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Pre Embryos: The Tiniest Speck of Potential Life Carrying the Seeds for Sweeping Change Kathryn L. Miehl

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### Introduction

The Bush administration has issued two announcements over the last six months which could shape the future of stem cell research, abortion and the disposition of frozen embryos. On July 25, 2002, the Department of Health and Human Services (HHS) announced that federal funds would be available to qualified applicants for the development and implementation of programs designed to promote public awareness of the option of "adopting" frozen embryos. Then, on October 1, 2002, the National Human Research Protections Advisory Committee under the Clinton Administration was reformed into the Secretary's Advisory Committee on Human Research Protections. Under its new charter, the Committee must provide advice concerning responsible research involving human subjects, with particular emphasis on pregnant women, embryos and fetuses.<sup>1</sup>

Combined with technological advances in artificial procreation, embryonic development, and life-sustaining procedures in and out of the womb, the inertia from these policy decisions may form the basis for a renewed debate on the legal protections afforded to individuals when life begins. Part I of this note explores the nature and legislative history of the announcements. Part

<sup>&</sup>lt;sup>1</sup> HHS Committee to Consider Embryos "Human Subjects", 10 Am. POLITICAL NETWORK, Am. HEALTH LINE 9 (2002).

II documents the present legal status of embryos according to case law, state statutes, and foreign regulation. Part III examines scientific developments which have the potential to create life and sustain viability outside of the womb, and their possible effects on abortion, the rights of gamete providers, and medical research. Finally, this note argues for Congress to resolve the legal status of frozen embryos, so that individuals contemplating in vitro fertilization ("IVF") can make an informed decision, and that the scientific community can more efficiently allocate its resources towards stem cell research.

## Part I. The Announcements

# A. The Embryo Adoption Awareness Campaign

Public Law 107-116 authorizes the Secretary of HHS to conduct a public awareness campaign promoting adoption of frozen embryos presently stored in clinics throughout the United States.<sup>2</sup> Congress allocated \$1 million for the selection of 3 to 4 applicants, granting \$200,000 to \$250,000 each to conduct the campaign. To be selected, the successful applicants must demonstrate experience in the field of IVF, the need for funds to generate and conduct an awareness campaign, and the ability to assess the success and progress of the program.<sup>3</sup> Applicants are limited to public agencies, for-profit organizations and non-profit organizations, which includes both faith-based and community-based organizations.<sup>4</sup> The applications must provide specific details for the proposed campaigns, such as the targeted audiences and supplemental materials, such as like brochures, handouts and visual aids.<sup>5</sup> Finally, applicants are required to demonstrate "familiarity with and understanding of professionally recognized

<sup>2</sup> Announcement of the Availability of Financial Assistance and Request for Applications to Support Development

and Delivery of Public Awareness Campaigns on Embryo Adoption, 67 Fed. Reg. 48654, 48655 (July 15, 2002). <sup>3</sup> Id. at 48654-56.

<sup>&</sup>lt;sup>4</sup> *Id.* at 48655.

<sup>&</sup>lt;sup>5</sup> *Id.* at 48656.

standards or practices (both medical and legal issues) pertaining to embryo adoption, as well as supportive services for donor and recipient couples." The announcement recommends following the embryo donation guidelines set forth by the American Society for Reproductive Medicine. They define "embryo adoption" as the donation of frozen embryo(s) from one party to a recipient wishing to bear and raise a child.<sup>7</sup>

A dilemma presents itself in the creation of frozen embryos with the process of cryopreservation of fertilized eggs. The IVF procedure begins with hormone therapy, in which a woman's ovaries are stimulated to produce multiple eggs.<sup>8</sup> Once ovulation occurs, the woman undergoes a laparoscopy (surgery performed under general anesthesia) to retrieve the eggs, which are then placed in a test tube or Petri dish.<sup>9</sup> If the physician determines that the eggs are suitable for fertilization, they are combined with a sperm sample. Once fertilized, the pre embryos begin to divide, reaching the four to six-cell stages, when they are either implanted into the woman's uterus or frozen for later use.<sup>10</sup>

Cryopreservation is the process of freezing tissue and cells. Embryos are typically frozen at the blastocyte stage, occurring five to seven days after fertilization.<sup>11</sup> After being placed in a protective solution, the embryos are frozen in liquid nitrogen at a temperature of minus 195 degrees centigrade.<sup>12</sup> The frozen embryos can remain in this state indefinitely. There are many practical advantages to this process: it cuts down on the number of IVF procedures, sparing the woman repeated hormone treatments and invasive egg retrieval procedures with added expense;

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<sup>&</sup>lt;sup>6</sup> *Id*.

<sup>&</sup>lt;sup>7</sup> *Id.* at 48655.

<sup>&</sup>lt;sup>8</sup> Kate W. Lyon, *Babies on Ice: The Legal Status of Frozen Embryos Involved in Custody Disputes During Divorce*, 21 WHITTIER L. REV., 695, 697 (2000).

<sup>&</sup>lt;sup>9</sup>Id. at 698 (citing Clifton Perry, Ph.D., L.L.M. & Kristen Schneider, J.D., *Cryopreserved Embryos: Who Shall Decide Their Fate?*, J. LEGAL MED. 463, 466 n.21 (1992)).

 $<sup>^{10}</sup>$  Id

<sup>&</sup>lt;sup>11</sup>Id. at 699 (citing John A. Robertson, *In the Beginning: The Legal Status of Early Embryos*, 76 VA. L. REV. 437, 441 (1990)).

<sup>&</sup>lt;sup>12</sup> *Id*.

it increases the likelihood of successful pregnancies by allowing implantation during a woman's natural cycle; it reduces the possibility of multiple births, created by the implantation of several embryos at once; and it provides hope for women who are unsuccessful in their initial IVF pregnancy attempts.<sup>13</sup>

Despite its practical advantages, cryopreservation creates legal and ethical issues. Typically, there are frozen embryos "left-over" after the woman has undergone IVF. Today, there are an estimated "100,000 spare frozen embryos stored in vitro fertilization clinics throughout the United States." This is due to either divorce or the ending of the gamete providers' desire for children. When this occurs, there are several options: equal division among gamete providers, donation to another infertile couple, donation to research facilities, or the disposal of the embryos by the infertility clinic. 15

The aforementioned HHS grant provision was inserted into a spending bill by Senator Arlen Specter, R-Pa., during stem cell research debates. After President Bush made the decision on August 9, 2001, to limit federal funding for research to the existing 64 stem cell lines, there were concerns as to whether those lines would be sufficient to sustain successful research. Senator Specter wished to differentiate between "cloning" and "somatic cell nuclear transfer," sometimes mistakenly referred to as "therapeutic cloning." According to Specter, genetic material is removed from the unfertilized egg, which is then inserted with the DNA of an adult cell. The

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<sup>&</sup>lt;sup>13</sup> *Id.* at 699-700.

<sup>&</sup>lt;sup>14</sup>Announcement of the Availability of Financial Assistance and Request for Applications to Support Development and Delivery of Public Awareness Campaigns on Embryo Adoption, 67 Fed. Reg. at 48655. Other estimates vary from 100,000 to 200,000. See also Resolve: The National Infertility Association, Receives Federal Grant to Implement Groundbreaking Educational Program on Use of Embryos, PR Newswire, Oct. 10, 2002; Jenny Deam, Waiting to be Born Frozen Embryos Hang in Balance After Pregnancy Discarding Frozen Embryos is Often a Terribly Difficult Decision for Parents Who Have Spent Years Trying to Make a Baby, The Denver Post, Jan. 16, 2001; Richard Jerome, Joanne Fowler & Ron Arias, Last Chance Family, People, Jan. 21, 2002; Deroy Murdock, The Adoption Option, National Review, Aug. 27, 2001.

<sup>&</sup>lt;sup>15</sup>Lyon, 21 WHITTIER L. REV. at 701 (citing *Kass v. Kass*, 696 N.E.2d 174,176 (N.Y. 1998); *Davis v. Davis*, 842 S.W.2d 588, 591 (Tenn. 1992)).

<sup>&</sup>lt;sup>16</sup> 147 CONG. REC. S12,024 (daily ed. Nov. 27, 2001)(statement of Senator Spector).

<sup>&</sup>lt;sup>17</sup> *Id*.

egg utilizes genetic material from the adult cell to create an exact copy of the donor. The process is intended for therapeutic purposes only, such as treatment for Parkinson's, Alzheimer's, heart disease, cancer, MS and other maladies.<sup>18</sup>

The controversy over stem cell research in the scientific community was compounded by an appropriations bill prohibiting federal funding to extract stem cells from the frozen embryos:

Sec. 510 (a) None of the funds made available in this Act may be used for

- (1) the creation of a human embryo or embryos for research purposes; or
- (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (U.S.C. 289g(b). (b) For purposes of this section, the term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.<sup>19</sup>

In response, Senator Specter successfully recommended the insertion of a \$1 million initial fund to promote the adoption of these existing embryos. These embryos could then be used for the highest calling - producing life. Furthermore, if they could all be adopted, there would be no embryos available for stem cell extraction, which would be the preferable choice. But, after adoption efforts fail, Senator Specter stated that, "If there are to be discarded embryos that are going to be thrown away, then it seems to me obvious it would make better sense to save lives as opposed to discarding them." 20

According to the HHS, grants were awarded to three projects: Resolve: the National Infertility Awareness Association of Somerville, MA; Women and Infants' Hospital of Rhode

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 $<sup>^{18}</sup>$  Id.

