

Reproductive Technology in Germany and the United States: An Essay in Comparative Law and Bioethics

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The development of assisted reproductive and genetic screening technologies has produced intense ethical, legal, and policy conflicts in many countries. This Article surveys the German and U.S. experience with abortion, assisted reproduction, embryonic stem cell research, therapeutic cloning, and preimplantation genetic diagnosis. This exercise in comparative bioethics shows that although there is a wide degree of overlap in many areas, important policy differences, especially over embryo and fetal status, directly affect infertile and at-risk couples. This Article analyzes those differences and their likely impact on future reception of biotechnological innovation in each country.

INTRODUCTION	190
I. THE IMPORTANCE OF CONTEXT	193
II. GERMAN PROTECTION OF FETUSES AND EMBRYOS	195
III. ABORTION	196
IV. ASSISTED REPRODUCTION	202
A. <i>Embryo Protection and IVF Success Rates</i>	204
B. <i>Reducing Multiple Gestations</i>	207
C. <i>Gamete Donors and Surrogates</i>	209
V. EMBRYONIC STEM CELL RESEARCH.....	211

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190	<i>COLUMBIA JOURNAL OF TRANSNATIONAL LAW</i>	[43:189
	A. <i>ES Cell Research in Germany</i>	212
	B. <i>ES Cell Research in the United States</i>	214
	C. <i>Moving Cut-off Dates as a Solution</i>	217
VI.	THERAPEUTIC CLONING	219
VII.	PREIMPLANTATION GENETIC DIAGNOSIS.....	221
VIII.	THE LESSONS OF COMPARATIVE BIOETHICS.....	225

INTRODUCTION

External fertilization of human eggs was a major triumph of medical science in the late twentieth century. After the first birth in England in 1978, assisted reproductive techniques (“ARTs”) quickly spread throughout the United States and Europe and have now led to the birth of over a million children worldwide.¹

Assisted reproduction involves in vitro fertilization (“IVF”) of eggs that have been surgically removed from a woman after hormonal stimulation of her ovaries.² The husband’s sperm or that of a donor is used to fertilize those eggs in the laboratory. After forty-eight to seventy-two hours of laboratory culture, one or more dividing embryos are placed in the woman’s uterus with the hope that at least one will implant and lead to a healthy pregnancy and birth.³ Remaining embryos may be frozen for later use, discarded, or donated to others.

The ability to create human embryos in the laboratory offers an array of other reproductive and genetic options. Eggs or sperm from a donor or gestation from a surrogate might be substituted for the contributions of an infertile partner. Excess embryos may be donated to sterile couples or used in research, including in the

1. See PRESIDENT’S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 3 (2004). The first U.S. birth occurred in 1981 and the first German birth in 1982.

2. See *id.* at 23–35 (providing a useful summary of assisted reproductive techniques).

3. Rather than transfer embryos that might not develop further, many programs transfer embryos that have developed to the 100-cell or more blastocyst stage of preimplantation development (after five to seven days of laboratory culture). Blastocyst-stage transfer has been found to enable better embryo selection and higher implantation rates. See, e.g., Basak Balaban et al., *Blastocyst-Stage Transfer of Poor-Quality Cleavage-Stage Embryos Results in Higher Implantation Rates*, 75 FERTILITY AND STERILITY 514, 516 (2001); see also David K. Gardner & Michelle Lane, *Blastocyst Transfer*, 46 CLINICAL OBSTETRICS AND GYNECOLOGY 231, 232–33 (2003).

derivation of embryonic stem cells for research or treatment. Growing knowledge of the human genome also allows early embryos to be screened genetically and chosen for disposal or transfer to the uterus based on their genetic make-up.

Assisted reproductive techniques are available in all developed and developing countries, but the process of acceptance has been fraught with conflict and controversy. The foremost focus of controversy has been the destruction or manipulation of embryos that ARTs often entail. Critics have also cited potential harm to offspring and the devaluation of family and kinship bonds from the use of donors, surrogates, and embryo screening.⁴ The growth of genetic knowledge and the emergence of reproductive cloning in mammals have intensified these conflicts by raising the specter of genomic engineering and commodification of offspring. The debate over these issues has posed special challenges in liberal democracies, which value personal freedom but also recognize the right of persons with religious objections to oppose technological control of reproduction.

As a result, there are important legal differences among nations in the terms and conditions of use of ARTs, including differences on such important issues as the status, storage, and disposal of embryos; the use of donors and surrogates; embryo research; and preimplantation genetic diagnosis ("PGD"). Regulatory regimes also vary. Some countries have strict prohibitions on certain techniques, such as egg donation and research with embryos; others allow wide choice but require prior regulatory approval of clinic procedures; and still others leave it to the discretion of the physician and patient, with minimal governmental oversight.⁵

The response to ARTs varies on both sides of the Atlantic. The United States, the United Kingdom, Belgium, and Israel have been highly permissive toward ARTs; Germany, Italy, Ireland, and Austria have been highly restrictive; Spain, France, and Canada occupy a middle position that accepts most ARTs but strongly resists more novel reproductive technologies.⁶ Germany is an especially

4. See John A. Robertson, *Procreative Liberty and Harm to Offspring in Assisted Reproduction*, 30 AM. J.L. & MED. 7 (2004) [hereinafter Robertson, *Procreative Liberty*].

5. See discussion *infra* of the regulatory positions of Germany, the United States, and the United Kingdom.

6. See generally THE REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGY (Jennifer Gunning & Helen Szoke eds., 2003); see also Bartha M. Knoppers & Sonia LeBris, *Recent Advances in Medically Assisted Conception: Legal, Ethical, and Social Issues*, 17 AM. J.L. & MED. 329, 333 (1991). There are important differences among members of each group and the situation is a dynamic one as countries deal with a steady stream of technological

interesting case. It is not only the most populous country in Europe, but it also has a rich scientific tradition that might suggest that it should be at the forefront of the advancement of reproductive and genetic technologies. Germany's history of science and human rights abuse, however, has made it hostile to technological and genetic control of reproduction. Along with Austria, Ireland, Italy, and Portugal, Germany restricts ARTs, PGD, and embryo research to a greater extent than most other countries, thus defining the most conservative end of the policy spectrum.⁷

This Article compares German and U.S. law on reproductive technology in five areas of current controversy: abortion, assisted reproduction, embryonic stem cell research, therapeutic cloning, and preimplantation genetic diagnosis. As with most comparative law, the purpose of the analysis is functional and ameliorative.⁸ The hope is that a look at the similarities and differences between the German and U.S. policy regimes will yield a better understanding of each system and generate more ideas for improvement than would a parochial preoccupation alone. In addition, such an assessment will provide a more accurate snapshot of the key ethical, legal, and social debates that reproductive technologies have inspired in the developed world and show the likely shape of future debates.

At stake, however, are relative rather than absolute differences. Although there are many differences in the details of application and regulation, the use of ARTs is widespread and thriving in both countries and indeed throughout most of the developed world. Understanding these details is nonetheless important, for they distinguish legal systems, indicate the fault lines of future development, and affect the lives of persons on whose

innovation. For example, France, which has the highest rate of IVF in Europe, was originally quite negative toward embryo research but recently announced measures allowing embryonic stem cell research. See *France Opens Door to Human Stem Cell Research*, Agence France-Presse, Oct. 5, 2004, available at 2004 WL 95425847.

7. The differences here thus reflect more than the usual split between Europe and the United States about which James Whitman has written so well. See generally James Q. Whitman, *The Two Western Cultures of Privacy: Dignity vs. Liberty*, 113 YALE L.J. 1151 (2004) [hereinafter Whitman, *Dignity vs. Liberty*]. Despite the profound difference between the United States and European countries in general in their willingness to trust the market and to allow citizens to go without health insurance, several countries in Europe, most notably the United Kingdom, Sweden, and Belgium, are roughly as permissive as the United States is with regard to ARTs. See Knoppers & LeBris, *supra* note 6, at 341 n.33. This split among European countries suggests that local perceptions and conditions exert a strong influence.

8. See Ruti Teitel, *Comparative Constitutional Law in a Global Age*, 117 HARV. L. REV. 2570, 2574-78 (2004) (reviewing COMPARATIVE CONSTITUTIONALISM (Norman Dorsen et al. eds., 2003)).

choices they impinge. As James Whitman notes:

[R]elative claims can be a good bit more revealing than absolute ones. Therein lies the unique strength of comparative law. It is precisely because they deal in relative claims that comparative lawyers can walk the high road to the understanding of human legal systems, as they have been trying to do since Montesquieu.⁹

Part I of the Article addresses the context of this comparative analysis. Part II discusses generally German protection of fetuses and embryos. Part III examines how each country has handled the overarching issue of fetus status and abortion. Part IV analyzes ART practices in Germany and the United States, with particular attention to IVF success rates, the problem of multiple births, and the use of gamete donors and surrogates. Part V looks at public policy in each country for embryo research and embryonic stem cell research. Part VI describes the therapeutic cloning debate in each country, and Part VII the use of preimplantation genetic diagnosis to screen embryos before transfer. Finally, Part VIII discusses the lessons learned from this comparative exercise in bioethics.

I. THE IMPORTANCE OF CONTEXT

Before addressing the similarities and differences in responses to ARTs, a few words about context are in order. Although Germany and the United States face many of the same ethical, legal, and social challenges in coming to terms with ARTs, they deal with them in different ways because of their different histories and traditions. As Whitman cogently notes, law “is not about the worldly realization of wisdom or sophistication as such. Law is about what works, what seems appealing and appropriate in a given society.”¹⁰ This is just as true of the German and U.S. approaches to ARTs as it is of their approaches to other major social issues, such as criminal justice and procedure or the protection of informational privacy.¹¹

The reception of ARTs in the United States cannot be adequately understood without an appreciation of the country’s long tradition of individual liberty, free market and free enterprise

9. JAMES Q. WHITMAN, *HARSH JUSTICE: CRIMINAL PUNISHMENT AND THE WIDENING DIVIDE BETWEEN AMERICA AND EUROPE* 16–17 (2003).

10. Whitman, *Dignity vs. Liberty*, *supra* note 7, at 1168.

11. *See generally id.*

orientation, and grants of wide autonomy to physicians and other professionals. At the same time, religious liberty is also highly valued in the United States, and strong religious views or religiosity often influence public policy debates. The U.S. response to these competing concerns has often been to sharply separate the public and private spheres. For example, individuals in the United States are free to practice abortion, contraception, assisted reproduction, and embryo research but have no right to receive state funds to do so.¹²

The cultural framework underlying German law generally and its law on ARTs in particular is quite different from the U.S. concern with protecting individuals from governmental intrusion into personal affairs. In Germany (and throughout Europe), legal change over the last 200 years has been toward recognizing the dignity of every person and granting each an equal place of honor in society.¹³ For example, Article 1 of the German constitution (Grundgesetz, or “Basic Law”), adopted by West Germany on May 23, 1949, recognizes that all persons have the right to life, and Article 2 grants the right of every person to the “free development of his personality.”¹⁴

The strong revulsion to the abuses of Nazism and the searing experience of the Holocaust have also marked much of contemporary German law, including the law that governs the use of reproductive and genetic technologies.¹⁵ Germany took the eugenic sterilization policies blessed by the U.S. Supreme Court in 1927 in *Buck v. Bell*¹⁶

12. See, e.g., discussion *infra* Parts III and V.

13. This emphasis on the honor and dignity of all persons is the result of efforts over 200 years to replace a hierarchical system of status and privilege accorded by birth with equal respect for all persons. Whitman frames the difference as the choice between social traditions oriented toward liberty and social traditions strongly oriented toward dignity. According to Whitman:

American privacy law is a body caught in the gravitational orbit of liberty values, while European law is caught in the orbit of dignity. There are certainly times when the two bodies of law approach each other more or less nearly. Yet they are consistently pulled in different directions, and the consequence is that these two legal orders really do meaningfully differ: Continental Europeans are more consistently drawn to problems touching on public dignity, while Americans are consistently more drawn to problems touching on the depredations of the state.

