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

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Abstract

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

The 1978 birth of a child conceived by in vitro fertilization (IVF) launched worldwide use of assisted reproductive technologies (ARTs) to have offspring and the ethical, legal, and social conflicts that they have raised. These technologies have been a boon for infertile couples and for persons who risk transmitting genetic disease to offspring. But the use of ARTs have also been highly controversial. Those techniques might require destruction of embryos and fetuses, and some uses threaten to harm children or to devalue family and kinship bonds. Coming to terms with these techniques pose special challenges in liberal democracies, where personal freedom has a high priority but groups with strong religious views also influence public policy.

IVF and other assisted reproductive techniques are now available in most countries. National health or public insurance systems often may cover them. But the process of acceptance has been fraught with conflict and controversy. As a result, there are important differences among nations concerning the terms and conditions of their use, including differences on such important issues as the number of embryos created and transferred, how they are stored, and their ultimate disposition.[1] Countries also vary in the intensity of regulation and their acceptance of more novel techniques, such as egg donation and research with embryos. Some have strict prohibitions, others require prior regulatory approval, and still others leave it to the discretion of the physician and patient.

Additional conflicts have arisen over the use of genetic information to prevent the birth of children with severe genetic disease or other characteristics. Such uses have grown as knowledge of the human genome has increased and new methods of prebirth

screening have developed. Most countries allow carrier and prenatal screening followed by abortion to prevent the birth of children with serious genetic or chromosomal disease. Much more controversial has been the screening of IVF embryos prior to placement in the uterus through preimplantation genetic diagnosis (PGD). While some countries have embraced PGD, others have greatly confined or even outlawed the procedure.[2]

In surveying these developments one is struck by the differences that exist even among highly developed countries. The United States, the United Kingdom, and Belgium, and Israel have been highly supportive, while Germany, Italy, Ireland, Austria, and have been highly restrictive, with Spain and France accomodating of most procedures but resistant to some aspects of reproductive technology.[3] Of special interest is the case of Germany. German legislation restricts ART, PGD, and embryo research to a degree that except for Italy, Austria, and Ireland, is unique in western Europe and serves to define the most conservative end of the policy spectrum. This posture has also made it difficult to do embryonic stem (ES) cell research, effectively preventing Germany (as well as its conservative counterparts) from playing a substantial role in this important developing field.[4]

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[1]For example,whether it is permissible to discard embryos or donate them to researchers and infertile couples.

[2] In the United States PGD fits neatly into the standard policy position that allows the private sector to offer new reproductive uses without prior approval as providers and patients deem useful. This position, however, does not guarantee that federal funding for it will be available.

[3] 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 innovation. For example, France, which has the highest rate of IVF in Europe, was originally quite negative toward embryo research and PGD. It now permits them in specified circumstances.

[4] Although not of the restrictions directly penalize or ban the pursuit of certain areas of science or prescribe a scientific orthodoxy as Lysenkoism did in the Soviet Union, a

Comparison sometimes yields insights not available from focus on a single country. I describe here the German legal and regulatory situation with regard to abortion, ARTs, embryonic stem cell research, therapeutic cloning, and preimplantation genetic screening of embryos and compare them with relevant features in the United States.[5] As an exercise in comparative bioethics, it attempts to show relative differences and the light they shed on policy in each country. Several interesting things emerge from this comparison.

The first is that rhetorical or formal legal differences may end up making less difference in practice than public battles over rhetoric would have led one to expect. This is most notable in the case of abortion and assisted reproduction through IVF. The differences "on the ground" of what is actually available to people are less than the rhetorical differences would have suggested. In these cases one can ask whether enough of meaning is at stake to justify the pitched battles over rhetorical frameworks that have occurred.

Yet there are also areas in which the rhetorical differences do have an important impact on practice, most notably with regard to the use of gamete donors and surrogates, preimplantation genetic diagnosis, and embryo research. Here persons in Germany are barred from practices or procedures that are available elsewhere. While some of them

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comparison to how Lysenkoism fared in the German Democratic Republic is nevertheless of interest. See Uwe Hossfeld and Lennart Olsson, "From the Modern Syntheiss to Lysenkoism, and Back?" *Science* 29:55-56 (2002).

[5] As James Whitman notes, "relative claims can be a 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."James Q. Whitman, Harsh Justice: Criminal Punishment and the Widening Divide Between America and Europe (Oxford Univ. Press, 2003). pp. 16-17.

can engage in "reproductive tourism" to get denied procedures, this is not easily available to all persons, and raises questions about whether the burdens on them are justified.[6]

Aspects of both points are also evident in the policy that has emerged in Germany for embryonic stem cell research policy. Although German policy applies both to the private and public sector while U.S. restrictions apply only to public funding, there are strong conceptual similarities and shared moral assumptions in each approach. The United States avoids the worse excesses of the German position, but is subject to soome degree to the same contradictions and threats to the scientific enterprise.

German Protection of Fetuses and Embryos

The distinguishing feature of the German reproductive policy landscape is its much stronger formal protection of fetuses and embryos. In Germany implanted embryos and fetuses are protected by the Basic Law, and thus entitled to the same right to life and dignity that all persons have.[7] Indeed, they even have a right to state protection of those rights--a rare example of positive constitutional rights.[8]

This more protective attitude toward fetuses and embryos is usually explained as a reaction to fascism and the excesses of the Nazi era combined with the deep religious roots of Germans, particularly German Catholics. Greens and feminists also fear the risk of impersonal technologies run amok, and joined with other groups to place embryo

[6] Reproductive tourism has also been suggested as a solution for those couples who can afford it to the highly restricted ART law recently passed in Italy. See Sophie Arie, "Fertility's Closed Italian Frontier," Christian Science Monitor, March 10, 2004, p. 1.
[7] The protection of peimplantation embryos has not yet been recognized as a constitutional duty. They are, however, protected by the Embryo Protection Act of 1990. See infra at pp.
[8] Positive constitutional rights exist in other legal systems as well. See South African constitutional court decision on the right to health care. Positive constitutional rights, however, have not yet been recognized as such in theUnited States.

screening issues within a human rights framework. While the law also recognizes the rights of women to personalty and identity, most notably in permitting women in some cases to have abortions, these must be balanced against the fetus and embryo's right to life.

The presumptive balance in favor of implanted fetuses and embryos has come to play a major role in policy and practices concerning assisted reproduction, in vitro fertilization, embryo research, and preimplantation genetic diagnosis. While policy similarities with the United States exist in many areas, the difference in embryo status leads to important differences in policy in several areas, as the following account shows.

That those differences exist, however, should not be surprising. Deeply held values about respect for human life, the importance of reproduction, and protection of women and offspring are at stake in these conflicts, and different groups and individuals will have different views of them. The hallmark of liberal democracy is that such decisions are for the populace at large, as translated through the agencies and bodies of state law-making. A more interesting question is whether different formal differences always translate into different practices. In several areas of reproductive technology policy we will see that the differences in practice are less than the difference in rhetoric, while in others the differences matter greatly. An interesting questions is why the line between rhetoric and reality is blurred in some cases, but not in others.[9] Further reflection on these questions suggests the outlines of a broader, largely accepting, stance toward reproductive and genetic technologies in Germany and other countries with a highly conservative stance on these techniques.

[9] Calabrese and Bobbitt, Tragic Choices (1977).

