released from storage for any purpose without the written consent of both of us." *Id.* at 587 (emphasis omitted).

70. *See id.* at 584.

71. *Kass v. Kass*, 1995 WL 110368, at *4 (N.Y. Sup. Jan. 18, 1995) (unpublished decision), *rev'd*, 663 N.Y.S.2d 581 (App. Div. 1997).

72. *Kass*, 663 N.Y.S.2d at 590.

73. *Id.*

74. *See Kass*, 1995 WL 110368, at *2-3.

75. *See Kass*, 663 N.Y.S.2d at 587 ("Since we conclude, in accordance with the analysis employed in *Davis*, that the agreement of the parties is dispositive of the present controversy, no further discussion of the facts of that case is material or relevant.").

76. *See id.* at 590.

legal status to avoid future confusion and inconsistency in the law.⁷⁷ Despite disagreement over the legal status of the embryo, however, the IVF precedents do share some common ground. They confirm that the biological parents' joint interest in determining what will happen to the embryos is the primary concern in any IVF dispute.⁷⁸

C. Embryo Experimentation

The federal courts recently had an opportunity to consider the legal status of the embryo as the subject of scientific research. In *Doe v. Shalala*,⁷⁹ the plaintiffs⁸⁰ filed a class action suit on behalf of the more than 20,000 embryos stored in various IVF labs across the United States.⁸¹ Before the National Institutes of Health Human Embryo Research Panel (the "Panel") published its findings,⁸² plaintiffs asserted that the Panel was not "fair[ly] balance[d]" within the meaning of the Federal Advisory Committee Act ("FACA").⁸³ They alleged that at least ten of the Panel members were "current or former NIH grantees who [had] firmly endorsed the principle and many of the protocols of extended and unfettered human embryo research."⁸⁴

Arguing that the Panel's potential favorable recommendations for the funding of embryo research would cause them irreparable harm,⁸⁵

77. Lal, *supra* note 19, at 528; see also Douglas J. Cusine, *Experimentation: Some Legal Aspects*, in *Experiments on Embryos* 120, 123 (Anthony Dyson & John Harris eds., 1990) ("What I have been suggesting for a long time is that we need some kind of legislative clarification. It is highly irresponsible for a government to allow people involved in human reproduction to operate in legal darkness." (commenting on confusion over the status of embryos in England prior to adoption of the HFE Act)).

78. See generally *York v. Jones*, 717 F. Supp. 421 (E.D. Va. 1989) (holding that the parents' possessory interests in the embryo required that the clinic consent to transfer); *Kass*, 663 N.Y.S.2d at 581 (holding that the parents' mutual intent as evidenced in the informed consent document controlled the disposition of surplus embryos); *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992) (holding that the parents' joint decisional authority over the embryos controlled their disposition), *cert. denied*, 507 U.S. 911 (1993).

79. 862 F. Supp. 1421 (D. Md. 1994).

80. The representatives of the class were Mary Doe, "a pre-born child in being as a human embryo," the "Michael Fund," a pro-life research organization, and Michael Polincastro, an adult suffering from Down's syndrome. *Id.* at 1423.

81. *Id.*

82. After Congress lifted procedural barriers to the funding of human embryo research, the National Institutes of Health assembled the Human Embryo Research Panel to determine whether and to what extent the federal government should finance this type of experimentation, with the expectation that their report would form the basis for final funding decisions. See *infra* Parts II, III.A (further explaining the NIH Panel and its findings).

83. *Doe*, 862 F. Supp. at 1425. This Act requires that "the membership of [an] advisory committee . . . be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee." FACA, 5 U.S.C.A. App. 2 § 5(b)(2) (West 1996).

84. *Doe*, 862 F. Supp. at 1425.

85. Plaintiffs alleged that Mary Doe and the other embryos would be deprived of "the right to life without due process of law," that the Michael Fund would lose other-

the plaintiffs sought a preliminary injunction to halt further Panel deliberation and publication of the Report before a trial on the merits.⁸⁶ The federal district court dismissed the suit for lack of standing.⁸⁷ The court based its opinion on the familiar *Roe* and *Casey* holdings that the unborn are not "persons" with legally assertable rights.⁸⁸ Thus, the plaintiffs could not maintain a class action on their behalf.⁸⁹

The *Doe* opinion did not consider whether the embryos deserved different treatment—or legal opportunities—as the subjects of scientific research. The court believed such questions had already been answered by *Roe* and *Casey*, stating: "The Court sees no distinction between fetuses *in utero* or *ex utero*."⁹⁰ Commentators have noted, however, that "the discussion of the embryo's status [as the subject of scientific procedures] must necessarily stand on a different legal footing than that of the discussion of fetal abortion."⁹¹ The abortion cases were decided in a normative adversarial context: The woman's right to control her own body was pitted against the fetus's proposed right to be born.⁹² *Roe* and its successors make clear that a woman's liberty interests in reproductive autonomy and bodily integrity often out-

wise available federal funding to competing researchers who use human embryos, and that Michael Polincastro and others with Down's Syndrome would be threatened with loss of life by embryo research, which devalues and condones the destruction of human life. *Id.*

86. *Id.* Specifically, the complaint requested: (1) a declaration that the Panel violated the FACA's fair balance requirement; (2) dissolution of the Panel; (3) an injunction against future meetings; and (4) a declaration that all actions undertaken by the Panel were null and void in their entirety. See International Found. for Genetic Research v. Shalala, 57 F.3d 1066 (4th Cir. 1995) (unpublished table decision), available in 1995 WL 361174, at *1 (recounting plaintiff's specific demands).

87. *Doe*, 862 F. Supp. at 1426. The court's "further reason" for dismissing the complaint was that the matter was non-justiciable: Because there were insufficient judicial standards to address alleged "imbalances" in the membership of such committees, the court refused to decide the issue. *Id.* at 1430. Rather, "[t]he concerns of this suit properly belong before the executive and legislative branches of government, not the judicial." *Id.* at 1431.

88. *Id.* at 1426.

89. *Id.* In 1995, the Fourth Circuit entertained the plaintiffs' appeal, but vacated the lower court's judgement and remanded the action for dismissal, because their request had become moot upon the issuance of the Panel's Report. *Genetic Research*, 1995 WL 361174, at *2 ("The actions that the appellants seek to enjoin have already occurred and cannot be undone. Accordingly, their claim for injunctive relief is moot." (internal quotations and citation omitted)).

90. *Doe*, 862 F. Supp. at 1426.

91. Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 Hous. L. Rev. 1597, 1652 (1993); see Annas, *supra* note 25 (urging the separation of abortion politics from the discussion of embryo research); *The Ramsey Colloquium*, *supra* note 23, at 1 ("The question of creating, using, and destroying human embryos cannot be separated entirely from the question of abortion, but the two questions can and should be distinguished."); cf. *infra* note 97-98 and accompanying text (observing fundamental differences between abortion and embryo research).

92. See generally *Roe v. Wade*, 410 U.S. 113 (1973) (endorsing a woman's right to abortion and rejecting the fetus's proposed rights as a person, under the Fourteenth Amendment to the U.S. Constitution).

weigh the State's interest in protecting unborn life.⁹³ Similarly, the IVF cases were decided against the background of reproductive choice.⁹⁴ Despite disagreement over the embryo's legal status,⁹⁵ these cases confirm that the parents' mutual decisional authority is the primary concern in an IVF dispute.⁹⁶

Experimentation involving deliberately fertilized embryos, however, is fundamentally different from both the abortion and IVF scenarios because individual reproductive autonomy is not implicated.⁹⁷ The woman is wholly removed from this equation: The research embryo is an independent entity whose existence does not require a woman to sacrifice her constitutionally protected autonomy.⁹⁸ The biological parents do not assert any rights to control the disposition of the potential child. Instead, only the researchers' right to investigate and the general public's interest in obtaining beneficial information from such experiments must be balanced against the embryo's proposed right not to be created and destroyed for the sole purpose of scientific research. Part II turns to an evaluation of this unique inter-relationship.

II. ANALYSIS OF RELATIVE RIGHTS

The preceding discussion has considered existing legal understandings of the embryo. The focus in each is on relative rights: In the abortion cases, a woman's right to bodily integrity and reproductive autonomy often outweighs the government's interest in preserving un-

93. See *supra* Part I.A; see also *Webster v. Reproductive Health Serv.*, 492 U.S. 490 (1989) (majority of the court either affirming or declining to address the constitutional validity of the central holding of *Roe*); *Thornburgh v. American College of Obstetricians and Gynecologists*, 476 U.S. 747 (1986) (affirming the central holding of *Roe*); *City of Akron v. Akron Ctr. for Reproductive Health, Inc.*, 462 U.S. 416 (1983) (same).

94. See, e.g., *supra* note 62 (discussing the conflict between the right to procreate and the right to avoid procreation in *Davis*).

95. See *supra* note 37.

96. See *supra* note 78.

97. Research involving "surplus" embryos may be more complex. Experiments using these embryos might be conducted to explore the reproductive health or status of the mother as part of an IVF protocol and, thus, could implicate reproductive autonomy. Cf. June Coleman, *Playing God or Playing Scientist: A Constitutional Analysis of State Laws Banning Embryological Procedures*, 27 *Pac. L.J.* 1331, 1380 (1996) (arguing that laws completely prohibiting procedures that use embryos to gather information for the purpose of making reproductive choices or promoting procreation are unconstitutional); Lal, *supra* note 19, at 537 ("[A] law banning IVF would undoubtedly be found unconstitutional because it would interfere with the right to procreate.").