Whitman, *Dignity vs. Liberty*, *supra* note 7, at 1163.

14. GRUNDGESETZ [GG] [Constitution] arts. 1–2 (F.R.G.).

15. See Michael Stolleis, *Preface* to DARKER LEGACIES OF LAW IN EUROPE: THE SHADOW OF NATIONAL SOCIALISM AND FASCISM OVER EUROPE AND ITS LEGAL TRADITIONS 3 (Christian Joerges & Navraj Singh Ghaleigh eds., 2003); Eric Brown, *The Dilemmas of German Bioethics*, THE NEW ATLANTIS, Spring 2004, at 38–40.

16. 274 U.S. 200, 207 (1927) (rejecting a due process challenge to a Virginia statute authorizing the sterilization of inmates with hereditary mental illness).

and applied them so expansively that “eugenics” remains a term of opprobrium.¹⁷ Eugenics was originally applied only to sterilization of the mentally ill and deformed. After the Nazis took power in 1933, the sterilization program was extended to euthanasia of such persons. These practices led in turn to the “final solution:” the extermination of Jews, Gypsies, and others who did not fit the “Aryan” biological model, often accompanied by the cruel medical experiments that inspired the Nuremberg Code for human experimentation.¹⁸

These uses of medical and genetic science imbued a deep aversion in German society to the use of genetic science to classify and extend rights to people and thus to reproductive and medical technologies that control the earliest stages of human life. Germans are thus more likely than Americans to credit slippery slope arguments and resist expanded use of reproductive and genetic technologies.¹⁹

II. GERMAN PROTECTION OF FETUSES AND EMBRYOS

With these differences in history and context in mind, we may now examine how Germany and the United States have actually responded to medical technologies that control reproduction and the genetic make-up of children. The distinguishing feature of the German reproductive policy landscape is its strong formal protection of fetuses and embryos. In Germany, implanted embryos and fetuses are constitutionally protected by the Basic Law, and are thus entitled to the same right to life and dignity that all persons have.²⁰ Indeed, they even have a right to obligatory state protection of those rights—

17. For a more comprehensive account of U.S. sterilization policies and how they influenced the Germans, see PHILIP P. REILLY, *THE SURGICAL SOLUTION: A HISTORY OF INVOLUNTARY STERILIZATION IN THE UNITED STATES* 103–10 (1991).

18. The Nuremberg Code provided ethical guidelines to protect human experimental subjects. See 2 *TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10*, at 181–82 (1949). See also Susan Bachrach, *In the Name of Public Health—Nazi Racial Hygiene*, 351 *NEW ENG. J. MED.* 417, 418 (2004).

19. Some German commentators have called on German scientists to exorcise those demons so that the fruits of reproductive and genetic technologies are available. See *German Scientists Must ‘Exorcise’ Nazi Demons*, *GUARDIAN* (London), Jun. 28, 2004, available at <http://www.guardian.co.uk/international/story/0,3604,1248954,00.html>.

20. See *Entscheidungen des Bundesverfassungsgerichts [BVerfGE] [Federal Constitutional Court] 39, 1 (F.R.G.)* (decision of Feb. 25, 1975). Preimplantation embryos resulting from IVF are protected by the Embryo Protection Act of 1990 but they have not yet been found to have constitutional status under Article 1 of the Basic Law. See Gerald L. Neuman, *Casey in the Mirror: Abortion, Abuse and the Right to Protection in the United States and Germany*, 43 *AM. J. COMP. L.* 273, 279 (1995).

an example of positive constitutional rights that is unknown in the United States.²¹

The more protective attitude toward fetuses and embryos that drives much of German reproductive policy is usually explained as a reaction to the abuses of the Nazi era combined with the deep religious roots of Germans, particularly German Catholics. Support for strict limitations on reproductive technologies, however, is not due to pro-life positions alone. Greens and feminists also oppose many of those technologies because of their antipathy to the power of impersonal technologies; they have joined pro-life groups in placing embryo screening issues within a human rights framework.²² While such groups also seek to protect the right of women to personality and identity, most notably in permitting women to have abortions, the emphasis in Germany on the need to balance these rights with the right to life of fetuses and embryos is greater than in the United States.

The presumptive priority accorded in Germany to implanted fetuses and embryos (as forms of human life) has come to play a major role in embryo protection issues that arise in ARTs, embryo research, and preimplantation genetic diagnosis. While many policy similarities with the United States exist, the explicit difference in embryo status in Germany has led to important differences in rhetoric and outcome in several areas, as the following account demonstrates.

III. ABORTION²³

In Germany, as in the United States, the law governing abortion is the result of judicial rulings on the constitutionality of legislative enactments. In 1975 and again in 1993, the German

21. Positive constitutional rights are generally not recognized in U.S. constitutional law, though they exist in other systems. Compare *Maier v. Roe*, 432 U.S. 464, 479–80 (1977) (holding that the U.S. Constitution imposes no obligation on states to fund nontherapeutic abortions for indigent women), and *Harris v. McCrae*, 448 U.S. 297, 317–18 (1980) (holding that there is no affirmative constitutional obligation requiring Congress to subsidize medically necessary abortions for indigent women), with *Minister of Health v. Treatment Action Campaign*, 2002 (5) SALR 721 (CC) (S. Afr.) (finding a constitutional right to health care in South Africa).

22. See Herbert Gottweis, *Stem Cell Policies in the United States and in Germany: Between Bioethics and Regulation*, 30 POL'Y STUDIES J. 441, 451 (2002) (citing MICHAELA BETTA, *EMBRYONENFORSCHUNG UND FAMILIE, ZUR POLITIK DER REPRODUKTION IN GROSSBRITANNIEN, ITALIEN UND DER BUNDESREPUBLIK* 81–125 (1995)).

23. Although abortion is not itself a new reproductive technology, an analysis of fetal status and women's rights in the context of a country's abortion laws sets the background for discussion of other reproductive rights.

Constitutional Court ruled on legislative attempts to liberalize abortion law. In each case, the court both struck down aspects of the laws and offered novel methods for resolving deep conflicts.²⁴

In the late 1960s and early 1970s, Germany, like many other liberal democracies, reformed its penal laws to make abortion more widely available. A 1974 law made abortion lawful during the first twelve weeks of pregnancy, up until twenty-two weeks for fetal defect, and beyond twenty-two weeks if there were threats to the woman's life or health.²⁵ Members of Parliament and state governments immediately challenged the law in the Federal Constitutional Court.

In 1975, the Constitutional Court ruled that German penal law must protect the embryo or fetus once pregnancy begins.²⁶ The court found that the fetus has a constitutional right to life that the state has a positive duty to protect by passing criminal laws to prevent unjustified harm to fetuses.²⁷ At the same time, the court found that Article 2 of the Basic Law, which protects the right of every person to "free development of personality," gives a pregnant woman some degree of control over her life.²⁸ Thus, a woman could not be expected to continue a pregnancy that threatened her life or health, resulted from rape, would lead to a child with severe defects, or would generally impose on her a great social burden.²⁹ The court, however, found that, on balance, the 1974 penal code reform law was insufficiently protective of fetuses.³⁰ The court invalidated the law and charged the legislature to differentiate more between the prerequisites for abortions in cases of rape, danger to the woman's

24. See *Entscheidungen des Bundesverfassungsgerichts [BVerfGE]* [Federal Constitutional Court] 39, 1 (F.R.G.) (decision of Feb. 25, 1975); BVerfGE 88, 203 (decision of May 28, 1993). See also Neuman, *supra* note 20, at 274–82.

25. Fünftes Gesetz zur Reform des Strafrechts (5. StrRG), v. 18.6.1974 (BGB1. I S.1297–98) (adding Strafgesetzbuch [StGB] [Penal Code] §§ 218a, 218c(1)).

26. See BVerfGE 39, 1 (3). Pregnancy was determined to begin after implantation of the embryo in the uterus, which ordinarily occurs at fourteen days after fertilization. My account of the German Federal Constitutional Court abortion decisions is based on Neuman, *supra* note 20, and Donald P. Kommers, *The Constitutional Law of Abortion in Germany: Should Americans Pay Attention?*, 10 J. CONTEMP. HEALTH L. & POL'Y 1 (1994). See also Edward Eberle, *Human Dignity, Privacy, and Personality in German and American Constitutional Law*, 1997 UTAH L. REV. 963 (1997). For a translation of the 1975 decision, see Robert E. Jonas & John D. Gorby, *West German Abortion Decision: A Contrast to Roe v. Wade*, 9 J. MARSHALL J. PRAC. & PROC. 605 (1976).

27. See BVerfGE 39, 1 (1, 42).

28. See *id.* at 43.

29. See *id.* at 49–50.

30. See *id.* at 1–2, 68.

health, or fetal defects, and for elective abortions.³¹ Germany subsequently adopted legislation reflecting the court's discussion. The revised law allowed an abortion only if a woman's physician and another physician both determined the existence of one of the four exceptional circumstances: a threat to the woman's health, birth defects, rape, or a "general situation of need."³² The law limited abortions under the latter two exceptions to the first trimester and limited those due to fetal defects to the first twenty-two weeks of pregnancy.³³ The law also required all women seeking an abortion to receive authorized counseling at least three days before the abortion.³⁴

This outcome—a strong rhetoric of fetal protection that nevertheless allowed most abortions in the first twelve weeks, as well as thereafter in more serious cases—provided policy stability until 1990, when it became a major obstacle in negotiations over the reunification of East and West Germany.³⁵ Because the East German abortion law was considerably more permissive than the West German statute carrying medical review and counseling requirements, East Germany insisted as one of the grounds for reunification that post-unification abortion law also be liberalized.³⁶ The resulting legislation removed the requirement of third-party medical review from first-trimester pregnancies, leaving only the imposition of mandatory counseling at least three days before the abortion.³⁷ The law continued to permit abortions after twelve weeks upon third-party medical determination of severe birth defects or a threat to the woman's health.³⁸

This law, too, was immediately challenged. In 1993, the Federal Constitutional Court again required the legislature to modify some provisions and upheld the basic notion that fetuses have a right to life under the Basic Law that the state has a duty to protect.³⁹ As in

31. *See id.* at 2–3, 65–68.

32. *See* Fünfzehntes Strafrechtsänderungsgesetz (15. StRAndG), v. 18.05.1976 (BGB1. I S.1213); Neuman, *supra* note 20, at 275–76.

33. *See id.*

34. *See id.*

35. The account in this paragraph is based on Neuman, *supra* note 20, at 276–278.

36. Article 31(4) Einigungsvertrag [Unification Treaty] of August 31, 1990.

37. *See* Gesetz zum Schutz des vorgeburtlichen/werdenden Lebens, zur Förderung einer kinderfreundlicheren Gesellschaft, für Hilfen im Schwangerschaftskonflikt und zur Regelung des Schwangerschaftsabbruchs (Schwangeren- und Familienhilfegesetz) [Pregnancy and Family Assistance Act], v. 27.07.1992 (BGB1. I S.1398) (adding StGB § 218a(1)).

38. *See id.*; Neuman, *supra* note 20, at 278.