Abortion

In the late 1960s and early 1970s Germany, like many other liberal democracies, reformed its laws to make abortion more widely available. A 1973 law made abortion lawful during the first twelve weeks of pregnancy, up until 22 weeks for fetal defect, and beyond if there were threats to the woman's life or health. Groups opposed to abortion immediately challenged the law in the Federal Constitutional Court.

In 1975 the Constitutional Court ruled that German penal law did not regulate the first fourteen days of human development from fertilization until implantion in the uterus, but did protect fetuses once pregnancy had begun.[10] As a result, the Court found that a fetus had a right to life which the state had a duty to protect by passing laws that would prevent unjustified harm to fetuses. At the same time it found that the Basic Law also protected a woman's right of personalty and gave her some degree of control over her life. Thus a woman could not be expected to continue a pregnancy that threatened her life or health, that resulted from rape, that would lead to a child with severe defects, nor where a great social burden would be imposed on her. The Court, however, found that in recognizing a woman's interests the 1973 reform law was insufficiently protective of fetuses. It invalidated the law but gave specific instructions for mandatory counseling and third party review that would pass constitutional muster. Legislation reflecting these requirements was then passed.

[10] My account of the German constitutional court abortion decisions is based on Gerard L. Neuman, *Casey* in the Mirror: Abortion, Abuse and the Right to Protection in the United States and Germany, 43 Amer. J. Compar. L. 273-315 (1995); Donald P. Kommers, "The Constitutional Law of Abortion in Germany: Should Americans Pay Attention?," 10 J. Contemp. Health Law & Policy 1-34 (1994). I have also benefited from Edward Eberle, "Human Dignity, Privacy, and Personality in German and American Constitutional Law, 1997 Utah Law Review 964-1058.

This outcome--a strong rhetoric of fetal protection that nevertheless allowed most abortions in the first 12 weeks, as well as thereafter in more serious cases-- provided policy stability until 1990. Those provisions then became a major obstacle in negotiations over the reunification of East and West Germany. Because the East German abortion law was considerably more permissive than the West German statute, East Germany insisted that post-unification abortion law also be liberalized. The resulting legislation made abortion lawful during the first trimester (12 weeks) after mandatory counseling three days before the procedure. Later abortions for health reasons or to prevent the birth of a child with severe defects were also permitted.

This law too was immediately challenged. In 1993 the Federal Constitutional Court again modified some provisions but upheld the basic notion that fetuses had a right to life under the Basic Law which the state had a duty to uphold. Women, however, also had important rights of personalty. While the state must give priority to the interest of the fetus, it had some leeway in its judgments about how to protect fetuses.

The Court placed great weight on the distinction between the *legality* and the *criminality* of abortion.[11] The state's duty to protect the right to life of fetuses meant that abortion (except where justified by threat to the mother's life or health) must remain unlawful. However, the state had some flexibility in determining what policies to pursue in implementing that illegality. For example, it need not criminalize unlawful abortions in all cases. Decriminalizing abortions in the first 12 weeks that occurred three days after

[11] While the distinction is not unknown in policy circles in the United States, it has been used in the Netherlands in recent years to decriminalize active euthanasia and in Canada to decriminalize small amounts of marijuana.

mandatory counseling fulfilled the state's constitutional duty to protect fetuses.[12] The Court found that this rule satisfied the legislature's constitutional duty to protect fetuses because 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 persuaded them to continue their pregnancy.

The Court also addressed a set of secondary conditions that could impact the abortion decision. It held that the state must protect women against landlords and employers penalizing them for having or not having an abortion, such as by enforcing no-children provisions in leases, and made it a crime for a husband to coerce a wife to have an abortion. The Court also found that the state had no obligation to include abortion in national health insurance and prohibited private health insurers from paying for elective abortions, even though it also found that those who were truly "needy" would receive state assistance to pay for an abortion.

American constitutional lawyers will 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 was similar in many respects to that drawn in the United States.[13] Although the German state had a legal obligation to protect the fetus, a woman's right over her person also deserved respect. That right did not trump the right to life of the fetus, but it did permit the legislature to distinguish between the *illegality*

[12] A doctor committed a criminal offense if he or she performed an abortion without a certificate of counselling for the woman. For further discussion of mandatory counselling, see infra at.

[13] German constitutional procedure differs from American. States or a number of legislators may bring cases to the court. The court may impose positive duties on the legislature and describe in detail the laws that must be passed.

and the *criminality* of abortion, thereby leaving a woman's choice still largely protected in the first trimester and in special circumstances beyond.

In many respects the German court's resolution is very similar to that achieved in 1992 in *Casey v. Planned Parenthood*.[14] The Federal Constitutional Court grants juridical status and rights to fetuses, is more directly legislative in tone, but in the end reaches a normative balance close to that reached in *Casey*. There is the important difference that the German state has a duty to protect fetuses, while *Roe* and *Casey* leave individual states free to decide how protective as long as they do not impose "undue burdens " on a woman's previability abortion decision. With a majority of states now imposing waiting periods and mandatory counseling, the United States situation approaches the German. Both German and American women are free after counseling to have abortion on demand in the first trimester and for fetal defect or other serious reason beyond. Predictably, pro-choicers in the United States attacked as too onerous the mandatory counseling that pro-lifers in Germany argued was too lenient.[15] A stablility has been achieved in both countries, though warfare over many details continues, perhaps more markedly in the United States with its ongoing controversies over partial-birth

[14]112 S.Ct. 2791 (1993).

[15] See discussion below. American scholars such as Mary Ann Case who view counselling requirements through the lens of women's rights argue that such requirements demean the decisionmaking ability of women since no counselling is required for more serious medical procedures undergone by men. Mary Anne Case, "How Viable Is the German Compromise on Abortion?" p. 2 (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 counselling and waiting periods in their own right. See Oregon law on physician assisted suicide.

abortion bans, parental notification, fetal status laws, and other attempts to gain legal protection for prenatal life.[16]

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*[17] and *McCrae v. Harris*[18] denied a positive right to state funding of abortion for poor persons, leaving it to individual states to decide as they wished. In Germany, by contrast, the 1993 decision held that it was illegal for public or private insurers to pay for decriminalized abortions. Yet the Court also found that the German government had an obligation to pay for those abortions for people who were in "straitened financial circumstances" and thus unable to pay themselves.[19] Subsequent regulations implementing the decision have interpreted the meaning of "straitened financial circumstances" very broadly, which has resulted in the state paying for the majority of abortions that now occur.[20] If this practice continues, it will be a further example of the difference between law on the books and on the ground of actual practice.

The mandatory counseling provisions of the German law have also led to a different debate than has occurred in the United States. In the United States counseling has been an issue for feminists who argue that it burdens the abortion decision and treats women as incapable of autonomous choice. *Casey* rejected such a critique, and left the

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[16] Nervous liberals worry about the fact that a change of one or two votes on the Court could overturn *Casey*, thus making each new Supreme Court appointment the focus of intense political debate. My own intuition is that the *Roe-Casey* framework of abortion rights reflects a reasonably stable equilibrium on the issue that will survive for some time to come.

[17] 432 U.S. 464 (1977)

[18] 448 U.S. 297 (1980).

[19] See Neuman, p. 287.

question of scope, extent, and timing of counseling to be fought out in the states. A majority of states now require a 24 hour wait and discussion or distribution of information about the development of the fetus, health risks from abortion, and adoption alternatives by the physician or center performing the abortion.