98. One of the most notable proponents of the right to abortion admits that, "[b]ut for its biological dependence on the woman, it is at least arguable that the fetus could be regarded as a holder of rights under the due process clause of the fifth and fourteenth amendments, as well as the equal protection clause of the latter." Laurence H. Tribe, *The Abortion Funding Conundrum: Inalienable Rights, Affirmative Duties, and the Dilemma of Dependence*, 99 *Harv. L. Rev.* 330, 340 (1985).

born life;⁹⁹ in the IVF cases, parents' joint decisional authority is likewise paramount.¹⁰⁰ The key question in the research embryo context, however, is whether the scientist's interest in performing her research and the general public's interest in learning from its results should outweigh whatever interests support protection of the embryo. This Part evaluates these competing interests from both sides of the embryo research debate and argues that the balancing of these interests requires that scientists be prevented from creating embryos solely for scientific use.

A. *The Right to Research*

Many commentators have suggested that the Constitution protects a scientist's right to conduct research.¹⁰¹ Broad readings of various Supreme Court opinions appear to support this position. For example, the Court acknowledged in *Meyer v. Nebraska*¹⁰² that the Fourteenth Amendment guarantees the freedom "to acquire useful knowledge."¹⁰³ Furthermore, in *Branzburg v. Hayes*,¹⁰⁴ the Court stated that, "[t]he informative function asserted by representatives of the organized press . . . is also performed by lecturers, political pollsters, novelists, *academic researchers*, and dramatists."¹⁰⁵

John Robertson, one of the leading legal scholars in the area of reproductive technologies,¹⁰⁶ takes a less direct approach to this constitutional query.¹⁰⁷ He begins by considering a ban on publication of

99. See *supra* Part I.A.

100. See *supra* Part I.B.

101. Michael D. Davidson, *First Amendment Protection for Biomedical Research*, 19 *Ariz. L. Rev.* 893, 894-95 (1977); Richard Delgado & David R. Millen, *God, Galileo, and Government: Toward Constitutional Protection for Scientific Inquiry*, 53 *Wash. L. Rev.* 349, 372-88 (1978); Jean Macchioroli Eggen, *The "Orwellian Nightmare" Reconsidered: A Proposed Regulatory Framework for Advanced Reproductive Technologies*, 25 *Ga. L. Rev.* 625, 653-57 (1991); James R. Ferguson, *Scientific Inquiry and the First Amendment*, 64 *Cornell L. Rev.* 639, 644 (1979); John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 *S. Cal. L. Rev.* 1203, 1216-18 (1977). *But see* Stephen L. Carter, *The Bellman, the Snark, and the Biohazard Debate*, 3 *Yale L. & Pol'y Rev.* 358, 369-73 (1985) (questioning whether the First Amendment protects the right to research); Gary L. Francione, *Experimentation and the Marketplace Theory of the First Amendment*, 136 *U. Pa. L. Rev.* 417, 430-59 (1987) (rejecting the theory that freedom of research as an essential component of full participation in the marketplace of ideas provides a basis for First Amendment protection).

102. 262 U.S. 390 (1923).

103. *Id.* at 399.

104. 408 U.S. 665 (1972).

105. *Id.* at 705 (emphasis added).

106. See Jennifer L. Carow, *Davis v. Davis: An Inconsistent Exception to an Otherwise Sound Rule Advancing Procreative Freedom and Reproductive Technology*, 43 *DePaul L. Rev.* 523, 541-42 (1994) (observing Robertson's distinction the field). John Robertson is the Thomas Wyatt Gregory Professor at the University of Texas School of Law. Robertson, *supra* note 23, at FN.a.

107. See Robertson, *supra* note 101, at 1251-53.

research results, which would most certainly violate a researcher's First Amendment right to free speech.¹⁰⁸ Robertson then argues that the underlying research activity, as an essential precursor to publication, is protected as well, in light of Supreme Court precedents that safeguard similar precursors.¹⁰⁹ The Court has extended First Amendment protections to: financing, the antecedent to speech in the political arena;¹¹⁰ learning and education, the antecedents to students and teachers' speech;¹¹¹ and gathering of news, the antecedent to reporting the same.¹¹²

Under Robertson's theory, however, virtually all conduct could be considered the precursor to some kind of speech.¹¹³ "If . . . *all* claims of experimentation were given prima facie protection and all regulations of experimentation were required to meet first amendment standards . . . [a]ny self-proclaimed scientist could require that regulation of her proposed experiment satisfy heightened scrutiny."¹¹⁴ Rather, as a National Bioethics Advisory Commission recently concluded in its report on human cloning, "[t]he freedom to pursue knowledge is distinguishable from the right to choose the method for achieving that knowledge [T]he government . . . may and should restrict or prohibit the means used by researchers if they involve sufficient harm to others."¹¹⁵ Thus, courts that have squarely considered the issue have concluded that "the rights of medical researchers are not fundamental under the Constitution"¹¹⁶

B. *Public Benefit*

In addition to scientists' interest in pursuing their work, embryo research is supported by considerable medical advances that might be

108. *Id.*

109. *Id.*

110. *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765, 788-92 (1978) (striking a Massachusetts statute that forbade certain kinds of corporations from contributing to candidates for public office or to referenda campaigns); *Buckley v. Valeo*, 424 U.S. 1, 16 (1976) (holding that the government's interest in preventing corruption was sufficient to justify limiting the amount an individual may contribute to a campaign, but striking expenditure ceilings as unconstitutional restrictions on the right to political expression and association).

111. *Sweezy v. New Hampshire*, 354 U.S. 234, 250 (1957).

112. *Branzburg v. Hayes*, 408 U.S. 665, 681-82 (1972).

113. Francione, *supra* note 101, at 501 (criticizing Robertson's theory).

114. *Id.*

115. Cloning Report, *supra* note 4, at 79.

116. *Wynn v. Scott*, 449 F. Supp. 1302, 1322 (N.D. Ill. 1978), *aff'd sub nom. Wynn v. Carey*, 599 F.2d 193 (7th Cir. 1979); *see also Margaret S. v. Edwards*, 488 F. Supp. 181, 220 (E.D. La. 1980) (stating that medical researchers do not have a constitutionally protected right to experiment on fetuses); Barry R. Furrow, *Governing Science: Public Risks and Private Remedies*, 131 Pac. L. Rev. 1403, 1406 (1983) (arguing that all scientific research is subject to regulation because it is action, not speech).

achieved from conducting experiments of this nature.¹¹⁷ For instance, embryo research may further develop and improve clinical protocols for the treatment of infertility.¹¹⁸ While IVF procedures are widely available in the United States,¹¹⁹ their efficiency is quite low: Less than five percent of oocytes collected give rise to live-born children.¹²⁰ Studies of the external factors associated with the *in vitro* culture environment, research into the biochemistry and metabolism of the early embryo, and the development of diagnostic testing for implantation embryos have great potential to improve the rate of IVF success and to assist infertile couples in the future.¹²¹

The potential benefits of human embryo research extend well beyond infertile couples.¹²² Studies for pre-implantation diagnosis of genetic and chromosomal abnormalities seek to assist couples who, though fertile, are at high risk for genetic disease in their offspring.¹²³ This experimental procedure would allow parents to choose—prior to implantation—whether to pursue a pregnancy that might result in a severely ill or handicapped child.¹²⁴ In addition, embryo studies may help researchers devise new methods of contraception and further the scientific understanding of human development, cancer, and transplant biology.¹²⁵ Human embryo research is also an essential component of the development of cloning techniques.¹²⁶

The NIH Panel believed that the public's interest in obtaining beneficial information from these experiments warranted performance of (and federal funding for) embryo experimentation—even where it involved the deliberate creation of research embryos.¹²⁷ Deliberately fertilized embryos are sometimes a practical necessity in studies of oocyte maturation, fertilization processes, and maternal-fetal drug interactions.¹²⁸ Moreover, restriction of research embryos might slow

117. Karen Dawson, *Introduction: An Outline of Scientific Aspects of Human Embryo Research*, in *Embryo Experimentation* 3, 3 (Peter Singer et al. eds., 1990) (stating that embryo experimentation is “a unique opportunity for the study of human reproduction and early development, with far-ranging implications for the treatment of infertility and for other areas of research”).

118. *Id.* at 9-10.

119. NIH Panel Report, *supra* note 5, at 11.

120. *See* Van Blerkom, *supra* note 6, at 14; *see also* Dawson, *supra* note 117, at 9 (“[A]bout three out of each hundred eggs collected [in IVF treatment] will result in a live birth.”).

121. Van Blerkom, *supra* note 6, at 9-17.

122. *See* Dawson, *supra* note 117, at 3.

123. Blank & Merrick, *supra* note 1, at 180; Dawson, *supra* note 117, at 11.

124. Dawson, *supra* note 117, at 11.

125. *Id.* at 6-8; Blank & Merrick, *supra* note 1, at 180; Mark W.J. Ferguson, *Contemporary and Future Possibilities for Human Embryonic Manipulation*, in *Experiments on Embryos* 6, *supra* note 77, at 16-20.