<sup>&</sup>lt;sup>19</sup> Pub. L. No. 107-116, § 510, 115 Stat. 2177, 2219 (2002).

<sup>&</sup>lt;sup>20</sup> 147 CONG. REC. S12,024-25. See also H.R. Rep. No. 107-342 (2001), at "Adoption Awareness."

Island in Providence, RI; and Nightlight Christian Adoptions in Fullerton, CA.<sup>21</sup> Resolve titled its program "Embryo Adoption-An Option." It plans to work with Harris Interactive in developing a national survey to ascertain the public understanding of embryo donation, and consequently develop educational materials to allow consumers to make informed decisions about embryo donation.<sup>22</sup>

The second recipient of the HHS grant was the Women and Infants' Hospital of Rhode Island, the teaching hospital of Brown University School of Medicine, with a highly successful Division of Reproductive Medicine. It specializes in IVF, serving the women and infants of Rhode Island, Connecticut and southeastern Massachusetts.<sup>23</sup>

The final recipient was Nightlight Christian Adoptions, the most activist recipient. It advocates the Snowflake Embryo Adoption Program. This program has matched thirty-six frozen embryo donor families with twenty-seven infertile adopting couples, producing eight babies and seven more pregnancies.<sup>24</sup> The program's goal is to insure that every existing embryo will be adopted; thus, there would be no need to create new embryos.<sup>25</sup> Nightlight Christian Adoptions incorporates its traditional adoption procedures into the embryo adoption sphere:

The Snowflakes program treats embryo adoption just like open adoptions of children who scream and scamper. Those who relinquish their embryos can choose potential adoptive parents who have passed a rigorous "home study" process that

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<sup>&</sup>lt;sup>21</sup> Email from Ms. Jeannine Nielson, Office of Population Affairs, OPA<u>OPA@OSOPHS.DHHS.GOV</u>, October 28, 2002.

<sup>&</sup>lt;sup>22</sup> RESOLVE: The National Infertility Association Receives Federal Grant to Implement Groundbreaking Educational Program on Use of Embryos, PR NewsWIRE, Oct. 10, 2002, available at LEXIS, News Library, PR Newswire File.

<sup>&</sup>lt;sup>23</sup> Women & Infants Hospital of Rhode Island homepage, *at* http://www.ahp.org/guide-to-giving/institutions/state/rhode-island/women.html (last visited October, 23, 2003) (on file with the Pittsburgh Journal of Technology Law and Policy).

<sup>&</sup>lt;sup>24</sup>Deroy Murdock, *The Adoption Option*, NATIONAL REVIEW, Aug. 27, 2001 (quoting Program Director JoAnn Davidson), *available at* LEXIS, News Library, National Review File. <sup>25</sup> *Id*.

Davidson calls "80 percent education and 20 percent screening." This includes counseling with social workers on parental responsibilities as well as background checks for credit problems or evidence of criminality or child abuse. Snowflakes even submits prospective parents' fingerprints for FBI clearance.<sup>26</sup>

## B. The Secretary's Advisory Committee on Human Research Protections

The revised charter of the Secretary's Advisory Committee on Human Research Protections, ostensibly aimed at the safety of pregnant women in research trials, is another step in the Bush administration's effort to bring embryos and fetuses "under the umbrella of federal health protections."<sup>27</sup> Although the directive does not immediately afford "human" protection to embryos, it does require the committee to offer recommendations outlining protections for embryos to HHS, which would then issue regulations or promote legislation based on those suggestions.<sup>28</sup> HHS Deputy Assistant Secretary Arthur J. Lawrence stated that the new wording was necessary because more women are included in clinical trials, and there is a possibility such research would harm a developing fetus.<sup>29</sup> This change could herald new restrictions on medical research and infertility treatments, particularly if committee members are opposed to stem cell research and espouse a pro-life philosophy. In fact, members of the old committee were informed that Mildred Jefferson, "a medical director who helped found the National Right to Life Committee and who three times served as that organization's president," is being considered for a position on the committee.<sup>30</sup> Considering that the restriction on federal funding for embryo-harming research requires

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<sup>&</sup>lt;sup>26</sup> Id

<sup>&</sup>lt;sup>27</sup>Rick Weiss, *New Status for Embryos in Research*, THE WASHINGTON POST, Oct. 30, 2002, at A1, *available at* LEXIS, News Library, The Washington Post File.

<sup>&</sup>lt;sup>28</sup> *Id*.

<sup>&</sup>lt;sup>29</sup> *Id*.

<sup>&</sup>lt;sup>30</sup> *Id*.

yearly Congressional approval, restrictions could be tightened further, perhaps with embryos given human status.<sup>31</sup>

# Part II. The Legal Status of Embryos

#### A. Overview

As of today, there is no definitive answer concerning the legal status of the human embryo. State courts have addressed the issue in divorce proceedings with mixed results. State legislatures have adopted regulations concerning fertility clinic contractual procedures. Moreover, a few states have even sought to define the rights of embryos within the IVF context and criminal circumstances. Foreign governments have also attempted to restrict cloning, IVF, and the longevity of embryos in their cryopreserved state. Eventually, the United States Supreme Court will be asked to confront this complex issue.

Typically, IVF clinics require prospective couples to sign consent forms stating the preferred disposition of unused embryos. This has become increasingly important in the context of the possibility of separation and divorce or the abandonment of the embryos. The clinics offer several options for couples regarding surplus embryos: (1) they can be donated for research; (2) they can be destroyed following a clinical protocol; (3) they can be stored indefinitely, with the couple bearing the expense, or; (4) they can be donated to another couple seeking to implant the embryos and become parents to the resulting children.<sup>32</sup>

In resolving subsequent disputes, courts have relied on either contract or property law, or an interim category. Recently, the Tennessee Supreme Court determined that embryos were not mere property, but something in between person and property, and were thus entitled to

 $<sup>^{31}</sup>$  Id

<sup>&</sup>lt;sup>32</sup> Erin P. George, Comment, *The Stem Cell Debate: The Legal, Political and Ethical Issues Surrounding Federal Funding of Scientific Research on Human Embryos*, 12 Alb. L.J. Sci. & Tech. 747, 751-55 (2002).

special respect.<sup>33</sup> This lack of clarity originates in the common law. Historically, embryos and fetuses were not considered persons with legal rights. Birth was the defining event which separated the child from its mother and afforded it rights of its own.<sup>34</sup> Starting in the mid 1970's, many courts and legislatures considered it a crime to kill a fetus, drawing on the groundwork laid by two earlier cases, Scott v. McPheeters, 92 P.2d 678 (Cal. App. Ct. 1939) [holding that late-term fetuses are a separate human being in a case involving injury during premature delivery], and Bonbrest v. Kotz, 65 F.Supp. 138 (D.D.C. 1946) [holding that when a fetus can survive outside the mother, it has the characteristics of a human being].<sup>35</sup>

The United States Supreme Court has addressed the legal status of embryos in the context of abortion. In Roe v. Wade, the Court held that fetuses and embryos are not "persons." Although the fetuses and embryos have some rights to sue for prenatal injuries and wrongful death and limited property rights, a woman's right to an abortion, which relies on her superior right to privacy in the Fourteenth Amendment's Due Process Clause, supercedes a nonviable embryo or fetus' right to life. Then, in Planned Parenthood v. Casey, the Court recognized a state's legitimate interest in protecting prenatal rights, and allowed states to regulate abortion, provided that it does not interfere with a woman's constitutional privilege. On several occasions, the Court has been given the opportunity to rule on the disposition of frozen embryos; however, they have denied certiorari on every occasion, leaving state courts to decide cases in unreliable ways.

## **B.** State Supreme Court Decisions

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<sup>&</sup>lt;sup>33</sup> Davis v. Davis, 1992 Tenn. LEXIS 400; 842 S.W.2d 588, 597 (Tenn. 1992).

<sup>&</sup>lt;sup>34</sup> George, *supra* note 32 at 760.

<sup>&</sup>lt;sup>35</sup> *Id*. at 761.

<sup>&</sup>lt;sup>36</sup>Id. At 762 (citing Roe v. Wade, 410 U.S. 113, 159-60 (1973)). The Supreme Court chose not to decide the issue of when life begins at that time, as medical science had not yet identified the defining moment.

<sup>&</sup>lt;sup>37</sup> *Id.* at 760 (citing Planned Parenthood v. Casey, 505 U.S. 833 (1992)).

<sup>&</sup>lt;sup>38</sup> Lyon, *supra* note 8, at 713 (referring to Stowe v. Davis, 507 U.S. 911 (1993)).

