# THE COSTS OF MULTIPLE GESTATION PREGNANCIES IN ASSISTED REPRODUCTION

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## I. INTRODUCTION

It has been thirty years since the birth of Louise Brown, the world's first baby to be conceived and born after in vitro fertilization ("IVF").[1] During these thirty years, Louise has grown up, married, and had a child of her own,[2] and IVF and other assisted reproductive technologies ("ARTs") have, similarly, matured.[3] By 2005, the ART industry had grown from a marginal field of medicine into a $3.3 billion business[4] that in the United States alone employs thousands of physicians and health care workers in 475 fertility clinics[5] and accounts for more than 1% of all births.[6]

ART has brought great joy to millions of infertile couples around the world by enabling them to have biological children.[7] At the same time, laymen and scholars alike, although acknowledging the benefits of ART, have been critical of ART for a variety of ethical, medical, social, political, and economic reasons.[8] American lawyers and philosophers have primarily focused on ethical implications of stem cell research, cloning, and embryo

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[1] *See Baby Son Joy for Test-Tube Mother*, BBC NEWS, Jan. 14, 2007, http://news.bbc.co.uk/2/hi/uk_news/6260171.stm.

[2] *Id.*

[3] Different institutions define assisted reproductive technologies differently. The Centers for Disease Control and Prevention ("CDC"), for example, defines assisted reproductive technologies as "all fertility treatments in which both eggs and sperm are handled," which excludes treatments where only sperm is handled (intrauterine insemination or "IUI") or procedures where a woman takes medicine, usually hormones, to stimulate her egg production. Dep't of Health and Hum. Servs., CDC, Assisted Reproductive Technology: Home, http://www.cdc.gov/art (last visited Apr. 16, 2009). For the purposes of this Article, I will assume that ART includes all three types of treatment: IVF (where eggs and sperm are handled), IUI, and hormonal treatment.

[4] *See* Debora Spar, *Buying Our Children. Selling Our Souls?*, CONSCIENCE, Autumn 2006, at 14.

[5] *See* Am. Soc'y for Reprod. Med., ASRM Resources for Health Professionals, http://www.asrm.org/Professionals/mainprof.html (last visited Apr. 16, 2009) (noting that ASRM, the predominant U.S. association of fertility professionals, has 9000 members).

[6] DEP'T OF HEALTH AND HUM. SERVS., CDC, 2005 ASSISTED REPRODUCTIVE TECHNOLOGY (ART) REPORT 13, *available at* http://www.cdc.gov/ART/ART2005/508PDF/2005ART508.pdf (last visited Apr. 16, 2009) [hereinafter CDC, 2005 ART REPORT] (reporting that over 52,000 ART children were born in 2005).

[7] *See* Caroline Ryan, *More Than 3m Babies Born from IVF*, BBC NEWS, June 21, 2006, *available at* http://news.bbc.co.uk/1/hi/health/5101684.stm.

[8] *See* Steven Goldberg, *Technology Unbound: Will Funded Libertarianism Dominate the Future?*, 21 STAN. L. & POL'Y REV. 21, 21 (2007).

preservation, and on the scope of the right to procreate or not to procreate.[9] Fertility scientists, on the other hand, have focused on the medical aspects of ART.[10] In the 1980s and the early 1990s, fertility scientists focused on improving ART success rates, which used to be in the single digits, and on developing more effective techniques.[11] As success rates improved, fertility scientists shifted their attention to the safety and potential medical risks that ARTs pose to the women and their children.[12] One of the most serious adverse outcomes they identified in the 1990s was the high rate of multiple births to parents using ART. Although multiple births do occur naturally, American ART infants are more likely than spontaneously-conceived infants to be born as part of a set.[13]

As a result of these ethical and medical lines of research, many developed countries, mostly in Europe, have adopted strict rules governing the industry.[14] The United States, on the other hand, with its long tradition of individual liberty, laissez-faire approach to markets, and legislative fear of religious or ethical entanglement, has left ARTs largely unregulated, except for modest and non-binding self-regulation.[15] This freedom has enabled American doctors to develop new techniques and procedures, and has enabled American consumers of infertility services, whether single or married, straight or gay, young or old, to choose from a wide array of differently-priced ART techniques.[16]

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[9] *See, e.g.*, Russell Korobkin, *Embryonic Histrionics: A Critical Evaluation of the Bush Stem Cell Funding Policy and the Congressional Alternative*, 47 JURIMETRICS J. 1 (2006); John A. Robertson, *Liberty, Identity, and Human Cloning*, 76 TEX. L. REV. 1371 (1998).

[10] *See, e.g.*, Committee Opinion, *Perinatal Risks Associated with Assisted Reproductive Technology*, 106 OBSTETRICS & GYNECOLOGY 1143 (2005).

[11] *See* ELIZABETH BARTHOLET, FAMILY BONDS: ADOPTION, INFERTILITY, AND THE NEW WORLD OF CHILD PRODUCTION 208 (1999) (noting that during the 1986–1988 period between 6% and 9% of initiated IVF cycles resulted in a live birth); P.O. Karlström & C. Bergh, *Reducing the Number of Embryos Transferred in Sweden — Impact on Delivery and Multiple Birth Rates*, 22 HUM. REPROD. 2202, 2202 (2007) (reporting on the purposes of early IVF research).

[12] *See generally* M.A. Reynolds & L.A. Schieve, *Trends in Embryo Transfer Practices and Multiple Gestation for IVF Procedures in the USA, 1996–2002*, 21 HUM. REPROD. 694 (2006).

[13] In fact, according to one source, 75% of triplets, 90% of quadruplets and "essentially all" the quintuplets in the United States are born to women under treatment for fertility problems. Barbara Carton, *Agonizing Decision: Multiple Pregnancies Are Often Pared Back in "Fetal Reductions,"* WALL ST. J., Nov. 21, 1997, at A1.

[14] *See* John A. Robertson, *Reproductive Technology in Germany and the United States: An Essay in Comparative Law and Bioethics*, 43 COLUM. J. TRANSNAT'L L. 189, 191–93 (2004); Ellen Waldman, *Cultural Priorities Revealed: The Development and Regulation of Assisted Reproduction in the United States and Israel*, 16 HEALTH MATRIX 65, 67–70 (2006).

[15] *See* Goldberg, *supra* note 8, at 21 ("[I]n the United States, [ART] takes place in an unregulated environment reminiscent of the Wild West."). The Fertility Clinic Success Rate and Certification Act of 1992 is the sole federal statute regulating ART. 42 U.S.C. § 263a-1 (2006).

[16] Debora Spar, *Where Babies Come From: Supply and Demand in an Infant Marketplace*, HARV. BUS. REV., Aug. 2006, at 134–35.

While the benefits of unregulated and commercialized ART are easily observable, the costs are more difficult to discern. There is mounting evidence that children born using ART are at risk of serious harm. ART children are more likely to have certain types of birth defects, including cleft lip and heart and gastrointestinal defects, than children conceived naturally.[17] Children conceived in vitro are also more frequently admitted to hospitals and spend significantly more days in the hospital than their peers who were conceived without medical assistance.[18] But the most significant risks of pre- and postnatal harm to ART children are associated with the high rate of multiple gestation pregnancies: twins, triplets, and higher-order multiples. Multiples, including twins, have a significantly higher incidence of premature birth, low birth weight, and increased rates of mortality and morbidity.[19] Multiple gestation pregnancies are also significantly more risky to mothers.[20] In addition to increased medical risks, a multiple gestation birth is more stressful and emotionally draining for the parents than a singleton birth, and significantly more costly.[21]

By choosing to carry multiple babies, American ART consumers are also imposing costs on the rest of society. Though cost estimates are notoriously difficult to make, a U.K. source reports that a twin birth is sixteen times more expensive than a singleton birth,[22] and a triplet or higher-order multiple birth can easily cost several hundred thousand dollars.[23] American ART parents may pay a high price to conceive children, but they do not pay out-of-pocket for the medical expenses of multiple gestation pregnancies. U.S. consumers do, through higher insurance premiums, hospital fees, and higher taxes, which are used to treat, educate, and care for children with medical problems.[24]

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[17] *See* Dep't Health & Hum. Servs., CDC, Press Release, National Birth Defects Prevention Study Shows Assisted Reproductive Technology is Associated with an Increased Risk of Certain Birth Defects (Nov. 17, 2008), http://www.cdc.gov/media/pressrel/2008/r081117.htm.

[18] *See* Sari Koivurova, Anna-Liisa Hartikainen, Mika Gissler, Elina Hemminki, & Marjo-Riitta Järvelin, *Post-Neonatal Hospitalization and Health Care Costs Among IVF Children: A 7-Year Follow-Up Study*, 22 HUM. REPROD. 2136, 2136 (2007).

[19] *See infra* text accompanying notes 71–83. In 2005, more than 35% of all IVF pregnancies where the number of implanted embryos was reported were multiple pregnancies. CDC, 2005 ART REPORT, *supra* note 6, at 22 fig.10.

[20] *See* Tracy Shevell et al., *Assisted Reproductive Technology and Pregnancy Outcome*, 106 OBSTETRICS & GYNECOLOGY 1039, 1039 (2005).

[21] *See* Mary Ann Davis Moriarty, *Addressing In Vitro Fertilization and the Problem of Multiple Gestations*, 18 ST. LOUIS U. PUB. L. REV. 503, 509–10 (1999).

[22] *See Quality, Not Quantity*, ECONOMIST, Apr. 7, 2007, at 54, 55. Cost-benefit analyses and marginal cost estimates are notoriously imprecise. In conducting the study, statisticians must decide on the relevant test group and control group, and the observation period. Results can easily underestimate costs of multiple births by choosing an observation period that is too short (e.g., only one month after childbirth), or overestimate the costs of multiple births by not subtracting the costs of additional IVF cycles.

[23] *See* Spar, *supra* note 16, at 141 ("The costs of [a quintuplet] delivery almost certainly ran to well over $400,000.").