39. *See* BVerfGE 88, 203. The Court found that “[t]he Basic Law obligates the state to protect human life. The unborn belongs to human life. Therefore, [the unborn] also receive the protection of the state.” *Id.* at 251. The majority, however, left open the legal status of a

1975, the Court found that while the state must give priority to the protection of the fetus, the legislature has some leeway in its judgments about how to protect fetuses.⁴⁰

In reaching this conclusion, the Court placed great weight on the distinction between the *legality* and the *criminality* of abortion⁴¹—a strategy that is frequently adopted in Europe but less so in the United States.⁴² The state's duty to protect the right to life of fetuses meant that abortion (except where justified by a threat to the mother's life or health or severe birth defects, or in cases of a sexual crime) must remain unlawful.⁴³ However, the court also recognized that the state should have some flexibility in determining what policies to pursue in implementing that illegality. For example, it need not criminalize unlawful abortions in all cases: decriminalizing first-trimester abortions that occurred three days after mandatory counseling was deemed to fulfill the state's constitutional duty to protect fetuses.⁴⁴ The court reasoned that the legislature could reasonably believe that criminalizing all abortions would drive women to seek illegal abortions, thus missing out on the counseling that might have protected fetuses by persuading them to continue their pregnancies.⁴⁵

The court also addressed other conditions that could impact the abortion decision. First, it held that the state must protect women against landlords and employers who might penalize them for a

fertilized egg prior to implantation, since it is not included in the definition of pregnancy and therefore does not come under the relevant provisions of §§ 218 et seq. of the German Penal Code [StGB].

40. *See id.* at 254.

41. *See id.* at 273–81.

42. This distinction is not unknown in policy circles in North America; it has been advanced most frequently in connection with arguments for decriminalizing marijuana while retaining civil penalties. *See, e.g.,* Colin Campbell, *World Briefing: Americas: Marijuana Policy*, N.Y. TIMES, July 22, 2004, at A6 (reporting that the Prime Minister of Canada favors decriminalization). The distinction has also been used in the Netherlands to permit active euthanasia while keeping it formally illegal. *See* JOHN GRIFFITHS ET AL., *EUTHANASIA AND LAW IN THE NETHERLANDS* 95 (1998).

43. Neuman notes that the court “made clear its belief that the ‘general situation of need’ criterion had been too loosely applied” and that “other situations of personal necessity” for an abortion must be “comparable in intensity” to the exceptional circumstances involving rape, birth defects, or a threat to the mother's life. Neuman, *supra* note 20, at 280.

44. *See* BVerfGE 88, 203 (279–81). A doctor committed a criminal offense if he or she performed an abortion without a certificate of counseling for the woman. *See* § 218b(1) of the German Penal Code as amended on July 27, 1992 by the Pregnancy and Family Assistance Act, *supra* note 37. For further discussion of mandatory counseling, see Neuman, *supra* note 20, at 282–85.

45. *See* BVerfGE 88, 203 (265).

decision either to have or not to have an abortion.⁴⁶ For example, no-children provisions in housing leases would be unenforceable. Second, the court pointed to the need for penal rules to prevent a father from coercing the woman expecting his child to have an abortion.⁴⁷ Third, the court found that although the state has no obligation to include abortion in national health insurance⁴⁸ and insurance contracts with private health insurers that provided for coverage for elective abortions would be void,⁴⁹ the state does have an obligation to pay for abortions for those who are truly needy.⁵⁰

Constitutional lawyers in the United States may marvel at the ease and specificity with which the Federal Constitutional Court gave directions to the legislature, but they will quickly recognize that the balance struck in Germany was similar in many respects to that drawn in the United States.⁵¹ Although the German state has a legal obligation to protect the fetus, a woman's right over her "personality" also deserves respect under Article 2 of Germany's Basic Law. That right does not trump the right to life of the fetus, but it does permit the legislature to distinguish between the *illegality* and the *criminality* of abortion, thereby leaving a woman's choice still largely protected in the first trimester and, in special circumstances, further into the pregnancy.

The German court's endpoint is very similar to that achieved by the U.S. Supreme Court in 1992 in *Planned Parenthood v. Casey*.⁵² To be sure, the German Federal Constitutional Court's ruling is more directly legislative in tone, but in the end it reaches a normative balance close to that reached in *Casey*. An important difference is that while the German court held that the state has a duty to protect fetuses, the Court in *Roe v. Wade*⁵³ and *Casey* leaves individual states free to decide how protective they wish to be as long as they do not impose "undue burdens" on a woman's pre-viability abortion decision.⁵⁴ With a majority of states now imposing waiting periods

46. *See id.* at 258–60, 321.

47. *See id.* at 258–60, 296–98.

48. *See id.* at 319–21.

49. *See id.* at 317–18.

50. *See id.* at 321–22.

51. German constitutional procedure differs from that of the United States. States or a certain number of legislators may bring cases to the court and the court may impose positive duties on the legislature and describe in detail the laws that must be passed. *See* Neuman, *supra* note 20, at 275.

52. 505 U.S. 833 (1992).

53. 410 U.S. 113 (1973).

54. The "undue burden" test comes from the O'Connor, Kennedy, and Souter plurality

and mandatory counseling, however, the situation on the ground in the United States approaches that in Germany, though some differences remain.⁵⁵ Both German and U.S. women are free, after counseling, to have abortion on demand in the first trimester and for fetal defect or other serious health reason beyond. Predictably, pro-choice activists in the United States have attacked mandatory counseling and waiting periods as too onerous, while pro-life activists in Germany have argued that the counseling and three-day waiting period requirements in Germany are too lenient.⁵⁶ Although a state of stability has been achieved in both countries, warfare over many details continues, especially in ongoing controversies in the United States over partial-birth abortion bans, parental notification, fetal protection laws, and other attempts to gain legal protection for prenatal life.⁵⁷

One area of important difference is the question of state funding for abortion. The question was settled in the United States in the 1980s when *Maher v. Roe*⁵⁸ and *Harris v. McCrae*⁵⁹ denied a positive right to state funding of abortion for poor persons, leaving it to individual states and private insurers to provide funding as they chose. Although many states do not fund abortion for indigent patients, about fifteen states and most private health insurance policies do provide coverage. In Germany, by contrast, the 1993 decision held that while it is illegal for public or private insurers to

opinion in *Casey*, which recognized “the right of the woman to choose to have an abortion before viability and to obtain it without undue interference from the State.” 505 U.S. at 846. It is now the determinative standard for judging U.S. abortion restrictions. See *Stenberg v. Carhart*, 530 U.S. 914, 921 (2000).

55. See Neuman, *supra* note 20, at 273 (“In practical terms, the situation in Germany now resembles the post-*Casey* situation in Pennsylvania. Abortion is available after burdensome preliminaries.”).

56. See Nanette Funk, *Abortion Counselling and the 1995 German Abortion Law*, 12 CONN. J. INT’L L. 33, 40–41 (1996). U.S. scholars like Mary Anne Case, who view counseling requirements through the lens of women’s rights, argue that such requirements demean the decision-making ability of women, since no counseling is required for serious medical procedures undergone by men. See Mary Anne Case, *How Viable Is the German Compromise on Abortion?* 3–4 (2002) (unpublished paper, on file with author). I am less troubled by the requirement than is Professor Case. Decisions for abortion or assisted suicide are sufficiently weighty to justify counseling and waiting periods in their own right, even if such counseling is not required for other medical procedures. See, e.g., *The Oregon Death With Dignity Act*, OR. REV. STAT. §§ 127.800–127.897 (2003) (requiring, for example, review by two physicians under § 127.820 and a fifteen-day waiting period under § 127.850).

57. Many pro-choice supporters worry about the fact that a change of one or two votes on the Supreme Court could overturn *Casey*, thus making each new Court appointment the focus of intense political debate.

58. 432 U.S. 464 (1977).

59. 448 U.S. 297 (1980).

pay for decriminalized abortions,⁶⁰ the German government has an obligation to pay for those abortions for financially needy people.⁶¹ Subsequent regulations implementing the decision have interpreted the meaning of “needy” very broadly and the state now pays for the majority of all abortions.⁶²

The mandatory counseling provisions of the German law have also led to a different debate in Germany than that which has occurred in the United States—a debate over who may do counseling rather than whether it should occur at all. In the United States, counseling has been an issue for feminists who argued in *Casey* and later legal challenges that mandatory counseling burdens the abortion decision and treats women as incapable of autonomous choice.⁶³ *Casey* rejected such a critique, and left the question of scope, extent, and timing of counseling to be decided by states. A majority of states now require a twenty-four hour waiting period and the physician or center performing the abortion to discuss or distribute information about the development of the fetus, health risks from abortion, and adoption alternatives. In Germany, abortion counseling occurs in government-funded or private centers outside of physicians’ offices. Interestingly, some pro-choice lay Catholics formed their own counseling centers after the Vatican banned the Catholic Church from participating, because a certificate from a counseling center facilitates obtaining an abortion.⁶⁴

IV. ASSISTED REPRODUCTION

The use of assisted reproduction—the laboratory fertilization of eggs surgically removed after hormonal stimulation—has been the subject of direct legislation in Germany to an extent that has not occurred in the United States.⁶⁵ The Federal Constitutional Court’s 1975 abortion decision concerned only penal code provisions

60. See BVerfGE 88, 203 (315–20).

61. See *id.* at 321–22; Neuman, *supra* note 20, at 287.

62. See *Case*, *supra* note 56, at 5.

63. See, e.g., *Casey*, 505 U.S. at 881–886; see also Brief for Amicus Curiae American Psychological Association in Support of Petitioners at 18–30, *Planned Parenthood v. Casey*, 505 U.S. 833 (1992) (Nos. 91-744, 91-902).

64. See *Case*, *supra* note 56, at 2; Donum Vitae berät 70000 Frauen, STUTTGARTER ZEITUNG, Nov. 21, 2003, at Politik 2.

65. See Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz – ESchG) [Embryo Protection Act], v. 13.12.1990 (BGBl. I S.2746) (F.R.G.) [hereinafter Embryo Protection Act].

addressing the termination of pregnancy, and thus did not bear on IVF and the status of laboratory-created extracorporeal embryos. Neither that decision nor the 1993 decision addressed the legal status of fertilized eggs between fertilization and the more developed blastocyst stage, when nidation or implantation in the uterus occurs, the fourteen-day time period during which IVF gives control over the embryo.⁶⁶ As a result, the strong defense of the rights to life and dignity of fetuses in those cases applied only to fetuses and to embryos already implanted in the uterus, not to preimplantation embryos created in the laboratory by IVF.

As IVF became more widely used in Germany in the mid and late 1980s, controversy arose over the status of those embryos and the need for regulation of the IVF procedures that created them.⁶⁷ Extracorporeal fertilization was a significant step forward in technical and medical control of reproduction, but it raised many questions about the legal and moral status of preimplantation embryos, including whether embryos should be used in research.⁶⁸ These concerns led to the Embryo Protection Act of 1990.⁶⁹ While leaving doctors free in other respects to provide IVF treatments as they see fit, the law strictly regulates the creation and disposition of embryos.

Meanwhile, the United States has taken a largely hands-off approach to IVF, leaving it to the private market of doctors and patients to decide what services will be offered, subject to the laws of torts and contracts and an optional clinic reporting system.⁷⁰ Embryos have no inherent constitutional status, and there are for the most part no laws against creating extra embryos, discarding them, donating them to others, or otherwise specifying what may be done with them. Although a few states have prohibited embryo or fetal research in broad terms, when challenged, these laws have been held unconstitutional and do not appear to have deterred research with embryos or stem cells derived from them.⁷¹

66. See Neuman, *supra* note 20, at 279 n.38.

67. See Gottweis, *supra* note 22, at 450–52.

68. See *id.* at 451.

69. Embryo Protection Act, *supra* note 65.

70. Although often criticized as having no regulation, a variety of regulatory mechanisms impinge on ART practice in the United States. See David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 78 FERTILITY AND STERILITY 932 (2002). For example, a federal law enacted in 1992 creates a system of incentives for accurate reporting of clinic results to provide consumers with reliable data about program efficacy. Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C.A. § 201 (1992).