There have been five state Supreme Court decisions regarding the disposition of surplus frozen embryos. Each case has presented a unique set of circumstances and the courts have provided a different rationale for each decision: in Davis v. Davis, 842 S.W.2d 588 (Tenn. 1992), the Tennessee Supreme Court held that the fertility clinic could not be forced to hand over frozen embryos to the ex-wife, as no prior agreement existed between the couple and the clinic; in Kass v. Kass, 696 N.E.2d 174 (Ct. App. N.Y. 1998), the New York Court of Appeals upheld a prior agreement to donate the embryos to the IVF program for research; in A.Z. v. B.Z., 725 N.E.2d 1052 (Mass. 2000), the Massachusetts Supreme Court disallowed a consent form as a binding agreement; in J.B. v. M.B., 783 A.2d 707 (N.J. 2001), the New Jersey Supreme Court refused to force the ex-wife to become a biological parent, despite the ex-husband's contention that they had entered into a separate binding contract to either use the frozen embryos to become pregnant or donate them to an infertile couple; and in the most recent case, Litowitz v. Litowitz, 48 P.3d 261 (Wash. 2002), the Washington Supreme Court upheld a cryopreservation contract in which the frozen embryos, created from the husband's sperm and donor eggs, were to be thawed and prevented from further growth.

The first significant case involving the disposition of surplus frozen embryos was <u>Davis v. Davis.</u> It was a Tennessee case involving an ex-wife who was awarded custody of seven frozen embryos created with her eggs and her ex-husband's sperm. At the trial court level, where it held that the embryos were human beings from the moment of fertilization, her desire was to have the embryos implanted. As the case reached the Tennessee Court of Appeals, both had remarried, and Mary Sue Davis (Stowe) wanted the authority to donate the embryos to another childless couple.<sup>39</sup> Junior Davis, the ex-husband, who prevailed in the

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<sup>&</sup>lt;sup>39</sup> Davis, 842 S.W.2d at 589, 590.

Court of Appeals based on his constitutionally protected right not to procreate, particularly absent a compelling state interest, objected to donation. He wanted the embryos discarded.<sup>40</sup>

The Supreme Court of Tennessee addressed the legal status of the embryos. It stated that the Court of Appeals correctly held that the embryos "cannot be considered 'persons' under Tennessee law." Tennessee statutes and case law do not allow for wrongful death actions for fetuses not born alive, and the Tennessee abortion law incorporates the trimester approach from Roe v. Wade. The Court then considered the chances of the successful implantation of the embryos, and found that they only have a 13-21% chance of achieving implantation, and after that, only a 56-75% chance of being born alive. Conversely, a viable fetus has an excellent chance of being born. Furthermore, the Court feared that allowing the trial court's ruling to stand would vest the embryos with legal interests separate from their gamete providers, and would ultimately outlaw IVF in Tennessee. Relying on the report of the Ethics Committee of the American Fertility Society, the Court concluded that "special respect" must be afforded to the embryo as potential offspring, particularly regarding research and intervention.

<sup>&</sup>lt;sup>40</sup> *Id.* at 590.

<sup>&</sup>lt;sup>41</sup> *Id.* at 594.

<sup>&</sup>lt;sup>42</sup>*Id.* at 594-95. The court was referring to Tenn. Code. Ann. § 20-5-106, denying wrongful death to fetuses not reasonably capable of living outside the uterus, and Tenn. Code Ann. § 39-15-201, which allows a woman and her doctor complete discretion concerning abortion at an approved facility in the second trimester, and during the third, when viability is presumed exist, only to save the life of the mother. Although the legal status of the embryo and fetus may increase, they are not given the legal status of an already born person. The court noted that the concept was given further strength in the murder and assault statutes, Tenn. Code Ann. §§ 39-13-107 and 39-13-210, which make murder or assault on a viable fetus a crime, whereas abortion is not.

<sup>&</sup>lt;sup>43</sup> Davis, 842 S.W.2d at 595 n.19 (citing Eliza Kristine Poole, *Allocation of Decision-Making Rights to Frozen Embryos*, 4 Am. J. FAM. L. 101 n.145 (1990)).

<sup>&</sup>lt;sup>44</sup> *Id.* at 596 (citing The Ethics Committee of the American Fertility Society, *Ethical Considerations of the New Reproductive Technologies*, 46 FERTILITY & STERILITY Supp. 1, 34S-35S (1986)). The court considered the three views of embryo status set forth, then further acknowledged that a person's right to procreate or not was implicated in any decision regarding embryos.

The Tennessee Supreme Court then addressed the contract the couple had signed at the outset of IVF, which failed to include a provision for unused embryos.<sup>45</sup> The Court stated that, "an agreement regarding disposition of any untransferred preembryos in the event of contingencies (such as death of one or more of the parties, divorce, financial reversals, or abandonment of the program) should be presumed valid and should be enforced as between the progenitors."<sup>46</sup> In this case, the Court refused to decide on any implied contract Mary Sue might have relied upon in participating in IVF.<sup>47</sup>

Finally, the Court used a balancing test in considering the two individuals' rights to procreation. If donation was permitted, the Court would impose unwanted fatherhood on the sperm donor, complete with possible financial and psychological burdens. Raised by a single mother, he was vehemently opposed to exposing his child to the same fate. He testified that he would fight for custody of any resulting child(ren), noting that his "procreational autonomy would be defeated and his relationship with his offspring would be prohibited." If the embryos were destroyed, Mary Sue would bear the "burden of knowing that the lengthy IVF procedures she underwent were futile, and that the preembryos to which she contributed genetic material would never become children."

Ultimately, the Court created a rebuttable presumption that the party seeking to avoid procreation should prevail, provided that the other party wishing to procreate had other means available, such as natural pregnancy or further IVF treatments. In this case, where donation

<sup>45</sup> Davis, 842 S.W.2d at 597.

<sup>&</sup>lt;sup>46</sup> Id

<sup>&</sup>lt;sup>47</sup> *Id*. at 598.

<sup>&</sup>lt;sup>48</sup> *Id.* at 603-04.

<sup>&</sup>lt;sup>49</sup> *Id*. at 604.

was the goal, Junior Davis would prevail. Thus, the Knoxville fertility clinic was given permission to dispose of the embryos.<sup>50</sup>

In Kass v. Kass, the Court of Appeals of New York affirmed the appellate court's order to uphold donation of the unused embryos for research on two fundamental issues: "First, a woman's right to privacy and bodily integrity are not implicated before implantation occurs. Second, when parties to an IVF procedure have themselves determined the disposition of any unused fertilized eggs, their agreement should control."51 The former wife, Maureen Kass, appealed the reversal of the trial court order granting her custody of five frozen embryos which she wished to implant into her uterus. Before entering into the IVF program, the couple had signed an informed consent document, unequivocally manifesting their intention to donate unused embryos to the clinic for research purposes in the event of separation.<sup>52</sup> The Court found it imperative to honor choices made by contract so that couples would understand the "seriousness and integrity of the consent process." <sup>53</sup>

The Court resolved an ambiguity noted by the plurality opinion of the appellate division: that ownership of the embryos would be determined in a property settlement. The provision was included in the consent agreement to insulate the IVF clinic from liability, and not to govern proper custody. The Court looked to an uncontested divorce instrument in deciding that "neither party would alone lay claim to possession of the pre-zygotes."<sup>54</sup>

In 2000, the Supreme Judicial Court of Massachusetts upheld a lower court's permanent injunction, prohibiting a former wife from using four frozen embryos for implantation. The

<sup>51</sup> Kass v. Kass, 696 N.E.2d 174, 177 (N.Y. 1998).

<sup>&</sup>lt;sup>50</sup> *Id.* at 605.

<sup>&</sup>lt;sup>53</sup> *Id.* at 180 (referring to an agreement made by the parties which stated that, in the event the couple was unable to make a mutual decision regarding the disposition of the frozen embryos, the IVF program could dispose of them for biological studies and dispose of them for approved research studies).

<sup>&</sup>lt;sup>54</sup> *Id.* at 181-82.

couple had signed consent forms prior to egg retrieval, in which they had agreed to "have the embryos returned to the wife for implant," in the event of separation.<sup>55</sup> However, the husband had signed blank forms, with the wife filling in the dispositions and then signing the forms herself. The probate judge concluded that equity required that the agreements be held unenforceable in light of a change in circumstances, the birth of twins and the divorce. The best solution was to balance the wife's desire for procreation against the husband's interest in avoiding it and its attending responsibilities, both real and psychological.<sup>56</sup> In this case, the husband's interest outweighed his wife's.

The Supreme Judicial Court of Massachusetts cited both the Tennessee and New York decisions, but offered its own analysis for these unique circumstances. In upholding the lower court decision, the Court determined that: (1) the consent forms were intended to explain benefits and risks, and not to act as binding agreements; (2) because there was no duration provision in the consent form, it could not be assumed it would be operative four years after execution, and; (3) because the form addressed "separation" and not "divorce," which legally ends a marriage and precipitates changes by operation of law, it could not govern.<sup>57</sup> Furthermore, it would be against public policy to "compel one donor to become a parent against his or her will."

In <u>J.B. v. M.B.</u>, the Supreme Court of New Jersey once again addressed the problem of "advances in medical technology that have far outstripped the development of legal principles to resolve the inevitable disputes arising out of the new reproductive opportunities now

 $<sup>^{55}</sup>$  A.Z. v. B.Z., 725 N.E.2d 1051, 1053-54 (Mass. 2000) (citing No. 95-1683, Suffolk Co. Prob. Ct., May 14, 1996).  $^{56}$  A.Z. v. B.Z., 725 N.E. 2d at 1055.

<sup>&</sup>lt;sup>57</sup> *Id.* at 1056-57.