[24] *Id.*

Through regulation, European countries have reduced the ART multiple pregnancy rate to 22.7%, and some European countries have been able to reduce the incidence of twins and higher-order births even further, to 11% or less.[25] The United States, on the other hand, where ART is essentially unregulated, has been unable to reduce the number of multiple gestation pregnancies below 32% of all ART births.[26]

The dominant legal argument against regulating ARTs in the United States is that ART is a part of constitutionally-protected procreative liberty since it enables infertile couples to do what fertile couples can do without medical help: become biological parents.[27] Since coital biological procreation is protected as a fundamental right, so must be non-coital biological procreation.[28] And as a fundamental right, ART cannot be restricted absent a compelling state purpose.[29]

In this Article, I argue that there exists such an important purpose: multiple gestation pregnancies impose significant costs on parents, children, and society that the current regime cannot reduce, and might, indeed, have increased. In Part II, I cull and summarize the available data on the medical, psychological, and financial costs of multiple gestation pregnancies. I do not address the ethical concerns associated with ART, yet I suggest that regulation is necessary even without considering the ethical concerns that ART raises. In Part III, I explore the current ART regime in the United States. I show that not only has the regime been unable to address the concerns raised by fertility scientists about multiple births, but has in fact encouraged con-

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[25] Sweden and Belgium have 11% or lower rates of multiple births after ART, and all but a few countries with relatively undeveloped ART markets produce as many multiple births as the United States (e.g., Turkey, Lithuania, and Hungary). *See* A. Nyboe Andersen et al., *Assisted Reproductive Technology in Europe, 2004: Results Generated From European Registers by ESHRE*, 23 HUM. REPROD. 756, 765 (2008); *see id.* at 765 tbl.X. Reducing rates of multiple gestation pregnancies usually lowers success rates, which is what makes the issue controversial in the United States. In the United States, the live-birth per egg retrieval rate for IVF is 32.7%, while in Europe, the pregnancy rate per egg retrieval for IVF is 26.6%. *See id.* at 756; CDC, 2005 ART REPORT, *supra* note 6, at 40 fig.28.

[26] *See* CDC, 1997 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 19 (1999) (reporting that 38% of all ART births were twins or higher-order multiples) [hereinafter CDC, 1997 ART SUCCESS RATES]; CDC, 2005 ART REPORT, *supra* note 6, at 22 fig.10.

[27] *See* John A. Robertson, *Procreative Liberty and Harm to Offspring in Assisted Reproduction*, 30 AM. J.L. & MED. 7, 20 (2004).

[28] *See id.*

[29] *See* Note, *Assessing the Viability of a Substantive Due Process Right to In Vitro Fertilization*, 118 HARV. L. REV. 2792, 2808–13 (2005). Although *Roe v. Wade* requires that "any regulation touching upon the abortion decision must survive strict scrutiny, to be sustained only if drawn in narrow terms to further a *compelling* state interest," Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 871 (1992) (emphasis added), subsequent U.S. Supreme Court decisions have chipped away at the standard in the area reproductive rights. *See, e.g.*, *Casey*, 505 U.S. at 874 ("Only where state regulation imposes an *undue burden* on a woman's ability to make this decision does the power of the State reach into the heart of the liberty protected by the Due Process Clause.") (emphasis added).

sumers of infertility services and fertility doctors to risk multiple gestation pregnancies. In particular, I compare the U.S. approach with the approach taken by some countries in Europe, and suggest that industry self-regulation and reliance on market forces cannot sufficiently reduce the incidence and the costs of multiple births. In Part IV, I suggest that the United States could, constitutionally, regulate ART to reduce the number of multiple gestation pregnancies. I propose that improved reporting, disclosure, and clinic supervision, combined with more strictly enforced embryo transfer practices, would reduce the costs of multiple births without severely limiting the right to procreate.

## II. Multiple Gestation Pregnancies: Direct and Indirect Costs of an Unregulated ART Market

ART imposes costs on parents, children, and society. In the following sections, I first discuss the causes of multiple gestation pregnancies that result from ART. Then, I discuss the associated medical, psychological, and financial costs of free-market ART as it has developed in the United States. These costs include direct out-of-pocket expenses as well as expected costs, calculated by multiplying the probability (that is, risk) that a particular outcome will happen and the cost if the outcome does happen.

### *A. Causes of Multiple Gestation Pregnancies in ART*

A spontaneously-conceived infant has a one in ninety chance of being a twin, and a tiny chance of being a triplet or more.[30] An ART infant, on the other hand, is thirty times more likely to be a twin.[31] The increased odds result from medical procedures used in ART. Some women undergoing infertility treatment take powerful hormones that stimulate their egg production. Instead of producing only one or two eggs per cycle, they can produce as many as forty eggs.[32] While not every egg will be fertilized, doctors have reported seeing as many as twelve fetuses following ovarian stimulation.[33] Sixty-two percent of quadruplet pregnancies and virtually all quintuplet and

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[30] Childbirth Solutions, Inc., Odds of Multiples, http://www.childbirthsolutions.com/articles/pregnancy/oddmulti/index.php/ (last visited Apr. 16, 2009). In 1980, when many of the ART techniques, except for IVF, were already being used, 1.9% of American infants were twins. In 2005, 3.2% of all American infants were twins. Naturally, only 30 in 100,000 infants are triplets, while in 2005, 162 out of 100,000 were triplets. CDC, *Births: Final Data for 2005*, 56 Nat'l Vital Stats. Rep. 1, 3 (2007) [hereinafter CDC, *Births*].

[31] ART babies have a 29.6% chance of being twins and a 2.4% chance of being triplets or more. CDC, ART Report, *supra* note 6, at 22 fig.10.

[32] Philip G. Peters, Jr., How Safe Is Safe Enough?: Obligations to the Children of Reproductive Technology 210 (2004).

[33] *See* A. Monteagudo & I.E. Timor-Tritsch, *An Approach to Multifetal Pregnancy Reduction in a Pregnancy of Grand Order (12 Fetuses)*, 4 Ultrasound Obstetrics & Gynecology 339 (1994).

higher-order pregnancies in the United States result from ovarian stimulation alone or combined with intrauterine insemination.[34] While doctors can monitor patients and cancel cycles that produce too many eggs, this technique is not widely used.[35] The main reason is that doctors would have to cancel as many as one-third of all cycles, which many of the patients are unwilling to do because of the high cost of treatment[36] and the emotional and physical pain associated with it.[37] Out-of-pocket costs also make other procedures used to reduce the number of eggs that could potentially fertilize, such as IVF or removal of excess eggs from the ovaries, relatively unpopular.[38]

Unlike ovarian stimulation, IVF enables the doctor and the patient to choose the number of embryos they will transfer. In the early days of IVF, when 6 to 9% of cycles resulted in a live delivery,[39] infertility doctors frequently transferred as many live embryos as were available, often five or more, to increase the odds of achieving a pregnancy.[40] Medical studies conducted in the 1980s reported that there was a significant correlation between pregnancy rates and the number of embryos transferred. Furthermore, the same studies reported only a modest increase in multiple birth rates resulting from transferring multiple embryos in IVF.[41]

Since the 1980s, success rates per cycle have dramatically improved—they are now above 20% in most developed countries and above 25% in the United States.[42] As the effectiveness of ART improved, European countries and the United States began reporting significantly elevated rates of twins and higher-order multiple births.[43] Triplet birth rates in the United States peaked in 1998, when 193.5 children per 100,000 live births were triplets or more (in 1971, 29 out of 100,000 live-born children were triplets or more[44]),

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[34] *See* Shari Roan, *Multiple Births, Multiple Risks: The Recent News of Sextuplet Births Isn't Being Celebrated by Fertility Experts*, L.A. TIMES, June 25, 2007, at F14.

[35] *See* Eli Y. Adashi et al., *Infertility Therapy-Associated Multiple Pregnancies (Births): An Ongoing Epidemic*, 7 REPROD. BIOMED. ONLINE 515, 518 (2003), *available at* http://www.rbmonline.com/Article/1102.

[36] *See id.*

[37] *See* Francois Bissonnette et al., *Incidence and Complications of Multiple Gestation in Canada: Proceedings of an Expert Meeting*, 14 REPROD. BIOMED. ONLINE 773, 781 (2007).

[38] *See* Adashi et al., *supra* note 35, at 518.

[39] *See* BARTHOLET, *supra* note 11, at 208 (noting that during the 1986–1988 period between 6% and 9% of initiated IVF cycles resulted in a live birth).

[40] *See* CDC, 2005 ART REPORT, *supra* note 6, at 66 fig.54 (reporting that as late as 1996, 62% of IVF transfers included four or more embryos). Although most clinics have reduced the number of embryos that they transfer in each cycle to two or three, not all have. A recent example that epitomizes this issue is the woman whose doctor transferred six embryos, of which two split, resulting in eight babies born in California on January 26, 2009. Stephanie Saul, *Birth of Octuplets Puts Focus on Fertility Clinics*, N.Y. TIMES, Feb. 12, 2009, at A1, *available at* http://www.nytimes.com/2009/02/12/health/12ivf.html.

[41] *See* Karlström & Bergh, *supra* note 11, at 2202.

[42] *See* CDC, 1997 ART SUCCESS RATES, *supra* note 26, at 16 fig.7; Nyboe Andersen et al., *supra* note 25, at 761.

[43] *See* Karlström & Bergh, *supra* note 11, at 2202.

[44] R.P. Dickey & B.M. Sartor, *The Impact of Ovulation Induction and* In Vitro *Fertilization on the Incidence of Multiple Gestations*, *in* MULTIPLE PREGNANCY: EPIDEMIOLOGY,

but the twinning rate and the overall rate of multiple births have continued to increase.[45] Since 1980, before IVF was available in the United States, the rates of twin and triplet or higher-order births have increased by 59% and 402%, respectively.[46] Although the percentage of multiple births among IVF pregnancies in the United States has slightly decreased (32% of all IVF live births in 2005 were multiples, compared with 38% in 1996),[47] the overall use of IVF and other forms of ART has been increasing, as has the aggregate number of multiple births.[48]

In Europe, on the other hand, multiple births as a result of IVF are less common. In 1997, 29.6% of all IVF births were multiples,[49] and by 2004 the percentage had decreased to 22.7%.[50] The main reason for the disparity between the United States and Europe is that fertility doctors in Europe transfer fewer embryos in each IVF procedure. According to the latest CDC survey, American doctors transfer two or more embryos in all but 9% of cases.[51] In Europe, on the other hand, doctors transfer a single embryo in 19.2% of cases.[52]

There are a number of factors that contribute to higher embryo transfer rates in the United States: history, inertia, and lack of regulation, combined with patient demands, greater respect for patient autonomy and procreative freedom, and lack of patient education (or the inability of patients to fully understand the risks when the financial and emotional pressures are high).[53] In addition, insurance companies' limited coverage of IVF, but broader coverage of maternal, neonatal, and long-term care of affected mothers and infants, drives patients to desire multiple babies, particularly if success rates are also increased.[54] Finally, success-rate reporting and competition among clinics in the United States have made it more difficult for individual clinics to change their embryo transfer practices and reduce the incidence of multiple births.[55]

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GESTATION & PERINATAL OUTCOME 119, 121 (Isaac Blickstein & Louis G. Keith eds., 2d ed. 2005).

[45] CDC, *supra* note 30, at 24.

[46] *See* Tarun Jain & Mark D. Hornstein, *To Pay or Not to Pay*, 80 FERTILITY & STERILITY 27, 27 (2003). The rate of multiples has been increasing for three main reasons: (1) delayed childrearing (older women are naturally more likely to have twins or triplets because they are more likely to release more than one egg per cycle); (2) ovarian stimulation; and (3) IVF. *See* CDC, *Births*, *supra* note 30, at 25.

