

ARTICLE

THE HUMAN PREEMBRYO, THE PROGENITORS, AND THE STATE: TOWARD A DYNAMIC THEORY OF STATUS, RIGHTS, AND RESEARCH POLICY

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I. INTRODUCTION

Technology continues to revolutionize our view of human life. In 1965, *Life* magazine featured the first, remarkable photographs of the human embryo and fetus floating within the womb.¹ Now, as the technology of human reproduction has advanced, it has become possible to see the human "preembryo"—fertilized, sustained, and even frozen outside the human body.² Adopted in 1986, the term "preembryo" refers to the initial phase of human development,³ beginning with the first cell division, continuing for some fourteen days after conception, and ending as the embryo appears and major body systems begin to form.⁴

1. *Drama of Life Before Birth*, LIFE, Apr. 30, 1965, at 62 (photographed by Lennart Nilsson); see also M. FURUJELM, A. INGELMAN-SUNDBERG & C. WIRSEN, A CHILD IS BORN (rev. ed. 1976) (original ed. 1965) (featuring photographs by Lennart Nilsson of the unborn embryo and fetus).

2. See *infra* notes 70-91 and accompanying text.

3. C. GROBSTEIN, SCIENCE AND THE UNBORN 58-62 (1988); Jones & Schrader, *And Just What Is a Pre-embryo?*, 52 FERTILITY & STERILITY 189, 189-90 (1989).

4. See *infra* notes 43-69 and accompanying text. For the sake of consistency, the term "preembryo" will be used to refer to this stage of human development even if a reference which is cited or discussed in the Article refers to an "embryo," "fetus," "product of conception," etc. This usage is not meant to distort the original source, but rather to maintain the clarity of the argument developed herein. Quotations, however, will not be altered by substituting "preembryo" for some other term.

The preembryo has become the subject of observation, manipulation, and controversy through the process of *in vitro* fertilization. With this process, human conception can be effected "in glass" or outside the body,⁵ and the resulting preembryo can be transferred into a woman's uterus.⁶ If the procedure is successful, the preembryo will implant in the uterine wall and a pregnancy will begin.⁷

As a form of assisted reproduction, *in vitro* fertilization or "IVF" has become more and more important as a treatment for infertility.⁸ In 1978, the first infant conceived by means of IVF was born in England.⁹ In 1985, the first birth from a frozen or "cryopreserved" preembryo was reported.¹⁰ In 1988, at least 2,133 babies were born as a result of IVF in the United States¹¹ and transfer cycles following cryopreservation accounted for another 73 deliveries.¹²

The growing importance of IVF can also be measured by controversy. In 1989, Risa Adler-York and Steven York filed a lawsuit in federal court to obtain their frozen preembryo from an IVF program in Virginia and transport the preembryo to a program in California.¹³ The parties assumed that the preembryo was the Yorks' property, but disputed the extent of their property interest.¹⁴ The court also assumed that the preembryo was personal property and upheld the Yorks' right to sue under traditional property doctrines.¹⁵

5. See C. GROBSTEIN, *supra* note 3, at 59.

6. See *infra* notes 70-79 and accompanying text.

7. See *infra* notes 80-81 and accompanying text.

8. Medical Research International and the Society for Assisted Reproductive Technology, The American Fertility Society, *In Vitro Fertilization-Embryo Transfer in the United States: 1988 Results from the IVF-ET Registry*, 53 FERTILITY & STERILITY 13, 13 (1990) [hereinafter 1988 Results]; see also HOUSE COMM. ON GOVERNMENT OPERATIONS, INFERTILITY IN AMERICA: WHY IS THE FEDERAL GOVERNMENT IGNORING A MAJOR HEALTH PROBLEM?, H.R. REP. NO. 389, 101st Cong., 1st Sess. 3, 7, 9-10 (1989) [hereinafter INFERTILITY IN AMERICA]; Seibel, *A New Era In Reproductive Technology In Vitro Fertilization, Gamete Intrafallopian Transfer, and Donated Gametes and Embryos*, 318 NEW ENG. J. MED. 828, 828 (1988).

Infertility commonly is defined as "the failure of a couple to conceive after one year of intercourse without using contraception." INFERTILITY IN AMERICA, *supra*, at 3. The number of infertile couples in America who want to have children has been estimated at 2.4 million, *id.*, and 2.8 million. Seibel, *supra*, at 828.

9. Seibel, *supra* note 8, at 828.

10. Fugger, *Clinical Status of Human Embryo Cryopreservation in the United States of America*, 52 FERTILITY & STERILITY 986, 986 (1989).

11. 1988 Results, *supra* note 8, at 14 (deliveries include 356 twin deliveries, 55 triplet, 8 quadruplet, and 2 quintuplet deliveries).

12. 1988 Results, *supra* note 8, at 18 (deliveries include 7 twin deliveries and 1 set of triplets).

13. York v. Jones (No. 89-373-N E.D. Va.) (verified complaint filed on May 10, 1989).

14. *Id.*

15. See York v. Jones, 717 F. Supp. 421 (E.D. Va. 1989) (denying defendants' motion to dismiss, under FED. R. Civ. P. 12(b)(6), for failure to state a claim upon which relief could be granted). The suit was settled out of court, and the Virginia center agreed to release the

Another couple, Mary Sue and Junior Davis, filed a divorce action in 1989¹⁶ and went to trial to determine the disposition of seven frozen preembryos they had created during their marriage. Mary Sue Davis wanted to become pregnant and bring the preembryos to term, if possible, but Junior Davis objected.¹⁷ Concluding that the preembryos were human beings¹⁸ and "children, *in vitro*"¹⁹ whose best interest was served by the opportunity to be brought to term, the Tennessee trial court gave "temporary custody ... for the purpose of implantation"²⁰ to Mary Sue Davis.²¹

Junior Davis appealed and the Tennessee Court of Appeal reversed the trial court.²² Emphasizing the fact that a pregnancy had not yet occurred, the appellate court determined that Junior Davis had a "constitutionally protected right not to beget a child where no pregnancy has taken place",²³ that it would be "repugnant and offensive to constitutional principles to order Mary Sue to implant"²⁴ the preembryos; and "equally repugnant to order Junior to bear the psychological ... consequences of paternity."²⁵ Hence, the Court of Appeal concluded that Mary Sue Davis and Junior Davis should have "joint control of the fertilized ova ... with equal voice over their disposition."²⁶

Further, controversy has simmered for some time with respect to IVF research and research with the preembryo. The controversy is linked to the abortion debate and to the political (if not the legal) issue of when life begins.²⁷ As a result, federal policy regarding IVF research and research with the preembryo has become a policy of avoidance—

preembryo. Board of Trustees Report, *Frozen Pre-embryos*, 263 J. A.M.A. 2484, 2484 (1990) [hereinafter J.A.M.A. Report].

16. Davis v. Davis, 15 Fam. L. Rep. (BNA) 2097, 2099 (Tenn. Cir. Ct. Sept. 21, 1989).

17. *Id.* at 2104.

18. *Id.* at 2097, 2103.

19. *Id.* at 2097, 2104.

20. *Id.* at 2097.

21. *Id.*

22. Davis v. Davis, No. 180 (Tenn. Ct. App. Sept. 13, 1990) (LEXIS, States library, Tenn. file) (An application for hearing before the Tennessee Supreme Court was pending when the present Article was prepared for publication. Telephone interview with Deputy Clerk, Tenn. Ct. App. (Oct. 24, 1990)). At the time of the appellate court's decision, Mary Sue Davis and Junior Davis had each remarried; neither wanted a child with the other as a parent; and Mary Sue Davis, whose name had changed to Mary Stowe, sought authority not to implant the preembryos, but to donate them to a childless couple. *Davis*, (LEXIS, States library, Tenn. file) at 1, 1-2 n.1.

23. *Id.* at 6.

24. *Id.* at 8.

25. *Id.* at 9

26. *Id.*

27. See generally Fletcher & Schulman, *Fetal Research: The State of the Question*, 15 HASTINGS CTR. REP. 6 (Apr. '85) (summarizing history of relevant federal regulations and urging federal action).

guidelines have yet to be formulated and there is no forum for productive debate.²⁸ State laws form a political patchwork, generally designed to prevent nontherapeutic research but uncertain in scope and application.²⁹

Therefore, at this point, our legal institutions must respond to the challenge of IVF technology. The legal status of the preembryo must be defined. Is the preembryo property, as the York court assumed; a human being, as the Tennessee trial court concluded; or neither, as the Tennessee appellate court seemed to believe? Likewise, the relationship between the preembryo, its progenitors,³⁰ and the state must be analyzed. What rights do the progenitors have relative to the preembryo, the state, and each other? What principles should guide research policies?

This Article will examine these issues.³¹ In Part II, the preembryonic stage of development and IVF technology will be described.³² In Part III, the legal status of the preembryo will be analyzed and the argument will be made that the preembryo should not be defined as either property or a person.³³ Instead, the preembryo should be given a *sui generis* status which entitles it to profound respect.³⁴ This approach is essentially heuristic in nature. It embodies the value which we attach to the preembryo and supplies a frame of reference for further analysis, but frees our analysis from categories and assumptions which do not seem appropriate when applied to the preembryo.³⁵

28. See *infra* notes 257-270 and accompanying text.

29. See *infra* notes 275-308 and accompanying text.

30. As used in this Article, the term "progenitors" refers to the "gamete providers," those individuals who provide the egg or sperm cells from which the preembryo is created. Both terms are fairly common. Compare *York v. Jones*, 717 F. Supp. 421 (E.D. Va. 1989) (using "progenitors") and *Andrews, The Legal Status of the Embryo*, 32 LOYOLA L. REV. 357 (1986) (same) with *Robertson, In the Beginning: The Legal Status of Early Embryos*, 76 VA. L. REV. 437 (1990) (using "gamete providers").

31. Other issues involving the preembryo can be illustrated by the following example: In 1983, two California residents, Elsa and Mario Rios, were killed in a plane crash, leaving two preembryos frozen in Australia. The preembryos had been created in 1981, using IVF techniques, with Mrs. Rios' eggs and the sperm of an anonymous donor. The couple left an estate of \$8 million, but no instructions as to how the preembryos should be disposed of upon their death. As of October 1989, the preembryos remained frozen. Lieber, *The Case of the Frozen Embryos*, SATURDAY EVENING POST, Oct. 1989, at 50.

A number of questions arise from these facts. For example: How should the preembryos be disposed of? Who should decide and by what standards? If the preembryos ultimately are born alive, who should be defined as their legal parents—the deceased Mr. and Mrs. Rios, the woman to whom they were transferred for gestation and birth, the individuals who might adopt them, some combination of the above, or none at all? Such questions are fascinating but are beyond the scope of this Article.

32. See *infra* notes 42-91 and accompanying text.

33. See *infra* notes 92-159 and accompanying text.

34. See *infra* notes 160-174 and accompanying text.

35. See *infra* notes 94 & 174 and accompanying text.

In Part IV, the progenitors' rights will be analyzed in terms of the constitutional principles which protect and define our reproductive freedom vis-a-vis the state.³⁶ Based on these vital principles, an argument will be made supporting the progenitors' right to make procreative decisions regarding the preembryo, including decisions which will determine whether a preembryo is transferred with the hope that the progenitors will become parents, donated to other prospective parents, used in research, or disposed of and allowed to die.³⁷ Further, like the *Davis* appellate court, the Article will conclude that a state cannot resolve a dispute between the progenitors by imposing the choice of one progenitor on the other.³⁸ However, the implications of this position must be confronted. If each progenitor has an "equal voice" regarding the preembryos' disposition, the progenitors cannot agree to the manner of disposition, and the state cannot intervene in support of one progenitor over another, then the deadlock can only be resolved by allowing the preembryos to deteriorate and die.³⁹

Finally, moving outside the area of reproductive rights, Part V will review the state of the law regarding IVF research and research with the preembryo.⁴⁰ Also, it will develop an argument supporting such research and propose a set of research guidelines.⁴¹

Before proceeding further, a caveat is in order. The issues examined in this Article can be emotional and controversial. To make matters even more difficult, the issues require us to confront ambiguity, change, and the subjective meaning of competing values. "Respect," for example, is a subjective, value laden concept, and we may "respect" the preembryo but not always act to preserve its life. Further, we may "respect" the preembryo but treat the preembryo differently than we would treat the newborn, viable fetus, or even the developing embryo. It may be difficult and unsettling to make these distinctions, but we cannot ignore the phenomena of change and human development.

Therefore, as we approach some of the legal issues surrounding the preembryo, we must be ready to look beyond the "bright lines" which are so familiar in legal analysis. We must look beyond our traditional concepts of "property" and "person." We must interpret rights in terms of their human meaning and context, without looking for "winners" and "losers." Further, we must endeavor to define policies which may enrich our common humanity.

36. See *infra* notes 175-224 and accompanying text.

37. See *infra* notes 225-237 and accompanying text.

38. See *infra* notes 240-248 and accompanying text.

39. See *infra* note 249 and accompanying text.

40. See *infra* notes 257-308 and accompanying text.

41. See *infra* notes 309-357 and accompanying text.

II. THE PREEMBRYO AND *IN VITRO* FERTILIZATION: A BRIEF JOURNEY THROUGH BIOLOGY AND REPRODUCTIVE TECHNOLOGY

A. The Preembryo⁴²

Reproduction begins with fertilization. Over a period of at least twenty-four hours, the sperm penetrates the egg⁴³ and "two cells fuse to become one."⁴⁴ The resulting one-cell "zygote" has a unique genetic identity or "genome" derived from the genetic material of egg and sperm.⁴⁵

From this point, the zygote begins to develop as a preembryo. Undergoing a process of cell division or "cleavage," it becomes a loose cluster of smaller cells or "morula"; then, a more compact cluster or "blastocyst."⁴⁶ The blastocyst is comprised of about a hundred cells and two cell populations: an external or peripheral layer and a smaller, inner cell mass.⁴⁷ The external cells are referred to as the "trophoblast" or "feeding layer."⁴⁸ They will penetrate the uterine wall, as the process of implantation begins, and are essential to the later formation of the placenta.⁴⁹ The inner cell mass will develop into the embryo.⁵⁰

As events continue, the inner cell mass forms two cavities which will become the amniotic cavity and yolk sac (both embryonic structures).⁵¹ The embryonic plate lies between the two cavities; it is a flat plate of cells and the precursor of the actual embryo.⁵² About fourteen days after fertilization, a linear thickening appears on the embryonic disc.⁵³ Referred to as the "primitive streak," it is a transient, relatively opaque line which marks the direction of what will become the long or head-to-tail axis of the future embryo.⁵⁴ Indeed, shortly after the streak

42. The present account of preembryonic development relies heavily on C. GROBSTEIN, *supra* note 3. For another excellent and concise account of preembryonic development, see Ethics Comm. of Am. Fertility Soc'y, *Ethical Considerations of the New Reproductive Technologies*, 53 FERTILITY & STERILITY 31S, 31S-32S (Supp. 1990).

43. Jones & Schrader, *supra* note 3, at 190.

44. C. GROBSTEIN, *supra* note 3, at 82.

45. *Id.* at 24-25, 82.

46. *Id.* at 59-60, 168.

47. *Id.* at 26-27, 60, 168.

48. *Id.* at 60.

49. *Id.* at 27, 60, 168.

50. *Id.*

51. *Id.* at 169.

52. *Id.*

53. *Id.* at 27, 83, 105.

54. *Id.* at 27, 83.

appears, body parts and organs begin to develop ahead of the streak and then appear to spin out from head to tail.⁵⁵

The appearance of the primitive streak marks the dividing line between the preembryonic and embryonic periods.⁵⁶ By scientific definition, an "embryo" refers to "an individual multicellular organism in the process of forming major parts and organs from rudimentary beginnings."⁵⁷ Before the primitive streak appears, twinning may occur or two preembryos may fuse into one.⁵⁸ However, the appearance of the primitive streak marks the initial organization of a single individual from a developmental point of view.⁵⁹

As indicated above, the embryonic period involves a process of extraordinary growth and differentiation.⁶⁰ During this period, the major organs and parts of the body appear, including the heart, spinal cord and brain, liver and pancreas, kidney, reproductive organs, head, face, and limbs.⁶¹ This process of "organogenesis" continues until some eight weeks after fertilization.⁶² By this point, the major body systems are still immature, but their basic outline has been established in terms of both form and function.⁶³ Further, primitive movements can be observed "in the form of weak, almost flickering twitches of the head and neck."⁶⁴ Hence, although there is no sharp dividing line, the transition from embryo to fetus has been accepted at the end of eight weeks.⁶⁵

To complete and greatly simplify this thumbnail sketch, the fetal period is characterized by rapid growth and steady maturation in terms of both function and behavior.⁶⁶ Fetal movement is an important signal of increasing individuality, for it indicates overt behavior as well as the maturation of the central nervous system that makes movement possible.⁶⁷ At the end of twenty-six weeks, the fetus is considered viable or able to survive *ex utero*.⁶⁸ At forty weeks, the fetus is term.⁶⁹

55. *Id.*

56. *Id.* at 27-28, 81-83.

57. *Id.* at 59.

58. *Id.* at 25; Jones & Schrader, *supra* note 3, at 190.

59. C. GROBSTEIN, *supra* note 3, at 27-28, 81-82.

60. *Id.* at 85.

61. *Id.* at 83.

62. *Id.* at 28, 83.

63. *Id.* at 84.

64. *Id.* at 85.

65. *Id.* at 30, 85, 108, 143.

66. *Id.* at 107-08, 143.

67. *Id.* at 143.

68. *Id.*

69. *Id.* at 124.