126. *See* Steinbock, *supra* note 10, at 34-37 (discussing George Washington University researchers' successful cloning of a human embryo).

127. NIH Panel Report, *supra* note 5, at 50-51.

128. *Id.* at 42-43. For example, the only way to determine whether a new contraceptive will be effective is to attempt fertilization. *Id.* at 43.

scientific inquiry when "spare" embryos are unavailable or unsuitable¹²⁹ for research purposes, and a ban would be very difficult to enforce.¹³⁰ "Weighing the importance of this research for the well-being of women and children, the Panel concludes that it would not be wise to prohibit altogether the fertilization of oocytes for research purposes."¹³¹ Thus, the Panel approved the creation of research embryos in limited circumstances where serious and compelling reasons justified their use.¹³²

C. *The Interests in the Embryo*

Any regulation of embryo experimentation necessarily rests on a basic assumption that the embryo is an instance of human life and inherently valuable. Both proponents and critics of embryo research express a minimum agreement on this point;¹³³ they diverge not as to whether, but to what degree, these lives should be protected.¹³⁴ The courts have also acknowledged that the embryo is a valued entity.¹³⁵ The Supreme Court's abortion jurisprudence has continuously affirmed that the government has a legitimate interest in protecting potential life even where Constitutional rights are at stake.¹³⁶

The Supreme Court has never acknowledged, however, that the unborn have any independent rights beyond what a state may choose to recognize.¹³⁷ Abortion opponents assert that the living embryo has an affirmative right to life, which would impose an obligation on a pregnant woman to provide that which is necessary (for example, nine

129. "Because the gametes and embryos derived from couples experiencing certain kinds of infertility tend to exhibit higher rates of abnormality, many of these embryos will be unsuitable for research . . ." *Id.* at 44.

130. *Id.* (noting that researchers could easily circumvent a ban on creation of research embryos by deliberately fertilizing excess embryos during couples' IVF treatments, then soliciting donation). *But see infra* Part II.D (rejecting this enabling rationale which permits scientists to act unlawfully).

131. NIH Panel Report, *supra* note 5, at 50.

132. The Panel concluded that fertilization of research embryos would be appropriate "[w]hen the research by its very nature cannot otherwise be validly conducted . . . [and that the research] is potentially of outstanding scientific and therapeutic value." *Id.* at 44-45.

133. *Compare* NIH Panel Report, *supra* note 5, at 44 ("The Panel recognizes, however, that the preimplantation embryo merits respect as a developing form of human life . . ."), *with The Ramsey Colloquim, supra* note 23, at 2 ("Honesty requires that we speak [of the embryo] not simply [as] human life but [as] a human being.").

134. *See infra* text accompanying notes 157-59.

135. *See, e.g., Roe v. Wade*, 410 U.S. 113, 162 (1973) ("We repeat . . . that the State does have an important and legitimate interest . . . in protecting the potentiality of human life."); *Davis v. Davis*, 842 S.W.2d 588, 597 (Tenn. 1992) (holding that the embryo is entitled to special respect as a developing form of human life), *cert. denied*, 507 U.S. 911 (1993).

136. *See Planned Parenthood v. Casey*, 505 U.S. 833, 879 (1992) (plurality opinion); *Roe*, 410 U.S. at 163.

137. *See supra* Part I.A.

months of pregnancy) for that right to be realized.¹³⁸ The Supreme Court has refused to acknowledge such a right primarily because of its corresponding effect on women's autonomy.¹³⁹ Opponents of the deliberate fertilization of research embryos, however, claim that embryos have a negative right not to be created, used, and ultimately destroyed for the sole purpose of scientific investigation.¹⁴⁰ Recognition of this right would not impose affirmative obligations on others but, rather, would require researchers to refrain from interfering with the right's bearer.¹⁴¹

Federal and state governments routinely protect negative rights—for example, by requiring that doctors and researchers obtain informed consent before subjecting patients to any experimental treatment.¹⁴² The Belmont Report¹⁴³ concluded that informed consent was an essential component of the basic ethical principle of respect for persons.¹⁴⁴ This principle is founded on two moral convictions: “first, that individuals should be treated as autonomous agents, and second, that those persons with diminished autonomy are entitled to protection.”¹⁴⁵ With respect to the latter, the Commission stated, “[N]ot every human being is capable of self-determination Respect for the immature and incapacitated may require protecting them as they mature or while they are incapacitated Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them.”¹⁴⁶

138. Cf. *Casey*, 505 U.S. at 927 (Blackmun, J., concurring in part and dissenting in part) (“[State-]compelled continuation of a pregnancy infringes upon a woman’s right to bodily integrity by imposing substantial physical intrusions and significant risks of physical harm.”).

139. See *Roe*, 410 U.S. at 162 (“[W]e do not agree that, by adopting one theory of life, Texas may override the rights of the pregnant woman that are at stake.”).

140. See generally *The Ramsey Colloquim*, *supra* note 23; John Marshall, *The Case Against Experimentation*, in *Experiments on Embryos* 55, *supra* note 77.

141. Cf. Blank & Merrick, *supra* note 1, at 3-5 (discussing the Lockean distinction between positive and negative rights).

142. See generally Fay A. Rozovsky, *Consent to Treatment: A Practical Guide* (2d ed. 1990) (analyzing the legal requirements of federal and state informed consent laws).

143. The Belmont Report summarizes the findings of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (April 18, 1979) <http://www.hunger.brown.edu/Administration/Research_Administration/belmont/belmont.html> [hereinafter *The Belmont Report*]. The Commission first gathered in February of 1976 to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop corresponding practical guidelines. *Id.* The Report is intended to inform and instruct the activities of scientists, government agencies, and federal employees. *Id.*

144. *Id.*

145. *Id.*

146. *Id.*

Clearly, embryos are incapable of giving consent to their own creation or use in experimental procedures.¹⁴⁷ In this sense, they are much like minor children who are sought as research subjects.¹⁴⁸ It is well-established that parents may give consent on behalf of their child for therapeutic experimental treatments.¹⁴⁹ Ethicists disagree, however, as to whether non-therapeutic research on children is ever justified.¹⁵⁰ Some oppose all such experiments because the children cannot give consent.¹⁵¹ Others endorse proxy consent for non-therapeutic research that poses no undue risk or discernable discomfort to the child.¹⁵²

Research embryos, however, are even more vulnerable than minor children. Experimental procedures are incidental to a child's existence; parents, as guardians, may choose whether to participate in such activities to further their child's best interest.¹⁵³ In contrast, experimental procedures are the very purpose of a research embryo's creation; researchers, as guardians, will choose to participate in these activities to further science and society's best interests.¹⁵⁴ Embryos are the most immature and utterly incapacitated human entities, subjected to the inevitable risk and ultimate harm of manipulation and destruction at the hands of researchers.¹⁵⁵ They are in need of extensive protection—even to the point of prohibiting scientists from breeding them as disposable research tools.¹⁵⁶

Proponents of unrestricted embryo research argue, however, that embryos are not entitled to the same protections afforded adults or children.¹⁵⁷ The NIH Panel concluded that the embryo should not be considered a "person" for the purpose of informed consent—and corresponding protection—until sometime later in development, when "increasing possession of qualities . . . make respecting it (and hence

147. Steinbock, *supra* note 10, at 29.

148. *Id.*

149. *Id.*

150. *Id.*

151. See Paul Ramsey, *The Enforcement of Morals: Nontherapeutic Research on Children*, Hastings Center Report 6(4):21-30 (1976).

152. See, e.g., Peter G. Brown, *Human Independence and Parental Proxy Consent*, in *Who Speaks for the Child* 209, 215-20 (Willard Gaylin & Ruth Macklin eds., 1982) (suggesting that parental consent is appropriate for non-therapeutic medical procedures that will not otherwise harm the child and are in accordance with the child's presumed wishes—such as donating a rare blood type to a sibling).

153. With respect to non-therapeutic research, parents might, at a minimum, choose whether to participate in activities which are neutral to their child's best interests.

154. See *supra* Parts II.A-B (discussing science and society's interests).

155. *The Ramsey Colloquium*, *supra* note 23, at 6.

156. Part IV, *infra*, proposes a uniform federal ban on the creation and use of research embryos.

157. Ann Alpers & Bernard Lo, *Commodification and Commercialization, in Human Embryo Research*, 6 *Stan. L. & Pol'y Rev.* 39, 40 (1995); Maurizio Mori, *Is the Human Embryo a Person? No, in Conceiving the Embryo: Ethics, Law and Practice in Human Embryology* 151 (Donald Evans ed., 1996).

limiting others' liberty in relation to it) more compelling."¹⁵⁸ Although the embryo warranted "serious moral consideration," the Panel believed that the embryo's lack of "most . . . qualities considered relevant to the moral status of persons" justified a lesser degree of protection.¹⁵⁹

This reasoning, however, reduces personhood, and thus "protectability," to possession of certain characteristics which society deems worthwhile—such as sentience or the ability to feel pain.¹⁶⁰ The logical extension of this position is that "protect-ability" also decreases with the decreasing possession of those qualities.¹⁶¹ Taken to its extreme, this position has potential to threaten other members of society who lack or lose those favored qualities—such as the elderly, handicapped, and mentally or physically ill—with decreased protection from harmful research, or even eugenics.¹⁶² The question should not be whether embryos are "protect-able" according to these arbitrary criteria, but whether embryos are instances of human life that are in need of protection.¹⁶³ The answer to the latter is most certainly yes, because embryos are developing human lives¹⁶⁴ and researchers, "must inevitably destroy [them] in order to gain the knowledge that [they] want."¹⁶⁵ The federal government should meet this need by granting these immature and incapacitated entities a negative right not to be created, used, and discarded for research purposes.