[47] *See* CDC, 2005 ART REPORT, *supra* note 6, at 70.

[48] *Id.* at 61 fig.49.

[49] *See* K.G. Nygren & A. Nyboe Andersen, *Assisted Reproductive Technology in Europe, 1997: Results from European Registers by ESHRE*, 16 HUM. REPROD. 384, 384 (2001).

[50] *See* Nyboe Andersen et al., *supra* note 25, at 756.

[51] *See* CDC, 2005 ART REPORT, *supra* note 6, at 66 fig.54.

[52] *See* Nyboe Andersen et al., *supra* note 25, at 759.

[53] *See* Robert J. Stillman, *A 47-Year-Old Woman with Fertility Problems Who Desires a Multiple Pregnancy*, 297 J. AM. MED. ASS'N 858, 861 (2007).

[54] *See id.*

[55] *See id.*

This increase in multiple birth rates is of concern due to the medical, psychological, and financial costs associated with multiple births. The following sections summarize the marginal medical, psychological, and financial costs associated with multiple gestation pregnancies and births.

### *B. Medical Risks of Multiple Gestation Pregnancies*[56]

Numerous medical studies suggest that like any other medical procedure, ART imposes risks on women undergoing infertility treatment, and also on their children. The risks include short-term side effects from ovarian stimulation, such as nausea and fluid retention; surgical risks, such as infection; and long-term risks, such as ovarian cancer.[57] The most significant risks of infertility treatment, however, are associated with pregnancy, and, in particular, with multiple gestation pregnancy.

Carrying more than one child at once puts a woman's body under a significant strain and makes it more likely that she will need more pre- and postnatal medical attention than her peer carrying a single fetus. A multiple gestation pregnancy is even more risky for the potential children and is considered by fertility scientists to be "a major problem."[58]

#### 1. *Increased Medical Risks to Mothers of ART Multiples*

Most of the data regarding the use of ART procedures and their impact on the health of the mothers comes from Europe, where information is often included in national health records.[59] Unfortunately, the United States only consistently collects data on vital birth statistics, such as the overall number of multiples, birth weight, preterm labor, Cesarean deliveries, and on IVF success rates, defined as "the number of pregnancies which result in live births [per] ovarian stimulation procedure[ ] . . . and . . . successful oocyte retrieval procedure[ ]."[60]

Nevertheless, there is sufficient evidence to suggest that mothers carrying multiple ART infants are putting their health at risk. A woman pregnant with twins has a 10.3% chance of developing preeclampsia, compared to a

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[56] In this section, I use the word "risk" to refer to health risks and "cost" to refer to financial expense associated with treatment. Any risk can be translated into an expected cost by multiplying the probability that an outcome will happen (that is, the risk) with the associated cost of the outcome. However, since the phrase "medical cost" might mislead the reader into considering only actual out-of-pocket expenses and not expected costs that may or may not materialize, I use the word "risk" to refer to potential adverse medical outcomes.

[57] INST. OF MEDICINE AND NAT'L RESEARCH COUNCIL, ASSESSING THE MEDICAL RISKS OF HUMAN OOCYTE DONATION FOR STEM CELL RESEARCH: WORKSHOP REPORT 2 (2007), *available at* http://www.nap.edu/catalog/11832.html.

[58] Adashi et al., *supra* note 35, at 515.

[59] Tracy Hampton, *Panel Reviews Health Effects Data for Assisted Reproductive Technologies*, 292 J. AM. MED. ASS'N 2961, 2962 (2004).

[60] 42 U.S.C. § 263a-1 (2006).

4.4% chance in a singleton pregnancy, and the onset occurs earlier.[61] Women carrying multiple babies are also significantly more likely than women carrying singletons to suffer from hypertensive disorders, anemia, hemorrhage, and fluid overload.[62] They are much more likely to suffer a myocardial infarction and heart failure: a Canadian study reports that a woman carrying multiple fetuses is 3.7 times more likely to suffer an infarction and 12.9 times more likely to suffer from heart failure.[63] A woman carrying multiple fetuses is "more likely to require long periods of bed rest, hospitalization, administration of medication to prevent pre-term labour, surgical procedures, such as emergency Cesarean section and . . . premature labour."[64] She is also more likely to suffer from delivery complications and require a hysterectomy, which would leave her unable to have any more children.[65] A multiple pregnancy increases maternal mortality rates from approximately 5 in 100,000 to 15 in 100,000.[66] Since a multiple gestation pregnancy is more taxing on the body than a singleton pregnancy, it is more likely to aggravate preexisting medical conditions.[67] The magnitude of these risks increases with the number of babies the woman is carrying.[68] Compared with singletons, medical risks are significantly greater not only for triplets and higher-order multiples, but also for twins.[69]

### 2. *Increased Medical Risks of a Multiple Gestation Pregnancy to ART Children*

The risks to infants resulting from a multiple gestation pregnancy are even more serious than the risks to the mothers. Most of the complications are attributable to the fact that children in a multiple gestation pregnancy "are more likely to be born prematurely and with a low birth weight than babies from singleton pregnancies."[70]

A full-term pregnancy lasts forty weeks. On average, each additional fetus reduces the expected gestational age at birth by about three weeks.[71] A median twin can expect to be born at thirty-six weeks gestation, a median

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[61] LIZA MUNDY, EVERYTHING CONCEIVABLE: HOW ASSISTED REPRODUCTION IS CHANGING MEN, WOMEN, AND THE WORLD 219 (2007). Preeclampsia is a rapidly progressive condition that occurs during the second or third trimester of pregnancy. The condition causes 18% of all maternal deaths in the United States and 15% of all premature births. *See* Preeclampsia Foundation, Statistics, http://www.preeclampsia.org/statistics.asp (last visited Apr. 16, 2009).

[62] *See* Adashi et al., *supra* note 35, at 518.

[63] *See* Bissonnette et al., *supra* note 37, at 775.

[64] Adashi et al., *supra* note 35, at 518.

[65] *See* Bissonnette et al., *supra* note 37, at 775.

[66] *See* Adashi et al., *supra* note 35, at 518.

[67] *See* THE PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 43 (2004).

[68] *See* Bissonnette et al., *supra* note 37, at 776.

[69] *Id.* at 774–75.

[70] Adashi et al., *supra* note 35, at 519.

[71] *Id.*

triplet at thirty-two to thirty-three weeks gestation, and a median quadruplet at twenty-nine weeks gestation.[72] Such children are born preterm, which is defined as "when a woman gives birth before thirty-seven full weeks of pregnancy."[73] In 2005, 62% of twins and 97% of triplets were born preterm, at less than thirty-seven weeks gestation.[74] On average, "the birth weight of [a] triplet was approximately half of that for the average singleton."[75]

Because of their prematurity, twins are seven times, and triplets twenty times, more likely than singletons to die within a month of birth.[76] According to a 1996 U.K. study, "[a]lthough multiple births represented only 2.5% of all births, they accounted for 8% of all stillbirths, 19% of all neonatal deaths and 7% of all post-neonatal deaths in 1991."[77] Those that survive the early postnatal period are more likely to suffer from long-term medical and developmental problems. A Japanese study reports that "at least one child was handicapped in 7.4% of twin pregnancies, 21.6% of triplet pregnancies, and 50% of quadruplet and quintuplet pregnancies."[78] These risks are higher than one would expect to see if the chance of each child being disabled were unrelated to the number fetuses. Multiples are also much more likely than singletons to suffer from cerebral palsy, delayed mental and language development, and motor and coordination difficulties.[79]

While the data above includes ART and non-ART multiples, several studies show that IVF twins, in particular, have worse perinatal outcomes than spontaneously conceived twins, even though their health outcomes would be expected to be better due to the decreased proportion of monochorionic twins (that is, twins that share a single placenta and, on average, have worse health outcomes than twins with two placentas), a lower rate of smoking, and higher socio-economic status of their parents.[80] IVF twins are 48% more likely than spontaneously conceived twins to be born between thirty-two and thirty-six weeks of gestation,[81] and are hence more likely to have more serious health problems.

Children from multiple gestation pregnancies are also more likely than singletons to spend a significant amount of time in neonatal intensive care units ("NICUs"), separated from their parents.[82] Prematurely delivered babies are usually discharged from NICU when they are at least at thirty-six

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[72] *See id.* (noting that "[m]ost babies born before twenty-four weeks of gestation die, and only half of all babies born at twenty-five weeks survive, many with life-long disability").

[73] *See* CDC, *supra* note 30, at 23.

[74] *See id.*

[75] *See* Adashi et al., *supra* note 35, at 519.

[76] *See id.*

[77] *Id.*

[78] *Id.* at 520.

[79] *See id.*

[80] Bissonnette et al., *supra* note 37, at 774.

[81] *See id.*

[82] *Id.* at 776.

weeks' gestation, which means that an average triplet spends four weeks in an incubator before her parents can take her home.[83]

In summary, infants born from multiple gestation pregnancies are at a serious risk of short- and long-term medical problems compared with their singleton peers. While medical risks are more serious for triplet and higher-order multiples, they are significant for twins too.

To lower the risks, doctors often recommend selective reduction, addressed in the next section, a procedure that usually reduces a triplet, quadruplet or higher order pregnancy to twins. Although the procedure does reduce the risks to the remaining fetuses, selective abortion is often an unattractive option for parents, who previously struggled to conceive and an insufficient answer to the problem of multiple gestation pregnancies in IVF.[84]

### 3. *Selective Reduction*

Once diagnosed with a high-order pregnancy, many couples are advised to consider selective reduction in order to improve the chances that at least some of their children will be born healthy.[85] Selective reduction is usually performed between the ninth week and the twelfth week of gestation. The procedure commonly involves inserting a needle through the abdominal wall and injecting potassium chloride into one or more fetuses to stop their hearts.[86] The procedure is conceptually very similar to an abortion, except that its ultimate purpose is to salvage at least part of a pregnancy, not to terminate the entire pregnancy.[87]

There is a substantial body of evidence to show that selective reduction prolongs gestation of the remaining fetuses and reduces the risks of preterm delivery.[88] Most frequently a triplet, quadruplet, or higher-order pregnancy is reduced to a twin or a singleton pregnancy. Reduction of a triplet pregnancy to twins prolongs gestation by two to three weeks, and reduction from a higher-order gestation prolongs the pregnancy even more.[89]

Despite the benefits of selective reduction, the decision to go ahead with the procedure is difficult for most couples. Surveys show that one-third of infertile couples would refuse selective reduction on religious or ethical grounds.[90] In addition, once they discover that they are carrying multiple

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[83] *See id.* at 775–76.

[84] *See* Siddharth Khanijou, *Multifetal Pregnancy Reduction in Assisted Reproductive Technologies: A License to Kill?*, 8 DEPAUL J. HEALTH CARE L. 403, 405 (2005).