In Germany abortion counseling occurs in centers outside of the physician's office. Government funded counseling centers exist throughout Germany, as do centers run by private groups and until recently, the Catholic Church. Because a certificate from the counseling center facilitates obtaining an abortion, the Vatican eventually decreed that the German Catholic hierarchy could not participate in counseling. Interestingly, some pro-choice Catholic laity have formed their own counseling centers.[21]

Assisted Reproduction.

With IVF not available in Germany until the mid 1980s, there was no need in the 1975 abortion decision to discuss IVF and the status of laboratory-created extracorporeal embryos. As a result, that decision did not address the legal status of fertilized eggs from fertilization to the blastocyst stage when nidation or implantation in the uterus occurs, the time period over which IVF gives control. Nor did the 1993 decision. As a result, the strong defense of the rights to life and dignity of fetuses in those cases applied only to embryos implanted in the uterus and fetuses, not to preimplantation embryos created in the laboratory by IVF.

As IVF became more widely used in Germany in the middle and late 1980s, controversy arose over the status of laboratory embryos and the need for regulation of the

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[20] I rely again on Mary Anne Case's "How Viable Is the German Compromise on Abortion?" p. 5 (unpublished paper on file with author).
[21] Case at 2.

IVF procedures that created them. The ability to create human embryos in the laboratory, to culture and to freeze them, and to screen them for health or disease met the strong demand of the 10-15% of couples who suffered from infertility. Extracorporeal gestation was a significant step forward in control of reproduction, and many questions arose about the legal and moral status of preimplantation embryos. There were concerns about how many were created, the disposition of extras, who had authority to control them, and whether they could be discarded, used in research, or donated to others.

The United States has taken a largely hands-off posture toward IVF, leaving it to the private market of doctors and patients to decide what services would be offered, subject to the law of torts and contract and an optional clinic reporting system.[22] Embryos have no inherent moral or constitutional status, and there are for the most part no laws against creating extra embryos, discarding them, donating them to others, or specifying what may be done with those leftover. Most private clinics and researchers, however, have not engaged in the full extent of manipulation of embryos that is legally permitted. A few states prohibit in broad terms "embryo" or fetal research, but whenever challenged, they have been declared unconstitutional and do not appear to have deterred research with embryos or stem cells derived from them.[23] In any case, they do not affect the practice of IVF, only what can be done with unwanted embryos. A federal law

[22] Although oft 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," Fertility and Sterility 75:932-950 (2002).

[23] Lori Andrews, Legislators as Lobbyists: Proposed State Regulation of Embryonic Stem Cells Research, Therapeutic Cloning and Reproductive Cloning, in President's Bioethics Council, Monitoring Stem Cell Research, Appendix E, pp. 220-201 (2004).

enacted in 1992 does create a system of incentives for accurate reporting of clinic results which does provide consumers with reliable data about program efficacy.

The United Kingdom also does not grant legal status to embryos. It permits embryo research, including research on embryos created for that purpose. A national regulatory authority, the Human Fertilisation and Embryology Authority, plays a major regulatory role. It licenses clinics, collects data on results, and sets practice policies pursuant to Parliamentary instruction.[24] The HFEA has limited the number of embryos that can be transferred at any one time to two, but has granted licenses for preimplantation genetic diagnosis and several kinds of embryo research. Unlike the United States, however, it does not permit payments to sperm and egg donors or to surrogate mothers, and so has a much lower rate of those practices.

Embryo Protection and IVF Success Rates

German legislation on assisted reproduction grew out of publicity in the late 1980s about doctors who created embryos for research, which provoked an intense public debate and calls for regulation. The National Chamber of Doctors tried to stave off legislation by issuing guidelines for embryo research, but they were widely seen as too permissive. 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."[25]

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[24] Human Fertilisation and Embryology Act, Ch. 37, #12 (1990); Human Fertilisation and Embrology Authority, *Code of Practice*, Jan. 2004, 41, at http://www.hfea.gov.uk/HFEAPublications/CodeofPractice.

[25] Gerard L. Neuman, *Casey* in the Mirror: Abortion, Aubse and the Right to Protection in the United States and Germany, 43 Amer. J. Compar. L. 273-315 (1995).

The result was the 1990 Embryo Protection law.[26] Although not based on constitutional grounds as were the two Constitutional Court abortion decisions on the legal status of fetuses, this statute was highly protective of embryos as incipient forms of human life. Its definition of embryo chose the point after fertilization at which nuclear fusion or syngamy had occurred, which ordinarily occurs about 20 hours after insemination.[27] Although the law is highly restrictive and places Germany near the conservative end of the regulatory spectrum, its definition of embryo leaves some room for maneuver that practice patterns have fully exploited.[28] The law made it a crime punishable by three years in prison to transfer more than three embryos to the uterus, to fertilize more eggs that if attaining syngamy could be transferred to a woman in one cycle, to engage in egg donation and gestational surrogacy, or to create embryos for research. It also prohibited nonmedical sex selection and posthumous in vitro fertilization.[29]

The German law was among of the most restrictive laws enacted in Europe, a far cry from the liberal policies recognized in the United States and United Kingdom. The

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[26] Under the Federal Court's 1975 abortion decision, prior to nidation (syngamy) there is no protectible individual. The German constitutional court has not yet ruled on whether pre-nidation embryos are constitutionally protected under the Basic Law, and thus whether the legislature's failure to enact embryo protection laws would have violated the constitution.

[27] 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 the embryo is usually described as "pro-nuclear" because it has the unfused pronuclei of each haploid gamete.

[28] The new Italian law is even more restrictive because it defines the embryo from the time of insemination. On the new Italian law, see Robin Marantz Henig, "On High-Tech Reproduction, Italy Will Practice Abstinence," New York Times, March 2, 2004, D5; Sophie Arie, "Fertility's Closed Italian Frontier," Christian Science Monitor, March 10, 2004, p. 1.

law restricted the practice of IVF by limiting the number of embryos that could be created and transferred, banned embryo freezing, and outlawed embryo research. Because embryos exist only after nuclear fusion, which occurs roughly 20 hours after fertilization, and all embryos must be transferred to the uterus, fertilized eggs or embryos that have reached syngamy cannot be frozen for later use. As a result, there is not time to judge the quality of the three embryos that can be transferred because selection for transfer must occur before their ability to divide normally can be assessed.

It is plausible to think that the strictures of German law do have an effect on the efficacy of IVF or access to it. German fertility doctors hyperstimulate women to produce multiple eggs just as they do in the United States, though they may use lesser amounts of drugs and retrieve fewer eggs. Most eggs are inseminated or undergo intracytoplasmic sperm injection (Germany has the highest rate of ICSI in Europe).[30] Those that will not be transferred in the retrieval cycle are frozen at the pronuclear stage before fusion at syngamy of the haploid chromosomal contributions of the male and female gametes 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 success rates would be lower in Germany than in the United States.

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[29] An even heavier sentence--five years--was authorized for germline alteration of embryos; creating an embryo with the DNA of another embryo, fetus, living or deceased person; or creating human-human and human-animal chimeras and hybrids.

[30] In 1998 it did 15,703 IVF and 24,336 ICSI cycles. France by comparison did 21,831 cycles of IVF and 17,583 of ICSI while the United Kingdom did 17,641 cycles of IVF and only 10,154 of ICSI. European Society of Human Reproduction and Embryology. assisted reproductive technology in Euroe, 1998. Results generated from European registers by ESHRE. Human Reproduction; 116: 2459-2471 (2001).