D. Public Detriment

The risks associated with this type of experimentation are not confined to embryos alone. Research conducted with deliberately fertil-

158. *The Ramsey Colloquium*, *supra* note 23, at 3 (quoting the NIH Panel Report).

159. NIH Panel Report, *supra* note 5, at x.

160. The NIH Panel concluded that the embryo's inability to feel pain and its lack of brain activity, consciousness and self-awareness "all support the conclusion that the preimplantation embryo does not merit the same degree of moral protection given to children or adult human beings." *Id.* at 37. The Panel did acknowledge, however, that this view faces "conceptual and practical difficulties." *Id.* at 38. Insistence on sentience and brain activity as criteria for personhood might require extending equal moral respect to animals, a move that might "run[] counter to our practices of using animals . . . in scientific research." *Id.* Additionally, a criterion of consciousness, reasoning, or self-conceptualization might result in the exclusion of newborns from the "class of protected subjects." *Id.*

161. *The Ramsey Colloquium*, *supra* note 23, at 3.

162. "Eugenics" is a science that deals with the improvement of hereditary qualities of a race or breed by social control of mating and reproduction. Webster's Third New International Dictionary 783 (1986).

163. *The Ramsey Colloquium*, *supra* note 23, at 3. This argument does not imply that human tissues or cells also require protection. Unlike "[s]kin and intestinal tissue, [or] even eggs and sperm . . . the embryo from the earliest moment has the active capacity to articulate itself into what everyone acknowledges is a human being. The embryo is a being; that is to say, it is an integral whole with actual existence." *Id.* at 2.

164. *See supra* note 133.

165. Marshall, *supra* note 140, at 56.

ized embryos has broader social ramifications which impact the decision of whether to conduct these experiments.

The practice of realizing large profits from the sale of human embryos results in their commercialization.¹⁶⁶ Embryos are thereby reduced to commodities, insofar as they are treated as merchandise or vendible goods.¹⁶⁷ Such practices can lead to exploitation and objectification of individuals and humanity as a whole.¹⁶⁸ Infertile women, who are anxious to conceive and vulnerable to pressure from their doctors, may agree to donate eggs for research despite personal reservations.¹⁶⁹ Fertile women may also be subject to exploitation if they consent to risky¹⁷⁰ donation procedures in exchange for money.¹⁷¹ The buying and selling of embryos not only devalues the embryos, but also contributes to the denigration of gamete providers, by defining them as mere sources of research materials.¹⁷² In addition, financial benefit instills a profit motive in medical researchers, which itself can yield serious conflicts of interest.¹⁷³

The risks of commercialization and commodification are particularly great when embryos are deliberately created for the sole purpose of research. In her partial dissent from the NIH Panel Report, Dr. Patricia King noted that, "[t]he fertilization of human oocytes for research purposes is unnerving because human life is being created solely for human *use*. I do not believe that this society has developed the conceptual frameworks necessary to guide us down this slope."¹⁷⁴ Such activities reduce the embryo to nothing more than a research tool.

Oddly enough, the NIH Panel concluded that commercialization and commodification were reasons to permit, rather than prohibit, the creation of research embryos.¹⁷⁵ If researchers were confined to using

166. Alpers & Lo, *supra* note 157, at 40. "Commercialization refers to the practice of realizing large profits from the development and sale of techniques or products that involve distinctive human material . . ." *Id.*

167. *Id.* "Commodification" refers to the symbolic devaluation of human life that results from its commercial use. *Id.* Such concerns usually take two forms: "[T]he idea of making money from the origins of human life offends those who believe human embryos deserve more reverential treatment . . . [and] the discrepancy between the profits paid to researchers and those paid to the progenitors of the embryos disturb those who criticize the profit motive in science." *Id.*

168. *Id.*

169. *Id.*

170. While donated sperm can be collected through ejaculation, ova are commonly retrieved through a surgery called laparoscopy, which involves general anesthesia, several small incisions in the abdomen, and removal of the ova through needle aspiration. Bonnicksen, *supra* note 7, at 148-49. Alternatively, egg collection can be performed non-surgically, by inserting the aspiration needle directly through the abdomen and bladder or through the vagina. *Id.* at 149.

171. Alpers & Lo, *supra* note 157, at 44.

172. *Id.*

173. *Id.*

174. See NIH Panel Report, *supra* note 5, at A-3.

175. *Id.* at 44.

“surplus” embryos, “any intelligent administrator of any IVF program [could], by minor changes in his [sic] ordinary clinical ways of going about things, change the number of embryos that are fertilized.”¹⁷⁶ A ban could also cause doctors to exert “particularly acute” pressure on women in infertility programs to donate their remaining embryos.¹⁷⁷

The NIH Panel’s reasoning, however, encourages lawmakers to avoid the problem merely because it is complex and difficult to solve. Regulations of human embryo research, like any other laws, will entail their own challenges and difficulties. Fear that scientists will attempt to circumvent the laws¹⁷⁸—or that they will react inappropriately and unethically¹⁷⁹—however, should not justify inaction. Rather, donors should be protected and researchers should be made accountable by strict enforcement of the laws.

The government certainly has a legitimate interest in preventing commercialization and commodification that may result from human embryo research.¹⁸⁰ Individual states’ attempts to address these concerns, however, are inadequate. Although some state laws prohibit the sale of fertilized embryos,¹⁸¹ they do nothing to prevent the sale of gametes (sperm and eggs), which can easily be converted into research embryos through deliberate fertilization.¹⁸² Payment for sperm and eggs is widespread among American infertility clinics: sperm donors typically receive \$50, and egg donors receive \$2,000, per donation.¹⁸³

As the NIH Panel observed, prices for these “raw materials” are set by supply and demand.¹⁸⁴ Thus, as research needs expand, so too will the prospects for commercialization and commodification. The Panel attempted to curb this potential by recommending that neither donors nor “brokers” be permitted to receive payment (beyond compensation for expenses incurred) for gametes or embryos used in re-

176. *Id.*

177. *Id.*

178. *See supra* text accompanying note 176.

179. *See supra* text accompanying note 177.

180. *Cf. infra* note 275 (noting the government’s legitimate interest in preventing the dangers inherent in developing research areas).

181. *See infra* note 244.

182. *See* Bonnicksen, *supra* note 7, at 150 (describing the process of laboratory fertilization of human embryos, wherein sperm and eggs are combined in a glass petri dish, and noting that “[m]ost of the time fertilization occurs”).

183. *See* Alpers & Lo, *supra* note 157, at 41.

184. *See* NIH Panel Report, *supra* note 5, at 54-55.

search.¹⁸⁵ In the absence of comprehensive laws applicable to privately funded facilities, however, such practices go unchecked.¹⁸⁶

E. *Balancing the Interests*

The previous sections have assessed the relative interests at play in the research embryo. The ultimate question, however, is whether a weighing of these interests justifies the deliberate fertilization of human life or require its prohibition.

Although a right to research is not clearly protected by the Constitution,¹⁸⁷ scientists nonetheless have an important interest in pursuing their work. There is an equally strong governmental interest, however, in protecting community health, safety, and welfare.¹⁸⁸ Researcher's interests are especially limited where their work involves vulnerable individuals or those with diminished capacity to consent.¹⁸⁹ Regulation of medical experimentation is thereby proper, so long as it is rationally related to a legitimate purpose.¹⁹⁰

The deliberate creation and use of embryos endangers the health and safety of those research subjects¹⁹¹ and poses risks to the welfare of society at large.¹⁹² Because embryos are inherently vulnerable,¹⁹³ regulation is particularly appropriate to guard their safety and well-being. Restriction of embryo research is proper because it is rationally related to the government's interests in protecting unborn life and

185. *Id.* Critics have argued, however, that such a rule is inadequate because it presents a "profit paradox," enabling scientific investigators to profit from research but prohibiting donors from doing so. See Alpers & Lo, *supra* note 157, at 44-45. An analogous difficulty arose in *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991). In that case, the California Supreme Court refused to grant the plaintiff a property interest—and corresponding action for conversion—in his cell line after doctors had extracted it from his body and used it in research. *Id.* at 488. Justice Broussard noted in dissent that the majority's holding failed to "elevat[e] these biological materials above the marketplace;" rather, it stripped the patient of civil remedy while enabling researchers to "retain and exploit the full economic value of their ill-gotten gains." *Id.* at 506 (Broussard, J., concurring and dissenting).

186. Again, in contrast, other countries such as Great Britain and Canada require licensing of embryo research and prohibit all buying and selling of gametes and embryos. Alpers & Lo, *supra* note 157, at 41.