71. See Lori Andrews, *Legislators as Lobbyists: Proposed State Regulation of*

A third model of regulation intermediate between the liberal approach in the United States and the legislative strictures in Germany is the central regulatory authority relied upon in the United Kingdom. Although the United Kingdom does not provide legal protection to embryos and permits embryo disposal and research, a 1990 law invested a new agency, the Human Fertilisation and Embryology Authority (“HFEA”), with the power to license clinics, collect data on results, and set practice policies pursuant to parliamentary instruction.⁷² A clinic must have a license from the HFEA to provide assisted reproduction, a requirement to which there is no analogue in the United States or Germany. The HFEA has also limited the number of embryos that can be transferred to the uterus at any one time to two, but has granted licenses for preimplantation genetic diagnosis, embryo research, and even therapeutic cloning.⁷³ Unlike the United States, however, the United Kingdom does not permit payments to sperm and egg donors or to surrogate mothers.⁷⁴

A. *Embryo Protection and IVF Success Rates*

German legislation on assisted reproduction grew out of publicity and intense debate in the late 1980s about doctors who created embryos for research.⁷⁵ The National Chamber of Doctors tried to stave off legislation by issuing guidelines for embryo research, but they were widely seen as too permissive.⁷⁶ Major research organizations offered support, but a coalition of radical Greens, feminists, and conservatives “rallied behind the call for the state to protect embryos from abuse, instrumentalization, and destruction.”⁷⁷

Embryonic Stem Cells Research, Therapeutic Cloning and Reproductive Cloning, in PRESIDENT’S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH, App. E, 199–224 (2004). In any case, these laws do not affect the practice of IVF but only what can be done with unwanted embryos.

72. Human Fertilisation and Embryology Act, 1990, c. 37, § 12 (Eng.). See also HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY, CODE OF PRACTICE 41 (2004), available at <http://www.hfea.gov.uk/HFEAPublications/CodeofPractice>.

73. See Ginanne Brownell, *Alison Murdoch: A Green Light For Research*, NEWSWEEK, Aug. 23, 2004, at 58 (Atlantic Edition) (interview with Director of Research of program receiving HFEA approval to conduct therapeutic cloning research).

74. See Human Fertilisation and Embryology Act, 1990, c. 37, § 12 (Eng.).

75. See Gottweis, *supra* note 22, at 451.

76. See *id.*

77. *Id.*

The result was the 1990 Embryo Protection Act.⁷⁸ The Act is highly protective of embryos as incipient forms of human life. Its definition of embryo chooses the point after fertilization at which nuclear fusion, or syngamy, occurs (ordinarily about twenty hours after insemination).⁷⁹ The Act makes it a crime punishable by three years in prison to fertilize more eggs that have attained syngamy than can be transferred to a woman in one cycle, to transfer more than three embryos to the uterus, to engage in egg donation and gestational surrogacy, or to create embryos for research.⁸⁰ It also prohibits non-medical sex selection⁸¹ and posthumous in vitro fertilization.⁸² Although the law is highly restrictive and places Germany near the conservative end of the regulatory spectrum,⁸³ its definition of embryo as existing only after syngamy leaves some room for maneuvering. Specifically, it does not prohibit Germans from freezing zygotes or pronuclear embryos before syngamy, a practice that provides many of the advantages of post-syngamy freezing.

It is plausible to presume, however, that the strictures of the German law do affect access to and the efficacy of IVF. Although German fertility doctors hyperstimulate women to produce multiple eggs, just as they do in the United States, they are likely to use smaller amounts of drugs and retrieve fewer eggs. Most eggs are inseminated or are injected with a single sperm in a procedure called intracytoplasmic sperm injection (“ICSI”), with Germany having the third highest rate of ICSI in Europe.⁸⁴ The inseminated or injected

78. See Embryo Protection Act, *supra* note 65.

79. See *id.* § 8(1). This is the point at which the haploid genomes of the egg and sperm become diploid and the one-celled zygote is formed. Prior to syngamy or nidation the embryo is usually described as “pro-nuclear” because it has the unfused pronuclei of each haploid gamete.

80. See *id.* § 1(1).

81. See *id.* § 3.

82. See *id.* § 4(1). An even heavier sentence of five years is authorized for germline alteration of embryos; creating an embryo with the DNA of another embryo, fetus, living or deceased person; or creating human-human or human-animal chimeras and hybrids.

83. A 2003 Italian law is even more restrictive because it defines the embryo from the time of fertilization. Law 40/2004 of Feb. 19, 2004, 2004 Gazz. Uff. No. 45, Feb. 24, 2004. On the new Italian law, see Robin Marantz Henig, *On High-Tech Reproduction, Italy Will Practice Abstinence*, N.Y. TIMES, Mar. 2, 2004, at D5; Sophie Arie, *Fertility's Closed Italian Frontier*, CHRISTIAN SCI. MONITOR, Mar. 10, 2004, at 1. I have suggested that Italy might relieve some of the burdens that its highly restrictive law imposes on women by adopting the German definition of an embryo. See John A. Robertson, *Protecting Embryos and Burdening Women: Assisted Reproduction in Italy*, 19 HUMAN REPRODUCTION 1693 (2004).

84. In 2000, Germany did 35,285 IVF cycles, 16,991 of which were by ICSI. France by comparison did 23,347 cycles of IVF, 23,228 of which were by ICSI, while the United Kingdom did 15,694 cycles of IVF and only 10,154 of ICSI. See A. Nyboe Andersen et al., European Society of Human Reproduction and Embryology, *Assisted Reproductive*

eggs that will not be transferred to the uterus in that cycle are then frozen before syngamy has fully occurred. Given the restrictions on the number of embryos that can be transferred and the inability to assess the viability of pronuclear embryos, it is logical to expect that per transfer pregnancy success rates would be lower in Germany than in the United States.

The data does establish that Europe generally has a lower success rate than the United States. For example, the clinical pregnancy rate per transfer for IVF in Europe for 2000 was 28.4%,⁸⁵ compared to 38.2% in the United States.⁸⁶ Transfers of cryogenically preserved embryos (in Germany, only pronuclear embryos are frozen) were also more successful in the United States, with approximately 20% clinical pregnancies in 2000⁸⁷ versus approximately 16% in Europe.⁸⁸ But it is unclear whether the lower success rates are due to the limits that exist in most of Europe on the number of embryos transferred, the inability to select the best embryos, or some other factor. In any event, the per transfer success rate may be less important than the success rate per cycle achieved after all frozen pronuclear embryos are used. Even if some number of them lead to pregnancies as well, the success rate is still likely to be lower in Europe as a whole and in Germany than in the United States.

If, as appears to be the case, there is a trade-off between pregnancy rates and restrictive embryo freezing and transfer policies, one can question whether the gain in respect for embryos justifies the burden on women of having to go through additional transfer or stimulation cycles to achieve pregnancy. Countries might legitimately disagree over which values should take priority. However, the goal of limiting the number of embryos that can be transferred appears aimed more at minimizing the frequency of multiple gestations than at protecting embryos as such. This limitation also provides a stronger explanation for the resultant decrease in pregnancy rates.⁸⁹

Technology in Europe, 2000, 19 HUMAN REPRODUCTION 490, 492 (2004) [hereinafter ESHRE Report].

85. *See id.* at 491.

86. *See* Society for Assisted Reproductive Technology and the American Society for Reproductive Medicine, *Assisted Reproductive Technology in the United States*, 81 FERTILITY AND STERILITY 1207, 1209 (2004) [hereinafter SART/ASRM Report].

87. *See id.*

88. *See* ESHRE Report, *supra* note 84, at 491.

89. Another more important constraint is whether IVF will be covered in public or private insurance schemes. In Germany, free market scholars and religious opponents have both argued that a procedure as morally controversial as IVF should not be supported by

B. Reducing Multiple Gestations

The high rate of multiple gestations associated with IVF is a major problem in all countries.⁹⁰ Pregnancies with two or more fetuses carry extra burdens and substantial health risks for both the woman and the offspring. They also lead to greater overall health care and social costs due to the extra burdens that twins and higher order multiple births cause. In Europe in 2000, IVF and ICSI produced deliveries of twins in 24% of cases, triplets in 2.0%, and quadruplets in 0.04%, with comparable figures for Germany.⁹¹ In the United States in 1998, the respective rates were 31.7%, 6.2%, and 0.2%.⁹²

The problem of reducing the number of multiples, particularly twins, arises from the conflict between the interests of the patient in a successful pregnancy and the effect of multiple births on children and the healthcare system.⁹³ Resolution of this conflict will depend on the increased costs and morbidity from having twins, the impact on pregnancy success rates, and the power of physicians to resist direct regulation.

A range of policy options exists here, from market-based solutions, such as insurance incentives for transferring fewer

public funds. See Harmut Kliemt, Lecture at the University of Giessen Medical School (June 13, 2003) (notes on file with author). By contrast, the reluctance to fund IVF in the United States is due less to moral concerns than to budgetary ones.

90. Multiple pregnancies after ovulation induction not involving IVF is also a serious problem, but I do not discuss it here. See generally Richard P. Dickey, *A Year of Inaction on High-Order Multiple Pregnancies Due to Ovulation Induction*, 79 FERTILITY AND STERILITY 14 (2003).

91. See ESHRE Report, *supra* note 84, at 496.

92. See James P. Toner, *Progress We Can be Proud of: U.S. Trends in Assisted Reproduction over the First 20 Years*, 78 FERTILITY AND STERILITY 943, 949 (2002). Toner optimistically reports that while these higher rates are problematic, they have declined somewhat in 1999 from previous years without an associated decline in overall pregnancy or delivery rate.

93. An excellent summary of the issues is Howard W. Jones, Jr., *Multiple Births: How are We Doing?*, 79 FERTILITY AND STERILITY 17 (2003). The problem is that infertile couples want to maximize their chance of pregnancy and thus may ignore or downplay information about the risks of multiple-child pregnancy. Physicians want to please their patients and may find it difficult to resist their demands for immediate success, particularly since the success rate reporting system records the overall number of pregnancies but not the number of multiples. As a result, they might not adequately inform patients of the chances of a multiple birth and the very serious consequences for mother and fetuses which result. Some physicians might also think that a patient's procreative liberty entitles them to transfer as many embryos as they wish. Finally, the lack of health insurance coverage for IVF procedures leads patients paying out of pocket to try to maximize the return from any one attempt.

embryos, to direct regulation, such as limits on the number of embryos that may be transferred.⁹⁴ Germany and most countries in Europe, including more liberal IVF countries like the United Kingdom and Belgium, restrict the number of embryos that can be transferred to the uterus at one time to two or three, in order to minimize the number of multiple gestations and births. While this practice has been effective in keeping the number of higher order multiple births down, it has not prevented a high rate of twinning. Efforts to reduce the rates of twins vary by country. In the United Kingdom, only two embryos may be transferred in any case. Belgium, which is generally permissive on embryo status issues, has restricted the number of embryos that can be transferred into healthy younger women to one.⁹⁵ Sweden provides insurance incentives for single-embryo transfers.⁹⁶

In both Germany and the United States, the adoption of policies to reduce the incidence of twins is left largely to the doctors and patients involved. Although German law prohibits doctors from transferring more than three embryos at a time, it does not otherwise aim to reduce the number of twins or triplets. The legislature could directly regulate procedures that increase the risk of twins if physician associations are not able to reduce the rate through professional guidelines.