[85] *See* Adashi et al., *supra* note 35, at 521.

[86] *See* Khanijou, *supra* note 84, at 413.

[87] *Id.*

[88] Adashi et al., *supra* note 35, at 521.

[89] *Id.*

[90] Carson Strong, *Too Many Twins, Triplets, Quadruplets, and So On: A Call for New Priorities*, 31 J.L. MED. & ETHICS 272, 275 (2003).

babies, many couples become attached to all and refuse to terminate some to save the others, instead choosing to hope that all might survive.[91]

Selective reduction can lead to an unintended loss of the entire pregnancy, and the loss rate increases with the number of initial fetuses.[92] In addition, the overwhelming majority of patients who are candidates for selective reduction have conceived following infertility treatment.[93] For a couple who just learned the happy news that they are finally pregnant, the decision to kill some of the fetuses in order to save the remaining fetuses is very difficult.[94] Most patients report feeling sad and guilty for a number of years after the procedure,[95] even if they delivered healthy babies afterwards.

As a result, selective reduction and similar post-pregnancy procedures are an inadequate remedy for the serious health risks posed by multiple gestation pregnancies to the mother and the babies.

### *C. Psychological Costs of Multiple Gestation Pregnancies*

In addition to significant medical risks, ART parents of multiple gestation babies, the children, and their siblings are more likely to suffer serious psychological costs. The parents often find it more difficult than expected to care for multiple same-age children, particularly if the children are disabled.[96] If they opted for selective reduction, they usually grieve for the children they lost. Although ART parents tend to be very good at parenting, the children nevertheless suffer because they have to share their overworked parents with their siblings.[97]

#### 1. *Psychological Costs to Parents of ART Multiples*

Many patients treated for infertility do not already have children, and hence often have unrealistic expectations about children and about them-

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[91] *Cf.* Adashi et al., *supra* note 35, at 522 (noting that the decision to terminate some of the fetuses to reduce the chance that all *might* be harmed is difficult when everything is progressing well).

[92] *See* Strong, *supra* note 90, at 275.

[93] Selective reductions are usually considered in triplet or higher-order pregnancies, most of which result from infertility treatment. *See* Carton, *supra* note 13. "75 percent of [selective reduction] patients have gotten pregnant through IVF . . . . Now it's 5 to 10 percent very high-order multiples, 20 percent quads, 60 percent triplets, and about 10 to 15 percent twins." Lisa Mundy, *Too Much to Carry?*, WASH. POST, May 20, 2007, at W14.

[94] According to two European programs, "fewer than 15% of patients carrying triplets or quadruplets opt for fetal reduction." *See* Peters, Jr., *supra* note 32, at 214. For constitutional reasons, selective reduction is not likely to be made mandatory. *Cf.* Gonzalez v. Carhart, 550 U.S. 124 (2007) (upholding a partial birth abortion ban, suggesting that it is highly unlikely that the Supreme Court would ever mandate abortion).

[95] *See* Adashi et al., *supra* note 35, at 522 (stating that feelings of sadness and guilt do not normally last more than two years).

[96] *See* Bissonnette et al., *supra* note 37, at 776–77.

[97] *See* Adashi et al., *supra* note 35, at 521.

selves as parents.[98] They very much want a child and have usually spent years trying for one. The process of achieving and carrying to term a pregnancy produced by ART can be an extraordinarily stressful mix of ups and downs.[99] The transfer of embryos creates expectations only to crush them two weeks later with a negative pregnancy test. As a result, women undergoing infertility treatment often express pleasure at the prospect of twins and an "instant family."[100] They want to "get it over with" and complete their family without having to return to infertility treatment.[101] According to 1995 research findings, "up to ninety percent of patients surveyed . . . wished for twins and fifty percent would be happy with triplets."[102] Once the baby comes, however, the new parents may be unprepared for the trials and tribulations of parenting. This is particularly true when more than one baby comes at once.

IVF parents tend to be as good, or better, at parenting as parents of spontaneously conceived children.[103] But both IVF mothers and fathers report feeling less competent at parenting than parents of spontaneously conceived children.[104] They report significantly higher stress levels, and IVF fathers in particular report more dysfunctional interactions with their children, whom they perceive as being more difficult than do fathers of spontaneously conceived children.[105] This difference may be due to the fact that they are unable to live up to the high standard of parenting they had dreamt of for so long.[106]

Parents with twins and higher-order multiples fare even less well. One U.K. study reports that expectant parents of IVF twins and triplets are significantly more stressed during pregnancy than their peers expecting singletons, and over 30% of expectant mothers of multiple babies reported levels of anxiety suggesting a clinical disorder.[107] This poses health risks to both the mother and her children: evidence indicates that "stress during pregnancy is associated with poorer health outcomes for infants, such as low birth weight."[108]

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[98] *See* Rachel Cook, Sally Bradley & Susan Golombok, *A Preliminary Study of Parental Stress and Child Behaviour in Families With Twins Conceived by In-vitro Fertilization*, 13 HUM. REPROD. 3244, 3244 (1998).

[99] *See* Nicky Blackburn, *I Will Become a Mother at Any Cost*, TIMES ONLINE, Jul. 19, 2004, http://www.timesonline.co.uk/tol/life_and_style/article458210.ece.

[100] *See* Cook et al., *supra* note 98, at 3244.

[101] *See* Bissonnette et al., *supra* note 37, at 780.

[102] *Id.* at 781.

[103] *See* Cook et al., *supra* note 98, at 3245.

[104] *See id.* at 3244.

[105] *Id.* at 3245.

[106] *See* Adashi et al., *supra* note 35, at 520.

[107] *See* Christine Glazebrook, Sara Cox, Margaret Oates & George Ndukwe, *Psychological Adjustment During Pregnancy and the Postpartum Period in Single and Multiple In Vitro Fertilization Births: A Review and Preliminary Findings from an Ongoing Study*, 10 REPROD. TECHS. 112, 117 (2001).

[108] *See id.*

Multiple gestation infants often require long stays in the NICU, which produces additional psychological costs. Sometimes, the children have to be transferred to different units because there are not enough cots in a single unit.[109] This puts a logistical strain on both parents, and generates emotional stress for the mother in particular, since she may not be able to spend enough time with all of her children.[110]

But many of the greatest stresses for the new parents occur when the babies are discharged from the hospital.[111] The new parents, most of whom did not have children before, now have to take care of multiple tiny babies who might have significant health problems. In addition to being concerned about their children's health, parents of multiples are seriously sleep deprived.[112] According to one study, caring for healthy six-month-old triplets requires 197.5 hours per week, but there are only 168 hours in any given week.[113]

Parents lose "couple time" because they are too tired and because it is extremely difficult to arrange babysitting for multiple same-age babies, especially if the children have serious health problems.[114] Even if the children are healthy, it is often very difficult to organize an outing with several same-age children. No mother can safely carry three babies at once, and many become homebound and report feeling isolated.[115]

As a result, parents of multiples are more likely to be exhausted, depressed, and anxious after the birth of their babies than are parents of singletons.[116] Their negative feelings may be exacerbated if one or more of the babies died or if they had to undergo selective reduction during pregnancy. Despite the death of one or more of their children or despite having to sacrifice one or more fetuses to save the lives of the remaining babies in a selec-

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[109] *See* Adashi et al., *supra* note 35, at 520.

[110] *Id.*

[111] *See* Bissonnette et al., *supra* note 37, at 776.

[112] "Sleep is the new crack cocaine. It's the new wine, the new tobacco. Sleep, sadly, is the new sex. It's what you think about and talk about and crave when you are the new parents of one, two, three beautiful, bouncing, crying, shitting, screaming babies." Cole Moreton, *Focus: I Have IVF Triplets. I Have Been Knackered, Angry and Depressed. And, Yes, I Have Resented Them*, THE INDEP., Oct. 19, 2003, http://www.independent.co.uk/uk/health_medical/article92010.ece.

[113] Bissonnette et al., *supra* note 37, at 781.

[114] *See id.* at 777.

[115] Adashi et al., *supra* note 35, at 521. A U.K. study found that mothers of IVF twins or triplets worked a median of zero hours outside the home twelve months after the children were delivered, while mothers of an IVF singleton worked a median of 17.75 hours per week. Cris Glazebrook, Charlotte Sheard, Sara Cox, Margaret Oates & George Ndukwe, *Parenting Stress in First-Time Mothers of Twins and Triplets Conceived After In Vitro Fertilization*, 81 FERTILITY & STERILITY 505, 509 (2004).

[116] A U.K. study reports that all mothers of triplets in their sample reported continuing emotional distress four years after giving birth, and 35% were taking medication to treat depression. Glazebrook et al., *supra* note 115, at 505–06.

tive reduction procedure, a couple that is left with at least one live baby often receives very little sympathy about the death of their other children.[117]

### 2. *Psychological Costs of a Multiple Gestation Pregnancy to ART Children and Their Siblings*

A multiple gestation pregnancy imposes real psychological costs on the multiple children, as well as on their older siblings. Children resulting from multiple gestation pregnancies suffer from having to share their parents with their siblings.[118] Even when the children are healthy, their parents are unable to give them the same amount of attention that they would have received if they were born as singletons.[119] And when one or more of them is sick, the problems are exacerbated. A disabled child finds it difficult to understand why she, and not her siblings, is affected, and may feel jealous, angry, or depressed.[120] The healthy child may also feel jealous about the extra time her disabled sibling gets to spend with her parents.[121] Later in life, however, these feelings might be replaced with guilt and an excessive burden of responsibility for the disabled sibling.[122] Children whose siblings died in the perinatal period often suffer from both the loss of their companion(s) and the grief of their parents.[123] They may feel guilty for having survived and feel angry at their parents for allowing the death to happen.[124]

Older siblings might also be negatively affected by the arrival of multiple younger siblings, who demand a lot of their parents' time and attention. A sibling is likely to be more disturbed by the arrival of twins than of a single younger sibling, and behavioral problems with the older child are much more common following a multiple birth.[125] Like medical problems, psychological problems are exacerbated as the number of new children increases.[126]

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[117] *See* Adashi et al., *supra* note 35, at 521.
[118] *See id.*
[119] *Id.*
[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] *See id.*
[124] *Id.*
[125] *Id.*
[126] When the McCaughey septuplets were born in 1997, some observers expressed concerns about the septuplets' twenty-two-month-older sister Mikayla, who went from being an only child to being one of eight. "For a little girl to have her sisters and brothers continuously photographed and to see their pictures displayed all over is not normal. She will be very jealous and feel very, very left out. And, I'm afraid, very lonely." Michael D. Lemonick, *"It's a Miracle,"* TIME, Dec. 1, 1997, at 34, 38.