187. See *supra* Part II.A.

188. See *Great Atl. & Pac. Tea Co. v. Cottrell*, 424 U.S. 366, 371 (1976).

189. *Margaret S. v. Edwards*, 488 F. Supp. 181, 220 (E.D. La. 1980) (stating that the rights of medical researchers are particularly limited when the experiments involve minors and fetuses and are non-therapeutic).

190. *England v. Louisiana State Bd. of Med. Exam'rs*, 263 F.2d 661, 667 (5th Cir. 1959). If the right to research were held to be protected under the First Amendment, regulations of medical experimentation would be subject to more rigorous scrutiny. See Coleman, *supra* note 97, at 1392 (applying the substantial justification and narrow tailoring requirements to restrictions on embryo research).

191. See *supra* text accompanying note 165.

192. See *supra* Part II.D.

193. See *supra* Part II.C.

preventing commercialization and commodification of human life.¹⁹⁴ More importantly, such legislation is necessary to protect embryos from activities that can only harm them.

Potential community benefit does not tip the scale in favor of embryo research. The benefits rationale endorsed by the NIH Panel and other proponents¹⁹⁵ of embryo research raises serious moral concerns.¹⁹⁶ While claiming to make its evaluations independent of a particular morality or philosophy,¹⁹⁷ the Panel did exactly the opposite—by endorsing utilitarianism.¹⁹⁸ Indeed,

[i]t is a primitive and unreflective version of utilitarianism . . . but the message is unequivocal: the end justifies the means. If there are “serious and compelling reasons,” it would seem that the end would justify any means. Certainly it justifies producing, using, and destroying human beings who are valued only for their utility as tools serving the purposes of scientific research. The Panel’s is not a “multi-factorial” judgement. There is ultimately only one factor: scientific utility.¹⁹⁹

Recent historical events have taught the world that anticipated community benefit cannot be absolute in any moral society.²⁰⁰ In the wake of the unspeakable crimes of Nazism, for instance, the Nuremberg Code declared, “No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur”²⁰¹ The noted ethicist Claude Bernard has also stated that research which injures another should not be conducted regardless of the benefits that might come to others.²⁰² Such admonitions are particularly pertinent in the research embryo context, where

194. See *supra* Parts II.C-D.

195. See Robert Edwards, *Ethics and Embryology: The Case For Experimentation, in Experiments on Embryos, supra* note 77, at 42 (arguing that the benefits of human embryo research justify its continued performance); Steinbock, *supra* note 10, at 29 (presenting John Harris’s position that banning embryo research might be immoral because there are millions of people who might have benefitted from that research had it been performed).

196. Additionally, the benefits rationale is, to a certain extent, based on artificial choices. Marshall, *supra* note 140, at 63.

“Would you allow experimentation on embryos which would lead to the relief of handicap?”. Obviously the vast majority of the population is likely to say yes when [the question] is presented in that way. The fact that experimentation is very unlikely to lead to relief of handicap was not part of the question.

Id.

197. NIH Panel Report, *supra* note 5, at ix.

198. *The Ramsey Colloquium, supra* note 23, at 5 (criticizing the NIH Panel Report).

199. *Id.*

200. *Id.*

201. The Nuremberg Code, *reprinted in* Robert J. Levine, *Ethics and Regulation of Clinical Research* 425, 426 (2d ed. 1986).

202. *The Belmont Report, supra* note 143.

scientists know from the outset that their procedures will result in the destruction of human life.²⁰³

This type of utilitarian rationale also runs contrary to the underpinnings of the medical profession itself. Although the medical community seeks to safeguard the health of all people, each physician or researcher owes a primary and uncompromising duty to the individual patient.²⁰⁴ The Helsinki Declaration²⁰⁵ of the World Medical Association confirmed this basic principle underlying all experimental research: "Concern for the interests of the subject must always prevail over the interest of science and society."²⁰⁶ In research performed on deliberately fertilized embryos, however, the latter prevails.²⁰⁷

Admittedly, some future benefit may be lost by preventing the creation and use of research embryos. Regulation may also frustrate the work of some well-intentioned scientists. Opponents of this type of research do not deny those probable outcomes.²⁰⁸ The factors that support embryo research do not, however, outweigh the present interests in the embryo and potential risks that counsel against it. This Note, therefore, advocates a uniform ban on the deliberate creation, use, and destruction of research embryos.²⁰⁹

III. CURRENT REGULATION OF EMBRYO EXPERIMENTATION

The preceding discussion considered the relative rights at play in the research embryo context and suggested that embryos should not be created for scientific research. This Part examines the manner and extent to which existing federal and state laws protect the interests outlined above and identifies those laws' limitations and inadequacies.

203. Marshall, *supra* note 140, at 56; *see also supra* note 133 and accompanying text (observing that both proponents and opponents of this research agree that the embryo is an instance of human life).

204. 18th World Medical Assembly, *World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects* (1964), reprinted in Levine, *supra* note 201, at 427 [hereinafter *Declaration of Helsinki*]; *see* Steinbock, *supra* note 10, at 27 (discussing the embryo as a patient).

205. The World Medical Assembly identified the basic principles of biomedical research involving human subjects as a "guide to physicians all over the world." *Declaration of Helsinki*, *supra* note 204, at 428. Although they do not have the force of law, the basic principles and ethical guidelines adopted are a most eloquent statement of the "mission of the medical doctor to safeguard the health of the people." *Id.* at 427.

206. *Id.* at 428.

207. *See supra* text following note 153.

208. Marshall, *supra* note 140, at 63 ("In opposing experimentation [which leads to the destruction of human embryos,] I recognize and do not hide the fact that some advances in knowledge will be lost . . .").

209. *See infra* Part IV.

A. Federal Law

The history behind federal funding of human embryo research evinces uneasy disapproval of this type of experimentation. Since 1980, the federal government has withheld funding for human embryo research by *de facto* moratorium.²¹⁰ Until 1993, Congress authorized federal funding of embryo research subject to approval of such projects by a Department of Health and Human Services Ethical Advisory Board ("EAB").²¹¹ The first—and only—EAB appointed to evaluate embryo research concluded that it was ethical as a theoretical matter for the purpose of developing IVF techniques.²¹² Despite this approval, the NIH neither took action on a specific project nor appointed additional EAB's, and funding was never allocated for projects involving embryo research.²¹³

The National Institutes of Health Revitalization Act of 1993²¹⁴ eliminated the EAB approval requirements of 45 C.F.R. § 46.204(d).²¹⁵ At that time, Congress believed embryo research was a promising area, particularly for the treatment of infertility.²¹⁶ Members were concerned that the existing regulation hindered embryo research and left privately funded investigators to perform these experiments without adequate medical and ethical guidelines.²¹⁷

Before allocating any funds, however, the NIH convened the Human Embryo Research Panel.²¹⁸ The Panel gathered nineteen participants with expertise in clinical research, ethics, law, social science, public health, and public policy to consider the moral and ethical implications of human embryo research, and to develop funding guidelines for that research.²¹⁹

After listening to testimony from more than forty witnesses and reviewing correspondence from 30,000 individuals,²²⁰ the Panel concluded that embryo research should be funded by the federal government.²²¹ The members found that human embryo experimen-

210. Blank & Merrick, *supra* note 1, at 185.

211. See 45 C.F.R. § 46.204(d) (1980). EAB's are an integral component of the federal funding process. These panels are composed of specialists and representatives of the general public who evaluate the medical, legal, social, and other issues related to the subject matter of incoming grant applications. See *id.* § 46.204(a).

212. See Coleman, *supra* note 97, at 1338.

213. *Id.*

214. Pub. L. No. 103-43, 107 Stat. 122 (codified in scattered sections of 42 U.S.C.).

215. *Id.* § 121(c).

216. H.R. Rep. No. 103-28, at 80 (1993).

217. *Id.*

218. NIH Panel Report, *supra* note 5, at 3.

219. *Id.*

220. *Id.* at 4. The Panel received letters, postcards, and petitions from private parties and organizations, expressing views on human embryo research and some other issues, such as abortion and fetal tissue research which were outside the Panel's scope. *Id.*

221. *Id.* at xvii.

tation would generate significant advances in scientific research—particularly in the areas of infertility, genetic defects, and disease therapy.²²² The Panel struggled, however, with the ethical implications of research conducted with deliberately fertilized embryos.²²³ While they did not define the precise moral or legal status of the embryo, they attempted to design their recommendations with “respect” for the embryo as a symbol of human life.²²⁴ The Panel believed that their guidelines and corresponding public funding would also stimulate ethical and scientific review of privately funded embryo research.²²⁵

The Panel specifically recommended that embryos be used sparingly and at the earliest possible stages of development.²²⁶ Use of embryos more than fourteen days past fertilization—the point at which the “primitive streak”²²⁷ develops—was discouraged,²²⁸ though the Panel approved the possibility of using them up to twenty-one days after fertilization.²²⁹ It also urged that only embryos left over from IVF treatments and donated voluntarily by parents be used for research purposes.²³⁰ The Panel did recommend, however, that researchers who desired to study aspects of fertilization and initial cell division be permitted to deliberately inseminate unfertilized eggs under limited circumstances.²³¹

The Advisory Committee to the Director of the NIH (“ACD”) approved all of the Panel’s recommendations—including the one permitting deliberate creation of research embryos—and passed the recommendations on to the NIH Director, Harold Varmus, for the ultimate funding decision.²³² Within hours of that vote, however, President Clinton stated: “I do not believe that federal funds should be used to support the creation of human embryos for research purposes, and I have directed that the NIH not allocate any resources for such research.”²³³ William Galston, deputy director of Clinton’s Domestic Policy Council, later confirmed that the Clinton administration had decided even before the ACD’s meeting that deliberate creation

222. *Id.* at 65.