Although legislation in the United States does not limit the number of embryos that may be transferred, the professional organization of fertility doctors has become active in establishing guidelines for its members to meet and taking such proactive steps, such as informing outlier programs of the need to improve their rates.⁹⁷ A number of doctors on their own are also urging single-

94. See Tarun Jain et al., *Trends in Embryo-Transfer Practice and in Outcomes of the Use of Assisted Reproductive Technology in the United States*, 350 *NEW ENG. J. MED.* 1639, 1643-44 (2004).

95. See *id.* at 1644. This policy applies only to women with the best prospects for pregnancy.

96. The Swedish healthcare system will cover an unlimited number of IVF cycles in which a single embryo is transferred, but only four cycles if more than one embryo is transferred. See *id.*

97. The Practice Committee of the American Society of Reproductive Medicine has recommended that patients with a good prognosis (in general, age younger than thirty-seven) have no more than two embryos transferred; that those with an average prognosis (age thirty-eight to forty) have no more than four transferred; and that those with below-average prognosis (age older than forty or with previously identified difficulties) have no more than five transferred. See AMERICAN SOCIETY OF REPRODUCTIVE MEDICINE, GUIDELINES ON NUMBER OF EMBRYOS TRANSFERRED COMMITTEE REPORT (2004), at <http://www.asrm.org/Media/Practice/NoEmbryosTransferred.pdf>. For a skeptical view of earlier versions of professional guidelines, see Carson Strong, *Too Many Twins, Triplets*,

embryo transfer wherever feasible, with at least one program offering free transfer of frozen blastocysts if a previous fresh transfer of a single blastocyst was not successful.⁹⁸ A direct ban in the United States on procedures that increase the risk of twins may be subject to attack as a violation of procreative liberty.⁹⁹

C. Gamete Donors and Surrogates

Another important area of differences between the United States and Germany lies in their respective policies regarding egg donation and gestational surrogacy (where one woman carries the embryo of another person or couple). Sperm donation for couples with severe male factor infertility is legal in both countries, but egg donation and surrogacy, even if unpaid, are outlawed in Germany under the Embryo Protection Act.¹⁰⁰

With its orientation toward personal liberty and presumption against government regulation, the United States has erected few barriers to the use of these particular ARTs. Egg donation and gestational surrogacy are legal, as is the payment of fees in most cases to women who undergo the burdens and risks of egg donation or gestational surrogacy.¹⁰¹ Although only a few states formally recognize the rearing rights of parents using egg donation and surrogacy, no U.S. jurisdiction directly bans those procedures. Egg donation, which serves the needs of older women who have fewer

Quadruplets, and So On: A Call for New Priorities, 31 J.L. MED. & ETHICS 272, 276–77 (2003).

98. Interview with Dr. Craig Winkel, reproductive endocrinologist, in Austin, Tex. (June 12, 2004).

99. See Robertson, *Procreative Liberty*, *supra* note 4, at 26. A couple's claim of procreative liberty should not settle the matter, however, because a one-embryo transfer policy may require more transfers without substantially burdening the woman. Embryo transfer is the least onerous part of the IVF process; the health and social costs of multiple births are substantial.

100. The United Kingdom allows egg donation but not compensation to egg donors beyond their expenses and costs in serving as donors. See Human Fertilisation and Embryology Act 1990, c. 37, § 12 (Eng.). However, the Human Fertilisation and Embryology Authority permits sharing eggs produced by one woman undergoing an IVF cycle with another woman who pays the costs of the first woman's cycle. See HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY, *supra* note 72, at 135–39.

101. California, for example, enforces the contractual intentions of parties in gestational surrogacy arrangements. See *Johnson v. Calvert*, 851 P.2d 776, 782 (Cal. 1993). New Jersey, on the other hand, prohibits both payment and enforcement of surrogacy contracts where the egg is also provided. See *In re Baby M*, 537 A.2d 1227, 1240 (N.J. 1988). Texas adopted detailed legislation authorizing gestational surrogacy agreements in 2003. See TEX. FAM. CODE §§ 160.751–160.763 (2004).

viable eggs, has become a growth sector for ART in the United States.¹⁰² In 2000, the last year for which official numbers are available, 7,581 egg donation cycles were initiated in the United States. This led to 6,684 transfers and 2,920 deliveries (38.5% per transfer).¹⁰³ The multiple birth rate was even higher here than with IVF. Approximately 40% of the deliveries involved multiples (36.7% twins, 3.7% triplets, and no higher order multiples).¹⁰⁴ With regard to gestational surrogacy in the United States, 1066 host uterus transfers occurred in 2000, resulting in 382 deliveries (35.8% per transfer), 35.3% of which were twins and 1.8% triplets.¹⁰⁵

The German ban on egg donation and surrogacy arises from different philosophical positions on the acceptability of donor-created families and of payments to gamete donors and surrogates for their contributions to making offspring possible for infertile couples. This approach, however, burdens the important subset of infertile women who could not have biologically-related offspring without these procedures. It also provides no persuasive explanation for why donor gametes are available for male but not for female gametic failure.¹⁰⁶

The fact that egg donation and gestational surrogacy can serve the needs of women who due to age or disease no longer have viable eggs or who have lost their uterus but retain ovaries provides strong support for making these practices available in other developed countries. The interest of these women in reproducing deserves a higher priority than moral objections that are not firmly grounded in direct harm to offspring or others. The smaller number of women in this category, however, lessens the pressure to put legal access to egg donation and surrogacy on the policy agenda in Germany and other restrictive countries.

102. Unless family donors are used, most egg donors in the United States are paid. Highly publicized stories of offers of "\$50,000 for a tall, blond, Ivy League donor" have shocked or offended many people. Compare Kenneth R. Weiss, *The Egg Brokers*, L.A. TIMES, May 27, 2001, at A1, and Irene Sage, *A \$50,000 Dilemma on Campus*, B. GLOBE, Mar. 6, 1999, at A1, with The Ethics Committee of the American Society for Reproductive Medicine, *Financial Incentives in Recruitment of Oocyte Donors*, 74 FERTILITY AND STERILITY 216, 216 (1999).

103. See SART/ASRM Report, *supra* note 86, at 1213.

104. See *id.*

105. See *id.* at 1214. Gestational surrogacy is less common than egg donation because few women who have lost their uterus retain functioning ovaries and would benefit from this option.

106. The recipient of an egg donation will still gestate even if she does not provide the egg and its genetic contribution to her offspring.

V. EMBRYONIC STEM CELL RESEARCH

An area rife with contradictions for both Germany and the United States has been the debate over embryonic stem (“ES”) cell research. In 1998, scientists at the University of Wisconsin and Johns Hopkins University independently launched a new paradigm for understanding and treating disease when they succeeded in the laboratory culture of human embryonic stem cells.¹⁰⁷ Embryonic stem cells are precursor cells for all tissue in the body. They arise in the inner cell mass that forms at the blastocyst stage of preimplantation embryonic development.¹⁰⁸ Although ES cells are pluripotent (capable of forming all the tissues in the body), they are not totipotent (capable of developing into new individuals).¹⁰⁹ As a result, though derived from embryos, they are not themselves embryos. Controlled differentiation of ES cells into particular types of tissue could produce replacement tissue for diabetes, Parkinson’s disease, cardiovascular diseases, spinal cord injuries, and other diseases that affect millions of people.¹¹⁰ Reaching that goal, however, will require considerable research involving embryos.¹¹¹

The most common type of embryonic stem cells used for research purposes derive from embryos created by couples undergoing IVF who no longer need them. In the future, it may be more desirable to create embryos simply to extract ES cells from them to study. Many people, however, strongly object to creating human embryos solely for research purposes.¹¹² Research with adult

107. See James A. Thompson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCIENCE 1145 (1998); Michael J. Shamblott et al., *Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cell*, 95 PROC. NATL. ACAD. SCI. USA 13726 (1998).

108. See Ann A. Kiessling, *What Is an Embryo?*, 36 CONN. L. REV. 1051, 1062–63 (2004).

109. Although most discussion of ES cells assumes that they are not totipotent, some have argued that based on mouse studies, they are totipotent. See Samuel B. Casey & Nathan A. Adams, IV, *Specially Respecting the Living Human Embryo by Adhering to Standard Human Subject Experimentation Rules*, 2 YALE J. HEALTH POL’Y & ETHICS 111, 119–20 (2001). But see C.R. Towns & D.G. Jones, *Stem Cells, Embryos, and the Environment: A Context for Both Science and Ethics*, 30 J. MED. ETHICS 410 (2004).

110. See PRESIDENT’S COUNCIL ON BIOETHICS, *supra* note 71, at 130–39.

111. See, e.g., Roger Pederson, *Stem Cell Research Must Go Global*, FIN. TIMES, June 17, 2003, at 23.

112. President Clinton, for example, issued an order against funding the creation of embryos solely for research even before the National Institutes of Health Human Embryo Research Panel, which had recommended such funding in limited circumstances, had delivered its final report. See Warren E. Leary, *Clinton Rules Out Federal Money for Research on Human Embryos Created for the Purpose*, N.Y. TIMES, Dec. 3, 1994, at A8;

stem cells not derived from embryos may also prove fruitful.¹¹³

Moral controversy over the use of ES cells in research or therapy arises from the contested moral status of preimplantation human embryos. People who believe that embryos have inherent moral status oppose creating embryos that will then be destroyed for research or therapy. They also oppose the destruction of leftover embryos to derive ES cells for research or therapy, even if those embryos will otherwise be discarded. On the other hand, persons who view embryos as too rudimentary in development to have inherent value accept derivation and use of ES cells as long as informed consent to donation and related norms are followed.

These differences in assessment of embryo status drive the debate over public policy on embryo research and the use of embryonic stem cells derived from embryos. While some countries limit public funding, the time period, and the purposes of embryo research, Germany is almost alone among major developed countries in imposing a near total prohibition on the use of embryos in research.¹¹⁴ Until the development of embryonic stem cell lines in 1998, such a prohibition would have primarily affected only a small group of researchers seeking ways to improve IVF and contraception and to understand the origin of genetic disease. The development of ES cell lines has greatly changed the stakes in embryo research and the social costs of having highly restrictive embryo research policies.

A. *ES Cell Research in Germany*

Countries that take a highly protective view of embryo status, and thus a restrictive approach to embryo research, risk losing out on participating in what may be one of the most important scientific and therapeutic enterprises of the next several decades. For example, Germany has a long and distinguished history in biological and medical research, and has played a major role in the development of modern embryology and developmental and cell biology.¹¹⁵ Because of its strong protective stance toward embryos, however, it presently

John Schwartz & Ann Devroy, *Clinton to Ban U.S. Funds for Some Embryo Studies*, WASH. POST, Dec. 3, 1994, at A1.

113. See PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 71, at 121–25.

114. Ireland and Austria also prohibit all embryo research and thus would ban ES cell research. See Peter Gruss, *Human ES Cells in Europe*, 301 SCIENCE 1017 (2003).