B. In Vitro Fertilization

We will now turn to reproductive technology. IVF alters "natural" reproduction through four basic steps: the induction and timing of ovulation, the retrieval of eggs or "oocytes," fertilization *in vitro*, and the transfer of the preembryo to the uterus.⁷⁰ Ovulation is controlled by a regimen of fertility drugs to stimulate the simultaneous maturation of more than one oocyte.⁷¹ Only one oocyte matures during the natural cycle, but the success rate of IVF is increased when more than one preembryo is transferred.⁷² Further, the drug regimen will cause ovulation to occur at a specific time which, in turn, allows the retrieval procedure to be scheduled for a specific time.⁷³

Oocytes are retrieved by means of a laparoscopy or ultrasound techniques.⁷⁴ The former involves a surgical procedure in which a surgeon looks into the abdomen through a laparoscope to collect the oocytes through a needle tip.⁷⁵ Ultrasound techniques, which are now more common,⁷⁶ are less invasive and allow the internal organs and needle tip to be visualized by placement of an ultrasound transducer on the woman's abdomen.⁷⁷

After the oocytes are retrieved, they are placed in a culture medium and sperm are added.⁷⁸ Assuming that fertilization occurs and cleavage begins, the preembryo(s) will be transferred to the uterus, at the two to eight cell stage, by means of a thin catheter.⁷⁹ At present, the clinical pregnancy and live delivery rates following the transfer procedure correlate with the number of preembryos transferred. According to one set of data regarding transfers initiated in the United States in 1988, the pregnancy and delivery rates were, respectively, 16% and 12% when less than three preembryos were transferred, and 22% and 16% when four or more preembryos were transferred.⁸⁰ Further, as the pregnancy and delivery rates increased with the number of preembryos transferred, the rate of multiple deliveries increased from 2.8% to 4.3%.⁸¹

70. Seibel, *supra* note 8, at 829-31.

71. *Id.* at 829.

72. *Id.*

73. *Id.*

74. *Id.* at 829-30.

75. *Id.* at 829.

76. 1988 *Results*, *supra* note 8, at 14, 19.

77. Seibel, *supra* note 8, at 829-31.

78. *Id.* at 830.

79. *Id.* at 830-31.

80. 1988 *Results*, *supra* note 8, at 13-14.

81. *Id.* at 14-15.

If the retrieval, fertilization, and transfer procedures result in "extra" preembryos, the preembryos can be frozen by special procedures or "cryopreserved" for future use.⁸² Cryopreservation has become an accepted therapeutic practice⁸³ and offers several benefits. It can increase the number of potential transfer cycles, reduce the risk of multiple gestation by allowing a maximum of three preembryos to be transferred per cycle, and reduce the overall cost of IVF by eliminating the need for another retrieval procedure.⁸⁴ Further, according to current data, the majority of frozen-thawed preembryo transfers are accomplished without using fertility drugs to stimulate and control the woman's natural cycle.⁸⁵

In the early cryopreservation programs of the mid nineteen eighties, only preembryos of two to six cells were frozen.⁸⁶ However, data collected through 1988 regarding cryopreservation programs in the United States, show that IVF centers now have experience in freezing zygotes, preembryos in the two cell to morula stage (cleaved preembryos), and preembryos in the blastocyst stage.⁸⁷ The survival rate for each group, based on the number transferred per the number thawed, has been similar, (69.4%, 69.5%, and 74.2% respectively),⁸⁸ but the pregnancy rate per transfer has varied as follows: 17.4% for zygotes, 12.5% for cleaved embryos, and only 4.3% for blastocysts.⁸⁹ Further, fewer zygotes were transferred per pregnancy than with other groups. The statistics are significant: 11.5 zygotes compared to 16 cleaved embryos and 46 blastocysts for each resulting pregnancy.⁹⁰ Hence, at present, cryopreservation appears most successful at the zygote stage of development.⁹¹

82. C. GROBSTEIN, *supra* note 3, at 64; see generally Fugger, *supra* note 10.

83. Fugger, *supra* note 10, at 986.

84. *Id.* at 987.

85. *Id.* at 988.

86. *Id.* at 989.

87. *Id.*

88. *Id.* at 988-89.

89. *Id.*

90. *Id.*

91. *Id.* at 989. The arguments developed in this Article regarding the preembryo would apply with equal force to the zygote (the one cell fertilized egg). For convenience, however, the analysis will refer only to the preembryo.

III. THE LEGAL STATUS OF THE PREEMBRYO: A NEW VIEW AT THE EDGE OF LIFE

A. Something Is Wrong When the Preembryo Is Seen as Property

Long ago, Shakespeare queried, "What's in a name? that which we call a rose By any other name would smell as sweet"⁹² In this famous passage from *Romeo and Juliet*, Juliet pondered her star-crossed love for Romeo and observed with some feeling, " 'Tis but thy name that is my enemy; Thou art thyself, though not a Montague."⁹³ In much the same way, the status of the preembryo requires us to ponder the meaning of a name. Is the preembryo "property," a "person," or something uniquely different and still unnamed?

The legal name given to the preembryo may be analyzed on a number of levels. On one level, the naming process is irrelevant. A rose is a rose, regardless of what it is called. A preembryo is a biological entity developing for some fourteen days after conception, regardless of its legal appellation. Further, a legal definition will not necessarily influence the outcome of particular issues involving the preembryo for, at least to some extent, these issues must be analyzed in terms of whatever competing policies are at stake. Nevertheless, the status given to the preembryo will determine the legal principles which are brought to bear on issues involving the preembryo. Moreover, the process of giving the preembryo some legal definition is part of a dynamic process through which our community will define its assumptions, values, beliefs, and desires. Hence, a preembryo will be a preembryo regardless of its name, but the preembryo's legal definition will say something about our society and also influence the society we are becoming.⁹⁴

The view of the preembryo as property has been developed to advance the rights of the progenitors. Under this line of reasoning, if the

92. ROMEO AND JULIET, Act 2, Scene 2, Lines 43-44.

93. *Id.* at Act 2, Scene 2, Lines 38-39.

94. See generally West, *Communities, Texts, and Law: Reflections on the Law and Literature Movement*, 1 YALE J. L. & HUMANITIES 129, 154-56 (1988) (laws constitute "one form of cultural text" as well as one of the ways through which the members of a community communicate and interact with one another); Tribe, *Technology Assessment and the Fourth Discontinuity: The Limits of Instrumental Rationality*, 46 S. CAL. L. REV. 617, 652-54 (1973) (arguing that our "instrumental rationality" must become a "constitutive rationality" which accommodates an organic relationship between personal and communal identity, actors and actions, reason and desire, means and ends); Tribe, *Ways Not to Think About Plastic Trees: New Foundations for Environmental Law*, 83 YALE L. J. 1315, 1326-27, 1327 n.58 (1974) (developing the same idea).

preembryo is considered property and the progenitors are considered owners, the progenitors' decision making authority over the preembryo will be superior to that of a physician, scientist, fertility center, or other third party.⁹⁵

By definition, the property approach defines the preembryo as a thing subject to ownership. Ownership is a right of dominion: a right to possess, use, or dispose of something according to one's own pleasure.⁹⁶ As long established in California,

[t]here may be ownership of all inanimate things which are capable of appropriation or of manual delivery; of all domestic animals; of all obligations; of such products of labor or skill as the composition of an author, the goodwill of a business, trademarks and signs, and of rights created or granted by statute.⁹⁷

Thus, if the preembryo is considered personal property, it will be subject to the same doctrines as inanimate things, domestic animals, and various intangibles.

Property doctrines were applied to the preembryo in *York v. Jones*, and another word about the case is in order. Before undergoing a fourth IVF attempt at a fertility institute in Virginia, the Yorks signed a consent form which explained that cryopreservation was an option if more than five preembryos were produced during the IVF process, described the freezing procedure, and outlined the Yorks' rights relative to any frozen preembryo.⁹⁸ The IVF procedure went forward: six preembryos were produced, five were transferred unsuccessfully, and one was frozen.⁹⁹ A year later, the Yorks advised the Virginia institute of their intent to retrieve the preembryo and transport it to a California institute where Mrs. York would undergo another transfer cycle, but the Virginia institute refused to release the preembryo.¹⁰⁰

Litigation ensued and the federal court upheld the complaint against a motion to dismiss for failure to state a claim upon which relief could be granted.¹⁰¹ The court construed the consent form as a bailment contract which created a bailor-bailee relationship between the Yorks and the Virginia institute.¹⁰² Under Virginia law, a bailment was created by

95. See Robertson, *supra* note 30, at 454-60; Andrews, *My Body, My Property*, 16 HASTINGS CTR. REP. 28, 28-31, 35-37 (Oct. 1986).

96. See CAL. CIV. CODE § 654 (Deering 1971).

97. *Id.* § 655; see also *Yuba River Power Co. v. Nevada Irrigation Dist.*, 207 Cal. 521, 523 (1929) (property extends to "every species of estate, real and personal, and everything which one person can own and transfer to another." (quoting 22 R.C.L., p. 43, sec. 10)).

98. *York v. Jones*, 717 F. Supp. 421, 423-24 (E.D. Va. 1989).

99. *Id.* at 424.

100. *Id.*

101. *Id.* at 427.

102. *Id.* at 425.

the elements of "lawful possession ... and [a] duty to account for the thing as the property of another."¹⁰³ The court found these elements to be satisfied on the facts before it. The institute had lawfully possessed the preembryo under the terms of the consent form, and the terms and provisions of the form established that the institute had a duty to account for the preembryo as property of the Yorks.¹⁰⁴ Hence, since the purpose of the bailment had terminated, the institute had an absolute obligation to return the property to the Yorks.¹⁰⁵

Property law, however, does not appear to provide the most appropriate doctrines by which to govern the status of the preembryo.¹⁰⁶ There is a qualitative difference between the preembryo and other "things" recognized as property, and even the commentators who advocate the property approach seem to avoid equating the preembryo with a fungible object. For example, Professor John Robertson has tried to limit the concepts of ownership and property to a question of decision making authority: "Applying terms such as 'ownership' or 'property' to early embryos risks misunderstanding. Such terms do not signify that embryos may be treated in all respects like other property. Rather, the terms merely designate who has authority to decide whether legally available options with early embryos will occur."¹⁰⁷ Similarly, Lori Andrews has argued in favor of a "quasi-property approach"¹⁰⁸ which would allow individuals to treat their own body parts as property (including excorporeal embryos), but would prevent others from treating them as property.¹⁰⁹ Thus, she argues, this approach would "guard

103. *Id.* at 425 (quoting *Crandall v. Woodard*, 206 Va. 321, 327, 143 S.E.2d 923, 927 (1965)).

104. *Id.* at 425-27.

105. *Id.* at 424-25, 427. The court's opinion does not expressly state but strongly implies that the purpose of the bailment was terminated when the Yorks decided to transfer their preembryo from the Virginia institute to the California institute. The court also upheld a detinue theory which would require proof of the following elements: a "property interest in the thing sought to be recovered," "the right to immediate possession," "property ... capable of identification," "property ... of some value," and defendants' "possession at some time prior to the institution of the act." *Id.* at 427. Further, the court explained that in the context of a bailment relationship, "an action in detinue accrue[d] upon demand and refusal to return the property or upon a violation of the bailment contract by an act of conversion." *Id.*

106. Cf. *Moore v. The Regents of the Univ. of California*, 51 Cal. 3d. 120, 134-47, 793 P.2d 479, 487-97, 271 Cal. Rptr. 146, 154-64 (1990) (cells removed from body and used in medical research cannot be considered property for purpose of conversion action).

107. Robertson, *supra* note 30, at 454-55. Robertson further explains: "Having a property or ownership interest in early embryos ... should not be thought of as identical to having a property interest in furniture or cars, though there are many similarities. The important question is who has dispositional authority and what limits are there on what they may do." *Id.* at 455 n.48.

108. Andrews, *supra* note 95, at 36; see also Andrews, *supra* note 30, at 366 n.47.

109. Andrews, *supra* note 95, at 36, 37.

against the appearance that people are commodities¹¹⁰ and prevent people from becoming "objects."¹¹¹

One may wonder whether the property or quasi-property approach can be limited so the preembryo does not become an ordinary thing or object. Ideas are powerful; and, once the preembryo is defined as some kind of property, it will be difficult to avoid the implications of property law.¹¹² Further, property law is not the only source from which the progenitors' decision making authority can be derived. Constitutional law fully supports the progenitors' decision making autonomy.¹¹³ This point will be developed below, after the preembryo's status is analyzed more fully.

B. Familiar Concepts Do Not Apply When the Preembryo Is Considered a Person

At the other end of the spectrum, the preembryo sometimes has been deemed to be a legal "person" with rights. Under a group of Louisiana statutes, enacted in 1986, the "*in vitro* fertilized human ovum" is defined to be a "juridical person"¹¹⁴ and "a biological human being."¹¹⁵ It is entitled to sue and be sued,¹¹⁶ and a curator may be appointed to protect its rights.¹¹⁷ If the egg and sperm donors "renounce their parental rights for *in utero* implantation,"¹¹⁸ then the fertilized ovum must be made available for "adoptive implantation."¹¹⁹ If it develops over a thirty-six hour period, it is considered "viable"¹²⁰ and cannot be "intentionally destroyed."¹²¹ Finally, the responsible physician or medical facility has a duty of "safekeeping"¹²² toward the *in vitro* fertilized human ovum, the egg and sperm donors "owe it a high duty of

110. *Id.* at 36.

111. *Id.*

112. Cf. *Moore v. The Regents of the Univ. of Cal.*, 51 Cal. 3d. 120, 149, 793 P.2d 479, 498, 271 Cal. Rptr. 146, 165 (1990) (Arabian, J., concurring) ("The ramifications of recognizing and enforcing a property interest in body tissues are not known, but are greatly feared—the effect on human dignity of a marketplace in human body parts, the impact on research and development of competitive bidding for such materials, and the exposure of researchers to potentially limitless and uncharted tort liability").

113. Professor Robertson favors a property approach but admits that a constitutional argument might be persuasive. See Robertson, *supra* note 30, at 460.

114. L.A. REV. STAT ANN. § 9:123 (West Supp. 1990).

115. *Id.* § 9:126.

116. *Id.* § 9:124.

117. *Id.* § 9:126.

118. *Id.* § 9:130.

119. *Id.*

120. *Id.* § 9:129.

121. *Id.*

122. *Id.* § 9:127.

care and prudent administration,"¹²³ and any dispute is to be resolved according to its "best interest."¹²⁴

In the *Davis* case, the trial court concluded that "[h]uman life begins at conception"¹²⁵ and that the frozen preembryos were "human beings, *in vitro*."¹²⁶ Such "children, *in vitro*"¹²⁷ were subject to the state's *parens patriae* protection, so the court's sole duty was to determine their best interest.¹²⁸ Therefore, as the court explained, "it is to the manifest best interest of the children, *in vitro*, that they be made available for implantation to assure their opportunity for live birth; implantation is their sole and only hope for survival."¹²⁹

Rejecting this analysis, the Tennessee Court of Appeal never speculated as to when life might begin. Instead, it steadfastly referred to the preembryos as "fertilized ova"¹³⁰ and observed that "[t]here are significant scientific distinctions between fertilized ova that have not been implanted and an embryo in the mother's womb."¹³¹ Further, based on the progenitors' constitutional rights, it held that it could not "order[] implantation against the will of either party."¹³²

The appellate court's decision in *Davis* is significant, but it has not settled the issue of whether the preembryo can be deemed to be some kind of independent person with independent rights. The Louisiana statutes still stand; other states may try to protect the preembryo as a person within the context of *in vitro* fertilization;¹³³ and the question of

123. *Id.* § 9:130.

124. *Id.* § 9:131.

125. 15 FAM. L. REP. at 2097; *see also id.* at 2103.

126. *Id.* at 2097.

127. *Id.* at 2097, 2104.

128. *Id.* at 2104.

129. *Id.*

130. *Davis v. Davis*, No. 180 (Tenn. Ct. App. Sept. 13, 1990) (LEXIS, States library, Tenn. file) at 2-7.

131. *Id.* at 2.

132. *Id.* at 5.

133. For example, as part of a statutory scheme regulating abortion, the Missouri legislature has found: (1) that "[t]he life of each human being begins at conception," MO. REV. STAT. § 1.205.1(1) (Vernon Supp. 1990), (2) that unborn children have "protectable interests in life, health, and well-being," *id.* § 1.205.1(3) (with unborn children defined to include "offspring ... from the moment of conception until birth," *id.* § 1.205.2(3)), and (3) that Missouri laws are to be "construed to acknowledge on behalf of the unborn child at every stage of development, all the rights, privileges, and immunities available to other persons, citizens, and residents." *Id.* § 1.205.2. These "findings," of course, are broad enough to include the preembryo.

In *Webster v. Reproductive Health Servs.*, ____ U.S. ___, 109 S. Ct. 3040, 3049-50 (1989), the Supreme Court declined to determine whether these statutory provisions were constitutional because they could be read to express a mere value judgment and had not yet been interpreted by the Missouri courts or applied in any concrete way.

when life begins has been debated with respect to IVF policy at the federal level.¹³⁴

Our current jurisprudence cannot support the definition of a preembryo as a person with independent rights. Such a definition cannot be maintained under *Roe v. Wade*.¹³⁵ In *Roe*, the Supreme Court held that "the word 'person,' as used in the Fourteenth Amendment, does not include the unborn."¹³⁶ Further, the Court declined to endorse any particular theory as to when life begins,¹³⁷ although it determined that states had an important interest in "the potentiality of human life"¹³⁸ which became compelling when a fetus became viable.¹³⁹

The Court adjudicated the constitutional status of the unborn within the context of the abortion debate. Holding that the right of privacy includes the abortion decision,¹⁴⁰ it determined that the right is fundamental but not absolute.¹⁴¹ Hence, in order to protect fetal life, states can regulate or even proscribe abortion after viability, except when abortion is necessary to preserve the life or health of the pregnant woman.¹⁴²

Roe has been controversial since it was decided in 1973. In the political arena, the abortion debate has been polarized into "pro-choice" and "pro-life" camps, with little meaningful dialogue between the two sides. Even the Court has become more and more divided, and *Roe* and its progeny now form a body of majority, plurality, concurring, and dissenting opinions in which the Court continues to debate the extent of the state's interest in potential life.¹⁴³ Nevertheless, the Court has never

134. Compare INFERTILITY IN AMERICA, *supra* note 8, at 18 (noting religious opposition to IVF and related research and concern regarding destruction of human embryos) with *id.* at 33 (dissenting views) (the view that life begins at conception is based not only on religious beliefs but also on "strong scientific and philosophic reasons" and requires Congress to consider whether "frozen embryos ... have rights which should be protected").