223. *See id.* at 35-51.

224. *See id.* at xii.

225. *Id.* at x.

226. *Id.* at 66-67.

227. The “primitive streak” is an advancing groove that develops about fourteen to fifteen days after fertilization. This “milestone in embryo development” reveals the embryo’s head-tail and left-right orientations. *Id.* at D-7.

228. *Id.* at 67.

229. *Id.* at 78.

230. *Id.* at xi-xii, 68.

231. *Id.* at 50 (concluding that fertilization of research embryos is permissible only for research with outstanding potential scientific and therapeutic value and which, by its very nature, requires the deliberate fertilization of embryos).

232. Charo, *supra* note 34, at 14.

233. *Id.* (quoting Statement by the President on NIH Recommendation Regarding Human Embryo Research, U.S. Newswire, Dec. 2, 1994).

of human embryos for experimentation exceeded the public's tolerance for "exotic" research.²³⁴

The President's announcement did not prevent Varmus from implementing the NIH Panel's other recommendations—such as renewed funding for experimentation on "surplus" embryos.²³⁵ Congress, however, has since passed broader restrictions. Under Public Law 105-78,²³⁶ federal funds are presently unavailable not only for the creation of research embryos, but also for any type of research in which human embryos are destroyed, discarded, or knowingly subjected to risks of injury or death.²³⁷ In effect, the moratorium on federally-funded embryo research continues. No federal legislation, however, exists to regulate embryo research conducted in the private sector.

B. State Law

In the absence of federal regulation of privately funded embryo research, "private researchers can do whatever they please . . . and it can go on anywhere."²³⁸ In response, several states have implemented statutory schemes to limit both privately and publicly-funded experimentation.²³⁹ While the lack of federal funding reflects—at a minimum—the American public's unwillingness to finance embryo research, these state laws illustrate opposition to the research itself.

234. Charo, *supra* note 34, at 14.

235. *Id.*

236. Departments of Labor, Health and Human Services, Education and Related Agencies Appropriations Act of 1998, Pub. L. No. 105-78, 111 Stat. 1467.

237. *Id.* at 1517 (withholding all federal funds from embryo research conducted in fiscal year 1998).

238. Julie Marquis & Lisa Richardson, *Fertility Researchers Fear Taint from UC Scandal*, L.A. Times, Feb. 14, 1996, at A3 (quoting ethicist Ronald M. Green, voicing concern over scientific abuses in the absence of federal oversight).

239. Ten states currently regulate embryo research to varying degrees. See Fla. Stat. Ann. § 390.0111(5) (West Supp. 1998) (prohibiting all research except that which preserves the life or health of the fetus); La. Rev. Stat. Ann. § 9:122 (West 1991) (banning all investigational research on embryos and prohibiting the cultivation of embryos for the same); Me. Rev. Stat. Ann. tit. 22, § 1593 (West 1992) (prohibiting all use of the product of conception in scientific research); Mass. Ann. Laws ch. 112, § 12J (Law. Co-op. 1991) (regulating the use of a live conceptus and banning non-therapeutic experimentation thereupon); Mich. Comp. Laws Ann. § 333.2685 (West 1992) (banning non-therapeutic research on embryos, if that research substantially jeopardizes the embryo's life/health or if the embryo is the subject of a planned abortion); Minn. Stat. Ann. § 145.422 (West 1989) (banning all use of a conceptus in scientific research except where it is "harmless" to the conceptus); N.H. Rev. Stat. Ann. § 168-B:15 (1994) (limiting the maintenance of non-frozen pre-embryos *ex uero* to fourteen days and prohibiting the transfer of a research pre-embryo to a uterine cavity); N.D. Cent. Code § 14-02.2-01 (1991) (criminalizing the use of a fetus in experimentation except where the purpose is to determine/preserve the life/health of the fetus or mother); 18 Pa. Cons. Stat. Ann. § 3216 (West Supp. 1997) (criminalizing all non-therapeutic research on the conceptus); R.I. Gen. Laws. § 11-54-1 (1994) (prohibiting experimentation on living embryos except as necessary for the life or health of the mother).

The most lenient of the restricting states is New Hampshire, which permits embryo experimentation, but limits it to the first fourteen days after fertilization and forbids transfer of such an embryo into a woman for implantation.²⁴⁰ Intermediate states, such as Michigan, permit experimentation only if it does not pose any increased risks to the embryo.²⁴¹ The most conservative states fully ban investigational embryo research. Louisiana, for example, requires that any use of an embryo *in vitro* be intended for eventual *in utero* implantation and development.²⁴² Louisiana also directly addresses the issue of deliberately-created embryos, insofar as it prohibits the "farm[ing]" of human embryos for research purposes.²⁴³ Even states that do not expressly limit experimentation, however, address concerns over commercialization of embryos by limiting the sale, transfer, or distribution of embryos for valuable consideration.²⁴⁴

State regulations of embryo research have not gone unchallenged. On three separate occasions, federal courts have evaluated claims that such regulations violate fundamental constitutional rights.²⁴⁵ The only successful basis courts have used to invalidate these statutes, however, has been the Fourteenth Amendment "void for vagueness" doctrine.²⁴⁶

In *Margaret S. v. Edwards*,²⁴⁷ the Fifth Circuit examined a Louisiana abortion statute that prohibited and criminalized experimentation on any unborn child²⁴⁸ resulting from abortion, unless such experi-

240. N.H. Rev. Stat. Ann. § 168-B:15.

241. Mich. Comp. Laws Ann. § 333.2685.

242. La. Rev. Stat. Ann. § 9:122.

243. *Id.*

244. Eleven states and the District of Columbia prohibit the sale of embryos. D.C. Code Ann. § 6-2601(b) (1995); Fla. Stat. Ann. § 873.05(1)-(3) (West 1994); 755 Ill. Comp. Stat. 50/8.1 (West 1992); La. Rev. Stat. Ann. § 9:122 (West 1991); Minn. Stat. Ann. § 145.422(3) (West 1989); 18 Pa. Cons. Stat. Ann. § 3216(b)(3) (West Supp. 1997); Tex. Penal Code Ann. § 48.02 (West Supp. 1994); Utah Code Ann. § 76-7-311 (1997); Va. Code Ann. § 32.1-289.1 (Michie 1997); see GA Code Ann. § 16-12-160(b)(5) (1996) (allowing payment for embryos to be used for health services education); Mich. Comp. Laws Ann. § 333.2690 (West 1992) (prohibiting payment for embryos used for illegal purposes); R.I. Gen. Laws. § 11-54-1(f) (1994) (disallowing commercialization of unlawful embryo transfers). Four states specifically prohibit the sale of embryos for research purposes. See Me. Rev. Stat. tit. 22, § 1593 (West 1992); Mass. Ann. Laws ch. 112, § 12(J)(a)(IV) (Law Co-op 1991); Mich. Comp. Laws Ann. § 333.10204(1) (West 1992); N.D. Cent. Code 14-02.2-02(4) (1991).

245. See *Jane L. v. Bangerter*, 61 F.3d 1493 (10th Cir. 1995); *Margaret S. v. Edwards*, 794 F.2d 994 (5th Cir. 1986); *Lifchez v. Hartigan*, 735 F. Supp. 1361 (N.D. Ill. 1990).

246. See, e.g., *infra* note 256 and accompanying text (defining the "void for vagueness" doctrine).

247. 794 F.2d 994 (5th Cir. 1986).

248. The court recognized that because the Louisiana statute defined "unborn child" as "the unborn offspring of human beings from the moment of conception through pregnancy and until termination of the pregnancy," it applied to embryos. *Edwards*, 794 F.2d at 998 n.10 (quoting La. Rev. Stat. Ann. § 40:1299.35.1(2) (West

ments were therapeutic to the child.²⁴⁹ The plaintiffs²⁵⁰ opposed the statute on three grounds. First, they alleged that the law unconstitutionally burdened a woman's right to choose an abortion insofar as it criminalized procedures that were necessary to preserve the life or health of the mother—namely, post-abortion procedures that might benefit the mother, but not the child.²⁵¹ Second, they argued that the law unconstitutionally burdened the medical doctors' right to do research.²⁵² Finally, they urged that the language of the statute was unconstitutionally vague.²⁵³

1992)). According to this definition, the Louisiana statute would apply to all human embryos, whether fertilized for research or implantation in a woman.