115. See MICHAEL C. BISHOP, HOW TO WIN THE NOBEL PRIZE 137–38 (2003) (recounting the work of German scientists in discovering the cell, how it replicates, and the chromosomal and oocyte basis for life).

plays a minor role in this important developing area of research at a time when the United Kingdom, the United States, and other countries in Europe and throughout the world are forging ahead with ES cell research.¹¹⁶

The prospect of European Union funding for embryonic stem cell research projects, however, is currently on hold. Germany, along with Italy, Austria, Spain, and Portugal, blocked a compromise that would have permitted research to be conducted on embryos created before the June 27, 2002 adoption of the European Union's science funding program.¹¹⁷ It is unclear under what conditions, if any, the European Union will fund ES cell research.¹¹⁸

The German absence from ES cell science is the result of the 1990 Embryo Protection Act, which forbids the creation of embryos that will not be transferred to the uterus and, by implication, criminalizes the destructive derivation of ES cells from blastocysts prior to implantation.¹¹⁹ Under this law, no ES cell lines may be derived from embryos in Germany.¹²⁰ A Parliamentary Ethics Committee also voted against allowing the importation of ES cells for research from other countries. Unhappy with this policy, Chancellor Gerhard Schroeder appointed a National Ethics Council that recommended such importation.¹²¹ After an intense national debate, the federal parliament authorized research with ES cells imported from countries where derivation is legal and where the cell lines had been derived prior to January 1, 2002.¹²²

116. The Medical Research Council in the United Kingdom is spearheading an effort to develop a worldwide repository of human ES cell lines for research and eventual therapy. See Gruss, *supra* note 114.

117. See Gretchen Vogel, *E.U. Stem Cell Debate Ends in a Draw*, 302 SCIENCE 1872 (2003).

118. See *id.*

119. See Embryo Protection Act, *supra* note 65; discussion *supra* Part IV.A.

120. Unlike Lysenkoism in the former Soviet Union, when the ideas of Mendelian genetics themselves were banned, at issue here are the methods for acquiring knowledge, not the knowledge that would be acquired. The government is thus not imposing an orthodoxy of ideas, such as occurred during Lysenkoism in the Soviet Union and to some extent in the German Democratic Republic. See Uwe Hossfeld & Lennart Olsson, *From the Modern Synthesis to Lysenkoism, and Back?*, 297 SCIENCE 55 (2002). Of course, a ban on research methods can obstruct the development of new knowledge just as much as a ban on the ideas to which research might lead.

121. See GERMAN NAT'L ETHICS COUNCIL, OPINION ON THE IMPORT OF EMBRYONIC STEM CELLS (2001), available at http://www.ethikrat.org/english/publications/stem_cells/opinion_human_embryonic%20stem_cells.pdf.

122. See Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen (Stammzellgesetz), v. 28.6.2002 (BGB1. I S.2277) (F.R.G.).

Although the law allows some ES research to go on in Germany, there are significant bureaucratic hurdles. To import ES cells for research, a researcher must demonstrate to the agency charged with implementing the law that they were derived legally from embryos created for infertility treatments without payment to the donors prior to January 1, 2002.¹²³ By September 2004, only eight proposals to import ES cells had been submitted and only five approved.¹²⁴ The German embryonic stem cell importation law also criminalizes collaboration with scientists in other countries using ES cell lines derived after the January 1, 2002 date or otherwise not complying with its conditions.¹²⁵ In addition, university professors and other governmental employees are prohibited from working in a foreign lab with ES cells derived after January 1, 2002 unless they take an official leave of absence.¹²⁶ Because of these restrictions, many young researchers are choosing other areas of research, while more established scientists have moved to countries with more favorable research environments.¹²⁷ If these conditions continue, Germany is unlikely to become a leading center of ES cell science.

B. *ES Cell Research in the United States*

It is interesting to compare the highly restrictive German position with the less restrictive U.S. position. Although the U.S. restrictions apply only to federal funding and not also, as in Germany, to private sector research, the Bush administration's position on ES cell research shares a common moral vision with its German counterpart and faces some of the same contradictions. Given current investor disaffection with the biotechnology sector, the strict limits on federal funding could have a significant impact on development of the field.

ES cell research has been as morally contentious in the United

123. *See id.* § 4.

124. *See* Ned Stafford, *Dispute Over German Law*, THE SCIENTIST, Aug. 3, 2004, available at <http://www.biomedcentral.com/news/20040803/02/>.

125. *See* Ned Stafford, *Stem Cell Collaboration Illegal: In Germany, Scientists Who Advise Overseas Colleagues on New Lines May Face Prosecution*, THE SCIENTIST, August 31, 2004, available at <http://www.biomedcentral.com/news/20040831/04/>.

126. *See* Gretchen Vogel, *Visiting German Profs Could Face Jail*, 301 SCIENCE 577 (2003). With the status of employees of Germany's many non-university research units unclear, they are also advised to take a leave of absence.

127. For example, one of the scientists on the U.K. team that received the first license from the HFEA to undertake therapeutic cloning with human embryos is a German citizen who left Munich because of research restrictions. *See* Stafford, *supra* note 125.

States as in Germany because of the strongly held views of some groups that embryos are themselves persons or subjects with inherent moral status and rights. This view is largely shared by the Bush administration. Because Congress has repeatedly withheld authorization for any spending on embryo research, the federal government cannot fund the derivation of embryonic cells or cell lines.¹²⁸ Congress's ban on funding embryo research does not extend, however, to federal funding for research using ES cells derived with private funds, since ES cells are not themselves embryos.¹²⁹ After advice from the National Bioethics Advisory Commission, the Clinton administration announced in 2000 that it would fund ES cell research and authorized the National Institutes of Health ("NIH") to develop procedures for doing so. The NIH adopted guidelines for research funding and was prepared to make the first grants when the Bush administration put such grants on hold in March 2001.¹³⁰ After further review, President Bush announced that his administration would fund ES cell research only with cell lines that had been derived before August 9, 2001, the date of his announcement.¹³¹

The Bush compromise on ES cell research initially gave a boost to the field. Although limiting federal funding to particular cell lines, it signaled that the topic was an important and acceptable area of scientific research for which the federal government would provide some support. It soon became clear, however, that far fewer viable cell lines than the sixty or more trumpeted by the administration would be available for federal funding.¹³² In addition, intellectual property rights in cell lines and products derived from them could

128. The Dickey Amendment has been enacted in every Congress since 1994 to ban any federal funding of embryo research. See Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996).

129. See Memorandum from Harriet Raab, Department of Health and Human Services, to Dr. Harold Varmus, Director, National Institutes of Health, Federal Funding for Research Involving Human Pluripotent Stem Cells (January 15, 1999) (on file with author) (stating that "statutory prohibition on the use of funds appropriated to HHS for human embryo research would not apply to research utilizing human pluripotent stem cells because such cells are not a human embryo within the statutory definition").

130. See National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000); National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells; Correction, 65 Fed. Reg. 69,951 (Nov. 21, 2000). See Katharine Q. Seelye & Frank Bruni, *A Long Process that Led Bush to His Decision*, N.Y. TIMES, Aug. 10, 2001, at A1.

131. See Seelye & Bruni, *supra* note 130. For an in-depth account of the bureaucratic and intellectual property hurdles to obtaining pre-August 9 ES cell lines for research, see STEPHEN HALL, *MERCHANTS OF IMMORTALITY: CHASING THE DREAM OF HUMAN LIFE EXTENSION* 271, 305-06 (2003).

132. An internal governmental report has found that around twenty-two lines might be viable for research use, but not all researchers agree. See Editorial, *The Privatization of Stem Cells*, N.Y. TIMES, Mar. 9, 2004, at A24.

limit or discourage their use by researchers.¹³³ Moreover, private investment has not been a certain or stable source of funds to make up for the lack of government support. Since 2001, the biotechnology sector has experienced a severe slump that has limited private investment in ES cell technology.¹³⁴

Even more important has been the realization that the pre-August 9, 2001 cell lines were cultured on layers of mouse feeder cells which should not be used in clinical research or therapy because they might contain viruses harmful to humans.¹³⁵ In addition, these cell lines lack the wide versatility in genotype that would make them most useful to researchers searching for the genetic and developmental basis of particular diseases. The need to generate new ES cell lines has thus become apparent and led some universities to support the development of particular cell lines.¹³⁶ It is also possible that for ES cell therapies to be compatible with the tissue of recipients, embryos from a recipient's own cells may be required as the source of ES cells from which replacement tissue is derived.¹³⁷

As the limitations of available lines have become more apparent, the pressure on the Bush administration to relax the August 9 limit has increased. Bipartisan groups of senators and representatives, for example, have asked President Bush to make more lines available for federal funding.¹³⁸ Federal funding of ES cell research also became an issue in the 2004 presidential race.¹³⁹

With the re-election of President Bush, however, the funding

133. See *Stem Cells Ethical Issues and Intellectual Property Rights: Hearing Before the Senate Comm. on Appropriations: Subcomm. on Labor, Health and Human Services, Education*, 107th Cong. (2001).

134. Several universities, including Harvard University and others in Wisconsin, Minnesota, and California, have sought to provide funds for derivation and research with new lines. See, e.g., *Harvard Seeks Private \$100 Million to Build Stem-Cell Centre*, 428 NATURE 8 (2004). California and New Jersey have also undertaken to provide state support for ES cell research. See John M. Broder & Andrew Pollack, *Californians to Vote on Spending \$3 Billion on Stem Cell Research*, N.Y. TIMES, Sept. 20, 2004, at A1. Without federal funding, however, they are unlikely to be able to provide the level of resources needed for rapid progress and translation of research findings into practical therapies.

135. See Liza Dawson et al., *Safety Issues in Cell-Based Intervention Trials*, 80 FERTILITY AND STERILITY 1077 (2003).

136. See, e.g., Editorial, *The Privatization of Stem Cells*, *supra* note 132.

137. See PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 71, at 131–32.

138. See Rick Weiss, *Looser Rules for Stem Cells Sought; House Members Petition President*, WASH. POST, April 29, 2004, at A17; Bob Davis & Antonio Regalado, *How Stem Cells Became Hurdle for GOP Campaign*, WALL ST. J., Aug. 31, 2004, at A1.

139. Ron Reagan, Jr. addressed the Democratic National Convention on the topic and Senator Kerry also mentioned it in his acceptance speech. See Davis & Regalado, *supra* note 138.

limits of current policy are likely to remain in place. Although President Bush could remain true to the moral premises of the 2001 cut-off date and move the cut-off date forward at least once to encompass funding for research on the many ES cell lines created since 2001,¹⁴⁰ strong right-to-life opposition to ES cell research makes such a move unlikely. Although the political landscape in Germany is different, strong pressure to move the funding line could arise there as well.

C. *Moving Cut-off Dates as a Solution*

Normatively, both the Bush administration's and Germany's position assume that the embryo is a person or moral subject and should not be destroyed for ES cells or for any other purpose. However, if persons in the private sector or outside the country have destroyed embryos to obtain ES cell lines, both countries have accepted that those lines may be funded or used in research as long as there is no reasonable basis for thinking that doing so will cause further destruction of embryos. Thus, both the U.S. policy limiting research to those cell lines derived before President Bush's speech on August 9, 2001, and Germany's restriction on the use of ES cells derived after January 1, 2002, accept a moral distinction between causing and benefiting from another person's moral wrong in deriving ES cells from embryos. In both cases, the acceptable cell lines could not have been derived in reliance on the government's policy, for that policy did not exist nor could have reasonably been anticipated at the time of derivation.