### D. *Financial Costs of Multiple Gestation Pregnancies*

In addition to medical and psychological costs, multiple gestation pregnancies are associated with increased financial costs. Infertile patients carrying multiple fetuses and their children require more pre- and postnatal care, which is often very expensive. While the cost of infertility treatment is usually borne by the infertile patients, American buyers of health insurance pay for the higher medical expenses associated with multiple gestation pregnancies through higher health insurance premiums. And, since twins and higher-order multiples are more likely to require special education and other programs financed by the local, state, and federal governments, all American taxpayers—and not just the parents—pay to raise and educate them. As a result, although American ART patients are paying a high price for their babies, they are not paying the full cost of their decisions.

#### 1. *Financial Costs to Parents of ART Multiples*

Many infertility patients have health insurance, which covers most or all prenatal, delivery, and postnatal medical expenses.[127] Infertile women carrying multiple fetuses are likely to be monitored more closely during pregnancy than their peers carrying singletons. Even if their out-of-pocket medical expenses are the same, more visits to the doctor's office and more ultrasounds require women carrying multiple fetuses to take more time off work. Since they are more likely than their peers to have pregnancy complications that require hospitalization or long-term bed rest, they may have to stop working altogether, and hence lose income.

There are also significant financial implications to raising more than one same-age baby at once. Parents must buy toys, clothing, cribs, and car seats in multiples, since they are all needed at the same time. They must often buy specialized strollers, a new car, and sometimes a new house, to accommodate a larger family.[128] If they are able to find childcare, it is usually significantly more expensive than childcare for a singleton. As a result, caring for multiple same-age children, even if they are healthy, is likely to make it difficult for both parents to return to full-time work. A U.K. study

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[127] According to the latest census, 15.3% of Americans are uninsured, implying that 84.7% are covered by private or government health insurance, or both. Carmen DeNavas-Walt, Bernadette D. Proctor & Jessica C. Smith, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2007 19 (2008), *available at* www.census.gov/prod/2008pubs/p60-235.pdf. I am not aware of data surveying infertility patients only, but general population data is an adequate reference since there is no indication that infertility patients are less likely than the general population to be insured.

[128] When the McCaughey family had septuplets, they received a substantial amount of media attention, which generated a wave of generosity in their community: local businesses pledged to buy them a new house, Chevrolet gave them a 15-seat van, Procter & Gamble offered free diapers for life, and a college in Missouri promised scholarships for all seven children. Lemonick, *supra* note 126, at 36–37. Most parents of twins or triplets, however, must pay all of these costs themselves.

found that mothers of IVF twins or triplets worked a median of zero hours outside the home twelve months after the children were delivered, while mothers of an IVF singleton worked a median of 17.75 hours per week.[129] In addition to reducing the family income while the mother stays at home to care for the children, her inability to work is likely to reduce her lifetime earning potential. Taking several years off work to raise children usually makes it difficult for the mother to return to the same job that she had before having children. Instead, her only choice is often a job that pays less and has limited potential for career advancement.[130]

2. *Financial Costs to Society*

Because of the way we finance health care, parents of children from multiple gestation pregnancies do not bear the full medical costs for their care.[131] Mothers carrying multiple fetuses require more prenatal medical attention than their peers carrying singletons: on average, they have more prenatal appointments, more laboratory tests, and more ultrasounds.[132] They are also more likely to need hospitalization, and have significantly higher rates of delivery complications that require more expensive treatment.[133] If they have health insurance, the plan usually covers most or all of the associated expenses. Ultimately, every member of the same health plan pays for the incremental cost of additional medical attention to ART patients carrying multiple fetuses through higher health insurance premiums.

Delivering multiple children is also significantly more expensive than delivering a singleton, primarily because multiples are more likely to be born premature. As a result, they are many times more likely than singletons to require neonatal intensive care, drug therapy, inhalation therapy to help them breathe, expensive imaging, and other diagnostic procedures.[134] A U.S. study from 1999 reports that a twin delivery costs $43,300 more than a singleton delivery, a triplet delivery $120,000 more, and a quadruplet delivery $174,000 more.[135] These figures include only medical expenses of delivery and immediate postnatal care. Accounting for the fact that health care costs have been rising faster than inflation, the figures today are likely to be at least 50% higher.

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[129] *See* Glazebrook et al., *supra* note 115, at 509.

[130] *Cf.* Felice N. Schwartz, *Management Women and the New Facts of Life*, HARV. BUS. REV., Jan.–Feb. 1989, at 65, 65 ("[W]omen . . . have a greater tendency to plateau or to interrupt their careers in ways that limit their growth and development.").

[131] For a discussion of health insurance and its impact on choices, *see infra* section II.A.iv.

[132] *See* Ann Thurin Kjellberg, Per Carlsson & Christina Bergh, *Randomized Single Versus Double Embryo Transfer: Obstetric and Paediatric Outcome and a Cost-Effectiveness Analysis*, 21 HUM. REPROD. 210, 211 (2006).

[133] *See id.*

[134] *See* Bissonnette et al., *supra* note 37, at 777.

[135] *See* Adashi et al., *supra* note 35, at 523.

In addition, multiples often have long-term medical problems that require continued monitoring and care throughout their childhood years and beyond. Beside medical expenses, they often need special care. In fact, 45% of the children who were born premature and at low birth weight need to attend special education programs.[136]

Parents of multiples bear some of these costs, but the majority of the expenses are either covered by health insurance and shared by all other participants in the plan through higher premiums, or paid for through taxes. While parents of spontaneously conceived twins or triplets do not choose to have multiple children at once, the situation is often different for infertile patients. Many actively desire an "instant family" and prefer twins or triplets to a single child, or are, at the least, willing to risk having multiple children if that increases their chance of conceiving by as little as 1%.[137] This desire is understandable: it stems in part from the fact that infertility treatment is unpleasant and stressful, but largely from the fact that it is very expensive. Changing the way we pay for infertility treatment and for the pregnancies it produces could help reduce the rates of multiple gestation pregnancies.[138]

## III. Regulation of ART and Its Effect on the Incidence of Multiple Gestation Pregnancies

The United States differs from most developed countries in that ART takes place in a largely unregulated environment. Federal regulation of ART has been minimal. State regulation has been sporadic and is "the exception rather than the rule."[139] Instead, the ART industry has primarily self-regulated and has relied on market forces to determine what procedures are available and at what prices.

In this section, I suggest that federal and state regulation, self-regulation of ART, market forces, providers of health insurance, and malpractice litigation have been unable to address the concerns raised by fertility scientists about multiple gestation pregnancies, and may have aggravated the problem. I begin by presenting the current U.S. regulatory structure, in which decision-making authority in ART is divided between the federal and

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[136] Spar, *supra* note 16, at 141.

[137] One group of U.S. researchers reported that a majority of IVF patients would choose to transfer one embryo (instead of two) only if pregnancy rates were equivalent or better, despite the fact that implanting two embryos is accompanied by a tenfold increase in the rate of twins (50% v. 5%). Ginny L. Ryan, Amy E.T. Sparks, Christopher S. Sipe, Craig H. Syrop, Anuja Dokras & Bradley J. Van Voorhis, *A Mandatory Single Blastocyst Transfer Policy with Educational Campaign in a United States IVF Program Reduces Multiple Gestation Rates Without Sacrificing Pregnancy Rates*, 88 Fertility & Sterility 354, 356 (2007).

[138] *See infra* section III.A.iv.

[139] *See* Jennifer L. Rosato, *The Children of ART (Assisted Reproductive Technology): Should the Law Protect Them from Harm?*, 2004 Utah L. Rev. 57, 66 (2004).

state governments, professional organizations, the market, health insurers, and courts, and by discussing the limitations of each source of regulation. I continue by describing the regulatory approaches taken by some countries in Europe. Relying on evidence from the United States and Europe, I suggest that self-regulation and market forces are unlikely to be effective in the United States, and that state or federal intervention is necessary to reduce the costs associated with multiple gestation pregnancies in ART.

### *A. Current U.S. Regulation of ART*

The ART industry in the United States has been allowed to develop without much federal or state intervention. As Jennifer Rosato notes, "although there is some self-regulation of fertility practices through professional medical organizations, the system is not well-equipped to curb harmful or unethical practices."[140]

This section describes the existing federal and state law, self-regulation, market regulation, regulation by providers of health insurance, and regulation by courts. In particular, the section considers why each of these sources of regulation has either been unable to address the problem of multiple gestation pregnancies resulting from ART, or has created incentives that make multiple gestation pregnancies more likely.

#### 1. *Federal and State Regulation*

In the early days of ART, and of IVF in particular, the greatest concern of the regulators was that "women, desperate to conceive, might be exploited, taken in by unrealistic promises and charged extortionate fees for futile or dangerous treatment."[141] The lone piece of congressional legislation, the Fertility Clinic Success Rate and Certification Act of 1992,[142] was a response to those concerns. The Act requires infertility clinics to report information regarding their success rates, measured by the number of pregnancies or live births per IVF cycle or per transfer.[143]

While the Act makes comparisons between different clinics easier, it also creates perverse incentives. Infertile patients, motivated to conceive quickly, aggressively pursue providers that give them the best chance of a child. Clinics that can report the best numbers can attract more patients. To keep their numbers high, fertility clinics may be inclined to turn away pa-

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[140] *Id.* at 62.

[141] Mary Warnock, *The Ethical Regulation of Science*, NATURE, Nov. 2007, at 615, 615.

[142] Pub. L. No. 102-493, 106 Stat. 3146 (codified as amended at 42 U.S.C. §§263a-1 to -7 (2006)).

[143] 42 U.S.C. § 263a-1(b)(2).

tients with poor prognoses.[144] More troubling, however, is the competitive pressure on the clinics to improve their pregnancy rates by transferring more embryos per procedure.[145] In the early days of IVF, the best results were achieved when five or more embryos were transferred.[146] Today, generally the best pregnancy rates are achieved when two or three embryos are transferred, though rates when a single embryo is transferred do not lag very far behind.[147] Increased pregnancy rates, however, come at a cost of multiple births and worse medical outcomes.[148] Clinics are required to report only their pregnancy rates per transfer, and do not disclose the number of multiple gestation pregnancies nor the numbers of infants with medical problems. As a result, the Act indirectly gives doctors the incentive to transfer more embryos per cycle in order to improve the clinic's numbers and appease their patients.[149] The Act does not require clinics to report that improvement in pregnancy rates, which is often marginal at best, comes at a high cost of multiple gestation pregnancies.[150]

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[144] *See* Joseph D. Schulman, *"What's Your Success Rate?": Understanding IVF Pregnancy Statistics*, http://www.givf.com/library/whatisyoursuccessrate1.cfm/ (last visited Apr. 16, 2009) (noting that "the key to making success rate statistics look good is to control the population data"). This article is published on a web site of Genetics & IVF Institute, "the world's largest, fully integrated, specialized provider of infertility and genetics services." Genetics & IVF Inst., Homepage, http://www.givf.com/ (last visited Apr. 16, 2009).