<sup>&</sup>lt;sup>58</sup> *Id.* at 1057-58.

available."<sup>59</sup> In this case, the ex-husband appealed the decision to allow the destruction of eleven pre embryos. Because they had signed an agreement relinquishing "control, direction, and ownership" of the embryos to the clinic in the event of a divorce, unless a court specifies otherwise, the Court once again followed a balancing test.<sup>60</sup> Agreeing with the Tennessee Supreme Court's decision in <u>Davis v. Davis</u>, and noting that the husband was not infertile and could achieve parenthood by natural means, the Court adopted a rule to "enforce agreements entered into at the time in vitro fertilization is begun, subject to the right of either party to change his or her mind about disposition up to the point of use or destruction of any stored pre embryos."<sup>61</sup>

The New Jersey Court rejected two of the husband's arguments: (1) that the couple had undertaken the IVF procedure to "create life," and; (2) that his constitutional rights outweighed his ex-wife's right not to procreate because "her right to bodily integrity is not implicated, as it would be in a case involving abortion." The Court agreed with the lower courts' assessment that an agreement to procreate and compel parenthood would be against public policy. However, although the party wishing to avoid parenthood would normally prevail, the Court emphasized the necessity of evaluating the interests of both parties on a case by case basis, and expressed no opinion "in respect of a case in which a party who has become infertile seeks use of stored pre embryos against the wishes of his or her partner."

<sup>&</sup>lt;sup>59</sup> J.B. v. M.B., 783 A.2d 707, 715 (N.J. 2001).

<sup>&</sup>lt;sup>60</sup> *Id.* at 710

<sup>&</sup>lt;sup>61</sup> *Id*. at 719.

<sup>&</sup>lt;sup>62</sup> *Id.* at 711-12.

<sup>&</sup>lt;sup>63</sup> *Id.* at 717; *see also* J.B. v. M.B., 751 A.2d 613, 619 (N.J. Super. Ct. App. Div. 2000). The court also acknowledged its agreement with the Massachusetts Supreme Court in A.Z. v. B.Z., *supra* note 55, stating that to force implantation would be similar to enforcing marriage contracts or forcing someone to give up a child for adoption prior to the fourth day after birth.

<sup>&</sup>lt;sup>64</sup> J.B. v. M.B., 783 A.2d at 720.

Eric Spevak, attorney for the ex-husband, defendant-appellant M.B., commented in an interview following the ruling:

> The bottom line is that there are certain circumstances that, in a situation where people do change their mind, even in an agreement, if, for example, in my case, if my client was sterile and was unable to have children, the state Supreme Court in New Jersey, one of the most well respected courts in the country, perhaps would have rules based on the dicta in the case, that he could have had the embryos to himself and implanted.<sup>65</sup>

The most recent case addressing the disposition of unused frozen embryos was from the state of Washington. In Litowitz v. Litowitz, the Supreme Court of Washington considered whether a contractual agreement stating that "pre embryos be thawed but not allowed to undergo further development" would be honored. 66 The petitioner, Becky Litowitz, was not a progenitor, although her ex-husband, David Litowitz was. According to the "egg donor" agreement, the eggs were "the property of the Intended Parents and as such, the Intended Parents shall have the sole right to determine the disposition of said eggs."<sup>67</sup> The Court found that the "egg donor" agreement afforded her equal rights to the eggs, but that it did not relate to the resulting two pre-embryos.<sup>68</sup>

The Court, focusing on contract law, looked to the intent of the parties, and found that they had unequivocally chosen the option to thaw the embryos and prevent further development. It refused to entertain a discussion of whether the correct term was "child" instead of "embryo," in spite of Becky Litowitz's claim that she had a constitutional right to

<sup>&</sup>lt;sup>65</sup> Eric Spevak, Fox News: Edge with Paula Zahn, August 15, 2001, available at 2001 WL 5895729.

<sup>66</sup> Litowitz v. Litowitz, 48 P.3d 261, 264 (Wash. 2002).

<sup>&</sup>lt;sup>68</sup> *Id.* at 268.

custody.<sup>69</sup> Colleen Grady, her attorney, was disappointed that the Court shirked its responsibility in sidestepping the question of whether the embryos were "children," but Lisa Stone, executive director of the Northwest Women's Law Center, was gratified that Becky Litowitz was given equal rights.<sup>70</sup>

Contract law dominated the five state Supreme Court cases, with the Washington Supreme Court in Litowitz v. Litowitz being the only body refusing to examine the issues of the legal status of the embryo or custodial preferences. In affirming the order of the Appellate Court, the Court of Appeals of New York upheld the prior agreement in Kass v. Kass. In Kass, the Court noted, "a woman's right to privacy and bodily integrity are not implicated before implantation occurs." Although the decision worked to deny implantation and further development of the embryos, the Court's reasoning could endorse mandatory adoption of unused frozen embryos, possibly the next step to the adoption programs funded by the HHS grants.

The Supreme Court of Tennessee was the first to use a balancing test in determining a rebuttable presumption that the party seeking to prevent procreation should prevail.<sup>73</sup> However, it left the door open for compulsory procreation in cases where the petitioning party possessed no other means to achieve parenthood.<sup>74</sup> Although both the Supreme Judicial

<sup>&</sup>lt;sup>69</sup> *Id.* at 269. The court stated that it was not a relevant inquiry, and that there was not sufficient authority to substantiate her claim. "It is not necessary for this court to engage in legal, medical or philosophical discussion whether the preembryos in this case are 'children," nor whether Petitioner (who was not a biological participant) is a progenitor as is Respondent (who was a biological participant). We base our decision in this case solely upon the contractual rights of the parties...." *Id.* at 271. The trial court, on the other hand, adopted the "best interests of the child" criterion. *Id.* at 272 (Sanders, J., dissenting).

<sup>&</sup>lt;sup>70</sup> Carol M. Ostrom, *Destroy Frozen Embryos; State's Justices Base Ruling on Contract*, THE SEATTLE TIMES, June 14, 2002, at A1. *See also* Sarah Duran, *Court sticks to contract in 'pre-embryos' ruling*, The News Tribune, June 14, 2002, at A1; David Eggert, 'Best Interests of the Child' Key to Embryo Ruling; Husband Urged Adoption; Wife Wanted the Children, but the Contract Had Expired, Seattle Post-Intelligencer, June 15, 2002, at B2.

<sup>&</sup>lt;sup>71</sup> See Litowitz, supra note 66, at 269.

<sup>&</sup>lt;sup>72</sup> See Kass v. Kass, supra note 51, at 177.

<sup>&</sup>lt;sup>73</sup> Davis v. Davis, *supra* note 33, at 605.

<sup>&</sup>lt;sup>74</sup> *Id*.

Court of Massachusetts and the New Jersey Supreme Court each cited <u>Davis v. Davis</u> for the use of the balancing test, only the New Jersey Court entertained possible reversal of the rebuttable presumption on a case-by-case basis.<sup>75</sup> Nonetheless, both the New Jersey and Massachusetts courts noted that it would be against public policy to compel parenthood, despite possible changes in circumstances of the gamete providers, and even with a prior valid agreement in place.<sup>76</sup>

Ultimately, each court confined its decision to the narrow issues presented. By focusing mainly on whether prior agreements existed, or whether the agreements in existence were valid, they sidestepped the broader issues of the legal status of the frozen embryos, the rights of the gamete providers, and the intended parents rights to force procreation on the other parent. Although public policy would weigh heavily against forced procreation, many doors were left open. There appears to be overwhelming public support for the public awareness adoption program. Eventually, if the public awareness adoption program proves successful, these open doors, coupled with scientific developments further separating gamete providers from the very process of implantation and gestation, could lead mandatory procreation not only in the IVF sphere, but regarding abortion as well.

### C. State Statutes

Currently, only a minority of states have statutes regarding the disposition of frozen embryos. Florida emphasizes the contractual approach by requiring couples and their physicians to enter into a written agreement covering the possibilities of divorce, death, or unforeseen circumstances.<sup>77</sup> It allows for the destruction of embryos. If a written agreement

<sup>75</sup> See J.B. v. M.B., supra note 59, at 719-20.

<sup>&</sup>lt;sup>76</sup> *Id. See also* A.Z. v. B.Z., *supra* note 55, at 1057-58.

<sup>&</sup>lt;sup>77</sup> Fla. Stat. Ann. 742.17 (West 2001).

does not exist, custody of the gametes remains with the providers. Florida is the only state that has passed legislation recognizing the validity of the agreements.<sup>78</sup>

Louisiana and New Mexico have the most restrictive laws regarding frozen embryos. Louisiana requires implantation of all embryos created by IVF, finding that they are juridical persons which shall not be intentionally destroyed by either their gamete providers or the IVF clinics that created them.<sup>79</sup> Moreover, the embryo is not the property of the gamete providers, IVF physicians, or clinic. If the couple relinquishes parental rights prior to implantation, the embryo must be made available for adoption. The result is that it may deter physicians from offering the most basic IVF procedures to couples, out of fear of future prosecution for not implanting the embryos because of health risks to the mother, who does not wish to offer the embryos for adoption.<sup>80</sup> New Mexico does not define the embryos as persons with separate legal rights, but does require implantation of all IVF-created embryos.<sup>81</sup> It states that a fetus, the product of conception until birth, cannot be subject to anything that places it at risk unless it serves the health needs of the fetus and the risk is minimal.<sup>82</sup> Both of these statutes deprive the procreative rights of IVF participants without sufficient state interest.<sup>83</sup>

Illinois, Kentucky, and Michigan have all passed legislation dealing with the experimentation and destruction of embryos created through IVF. The Illinois statute prohibits the sale of or experimentation on a human embryo unless it is therapeutic.<sup>84</sup>

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<sup>&</sup>lt;sup>78</sup> Carl H. Coleman, *Procreative Liberty and Contemporaneous Choice: An Inalienable Rights Approach to Frozen Embryo Disputes*, 84 MINN. L. REV. 55, 66 (1999).