Indeed, the data shows quite clearly that success rates in Germany and in Europe generally are less than those of the United States. For example, the clinical pregnancy rate per transfer for IVF in Europe for 1998 was 27% versus 37.8% in the United States. Even transfers of cryopreserved embryos were more successful in the United States, with 24.3% clinical pregnancies versus 14.5% in Europe. But it is unclear whether the lower success rates are due to the limits on the number of embryos transferred, which exist in most of Europe, 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 less than in the United States.

If, as appears to be the case, there is a trade-off between pregnancy rates and 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 at minimizing the frequency of multiple gestations and their sequelae, not to protect embryos as such. This goal provides a much stronger justification for a trade-off in pregnancy rates.[31]

[31] A more important constraint is whether IVF will be covered in public or privatre 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 public funds. By constrast, the reluctance to fund IVF in the U.S. is due less to moral concerns than to budgetary ones.

Reducing Multiple Gestations

Counterbalancing the higher pregnancy rates in the United States are higher rates of multiple pregnancies. In Europe in 1998, IVF produced deliveries of twins in 23.9% of IVF deliveries, triplets in 2.3%, and quadruplets or more in 0.1%. In the United States the comparable rates were 31.7%, 6.2%, and 0.2% (38% of all deliveries versus 26% in Europe).[32]

The high rate of multiple gestations associated with IVF is a major problem in all countries, but particularly so in the United States.[33] Pregnancies with two or more fetuses carrry extra burdens and substantial health risks for both the woman and offspring. They also lead to greater overall health care and social costs due to the extra burdens that twins and higher order multiples cause. Germany and most countries in Europe, including such liberal IVF countries as the U.K. and Belgium, restrict the number of embryos that can be transferred to the uterus at one time to two or three. This limit is designed to minimize the number of multiple gestations and births, not to protect embryos as such.

There are several reasons for the high rate of multiples in the United States.[34] Infertile couples want to maximize their chance of pregnancy and thus may ignore or

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[32] James P. Toner, "Progress We Can be Proud of: U. S. Trends in Assisted Reproduction over the First 20 Years, 78 Fertility and Sterility, 943-950 (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. Id.

[33] Multiple pregnancies after ovulation induction not involving IVF is also a serious problem but I do not discuss it here. See Richard P. Dickey, A year of inaction on high-order multiple pregnancies due to ovulation induction. Fertility and Sterility; 79:14-16 (2003).

[34] The best recent account is Howard W. Jones, Jr., Multiple births: how are we doing?, Fertility and Sterility 79:17-21 (2003).

downplay information about risks of multiple 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. Misunderstanding of the scope of procreative liberty may also be a factor.[35] Finally, the lack of health insurance coverage for IVF procedures lead patients paying out of pocket to maximize the return from any one attempt.

Given the general reluctance to interfere in medical decision-making in the United States, it is unlikely that laws limiting the number of embryos will be enacted. The burden of reducing the number of IVF-related multiples has thus fallen to professional guidelines. Modifying more liberal guidelines issued in 1998, the Practice Committee of the American Society of Reproductive Medicine recommended in 1999 that patients with good prognosis (age younger than 35) should have no more than two embryos transferred; those with an average prognosis (age 35-40 years) could have three transferred; and those with below-average prognosis (age older than 40 or previous difficulties that could be identified could have four transferred.[36]

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[35] This is not an accurate understanding of what constitutional or moral doctrines of procreative liberty would require. The procreative liberty of infertile persons does not give them the right to risk multiple gestations which impose health risks on mother and child. A plausible version of that right gives a right to have one child at a time but not multiples if doing so would impose grave risks on women and offspring. See John A. Robertson, "Procreative Liberty and Harm to Offspring in Assisted Reproduction," (forthcoming, 2004).

[36] Guidelines on number of embryos transferred. American Society of Reproductive Medicine: a committee opinion. An educational bulletin Birmingham, AL: November, 1999.

Although only advisory, those recommendations, if followed generally, should greatly reduce the number of higher order multiples. The guidelines may also reduce the number of twins but will do so at the cost of a reduced delvery rate per transfer.[37] A transfer policy of only one embryo per cycle would eliminate twin deliveries from IVF as well, but at an even greater cost in deliveries per transfer and to women who have to go through additional transfers or stimulation and retrieval cycles to achieve pregnancy.[38] The key policy issue is where to locate the tradeoff between reducing the rate of mutliple pregnancies and increasing the failure rate per transfer. Put differently, should infertile couples be required to put the goal of minizing multiple births ahead of their interest in fewer transfer and cycles to achieve pregnancy? [39]

As the debate over reducing the number of multiple pregnancies continues, the main role of the legal system may be to ensure that couples are adequately informed of the risks of multiple gestation. Professional guidelines may also play a role in identifying the applicable standard of care in litigation brought by couples who suffered harm as a result of multiple gestations. They should encourage doctors to discuss more fully with patients and make more considered judgments about the number of embryos transferred than they may have been in the past. Lawsuits for multiple gestation are most likely from women who give birth to triplets or more. They are are less likely from women who give

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[37] Allan Templeton and Joan K. Morris, "Reducing the Risk of Multiple Births by Transfer of Two Embryos After In vitro Fertilization," 339 New Eng. J. Med. 573-577 (1998).

[38] Culturing embryos to the blastocyst stage might make single-embryo transfer policy less costly in success rates. Even with single embryo transfers, spontaneous twinning might still occur just as it does after non-IVF conception..

[39] The couple's claim of procreative liberty does not settle the matter because a one-embryo transfer policy may require more transfers without substantially burdening the

birth to twins, unless mother or children suffer severe complications. While professional organizations of fertility doctors believe that professional guidelines will alleviate most of the problem, others are skeptical that they will have that effect.[40]

Gamete Donors and Surrogates

One area of both rhetorical and practical difference between the U.S. and Germany is policy regarding egg donation and gestational surrogacy. These differences arise 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.. Sperm donation for artificial insemination is legal in both countries, but egg donation and surrogacy, even if unpaid, are outlawed in Germany, thus depriving German women of ways to treat infertility available in other developed countries.[41]

In the United States, by contrast, egg donation and gestational surrogacy is legal, as is the payment of fees in most cases to women for undergoing the burdens and risks of donation or surrogacy. Although only a few states formally recognize the rearing consequences of egg donation and surrogacy, no U.S. jurisdiction directly bans those procedures. Egg donation, for example, which serves the needs of older women who

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woman. Embryo transfer is the least onerous part of the IVF process, and the health and social costs of multiple births is substantial.

[40] Carson Strong, "Too Many Twins, Triplets, Quadruplets, and So On: A Call for New Priorities," 31 J. of Law, Medicine, & Ethics, 272-282 (2003).