[145] *See* Jamie Grifo, David Hoffman & Phillip I. McNamee, *We Are Due for a Correction . . . and We are Working to Achieve One*, 75 FERTILITY & STERILITY 14, 14 (2001).

[146] *See* DEP'T OF HEALTH & HUM. SERVS., ET AL., 1995 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS VOLUME 1 — EASTERN UNITED STATES 18 (1997), *available at* http://www.cdc.gov/ART/ArchivedARTPDFs/95eastern.pdf (reporting that the best success rates were achieved when five or more embryos were transferred).

[147] In 2005 the success rates for women under 35 who produced more eggs that they chose to transfer were as follows: 43.3% of women who chose to transfer a single embryo gave birth to a live baby; 52.8% of women who chose to transfer 2 embryos gave birth to a live baby; 47.5% of those who transferred 3 embryos did; 45.8% of those who transferred 4 embryos did; 41.9% of those who transferred 5 embryos did. CDC, 2005 ART REPORT, *supra* note 6, at 69 fig.57.

[148] In the same sample, of those women who had a live birth, only 2% of women choosing to transfer a single embryo gave birth to twins; 33.2% of those who transferred two embryos gave birth to twins or triplets; while 34.3% of those who transferred three embryos gave birth to twins or triplets. CDC, 2005 ART REPORT, *supra* note 6, at 45 fig.33.

[149] One fertility doctor reports that although his clinic had the better history, credentials, services, and pregnancy outcomes, a doctor from another state chose to cooperate with a different clinic because their pregnancy rates were a few percentage points higher. *See* Michael M. Alper, *In Vitro Fertilization Outcomes: Why Doesn't Anyone Get It?*, 81 FERTILITY & STERILITY 514, 515 (2004).

[150] The Act requires the Secretary of the Department of Health & Human Services, when defining pregnancy success rates, to include the ratio between the number of live birth rates and the number of ovarian stimulations or oocyte retrievals conducted in any one ART center. 42 U.S.C. § 263a-1(b)(2) (2006). The Act also provides that the pregnancy success rate should take into account the effect of age and diagnosis on the live birth rate. *Id.*

Relatively few states have adopted laws about assisted reproduction.[151] The majority of the states that have decided to regulate ART provide for full or partial insurance coverage for some, but not all, ART procedures.[152] Most of the state statutes concern particular ART methods (such as sperm, egg, and embryo donation), surrogacy, the status and storage of fertilized eggs and embryos, and consumer protection (e.g., Virginia requires all ART patients to sign a disclosure statement indicating the clinic's success rates).[153] New Hampshire is an exception in its concern with the welfare of the potential child: the state requires both a medical evaluation and a psychological evaluation akin to adoption proceedings, as well as a home study. The stated purpose of the screenings is to ensure that the couple can give the child adequate emotional and material support.[154] Yet not even the New Hampshire statute addresses what is likely the most significant threat to the well-being of the ART child: being born from a multiple gestation pregnancy.

2. *Self-Regulation*

In the relative absence of federal and state regulation, various professional groups have expressed opinions on what is acceptable for the practice of ART in the United States.

The American Medical Association Code of Medical Ethics, for example, requires doctors to inform infertility patients about clinic-specific success rates and fee structures and prohibits basing payment on clinical outcomes. The Code requires that doctors inform patients of "all aspects of ART applicable to their particular clinical profile" but does not provide more specific guidelines.[155]

The American Society for Reproductive Medicine ("ASRM"), the primary professional organization that oversees the field of ART, and the Society for Assisted Reproductive Technology ("SART"), an affiliated organization that specifically covers IVF, have developed more specific guidelines. ASRM and SART have attempted to reduce the multiple pregnancy rate by publishing guidelines on the number of embryos that should be transferred in each IVF cycle. The 1999 guidelines recommended that two or three embryos be transferred in women under thirty-five with

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[151] *See* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 67, at 54.

[152] *See id.* at 51. Laws in Arkansas, Hawaii, Maryland, and Texas concern coverage only for IVF, while California and New York exclude IVF from coverage mandates. Most coverage mandates are limited in some way: Arkansas limits the maximum lifetime benefit to $15,000, and Hawaii covers only one IVF cycle (and no other ART procedure). *See* Am. Soc'y of Reprod. Med., State Infertility Insurance Laws, http://www.asrm.org/Patients/insur.html (last visited Apr. 16, 2009).

[153] *See, e.g.*, VA. CODE ANN. § 54.1-2971.1 (2008); *see also* Moriarty, *supra* note 21, at 512–13; Rosato, *supra* note 139, at 64–66.

[154] N.H. REV. STAT. ANN. § 168-B:13 (1995); *see also* Moriarty, *supra* note 21, at 513–14.

[155] *See* AM. MED. ASS'N, CODE OF MEDICAL ETHICS 533 (2008), http://www.ama-assn.org/ama/no-index/legislation-advocacy/8152.shtml/ (last visited Apr. 16, 2009).

favorable prognoses, that up to four embryos be transferred in women between thirty-five and forty, and that no more than five embryos be transferred in women over the age of forty or those with multiple IVF cycle failures.[156] The number of cycles where four or more embryos are transferred has halved since 1999, and the number of cycles where two or three embryos are transferred has significantly increased.[157]

In November 2006, after continued reports about high-order multiple pregnancies resulting from IVF, ASRM modified its guidelines to recommend that only one embryo be transferred in women under thirty-five with the best prognoses and with excess embryos available for cryopreservation.[158] The new guidelines begin with a statement that a triplet or higher-order pregnancy is an "undesirable consequence" of ART.[159] By omitting any reference to twins, however, ASRM is indirectly endorsing twins as a desirable result of infertility treatment, despite the significantly increased medical risks compared to singletons.

Although ASRM's guidelines, coupled with increasing success rates, have resulted in lower numbers of embryos that are transferred in IVF, they have been unable to reduce the incidence of lower-order multiple gestation pregnancies. This is in part because current infertility guidelines are based on assumptions rather than solid clinical evidence.[160] Very few clinical studies have been performed in the United States on the success rates with fewer embryos for different cohorts of women, and on the health consequences of infertility treatment on the mothers and their children. Most data comes from European studies. The data that does exist is often selected and presented to prove a particular point. For example, the overall percentage of live births per transfer when a single embryo is transferred is 16.7%, compared with a whopping 40.9% when two embryos are transferred.[161] But what the numbers do not show is that when a single embryo was transferred, in many cases, it was the only embryo available, and may have been, at best, of marginal quality.[162] When patients had a choice — that is, their ovaries produced many healthy eggs that were fertilized — and chose to transfer a single embryo instead of two or more, they had a 43.3% chance of giving

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[156] *See* Adashi et al., *supra* note 35, at 525.

[157] Four or more embryos were transferred in 36% of IVF procedures in 1999, compared with 18% in 2005. Two or three embryos were transferred in 57% of IVF transfers in 1999, and in 73% of IVF transfers in 2005. *See* CDC, 2005 ART REPORT, *supra* note 6, at 66 fig.54.

[158] *See* The Practice Comm. for SART and the Practice Comm. for ASRM, *Guidelines on Number of Embryos Transferred*, 86 FERTILITY & STERILITY S51, S52 tbl.1 (2006).

[159] *Id.* at S51.

[160] *See* Adashi et al., *supra* note 35, at 527.

[161] *See* CDC, 2005 ART REPORT, *supra* note 6, at 45 fig.33.

[162] *Compare id.* at 46 fig.33, *with id.* at 46 fig.34 (recording a significant difference in single-embryo-transfer success rates between women with multiple available embryos (43.3%) and those with a single available embryo (16.7%)).

birth to a live baby.[163] Their peers, who chose to transfer two embryos, had a 52.8% chance of delivering a live baby, but they also had an almost 40% chance of delivering twins or triplets (compared with a 2% chance in the single-embryo transfer group).[164]

ASRM's self-regulatory powers are limited because its enforcement mechanisms are ineffective. Compliance with the infertility guidelines is largely voluntary, and ASRM has no way of punishing noncompliant clinics.[165] Also, according to the ASRM guidelines, clinics can develop their own guidelines on the number of embryos they will transfer and "can make individual determinations as to the appropriate number."[166] The decisive factor is the likelihood of achieving any pregnancy, not a singleton pregnancy, particularly since success rates continue to be measured in live births per cycle and not in singleton live births per cycle.[167] While it is true that infertility patients vary, and that a uniform policy might be overly restrictive for some patients, an entirely flexible policy fails to convey the seriousness of the problem that multiple gestation pregnancies pose.[168] In addition, clinics do not have to be members of ASRM to offer infertility services and are hence not even loosely bound by ASRM's embryo transfer guidelines.

As a result, self-regulation of the ART industry has been, and will likely remain, unable to address the concerns that fertility scientists, psychologists, and public health researchers have raised about multiple gestation pregnancies.

### 3. *The ART Market*

Economic theory posits that perfectly competitive markets will lead to both optimal allocation and efficient use of resources and maximization of social welfare.[169] According to theory, competitive markets accurately price goods and services on offer, so that the price reflects all costs associated with the good or service.[170] The model assumes that consumers take into consideration the potential risks of the good or service and are willing to pay less for a more risky good or service.[171] Economic theory, however, also predicts that where all the conditions for a perfectly competitive market are

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[163] *See* CDC, 2005 ART REPORT, *supra* note 6, at 46 fig.34.

[164] *See id.*

[165] *See* Lyria Bennett Moses, *Understanding Legal Responses to Technological Change: The Example of In Vitro Fertilization*, 6 MINN. J. L. SCI. & TECH. 505, 592–93 (2005).

[166] Rosato, *supra* note 139, at 68.

[167] *Cf.* Alper, *supra* note 149, at 514 ("Patients focus solely on pregnancy and pay little attention to the adverse outcomes of multiple gestations.").

[168] *Cf. id.* at 515 ("Why don't we, the medical community, get it? How can we expect our patients to heed our advice when we cannot heed our own?").

[169] *See generally* JOSEPH E. STIGLITZ, ECONOMICS OF THE PUBLIC SECTOR 63–64 (3d ed. 2000).

[170] *See id.* at 76.

[171] *See id.* at 77–79.

not satisfied and there exist market failures—for example, if information is not perfect or if there are negative externalities—markets may not maximize social welfare.[172]

The ART industry in the United States has been allowed to develop in a largely unregulated environment. The market for ART services has failed to produce welfare-maximizing outcomes because of a number of market failures: asymmetric information, uneven bargaining position of consumers, and negative externalities.