135. 410 U.S. 113 (1973).

136. *Id.* at 158.

137. *Id.* at 159-62.

138. *Id.* at 162, 164.

139. *Id.* at 162-65.

140. *Id.* at 153.

141. *Id.* at 153-54.

142. *Id.* at 164-65. The Court also held that states have an important interest in maternal health which becomes compelling at approximately the end of the first trimester. *Id.* at 162-63. From and after that point, the state can regulate abortion in ways reasonably related to maternal health. *Id.* at 163-64. For example, the state could regulate the qualifications and licensure of the person performing the abortion or the nature and licensure of the facility where the abortion is to be performed. *Id.* at 163.

143. This debate has centered on the designation of viability as the point at which the state's interest becomes compelling. Compare *id.* at 162-65 (state's interest in potential life becomes compelling at viability) with *City of Akron v. Akron Center for Reproductive Health, Inc.*, 462 U.S. 416, 427-28 (1983) (same) and *Akron*, 462 U.S. at 459-61 (O'Connor, J., dissenting) (state's interest in potential life is compelling throughout pregnancy) and

questioned its holding "that a fetus is not a 'person' within the meaning of the Fourteenth Amendment."¹⁴⁴

It would be a mistake to abandon the relevant principles of *Roe* and, in either substance or effect, to recognize the preembryo as a person in any kind of constitutional sense. Our rights jurisprudence simply cannot stretch in any meaningful way to include the preembryo.

The principle of autonomy is central to our rights jurisprudence. Deeply rooted in our history, this principle is built on a model of the rational, competent adult, free to exercise his or her rights according to his or her own values.¹⁴⁵ Thus, in often majestic terms, our jurisprudence has been extended to protect an individual's freedom

to contract, to engage in any of the common occupations of life, to acquire useful knowledge, to marry, establish a home and bring up children, to worship God according to the dictates of his own conscience, and generally to enjoy those privileges long recognized ... as essential to the orderly pursuit of happiness by free men.¹⁴⁶

Thornburgh v. Am. College of Obstetricians and Gynecologists, 476 U.S. 747, 759 (1986) (reaffirming general principles of *Roe* and *Akron*) and *Thornburgh*, 476 U.S. at 778 (Stevens, J., concurring) (arguing in favor of the viability standard because prenatal development is not "static" and the state's interest "increases progressively and dramatically as the organism's capacity to feel pain, to experience pleasure, to survive, and to react to its surroundings increases day by day") and *Thornburgh*, 476 U.S. at 795 (White, J., dissenting) (if state interest in the fetus is compelling after viability, it is compelling before viability) and *Webster v. Reproductive Health Servs.*, ___ U.S. ___, 109 S. Ct. 3040, 3057 (1989) (plurality portion of opinion delivered by Rehnquist, C. J. and joined by White, J. and Kennedy, J.) ("we do not see why the state's interest in protecting potential human life should come into existence only at the point of viability") and *Webster*, 109 S. Ct. at 3075-76 (Brennan, J., dissenting) (arguing in favor of viability standard).

144. *Webster*, 109 S. Ct. at 3083 n.13 (Stevens, J., concurring in part and dissenting in part).

145. John Stuart Mill's famous essay of 1859 defines the autonomous individual in terms which still ring familiar and true:

[T]he only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinions of others, to do so would be wise or even right. These are good reasons for remonstrating with him, or reasoning with him or persuading him, or entreating him, but not for compelling him or visiting him with any evil in case he do otherwise. To justify that, the conduct from which it is desired to deter him must be calculated to produce evil to someone else. The only part of the conduct of anyone for which he is amenable to society is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. *Over himself, over his own body and mind, the individual is sovereign.*

J. MILL, *ON LIBERTY* (1859) (emphasis added), reprinted in J. AREEN, P. KING, S. GOLDBERG & A. CAPRON, *LAW, SCIENCE, AND MEDICINE* 356, 356 (1984) [hereinafter *LAW, SCIENCE, AND MEDICINE*]; see generally, Schneider, *Rights Discourse and Neonatal Euthanasia*, 76 CALIF. L. REV. 151, 157, 164-65 (1988) (paradigm of individual rights vis-a-vis the state generally conceived in terms of Mill's paradigm and the competent adult).

146. *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923).

To be sure, individual freedom is not absolute and may be tempered to serve the public good.¹⁴⁷ Likewise, rights are not only for the strong and able adult. Children have rights which may be modified to account for their special circumstances;¹⁴⁸ the developmentally disabled have rights;¹⁴⁹ and the permanently unconscious have rights which may be protected and exercised on their behalf.¹⁵⁰ Yet, our model of individual

147. See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (law which required vaccination for smallpox did not violate individual liberty because it was necessary to protect the public health and safety).

148. *Prince v. Massachusetts*, 321 U.S. 158, 169-70 (1944); *Bellotti v. Baird*, 443 U.S. 622, 633-39 (1979) (plurality opinion delivered by Powell, J.) (constitutional rights of children cannot be equated with those of adults because children are vulnerable, may not be able to make important decisions in a mature manner, and parents have a guiding role in child rearing).

149. See *Youngberg v. Romeo*, 457 U.S. 307 (1982) (adult with mental capacity of an 18 month old child, who was committed involuntarily to a state institution, had substantive liberty interests under the due process clause of the fourteenth amendment which protected his rights to safe conditions of confinement, freedom from bodily restraints, and to minimally adequate or reasonable training to ensure his safety and freedom from undue restraint); *Conservatorship of Valerie N.*, 40 Cal. 3d 143, 160-69, 707 P.2d 760, 771-78, 219 Cal. Rptr. 387, 398-405 (1985) (privacy and liberty interests guaranteed by the fourteenth amendment to the federal constitution and the California constitution encompassed the right of a developmentally disabled woman to undergo a sterilization procedure as a form of contraception if that procedure was necessary to her habilitation and the choice was made by a conservator on her behalf in proceedings with adequate safeguards); *Conservatorship of Drabick*, 200 Cal. App. 3d 185, 208, 245 Cal. Rptr. 840, 854 (1988), cert. denied, ___ U.S. ___, 109 S. Ct. 399 (1988) ("Valerie N. stands for the proposition that incompetence does not cause the loss of a fundamental right from which the incompetent person can still benefit").

150. In *Cruzan v. Director, Missouri Dep't of Health*, ___ U.S. ___, 110 S. Ct. 2841, 2851-52 (1990), the United States Supreme Court determined that a competent person would have a right to refuse lifesaving medical treatment as a liberty interest under the due process clause of the fourteenth amendment. If a person is incompetent because he or she is sustained in a persistent vegetative state (i.e., "evinces no indications of significant cognitive function," *id.* at 2845), the person's "right" must be exercised ... by some sort of surrogate." *Id.* at 2852. Depending on the specific standard within a particular state, the surrogate's treatment decision must be guided by what the patient would have wanted or what is in the patient's best interest. Compare, e.g., *id.* at 2852-55 (state of Missouri may require clear and convincing evidence that the withdrawal of nutrition and hydration conforms to the wishes which the patient expressed while competent) *with Barber v. Superior Court*, 147 Cal. App. 3d 1006, 1021, 195 Cal. Rptr. 484, 493 (1983) (if the patient's own desires cannot be determined from the desires and feelings which the patient expressed while competent, then a treatment decision can be based on the patient's best interest which depends on a variety of factors, including the relief from suffering, probable quality and expected duration of the patient's life, and the impact of the decision on the patient's loved ones) *with Drabick*, 200 Cal. App. 3d at 210-12, 218, 245 Cal. Rptr. at 856-57, 861 (prior statements of the patient do not compel particular treatment decisions but should be considered, along with other evidence, to determine what is in the best interest of the incompetent patient). Hence, although the standards of surrogate decision making may vary from state to state and evolve within a particular state, the decision making rights of the incompetent patient may be preserved and protected as a matter of constitutional law. (The problems of surrogate decision making may be avoided if, while

autonomy seems to break down when considered in terms of the preembryo. How can autonomy be defined relative to the preembryo? Developing from an entity of two cells to a barely organized cluster of cells, it lacks any kind of organ systems or neural capacity. Unlike children, the developmentally disabled, or the permanently unconscious, it lacks any present or past experience of self awareness. To be sure, the preembryo has a unique human genome and may develop the capacity for feeling, thought, and self reflection. However, our concept of the autonomous individual, free to exercise his or her rights according to his or her desires, values, or beliefs, simply cannot stretch in any meaningful way to include the preembryo *as a preembryo*.

Turning from the principle of autonomy to the concept of personhood, the same result obtains. Once again, the abortion debate is instructive. For many, the morality—and legality—of abortion depend on what constitutes a “person” and whether a “person” comes into being at conception, implantation, viability, live birth, or perhaps even some later time when the capacities for thought, feeling, and social relationships are further developed.¹⁵¹ Those who oppose abortion pose criteria which can be satisfied from conception or early in pregnancy, while those who would allow abortion pose criteria which cannot be satisfied until later in pregnancy or even after birth.¹⁵²

Relatively early in the abortion debate, a philosopher by the name of Jane English suggested that “our concept of a person cannot ... bear the weight”¹⁵³ of this controversy. Observing that our concept of a person could not be “captured in a straitjacket of necessary and/or sufficient conditions,”¹⁵⁴ English argued that it really involved a “cluster of features”¹⁵⁵ related to an individual’s biological and psychological makeup, reasoning ability, social nature, and legal identity.¹⁵⁶ Hence, it was impossible to say whether the fetus is a person.¹⁵⁷ Our concept of a

competent, the patient provided for an effective, advance directive by executing either a living will or durable power of attorney for health care. See, e.g., CAL. HEALTH & SAFETY CODE §§ 7185-7195 (Deering Supp. 1990) (California Natural Death Act); CAL. CIV. CODE §§ 2430-2444 (Deering 1986 & Supp. 1990) (California provisions regarding durable power of attorney for health care)).

151. See generally English, *Abortion and the Concept of a Person*, 5 CANADIAN J. PHIL. (1975), reprinted in BIOMEDICAL ETHICS 473, 474 (2d ed. 1986) (describing the different criteria for personhood developed by various scholars); Noonan, *An Almost Absolute Value in History*, THE MORALITY OF ABORTION: LEGAL AND HISTORICAL PERSPECTIVES 1, 51-58 (J. Noonan ed. 1970) (discussing various criteria in more detail).

152. See English, *supra* note 151, at 474.

153. *Id.*

154. *Id.*

155. *Id.*

156. See *id.* at 474-75.

157. *Id.* at 475.

person does not hinge on a single criterion and "a fetus lies in the penumbra region where our concept of a person is not so simple."¹⁵⁸

The same may be said of the preembryo within the context of *in vitro* fertilization and preembryo transfer. The preembryo may have a unique genetic identity but it lacks the more developed "cluster of features" which we associate with persons.

Thus, even though our rights jurisprudence can be a powerful and adaptable tool, the preembryo does seem to elude our common understanding of what it means to be an autonomous person with rights. To be sure, we might continue debating "bright line" criteria, but the debate has been futile within the abortion context and may very well be misguided. Jane English, for example, has argued that whether or not the fetus is defined as a person, there are good reasons to allow abortion early in pregnancy and good reasons to proscribe abortion late in pregnancy (except when necessary to prevent serious injury to the woman or death).¹⁵⁹ Therefore if we avoid the temptation to search for secure, bright line definitions which fit the preembryo, we may avoid the pitfalls of the abortion debate and more seriously consider the merits of a *sui generis* approach.

C. As a Unique Entity, the Preembryo Warrants Our Respect and a Unique Legal Status

Even if the view of the preembryo as a person or property is abandoned, the preembryo may still be given some legal status. The challenge is to determine what status is appropriate, and why. A number of advisory bodies have undertaken the study of *in vitro* fertilization and, in effect, given the preembryo a *sui generis* status. Rejecting familiar categories, they have concluded that the preembryo is neither a form of property subject to ownership nor a person with full moral and legal rights. Instead, the preembryo is unique and should be treated with serious respect.¹⁶⁰

158. *Id.*

159. *Id.* at 474, 479.

160. Advisory bodies, within both national governments and professional groups, have reached this conclusion. See HEW Support of Human In Vitro Fertilization and Embryo Transfer; Report of the Ethics Advisory Board, 44 Fed. Reg. 35,033, 35,056 (June 18, 1979) [hereinafter HEW Report] ("the human embryo is entitled to profound respect; but this respect does not necessarily encompass the full legal and moral rights attributed to persons"); Dep't of Health and Social Security, United Kingdom, Report of the Committee of Inquiry into Human Fertilisation and Embryology, 1984, Cmnd. No. 9314, § 11.17, at 63 [hereinafter Warnock Report] (British committee chaired by Dame Mary Warnock) ("the embryo of the human species ought to have a special status"), reprinted in III Bioethics Reporter, Ethical and Legal Issues in Medicine, Health Care Administration and Human Experimentation, Legislation 1 (1985) [hereinafter III Bioethics Reporter]

Likewise, Clifford Grobstein, an embryologist, argues that a preembryo is entitled to a special status but not the same status as a newborn. His argument is based on a number of factors: the preembryo is human in terms of its biological nature and has a unique genetic make-up,¹⁶¹ the preembryo is alive (measured by scientific criteria such as cell division, the exchange of respiratory gases, and the metabolism of chemicals),¹⁶² and the preembryo has the potential to develop into an infant and adult.¹⁶³ Nevertheless, the preembryo's potential has not been realized at the preembryonic stage.¹⁶⁴ In and of itself, the preembryo is a barely organized cluster of cells with only a slim chance of further development.¹⁶⁵ Three out of four zygotes are lost during the process of natural development, and many of these are lost during the preembryonic stage; others are subject to a spontaneous abortion after implantation.¹⁶⁶ Further, when fertilization occurs *in vitro*, the rate of preembryo loss is even higher, measured by the current rates of clinical pregnancy and live birth.¹⁶⁷

Therefore, Grobstein argues that a preembryo is entitled to "special concern"¹⁶⁸ if it has a chance to realize its highest potential as a full person.¹⁶⁹ Further, even if that potential does not exist, Grobstein maintains that "the value of the preembryo as a member of the human community should still be recognized and conserved."¹⁷⁰ Given its genetic identity, the preembryo has "inherent kinship relationships"¹⁷¹ and is part of the "hereditary web of the human family."¹⁷²

A *sui generis* approach, based on the preembryo's unique biological nature and giving the preembryo a unique legal status, is endorsed

(1985)]; Ethics Comm. of Am. Fertility Soc'y, *supra* note 42, at 32S-33S ("The existent preembryo ... must be treated with respect because it is human [like human cells, tissues, and organs], but it must also be treated with concern beyond respect as long as the possibility exists that it may achieve full human status"); *id.* at 35S ("[W]e find a widespread consensus that the preembryo is not a person but is to be treated with special respect because it is a genetically unique, living human entity that might become a person. In cases in which transfer to a uterus is possible, special respect is necessary to protect the welfare of potential offspring").

161. C. GROBSTEIN, *supra* note 3, at 65-66.

162. *Id.* at 66.

163. *Id.* at 67.

164. *Id.* at 77.

165. *Id.* at 75-77.

166. *Id.* at 77.

167. *Id.* at 78; see *supra* note 80 and accompanying text.

168. C. GROBSTEIN, *supra* note 3, at 82.

169. *Id.* at 82, 138.

170. *Id.* at 82.

171. *Id.* at 137.

172. *Id.* at 138.

here.¹⁷³ The implications of this approach must be developed in terms of specific issues and concrete facts. Nevertheless, a *sui generis* approach is important as an expression of the values and common understandings through which society defines itself and is defined. Further, a *sui generis* approach will serve a dynamic function in legal analysis for it will demand that our policies toward the preembryo be informed by respect, but free our policies from bright line principles which do not seem appropriate at the edge of life.¹⁷⁴

173. Cf. *Moore v. The Regents of the Univ. of Cal.*, 51 Cal. 3d. 120, 137, 793 P.2d 479, 489, 271 Cal. Rptr. 146, 156 (1990) ("the laws governing such things as human tissues, transplantable organs, blood, fetuses, pituitary glands, corneal tissue, and dead bodies deal with human biological materials as objects *sui generis*, regulating their disposition to achieve policy goals rather than abandoning them to the general law of personal property") (footnotes omitted); Andrews, *supra* note 30, at 368-95 (comprehensive review of the legal status of the embryo and fetus within the context of criminal law, tort law, inheritance law, welfare law, and tax law, showing that the legal identity of the embryo and fetus depends on the context as well as the policies served by legal protection).