[41] The United Kingdom allows egg donation but not compensation to egg donors beyond their expenses and costs in serving as donors. HUMAN FERTILISATION AND EMBRYOLOGY ACT, Ch. 37, #12 (1990). 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 Embrology Authority, *Code of Practice*, Jan. 2004, 41, *at* http://www.hfea.gov.uk/HFEAPublications/CodeofPractice.

have many fewer viable eggs, has become a growth sector for ART in the United States. In 1999, the last year for which official numbers are available, 6,509 egg donation cycles were iniated. This led to 5,808 transfers and 2,340 deliveries (41.8% per transfer). The multiple rate was higher than with IVF. 42% of the deliveries involved multiples (twins 37.4%, 4.4% triplets, and 0.1% higher order). [42]

Unless family donors are used, most egg donors in the United States are paid. While highly publicized stories of offers of "$50,000 for a tall, blond, Ivy League donor" shocked or offended many people, most payments are considerably less. As the evidence from abroad suggests, reliance on the altruism of strangers for egg donation will prove insufficient to meet the demands of the older patient groups that most benefit from egg donation. Due to the added cost of egg donation, many couples now share the same donor.[43] Fewer gestational surrogacy procedures occur because fewer women who have lost their uterus retain functioning ovaries and would benefit from this option.[44]

The German ban on egg donation and surrogacy does burden the important subset of infertile women who could not have biologically-related offspring without these

[42] Society for Assisted Reproductive Technology and the American Society for Reproductive Medicine. Assisted reproductive technology in the United States: 1999 results generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry. Fertility and Sterility; 78: 918-931 (2003).
[43] Programs have developed procedures for dealing with the cost of donors, for example, splitting the eggs from a donor between two couples. See note 42 for an account of how egg sharing is handled in the U.K.
[44] 737 host uterus transfers occurred in 1998, resulting in 245 deliveries (29.8% per initiated cycle and 33.6% per transfer). 32.7% of the deliveries were for twins and 4.1% were triplets. See SART/ASRM 1999 Registry. The legislative climate is changing now to give protection to gestational surrogacy arrangements. Texas, for example, has just passed a law authorizing gestational surrogacy.Texas H.B. 797 (2003).

procedures.[45] With its liberty-orientation and presumption against government regulation, the United States has chosen not to erect barriers to use of these devices. Because they do serve important needs, e.g., women who because of age or disease no longer have viable eggs or who have lost their uterus but retain ovaries, a strong argument can be made that both egg donation and gestational surrogacy should be available for couples with medical conditions necessitating their use. The smaller number of women in this category, however, makes it more difficult to put legal access to egg donation and surrogacy on the policy agenda both in Germany and other restrictive countries.

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

Embryonic Stem (ES) Cell Research

A new avenue for understanding and treating disease opened in 1998 when scientists at the University of Wisconsin and Johns Hopkins University succeeded in culturing human embryonic stem cells in the laboratory.[46] Because ES cells are the precursors of all types of cells in the body, the availability of human ES cell lines has opened the door to a much deeper understanding of cellular and somatic development and the potential to develop far-reaching therapies for millions of people. If scientists learn how to manipulate the growth factors that determine the subsequent differentiation of stem cells into particular types of tissue, they will be able to create replacement tissue for diseases such as diabetes, Parkinson's, Alzheimer's, and cardiovascular disease that affect millions of people.

Reaching that goal, however, will require considerable research and international cooperation involving embryos.[47] Embryonic stem cells are obtained by dissection from the blastocyst stage of the preimplantation embryo, thus destroying the ability of that embryo to develop further as a individual. Although ES cells are pluripotent (capable of forming all the tissues in the body), they are not totitpotent (capable of developing into a new individuals). As a result, they are not themselves embryos though they are derived from embryos.

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[46] Thomson JA, Itskovitz-Eldor J, Waknitz MA, Swiergiel JL et al. Embryonic stem cell lines derived from human blastocysts. Science, 1998. 282:1145-47; Shamblott MJ, Axelman J, Wang S, Littlefield EM et al. Derivation of pluripotent stem cells from cultured human primoridial germ cell. Proc. Natl. Acad. Sci. USA , 1998; 95:13726-13731.

[47] Roger Pederson, "Stem cell research must go global," Financial Times, June 17, 2003, p. 15.

The main source currently for embryonic stem cells are embryos created by couples undergoing IVF who no longer need them. In the future it may be more desirable to create embryos specifically to derive ES cells from them, for example, to study the impact of particular genetic defects on development or to obtain histocompatible tissue for cell replacement therapies, but many persons strongly object to creating human embryos solely for research purposes. Research with adult stem cells not derived from embryos may also prove fruitful.

Moral controversy over the use of embryonic stem (ES) cells in research or therapy arises from the contested moral status of preimplantation human embryos. Persons who believe that embryos have inherent moral status oppose creating embryos that will then be discarded or 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 status accept derivation and use of ES cells when informed consent to donation and related norms are followed.

These differences in assessment of embryo status drive 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 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.[48] Until recently, this prohibition has affected a small group of researchers seeking ways to improve IVF and contraception and to understand the origin of genetic disease. The development of embryonic stem cell lines

[48] Italy, Ireland, and Austria also prohibit all embryo research. See Gruss, note supra at .

in 1998 has greatly changed what is at stake in embryo research, and thus the costs of highly restrictive policies.

Countries that take a highly protective view of embryo status and thus a highly restrictive approach to embryo research risk losing out on participating in what may be one of the most important therapeutic enterprises of the next several decades. For example, Germany has a long and distinguished history in biological and medical research. It played a major role in the development of modern embryology and developmental and cell biology with the foundational work of Von Baer, Remak, Virchow, Weissmann, Haeckel, and many others.[49] Because of its strong protective stance toward embryos, however, it appears at present that it will play a relatively minor role in the rapidly developing and important area of ES cell research and therapy. This absence in an important new area of biomedical research is occurring at a time when Britain, the United States, and several other countries are forging ahead with ES cell research. The Medical Research Council in the U.K. is spearheading an effort to develop a worldwide repository of human ES cell lines for research and eventual therapy.[50] Indeed, even the Czech Republic has announced the creation of ES cell lines that will be available to researchers throughout the world.

The prospect, however, of European Union funding for embryonic stem cell research projects is currently on hold. Because their domestic laws ban destructive embryo research, Germany (along with Italy, Austria, Ireland, and Portugal) have sought to block European Union funding for ES cell research, including the derivation of new

[49] See Michael C. Bishop, How to Win the Nobel Prize, (Harvard Univ. Press, 2003) pp. 137-138 (Recounting the work of German scientists in discovering the cell, how it replicates, and the chromosomal and oocyte basis for life).

ES cell lines. A compromise on using only embryos created before the 27 June 2002 adoption of the E.U.'s science funding program failed because of opposition from Germany, Ireland, Portugal, Austria, and Italy.[51] At present it is unclear under what conditions, if any, the E.U. will fund ES cell research.[52]

The German absence from ES cell science is the result of the 1990 German Embryo Protection Act. 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.[53] The 1990 law forbids the creation of embryos that will not be transferred to the uterus, and by implication makes criminal the destructive derivation of ES cells from blastocysts prior to implantation. As a result, no ES cell lines may be derived from embryos in Germany. A Parliamentary Ethics Committee voted against allowing the importation of ES cells for research from other countries. Unhappy with this policy, Chancellor Gerhard Schroeder appointed a National Ethics Committee that recommended in favor of importation. After an intense national debate, the federal parliament did authorise research with ES cells imported from countries where derivation is legal but only if the cell lines had been

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[50] Peter Gruss, "Human ES Cells in Europe," *Science* 301:1017 (2003).

[51] One E.U. proposal required that the ES cells be derived from embryos that themselves have already been created by the date of its enactment in order to prevent creating embryos solely to obtain ES cells and to ensure that the couples who had created the embryos had time to think about whether the embryos were no longer needed for infertility treatment. The NIH Guidelines for funding ES cell research devised in the Clinton administration contain similar restrictions. (I am indebted to Carol Tauer for this point).

[52] Gretchen Vogel, "E.U. Stem Cell Debate Ends in a Draw," 302 Science 1872-73 (2003).