The Fertility Clinic Success Rate and Certification Act was adopted to address the first of these market failures, namely asymmetric information. While the Act has enabled consumers of infertility services to compare clinics directly, it does not require clinics to report adverse outcomes for the pregnancies they created.[173] As a result, consumers of infertility services may be unaware of the odds that they will conceive multiple babies. In addition, studies show that consumers of infertility services are often unaware of the health problems associated with multiple gestation pregnancies, even though they have signed consent forms before purchasing ART services.[174] While many know that triplets have an elevated risk of cerebral palsy, fewer than half know that twins, too, have an elevated risk.[175] In fact, twins are five to twelve times more likely than singletons to suffer from cerebral palsy.[176] Only a little over half of patients know that triplets have a higher risk of dying than singletons, and a mere 30% know that twins are also more likely to die in infancy.[177] Clinic reporting, combined with ineffective disclosure of potential side-effects and adverse outcomes of infertility treatment, may lead consumers to unknowingly choose procedures that are more risky than the alternative.[178]

Studies report that even when consumers of infertility services are aware of the medical, psychological, and financial costs of multiple births, they consistently downplay and underestimate them.[179] Some commentators suggest that selective media reporting about multiple births affects public perception. The McCaughey septuplets—the first to all survive—received national attention and were touted as a miracle.[180] The same media did not report the story of the last woman before Bobbi McCaughey to have sep-

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[172] *Id.* at 77.

[173] The Act requires that the Secretary of the Department of Health & Human Services define pregnancy success rates. *See* 42 U.S.C. § 263a-1 (2006). The Act does not mention multiple gestation pregnancies.

[174] *See* Ginny L. Ryan, Sunny M. Zhang, Anuja Dokras, Craig H. Syrop & Bradley J. Van Voorhis, *The Desire of Infertile Patients for Multiple Births*, 81 FERTILITY & STERILITY 500 (2004).

[175] *See id.* at 502 (reporting that only 49% of survey participants knew that the risk of cerebral palsy was elevated for twins).

[176] *See* Adashi et al., *supra* note 35, at 520 (reporting findings from several studies).

[177] *See* Ryan et al., *supra* note 174, at 502 tbl.2.

[178] *See* discussion *supra* Section III.A.i.

[179] *See* Bissonnette et al., *supra* note 37, at 781.

[180] *Id.*

tuplets: she lost one at birth, three over a few days, and the last three have severe health problems.[181] Other commentators suggest that consumers of infertility services are willing to risk multiple gestation pregnancies because they know they can later reduce the number of embryos through selective reduction.[182] Another reason why consumers of infertility services might underestimate the costs of multiple pregnancies is that most have not experienced parenthood. Moreover, parents of ART multiple children are often reluctant to express their distress once the babies arrive. They often feel that "they got what they asked for . . . [and] that expressing dissatisfaction would be ungrateful."[183]

As a result, although consumers of infertility services care about the health of the children they are creating, they are unlikely to pressure fertility clinics for safer outcomes. All are eager to conceive as soon as possible, and most are eager to conceive twins or more.[184] They want to avoid having to undergo additional infertility treatments to give their baby a sibling, both because infertility treatment is emotionally and physically draining, and because it is very expensive.[185] Hence, while improved disclosure may help reduce the rate of multiple gestation pregnancies to some extent, it is unlikely to go far enough.

A second market failure is the unequal bargaining position of consumers of infertility services. Since the fertility clinic might be their only chance of having a biological child, they are unlikely to bargain hard for a lower price. Instead, infertile couples will try to reduce their out-of-pocket cost of creating a family by opting for a procedure that is likely to increase their chances of getting pregnant and will possibly result in twins or triplets. Since consumers of infertility services are not just buying a service—one IVF procedure, for example—but the chance of a child that they value as priceless, the price they are willing to pay depends largely on their available resources.[186] Their demand is inelastic, which means that the quantity of ART services clinics can sell will not significantly fall if prices increase, unless the price increase is so significant that consumers will opt out of the ART market entirely. Supply of infertility services has increased many times over since the 1980s, yet prices, too, have increased rather than decreased.[187] This is because production in the fertility trade is relatively concentrated: there are few hormone manufacturers, few donor services and relatively few large and experienced clinics.[188] Together, the price insensitivity of dispersed consumers of fertility services and the concentrated sup-

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[181] *Id.*
[182] *Id.*
[183] *Id.*
[184] *See id.*
[185] *Id.* at 780–81.
[186] *See* DEBORA SPAR, THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION 32 (2006).
[187] *Id.* at 33.
[188] *Id.* at 32–33.

ply of ART providers have kept prices in the United States relatively stable, despite a large overall increase in supply.[189] High prices combined with an absence of health insurance coverage put financial pressure on the infertile consumers to conceive as quickly as possible and with multiple children at once.[190] When out-of-pocket costs of infertility treatment, in particular IVF, can exceed $15,000 per attempt, few couples can afford one try, let alone the several that it would take to have more than one child.

One would expect that fertility doctors could effectively inform their patients of the risks associated with multiple gestation pregnancies and thereby reduce the incidence of multiple gestation pregnancies, but this, too, is unlikely to happen. The fertility industry is subject to "significant economies of scale, meaning that clinics must serve a large number of clients simply to cover their fixed costs."[191] As a result, there is fierce competition among clinics for patients. The profitability of a particular fertility practice depends on the success of the practice, measured by the number of pregnancies and live births per cycle. The more successful the practice, the more patients it will get, and the more profitable it will be. The structure of the business and the reporting requirements generate an intense pressure on doctors to maximize their success rates.[192] When every percentage point counts, even doctors seriously concerned about the risks of multiple gestation pregnancies are unable to reduce the rates significantly. At the same time, doctors also deeply care about their patients and want to help them, if possible. As Rosato notes, "some of these patients ask their doctors to take risks to help them have a baby quickly" or to have multiple babies "by transferring too many embryos at one time."[193] Respecting patient autonomy, doctors feel the obligation to respond to their strong desires.[194] Lastly, since fertility doctors do not provide pre- and postnatal care to women they helped conceive, they do not have to face the direct consequences of their actions.

Finally, ART, as practiced in the United States, produces a third market failure: negative externalities. ART has an adverse impact on people who are not party to the transaction between the clinic and the consumers of infertility services: the children, American insurance buyers, and taxpayers. Even if consumers of infertility services were taking into account the risks of a multiple gestation pregnancy to themselves and their potential children, they would not be bearing the full costs of their decision. While they are paying for the infertility treatment out of pocket, they can shift most financial costs associated with a multiple gestation pregnancy onto others.[195] The

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[189] *Id.* at 33.
[190] *See* Bissonnette et al., *supra* note 37, at 782.
[191] SPAR, *supra* note 186, at 33.
[192] Rosato, *supra* note 139, at 73.
[193] *Id.*
[194] *Id.*
[195] *See supra* Section II.D.ii.

combined medical costs of a multiple gestation pregnancy are significantly greater than the costs of two singleton pregnancies.[196] For the infertile couple, however, getting two children from a single IVF procedure is like a two-for-one sale. Given the marginal hospital cost of a multiple pregnancy—$43,300 for twins[197]—it is likely that the infertile couple would have chosen a different procedure if they had to bear the full costs of their decision.[198]

As a result of these market failures—asymmetric information, unequal bargaining power, and negative externalities—the market for ART in the United States is unlikely to efficiently regulate the ART industry and provide optimal incentives to providers and consumers of ART services.

4. *Problems with Insurers*

Arguably, there is no need to rely on the market, the government, or providers themselves to regulate behavior. Health insurance companies frequently charge people who engage in risky behavior that increases potential medical costs, such as smoking, higher premiums than other participants in the insurance pool.[199] Health insurers are very good at determining the appropriate premiums on the basis of risk factors. Actuarial tables provide precise estimates of risk in any particular group of insureds. Pregnancy and delivery are generally covered under most health plans. Since insurance companies pay the ultimate bill of caring for multiple gestation pregnancies, one would expect them to regulate the industry, either by covering infertility treatment[200] or by refusing to cover subsequent pregnancies and deliveries

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[196] *See* Bissonnette, *supra* note 37, at 782 (reporting that the average delivery and neonatal care costs in Canada are C$7121 for singletons, C$42,130 for twins, and C$237,203 for triplets).

[197] Adashi et al., *supra* note 35, at 523.

[198] The total marginal cost of a multiple pregnancy is lower when the cost of infertility treatment is included, but the difference remains substantial. The cost of an IVF cycle normally includes hormonal injections, multiple ultrasounds, egg retrieval, in vitro fertilization, and implantation. Each complete IVF cycle usually produces several embryos, some of which are used while the rest are frozen. Subsequent attempts using frozen embryos cost only a fraction of the original IVF cycle. *See, e.g.*, Genetics & IVF Inst., Pricing, http://www.givf.com/financialprograms/pricing.cfm (last visited Apr. 16, 2009) (listing that a normal IVF cycle costs $8900, while frozen embryo transfer costs $4500).

[199] *See, e.g.*, Lisa Cornwell, *Smokers Pay More for Health Benefits: Employers Ask Smokers to Pay Higher Health-Care Premiums* (Feb. 17, 2006), http://www.mindfully.org/Health/2006/Smokers-Pay-More17feb06.htm; Join Together, S.C. State Workers Will Pay Higher Premium for Smoking (Aug. 19, 2008), http://www.jointogether.org/news/headlines/inthenews/2008/sc-smokers-to-pay-more.html (reporting that South Carolina would in 2010 join seven other states whose government workers pay more for their state health insurance if they or their spouse uses tobacco).

[200] There is some evidence to suggest that providing coverage for infertility treatment may be cost-effective: the marginal cost of full insurance coverage for IVF is lower than the marginal cost of multiple gestation pregnancies caused by IVF. *See* Jain & Hornstein, *supra* note 46, at 27–28.

resulting from risky infertility practices. But, for a number of reasons, health insurance companies are unlikely to regulate ART effectively.

First, insurance policies are rarely written to deny coverage for multiples, whether naturally-conceived or not.[201] Policies would have to be changed, which might be difficult politically. The likelihood of a multiple gestation pregnancy from ART varies from patient to patient. It is often difficult to determine whether an infertility patient was "at fault" in creating a multiple gestation pregnancy: whether there was intent on the part of the doctor and the patient to create twins or more. Unless all multiples—ART and non-ART—were not covered, which is unlikely to happen, the insurance provider would have to determine in each case whether coverage was warranted and would likely be sued whenever coverage was denied. In addition, it is often difficult to predict how many embryos will implant, particularly on the first attempt, and even then, embryos might split after implantation.[202] Even in cases where multiples could have been prevented, they often result as much from the parents' desire to have a child as they do from the doctor's desire to give the couple a baby and to maintain a high success rate. Many doctors inform their patients that implanting more embryos will increase their odds of conception as well as the odds that they will conceive multiple babies at once but do not sufficiently advise their patients about the costs and risks of multiple gestation pregnancies.[203] This is often unintentional: pregnancy rates are quantifiable and memorable, but risks of multiple gestation pregnancies are more difficult to personalize and convey in an easy-to-grasp fashion.[204]

Second, insurers are reluctant to provide coverage for infertility treatment because there is a "notion that infertility is a self-imposed . . . infliction that doesn't deserve coverage."[205]

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[201] Note that some insurance policies pay only a limited amount per delivery. *See, e.g.*, CINDY MARGOLIS, HAVING A BABY . . . WHEN THE OLD-FASHIONED WAY IS NOT WORKING 90 (2008) ("If, once you get pregnant, your pregnancy is determined high risk, for instance, your insurance may deny coverage altogether for the costs associated with that, such as a long prebirth hospital stay.").