174. Professor Robertson appears to assume that "respect" for the preembryo amounts to respect for a symbol or reminder of the "unique gift of human existence," Robertson, *supra* note 30, at 447, and "our membership in the human community." *Id.* at 448. Further, he observes that such respect is merely constitutive or a value choice which does not carry any particular duties or obligations. *Id.* at 448, 450. Hence, Robertson advocates a property approach because the "abstract concept of respect must eventually confront the concrete situations in which the content of special respect is constituted," *id.* at 448, and these situations will be resolved according to whatever competing policies are at stake. *Id.* at 449-50.

This position may be questioned on two grounds. First, it seems that the preembryo is entitled to respect as something more than a "symbol" or "reminder" of something else. To be sure, the preembryo does serve a symbolic function and symbols are an important part of our cultural life; but, it seems that the preembryo is entitled to respect, in and of itself, because of its own unique nature.

Second, the authors of this Article agree that "respect" is a constitutive concept which must be defined through concrete situations. However, constitutive concepts need not be rejected on that ground, for legal analysis can be seen as a constitutive process. See *supra* note 94 and accompanying text; see also Tribe, *The Curvature of Constitutional Space: What Lawyers Can Learn from Modern Physics*, 103 HARV. L. REV. 1, 37, 38 (1989) (argument, based on insights derived from post Newtonian physics, that we must "think of law, and of governmental action, as changing the social landscape and redirecting the 'geometry' of human interactions, instead of regarding government as a physical entity that, through the 'forces' exerted by its component parts, tugs and pulls at people who are 'out there' in a 'state of nature'"; in other words, legal analysis must encompass "the *social meaning* of whatever the state has done") (emphasis in original).

IV. THE PROGENITORS, THE PREEMBRYO, AND THE STATE: THE CHALLENGE TO PROCREATIVE FREEDOM

A. Procreative Freedom Is Protected by a Dynamic, Albeit Turbulent, Jurisprudence

In the previous section, the status of the preembryo was explored in terms of what it means to be an individual within the meaning of our jurisprudence. In this section, the rights of the progenitors will be explored, relative to the preembryo, the state, and each other, focusing on the present legal status of reproductive rights.

In 1928, Justice Brandeis penned these famous words, dissenting in *Olmstead v. United States*:¹⁷⁵

The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfaction of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, *the right to be let alone*—the most comprehensive of rights and the right most valued by civilized men.

These sentiments lie at the heart of the constitutional right of privacy,¹⁷⁶ and the right of privacy protects reproductive freedom.

The right of privacy began to develop, as an explicit constitutional right, in *Griswold v. Connecticut*.¹⁷⁷ In a sweeping opinion, Justice Douglas recognized that "specific guarantees in the Bill of Rights have penumbras"¹⁷⁸ which "create zones of privacy,"¹⁷⁹ and that marriage, which involves "a right of privacy older than the Bill of Rights,"¹⁸⁰ is protected by "the zone of privacy created by several fundamental constitutional guarantees."¹⁸¹ Indeed, as the Court struck down a statute which had forbidden the use of contraceptives by married persons, Justice Douglas queried: "Would we allow the police to search the sacred precincts of marital bedrooms for telltale signs of the use of

175. 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting) (emphasis added).

176. See *Roe v. Wade*, 410 U.S. 113, 152 (1973) (citing *Olmstead*, 277 U.S. at 478); *Bowers v. Hardwick*, 478 U.S. 186, 199 (1986) (Blackmun, J., dissenting) (quoting *Olmstead*, 277 U.S. at 478 (portions of the last sentence of the passage reproduced above)).

177. 381 U.S. 479 (1965); see *Carey v. Population Servs. Int'l*, 431 U.S. 678, 685 (1977) (right of privacy was first explicitly recognized in *Griswold*).

178. 381 U.S. at 484.

179. *Id.*

180. *Id.* at 486.

181. *Id.* at 485.

contraceptives? The very idea is repulsive to the notions of privacy surrounding the marriage relationship.”¹⁸²

In *Eisenstadt v. Baird*,¹⁸³ the Court further established the right of privacy as a right to be let alone, invalidating a statutory scheme under which contraceptives could be distributed to a persons to prevent pregnancy, but not to unmarried persons for the same purpose. Writing for the Court, Justice Brennan declared: “If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.”¹⁸⁴

In *Roe v. Wade*, the Court observed that the right of privacy was not specifically guaranteed by the Constitution, but arose from the “Fourteenth Amendment’s concept of personal liberty”¹⁸⁵ and “ha[d] some extension to activities relating to marriage ... procreation ... contraception ... family relationships ... and child rearing and education”¹⁸⁶ The Court also held that “the right of personal privacy includes the abortion decision”¹⁸⁷

Thus, as the right of privacy has developed, it has created a zone of private life which “concerns the most intimate of human activities and relationships”¹⁸⁸ and “will be kept largely beyond the reach of government.”¹⁸⁹ The right seems to rest on our familiar principle of individual autonomy¹⁹⁰ and has evoked stirring visions of personal freedom.¹⁹¹ Nevertheless, the members of the Court continue to debate the scope of the privacy right. In the years since *Roe*, the nature of the abortion decision has become an ever more divisive issue¹⁹² and, in

182. *Id.* at 485-86.

183. 405 U.S. 438 (1972).

184. *Id.* at 453 (emphasis omitted).

185. *Roe v. Wade*, 410 U.S. 113, 153 (1973).

186. *Id.* at 152-53.

187. *Id.* at 154.

188. *Carey v. Population Servs. Int’l*, 431 U.S. 678, 685 (1977).

189. *Thornburgh v. Am. College of Obstetricians and Gynecologists*, 476 U.S. 747, 772 (1986).

190. See *supra* notes 145, 175 and accompanying text.

191. See, e.g., *Thornburgh*, 476 U.S. at 771-72 (Blackmun, J., part V of Court’s opinion); *Webster v. Reproductive Health Servs.*, ___ U.S. ___, 109 S. Ct. 3040, 3067, 3077-79 (1990) (Blackmun, J., dissenting).

192. Compare *Roe*, 410 U.S. at 153-54 (right of privacy includes the abortion decision) (7-2 decision with Court’s opinion delivered by Blackmun, J. and joined by Burger, C. J., Douglas, J., Brennan, J., Stewart, J., Marshall, J., and Powell, J.) with *City of Akron v. Akron Center for Reproductive Health, Inc.*, 462 U.S. 416, 419-20 (1983) (reaffirming *Roe*) (6-3 decision with Court’s opinion delivered by Powell, J. and joined by Burger, C. J., Brennan, J., Marshall, J., Blackmun, J., and Stevens, J.) with *Akron*, 462 U.S. at 453-59 (O’Connor, J., dissenting) (trimester approach is unworkable because improved technology will move forward toward childbirth the point at which the state can regulate to protect maternal health, and move backward toward conception the point at which the

Bowers v. Hardwick,¹⁹³ a closely divided Court held that the right of privacy does not extend to acts of "homosexual sodomy"¹⁹⁴ performed between consenting adults within the privacy of the home.¹⁹⁵

To some extent, the controversies surrounding the privacy right are inherent in its general nature. The privacy right only includes "personal rights that can be deemed 'fundamental,'"¹⁹⁶ but a right can be deemed fundamental only if it is "'implicit in the concept of ordered liberty.'"¹⁹⁷

state can regulate to protect the viable fetus) *with Thornburgh*, 476 U.S. at 759 (reaffirming *Roe* and *Akron*) (5-4 decision with court's opinion delivered by Blackmun, J. and joined by Brennan, J., Marshall, J., Powell, J., and Stevens, J.) *with Thornburgh*, 476 U.S. at 788-94 (White, J., dissenting) (abortion decision is a liberty protected by the due process clause of the fourteenth amendment, but is not a fundamental right) *with Webster*, 109 S. Ct. at 3058 (1989) (plurality opinion delivered by Rehnquist, C. J. and joined by White, J. and Kennedy, J.) (abortion is ordinary liberty interest protected by fourteenth amendment rather than fundamental right) (plurality "would modify and narrow *Roe* and succeeding cases" but found no occasion to do so in the case before it) *with Webster*, 109 S. Ct. at 3064 (Scalia, J., concurring in part and concurring in the judgment) (would overrule *Roe* "explicitly") *with Webster*, 109 S. Ct. at 3067-79 (Blackmun, J., joined by Brennan, J. and Marshall, J., concurring in part and dissenting in part) (sharp critique of plurality opinion and impassioned defense of abortion rights) *with Hodgson v. Minnesota*, ____ U.S. ____ 110 S. Ct. 2926, 2936 (1990) (plurality opinion delivered by Stevens, J. and joined by Brennan, J.) ("[a] woman's decision to beget or to bear a child is a component of her liberty that is protected by the Due Process Clause of the Fourteenth Amendment") *with Hodgson*, 110 S. Ct. at 2951-52 (Marshall, J., joined by Brennan, J. and Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part) (right of privacy includes fundamental right to make abortion decision).

193. 478 U.S. 186 (1986).

194. *Id.* at 190, 191, 196. The Georgia statute which was in issue provides that criminal "sodomy" occurs when one person "performs or submits to any sexual act involving the sex organs of one person and the mouth or anus of another." GA. CODE ANN. § 16-6-2 (1984), quoted in *Bowers*, 478 U.S. at 188 n.1.

195. In a five to four decision, the Court upheld the statute as applied to acts of sodomy which had been performed by two consenting, adult, homosexual men within the bedroom of one of their homes. The Court's opinion was written by Justice White and joined by Chief Justice Burger together with Justices Powell, Rehnquist, and O'Connor. Justice Blackmun's dissenting opinion was joined by Justices Brennan, Marshall, and Stevens.

196. *Roe*, 410 U.S. at 152.

197. *Id.* (quoting *Palko v. Connecticut*, 302 U.S. 319, 325 (1937)). The Court also has defined as "fundamental" those liberties which are "deeply rooted in this Nation's history and tradition." *Bowers*, 478 U.S. at 192 (White, J.) (quoting *Moore v. East Cleveland*, 431 U.S. 494, 503 (1977) (plurality opinion delivered by Powell, J.)); *Thornburgh v. Am. College of Obstetricians and Gynecologists*, 476 U.S. 747, 791 (1986) (White, J., dissenting) (quoting *Moore*, 431 U.S. at 503).

In *Michael H. v. Gerald D.*, ____ U.S. ___, 109 S. Ct. 2333 (1989) (plurality opinion), Justice Scalia appeared to offer a new, more restrictive view of the liberties protected by the due process clause: "In an attempt to limit and guide interpretation of the Clause, we have insisted not merely that the interest denominated as a 'liberty' be 'fundamental' (a concept that in isolation is hard to objectify), but also that it be an interest traditionally protected by our society." *Id.* at 2341 (emphasis added). Unfortunately, however, this view seems to distort our present jurisprudence in at least three ways.

This test was designed to prevent the justices from interpreting the Constitution according to their own values or preferences;¹⁹⁸ but, at least on some level, the determination of what is "fundamental" requires a subjective interpretation of our nation's history, tradition, or values.¹⁹⁹

First, it seems to suggest that due process only protects unspecified liberties if those liberties can be deemed to be fundamental. To the contrary, however, the liberty guaranteed by the due process clause extends to both "ordinary" liberties and "fundamental" liberties. To be sure, ordinary liberties are entitled only to ordinary judicial protection while fundamental rights are entitled to heightened protection; but, this is not to say that the protection of the due process clause extends only to fundamental rights. *See infra* notes 201-203 and accompanying text.

Second, Justice Scalia's interpretation of our due process jurisprudence seems to equate a conclusion with a method of analysis by insisting that a protectable liberty must be defined as "'fundamental'" and "an interest traditionally protected by our society." Justice Scalia also fails to suggest how a right can be fundamental apart from its reference to some type of tradition or other standard of measurement.

Finally, Justice Scalia's narrow, exclusively historical approach appears to depart from the Court's more interpretive tradition. Further explanation will demonstrate the point.

In *Michael H.*, the putative natural father of a child born to the wife of another man raised a due process challenge to California Evidence Code § 621 which creates a statutory presumption that "the issue of a wife cohabiting with her husband, who is not impotent or sterile, is ... a child of the marriage," and only allows the presumption to be challenged by the husband or wife. CAL. EVID. CODE § 621 (Deering 1986), quoted and discussed in *Michael H.*, 109 S. Ct. at 2338-39. The putative natural father claimed that he had a liberty interest in his relationship with the child, and that the interest was infringed by the state.

In analyzing whether the claimed liberty was an interest traditionally protected by our society, Justice Scalia further explained his due process methodology: "We refer to the most specific level at which a relevant tradition protecting, or denying protection to, the asserted right can be identified." *Id.* at 2344 n.6 (joined only by Rehnquist, C.J.); *see id.* at 2346-47 (O'Connor J., joined by Kennedy, J., concurring in all but footnote 6 and criticizing this very specific, historical mode of analysis). Accordingly, Justice Scalia analyzed the claimed right in terms of the "historical traditions specifically relating to the rights of an adulterous natural father," *Id.* at 2344 n.6; that is, "the societal tradition regarding the natural father's rights vis-a-vis a child whose mother is married to another man." *Id.*; *see also id.* at 2342-44 (discussing this tradition). Not surprisingly, Justice Scalia concluded that the liberty interest was not fundamental, and upheld the statute. *Id.* at 2344-46.

Hopefully, Justice Scalia's new methodology will not win the day. For a sharp critique of Justice Scalia's opinion, *see id.* at 2349-59 (Brennan, J., dissenting) (arguing, among other things, that the relevant liberty interest was a more general interest in "parenthood"); *see generally* Grey, *Do We Have an Unwritten Constitution?*, 27 STAN. L. REV. 703 (1975) (thoughtful defense of the kind of constitutional adjudication in which courts go beyond the interpretation of norms which are implicit in the text and original history of the Constitution, and accept their role in expounding basic ideals of liberty and fair treatment).

198. *Bowers*, 478 U.S. at 191-92; *see also* *Palko v. Connecticut*, 302 U.S. 319, 325-28 (1937) (Cardozo, J.) (concept of ordered liberty refers to our basic principles of liberty and justice).

199. *See, e.g., Michael H.*, 109 S. Ct. at 2349 (Brennan, J., dissenting) ("reasonable people can disagree about the content of particular traditions, and ... even about which traditions are relevant to the definition of 'liberty'"); compare, *e.g.*, *Bowers*, 478 U.S. at 191-94 (White, J.) (right to engage in consensual "homosexual sodomy" is neither "'implicit in the concept of ordered liberty'" (quoting *Palko*, 306 U.S. at 325-26) nor "'deeply rooted in this Nation's history and tradition'" (quoting *Moore*, 431 U.S. at 503)) with *id.* at 206, 213-14

Further, adjudicating the constitutional boundaries of the privacy right entails a basic question of political philosophy: Who is sovereign, the individual or the state, when an intimate decision with moral and political overtones is in issue? Those justices who have upheld or would expand the right of privacy have resolved the issue in favor of the individual, while those who have or would restrict the privacy right have tipped the balance in favor of the state.²⁰⁰

The results of this analysis are of more than theoretical concern. If a right is deemed fundamental, then any state action which limits the right is subject to strict judicial scrutiny. In other words, to be upheld, such a burdensome action must serve a "'compelling state interest'"²⁰¹ and "be narrowly drawn to express only the ... interest[] at stake."²⁰² On the other hand, if a right is not deemed "fundamental," any state action which burdens the right is subject to only minimal scrutiny and will be upheld if it is rationally related to a legitimate state interest.²⁰³

(Blackmun, J., dissenting) (liberty at stake is "fundamental interest all individuals have in controlling the nature of their intimate associations with others" and deprivation of this right threatens "the values most deeply rooted in our Nation's history").

200. Justice Stevens and Justice White addressed this issue in *Thornburgh*. Concurring with the majority, which invalidated a statutory scheme designed to inhibit the abortion decision, Justice Stevens argued in defense of individual sovereignty:

Roe v. Wade ... places the primary responsibility for decision in matters of childbearing squarely in the private sector of our society.

In the final analysis, the holding in *Roe v. Wade* presumes that it is far better to permit some individuals to make incorrect decisions than to deny all individuals the right to make decisions that have a profound effect upon their destiny [T]he lawmakers who placed a special premium on the protection of individual liberty have recognized that certain values are more important than the will of a transient majority.

Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747, 781-82 (1986) (Stevens, J., concurring).

Dissenting, Justice White argued in favor of state sovereignty:

Abortion is a hotly contested moral and political issue. Such issues, in our society, are to be resolved by the will of the people, either as expressed through legislation or through the general principles they have already incorporated into the Constitution they have adopted I would return the issue to the people by overruling *Roe v. Wade*.

Id. at 796-97 (White, J., dissenting).

201. *Roe v. Wade*, 410 U.S. 113, 155 (1973) (quoting *Kramer v. Union Free School Dist.*, 395 U.S. 621, 627 (1969) and *Sherbert v. Verner*, 374 U.S. 398, 406 (1963), and citing *Shapiro v. Thompson*, 394 U.S. 618, 634 (1969)); see also *Carey v. Population Servs. Int'l*, 431 U.S. 678, 685-86, 688-89 (1977).

202. *Roe*, 410 U.S. at 155 (citations omitted); see also *Carey*, 431 U.S. at 685-86, 688-89.

203. See *Hodgson v. Minnesota*, ___ U.S. ___, 110 S. Ct. 2926, 2937 (1990) (plurality portion of opinion by Stevens, J. and joined by Brennan, J.) ("[u]nder any analysis, the Minnesota [abortion] statute cannot be sustained if the obstacles it imposes are not reasonably related to legitimate state interests").