<sup>&</sup>lt;sup>79</sup>La. Rev. Stat Ann. § 9:129 (West 2002).

<sup>&</sup>lt;sup>80</sup> Diane K. Yang, What's Mine is Mine, But What's Yours Should Also Be Mine: An Analysis of State Statutes That Mandate the Implantation of Frozen Pre Embryos, 10 J.L & Pol'y 587, 615 (2002).

<sup>81</sup> N.M. STAT. ANN. § 24-9A-[1]-[7] (Michie 2001).

<sup>&</sup>lt;sup>32</sup> *Id*. at [1][g].

<sup>83</sup> See generally Kramer v. Union Free Dist., 395 U.S. 621, 627 (1969).

<sup>&</sup>lt;sup>84</sup> 720 ILL. COMP. STAT. § 510/6(7) (2001).

Kentucky forbids the use of public funds for IVF treatments that will result in the intentional destruction of human embryos. Michigan law permits "experimentation only if it does not pose any increased risks to the embryo."

Pennsylvania and New Hampshire have procedural regulations that do not address the sensitive issues of when life begins and intentional destruction of embryos. New Hampshire requires medical exams and counseling for the gamete providers prior to IVF. It also mandates that embryos must be implanted, discarded, or otherwise used within fourteen days of being thawed, and the judicial pre-authorization of all written consent agreements. Pennsylvania has only IVF reporting requirements, dealing with procedures, numbers if participants, pregnancy rates, and use of spare embryos. 88

The Louisiana and New Mexico statutes are the most closely aligned with the new charter of the Secretary's Advisory Committee on Human Research Protections. While they both require the implantation of all IVF-created embryos, mirroring the HHS adoption program, New Mexico's statute is almost a verbatim directive to the federal mandate restricting research or medical procedures that would harm a developing fetus. They would both require minimizing the risk and serving the needs of the individual fetus.<sup>89</sup>

However, Illinois, Kentucky, and Michigan have also passed strict laws regulating forbidding the sale of or experimentation on human embryos, with Kentucky refusing public funds for any IVF treatments that will not result in pregnancy.<sup>90</sup> These statutes demonstrate the wide public support for the current Bush Administration's decision to revise the

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<sup>85</sup> Ky. Rev. Stat. Ann. § 311.715 (Banks-Baldwin 2001).

<sup>&</sup>lt;sup>86</sup> MICH. COMP. LAWS ANN. § 333.2685 (West 2002).

<sup>&</sup>lt;sup>87</sup> N.H. REV. STAT. ANN. § 168-B:1, B:13-14 (2001).

<sup>&</sup>lt;sup>88</sup> 18 PA. STAT. ANN. § 3213 (West 2003).

<sup>&</sup>lt;sup>89</sup> See generally American Political Network, supra note 1; N.M. Stat. Ann. § 24-9a-1-[1]-[7] (Michie 2001), supra note 81.

<sup>&</sup>lt;sup>90</sup>720 ILL. COMP. STAT. § 51016(7) (2003), *supra* note 84; KY. REV. STAT. ANN. § 311.715 (Banks-Baldwin 2001), *supra* note 85; MICH. COMP. LAWS ANN. § 333.2685 (LexisNexis 2002), *supra* note 86.

Committee's charter to include protections for the unborn, and for the subsequent decision to limit federal funding for stem cell research in August, 2001.<sup>91</sup> Once again, if enough states follow this trend, public policy could change, allowing further restrictions and possible bans on all embryonic research and non-life-saving abortion procedures.

#### **D.** Other Countries

Of the countries mandating the fate of unused frozen embryos, Britain has the most rigorous laws. In 1991, the British Parliament enacted the British Human Fertilisation and Embryology Act, which required embryos stored longer than five years to be removed from their liquid nitrogen containers, placed in a solution of vinegar and alcohol, and destroyed. This measure was enacted to prevent the accumulation of frozen embryos. The original destruction date was July 31, 1996, at which time 3,300 surplus embryos were destroyed. Prior to the destruction of the embryos, couples and the sixty-one clinics in Britain are notified of the impending deadline. The patients are then asked whether they would like to continue storage, donate them for research or implantation by another couple, or have them discarded. The patients are the sixty-one clinics in Britain are discarded.

One of the resulting problems concerned foreigners who had stored their embryos in the 1980's and were unaware of the passage of the law. Clinics faced the dilemma of destroying the embryos without proper notification and authorization from the donors. Also, anonymous

<sup>&</sup>lt;sup>91</sup> Carly Goldstein, *Dipping Into Uncle Sam's Pockets: Federal Funding of Stem Cell Research: Is It Legal?*, 11 B.U. INT. L.J. 229 (2002). Funding for stem cell research will be discussed further in Federal Regulations.

<sup>&</sup>lt;sup>92</sup> George, *supra* note 32 at 752; *See also* LORI B. ANDERSON, THE CLONE AGE: ADVENTURES IN THE NEW WORLD OF REPRODUCTIVE TECHNOLOGY 69 (1999). The law was later amended in May 1996 to allow continued storage if both "parents" consent, *id.* at 69; but in no event is storage to continue past the woman's fifty-fifth birthday. George, *supra* note 32, at 752.

<sup>&</sup>lt;sup>93</sup> ANDREWS, supra note 92, at 96. Physicians who fail to destroy the embryos according to the deadlines and guidelines can be fined, jailed, or both.

sperm donors could not be contacted, forcing the woman to either have them implanted immediately or have them discarded. 94

The Vatican condemned the British order for mass destruction of the stored embryos, calling it "prenatal massacre." They called upon married Italian women to volunteer to bring the embryos to term through adoption, similar to taking in an orphan or abandoned child. Over one hundred women volunteered, including two elderly nuns. 96

France, Australia, and Canada have laws requiring the destruction of embryos stored past five years. Australia allows implantation into another woman if there is no written objection by the donor. Much of the responsibility for the disposition of frozen embryos in France is placed with the fertility clinic. Couples are required to undergo pre-treatment evaluations, and must possess certain social and psychological traits. Because the reproductive act is displaced from the private sphere into the laboratory, and the network of participants is broadened, a dilemma concerning the gamete providers' rights over the embryos has emerged. One controversial case in France involved a 37-year old woman who had suffered the miscarriage of twins created through IVF. Her husband was killed in an automobile accident on his way to the hospital, and the woman wanted to implant the two remaining embryos. The hospital refused, and the court upheld the decision, based on a "bioethics" bill restricting IVF to heterosexual couples with infertility problems, and requiring both partners to be alive and consenting to the transfer or insemination.

<sup>&</sup>lt;sup>94</sup> ANDREWS, *supra* note 92, at 70-71.

<sup>&</sup>lt;sup>95</sup> Id. at 71. See also George, supra note 32, at 752 (citing Heidi Forster, The Legal and Ethical Debate Surrounding the Storage and Destruction of Frozen Human Embryos: A Reaction to the Mass Disposal in Britain and the Lack of Law in the United States, 76 WASH. U.L.Q. 759,764 (1998)).

<sup>&</sup>lt;sup>96</sup> ANDREWS, *supra* note 92, at 71.

<sup>&</sup>lt;sup>97</sup> George, *supra* note 32, at 752.

<sup>&</sup>lt;sup>98</sup> SIMONE BATEMAN NOVAES AND TANIA SALEM, *Embedding the Embryo*, THE FUTURE OF HUMAN REPRODUCTION: ETHICS, CHOICE, AND REGULATION 104 (John Harris and Soren Holmes, eds., 1998).

<sup>&</sup>lt;sup>99</sup> *Id.* at 103-03 (citing Jugement du 11 mai 1993, Tribunal de Grande Instance de Toulouse, Premiere Chambre).

The Netherlands and Germany store frozen embryos indefinitely. In fact, the German Research Association intends to import human embryo stem cells from the United States because Germany has strict laws banning the killing of human embryos for research. Oddly enough, the importation of stem cells is not illegal in Germany. 101

England, France, Canada and Australia take a very pragmatic approach the problem of unused frozen embryos, requiring destruction after a definite number of years and allowing experimentation and donative implantation absent specific instructions from the gamete providers. Germany is the least decisive and most closely paralleled to the ongoing debate in the United States. On the one hand, the German government stores the frozen embryos indefinitely and bans the killing of them for research purposes; on the other hand, the government wants to reap the possible benefits of embryonic research, and allows stem cell importation. This dichotomy was also apparent when Senator Specter successfully inserted the embryo adoption program grants into the spending bill. While he wanted to acknowledge the current President Bush's concern for embryo destruction in creating stem cell lines, he also wanted to preserve the possibility for future benefits for millions of Americans suffering from the targeted diseases thought to be effected by stem cell developments. 103

### E. Federal Regulations

Federal regulation deals mainly with reporting statistics of IVF success rates, in response to consumer concerns over exaggerations of pregnancy success rates. President Ronald Reagan placed a moratorium on federal funding for human embryo research in the 1980's,

<sup>&</sup>lt;sup>100</sup> George, *supra* note 32, at 752-53..