Inconsistent terminology in this respect, however, raises additional vagueness concerns. As one NIH Panel advisor noted, many state laws ignore the scientific distinction between "embryo" and "fetus." Lori B. Andrews, *State Regulation of Embryo Research*, in National Institutes of Health, Papers Commissioned for the Human Embryo Research Panel 297, 298 (1994); cf. *supra* note 5 (stating the different scientific definitions for "embryo" and "fetus"). Some state fetal research laws, such as Louisiana's, define the term "fetus" or "unborn child" to include the embryo. Some laws fail to define the meaning altogether, but are recognized as applying to embryos. Andrews, *supra*, at 298; see, e.g., Me. Rev. Stat. Ann. tit. 22, § 1593 (West 1992) (prohibiting the use of any live extrauterine fetus or product of conception for any form of experimentation) (recognized as applying to embryos in the NIH Panel Report's Appendix A). Other statutes use the term "conceptus" to apply to embryos. See, e.g., Minn. Stat. Ann. § 145.422 (West 1989) (prohibiting non-therapeutic use of "a living conceptus"). "Pre-embryo" is another common term used to refer to the embryo prior to implantation. See NIH Panel Report, *supra* note 5, at D-7; see also Marshall, *supra* note 140, at 63 (observing that the embryo research debate has given birth to this novel terminology). These ambiguities can be easily resolved by defining the terms from the outset, and must be clarified to give researchers and the general public adequate notice of the scope of these statutes.

249. *Edwards*, 794 F.2d at 998. Plaintiffs also challenged the constitutionality of another portion of the Louisiana statute, which required the attending physician to inform a woman of her disposal options for the fetal remains within twenty-four hours of her abortion. *Id.* at 997. The court struck this provision as unconstitutional, based on the Supreme Court's prior holding that a statute which required that a physician (rather than other health care workers) disclose informed consent information was unconstitutional. *Id.* at 998 (citing *City of Akron v. Akron Ctr. for Reproductive Health, Inc.*, 462 U.S. 416 (1983)).

250. This suit was a class action brought on behalf of pregnant women who desired abortions, three physicians who performed abortions, and five clinics that provided abortion facilities. *Margaret S. v. Treen*, 597 F. Supp. 636, 642 (E.D. La. 1984) (lower court opinion), *aff'd sub. nom. on modified grounds*, *Margaret S. v. Edwards*, 794 F.2d 994 (5th Cir. 1986).

251. *Treen*, 597 F. Supp. at 673. Arguably, experimental procedures might include pathological testing to diagnose infections or illnesses in women who have undergone abortion. *Id.*

252. *Id.*; see *supra* Part II.A (discussing scientists' right to research).

253. *Treen*, 597 F. Supp. at 672. The disputed statute stated, "[n]o person shall experiment on an unborn child or on a child born as the result of abortion, whether the unborn child or child is alive or dead, unless the experimentation is therapeutic to the unborn child or child." *Id.* at 671 n.29 (quoting La. Rev. Stat. Ann. § 40:1299.35.13 (West 1992)). Plaintiffs argued that the statute was unclear as to what was included in the category of "dead or alive child born as the result of an abortion." *Id.* at 672.

The lower court found merit in each of the plaintiffs' arguments and declared the provision unconstitutional.²⁵⁴ On appeal, however, the Fifth Circuit affirmed the decision on the sole ground that the terms "experiment" and "experimentation" rendered the statute impermissibly vague.²⁵⁵ A statute is void for vagueness under the Due Process Clause of the Fourteenth Amendment if it "is inherently standardless, enforceable only on the exercise of an unlimited, and hence arbitrary, discretion vested in the state."²⁵⁶ The court was swayed by the expert testimony that physicians do not, and cannot, clearly distinguish between medical "tests" and medical "experiments"—many medical treatments can be described as both.²⁵⁷ One doctor explained that "experimentation" can have at least two distinct meanings: 1) "[W]hen you do things to see - just wonder 'What would happen if I did this . . . what would be the outcome[?]' " and 2) performing a procedure "without a 'data base of many cases to rely upon.'"²⁵⁸ Because the statute "simply [had] no core" that applied to specific activities, it was held to be unconstitutional.²⁵⁹

The Tenth Circuit came to a similar conclusion in evaluating a Utah fetal experimentation law in *Jane L. v. Bangerter*.²⁶⁰ Unlike the Louisiana law, this Utah criminal statute²⁶¹ permitted discretionary experimentation aimed at acquiring genetic information about the embryo or fetus.²⁶² The district court upheld the statute by narrowly interpreting "experimentation" to mean "tests or medical techniques which are designed solely to increase a researcher's knowledge and are not intended to provide any therapeutic benefit to the mother or child."²⁶³ The Court of Appeals reversed, however, asserting that the district court "blatantly rewrote the statute, choosing among a host of competing definitions for 'experimentation.'"²⁶⁴ Judge Seymour went on to attack the sufficiency of the definition itself, insisting that "benefit" was an equally uncertain term.²⁶⁵ Because the law did not clearly demarcate criminal conduct from permitted action, the court held it to be unconstitutionally vague.²⁶⁶

254. *Id.* at 673-76.

255. *Edwards*, 794 F.2d at 999.

256. *Id.* (quoting *Ferguson v. Estelle*, 718 F.2d 730, 735 (5th Cir. 1983)).

257. *Id.*

258. *Jane L. v. Bangerter*, 61 F.3d 1493, 1501 (10th Cir. 1995) (citing expert testimony from *Treen*, 794 F. Supp. at 994).

259. *Treen*, 794 F.2d at 999 (quoting *Smith v. Goguen*, 415 U.S. 566, 578 (1974)) (emphasis deleted).

260. 61 F.3d 1493 (10th Cir. 1995).

261. Utah Code Ann. § 76-7-310 (1995).

262. *Bangerter*, 61 F.3d at 1499-1500.

263. *Id.* at 1501 (citation omitted).

264. *Id.*

265. *Id.* at 1502.

266. *Id.*

In *Lifchez v. Hartigan*,²⁶⁷ the Northern District of Illinois scrutinized the term "therapeutic."²⁶⁸ The challenged statute criminalized fertilization of embryos for the purpose of experimentation, unless such research was "therapeutic to the fetus thereby produced."²⁶⁹ The statute also stated that it was not intended to prohibit the performance of IVF.²⁷⁰ The court noted that various experimental procedures, such as embryo transfer²⁷¹ and genetic screening,²⁷² were arguably non-therapeutic but not clearly intended to fall within the ban.²⁷³ Again, because the legislature failed to specifically define "therapeutic" in the statute, the court found it to be unconstitutionally vague.²⁷⁴ Although none of the statutes challenged in the federal courts have survived constitutional scrutiny, this precedent does not pose a significant obstacle to the regulation of embryo research. None of the above noted cases questioned the states' legitimate interest in limiting the use of embryos in scientific experiments.²⁷⁵ They merely require that legislatures choose a definition for each term employed and specify that meaning explicitly for the statutes to survive vagueness challenges. Mindful of this requirement, Part IV proposes legislation that can withstand judicial scrutiny.

IV. PROPOSED STATUTE

Neither potential community benefit nor freedom of scientific inquiry justify the deliberate fertilization of human embryos for investigational embryo research.²⁷⁶ The creation and use of research embryos is a serious misuse of human life which threatens its subjects²⁷⁷ and society in general.²⁷⁸ The federal government has acknowledged this problem by refusing to finance any embryo experimentation,²⁷⁹ but its policy affects only those researchers who rely upon federal funds.²⁸⁰ Regulations of private research activities

267. 735 F. Supp. 1361 (N.D. Ill. 1990).

268. *See id.*

269. *Id.* at 1363-64 (quoting Ill. Rev. Stat. Ch. 38 ¶ 81-26, § 6-7 (1989)).

270. *Id.*

271. Embryo transfer is part of IVF procedures whereby a pre-implantation embryo is introduced into the uterus or fallopian tube. *See* NIH Panel Report, *supra* note 5, at D-4.

272. Genetic screening is a synonym for pre-implantation diagnosis. *See supra* note 15.

273. *Lifchez v. Hartigan*, 735 F. Supp. 1361, 1367-68 (N.D. Ill. 1990).

274. *Id.* at 1376.

275. In a precursor case to *Margaret S. v. Edwards*, the district court explicitly held that Louisiana has a legitimate interest in regulating embryo experimentation to protect its citizens from the "dangers of abuse inherent in any rapidly developing field." *Margaret S. v. Edwards*, 488 F. Supp. 181, 221 (E.D. La. 1980).

276. *See supra* Part II.A-B.

277. *See supra* Part II.C.

278. *See supra* Part II.D.

279. *See supra* Part III.A.

280. *See supra* note 238 and accompanying text.

vary from state to state²⁸¹ and are prone to constitutional challenges due to vague statutory language.²⁸² A uniform ban on the creation of embryos for investigational embryo research, one that both affords embryos negative rights and clearly defines the limitations on researchers, is therefore both appropriate and necessary. Accordingly, this Note proposes the following federal²⁸³ bill:

A BILL

SECTION 1. SHORT TITLE

This Act may be cited as the "Research Embryo Act."

SECTION 2. PROHIBITION AGAINST CREATION OF HUMAN EMBRYOS FOR INVESTIGATIONAL SCIENTIFIC RESEARCH

(a) DEFINITIONS:

For the purposes of this statute: (1) "Creation" of a human embryo means the fertilization of a human ovum with human sperm; (2) "Embryo" means the living organism resulting from fertilization; (3) "Gamete" means the egg (ovum) or sperm (spermatazoa); and (4) "Investigational embryo research" means tests, techniques, or procedures which are designed to increase the knowledge of the researcher or scientific discipline, but are not intended to diagnose or improve the life or health of the embryo or individual biological parent, and which result in the destruction of the embryo.