[53]The government is thus not imposing an orthodoxy of ideas, as occurred during Lysenkoism in the Soviet Union. See Uwe Hossfeld and Lennart Olsson, "From the

derived prior to January 1, 2002.[54] Although the law allows some ES research to go on, the bureaucratic hurdles that must be overcome and the inability to work with more advanced cell-lines created after January, 2002 make it unlikely that Germany will be a center of ES cell science.[55]

It is interesting to compare the highly restrictive German position with the less restrictive American position. Although the United States restrictions apply only to federal and not as in Germany also to private funding, the Bush administration position on federal funding of ES cell research shares a common moral vision with the German position and faces some of the the same contradictions. With 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 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, a view largely shared by the Bush administration. Because Congress has repeatedly withheld authorization for any

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Modern Syntheiss to Lysenkoism, and Back?," Science 29:55-56 (2002). However, a ban on research methods could have as obstructive effect on research as a ban on ideas.

[54] German researchers who were not governmental employees could derive new stem cell lines in other countries and use them there, though they could not import them to Germany. Because university professors and other governmental employees are required by law to adhere to German regulations anywhere in the world, they are prohibited from working in a foreign lab with newly derived stem cells. To avoid prosecution, professors would need to take an official leave of absence during any period of foreign work using more recently derived ES cells. With the status of employees of Germany's many nonunivesity research units unclear, they are advised to take a leave of absence as well. Gretchen Vogel, "Visiting German Profs Could Face Jail," Science 301:577 (2003).

[55] It may be that German scientists will focus their work on adult stem cells or on clinical uses of ES cell products. But much of that work is later down the road. Whether they will be permitted to use cell replacement tissue derived from embryonic stem cells must await future developments.

spending on embryo research, the federal government could not fund the derivation of embryonic cells or cell lines. But it could fund research with ES cells derived with private funds because ES cells are not themselves embryos and thus not within Congress' ban on funding embryo research.[56] After advice from the National Bioethics Advisory Commission, the Clinton administration in 2000 announced that it would fund ES cell research, and authorized the National Institutes of Health to develop procedures for doing so. The NIH adopted guidelines for research funding and was about to make the first grants when the Bush administration in March, 2001 put such grants on hold.

The Bush administration, elected with the strong support of the right-to-life community, was faced with the question of using federal funds to support research ES or leaving that research to the more limited resources of the private sector. After further reviews, President Bush announced on August 9, 2001 that his administration would fund ES cell research only with cell lines that had been derived before August 9, 2001, the date of the announcement of the Bush position.[57]

The Bush compromise on ES cell research initially gave a boost to the field. Although limiting federal funding to particular cell-lines, it signalled that the topic was an important and acceptable area of scientific research, for which the federal government would provide some backing. It soon became clear, however, that many fewer viable cell-lines than the 65 trumpeted by the administration were available, perhaps or 5 or

[56] John A. Robertson, Ethical and Policy Issues in Embryonic Stem Cell Research, Kennedy Institute Ethics Journal, 1999.

[57] At the time the administration announced to the great surpise of most working in the ES cell field that 64 such lines were available throughout the world. It soon became clear that the number of viable lines was many fewer (<10). For an in-depth account of the bureaucratic and intellectual property hurdles to getting pre-August 9 ES cell lines for

so.[58] In addition, there were intellectual property rights limits on access to those lines, and questions about whether those who held patents on the technique or who owned a cell-line would demand reach-through rights to eventual products, thus limiting or discourging their use by researchers. Nor was private investment a certain or stable source of funds to make up for the wide gaps in government coverage. Since 2001 the biotechnology sector has been in a severe slump that has put a crimp on private investment in ES cell technology. In 2004 several universities and the states of California and New Jersey to have undertaken to provide funding for ES cell research, federal research support remains crucial for rapid progress in the field and translation of research findings into practical therapies.

Normatively, both the Bush and German position assume that the embryo is a person or moral subject and should not be destroyed for ES cells or 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 have caused the destruction of embryos. Thus both the U.S. restriction on using only cell lines derived before President Bush's August 9, 2001 speech, and Germany's restriction

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research, see Stephen Hall, Merchants of Immortality: Chasing the Dream of Human Life Extension (New York: Norton, 2003), pp. 271, 305-306.

[58] An internal governmental report has found that only 15 lines might be viable for research use, but not all researchers agree. See New York Times, March 1, 2004. This is one of the reasons why researchers at Harvard have announced the development of 15 new lines that have genetic mutations related to diabetes and which they will share with other researchers. Harvard University has announced plans for a $100 million embryonic stem cell institute, and researchers at universities in Wisconsin, Minnesota, and California have also embarked on setting up privately funded efforts. New Jersey and California have also undertaken to provide state support for ES cell research. See "Harvard seeks private $100 million to build stem cell centre," 428 Nature 8 (2004)..

on 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 often accused of being specious or disingenuous, the distinction between *causing* a wrong and *profiting* from it has clear moral status. 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 furture evils of the kind that mades 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.[59]

If the distinction between causative and beneficial complicity is morally sound, it should eventually allow the use of additional cell lines derived after the dates specified in German and United States policy. Private sector derivation of new ES cell lines will

[59] Concerns about disrespect and taint may have special resonance in Germany because of the Nazi medical abuses of concentration camp inmates. However, both grounds for objecting to use of the fruits of past evil must face the problem of determining the circumstances and conditions in which the taint or disrespect is great enough to create a duty not to benefit from it. Because such principles are difficult to formulate, such judgments might best be left to the realm of personal choice, not national policy. See John A. Robertson, "Causative vs. Beneficial Complicity in the Embryonic Stem Cell Debate," Connecticut Law Review (2004).

continue in countries that permit it despite the limitations in U.S. and German policy.[60] New cell lines that do not use mouse feeder layers to culture cells are needed to avoid viral transfer to humans. New 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.[61]

Given the almost certain development of new cell-lines independent of German and U.S. policy, a change in U.S. and German policy 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 accomodate them. If so, public policy in Germany and the U.S. could allow those new and better lines to be used without violating the line between causing and benefiting from harm just as that distinction permitted the earlier dates of derivation now enshrined in policy.[62]

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[60] The leading ES cell producing countries are the United States, Belgium, the United Kingdom, India, Singapore, and Israel.

[61] See Faden et al, "Public Stem Cell Banks: Considerations of Justice in Stem Cell Research and Therapy," 33 Hastings Center Report 2-15 (2003).

[62] This argument, however, may not lend itself to more than one such revision in time limits. If Germany or the U.S. does accept new time limits, it will call into question the certainty of new and future time limits, and thus give some encouragement to persons who derive new lines in part on the expectation that whatever time limit is set will eventually be withdrawn. Whether that expectation is strong enough to constitute encouraging the future putatively evil acts would still be open to doubt.

If ES cell research leads to effective therapies, the inconsistencies in the German and Bush policies will make it more difficult to sustain those policies, while at the same time allowing those governments to use the distinction as moral cover for loosening up on them. If new cell lines will be developed regardless of the public policy of either country, their importation or funding can occur without causing future embryos to be destroyed. In the long run, however, stem cell therapies could eventually lead to the creation and destruction of embryos. At that point both the German and United States will have to decide whether moral concerns about very early embryos justify the impact on health of those who would then be denied effective therapies. It may be that individuals who believe so strongly in the inherent moral status of the embryo may continue to reject ES cell-derived therapies for themselves or their families, but it would be difficult to defend as a national policy if such a stance preventing millions of other persons with different beliefs getting them as well.[63]

Therapeutic Cloning

If scientists do learn to direct 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 solutions here would be the development of ES cell banks that are compatible with a wide range of tissue types.[64] Another solution --and the one currently creating the most controversy--is therapeutic

[63]The expression "there are no atheists in foxholes" comes to mind when one contemplates whether current opponents of embryonic stem cell research will also deny themselves or their family members ES cell-derived replacement therapies if they are later shown to be safe and effective. Stephen Hall makes the same point in Merchants of Immortality at p. 358.