While the distinction between strict scrutiny and minimal scrutiny has become well established, not every Supreme Court case is defined in these terms. See, e.g., *Cruzan v. Director, Missouri Dep't. of Health*, ___ U.S. ___, 110 S. Ct. 2841, 2851-52 (1990) (right to refuse medical treatment may be inferred as a liberty interest under the due process clause of the fourteenth amendment, and an alleged violation of the right must be "'determined

Despite the controversies associated with the privacy right and *Roe* in particular, it seems unlikely that the Court would entirely abolish those aspects of the right which have become an accepted part of our jurisprudence and generally protect individual decisions related to child rearing and education, family relationships, procreation, marriage and contraception.²⁰⁴ Nevertheless, the Court may have begun to retreat from the frontiers of privacy adjudication. In several recent cases, the Court has refrained from deciding an issue on privacy grounds and instead has resolved the issue in terms of the liberty interest directly guaranteed by the due process clause of the fourteenth amendment.²⁰⁵

by balancing [the individual's] liberty interests against the relevant state interests'" (quoting *Youngberg v. Romeo*, 457 U.S. 307, 321 (1982)).

Further, the appropriate level of review may be debated in any given case. Indeed, this has become another battleground of the abortion debate. In *Akron*, for example, Justice O'Connor acknowledged that abortion was a fundamental right in some circumstances, *City of Akron v. Akron Center for Reproductive Health, Inc.*, 462 U.S. 416, 459 (1983) (O'Connor, J., concurring), but argued that strict scrutiny is only triggered in abortion cases if a statute "unduly burdens" the abortion decision. *Id.* at 461-66. This argument, however, appears to misread prior cases by confusing the threshold inquiry with the conclusion of an analysis. To be sure, a statute must burden, restrict, or impinge on a right—to some debatable extent—before any judicial review is triggered. However, the burden only becomes "undue" if it fails to meet the appropriate level of scrutiny. This seems apparent in the cases cited by Justice O'Connor. *See, e.g., id.* at 461 n.8.

In *Webster*, the plurality formed by Chief Justice Rehnquist, Justice White, and Justice Kennedy entirely abandoned the compelling state interest test and upheld a Missouri statute which required a physician to perform certain tests to determine viability, on the ground that the statute "permissibly further[ed] the State's interest in protecting potential human life," *Webster v. Reproductive Health Servs.*, ___ U.S. ___, 109 S. Ct. 3040, 3057 (1990), and was "reasonably designed to ensure that abortions [were] not performed where the fetus [was] viable—an end which all concede is legitimate." *Id.* at 3058. Dissenting, Justice Brennan criticized the "permissibly furthers" test as "nothing more than a dressed-up version of rational basis review, [the] Court's most lenient level of scrutiny." *Id.* at 3076 (Brennan, J., dissenting). Further, Justice Brennan critiqued "[t]his newly minted standard," *id.*, on the ground that it posed "the question that courts must answer in abortion cases, not the standard for courts to apply." *Id.* (emphasis in original). Hence, the *Webster* plurality, like Justice O'Connor, appears willing to substitute conclusions for analysis—in all but the most extreme cases—in order to give the states more leeway in the abortion arena.

204. *See, e.g., Bowers v. Hardwick*, 478 U.S. 186, 190-91 (1986) (relying on the established reach of the privacy right, including the abortion right, to argue that the right of privacy did not extend to "homosexual sodomy").

205. *See infra* notes 216-224 and accompanying text; *Cruzan*, 110 S. Ct. 2841. In *Cruzan*, the Court upheld a Missouri requirement that life-sustaining treatment could only be withdrawn from a patient in a persistent vegetative state based on clear and convincing evidence that, while competent, the patient had expressed the desire to have treatment withdrawn in such circumstances. The Court analyzed the right to refuse treatment "in terms of a Fourteenth Amendment liberty interest," 110 S. Ct. at 2851 n.7 (citing *Bowers*, 478 U.S. at 194-95), and specifically declined to follow the "many state courts [which] have held that a right to refuse treatment is encompassed by a generalized constitutional right of privacy." *Id.*; *see also id.* at 2851-52.

On one level, at least in theory there are several reasons why this kind of shift should not really change the adjudication of privacy or liberty issues. First, the right of privacy is derived from the concept of liberty guaranteed by the fourteenth amendment²⁰⁶ and the Court has relied on due process cases to establish the present scope of the privacy right.²⁰⁷ Second, like the privacy right, a right claimed to be a substantive liberty under the due process clause can be deemed fundamental and thus entitled to strict judicial protection.²⁰⁸ Third, procreative rights already have been defined as fundamental under the due process clause. In *Skinner v. Oklahoma ex rel. Williamson*²⁰⁹—before the privacy right was recognized—the Court established that “procreation”²¹⁰ was “one of the basic civil rights of man”²¹¹ and “a basic liberty,”²¹² “fundamental to the very existence and survival of the race.”²¹³ Hence, laws which infringed that right were subject to strict scrutiny.²¹⁴ Further, the Court has acknowledged that *Griswold*, *Eisenstadt*, and *Roe* established a fundamental right under the due process clause “to decide whether or not to beget or bear a child.”²¹⁵

Nevertheless, within the context of the abortion debate, the shift from a privacy analysis toward a liberty analysis seems to reflect the disarray within the Court and the uncertain future of *Roe v. Wade*. In *Webster v. Reproductive Health Services*,²¹⁶ Chief Justice Rehnquist, Justice White, and Justice Kennedy formed a plurality arguing that abortion was an ordinary “liberty interest protected by the Due Process Clause”²¹⁷

In *Bowers*, the Court rejected the argument that the right of privacy extends to either “homosexual sodomy,” see *supra* notes 193-195 and accompanying text, or “any kind of private sexual conduct between consenting adults.” *Bowers*, 478 U.S. at 191. Further, as an entirely separate point, the Court declined to find a fundamental right to engage in homosexual sodomy within the substantive liberties directly guaranteed by the due process clause of the fourteenth amendment. *Id.* at 191-95.

206. *Roe*, 410 U.S. at 153; *Akron*, 462 U.S. at 426-27.

207. See *Roe*, 410 U.S. at 152-53 (right of privacy extends to child rearing and education, citing *Pierce v. Soc'y of Sisters*, 268 U.S. 510 (1925) (statute restricting private education violated liberty guaranteed by the fourteenth amendment)); *Meyer v. Nebraska*, 262 U.S. 390 (1923) (statute which restricted teaching of foreign language violated liberty guaranteed by fourteenth amendment)).

208. *Bowers*, 478 U.S. at 191-95.

209. 316 U.S. 535 (1942) (Douglas, J.).

210. *Id.* at 541.

211. *Id.*

212. *Id.*

213. *Id.*

214. *Id.* (invalidating Oklahoma law which provided for sterilization of some convicted felons).

215. *Bowers v. Hardwick*, 478 U.S. 186, 190 (1986).

216. ___ U.S. ___ 109 S. Ct. 3040 (1989).

217. *Id.* at 3058.

rather than a fundamental right.²¹⁸ Following this definition, the three justices relaxed the standard of review, arguing that a Missouri statute was constitutional because it was "reasonably designed to ensure that abortions [were] not performed where the fetus is viable—an end which all concede is legitimate."²¹⁹

In *Hodgson v. Minnesota*,²²⁰ Justices Stevens and Brennan also formed a plurality stating that "[a] woman's decision to beget or to bear a child is a component of her liberty that is protected by the Due Process Clause of the Fourteenth Amendment."²²¹ However, unlike the Webster plurality, the *Hodgson* plurality relied on the liberty interest to argue in favor of individual choice and preserve some kind of meaningful line between the individual and the state. As the plurality explained, "[T]he regulation of constitutionally protected decisions ... must be predicated on legitimate state concerns other than disagreement with the choice the individual has made."²²² Hence, even though a state might favor childbirth over abortion, that "value judgment"²²³ would not provide "adequate support ... for simply substituting a state decision for an individual decision that a woman has a right to make for herself."²²⁴

Thus, one can neither deny nor ignore the controversies inherent in our privacy jurisprudence and the uncertain future of the abortion right. Nevertheless, the right of privacy and right to liberty guaranteed by the fourteenth amendment staunchly protect a basic procreative freedom. To be sure, the limits of such freedom must be defined on a case by case basis, but the right to reproductive freedom is secured by our constitutional principles.

B. Procreative Freedom Should Extend to Procreative Decisions Regarding the Preembryo

The right to reproductive freedom should give the progenitors a fundamental right to make decisions regarding the preembryo.²²⁵ On one level, many decisions regarding the preembryo appear to be ordinary medical decisions which, like other medical decisions, must be analyzed in terms of standard medical practice and the medical goals to be achieved (such as curing infertility). However, these decisions may implicate basic procreative choices: for example, whether any given

218. *Id.*

219. *Id.*

220. ___ U.S. ___, 110 S. Ct. 2926 (1990).

221. *Id.* at 2936.

222. *Id.* at 2937.

223. *Id.*

224. *Id.*

225. *Accord Andrews, supra* note 30, at 358-61, 366, 402, 404-405.

preembryo is transferred with the hope of initiating a pregnancy, frozen for the possibility of future use, or discarded.

Further, it is hard to conceive of any state interest which would be sufficiently compelling to override the progenitors' decision making freedom.²²⁶ There is a genetic link between the progenitors and the preembryo which does not exist between the preembryo and any other persons or entity. Further, for at least some people, this link may be significant in terms of the historical and physical continuity between generations, the implications of kinship, or the potential relationship of parents with children. Indeed, the progenitors may perceive this link as not only immediate and personal, but also symbolic of our human condition and hope for the future.

By comparison, the state has an important—but attenuated—interest in the preembryo. The state represents a collective body, and the direct, biological link between the progenitors and the preembryo is lacking. Further, unlike each progenitor, the preembryo cannot be counted as a sovereign member of the state. The preembryo is human in nature and entitled to respect. However, it simply has not developed to the point where it can be considered part of the body politic as an autonomous individual.

Hence, the progenitors' reproductive rights should stand as a bulwark against the efforts of states, such as the state of Louisiana, to force "extra" preembryos to be given up for "adoptive implantation."²²⁷ The state interest in forcing adoption would consist of giving the preembryo a chance to develop further. However, as indicated above, the relationship between the progenitors, the preembryo, and the state gives the progenitors—not the state—the right to determine the preembryo's future life possibilities. The state would trammel that right without sufficient cause if it were to force unwilling progenitors to give up their preembryo for adoption.²²⁸ Indeed, the prospect of state interference evokes the chilling image of the totalitarian state, so well illustrated by literary works such as 1984²²⁹ and *The Handmaid's Tale*.²³⁰

In *Davis*, the Tennessee Court of Appeal upheld the importance of the progenitors' constitutional rights. Citing *Skinner*, the court observed that the "right to procreate is [a] 'basic civil right[]'";²³¹ and, conversely,

226. *Accord Andrews, supra* note 30, at 361-65.

227. LA. REV. STAT. ANN. § 9:130 (West Supp. 1990).

228. *Accord Andrews, supra* note 30, at 405-06.

229. G. ORWELL, 1984 (1949).

230. M. ATWOOD, THE HANDMAID'S TALE (1986).

231. *Davis v. Davis*, No. 180 (Tenn. Ct. App. Sept. 13, 1990) (LEXIS, States library, Tenn. file) at 5.

under *Griswold*, *Eisenstadt*, and *Carey v. Population Services International*,²³² that "an individual has a right to prevent procreation."²³³ Hence, the court determined that an award of the preembryos to Mary Sue Davis for implantation, against the will of Junior Davis, was "impermissible state action in violation of Junior's constitutionally protected right not to beget a child where no pregnancy has taken place."²³⁴ Further, the court concluded that "ordering implantation against the will of either party"²³⁵ could not be justified by any compelling state interest.²³⁶ Indeed, the court was so repelled by the notion of forced implantation that, in a footnote, it referred to the control of reproduction in Nazi Germany as "[a] haunting reminder of the evils of uncontrolled state action."²³⁷

Outside the zone of reproductive privacy, the state would have more leeway to enact reasonable regulations regarding the preembryo for such regulations would be justified if they were rationally related to a legitimate state goal.²³⁸ However, before turning to one such area, research policy regarding IVF and the preembryo,²³⁹ we must examine a difficult problem that remains: the relative weight of the progenitors' rights when their procreative desires conflict.

C. When the Progenitors Cannot Agree to a Procreative Decision, Preembryo Loss Will Be the Unfortunate Result

Within the context of the abortion decision, the relative weight of the progenitors' rights has been established: the woman alone has the right to decide. In *Planned Parenthood v. Danforth*,²⁴⁰ the Supreme Court held that a spouse could not be given the right to veto the abortion

232. 431 U.S. 678 (1977).

233. *Davis*, (LEXIS, States library, Tenn. file) at 5.

234. *Id.*

235. *Id.*

236. *Id.*

237. *Id.* at 6 n.7.

238. This requirement is based on the due process clause of the fifth amendment (applicable to the federal government) and the due process clause of the fourteenth amendment (applicable to the states). See *Bolling v. Sharpe*, 347 U.S. 497, 500 (1954) (construing due process clause of fifth amendment and holding that racial "segregation in public education is not reasonably related to any proper governmental objective, and thus it imposes . . . a burden that constitutes an arbitrary deprivation of . . . liberty"); *Village of Euclid, Ohio v. Ambler Realty Co.*, 272 U.S. 365, 395 (1926) (adjudicating municipal zoning laws under due process clause of fourteenth amendment and stating that the ordinance could only be stricken if it was "clearly arbitrary and unreasonable, having no substantial relation to the public health, safety, morals, or general welfare"); see also *Moore v. East Cleveland*, 431 U.S. 494, 498 & n.6 (1977) (affirming and elaborating on principle enunciated in *Euclid*).

239. See *infra* notes 250-356 and accompanying text.

240. 428 U.S. 52 (1976).

decision.²⁴¹ The Court was sensitive to the husband's interest in the pregnancy, the importance of the marital relationship, and the affect of the abortion decision on the relationship.²⁴² Nevertheless, the Court balanced the relative rights of husband and wife in favor of the wife:

We recognize, of course, that when a woman, with the approval of her physician but without the approval of her husband, decides to terminate her pregnancy, it could be said that she is acting unilaterally. The obvious fact is that when the wife and the husband disagree on this decision, the view of only one of the two marriage partners can prevail. *Inasmuch as it is the woman who physically bears the child and who is the more directly and immediately affected by the pregnancy, as between the two, the balance weighs in her favor.*²⁴³

The situation differs when the preembryo is maintained *in vitro* or frozen. To be sure, the woman who has undergone the medical procedures necessary to retrieve her oocytes has invested more in the reproductive process than the man who has provided his sperm by way of ejaculation. Further, from the time a preembryo is transferred into the uterus, the woman would be "more directly and immediately affected" by the hoped for pregnancy. Nevertheless, while the preembryo is maintained *in vitro* or frozen, the man and woman appear to have an equal interest in the preembryo. At that point, the woman's bodily integrity is not at issue, and both have an equal genetic link with the preembryo. Thus, when confronted with a decision regarding the preembryo, as opposed to the abortion decision, there does not appear to be as compelling a reason to favor the woman's procreative choice over that of her male partner.²⁴⁴

Alternatively, there are many reasons to favor the rights of the progenitor, male or female, who does not wish to continue the reproductive process. Clearly, a woman could not be forced to undergo a preembryo transfer. As the Court of Appeal recognized in *Davis*, such an act would violate a woman's most basic procreative freedom. Further, a forcible transfer would be a battery (or bodily invasion performed without the woman's consent).²⁴⁵ It would be absurd, for a woman would retain the right to abort any resulting pregnancy²⁴⁶ and yet be

241. *Id.* at 69-71.

242. *Id.* at 69-70.

243. *Id.* at 71 (emphasis added).

244. Accord J.A.M.A. Report, *supra* note 15, at 2486 (report prepared by Committee on Medicolegal Problems and Council on Ethical and Judicial Affairs of American Medical Association).

245. See *Cobbs v. Grant*, 8 Cal. 3d 229, 239-41, 104 Cal. Rptr. 505, 511-12 (1972) (medical procedure performed without consent constitutes battery).

246. See *Roe v. Wade*, 410 U.S. 113, 152-55, 162-66 (1973).

obliged to undergo a transfer procedure. Furthermore, from a woman's perspective, such a procedure might be akin to rape.²⁴⁷

Other scenarios are also disturbing. What if a woman desires to undergo a transfer procedure but the man no longer wants to become a father (like Mary Sue Davis and Junior Davis at the time of trial)? What if the man wants to have the preembryo transferred into a willing, gestational surrogate, with the understanding that he will raise any live born child, but the ova provider will not agree to the arrangement? What if either progenitor wants to donate the preembryo for adoption, but the other does not (like Mary Sue Davis and Junior Davis at the time of appeal)?

The common question raised by these possibilities is whether one progenitor can force the other to become a genetic parent against his or her will. In *Davis*, the trial court resolved the issue in favor of Mary Sue Davis, but the Court of Appeal concluded that "implantation" could not be ordered against the will of either progenitor. This conclusion appears correct. As a matter of constitutional law, it does seem that neither progenitor should be forced to become a parent against his or her will. Genetic ties may form a powerful bond between an individual and his or her progeny even if the progenitor is freed from the legal obligations of parenthood. Thus, forcing one to become a genetic parent may work a quiet form of violence and violate a vital freedom.²⁴⁸

This analysis of constitutional principles implies that a progenitor who does not want the reproductive process to continue should have a right to veto the desires of the progenitor who does, for the state's interest in the preembryo is insufficient to override the privacy rights of either progenitor. Hence, if one progenitor wants to continue with the reproductive process but the other does not, the preembryos should be allowed to deteriorate and die. This result may seem harsh to the extent that it favors the reproductive choice of one progenitor over the other or

247. A criminal rape may also constitute a civil battery. *Delia S. v. Torres*, 134 Cal. App. 3d 471, 480, 184 Cal. Rptr. 787, 793 (1982).