(b) IN GENERAL:

281. See *supra* note 239.

282. See *supra* Part III.B.

283. The federal government's authority to promulgate a law like this might be drawn from the Interstate Commerce Clause, which likewise gives Congress the power to establish the Federal Food, Drug, and Cosmetic Act to promote public health and safety. See *Carnohan v. United States*, 616 F.2d 1120 (9th Cir. 1980). FDA Commissioner Michael A. Friedman recently invoked that authority, warning researchers that the federal government would promulgate and enforce restrictions against human cloning—another procedure which presents "serious health and safety issues" for its subjects. *FDA Warns Against Human Cloning Attempt*, L.A. Times, Jan. 20, 1998, at B8. A bill now pending in the Senate to ban cloning permanently may indirectly restrict the use of research embryos. S. 1574, 105th Cong. (1998) ("PROHIBITION ON HUMAN CLONING. § 3 (a) IN GENERAL. — It shall be unlawful for any person to— (1) clone a human being; or (2) *conduct research for the purpose of cloning a human being or otherwise creating a human embryo.*" (emphasis added)). Due to the tentative climate of the cloning debate, however, a separate law dealing exclusively with research embryos is necessary. See Cloning Report, *supra* note 4, at 109 (suggesting that in three to five years the government re-evaluate the current recommendations against the cloning of humans).

Nevertheless, the issues of cloning and embryo research are inextricably intertwined. Last summer, Edmund Pellegrino, Professor of Medicine and Medical Ethics at Georgetown University, testified before Congress that failure to permanently ban cloning "begs the question of the moral wrong of human embryo experimentation which is the first and essential step in any cloning of human beings." *Ethics and Theology: A Continuation of the National Discussion of Human Cloning*, S. 541-41, 105th Cong. (1997) (statement of Edmund D. Pellegrino, *Cloning Human Beings—The Moral Necessity of a Permanent Ban*).

It shall be unlawful for anyone to— (1) create a human embryo for use in investigational embryo research; or (2) conduct investigational embryo research using a human embryo created for that purpose; or (3) buy, sell, or otherwise transfer human gametes for creating a human embryo to be used in investigational embryo research.

SECTION 3. SANCTIONS (a) CIVIL PENALTIES: Whoever knowingly or recklessly violates any part of Section 2(b) shall be subject to a civil penalty of not more than \$10,000 for each such violation. (b) INELIGIBILITY FOR FEDERAL FUNDS: Any individual or institution found to knowingly or recklessly violate Section 2(b) shall be ineligible to receive federal funding for research of any kind for a period of five years after such violation.

This statute addresses and overcomes the problems that have plagued state laws in the past. Section 2(a) clearly defines the meaning of each term employed, giving researchers adequate notice of the statute's scope and application.²⁸⁴ Section 2(a)(2) defines "embryo" in accordance with its scientific definition.²⁸⁵ Section 2(a)(4), in defining "investigational embryo research," does not employ subjective terms like "experimental,"²⁸⁶ "benefit,"²⁸⁷ or "therapeutic."²⁸⁸ Rather, it broadly covers any procedure which is designed to increase the knowledge of the researcher or scientific discipline, but is not intended to gather information about the health of the embryo or individual biological parent.²⁸⁹ Thus, the deliberate fertilization and use of human embryos for basic research and studies designed to improve IVF techniques as a whole²⁹⁰—which are conducted without regard to the welfare of the gamete providers or individual embryos—would be prohibited. This statute does not, however, address the performance of pre-implantation diagnosis, which is designed to determine the genetic status of an embryo in conjunction with an IVF protocol.²⁹¹ Nor would it affect the performance of arguably experimental IVF techniques,²⁹² so long as they are designed to improve the life of the biological parent by helping them conceive a child.

284. Cf. *supra* Part III.B (discussing state laws that were held unconstitutional because they failed to define "experiment" and "therapeutic").

285. See *supra* notes 5, 248.

286. See *supra* note 255 and accompanying text.

287. See *supra* text accompanying note 265.

288. See *supra* text accompanying note 274.

289. Cf. *supra* notes 263, 264 and accompanying text (noting that while judges are not free to "choos[e] among a host of competing definitions" legislatures may—and must—do so).

290. See *supra* Part II.B.

291. But see Dena S. Davis, *Genetic Dilemmas and the Child's Right to an Open Future*, 28 Rutgers L.J. 549 (1997) (discussing the divisive moral implications of pre-implantation diagnosis).

292. Cf. *supra* text accompanying note 271 (discussing the *Lifchez* court's confusion over whether the disputed statute encompassed "embryo transfer").

The latter part of section 2(a)(4) refrains from interfering with reproductive autonomy by permitting experimentation that might be performed to explore parents' reproductive status.²⁹³ This statute would, conceivably, permit researchers to create human embryos for tests or procedures solely relevant to the biological parent's health as part of an IVF protocol. This is not, however, a current use for research embryos.²⁹⁴ The experiments for which deliberately fertilized embryos are presently believed to be useful are limited to basic research and studies to improve IVF procedures as a whole.²⁹⁵ Such research is designed to increase only the knowledge of the researcher or scientific discipline and results in the eventual destruction of the embryo.²⁹⁶

This statute thus grants the human embryo a much-needed negative right not to be created, used, and destroyed for the sake of scientific research alone.²⁹⁷ By prohibiting both fertilization of and experimentation on research embryos, section 2(b)(1) and (2) accomplish the limited goal of banning research in which embryos are created expressly for that purpose. Section 2 further protects against commercialization and commodification by eliminating profit opportunities for both researchers and donors.²⁹⁸

This statute also imposes severe sanctions, commensurate with the serious nature of these activities. Section 3(a) imposes a \$10,000 fine on anyone who creates or uses a research embryo or purchases, sells, or traffics gametes for creation of a research embryo.²⁹⁹ Section 3(b) also threatens individuals and institutions with the loss of federal funding.³⁰⁰ The scienter requirement,³⁰¹ however, exempts individuals or institutions who innocently and unknowingly participate in such research.³⁰² These measures demand that researchers and research facilities vigilantly prevent abuses of the human embryo.

293. Cf. *supra* note 97 (noting possible Constitutional implications of restricting research designed for this purpose).

294. Cf. NIH Panel Report, *supra* note 5, at 42-44 (listing the potential uses for research embryos, all of which constitute investigational embryo research).

295. *Id.* at 43.

296. See *supra* text accompanying note 165.

297. See *supra* Part II.C.

298. See *supra* Part II.D.

299. Cf. H.R. 923, 105th Cong. § 2 (b) (1997) (proposing a maximum civil money penalty of \$5,000 for use of a human embryo in cloning); S. 1574, 105th Cong. § 3 (a) (1998) (same); Lal, *supra* note 19, at 542 (proposing a \$60,000 fine and an eight year prison term for those who participate in the sale of gametes or embryos, and a \$50,000 fine and five year prison term for those who use embryos without proper authorization).

300. Cf. S. 1574, 105th Cong. § 3 (b) (1998) (proposing five year withdrawal of federal funds from any individual who participates in human cloning research).

301. Section 3 imposes sanctions only on those who "knowingly or recklessly" violate the statute.

302. In 1996, NIH officials discovered that Dr. Mark Hughes, an employee of the National Human Genome Research Institute and a former member of the Human

Most importantly, this statute achieves what is perhaps most lacking in the present law: uniformity. The limitations and inadequacies of existing federal³⁰³ and state laws³⁰⁴ permit the private sector to choose where and how to conduct research with embryos, virtually free from oversight.³⁰⁵ As a federal law of general applicability, this proposed bill holds all researchers—regardless of their locale or source of funding—to the same standards of responsibility and respect for human life.

CONCLUSION

While investigational embryo research offers benefits for medical science, the harm inflicted on the human embryo and the risks to society at large caution against it—especially when such research involves the deliberate creation of human embryos. The federal government has recognized these dangers and refused to fund this type of experimentation. The federal laws, however, apply only to the activities of those who accept federal funds. Individual states have also responded by legislating against such research. State laws of general applicability, however, vary among jurisdictions, are often poorly drafted, and consequently are vulnerable in the courts due to vagueness of statutory language. Without comprehensive and well-defined regulations, the private sector is able to conduct virtually all embryo research without review or accountability.

The restriction proposed in this Note addresses this most egregious misuse of human embryos. Such a law would prohibit all scientists from creating and using unborn life for research purposes alone and would help prevent the commodification and commercialization of human embryos. Absent uniform laws, researchers are encouraged to forum shop to find a jurisdiction with lax, or nonexistent, regulation of their activities. Rather, scientists should be required to act responsibly and within the accepted boundaries of a society which values and protects human life.

Embryo Research Panel, was secretly conducting illegal human embryo research with NIH equipment and research fellows. *Continued Management Concerns at the NIH*, 105th Cong. H271-41 (1997) (testimony of Harold E. Varmus, *NIH Human Embryo Research Funding Policies*). In October of that year, the NIH terminated its relationship with Dr. Hughes and has implemented broader policies to inform scientists of their duties under present law. *Id.*

303. See *supra* Part III.A.

304. See *supra* Part III.B.

305. See *supra* note 238 and accompanying text.

Notes & Observations