Although accused of being specious or disingenuous, the distinction between *causing* a wrong and *profiting* from it has a clear moral basis. Killing another person is clearly wrong. However, the fruits of another's evil sometimes lead to others realizing a good. For example, we obtain organs from murder or suicide victims to extend the life of others and have used tissue from aborted fetuses to make vaccines and conduct research. In those cases, benefiting from the past evil does not appear likely to lead to future evils of the kind that made those benefits possible. Nor does it so clearly taint the user or disrespect the victim of the evil as to be objectionable on that ground alone.¹⁴¹

140. See discussion *infra* Part V.C.

141. Concerns about disrespect and taint may have special resonance in Germany because of the Nazi medical abuses of concentration camp inmates. However, both grounds

If the distinction between causative and beneficial complicity is morally sound, it should eventually favor the use of additional cell lines derived after the dates specified in German and U.S. policies, even for persons who view embryos as moral subjects. Private sector derivation of new ES cell lines will continue in countries that permit it, despite the limitations in the United States and Germany.¹⁴² New cell lines that do not use mouse feeder layers to culture cells are needed to avoid viral transfer to humans. ES cell lines with particular mutations are also needed to study the effect of those genes on development. In the future, cell lines that reflect a wide array of human antigens may be needed to prevent rejection of ES cell-derived replacement therapies.¹⁴³

Given the almost certain development of new cell lines independent of German and U.S. cut-off dates, a change in their policies to allow use or importation of later-derived cell lines (for example, those not grown on mouse feeder layers) could occur without moral complicity in causing the destruction of embryos or impermissibly tainting users. Such cell-lines will have been created in reliance on the demand for such cells from the many scientists in the private sector and in other countries who are studying them, and not on a reasonable expectation that German or U.S. policy will eventually change to accommodate them. If so, public policy in Germany and the United States could allow those new and better lines to be used without moral complicity in causing the destruction of those embryos or in impermissibly tainting researchers who use them.¹⁴⁴

for objecting to use of the fruits of past evil must face the problem of determining the circumstances and conditions under which the disrespect or taint is great enough to create a duty not to benefit from it. Because such principles are difficult to formulate, these judgments might best be left to the realm of personal choice rather than to national policy. See John A. Robertson, *Causative vs. Beneficial Complicity in the Embryonic Stem Cell Debate*, 36 CONN. L. REV. 1099, 1106–1109 (2004) [hereinafter Robertson, *Causative vs. Beneficial Complicity*].

142. The leading ES cell producing countries are the United States, Belgium, the United Kingdom, India, Singapore, and Israel. Singapore has been especially aggressive in filling the ES cell research niche. See Reuters, *Singapore Bans Cloning; Stem Cell Research Rapidly Expands Under Government Incentives*, at <http://www.cnn.com/2004/TECH/science/09/02/singapore.cloning.reut/index.html>.

143. See Ruth R. Faden et al., *Public Stem Cell Banks: Considerations of Justice in Stem Cell Research and Therapy*, 33 HASTINGS CTR. REP. 13, 13–15 (2003).

144. Although the use of cut-off lines assumes that supporting research with already derived ES cell lines will not directly induce the destruction of more embryos, the contrary position would hold that any support for ES cell research will inevitably lead to future demand for more cell-lines. See Robertson, *Causative vs. Beneficial Complicity*, *supra* note 141, at 1109–1113.

This solution, however, is likely to be credible only once. While such a change would foster a great deal more useful research, the same issue will arise concerning the cell lines that will be derived after the new cut-off date.¹⁴⁵ It will also arise with regard to the use of cell replacement therapies with ES cells derived after those dates. At some point, both Germany and the United States will face a more acute and direct trade-off between benefiting from or destroying early embryos and saving the life or health of individuals. Pressure from individuals and patient groups that would directly benefit from such therapies could lead to policy change in each country. Because U.S. policy in this area is based on an executive decision, it can be changed more easily than German policy, which is based on the Embryo Protection Act and would require a legislative amendment to the legal status of human embryos.

VI. THERAPEUTIC CLONING

If scientists do learn to direct the development of ES cells into the cellular material needed for safe and effective replacement therapies, they will also have to devise ways to make sure that replacement tissue will not be rejected by the recipient. One solution is the development of ES cell banks that are compatible with a wide range of tissue types.¹⁴⁶ A more controversial solution is therapeutic cloning through nuclear transfer from one of the recipient's cells to an enucleated oocyte, which is then activated and cultured to the blastocyst stage. At that point, ES cells would be derived and cultured to form the histocompatible tissue needed to treat the patient.

Nuclear transfer cloning has been a source of enormous controversy in most countries, not only because it deliberately creates and destroys embryos (albeit ones created by nuclear transfer and not by fertilization) but also because it is seen as facilitating or even encouraging the practice of reproductive cloning. A bill to ban all human cloning has twice passed the U.S. House of Representatives but not the Senate, and it remains legal with non-federal funds in most states.¹⁴⁷ The HFEA in the United Kingdom recently granted a

145. See George Q. Daley, *Missed Opportunities in Embryonic Stem-Cell Research*, 351 *NEW ENG. J. MED.* 627 (2004).

146. See Faden et al., *supra* note 143.

147. The Human Cloning Prohibition Act of 2003, which bans all human cloning, passed the House in February of 2003. H.R. 534, 108th Cong. (2003). A Senate version of that bill was introduced by Sen. Sam Brownback in January of that same year and awaits committee action. S. 245, 108th Cong. (2003). A competing bill, The Human Cloning Ban and Stem

license for therapeutic cloning research.¹⁴⁸

Many countries specifically ban therapeutic cloning either directly (e.g., Canada) or indirectly by application of more general laws against embryo destruction (e.g., Germany).¹⁴⁹ The United States has supported an international treaty to ban all forms of human cloning, with the support of Germany and the more restrictive European countries, which have also sought a ban by the European Union.¹⁵⁰

The strong opposition in many countries to creating and destroying embryos for the purpose of retrieving ES cells will pose a major dilemma if therapeutic cloning becomes the only safe and effective way to obtain histocompatible replacement tissue from ES cells. Because that moral objection could bar thousands of persons from obtaining needed therapies, there will be intense scrutiny of the reasons for maintaining the ban and great political pressure to change it. If the objection is more expressive and symbolic than rights-based, as it appears to be in many countries, then saving lives and minimizing suffering will likely be sufficient reasons to permit therapeutic cloning and justify foregoing those expressive benefits. On the other hand, if the objection is rooted in the inherent moral or legal status of embryos or the perception that it will foster reproductive cloning, then therapeutic cloning will be harder to accept.

Although the German position on the protection of embryos is legislative and not constitutional, as it is with fetuses, it will still be difficult to change the law to permit cloning for therapeutic purposes. In addition to the strong aversion to the destruction of embryos, therapeutic cloning is closely linked by many Germans and conservatives in the United States with reproductive cloning and its many connotations of genetic control or mastery of individuals. With the lessons and the legacy of the Holocaust still fresh in the minds of Germans, it will be more difficult to accept therapeutic cloning there

Cell Research Protection Act of 2003, was introduced in the Senate shortly after the Brownback bill by Sen. Orrin Hatch. S. 303, 108th Cong. (2003). The Hatch bill would ban cloning for reproductive purposes but would permit it for embryonic stem cell research. It awaits committee action as well.

148. See Brownell, *supra* note 73.

149. See *Canada Passes Bill to Ban Human Cloning*, available at <http://www.abc.net.au/news/newsitems/s1064416.htm>; see also *Spanish Lawmakers Clash Over Control of Stem-Cell Research*, 428 NATURE 7 (2004). Germany has not enacted an explicit ban, but it is clear that the Embryo Protection Act would prevent creating embryos that would be destroyed to obtain tissue for therapy. See discussion *supra* Part IV.

150. See Warren Hoge, *UN Assembly Puts Off Vote on Human Cloning*, INT'L HERALD TRIB., Dec. 11, 2003, at 1.

than in the United States. Despite these barriers to change, the Chair and several members of the German National Ethics Council have called for allowing such experiments to go forward, especially after the United Kingdom's decision to permit them.¹⁵¹ Since it is possible to draw a clear line between therapeutic and reproductive cloning, the need for research to uncover ways to protect human lives might ultimately triumph in Germany, as it is likely to do in the United States.¹⁵²

VII. PREIMPLANTATION GENETIC DIAGNOSIS

Another contradiction in German policy is its position on preimplantation genetic diagnosis (PGD). PGD involves the genetic screening of embryos, prior to transfer to the uterus, to assess the embryos' viability and genetic makeup. A single cell or blastomere removed at the four- or eight-cell stage undergoes chromosomal or genetic analysis. Based on that assessment, the embryo is transferred to the uterus or frozen for later use or eventual disposal. Approximately two-thirds of PGD cycles done throughout the world have been performed to determine whether the chromosomes have an improper number (aneuploidy) and are thus unlikely to implant.¹⁵³ The other third have been performed to determine whether the embryo is free of serious X-linked or autosomal recessive genetic disease, such as Tay-Sachs, cystic fibrosis, fragile X syndrome, and others.¹⁵⁴ More recently, use of PGD has been expanded to test for genetic mutations that indicate a high susceptibility to cancer and to select for offspring who would be a suitable match for an umbilical

151. See Gretchen Vogel, *German Panel Reportedly Supports Cloning Research*, 305 SCIENCE 1091 (2004).

152. The head of Germany's national medical association was strongly critical of the 2004 decision of the United Kingdom's HFEA to issue a license for therapeutic cloning research, calling for a European prohibition on any form of human cloning. At the same time, some members of the National Bioethics Committee have called for reevaluating whether or not there should be a ban on all forms of cloning. See Kristina Merkner, *Ethics Committee Divided on Cloning*, FRANKFURTER ALLGEMEINE ZEITUNG, Aug. 20, 2004, available at <http://www.faz.com/IN/INtemplates/eFAZ/docmain.asp?rub=%7BB1311FCC-FBFB-11D2-B228-00105A9CAF88%7D&doc=%7B916C4AE4-2CE9-4395-A9EB-21A90FEC391B%7D>.

153. See Report of the 11th Annual Meeting of International Working Group on Preimplantation Genetics, *Preimplantation Genetic Diagnosis: Experience of 3000 Clinical Cycles*, 3 REPROD. BIOMEDICINE ONLINE 49, 51-52 (2001).

154. See Yury Verlinsky et al., *Over a Decade of Experience with Preimplantation Genetic Diagnosis: A Multicenter Report*, 82 FERTILITY & STERILITY 292 (2004).

cord blood donation to a sibling with a serious disease.¹⁵⁵ PGD has also been sought for non-medical gender selection.

PGD has been ethically controversial because of its impact on embryos and its selection of embryos based on genetic quality. Some fear it as another step toward a “brave new world” of commodified and instrumentalized reproduction.¹⁵⁶ In fact, if shown to be safe and effective, PGD would simply provide another tool for meeting important medical needs of infertile persons or those with a high risk of having offspring with serious genetic disease. Although its use is now being expanded to susceptibility conditions, tissue matching for an existing child, and, to some extent, for gender, it is unlikely to be used for more general screening of offspring traits, such as intelligence or height, simply because the genetics of those traits are too complicated to be deciphered and the costs and burdens of using PGD for that purpose are too great for wide use.¹⁵⁷

PGD is available in the United States, the United Kingdom, Belgium, Israel, and many other countries for aneuploidy and genetic screening for medical reasons.¹⁵⁸ In Germany, however, PGD is not currently performed. Although its 1990 Embryo Protection Act does not directly address PGD, it does ban destroying or discarding embryos. The PGD process of removing a cell or blastomere at the four- or eight-cell stage, and then not transferring embryos that do not have a correct genetic profile, would violate the law’s requirement that all embryos must be transferred to the uterus. In addition, because a single blastomere removed from an early embryo for genetic analysis is totipotent, it is defined under the act as an embryo. It would thus be a violation of the law to destroy that blastomere in order to analyze its chromosomes or DNA.¹⁵⁹

155. See John A. Robertson, *Ethical Issues in New Uses of Preimplantation Genetic Diagnosis*, 18 HUM. REPROD. 465 (2003) [hereinafter Robertson, *PGD*].