248. Likewise, Professor Robertson argues that, as a general rule, the right to avoid reproduction should take priority over the right to reproduce because unwanted parenthood may impose significant financial and psychosocial burdens on an individual. Robertson, *supra* note 30, at 476-81. However, Robertson would carve an exception to the rule if the party who desires to reproduce will not have an "alternative opportunity to reproduce because the pleasures of parenthood will be deeper and more intense than the discomfort of unwanted biologic offspring." *Id.* at 481.

The J.A.M.A. Report also concludes that one progenitor's "choice not to have offspring should not be overridden by another person's desire to have offspring," J.A.M.A. Report, *supra* note 15, at 2486, and that, regardless of whether preembryos are used, donated, or discarded, both progenitors must consent to the manner of disposition. *Id.* at 2486-87. However, the Report does not resolve the issue of how disputes should be resolved when the progenitors cannot agree to one course of action. See *id.* at 2487.

to the extent that it favors a choice which allows a preembryo to be lost. Nevertheless, this result also seems to reflect the nature of the decision making process when natural reproduction is assisted by IVF.

IVF makes it possible to separate the genetic, gestational, and social aspects of parenthood in ways never before possible. Any number of individuals may share the traditional functions of parenthood: the woman and man who provide the egg and sperm, the woman who bears the child, and the individuals who raise the child. Further, the basic procreative process can be manipulated in ways never before possible: ova can be retrieved from a woman's body, fertilization can be achieved *in vitro*, preembryos can be sustained *in vitro* (at least to some point), and preembryos can be cryopreserved for future use.

When the component parts of the reproductive process can be isolated, controlled, and extended over time, there are many points for individual decision making. "The decision whether to bear or beget a child" can no longer be conceived as an isolated decision to engage in sexual intercourse, use contraceptives, or have an abortion. Instead, the decision must be seen as an ongoing process, from both a medical and personal point of view, subject to uncertainty and changing circumstances.²⁴⁹ During this process, each progenitor remains dependent on the other; and the preembryo's continued development remains dependent on the consent of each.

In sum, given the relationship between the state, the progenitors, and the preembryo, a deadlock between the progenitors should be resolved by allowing the preembryos to deteriorate and die. Preembryo loss is the price of the progenitors' freedom and mutual dependence. The price may be high, but it seems necessary to preserve our most personal rights and the integrity of our most personal relationships.

V. OUTSIDE THE ZONE OF REPRODUCTIVE FREEDOM: TOWARD A COMPREHENSIVE RESEARCH POLICY

A. The Preembryo Can Play a Unique Role as a Research Subject

The preembryo can play a critical and varied role as a research subject. The preembryo is a necessary subject in research designed to

249. For a similar analysis of the consent process involved with IVF, see J.A.M.A. Report, *supra* note 15, at 2486-87. Professor Robertson also argues that "[b]ecause so many contingencies could intervene to change original plans, creation of embryos alone should not be taken as an irrevocable commitment to reproduction." Robertson, *supra* note 30, at 475.

improve the efficacy of IVF.²⁵⁰ For example, the culture medium used to nourish fertilized eggs is based on animal research, usually involving mice, so further research with human zygotes or preembryos might improve the culture medium and, therefore, the success rate of IVF.²⁵¹ Further, research involving the preembryo might improve the clinical diagnosis of infertility, contraceptive technology, genetic diagnosis, and the medical management of congenital malformations.²⁵²

The unique nature of the preembryo also holds enormous promise for other kinds of research. Certain cells of the preembryo are totipotent: that is, they have the capacity to divide and differentiate into one or more of the many different cells comprising the human organism.²⁵³ Hence, research with the preembryo might be designed to study cell differentiation and malignancy.²⁵⁴ Also, preembryo research might be designed to culture specific cells and tissues with the hope of enhancing transplantation therapy.²⁵⁵ If such cultures could be produced, it might be possible to alleviate two problems that now plague human transplants: scarce resources and rejection because of immunological incompatibility.²⁵⁶

At present, the ethical and legal status of research involving the preembryo remains uncertain. There is a void in federal policy and a number of state laws are designed to prevent nontherapeutic research with certain categories of the unborn. The state of the law will be explained in more detail below and guidelines will be suggested to define the preembryo's role as a research subject.

B. The State of the Law

1. THE VOID IN FEDERAL POLICY

The issue of research involving the preembryo has been simmering within the federal government, in the form of research involving *in vitro* fertilization and preembryo transfer, since the mid-1970's. Given the politics of the abortion debate, the issue has yet to be resolved.

In 1974, the Department of Health, Education and Welfare ("HEW") (now Health and Human Services or "HHS") promulgated regulations which applied to all research involving human subjects conducted or

250. INFERTILITY IN AMERICA, *supra* note 8, at 7; C. GROBSTEIN, *supra* note 3, at 78-80.

251. INFERTILITY IN AMERICA, *supra* note 8, at 15, 19-20; see also Beardsley, *Aborted Research*, SCI. AM., Feb. 1990, 16.

252. C. GROBSTEIN, *supra* note 3, at 80; HEW Report, *supra* note 160, at 35,039.

253. C. GROBSTEIN, *supra* note 3, at 68; HEW Report, *supra* note 160, at 35,039.

254. C. GROBSTEIN, *supra* note 3, at 68; HEW Report, *supra* note 160, at 35,039.

255. C. GROBSTEIN, *supra* note 3, at 68-69.

256. *Id.* at 69.

funded by HEW.²⁵⁷ In general, research institutions were required to establish an Institutional Review Board ("IRB") to review and approve research protocols and to review the research while in progress.²⁵⁸ One criterion of approval was the informed consent of the research subject.²⁵⁹

In 1975, HEW promulgated additional regulations regarding fetal research,²⁶⁰ and defined the "fetus" as "the product of conception *from the time of implantation ... until a determination is made, following expulsion or extraction ... that it is viable.*"²⁶¹ Hence, these regulations did not apply to research with the preembryo; and, rather than promulgate any specific guidelines, HEW provided for additional review by an Ethical Advisory Board on a case by case basis: "No application ... involving human *in vitro* fertilization may be funded ... until the application ... has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint."²⁶²

An Ethical Advisory Board ("EAB") was appointed in September 1977, more than two years later,²⁶³ and convened in 1978.²⁶⁴ The board was asked to review a research application concerning IVF.²⁶⁵ Then, following the birth of Louise Brown, the first person to be born as a result of IVF, the board was asked to expand its review of the pending application to consider "the scientific, ethical, legal and social issues surrounding human *in vitro* fertilization and embryo transfer in general."²⁶⁶ An extensive study followed and the EAB's report was published in June 1979.²⁶⁷

In September 1980, the EAB lapsed when its charter and funding were allowed to expire.²⁶⁸ There have been many efforts, supported by scientists within HHS, major scientific and medical associations, and

257. 45 C.F.R. § 46.101(a) (1989); *see generally id.* §§ 46.101-46.124.

258. *See id.* §§ 46.102(h), 46.103, 46.107-46.115.

259. *Id.* §§ 46.111(a)(4), 46.111(a)(5), 46.116, 46.117.

260. *See generally id.* §§ 46.201-46.211; Fletcher & Schulman, *supra* note 27, at 6-7 (concise overview of events leading to adoption of fetal research regulations).

261. 45 C.F.R. § 46.203(c) (emphasis added).

262. *Id.* § 46.204(d). The regulations define *in vitro* fertilization as "any fertilization of human ova which occurs outside the body of a female, either through a mixture of donor human sperm and ova or by any other means." *Id.* § 46.203(g).

263. HEW Report, *supra* note 160, at 35,037.

264. Fletcher & Schulman, *supra* note 27, at 7.

265. HEW Report, *supra* note 160, at 35,034.

266. *Id.*

267. *See id.*

268. INFERTILITY IN AMERICA, *supra* note 8, at 6. Apparently, the EAB was allowed to lapse by mistake because an HEW official mistakenly advised Congress that an EAB would not be necessary in view of the newly appointed President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Hence, money was reprogrammed from the EAB to the Commission. INFERTILITY IN AMERICA, *supra* note 8, at 6; Fletcher & Schulman, *supra* note 27, at 8.

other government bodies to reconstitute the EAB or to allow funding for IVF research without EAB approval.²⁶⁹ However, the EAB has not been renewed and the regulation that requires EAB review of IVF research has not been lifted. The politics of preembryo research continue to implicate the volatile "right to life" debate and, in order to avoid that controversy, HHS appears to have succumbed to a policy of inaction.²⁷⁰

Accordingly, federal policy has been characterized by a *de facto* moratorium on HEW or HHS research involving IVF, extending from 1975 (when EAB review was required) to 1978 (when the EAB was convened), and then from 1980 (when the EAB lapsed) through the present writing in 1990. As a result, federal funds have not been available for IVF research;²⁷¹ the United States lags behind other countries in such research;²⁷² and, as a treatment for infertility, IVF remains more expensive—and ineffective—than it might be otherwise.²⁷³ Further, without an EAB, the federal government lacks the forum—contemplated by existing regulations—in which controversial research proposals could be studied and evaluated within the context of an ongoing public dialogue regarding the ethical implications of federal research policy.²⁷⁴

2. THE PATCHWORK OF STATE LAW

State laws are plagued by inconsistency and uncertainty. A number of state statutes are designed to prevent nontherapeutic research with certain categories of the unborn. Some statutes specifically ban research

269. See *INFERTILITY IN AMERICA*, *supra* note 8, at 13-18 (summarizing history of these efforts); *id.* at 21-22, 29 (urging HHS to exempt IVF research from EAB review and to establish an EAB which will be able to function effectively and review more controversial research proposals); *see also* Fletcher & Schulman, *supra* note 27, at 10-11.

270. *INFERTILITY IN AMERICA*, *supra* note 8, at 18-19.

271. For example, without an EAB, one investigator has not been able to obtain approval—or funding—for a well regarded study, using human zygotes or preembryos, which is designed to improve the culture medium used in IVF and hence the efficacy of IVF. *Id.* at 15, 19-20; Beardsley, *supra* note 251, at 16; *INFERTILITY IN AMERICA*, *supra* note 8, at 6-7. Further, according to one estimate, "100 IVF-related grant proposals would be submitted to NIH every year if such research was fundable." *INFERTILITY IN AMERICA*, *supra* note 8, at 7.

272. *INFERTILITY IN AMERICA*, *supra* note 8, at 7 (major developments are occurring in countries such as Australia and the United Kingdom); *see also* Beardsley, *supra* note 251, at 16 (noting that "Sweden and Canada, in particular, are making headway").

273. *INFERTILITY IN AMERICA*, *supra* note 8, at 19-20. In the absence of federal funding, IVF research has been supported through the private sector by university medical centers, large pharmaceutical companies, and private foundations. *Id.* at 19; *see also* Beardsley, *supra* note 251, at 16. At least some of these costs are passed on to patients in the form of medical fees. *INFERTILITY IN AMERICA*, *supra* note 8, at 19. Also, according to one source, the lack of federal funding has made foundations and pharmaceutical companies "skittish about sponsoring such work." Beardsley, *supra* note 251, at 16.

274. See 45 C.F.R. § 46.204(a)-(c) (1989) (describing structure and function of EAB); *INFERTILITY IN AMERICA*, *supra* note 8, at 21-22; Fletcher & Schulman, *supra* note 27, at 6, 11.

with any embryo or fetus subject to the abortion procedure. For example, a California statute makes it unlawful "to use any aborted product of human conception ... for any type of scientific or laboratory research or for any other kind of experimentation or study, except to preserve the life and health of the fetus."²⁷⁵ Others not only seek to proscribe research in the abortion setting, but also to regulate more broadly research with the embryo, fetus, or neonate. For example, a Michigan statute prohibits nontherapeutic research with an embryo or fetus known to be the subject of a planned abortion (unless the research is designed to protect the mother's life) as well as nontherapeutic research with "a live human embryo, fetus, or neonate [if] the research substantially jeopardizes the life or health of the embryo, fetus, or neonate."²⁷⁶

Some statutes also contain specific provisions regarding IVF. For example, the Maternal, Fetal and Infant Experimentation Act of New Mexico defines a "fetus" as a "product of conception from the time of conception until the expulsion or extraction of the fetus or the opening of the uterine cavity,"²⁷⁷ and proscribes nontherapeutic research as follows:

275. CAL. HEALTH & SAFETY CODE § 25956(a) (Deering 1988); *see also* ARK. STAT. ANN. § 20-17-802(b)(1) (1987); ARIZ. REV. STAT. ANN. § 36-2302A (1986); FLA. STAT. ANN. § 390.001(6) (West 1986); IND. CODE ANN. § 35-1-58.5-6 (West 1986); KY. REV. STAT. ANN. § 436.026 (Baldwin 1988); MO. ANN. STAT. § 188-037 (Vernon 1983); MONT. CODE ANN. § 50-20-108 (3) (1985) (banning nontherapeutic research with "premature infant born alive"); NEB. REV. STAT. § 28-346 (1989) (banning nontherapeutic research with "premature infant aborted alive"); OHIO REV. CODE ANN. § 2919.14 (Anderson 1987); OKLA. STAT ANN. tit. 63, § 1-735 (West 1984); 18 PA. CONST. STAT. ANN. §§ 3216 (a), (c) (Purdon 1990 Supp.); WYO. STAT. § 35-6-115 (1977 republished edition) (banning the sale, transfer, distribution, or giving away of "any live or viable aborted child for any form of experimentation").

276. MICH. COMP. LAWS § 333.2685 (1989); *see also* LA. REV. STAT. ANN. § 14:87.2 (West 1986) (no experimentation on human embryo or fetus *in utero* except to preserve the life or improve the health of the embryo or fetus); MASS. ANN. LAWS ch. 112, § 12J(a)(I) (Law. Co-op. 1985) (no research with "any live human fetus," but proscription does not apply if the procedures are directed to the fetus *in utero*, the procedures "do not substantially jeopardize the life or health of the fetus," and the fetus is not the subject of a planned abortion; likewise, proscription does not apply to diagnostic procedures designed to preserve the life or health of the fetus or mother); ME. REV. STAT. ANN. tit. 22, § 1593 (1980) (banning experimentation with "any live human fetus, whether intrauterine or extrauterine, or any product of conception considered live born"); MINN. STAT. ANN. §§ 145.421-145.422 (West 1989) (prohibiting research with "human conceptus," defined as "any human organism, conceived either in the human body or produced in an artificial environment ... from fertilization through the first 265 days thereafter," unless the research is therapeutic or harmless to the conceptus); N.D. CENT. CODE § 14-02.2-01 (Supp. 1989) (same general prohibition as Mass.); R.I. GEN. LAWS § 11-54-1 (1989 Supp.) (same general prohibition as Mass.); UTAH CODE ANN. § 76-7-310 (1990 replacement) (no experimentation with "[l]ive unborn children").

Some statutes are less restrictive. *See* S.D. CODIFIED LAWS ANN. § 34-23A-17 (1986 revision) (only prohibiting "[e]xperimentation with fetuses without written consent of the woman); TENN. CODE ANN. § 39-15-208 (Supp. 1990) (prohibiting research "upon an aborted fetus without the prior knowledge and consent of the mother").

277. N.M. STAT. ANN. § 24-9A-1(c) (1978 & Supp. 1989).

No fetus shall be involved as a subject in any clinical research activity unless the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs or no significant risk to the fetus is imposed by the research activity.²⁷⁸

"Clinical research" is defined to include "research involving human *in vitro* fertilization"²⁷⁹ but not "human *in vitro* fertilization performed to treat infertility."²⁸⁰ However, IVF performed to treat infertility is defined to be outside the scope of clinical research only if the "procedure ... include[s] provisions to insure that each living fertilized ovum, zygote or embryo is implanted in a human female recipient."²⁸¹

Arguably, each of these statutes could be interpreted to inhibit IVF. For example, each could be construed to prohibit any formal research protocol or IVF technique which contemplates preembryo loss. Thus, each of these statutes could make it unlawful to conduct any type of procedure which might not be directed toward the continued survival or development of a particular preembryo.

Although each statute must be analyzed individually, similar state statutes have been held unconstitutional. In *Margaret S. v. Edwards*,²⁸² the following provision of a Louisiana statute was at issue: "No person shall experiment on an unborn child or a child born as the result of an abortion, whether the unborn child or child is alive or dead, unless the experimentation is therapeutic to the unborn child or child."²⁸³ A federal appellate court held that the statute violated the due process clause of the fourteenth amendment because the terms "experiment" and "experimentation" were impermissibly vague.²⁸⁴ As the court explained, no meaningful distinction could be drawn, based on the statutory language, "between experimentation and testing, or between research

278. N.M. STAT. ANN. § 24-9A-3(a) (1978 & Supp. 1989).

279. *Id.* § 24-9A-1(D).

280. *Id.*

281. *Id.* A Minnesota statute regulating research with the "human conceptus," *see supra* note 276 and accompanying text, does not specifically mention IVF but defines the conceptus as "any human organism, conceived either in the human body or produced in an artificial environment other than the human body." MINN. STAT ANN. § 145.421, subd. 2 (West 1989). Hence, the statute would apply to research with the preembryo created through *in vitro* fertilization.

The Pennsylvania legislature has taken a different approach, apparently deciding to avoid the issues raised by IVF. The legislature mentioned IVF in its fetal experimentation statute, *see supra* note 275, but specifically stated that nothing in the statute should be "construed to condone or prohibit the performance of *in vitro* fertilization and accompanying embryo transfer." 18 PA. CONS. STAT. ANN. tit. 18, § 3216 (c) (Purdon 1990 Supp.).

282. 794 F.2d 994 (5th Cir. 1986).

283. *Id.* at 998 (quoting LA. REV. STAT. ANN. § 40:1299.35.13 (West 1977 & Supp. 1990)).