<sup>&</sup>lt;sup>101</sup> *Id.* (citing *Importing Stem Cells*, CHEMISTRY AND INDUSTRY, July 10, 2000, at 425).

<sup>&</sup>lt;sup>102</sup> George, *supra* note 32, at 753.

<sup>&</sup>lt;sup>103</sup> 147 CONG REC S 12024 (Nov. 27, 2001) (statement of Sen. Specter).

which lasted past the first Bush Administration.<sup>104</sup> Congress passed the Fertility Clinic Success Rate and Certification Act in 1992, which required clinics to report annually its pregnancy rates, and authorized the Center for Disease Control to develop and oversee staterun certification of IVF facilities.<sup>105</sup> Then, in 1996, Congress passed the Dickey Amendment, Jay Dickey (R. Ark.), which banned the use of federal funds for research requiring the destruction of embryos or subjecting them to possible death or injury.<sup>106</sup>

Currently there is a ban on using federal funds for embryonic research that "harms, destroys, discards or knowingly subjects to risk of injury or death, a human embryo." However, the National Institutes of Health (NIH) organized the Human Pluripotent Stem Cell Review Group (HPSCRG) to distinguish stem cells derived for research and those taken from embryos already destroyed or fetal tissue, noting that the cells themselves are not embryos. According to scientists, there are three different kinds of stem cells: totipotent, pluripotent, and multipotent. The totipotent cell has the ability to become any cell in the body. With its ability to form extra-embryonic membranes and supportive tissue, it can develop into a

<sup>&</sup>lt;sup>104</sup> Goldstein, *supra* note 91. at 237.

<sup>&</sup>lt;sup>105</sup> Yang, *supra* note 80 at 613 (citing 42 U.S.C. 263 (2001). The House report states that the act provides "the public with comparable information on the effectiveness of infertility services and to assure the quality of these services by providing for the certification of embryo laboratories." H.R. REP. No. 102-1096, at 26 (1992). <sup>106</sup> Goldstein, *supra* note 91, at 238. The Clinton administration called for federal funding of research on fetal tissue, but Congress launched a bitter campaign against it. Despite the Dickey Amendment, Pub. L. No. 106-113, 113 Stat. 1501 (1999), NIH guidelines allowed government funded scientists to research stem cells, because they had separated themselves from the destruction of the embryos accomplished in privately owned clinics. *Id.* at

<sup>&</sup>lt;sup>107</sup> George, *supra* note 32 at 764, (citing Departments of Labor, Health and Human Services and Education and Related Agencies Appropriations Act of 1998, 513 Pub. L. No. 105-78, 1997 U.S.C.C.A.N. (111 Stat.) 1467,1517). <sup>108</sup> *Id.* at 778-80. The guidelines do not restrict private institutions, unless they seek public grant money. Only embryos created for reproduction can be used, and this must be able to be documented. The donation of the embryos must be voluntary, and no financial incentives are permitted. If the available embryo is the result of an abortion, the decision to abort must have been made prior to the donation discussion. Informed consent of all of the possible uses of the embryo is required. In order to insure that the embryos are excess strictly from reproductive services, the physician handling the infertility treatment cannot be the same stem cell researcher, thus prohibiting the creation of embryos through "somatic cell nuclear transfer," or cloning. *Id*.

full human being as well.<sup>110</sup> The pluripotent cell, which is the subject of stem cell research, has the ability to develop into any tissue or organ in the body, but lacks the ability to become a fully functioning organism. They appear about four days following fertilization, during the blastocyst stage.<sup>111</sup> Finally, the multipotent cells are already specialized and can only further develop into certain tissues, such as bone, blood, muscle, etc.<sup>112</sup>

Until August 9, 2001, when President Bush allowed "limited research" on 64 previously existing stem cell lines from privately developed embryos, NIH guidelines allowed for considerable leeway. Now, federal funds will only be used for research on existing stem cell lines that were derived: (1) with informed donor consent; (2) from excess embryos created solely for reproductive purposes; and (3) without financial inducements for the gamete providers. No federal funds will be used for acquiring stem cell lines from newly destroyed embryos, the creation of human embryos for research, or the cloning of human embryos. Bush's decision, appearing to be a political compromise, may impede research. Critics argue that at least 200 stem cell lines are needed for adequate study, and private ownership rights will impede progress. On the other hand, opponents of stem cell research say the decision does not go far enough and they are attempting to prevent federal tax dollars from subsidizing research programs. 115

<sup>&</sup>lt;sup>110</sup> George, *supra* note 32, at 756-57.

<sup>&</sup>lt;sup>111</sup> *Id.* at 757; *See also* Goldstein, *supra* note 91, at 232. If placed in a Petri dish with the right environment, pluripotent cells will divide indefinitely, creating hundreds or thousands of cells. Scientists hope to cultivate stem cells into healthy tissues and organs, possibly curing diseases such as Alzheimer's, spinal cord injuries, diabetes, and Multiple Sclerosis. *Id.* (citing Nat'l Inst. Of Health, Stem Cells: A Primer (May 2000) <a href="http://www.nih.gov/news/stemcell/primer.htm">http://www.nih.gov/news/stemcell/primer.htm</a>.

<sup>&</sup>lt;sup>112</sup> See George, supra note 32, at 757.

<sup>&</sup>lt;sup>113</sup> *Id.* at 804. A stem cell line is taken from the embryo, placed in a test tube, and allowed to continue growth in the test tube.

<sup>114</sup> *Id.* 

<sup>&</sup>lt;sup>115</sup> Goldstein, *supra* note 91, at 242. Some members of Congress, particularly Senator Sam Brownback (R. Kans.), are urging further limitations on stem cell research, comparing it to "Nazi experiments on concentration camp prisoners during World War II." Others, most notably Senator Arlen Specter (R. Pa.), want research funding expanded under controlled circumstances, using left over embryos. *Id.* at 244. In requesting increased funding for

The embryo adoption program and the forthcoming HHS regulations regarding protection of embryos used in medical procedures do not, in themselves, threaten the future of IVF or embryonic research. At this point, a pluripotent cell does not qualify as a "person," entitled to the protection of the Fourteenth Amendment Due Process Clause. However, looming advances in medical technology may redefine "viability," affording embryos inside and outside a mother's womb the protections determined in <u>Roe v. Wade</u> and subsequent decisions. <sup>116</sup>

# Part III. Emerging Technology

## A. The Technology of Pregnancy

In a sense, biotechnological advances, which include a myriad of scientific curiosity, huge amounts of private capital, and a desire to transcend our human limitations, propel us toward a post-human society. It seems that once medical research creates an ethical dilemma, it will not be too long before it offers new technologies to solve it. We must ask ourselves, how many times can we resolve these problems and still remain human?<sup>117</sup> On the one hand, the American tradition is one that acknowledges an individual's right to obtain a better life; on the other hand, we are uneasy with new medical technologies that afford us our goals, while

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NIH, Senator Specter lauded the efforts made in stem cell research, and reiterated that if embryos earmarked for destruction could be used for life-saving research, "it seems to me the choice is clear: To use them to save lives....With the sequencing of the human genome, we will begin, over the next few years, to reap the benefits in many fields of research. And if the scientists are correct, stem cell research could result in a veritable foundation of youth by replacing diseased or damaged cells. I anxiously await the results of all of these avenues of remarkable research. This is the time to seize the scientific opportunities that lie before us." 148 CONG. REC. S 10729,10731 (2002).

Goldstein, *supra* note 91, at 247. In <u>Keith v. Daley</u>, 764 F.2d 1265 (1985), denied a pro-life organization's right to adopt fetuses that had survived abortions, stating there was no "direct or substantial interest" for the state to intervene as of right. The state could not assert a legitimate interest in protecting the fetus until the point of viability, when it would be capable of meaningful life outside of the womb. *Id*.

<sup>&</sup>lt;sup>117</sup> Simon Cooper, *The Small Matter of Our Humanity*, ARENA MAGAZINE, June 1 2002.

removing our bodies from the processes of life, health, and death.<sup>118</sup> Medical and technological advances in the field of procreation dominates the debate over where life begins and what protections it should be afforded.

Ultrasound, amniocentesis, and fetal surgery have promoted the representation of the embryo and the fetus as separate beings, distinguishable from the pregnant woman, such that they are already considered "second patients" for monitoring and surgery prior to birth. In fact, "the technology of pregnancy that we as a civilization have developed is a technology of separation and individuation- the technology is geared to recognizing the fetus as separate from the mother. Privileged technical access has given physicians a basis for claiming the right to speak on the embryo's behalf. IVF has removed from the woman the privileged position of being the center of conception. It replaces the idea of inseparability between the embryo and the mother's womb with physically discrete independence until implantation.