156. See *id.*

157. Many traits of concern are not controlled by single genes, but rather by genetic networks and cellular pathways that are very difficult to decipher. Gender is an exception because it can be determined by a chromosomal analysis without examining individual genes. The Convention on Human Rights and Biomedicine in Europe bans gender screening for non-medical reasons. Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, April 4, 1997, Council of Europe, E.T.S. No. 164, art. 14. See also John A. Robertson, *Preconception Gender Selection*, 1 AM. J. BIOETHICS 2 (2001).

158. See Verlinsky et al., *supra* note 154, at 293. It is unclear to what extent the new ART legislation in Italy will impact the availability of PGD to avoid transfer of embryos with aneuploidy or genetic disease. Italy has one of the three leading centers worldwide for PGD. See *id.* If its new law bans PGD, Italy will face the same contradictions that Germany does in allowing abortion but not PGD for the same condition. See Robertson, *PGD*, *supra* note 155.

159. See GERMAN NAT’L ETHICS COUNCIL, OPINION ON GENETIC DIAGNOSIS BEFORE AND

Some Germans also object to PGD because of fears that it will be used to harm women and persons with disabilities and will foster a eugenic approach to reproduction. Such concerns have a special resonance in Germany, where Nazi programs of mandatory sterilization, euthanasia, and genocide on the basis of genetic characteristics or ethnic identity are still fresh in the nation's collective memory. Indeed, the renowned philosopher Jürgen Habermas, who generally does not address questions of reproduction and bioethics, has spoken out strongly against PGD as the harbinger of a renewed eugenics regime.¹⁶⁰

An opposite view of PGD in Germany also exists. A majority of the Chancellor's National Ethics Council has determined that the law does not now bar PGD for serious genetic diseases that would cause a woman an existential dilemma about whether to start or continue such a pregnancy.¹⁶¹ Although the fetus is a constitutionally protected person, the woman still has a right to avoid serious health burdens or a child with a severe defect and may permissibly abort in such cases. In such cases of "existential dilemma," abortion is justified and therefore lawful, not merely decriminalized. Based on this reasoning, a woman who might abort a pregnancy because of a high risk of passing on a debilitating genetic disease to a child *a fortiori* should also be justified in using PGD to screen embryos. She, too, faces the existential dilemma of whether to start pregnancy at all and then undergo later screening and abortion. If abortion is justified or permitted in such existential dilemmas, so should be the creation and disposal of embryos with medical conditions that would later justify abortion.

Given the glaring inconsistency between permissible abortion and banned PGD, support for making PGD explicitly legal in some cases is growing. A coalition in Germany of Social Democrats, Liberals, and some Christian Democrats is backing legislation that would permit PGD along the restrictive line recommended by the National Ethics Council.¹⁶² In addition, some opponents might accept

DURING PREGNANCY 76–77 (2003), available at http://www.ethikat.org/_english/publications/Stn_PID_engl.pdf [hereinafter GERMAN NAT'L ETHICS COUNCIL, PGD OPINION].

160. See JÜRGEN HABERMAS, DIE ZUKUNFT DER MENSCHLICHEN NATUR: AUF DEM WEG ZU EINER LIBERALEN EUGENIK? (2001).

161. See GERMAN NAT'L ETHICS COUNCIL, PGD OPINION, *supra* note 159, at 134–35.

162. See Interview with Detlef Parr, Liberal Member of Deutscher Bundestag, in Berlin, F.R.G. (June 18, 2003) (on file with author). Such a change would apply only to PGD for serious genetic screening but could be crafted to permit PGD for aneuploidy screening as well. See also *PGD Should Be Allowed in Germany: Study Reveals Demand for a Change in the Law*, EUREKALERT, June 28, 2004, available at http://www.eurekalert.org/pub_releases/2004-06/esfh-psb062804.php [hereinafter *German PGD Study*].

decriminalization of PGD while keeping it unlawful—the solution reached for early non-therapeutic abortion after counseling.¹⁶³ Unless such legislation is passed, Germany will be in the anomalous position of allowing abortion for fetal defects and serious disease up to the twenty-second week of pregnancy but not selection and disposal of embryos prior to pregnancy for the same purpose.

Even if Germany changes its law to allow PGD for serious genetic indication, it will likely continue to ban embryo screening in all other cases. PGD would thus still not be available for aneuploidy screening to enhance IVF success rates in older women; tissue matching for an existing child; sex selection (for gender variety purposes); or any other non-medical purpose.¹⁶⁴ As such, German law on PGD would continue to be much more restrictive than that of many countries in Europe, North America, and Asia.

However, if existential dilemma is the justification for embryo screening and non-transfer, it may be that some other uses of PGD beyond avoiding the birth of children with severe genetic disease should also be allowed. For a woman with an inheritable risk of breast cancer, having a female child who also carries that mutation for cancer later in life could create as much of an existential dilemma as having a child with a severe congenital disease. The same is true of a family with a young child desperately in need of a hematopoietic stem cell transplant for Fanconi anemia or leukemia that seeks to use PGD to have a child who would be a close tissue match for an umbilical cord blood donation to the existing child. As one focuses more on the meaning or importance of a child with a particular genotype to a couple and its impact on their willingness to reproduce, such couples might legitimately claim that they experience the same existential dilemmas that should permit PGD in more severe cases and which now permit abortion on demand after counseling.

But while it is conceivable that German law will come to accept PGD for serious genetic disease, for aneuploidy screening, and perhaps for tissue-matching for an existing sick child, it is much less likely that it will accept PGD to screen embryos for non-medical reasons, such as gender, sexual orientation, or other traits. Indeed, most such uses will be highly controversial even in countries with permissive traditions like the United States.

163. A majority of the Chancellor's National Ethics Council supports such a position. See GERMAN NAT'L ETHICS COUNCIL, PGD OPINION, *supra* note 159, at 96–135.

164. Sex selection is already banned by the 1990 Embryo Protection Act.

VIII. THE LESSONS OF COMPARATIVE BIOETHICS

All law is reflective of the society and social context in which it arises. It should be no surprise that Germany and the United States take different positions on key ethical, legal, and social issues that arise from the development of ARTs and genetic screening technology. What is surprising is how close the two countries are on major issues of reproductive technology. Despite differences in the legal status of embryos and fetuses, abortion is readily available in both countries during the first twelve weeks of pregnancy and thereafter for health reasons. Germany bans the disposal and freezing of embryos, yet because it defines an embryo as existing only after syngamy, it enables as many fertilized eggs to be frozen at the pronuclear stage as are frozen at later stages in the United States. When later transfers are included, Germany has roughly comparable success rates for IVF. Both countries have also relied on professional society guidelines and physician discretion rather than law to reduce the number of twin and multiple births. Finally, the Bush administration's policy allows federal funding of ES cell research on the basis of a cut-off date for when ES cells were derived, just as German policy does.

Yet important differences exist—differences that have a real impact on infertile couples and others who seek to benefit from these new technologies. Germany's hostility to egg donation and surrogacy has made it more difficult for infertile women with ovarian or uterine problems to have children. ART patients may have to undergo several transfers to have a child. Legislation protecting embryos also discourages ES cell research to a much greater extent than lack of federal funding does in the United States. Germany's strict protection of embryos also makes PGD unavailable to couples that are at a high risk of producing children with severe genetic disease.

These differences indicate tensions and inconsistencies in German policy that will exert pressure for change. The area most likely to yield change is policy for medical use of PGD. Germany allows abortion after twelve weeks for fetuses with genetic disease, but not PGD to prevent pregnancies with such fetuses in the first place. The contradiction here is too stark and the burdens on at-risk couples are too great. As a recent poll indicates, a majority of Germans support PGD for such purposes.¹⁶⁵

Embryonic stem cell research policy may also prove amenable

165. See *German PGD Study*, *supra* note 162.

to modification. With the development of many new ES cell lines since 2002 and the need to have virus-free feeder layers, German scientists are as hampered by early cut-off dates, as are U.S. scientists, and, indeed, even more so, because the German restrictions apply to both public and private sector research. Even if German scientists do not push for change in ES cell research policy, once ES-cell derived therapies are available, there will be enormous pressure to allow patients to receive such treatments in Germany. Current opposition to all forms of cloning is also likely to be relaxed if nuclear transfer cloning with a patient's own cells is needed to obtain histocompatible therapies.

Other inconsistencies may persist, however, simply because the critical mass of persons needed to lobby for change does not exist. It is unclear why German legislation should rely so heavily on syngamy when the same potential for development into a new individual arises at insemination or injection of sperm. Yet the burdens of the additional transfers needed because freezing may occur only at the pre-syngamic pronuclear stage are probably too slight to lead to patients mobilizing for a change in the law. Similarly, the justification for allowing sperm, but not egg, donation is not readily apparent, particularly since recipients are able to gestate embryos, and viable eggs could be freely donated by IVF patients. Yet those who could benefit from egg donation but could not otherwise travel abroad to obtain it are too few in number to mount pressure for change.

U.S. policy has its own tensions and contradictions. Most notable is the distinction between the public and private sector as reflected in the debate over public funding of use and derivation of ES cell lines. The public outcry against federal funding of embryo and ES cell research is especially odd, given the lack of equivalent public concern with the fate of thousands of embryos created in private IVF clinics. A policymaker steeped in the German experience might also argue that Americans should pay more attention to respecting human life at its earliest stages and adopt policies that lead to the creation of fewer embryos, fewer embryos per transfer, less disposal of embryos, and a more careful private-sector attitude toward embryo research. Other critics might question whether the U.S. practice of relying on professional self-regulation has sufficient bite to count as meaningful regulation. A true test of the U.S. devotion to the reproductive autonomy of individuals will also arise if non-medical uses of PGD, gene alteration, or reproductive cloning become available.¹⁶⁶

166. For an analysis of those conflicts, see Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J.L. & MED. 7 (2004).

That such contradictions reflective of each system exist—and will continue to exist—is unavoidable because of the difficulty all nations face in arriving at the optimal balance among the competing interests and values at play in the use of reproductive and genetic technologies.¹⁶⁷ Sometimes the impact of formal contradictions is eased by the legal distinctions that we see at work in German abortion law and in its statutory definition of “embryo.” Often, however, they remain, with real impact on infertile couples, on persons at risk of having impaired children, and on societal attitudes generally toward the welfare of children and families. Whether or not they persist will depend on the progress of medical and genetic science, the impact on and the number of those affected, and the evolution of the politics and traditions of each system.

The foregoing comparative analysis has shown that despite important differences between the U.S. and the German reactions to ARTs, both societies have learned to live reasonably well with the genie that reproductive innovation has released from its technological bottle. Despite initial fears, assisted reproduction is now tightly woven into the fabric of medical care and family choice in these two (and most other) countries.¹⁶⁸ As experience grows, regulatory structures and responses will also adapt to new techniques and changed perceptions of old demands. The experience to date in dealing with ARTs will help both Germany and the United States confront existing and future genetic and reproductive challenges.

167. As Whitman has noted: “No generalization about any legal system is ever absolutely correct: Law is always something of a jumble, and there are always exceptions to any general description.” Whitman, *Dignity vs. Liberty*, *supra* note 7, at 1203.

168. Even the highly restrictive 2004 Italian law on ARTs accepts the use of IVF for infertile couples. *See* Arie, *supra* note 83.