284. *Id.* at 998-99.

and practice."²⁸⁵ To be sure, some procedures might be considered "experimental"²⁸⁶ and some might be considered "standard,"²⁸⁷ but a very broad area of medical practice is defined by a process in which experimental procedures become standard procedures, "a gradual process of observing the results, confirming the benefits, and often modifying the technique."²⁸⁸

In *Lifchez v. Hartigan*,²⁸⁹ a class of physicians, specializing in reproductive endocrinology and fertility counseling, challenged an Illinois statutory provision which banned nontherapeutic fetal experiments but permitted IVF. In relevant part, the statute read as follows:

No person shall sell or experiment upon a fetus produced by the fertilization of a human ovum by a human sperm unless such experimentation is therapeutic to the fetus thereby produced.... Nothing in this subsection ... is intended to prohibit the performance of *in vitro* fertilization.²⁹⁰

The federal district court struck down the statute on the ground that the terms "experimentation"²⁹¹ and "therapeutic"²⁹² were vague.²⁹³ As the court explained, the term "experimentation" has a number of medical and scientific definitions, including: pure research where the only goal is to increase knowledge and there is no direct benefit to the human subject,²⁹⁴ procedures which lack sufficient testing to produce a predictable outcome or veer from current practice,²⁹⁵ standard

285. *Id.* at 999.

286. *Id.*

287. *Id.*

288. *Id.*

289. 735 F. Supp. 1361 (N.D. Ill. 1990).

290. *Id.* at 1363-64 (quoting ILL. REV. STAT. ch. 38, para. 81-26, § 6(7) (1989)).

291. *Id.* at 1364.

292. *Id.*

293. An earlier version of the statute was enjoined on the ground that it was unconstitutionally vague. *Charles v. Carey*, 579 F. Supp. 377, 383 (N.D. Ill. 1983) (granting preliminary injunction); *Charles v. Carey*, 579 F. Supp. 464, 476 (N.D. Ill. 1983) (granting permanent injunction). The statute made it a felony to "use or sell any fetus or premature infant *aborted alive* for any type of scientific, research, laboratory or other kind of experimentation either prior to or subsequent to any abortion procedure except as necessary to protect or preserve the life and health of such premature infant aborted alive ..." 579 F. Supp. at 383 (quoting Illinois Abortion Law of 1975, as amended, § 6(3)) (emphasis added by the court). As the district court explained, the term, "aborted alive," was impermissibly vague because it could refer to "only the most minimal of life signs in a nonviable fetus or ... the capability of sustained survival." *Id.* (quoting *Charles v. Carey*, 627 F.2d 772, 791 (7th Cir. 1980) (striking other portions of the Illinois Abortion Law)).

294. *Lifchez*, 735 F. Supp. at 1364-65.

295. *Id.* at 1365.

procedures when performed by any particular person for the first time,²⁹⁶ and "any medical therapy where the practitioner applies what he [or she] learns from one patient to another."²⁹⁷

The statutory vagueness forced the physicians to guess whether various activities were unlawful.²⁹⁸ For example, the physicians performed amniocentesis and chorionic villi sampling, diagnostic procedures designed to identify genetic anomalies in the developing fetus.²⁹⁹ Amniocentesis was no longer considered experimental, but chorionic villi sampling was,³⁰⁰ so like the *Margaret S.* court, the *Lifchez* court observed that experimental procedures may become routine over time.³⁰¹

Likewise, IVF and related procedures were affected. To be sure, the statute allowed for *in vitro* fertilization, but if fertilization occurred *in vivo* and the preembryo was flushed from the uterus of one woman and transferred to the uterus of another, the procedure might not be "therapeutic" for the preembryo involved.³⁰² Likewise, if the genetic screening of a preembryo maintained *in vitro* was followed by the destruction of a defective preembryo, the screening procedure might not be considered therapeutic.³⁰³

Further, experiments designed to improve IVF might exceed the statutory definition of "*in vitro* fertilization" and might not be therapeutic for every preembryo. Again, by way of example, super-ovulation techniques may reduce the quality of the ova produced or the quality of the uterine lining, so it is more difficult for the preembryo to implant.³⁰⁴ Hence, some experiments might not be of any benefit to the preembryos involved because some experiments might fail; for example, experiments designed to improve super-ovulation or to determine the most effective shape of the laboratory container in which IVF occurs or the most effective growth medium in which ova are fertilized.³⁰⁵

The *Lifchez* court also struck down the statute on the ground that it restricted a woman's right of reproductive privacy. In a brief, cogent analysis, the court reviewed the various aspects of reproductive privacy,

296. *Id.*

297. *Id.*

298. *Id.* at 1364, 1376.

299. *Id.* at 1366-67.

300. *Id.*

301. *Id.* The court warned lawmakers of their responsibility to recognize "the fundamental progression from 'experiment' to 'routine,'" and to describe unlawful actions with particularity. *Id.* at 1367.

302. *Id.* at 1367-68.

303. *Id.* at 1368.

304. *Id.* at 1368-69.

305. *Id.* at 1369.

observed that the Illinois statute would prohibit chorionic villi sampling and the kind of preembryo transfer in which a preembryo is washed from one woman's uterus and transferred to another's, and concluded that both procedures were protected by the right of privacy.³⁰⁶ As the court explained, if the right of privacy protects the right to prevent pregnancy by using contraceptives, it protects the right to establish a pregnancy through preembryo transfer.³⁰⁷ Likewise, if the privacy right protects the right to abort during the first trimester, it protects the right to undergo chorionic villi sampling, a procedure which would be performed during the first trimester and would produce information relevant to the abortion decision.³⁰⁸

Hence, state laws offer little real guidance, if any, in the area of IVF research. A number of state statutes are designed to prevent non-therapeutic research with some category of the unborn. By and large, however, these statutes remain uncertain in scope and application, and may be subject to constitutional challenge. Given this dismal situation, the void in federal policy, and the volatile political climate surrounding any issue regarding the unborn, a thoughtful, comprehensive policy is necessary to guide research in this burgeoning field.

C. The Case for Preembryo Research

1. RESEARCH CAN BE JUSTIFIED BY THE COMMON GOOD AND INFORMED CONSENT

As a general proposition, research involving the preembryo, whether therapeutic or nontherapeutic, can be justified by the common good.³⁰⁹ For the purpose of this argument, "research" will be used in the

306. *Id.* at 1376-77.

307. *Id.* at 1377.

308. *Id.*

309. The argument developed here applies to research with the zygote (one cell fertilized egg) as well as to research with the preembryo. The preembryonic period begins with the first cell division and continues until the primitive streak appears—some 14 days after conception—and a single, biological entity begins to develop. See *supra* notes 46-59 and accompanying text. Hence, the argument is consistent with the position, supported by various advisory groups, that research involving the preembryo should be allowed up to 14 days after conception. See HEW Report, *supra* note 160, at 35,057 (supporting IVF research without preembryo transfer if "[n]o embryos will be sustained *in vitro* beyond the stage normally associated with the completion of implantation (14 days after fertilization)"); Ontario Law Reform Comm'n, Ministry of the Attorney General, II Report on Human Artificial Reproduction and Related Matters 216 (1985) (recommending, with respect to research involving the preembryo, that "no fertilized ovum outside the body should be allowed to develop beyond fourteen days after fertilization"); Warnock Report, *supra* note 160, § 11.22, at 66 (recommending, based on formation of primitive streak, that preembryo neither "be kept alive ... nor ... used as a research subject beyond fourteen

sense defined by the HHS regulations, namely, "a *systematic* investigation designed to develop or contribute to *generalizable* knowledge."³¹⁰ This definition includes "pure" research and clinical research in which a subject might derive some benefit, but does not include an experimental therapy performed outside the scope of a research protocol, an accepted therapy which an individual performs for the first time, or the more general process of observation and reflection through which an individual may enhance his or her clinical judgment or professional expertise. This definition grounds research in the common good and research, as such, is designed to advance human knowledge and thus advance the human condition.³¹¹

Nevertheless, when research involves a human subject, such research can proceed only with the informed consent of the research subject. This principle is fundamental both in ethics and in law.³¹² If an adult subject cannot consent, his or her "legally authorized representative"³¹³ must consent.³¹⁴ If the subject is a child, special provisions must be made for the child's "assent,"³¹⁵ if possible, and the

days after fertilisation"); The Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization, Victoria, Australia, Report on the Disposition of Embryos Produced By In Vitro Fertilization § 3.29, at 47 (1984) [hereinafter the Waller Report] (chaired by Professor Louis Waller) (concluding that any preembryo used for research "shall not be allowed to develop beyond the stage of implantation, which is completed 14 days after fertilization. It is after this stage that the primitive streak is formed"), reprinted in III Bioethics Reporter (1985), Legislation 226; Ethics Comm. of Am. Fertility Soc'y, *supra* note 42, at 63S (concluding "that it seems prudent ... not to maintain human preembryos for research beyond the 14th day of postfertilization development").

310. 45 C.F.R. § 46.102(e) (1989) (emphasis added).

311. See generally H. Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, in *EXPERIMENTATION WITH HUMAN SUBJECTS* 1, 13-14 (P. Freund ed. 1969); PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, *COMPENSATING FOR RESEARCH INJURIES* 11-12 (1982).

312. The informed consent of the research subject is required by federal regulations and some states. See 45 C.F.R. § 46.116 (1989) (HHS' general requirements for informed consent); CAL. HEALTH & SAFETY CODE §§ 24172-24176 (Deering 1988) (informed consent to medical experimentation required by California law); N.Y. PUB. HEALTH LAW §§ 2440-2444 (McKinney 1975). The principle of informed consent is also critical to international codes of research ethics. See II Trials of War Criminals, Before the Nuremberg Military Tribunals Under Control Council No. 10 181 (1949) (Nuremberg Code) (stating that "[t]he voluntary consent of the human subject is absolutely essential" as a moral, ethical, and legal principle of research); Eighteenth World Med. Assembly, 271 NEW ENG. J. MED. 473 (1964) (Declaration of Helsinki) (informed consent of research subject set forth as basic principle).

313. 45 C.F.R. § 46.116.

314. *Id.*

315. *Id.* §§ 46.402(b), 46.404, 46.405(c), 46.406(d), 46.407(b)(iii), 46.408(a), (e).

parents' "permission."³¹⁶ If the subject is a fetus, the consent of both the mother and father is necessary.³¹⁷

Likewise, if the subject is a preembryo, the progenitors' consent should be required. Whether or not the preembryo is a "human subject"³¹⁸ within the meaning of the HHS regulations, the preembryo is a human entity with a unique status. Hence, respect for the preembryo demands that research involving the preembryo incorporate the principle of informed consent; and, given the primary relationship between the progenitors and the preembryo, the right to give or withhold consent should rest with the progenitors. Further, if a research decision reflects a procreative decision, the progenitors' right to consent should be protected as a function of their right of privacy.

Thus, at a minimum, research involving the preembryo can be justified if it is designed to serve the common good and only proceeds with the informed consent of the progenitors.³¹⁹ Nevertheless, another issue remains: whether the preembryo's unique status requires any special limits on preembryo research.

2. LIMITS ON RESEARCH DEPEND ON A CAREFUL BALANCE OF RISK, BENEFIT, AND THE NATURE OF THE KNOWLEDGE TO BE GAINED

The question of limits can be illuminated by the HHS regulations governing research with human subjects, but cannot be resolved by a mechanical extension of those principles. The HHS regulations define the areas of permissible research in terms of risk, benefit, and the nature of the knowledge to be gained. For example, the risk to an adult subject must be minimized to the greatest extent possible³²⁰ and must be reasonable in terms of both the "anticipated benefits ... to subjects, and the importance of the knowledge that may reasonably be expected to result."³²¹

When a child serves as a research subject, the analysis is more elaborate. If the research only presents a "minimal risk,"³²² the research can proceed without any special consideration.³²³ If the research presents

316. *Id.* §§ 46.402(c), 46.405(c), 46.406(d), 46.407(b)(2)(iii), 46.408(b)-(d).

317. *Id.* §§ 46.208(b)-46.209(d).

318. *Id.* § 46.102(f).

319. For an argument supporting research which neither harms nor demeans the preembryo, see Robertson, *supra* note 30, at 504-06.

320. 45 C.F.R. § 46.111(a)(1) (1989).

321. *Id.* § 46.111(a)(2).

322. *Id.* § 46.404.

323. See *id.*

"more than minimal risk"³²⁴ but "holds out the prospect of direct benefit"³²⁵ to the child, the risk must be "justified by the anticipated benefit."³²⁶ Further, the "relation of the anticipated benefit to the risk"³²⁷ must be "at least as favorable ... as that presented by available alternative approaches."³²⁸ If the research presents more than minimal risk but does not hold out the prospect of direct benefit, the risk may only constitute a "minor increase over minimal risk,"³²⁹ the research experience must be "reasonably commensurate"³³⁰ with the child's experience in other areas of life,³³¹ and the research must be "likely to yield generalizable knowledge about the [child's] disorder or condition which is of vital importance for the understanding or amelioration of the ... disorder or condition."³³² Finally, if the research does not fit into any of these categories, it may proceed if it "presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children,"³³³ and "will be conducted in accordance with sound ethical principles."³³⁴

When the fetus is involved as a research subject, the regulations are even more stringent and are designed to ensure that every fetus is treated equally, regardless of its status in terms of the abortion decision.³³⁵ Hence, research can only be directed toward the fetus *in utero* if it satisfies the following criteria:

- (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.³³⁶

Further, the regulations subordinate research to the natural processes of fetal life and death. If research is directed toward the fetus *ex utero*, one must ascertain whether the fetus is viable. If this determination has not been made, the research can proceed only if "[t]here will be no

324. *Id.* § 46.405.

325. *Id.*

326. *Id.* § 46.405(a).

327. *Id.* § 46.405(b).

328. *Id.*

329. *Id.* § 46.406(a).

330. *Id.* § 46.406(b).

331. *See id.*

332. *Id.* § 46.406(c).

333. *Id.* § 46.407(b)(2)(i).

334. *Id.* § 46.407(b)(2)(ii).

335. *See* 42 U.S.C. § 289g(b) (1988) (risk standard to be "the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term").

336. 45 C.F.R. § 46.208(a) (1989).

added risk to the fetus"³³⁷ or "[t]he purpose of the activity is to enhance the possibility of survival of the ... fetus to ... viability."³³⁸ If the fetus is nonviable, the "[v]ital functions of the fetus [can] not be artificially maintained"³³⁹ and, conversely, experimental activities cannot be used "which of themselves would terminate the heartbeat or respiration of the fetus"³⁴⁰ In all cases, except where the research is designed to enhance the survival of the fetus to viability, the research must be designed to develop "important biomedical knowledge which cannot be obtained by other means"³⁴¹

337. *Id.* § 46.209(a)(1).

338. *Id.* § 46.209(a)(2); *see also* 42 U.S.C. § 289g(a)(2) (1988).

339. 45 C.F.R. § 46.209(b)(1); *see also* 42 U.S.C. § 289g(a)(1) (1988).

340. 45 C.F.R. § 46.209(b)(2).

341. *Id.* §§ 46.209(a)(1), 46.209(b)(3); *see also* 42 U.S.C. § 289g(a)(2) (1988). The HHS Secretary is authorized to modify or waive the requirements imposed by the fetal research regulations with the approval of an Ethics Advisory Board. 45 C.F.R. § 46.211. This authority, however, has become illusory for at least several reasons. First, the EAB existed for only a brief period (from 1978-1980) and has been defunct for years. *See supra* notes 260-270 and accompanying text. Second, any modifications or waivers under § 46.211 were subject to a statutory moratorium from November 20, 1985, through November 4, 1990. 42 U.S.C. § 289g(c)(2) (West Supp. 1990) (including Historical and Statutory Notes). Third, an effort to review the waiver standard recently failed at the Congressional level. In 1985, a bicameral Biomedical Ethics Board (the "Board") was established to "study and report to ... Congress ... on the ethical issues arising from the delivery of health care and biomedical and behavioral research" 42 U.S.C. § 275(c)(1); *see id.* § 275(a)-(c) (establishment of Board, membership, reports, etc.). As part of this task, the Board was directed to appoint a Biomedical Ethics Advisory Committee (the "Committee"), *see id.* § 275(d); and the Committee, in turn, was directed to study "the nature, advisability, and biomedical and ethical implications of exercising any waiver of the risk standard," *id.* § 289g(c)(1), applicable to all HHS research involving human subjects, including the fetus. *See id.*; 45 C.F.R. § 46.102(g). The Committee's report was due by November 4, 1990, 42 U.S.C. § 289g(c)(1), the same day the moratorium on modifications or waivers for fetal research was scheduled to end. *Id.* § 289g(c)(2).

Unfortunately, the Board and Committee were paralyzed by abortion politics. Hilts, *Abortion Debate Clouds Research on Fetal Tissue*, N.Y. Times, Oct. 16, 1989, § A, at 19, col. 1. Appointments to the Board and Committee were so controversial that it took a year to appoint the Board and another 2-1/2 years to appoint the Committee. *Id.* Then, in 1989, the Board's funding expired, INFERTILITY IN AMERICA, *supra* note 8, at 7; and, in October 1989, all Committee work stopped. Hilts, *supra*.

Hence, given the restrictions on fetal research, federal funding has been confined to research that presents no more than "minimal risk" to the fetus or is therapeutic to the fetus. *See* 45 C.F.R. §§ 46.206(a)(2), 46.207(a), 46.208(a), 46.209(a), (b); Hansen & Sladek, *Fetal Research*, 246 SCIENCE 775, 777 (1989); Fletcher & Schulman, *supra* note 27. As a result, at least some fetal research has been stymied, *see* Fletcher & Schulman, *supra* note 27, at 8-9, 11, and further research may advance slowly. Hansen & Sladek, *supra*.