Perhaps the strongest debate occurs over the moral status of the developing embryo prior to and just after implantation. Up to the four-cell stage, when most embryos are frozen and stored for later use, the cells are both totipotent and pluripotent; that is, they are all capable of forming the fetus and placenta and, given the right conditions, each will begin to divide and result in a further embryo which is identical to the first. Because individual rights presuppose individuation and differentiation, one reading of these biological facts leads to the opinion that an embryo lacks "personhood" prior to implantation or prior to the appearance of the

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<sup>&</sup>lt;sup>118</sup> *Id*.

<sup>&</sup>lt;sup>119</sup> Novaes, *supra* note 98, at 110.

<sup>&</sup>lt;sup>120</sup> *Id.* quoting Barbara Katz Rothman, The Tentative Pregnancy: Prenatal Diagnosis and the Future of Motherhood, at 114 (1987).

<sup>&</sup>lt;sup>121</sup> NovAES, *supra* note 98, at 121.

<sup>&</sup>lt;sup>122</sup> *Id.* at 111.

"primitive streak" at approximately fourteen days. At this stage, there is neither the manifest ability for individuality or reasoning. However, because there is still the potential for these, it is argued that these embryos should be treated with "profound respect," as echoed by the Supreme Court of Tennessee. 124

## **B.** The Development of Artificial Wombs

There has been significant progress in the development of artificial wombs in the United States and Japan. In 1997, Japanese researcher Yoshinori Kuwabara announced that he was close to developing "ectogenisis," a clear plastic box of warm amniotic fluid. In his process, the fetus is attached to a dialysis machine for oxygen replacement and blood cleansing. His device has only been tried on goats, by removing the fetuses from their mothers' wombs three weeks before their due date and placing them into the "womb" until they are removed, or "born." The goats have been successfully nourished for up to ten days, although they suffered from anemia, much like the clones in Aldous Huxley's *Brave New World*. In 1998, a Japanese biotechnology company started a program to grow cows outside the womb, by taking cells and placentas of cows and growing them into genetically enhanced placenta. Although they intend to implant the placentas into cows to limit the possibility of miscarriages, eventually they plan to create an independent gestational device. 1226

In the United States, Dr. Hung-Ching Liu of Cornell University has been implanting living human embryos left over from IVF treatments onto an artificial womb wall. The wall is made from cells extracted from women's wombs, cultured in serums of growth factors and

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<sup>126</sup> *Id*.

<sup>&</sup>lt;sup>123</sup> Knut W. Ruyter, *Embryos as Moral Subjects and Limits of Responsibility, in* Conceiving the Embryo: Ethics, Law and Practice in Human Embryology 179 (Donald Evans, ed., 1996). The primitive streak heralds the formation of the brain and nervous system, and roughly corresponds to the last opportunity for twinning. *Id.*<sup>124</sup> *Id.* (citing Department of Health and Social Security, *Report of the Committee of Inquiry into Human Fertilisation and Embryology (The Warnock Report)*, HER MAJESTY'S STATIONARY OFFICE 27, 63 (1984)).
<sup>125</sup> Andrews, *supra* note 92, at 73. *See also* Celeste McGovern, *A Womb With a View*, Report Newsmagazine, March 4, 2002.

hormones, and growing on a "biodegradable scaffold modeled on the shape of a uterus." Although she halted the experiment at ten days, she plans to continue further studies up to the fourteen days of experimentation on living human beings prescribed by the IVF industry. She is hoping that the embryos will put down roots and veins into the womb's walls, differentiating into primitive organs and a primitive placenta. According to Dr. Liu, her hope is that the research will afford women with damaged uteruses the opportunity to have their own babies in their own wombs. 129

Researchers are excited at the prospect that human embryos, conceived through IVF and/or washed from a woman's uterus, could be implanted into an artificial womb, where it will develop until term, and "birth." Some feminists, who consider pregnancy "barbaric," are happy as well. Shulamith Firestone, an active feminist from the 1970's, hailed the artificial womb as the "only way to give women true equality- with the added benefit of making men entirely useless." <sup>131</sup>

## C. The "Cloning of the Human Embryo" Issue in Congress

On February 24, 1997, a Scottish research team announced that it had cloned a sheep named "Dolly", using "somatic cell nuclear transfer" (SCNT).<sup>132</sup> This sparked an ongoing debate over the creation of human embryos using SCNT, which initially culminated in House Bill 2505, The Human Cloning Prohibition Act of 2001, passed by a 265 to 162 vote.<sup>133</sup> The bill included severe restrictions and punishments for scientists using SCNT to create human

<sup>&</sup>lt;sup>127</sup> McGovern, *supra* note 125.

<sup>&</sup>lt;sup>128</sup> *Id*.

<sup>&</sup>lt;sup>129</sup> *Id*.

<sup>&</sup>lt;sup>130</sup> ANDREWS, *supra* note 92, at 73.

<sup>&</sup>lt;sup>131</sup>McGovern, *supra* note 125.

<sup>&</sup>lt;sup>132</sup> Jonathan S. Swartz, *The Human Cloning Prohibition Act of 2001: Vagueness and Federalism*, 43 JURIMETRICS J. 79,79 (2002), (citing I. Wilmut, *Viable Offspring Derived From Fetal and Adult Mammalian Cells*, 385 NATURE 810 (1997)). Cloning involves taking the nucleus with full DNA composition from an adult cell and inserting it into an egg that has had its nucleus removed, thus creating a zygote. The process is similar to IVF. *Id.* at 81-82. <sup>133</sup> *Id.* at 79-80, (citing 147 CONG. REC. H4916, H4945 (daily ed. July 31, 2001)).

embryos for research and therapeutic purposes associated with stem cells. <sup>134</sup> The bill requires the General Accounting Office to explore: (a) new developments in SCNT cloning; (b) any potential necessity for using SCNT for medical advances; (c) emerging public attitudes and ethical considerations; and (d) legal implications of SCNT research, to assess the need to amend the Act within four years. 135 The Senate did not pass the bill in large part because it does not want to fully foreclose therapeutic cloning; consequently, the debate continues.

In June 2002, Senator Landrieu (D. La.) urged that a line be drawn on the issue of human cloning "until we can make a better determination about the risks and benefits associated with human cloning; that is, to stop the process before it begins."<sup>136</sup> While rebuking cloning proponents Kennedy (D. Mass.), Feinstein (D. Ca.), and Specter (R. Pa.) for attempting to draw a distinction between human cloning and therapeutic, reproductive, or somatic cell nuclear transfer, Landrieu warned that the Senate was on a "very slippery slope" that would result in the harvesting and destruction of human embryos in labs all around the country. 137 She feared that it would inevitably lead some scientist, patient, woman, or couple to cross the boundary suggested by the definitional limitations, implant a "legal" clone, and bring a cloned human being to term. 138

Landrieu feared that to jump into human cloning before reaching a consensus on stem cell research regarding unused IVF embryos would be perilous. Conceding that the rejection

<sup>134</sup> Id. at 80. Penalties include up to ten years in prison and, if there is a monetary gain, a fine of at least one million dollars. Persons transporting or importing created embryos will be subject to the same punishment. Id. at 81. <sup>135</sup> *Id.* at 82, (citing H.R. 2505, 107<sup>th</sup> Cong. § 2(b) (2001).

<sup>&</sup>lt;sup>136</sup> 148 CONG. REC. S 5659-01, 5660 (June 18, 2002).

<sup>&</sup>lt;sup>137</sup> Id. See also Charles Krauthammer, Research Cloning? No., WASH. POST. May 10, 2002, at A37. The author is concerned that human embryos will be dismembered and used for their parts. *Id.* 

<sup>&</sup>lt;sup>138</sup> 148 CONG. REC., at S5660. In fact, Clonaid, associated with a French-based UFO sect, the International Raelian Religion, announced on December 27, 2002, that "Eve," the first cloned human baby, was born to her thirty-one year old American mother, somewhere in the Bahamas. They claim to have four other pregnancies in progress, and twenty more volunteers lined up for January, 2003. There has been no verification. Severino Antinori, an Italian fertility expert who successfully impregnated a sixty-two year old Italian woman in 1993, has reported at least three clone pregnancies; and Panos Zavos, a Kentucky fertility expert, claims to have successfully implanted three human clones. Mike Toner, Clone Claim Meets Skepticism, Cox News Serv., Dec. 27, 2002.

issue often accompanying transplantation might tip the scales in favor of human cloning if no other method of saving lives is available, she said ethical considerations when saving a particular individual might outweigh concerns for creating life expressly to destroy it. However, she urged that scientific and medical technology is nowhere near that point. She urged the Senate to use common sense and ethical values to avoid getting ourselves in a direction where we cannot pull back and causing our population to have to deal with the birth of a first human clone.

### D. Frozen Eggs: Adding to the Mix

The opponents of IVF, who oppose the freezing of embryos and subsequent disposition of unused embryos because they view them as "persons", will find the emerging technique of freezing unfertilized oocytes (human eggs) perplexing.<sup>141</sup> Unlike sperm cryopreservation, a fairly simple technique for preserving male reproductive potential, storage of mature eggs is rarely successful. Eggs, which already number in the millions by the time a female fetus is eleven months old, are generally impossible to grow in a petri dish.<sup>142</sup> However, reimplantation of cryopreserved ovarian tissue has been applied to restore fertility in animals, and is currently being tried on humans, with some limited success.<sup>143</sup>

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<sup>&</sup>lt;sup>139</sup> 148 CONG. REC., at 5661.

<sup>140</sup> *Id*.