[64] See Faden et al, "Public Stem Cell Banks: Considerations of Justice in Stem Cell Research and Therapy," 33 Hastings Center Report 2-15 (2003).

cloning by creating an embryo 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.

Therapeutic cloning, however, has been a source of enormous controversy in most countries, both because it opens the door to reproductive cloning and because it debliberately creates and destroys embryos, albeit ones created by nuclear transfer and not by fertilisation. While some countries, most notably the UK and Israel, have legally authorized therapeutic cloning, others have explicitly banned it, including countries such as Canada and Germany, which both permit the use of leftover embryos to derive ES cells.[65] 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 get tissue for therapy. In the United States creating embryos for research or therapy is legal, though it could not be done with federal funding. Efforts in Congress to ban all forms of cloning, including reproductive and therapeutic cloning, have twice passed the House of Representatives but failed in the Senate. The Bush administration has also led an effort to have the United Nations enact a world-wide ban on all cloning.

The strong opposition in many countries to creating embryos that would then be destroyed to get ES cells, will pose a major dilemma if therapeutic cloning becomes the only safe and effective way to obtain histocompatible replacement cells from ES cells. Because that moral objection would then bar thousands of persons from needed therapies, there will be intense scrutiny of the reasons for maintaining 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 reason to justify incurring those expressive costs and be permitted. On the hand, if the objection is rooted in the inherent moral or legal status of embryos, then it may be harder to accept therapeutic cloning. As we have seen, the German position on protection of embryos is legislative, not constitutional as it is with fetuses. If so, there may be room for the German legislature to permit deriving embryos resulting from nuclear transfer cloning when necessary to obtain histocompatible tissue for therapy.

[65]"Canada passes bill to ban human cloning," Reuters, Friday, March 12, 2004; "Spanish lawmakers clash over control of stem-cell research," 428 Nature 7 (2004).

Preimplantation Genetic Diagnosis

An important development in assisted reproduction is screening of embryos prior to transfer to the uterus to assess their viability and their 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 discard. Referred to generally as preimplantation genetic diagnosis (PGD), two thirds of the 3500 PGD cycles done throughout the world have occurred to determine whether the chromosomes have an improper number (aneuploidy) and thus are unlikely to implant. The other third has been to determine whether the embryo is free of serious X-linked or autosomal recessive genetic disease.

More recently use of PGD has 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 cordblood donation to a sibling with a serious disease.[66] PGD has also been sought for nonmedical gender selection. Commentators speculate that it may also be used to screen embryos for desirable nonmedical traits such as intelligence, beauty, height, etc. However, due to the complicated multifactorial genetics of most nonmedical traits that might interest parents, such uses are unlikely for some time to come.

PGD has been ethically controversial because of its impact on embryos and its selection of embryos based on genetic quality. Some persons fear it as another step toward a "brave new world" of commodified and instrumentalized reproduction. In fact, PGD, if show to be safe and effective, would simply provide another tool for meeting

important medical needs of persons at high risk of aneuploidy or having offspring with serious genetic disease. Although its use is now being expanded to susceptibiity 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 simply because the genetics of those traits is too complicated to be deciphered and the costs and burdens of using PGD for that purpose are too great for wide use.

PGD is available in the United States, the United Kingdom, Belgium, Israel, and many other countries for aneuploidy and genetic screening for medical reasons. In Germany, however, PGD is not currently performed. Although the 1990 Embryo Protection Law does not directly address PGD, it does ban destroying or discarding embryos. The PGD process of removing a cell or blastomere at the 4 or eight cell stage, and then not transferrring 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 itself an embryo. Analyzing its chromosomes or DNA would destroy it in direct violation of the law.

Some Germans also object to PGD because of fears that it will be used to harm women and persons with disabilities, and speed the wider use of a eugenic approach to reproduction. Such concerns have a special resonance in Germany, where Nazi programs of mandatory sterilization, euthanasia, and then genoicde on the basis of the genetic or ethnic identity are still fresh in memory. Indeed, the renowned philosopher Jurgen

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[66] John A. Robertson, "Ethical Issues in New Uses of Preimplantation Genetic Diagnosis," *Human Reproduction* 18:465-471 (2003).

Habermas, who generally does not address questions of reproduction and bioethics, has spoken out strongly against PGD as the harbinger of a renewed eugenics.[67]

An opposite view of the legal posture of PGD in Germany also exists. A majority of the Chancellor's National Bioethics Council takes the view that the law does not now bar PGD for serious genetic diseases that cause a woman an existential dilemma about whether to start or continue such a pregnancy. 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. 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 as well. She too faces the existential dilemma of whether to get pregnant 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 discard of embryos with conditions that could be aborted.

Given the glaring inconsistency between permissible abortion and banned PGD, support for making PGD explicitly legal in some cases is growing.[68] A coalition of Social Democrats, Liberals, and some Christian Democrats backs legislation that permits PGD

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[67] Habermas, J. (2001). die Zukunft der menschlichen Natur. Auf dem Wege zu einer liberalen Eugenik. Frankfurt a.M.

[68] True, the embryos first have to be created, but as the National Bioethics Council's majority report on PGD effectively showed, this is not a meaningful distinction. German National Ethics Council, Genetic diagnosis before and during pregnancy (Opinion) (Berlin, 2003).

along the restrictive line recommended by the National Bioethics Committee.[69] In addition, some opponents might accept decriminalization of PGD while keeping it unlawful--the solution reached for early abortion after counseling.[70] Unless the law is passed, Germany will be in the anomalous position of allowing abortion for fetal defects and serious disease up to the 22nd week of pregnancy but not selection and discard of embryos for the same purpose.

But even if the law is changed to allow PGD for serious genetic indication, the law will still ban embryo screening in all other cases. PGD would still not be available for aneuploidy screening to enhance IVF success rates in older women, for tissue matching for an existing child, for sex selection for gender variety, or for any other nonmedical purpose.[71] As such, German law on PGD would be much more restrictive than the law of many countries in Europe, North America, and Asia.

If existential dilemma is the justification for embryo screening and nontransfer, it may be that some new uses of PGD should also be allowed. For a woman with an inheritable risk of breast cancer, having a female child who also carries that mutation could create as much of an existential dilemma as having a child with a severe congenital disease. The same might be true of a family with a young child desperately in need of a hematopoietic stem cell transplant for Fanconi anemia or leukemia. Rather than coitally conceive and bring to term a child who is not a close match, PGD would enable the couple to transfer to the uterus only embryos free of the disease and a close tissue match

[69] Interview with Liberal Parlimentarian. Such a change would apply only to PGD for serious genetic screening and not PGD for aneuploidy to increase IVF success rates, since that need is not as extreme.