This situation needs to be considered thoughtfully, for fetal research now holds the promise of continued advancement in the diagnosis of fetal disorders such as inherited chromosomal abnormalities, metabolic deficiencies, and anatomical malformations, as well as the development of surgical therapies designed to treat—*in utero*—disorders involving a single organ system or an isolated congenital malformation, and the assessment of the safety and efficacy of medications for both the fetus and pregnant

How should risk, benefit, and the value of knowledge be weighed in the context of research involving the preembryo? The HHS regulations generally define "minimal risk" to mean "that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."³⁴² Any given preembryo is subject to relatively great risk. The rate of preembryo loss which occurs naturally is relatively high. Within the context of IVF, the rate of loss is even higher. Hence, when the preembryo is involved, the concept of risk is more extreme than it is for an adult, child, or even a developing fetus: the likelihood of continued existence is highly uncertain.

Further, when evaluating risk in terms of the preembryo, it seems appropriate to consider whether or not the research will be followed by preembryo transfer. If the research will be followed by preembryo transfer, the preembryo should not be exposed to unnecessary risk by the research. In other words, the research should not increase the risk inherent in the natural process or the techniques of assisted reproduction.

woman. *Id.* at 775-77. Hence, fetal research now offers a number of therapeutic benefits to both the fetus and pregnant woman.

Likewise, fetal tissue research holds great promise but has been stymied by the abortion controversy. Fetal tissue research differs from research with the living fetus in that it involves studies with tissues or cells which have been derived from a dead fetus after a spontaneous or induced abortion. *Id.* at 775, 777. Fetal cells, cultured and grown in the laboratory, have been used to study gene regulation as well as cell interaction, function, differentiation, and growth. *Id.* at 777. Also, fetal cells have been used to develop and test vaccines and to determine whether new drugs are teratogens or carcinogens. *Id.* Further, the transplantation of fetal cells has been studied as a therapeutic tool to treat insulin-deficient diabetes mellitus, neurodegenerative disorders such as Parkinson's and Alzheimer's disease, and even immune deficiencies of other fetuses *in utero*. *Id.* at 777-79.

Technically, fetal tissue research is beyond the scope of the fetal research regulations and left to the regulation of any applicable state or local laws. See 45 C.F.R. § 46.210. However, in November 1989, HHS Secretary Louis W. Sullivan announced a permanent ban on federal funding for research involving the transplantation of fetal tissue derived from an elective abortion. Beardsley, *supra* note 251, at 16. The ban was surprising because a panel convened by the National Institutes of Health had concluded that federal support for research involving fetal tissue transplantation would be an acceptable public policy provided that the research would not be used to induce a woman to have an abortion. *Id.* Many other studies were in accord. See, e.g., COUNCIL ON SCIENTIFIC AFFAIRS AND COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, *Medical Applications of Fetal Tissue Transplantation*, 263 J. A.M.A. 565, 568-69 (1990) [hereinafter *Medical Applications of Fetal Tissue Transplantation*].

Hence, although fetal research and fetal tissue research offer enormous benefits, federal research policy continues to be dominated by the abortion debate. Federal policy needs to be examined more thoughtfully in terms which address the unique concerns raised by research in these areas, but such an examination is beyond the scope of this Article.

342. 45 C.F.R. § 46.102(g) (1989).

The research need not be therapeutic to the preembryo, but it should not jeopardize the preembryo's chance to develop into a healthy child. On the other hand, a greater level of risk seems acceptable if the preembryo will not be transferred. In that event, the preembryo must always be treated with respect, but greater risk will neither diminish the preembryo's chance to develop further nor jeopardize its healthy development. Indeed, Grobstein argues that "carefully considered research"³⁴³ with a preembryo which will not have a chance to develop further will allow the preembryo to "realize part of its human heritage and potential by fulfilling a significant and unique role in the human family."³⁴⁴

The concept of benefit to the research subject—a second variable in current federal regulations—also depends on whether the preembryo involved in research will be transferred. If the preembryo will not be transferred, benefit to the preembryo is not in issue. However, if the preembryo will be transferred, the benefit offered by the research is certainly relevant to the research design.

When relevant to the preembryo, the concept of benefit may require different levels of analysis. On one level, the analysis seems to be relatively basic and, like the analysis of risk, to focus primarily on the preembryo's chance to survive, implant, and continue developing. However, at some point in the future it may become necessary to consider the therapeutic benefits of genetic engineering. Genes, which are composed of the DNA molecule, govern each cell's structure and function.³⁴⁵ If the DNA structure of a particular gene is faulty, the gene may malfunction and cause a genetic disease such as cystic fibrosis, sickle

343. C. GROBSTEIN, *supra* note 3, at 82.

344. *Id.*; accord Jones & Schrader, *supra* note 3, at 191.

In contrast to the notions of risk proposed here, current federal regulations only allow the fetus to be involved in research if the research is designed "to meet the health needs of the mother or the particular fetus, [and] the risk to the fetus is minimal." 45 C.F.R. § 46.206(a)(2) (1989). The risk is not allowed to vary, depending on whether or not the fetus is to be aborted, and the same standard applies while the nonviable fetus, *ex utero*, is dying.

Nevertheless, it seems that the standard of risk should be allowed to vary in preembryo research. Even compared to the developing embryo and fetus, the preembryo is a unique biological entity: uniquely situated, having a unique relationship with its progenitors, and, whether measured in terms of natural reproduction or assisted reproduction, given only a slim chance of continued development. Hence, whatever level of risk may be appropriate in fetal research, the standard of risk in preembryo research must be analyzed in terms of the preembryo's own status and situation.

345. Nat'l Insts. of Health, Dep't of Health & Human Servs., Recombinant DNA Research: Actions Under Guidelines, 55 Fed. Reg. 7,438, 7,439 (Mar. 1, 1990) (public information brochure regarding human gene therapy, prepared by the Human Gene Therapy Subcommittee of the Recombinant DNA Advisory Committee ("RAC") of the National Institutes of Health ("NIH")).

cell anemia, or hemophilia.³⁴⁶ Research in "human gene therapy"³⁴⁷ is designed to alleviate or even cure a genetic disease by inserting a normal gene into the DNA of a cell with a malfunctioning gene.³⁴⁸ Hence, with further research, it may become possible to treat genetic disorders in the preembryo.³⁴⁹ If so, the concept of benefit will have to be expanded to consider factors related to the treatment of disease and the alleviation of suffering.³⁵⁰

A third variable in the federal regulations concerns the nature and value of the knowledge to be gained by research. In general, risk must always be proportionate to the importance of the knowledge to be gained,³⁵¹ and this relation is specially defined in special circumstances. If research presents greater than minimal risk to a child, it must be likely to yield knowledge "which is of vital importance for the understanding or amelioration of the subjects' disorder or condition,"³⁵² or "present[] a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children."³⁵³ When the fetus is involved as a research subject, the purpose of the activity must generally be to develop "important biomedical knowledge which cannot be obtained by other means."³⁵⁴

Likewise, in the context of preembryo research, risk should be justified by the importance of the knowledge to be gained. By necessity,

346. *Id.*

347. *Id.*

348. *Id.* at 7,438-39. Human gene therapy may affect "somatic" cells (non-reproductive cells) or "germ line" cells (reproductive cells including eggs in women and sperm in men). *Id.* At present, the NIH will fund research involving somatic cell gene therapy, but will not fund research involving germ line alterations. *Id.* at 7,444 ("Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA into the Genome of Human Subjects," prepared by the Human Gene Therapy Subcommittee and approved by the RAC). As the NIH has explained, "The purpose of somatic cell gene therapy is to treat an individual patient ... [while] [i]n germ line alterations, a specific attempt is made to introduce genetic changes into the germ ... cells of an individual, with the aim of changing the set of genes passed on to the individual's offspring." *Id.* One concern regarding somatic cell research, however, is that somatic cell changes may be transmitted unintentionally from an individual to his or her offspring. *Id.*

349. See Warnock Report, *supra* note 160, § 12.15, at 74; Waller Report, *supra* note 309, §§ 3.14-3.16, at 39-40.

350. The concept of benefit could also become highly controversial if a research proposal was designed to "enhance" or alter the preembryo's natural genome in order to produce specific characteristics in the potential child. For example, such research might be designed to produce children who were taller than they would be otherwise. Presently, such research remains speculative and futuristic, but is cause for concern. See Warnock Report, *supra* note 160, § 12.16, at 74.

351. 45 C.F.R. § 46.111(a)(2) (1989).

352. *Id.* § 46.406(a)(c).

353. *Id.* § 46.407(b)(2)(i).

354. *Id.* §§ 46.208(a), 46.209(a)(1), 46.209(b)(3).

this will involve a subjective, value oriented determination. Some knowledge will be worth the risk; some will not. Further, it seems appropriate to limit preembryo research to situations where important knowledge "cannot be obtained by other means." Arguably, this limitation is consistent with our respect for the preembryo and will help to maintain our respect. No matter how important the knowledge to be gained, the preembryo should not be treated as a commodity to be used whenever convenience or whim demands.

Nevertheless, by analogy to the regulations regarding children, it does not seem appropriate to limit research which presents relatively high risk to the preembryo to situations where the knowledge to be gained will be important to a "disorder or condition" of the preembryo or to "a serious problem affecting the health or welfare" of preembryos. Basic medical or scientific research involving the preembryo appears to be justified by the preembryo's unique status. Our duties toward the preembryo differ from our duties toward children.³⁵⁵ Further, the preembryo deserves our serious respect, but children have legal rights³⁵⁶ and warrant special protection as vulnerable research subjects.³⁵⁷ Hence, a wider scope of research appears justified in the case of preembryos than in the case of children.

3. SUGGESTED GUIDELINES

The analysis of risk, benefit, and knowledge can be summarized in a set of proposed regulations. First, if research involving the preembryo does not involve any particular risk to the preembryo or only involves minimal risk, the research should be able to proceed with the informed consent of the progenitors. In this context, "minimal risk" would be

355. Parents have the right and duty to care for and nurture their children. *See Prince v. Massachusetts*, 321 U.S. 158, 166 (1944), *Pierce v. Soc'y of Sisters*, 268 U.S. 510, 535 (1925). However, if parents abuse or neglect their children, the state has the right and duty under its *parens patrie* power to protect the children's well being. *See Prince*, 321 U.S. at 166-67; *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 627 & n.13 (1986) (plurality opinion by Stevens, J.).

356. *See supra* note 148 and accompanying text.

357. Although commentators have developed different theories to justify or limit research with children, there is some general accord that children are special research subjects deserving special consideration. *See P. RAMSEY, THE PATIENT AS A PERSON* 11-19 (1970) (nontherapeutic research with children cannot be justified because children lack the capacity to give a true consent); McCormick, *Proxy Consent in the Experimental Situation*, 18 PERSP. BIOLOGY & MED. 2, 13-14 (1974) (consent on behalf of children can be justified "when a particular experiment would involve no discernable risks, no notable pain, no notable inconvenience, and yet hold promise of considerable benefit"); Fried, *Children as Subjects for Medical Experimentation*, in *RESEARCH ON CHILDREN* 107, 111-15 (J. van Eys ed. 1978) (research with young children can be justified if inter alia there is a close connection between the child and the benefit produced by the research).

defined to mean a risk to the preembryo, equivalent in kind and/or degree, to the risk normally associated with reproduction, whether measured by natural processes or alternative technologies.

Second, if the research would involve greater than minimal risk to the preembryo and would be followed by preembryo transfer, the risk should be justified by the anticipated benefit to the preembryo. In this context, the relation between risk and benefit would be critical, and "benefit" would refer to the preembryo's chance for survival, implantation, continued development, or even, at some point in the future, to the treatment of genetic disease. Hence, research involving greater than minimal risk would be justified if it would be expected to improve the preembryo's chance to be born alive or free from genetic disease.

Third, if the research would involve greater than minimal risk to the preembryo and would not be followed by preembryo transfer, the research should be justified by the development of important knowledge which cannot be obtained by other means. Benefit would not be an issue; instead, the nature of the knowledge to be gained would be critical. For example, given the current research in animal breeding, it might be possible someday to transfer human preembryos into chimpanzees or gorillas so these primates can serve as "surrogates" for the purpose of gestation and birth.³⁵⁸ Such a phenomenon would be highly controversial and implicate many basic values, assumptions, and goals. Hence, it would be critical to evaluate the nature of the knowledge to be gained by a study designed to achieve this goal.

Finally, beyond these proposed regulations, two general restraints on preembryo research seem justified: preembryos should not be bought or sold for research³⁵⁹ and preembryos should not be created solely for research. The former point seems almost self-evident as a principle of bioethics. By way of either law or policy analysis, commercial transactions are either banned or disfavored in the settings of organ transplantation,³⁶⁰ surrogacy,³⁶¹ and fetal tissue transplantation.³⁶²

358. INFERTILITY IN AMERICA, *supra* note 8, at 21.

359. *Accord*, Robertson, *supra* note 30, at 512-14.

360. See, e.g., 42 U.S.C.A. § 274e (a) (West Supp. 1990) (organs for use in human transplantation cannot be sold through interstate commerce); CAL. HEALTH & SAFETY CODE §§ 7150-7156.5 (Deering Supp. 1990) (providing for donation of cadaver organs as a gift under the Uniform Anatomical Gift Act); CAL. PENAL CODE §§ 367f(a), (d), (e) (Deering 1985) (banning the commercial brokerage of human organs); Caplan, *Blood, Sweat, Tears and Profits: The Ethics of the Sale and Use of Patient Derived Materials in Biomedicine*, 33 CLINICAL RES. 448, 448-50 (1985).

361. See, e.g., *Matter of Baby M*, 109 N.J. 396, 537 A.2d 1227 (1988).

362. See e.g., CAL. HEALTH & SAFETY CODE § 7150.1(b) (Deering Supp. 1990) ("decent" defined to include a fetus for purpose of donating all or part of a human body,

The latter point seems consistent with our principles of constitutional law and public policy. The progenitors have a right to make reproductive decisions free from state interference, and this right should protect their right to conceive, freeze, transfer, donate, or discard a preembryo as part of the reproductive process. However, a decision to create a preembryo solely for research would exceed this protected domain. Moreover, the creation of preembryos solely for research can be criticized on policy grounds for it can be argued that the preembryo would become nothing more than a commodity to be produced, used, and discarded at will. As a result, our humanity would be denigrated and the research would be devalued.³⁶³

VI. CONCLUSION

As technology has advanced toward the edge of life, it has become necessary to look beyond the bright lines which usually define legal analysis. To define the legal status of the preembryo, we must look beyond our familiar concepts of "property" and "person" and account for the phenomenon of human development. To define the rights of the progenitors—relative to the preembryo, the state, and each other—it is necessary to examine and affirm our basic freedoms vis-a-vis the state. In doing so, however, it has become necessary to realize that freedom can only be exercised within the context of human relationships; that human relationships imply connections and interdependence; and that reproductive freedom must account for the phenomena of assisted reproduction and human development, phenomena which involve

including tissue, under the Uniform Anatomical Gift Act); *Medical Applications of Fetal Tissue Transplantation*, *supra* note 341, at 568-69.

363. See Annas, *The Ethics of Embryo Research: Not as Easy as It Sounds*, 14 LAW, MED. & HEALTH CARE 138, 138, 139-40 (1986). Commentators are divided. See Warnock Report, *supra* note 160, §§ 11.20-11.30, at 66-69 (members of committee divided over issue but agreed that it should be resolved by legislation); Waller Report, *supra* note 309, §§ 3.26-3.31, 6.14, at 46-47, 60 (acknowledging dissenting views but recommending that preembryos should not be created solely for research because they would be created solely as a means to an end); Ethics Comm. of Am. Fertility Soc'y, *supra* note 42, at 63S (some research may require production of preembryos solely for the research). The state of Victoria, Australia has enacted legislation to deal with the issue. See Buckle, Dawson & Singer, *The Syngamy Debate: When Precisely Does a Human Life Begin?*, 17 LAW, MED. & HEALTH CARE 174 (1989) (discussing the Infertility (Medical Procedures) Act and the Infertility (Medical Procedures) (Amendment) Act, enacted in 1984 and 1987; the former followed the Waller Committee and only allowed ova to be fertilized outside the body for the purpose of implantation, while the latter allows ova to be fertilized outside the body "for experimental procedures 'from the point of sperm penetration prior to but not including the point of syngamy,'" *id.* at 180, with syngamy referring to the point at which a new genotype is formed and the process of fertilization is complete).

change and extend over time.³⁶⁴ Finally, to define a policy adequate to guide IVF research and research with the preembryo, we must look beyond the polarized lines of the abortion debate and define the role of the preembryo within the larger human community.

As our jurisprudence expands to accommodate the implications of change and human relationships, our familiar assumptions are tested and patterns of reasoning are disrupted. However, as our jurisprudence expands, it also becomes more dynamic, responsive to the challenge of technology and to the shared meaning of our human situation.³⁶⁵

364. See generally Minow, *Interpreting Rights: An Essay for Robert Cover*, 96 YALE L. J. 1860, 1874-94 (1987) (developing an "interpretive" approach to rights in which rights arise within the context of human relationships, depend on human communities for recognition, and provide a language for community discourse regarding roles, relationships, and responsibility).

365. See generally, Martin & Lagod, *Biotechnology and the Commercial Use of Human Cells: Toward an Organic View of Life and Technology*, 5 SANTA CLARA COMPUTER & HIGH TECH. L. J. 211, 253-61 (1989) (discussing these themes within the context of our world view which arguably is shifting from the mechanistic view generated by the scientific revolution of the sixteenth and seventeenth centuries toward a more organic view).