<sup>&</sup>lt;sup>141</sup> Alex Mauron, What Developments of Human Embryo Research Would Be Philosophically Challenging?, in Conceiving the Embryo: Ethics, Law and Practice in Human Embryology, supra note 110, at 283, 289. <sup>142</sup>Claire Ainsworth, Stop The Clock, New Sci., June 30, 2001, at 38; see also J. A. Radford, et. al., Orthtopic Reimplantation of Cryopreserved Ovarian Cortical Strips After High-Dose Chemotherapy for Hodgkin's Lymphoma, 357 The Lancet 1172 (2001).

<sup>&</sup>lt;sup>143</sup>Radford, *supra* note 142. The procedure was developed to allow a woman about to undergo chemotherapy to protect ovarian tissue by removal and freezing, with reimplantation into the pelvic cavity upon completion of the treatment and verification that she is cancer free. If successful, the technique could be further developed to allow women to postpone pregnancy until later in life, or to act as a substitute for hormone replacement therapy during menopause. *Id*.

Currently, "clinics on at least three continents offer egg freezing to young women, and up to 60 babies worldwide have been born from frozen eggs." In October 2002, newspapers in England reported that a clinic in Birmingham was using a woman's frozen eggs instead of traditional IVF because she objected to freezing embryos on religious grounds. If techniques improve, it's estimated that young women born today will routinely utilize the egg-freezing procedures as an insurance policy for successful childbearing, once they have built a career or have found Mr. Right.

## **Conclusion**

Both the Embryo Adoption Awareness Campaign and the Secretary's Advisory Committee on Human Research Protections are viewed as the latest attempts by the Bush administration to undermine support for legal abortion and to erode efforts to fund embryo stem cell research. Some fertility researchers, such as the American Society for Reproductive Medicine, hesitate to apply for federal funds. They fear that to do so would indicate a preference for donating unused embryos to another couple over discarding them or using them for medical research. Abortion rights advocates, including Kate Michelman, president of the National Abortion and Reproductive Rights Action League, fear that embryo "adoption" will lay the legal groundwork to afford embryos full legal rights. This may create momentum in the effort to roll back Roe v. Wade.

<sup>&</sup>lt;sup>144</sup> Ainsworth, *supra* note 142.

<sup>145</sup> Steve Connor, New Inquiry to Check Health of IVF Babies, THE INDEP. (London), October 22, 2002, at 1.

<sup>&</sup>lt;sup>146</sup> Ainsworth, *supra* note142, ¶ 13.

<sup>&</sup>lt;sup>147</sup>Laura Meckler, \$1 Million Promotes 'Embryo Adoption', PITT. POST-GAZETTE, August 21, 2002, at A4.

<sup>&</sup>lt;sup>148</sup> *Id.* The concern is that by using the term "adoption," the process will be likened to the adoption of babies, and the analogy will become reality over time. *Id.* 

Assisted conception, including IVF and cloning, tends to eclipse part of a woman's participation in childbearing, one of the grounds for claiming the woman's pre-eminence over the determination of her child's continued existence.<sup>149</sup> This leads to uncertainty about "what defines the social and moral relationship between the woman and the embryo, usually intimately associated by pregnancy," but now, "not physically linked to one another."<sup>150</sup> Legislators may question why an eight-cell embryo is afforded protections, and not an eight-week-old fetus, and use a law protecting IVF embryos as a "Trojan Horse" to change abortions laws surreptitiously. Scientific advances such as the artificial womb would only advance the cause.<sup>151</sup>

Likewise, the reorganization of the Advisory Committee is seen as a religious and political intrusion into the field of scientific research. Although Arthur J. Lawrence, HHS's deputy assistant secretary for health operations and Assistant Surgeon General, said that the charter required the wording to protect women who may be pregnant and to resolve the confusion between "embryo" and "fetus," many are concerned that the committee itself will not be able to reach a consensus on issues. Emotions and beliefs, not amenable to scientific or rational discourse, will prevent progress and further delay advances in medicine. According to Sean Tipton, spokesman for the American Society for Reproductive Medicine, the committee, designed to protect human subjects, should not be regulating reproductive tissues including sperm, eggs, or embryos. Tighter rules could require elaborate approval procedures from review boards that can now ignore studies involved with cells instead of legal human beings. Furthermore, although the committee addresses only government

<sup>&</sup>lt;sup>149</sup> NOVAES, *supra* note 98, at 111-13.

<sup>&</sup>lt;sup>150</sup> *Id.* at 112-13.

<sup>&</sup>lt;sup>151</sup> ANDREWS, *supra* note 92, at 75.

<sup>&</sup>lt;sup>152</sup> Rick Weiss, New Status for Embryos in Research, WASH. POST, Oct. 30, 2002, at A1.

<sup>&</sup>lt;sup>153</sup> *Id*.

funded research, drug manufacturers as well as medical device experts seeking approval from the FDA may be adversely affected.<sup>154</sup>

The conundrum that Congress and the courts face is perhaps best illustrated by the story of Laurie Strongin and Allen Goldberg, a New York couple, who were attempting to save the life of their young son Henry, born with Fanconi anemia. It is a rare and deadly genetic malady that attacks the hearts of children and ravages them with numerous cancers, resulting in certain childhood death. When their son Henry was approaching his fifth birthday, and they realized that his only hope to survive leukemia was a bone marrow transplant, they decided to conceive a child who would be a genetic match for Henry, thus minimizing the possibility of rejection.

They had heard about a relatively new technique, Pre-Implantation Genetic Diagnosis (PGD), by which doctors could isolate IVF-created embryos which were a complete genetic match for Henry, but also free of the disease. The umbilical cord placental material, which is merely medical waste after birth, could be used to replace Henry's damaged bone marrow following chemotherapy. Allen and Laurie were not infertile, and had already conceived Henry's little brother. But, wishing to save Henry's life, Laurie underwent 353 hormone shots, producing 198 eggs. Only a handful matched; of those, none were successfully implanted into Laurie's womb. When Henry became too ill to wait any longer, he received a bone marrow transplant from a stranger. He died on December 12, 2002, at the tender age of seven.

Laurie and Allen were criticized for attempting to create a child to cure another's illness.

Responding to a New York Times reader who accused them of being mentally ill, and devoid

<sup>&</sup>lt;sup>154</sup> Politics & Policy Research: HHS Committee to Consider Embryos "Human Subjects," 10 Am. Pol. Network (2002). See also Weiss, supra note 139.

of all reason, decency and morality in trying to save a "genetically defective, not savable child," Laurie said:

> People have babies for lots of different reasons. Having one that would be able to survive and also, you know, essentially, cure an older sibling of a fatal disease seems like pretty on the top of the list of good reasons to have a baby, to me. 155

Even though the new medical technology was complicated, costly and controversial, it was their best hope. It did not work for Henry, but a six-year-old Minneapolis child benefited from the same procedure in late 2001. 156

There are obviously at least two legitimate positions in the debate over the status of the human embryo created through IVF or cloning. One the one hand, the discovery of stem cells may be the most significant advance since the discovery of antibiotics. Because scientists do not know whether adult or embryonic stem cell research will lead to treatments and cures for serious diseases afflicting millions of Americans, NIH concludes that both strategies are worth pursuing.<sup>157</sup> Proponents of stem cell research claim that the Bush administration and conservative supporters are disingenuous, in that they abhor abortion and stem cell research in a country that denied health care coverage to embryos and fetuses once they "come of age as newborns and children." <sup>158</sup>

On the other hand, to many, human embryos are our most precious and revered entity. The entire right-to-life movement is dedicated to protecting their right to be born, whether by protest, harassment or even violence. <sup>159</sup> The problem with this debate is that legislators are trying to decide simultaneously whether embryos belong to the class of humans, or are

<sup>&</sup>lt;sup>155</sup> Nightline Henry's Story (ABC News broadcast, Feb. 8, 2002; rebroadcast Dec. 12, 2002).

<sup>&</sup>lt;sup>157</sup> Julian Savulescu, An Each Way Bet in a Crucial Race, HERALD SUN, Nov. 13, 2002, at 20.

<sup>&</sup>lt;sup>158</sup>Lynn M. Morgan, *Research is a Good Life for a Dead Embryo*, SEATTLE POST-INTELLIGENCER, Nov. 29, 2002, at B11. More than 41 million Americans have no health care coverage, including pregnant women, although embryos will now qualify for federal benefits. Id.

<sup>&</sup>lt;sup>159</sup> ANDREWS, supra note 92, at 67.

members of a distinct class, worthy of special respect. Congress must face the issue and make the determination soon, so that clear guidelines can be enforced and scientific research can be fully supported and funded in the direction we choose to take. Given the pace of medical developments in the areas of IVF, stem cell research, and cloning, there is no turning back. But, there is need for direction.

You cannot put genies back into bottles. You can, however, try to make sure that the genies do not go around granting any old wish. You can give the genies some rules. 160

<sup>&</sup>lt;sup>160</sup> Arlene Judith Klotzko, J.D., *The Regulation of Embryo Research Under the Human Fertilisation and Embryology Act of 1990, in* Conceiving the Embryo: Ethics, Law and Practice in Human Embryology, *supra* n.111, at 303 (quoting Ian Kennedy, Treat Me Right: Essays in Medical Law and Ethics, at 119 (1988)).