[70] 12 members of the Chancellor's National Bioethics Council supported such a position. See German National Bioethics Council Opinion, note 43.

to the existing child. As one focuses more on the meaning or importance of a child with less serious conditions to a couple and on the impact such conditions might have on their willingness to proceed with reproduction, 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, it is much less likely that it will accept PGD to screen embryos for non-medical reasons, such as gender, deafness, perfect pitch, sexual orientation, or other conditions. Indeed, most countries will have difficulty accepting its use in those circumstances. Fortunately, most such screening is still off in the future. With the exception of gender, screening for nonmedical traits such as hearing ability, sexual orientation, IQ, or other potentially desirable traits is not now feasible and is unlikely to be so for some time to come.[72] Many traits of concern are not controlled by single genes, but rather by genetic networks and cellular pathways that will be very difficult to decipher. With research into medical uses having a much higher priority, identification of those interactions might not occur for some time. If nonmedical embryo screening ever becomes more available, Germany is unlikely to be an earlier user or pioneer of them.

The Lessons of Comparative Bioethics

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[71] Sex selection is already banned by the 1990 embryo law.

[72] An exception is gender, which can be done by karotyping the embryo alone without additional genetic analysis. The Biomedical Convention in Europe bans it for non-medical reasons, as does Germany. The question of PGD for gender selection may be more acceptable if used only for second or later children to create gender variety in the family. See John A. Robertson, "Ethical Issues in New Uses of Preimplantation Genetic

The comparative assessment of abortion, assisted reproduction, embryonic stem cell research, and preimplantation genetic diagnosis in Germany and the United States shows interesting similarities and differences. Germany projects a much more protective attitude toward fetuses and embryos than exists in the United States and many other countries. In some cases the differences are rhetorical and symbolic with little impact in practice, as the wide access to abortion in Germany through "decriminalization" shows. In other cases rhetorical differences have a real bite. For example, Germany's less friendly attitude toward assisted reproduction makes it more difficult for infertile couples with ovarian problems to have children. Its more conservative approach has also discouraged ES research, and made PGD unavailable to couples at high risk of producing offspring with severe genetic disease.

All countries face ethical or philosophical conflicts about how to deal with new reproductive and genetic technologies. Those conflicts involve questions of how to reconcile competing concerns about reproductive freedom, respect for the earliest stages of human life, ensuring healthy offspring, treating disease, and protecting women and persons with disabilities. Often there is no clear right answer as to whether public policy should support, discourage, or ignore particular applications, and thus no reason why all countries should adopt the same approach. It is no surprise that countries with such different histories, traditions, and cultures as Germany and the United States would reach a different balance in fashioning public policy for reproductive and genetic technologies.

A comparative analysis is useful for highlighting different traditions and illuminating the roots of difference. Understanding what we have done prepares us better

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Diagnosis," *Human Reproduction* 18:465-471 (2003); John A. Robertson, "Preconception

for responding to future developments. A focus on difference may also lead each nation to improve its own practices, particularly as contradictions and inconsistencies emerge, as this article has shown is the case in some areas. Comparison also reveals the extent to which informal practices, blurred categories, and legal and moral distinctions soften the rough edges of formal legal categories.[73]

This article has pointed to several inconsistencies in German policy: for example, in time limits for use of embryonic stem cell lines, and in allowing abortion but not embryo selection for the same serious genetic disease. One may also point to room for improvement in the American approach. A policymaker steeped in the German experience might argue that Americans should pay more attention to respecting human life at its earliest stages and adopt policies or practices that lead to fewer embryos, fewer embryos per transfer, less freezing and discard of embryos, and a more careful private-sector attitude toward embryo research. Such a change might compromise IVF success rates per transfer, but it need not greatly reduce the ability of most women undergoing IVF to have a child.

The United States needs to do more to rein in its high rate of multiple gestations, and might learn some valuable lessons from Europe in this regard. Guidelines for number of embryos to be transferred could be better observed. It is more difficult, however, to find a strong case for public policies that reduce the number of eggs retrieved and embryos frozen, particularly if doing so increases the costs or burdens for participants. Because of varying opinions about the moral status of the embryo, judgments which are

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Gender Selection," 1 American Journal of Bioethics 1-22 (2000).

[73] A similar pattern may be seen in societal reaction to active and passive euthanasia and assisted suicide. See John Griffiths on active euthanasia in the Netherlands.

mainly symbolic or expressive of embryo status rather than effects on women and offspring might be better left to patients and physicians rather than to national directives.

Still, Germany's more protective stance toward embryos is a good reminder of the importance of paying attention to the symbolic and expressive power of the first stages of a new human life. Even if the embryo lacks moral status in its own right, its potential to develop into a rights-bearing entity invests it with meanings that should not blithely be ignored. One can argue that even those with very liberal attitudes on these issues should seek ways to create fewer embryos and manipulate them only when a strong case for doing so arises. Americans, however, might well disagree on when such a strong case exists.

A cautious posture might also be recommended for rapidly extending preimplantation genetic screening. Screening for serious genetic disease and susceptibility conditions is justifiable and should be permitted. But PGD for non-medical conditions is ethically fraught and should not occur until strong reasons for doing so are shown. Such cases might exist, but it is too early in the trajectory of development of and debate about PGD to be confident about where ethical and policy lines should be drawn. We need much more analysis, debate, and discussion before significantly ratcheting up the degree of prebirth screening and selection of offspring characteristics.

The discussion has also reminded us that law on the ground is often more important than law on the books. The judgment and discretion of practitioners will in many cases be as important as legal policies. Those judgments often derive from the realm of personal moral or religious choice which, in a diverse and pluralistic society, a single national view cannot adequately capture. They may also be too fine-grained and

subjective for public policy to address. If so, practitioners have a special responsibility to use these techniques in a sensitive and responsible manner. They are the gatekeepers who control the terms and conditions under which these technologies are provided to persons seeking access to them. More decentralized systems, such as that in the United States, give practitioners and patients wide freedom in determining the scope of use. It is incumbent upon them to use that freedom responsibly. [74]

Finally, one should take note that beneath the differences in different countries a broader consensus about the acceptability of reproductive technology itself has emerged. Despite heated debate and bitter controversy, most countries have accepted the core uses of reproductive and genetic technologies, differing only in matters of detail and the intensity of regulation.[75] Use under regulated circumstances has been more common than prohibition. The prohibitions that do occur tend to occupy a narrow range of often novel uses, e.g., on PGD but not on abortion or IVF. Also, the differences may not be stable for long, as we have seen with the strains inherent in German and American ES cell research policy suggest.

Across the world there is recognition that we have long ago left the garden of technological innocence in reproduction. Many concerns exist about the ethical and social impact of new reproductive technologies, but few persons or countries argue that

[74] One might, for example, use more judgment and sentitivity in pushing the borders of practice. Europeans, for example, widely condemned the report of an American experiment that combined cells from male and female gametes to make an embryo. Although not illegal and arguably serving a valid scientific purpose of determining which cells best served as a marker for tracking cellular changes, the reasons for doing the study at this time were not clear, thus giving sustenance to those who think that reliance on professional judgment alone will suffice to prevent abuses.

we should not use these techniques at all. Most agree that we do not want to end up using them in ways that impair the human flourishing which they seek to increase, even if they differ over which uses would do so. Our comparative journey has shown that we are learning to live with the genies that reproductive innovation has released from its technological bottles. This experience will stand us in good stead as we head into the challenges of genomic selection and modification that await us later in this century.

[75] Even the highly restrictive 2004 Italian law on ARTs accepts the use of IVF for infertile couples. See Sophie Arie, "Fertility's Closed Italian Frontier," Christian Science Monitor, March 10, 2004, p. 1.