[202] Some embryos split into two after IVF transfer, and hence even single-embryo transfers have a 2% rate of twins. *See* CDC, 2005 ART REPORT, *supra* note 6, at 45 fig.33.

[203] *See* Alper, *supra* note 149, at 514 ("A blurb in a consent form about the risks of multiple gestations does not replace an open discussion on the topic. . . . Patients tend to listen to us on the basis of how we deliver the message. We can say, 'Twins have a fourfold increase in morbidity,' or we can say, 'You have a higher risk of having a disabled child requiring long-term care.' Which has more impact?").

[204] *See id.*

[205] MUNDY, *supra* note 61, at 222. Infertility often results from sexually transmitted diseases ("STDs"). CDC, Infertility & STDs, http://www.cdc.gov/std/infertility/default.htm#fact/ (last visited Apr. 16, 2009). Because contracting an STD requires sexual contact, often the implication is made that the woman had to have been promiscuous and that her infertility is due "punishment." *Cf.* SPAR, *supra* note 186, at 8 ("[T]he existence of childless prostitutes suggested that sex itself could lead to infertility . . . ."). According to a World Health Organization study, as many as 38% of infertility cases were caused by

Third, fertility doctors are not lobbying for more insurance coverage, and some openly admit that they do not want health insurance to cover infertility treatment.[206] Fertility doctors are not inclined to want this coverage, because insurance companies can exert considerably more negotiating leverage over fertility clinics than can individual consumers of infertility services.[207] When insurance covers a procedure, the price that doctors can bill for the procedure usually dramatically drops.[208]

Fourth, there has been very little research in the United States comparing the costs of full coverage for infertility treatment with the costs of care for multiples born as a result of infertility treatment. Because the cost of infertility treatment is real and significant—an average IVF cycle cost $12,400 in 2003,[209] and, on average, only 27.8% of all cycles produce a live baby[210]—and the cost savings from a reduced rate of multiple gestation pregnancies are uncertain and difficult to estimate, insurers are often unwilling to provide coverage. Insurers are concerned about being the first to implement a policy change and to provide coverage: they worry that they will have to pay the full cost of infertility treatment and the full cost of medical care for multiple gestation pregnancies.[211]

5. *Malpractice Litigation*

Malpractice litigation is also unlikely to reduce the incidence of multiple gestation pregnancies. A number of doctrinal barriers limit malpractice law's deterrent power. First, most U.S. courts "will not entertain wrongful life suits."[212] Second, even in states that do allow wrongful life or wrongful birth claims, courts limit the damages that the parents or the child can recover.[213] Third, parental lawsuits "may be barred by their prior consent."[214]

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STDs. Shira Graber, *STD-Induced Infertility*, YourTotalHealth, http://yourtotalhealth.ivillage.com/std-induced-infertility.html/ (last visited Apr. 16, 2009).

[206] MUNDY, *supra* note 61, at 222.

[207] *Id.*

[208] *See* SPAR, *supra* note 186, at 34. In developed countries, the greatest part of the cost of infertility treatment are the salaries of trained staff. *See* O. Hovatta & I. Cooke, *Cost-Effective Approaches to In Vitro Fertilization: Means to Improve Access*, 94 INT'L J. GYNECOLOGY & OBSTETRICS 287, 288 (2006).

[209] Spar, *supra* note 4, at 15.

[210] *See* CDC, 2005 ART REPORT, *supra* note 6, at 19 fig.7.

[211] Without the ability to change physician and patient behavior, providing insurance for IVF would be a double whammy for insurers. They would be paying for both infertility treatment and for the multiples that infertility treatment produces. Unless insurers can also regulate embryo transfer policies, they may be unable to reap the financial benefits of providing coverage for infertility treatment.

[212] *See* PETERS, JR., *supra* note 32, at 216; Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 639 & n.148 (2003) (indicating that twenty-nine states deny recovery for wrongful life claims and only three states allow limited recovery (citing Kassama v. Magat, 792 A.2d 1102, 1116–17 (Md. 2002))).

[213] PETERS, JR., *supra* note 32, at 216; Noah, *supra* note 212, at 639 & n.148.

[214] PETERS, JR., *supra* note 32, at 216.

Fertility clinics often require patients to sign consent forms including a form informing them that a multiple gestation pregnancy is possible, and that multiples have significantly worse health outcomes.[215] As explained above, infertile would-be parents are often conflicted, and want to have a child almost at any cost. Hence, they frequently underestimate the risks involved, even when fully informed. Fourth, many states "preclude finding negligence if a doctor's practices are widely shared with others in the field,"[216] or even if a significant minority of respected and reputable doctors accept the practice.[217] Thus, for example, even if the clinic refuses to follow the ASRM fertility guidelines limiting the number of embryos that should be transferred in each IVF, a doctor who deviates from the guidelines might not be found negligent.[218] Finally, "most negligently injured patients do not sue."[219] Infertility patients are even less likely to sue, and to prevail, than malpractice claimants in general.[220] As a result, malpractice liability is unlikely to change the current practices in ART and reduce the incidence of multiple gestation pregnancies.

### *B. Why and How Some European Countries Have Been Able to Reduce the Number of Multiple Gestation Pregnancies*

Most European countries heavily regulate ARTs and do so by statute rather than by guidelines or self-regulation.[221] Their approaches vary significantly. Some, such as Belgium and the United Kingdom, are viewed as highly permissive, while others, such as Germany, Ireland, and Austria, as highly restrictive; still others, like Spain and France, are viewed as somewhere in the middle.[222] But, in spite of their differences, countries in Europe share important characteristics: they all regulate the ART market to a greater extent than the United States, and all but a few provide at least partial coverage for ART under their mandatory national health insurance plans.[223]

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[215] *See, e.g.*, Reprod. Care Ctr., Patient Information, IVF Consent Form, *available at* http://www.fertilitydr.com/patientForms/Consent%20Forms%20for%20IVF/1-IVF%20Consent%20Form%20RCC%20v12.pdf ("We understand that the following are risks associated with the procedures: . . . [m]ultiple gestations.").

[216] *Id.*

[217] *See, e.g.*, Jones v. Chidester, 610 A.2d 964, 969 (Pa. 1992).

[218] *See* Noah, *supra* note 212, at 640.

[219] PETERS, JR., *supra* note 32, at 216.

[220] *See* Noah, *supra* note 212, at 635. Perhaps half a dozen cases on point have been decided. *Id.* In one case where the parents prevailed (the case settled for $2.1 million), Morgan v. Christman, 1990 U.S. Dist. LEXIS 12179 (D. Kan. 1990), the physician failed to disclose that Clomid carried a risk of a multiple gestation pregnancy. *Id.* at *3–4. The parents conceived quadruplets, delivered at 27 weeks, who suffered from a number of disabilities. *Id.*

[221] *See IFFS Surveillance 07*, 87 FERTILITY & STERILITY S1, S8–S9 (Howard W. Jones, Jr., Jean Cohen, Ian Cooke & Roger Kempers eds., 2007).

[222] *See* Robertson, *supra* note 14, at 191.

[223] Of the six countries that provide full coverage under national health plans, five are in Europe: Belgium, France, Greece, Slovenia, and Sweden (the sixth is Israel). The

As is the case with regulation of ART in general, European countries disagree about the importance of preventing multiple gestation pregnancies, yet only a few have post-ART treatment rates of multiples as high as the United States.[224] One commentator suggested that there appears to be greater appreciation in Europe for the "risks and costs of multiple gestation pregnancies to the patients and the society."[225] There is a consensus among European fertility doctors that a twin pregnancy rate exceeding 25% is unacceptable, and that the goal should be to reduce the rate of twinning to below 10%.[226] In addition, unlike American clinics, not all European clinics publicly report their individual success rates. Instead, data is reported on a country level, and individualized clinic information is available only to medical experts.[227] While this practice makes it more difficult for consumers to choose the clinic with the best success rates, it also reduces the pressure on fertility doctors to increase success rates by transferring more embryos despite the cost of more multiple births. Furthermore, since health care, and ART in particular, is usually at least partially publicly financed in Europe, both the patients and the doctors are more used to government regulation and rationing of medicine.[228] Finally, unlike the United States, some European countries expressly limit patient autonomy when the best interests of the fetus are at stake.[229] As a result, in Europe, regulations that lower pregnancy success rates are more likely to be publicly accepted if they improve the health outcomes of the children than similar regulations would be in the United States.

In the field of ART, many European countries have regulated the number of embryos that can be transferred in each procedure, either by imposing

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countries that do not provide partial coverage include conservative countries, such as Switzerland and Ireland, and countries that cannot afford to cover high-tech treatment, such as Latvia, Lithuania, and Russia. *See IFFS Surveillance 07*, *supra* note 221, at S14–S16.

[224] *See* Nyboe Andersen et al., *supra* note 25, at 765 (reporting that only Hungary, Lithuania, Turkey, and the Ukraine had rates of multiples exceeding 35%).

[225] *See* Alper, *supra* note 149, at 515.

[226] *See* Sylvie Gordts et al., *Belgian Legislation and the Effect of Elective Single Embryo Transfer on IVF Outcome*, 10 REPROD. BIOMED. ONLINE 436, 440 (2005) (reporting that the European Society of Human Reproduction & Embryology ("ESHRE"), the European equivalent to ASRM and SART, issued a statement about multiple gestation pregnancies, urging countries to reduce the incidence to 10% or less).

[227] ESHRE's website, for example, publishes national data, while only members have access to data on individual clinics. ESHRE, *European IVF Monitoring Program* (2006), http://www.eshre.com/page.aspx/15/ (last visited Apr. 16, 2009).

[228] *See* COUNCIL OF EUROPE, STEERING COMMITTEE OF BIOETHICS, REPLIES BY THE MEMBER STATES TO THE QUESTIONNAIRE ON ACCESS TO MEDICALLY ASSISTED PROCREATION (MAP) AND ON RIGHT TO KNOW ABOUT THEIR ORIGIN FOR CHILDREN BORN AFTER MAP 23–31 (2005) (reporting responses by member states to questions about financial aspects of ART).

[229] For example, the Human Fertilisation and Embryology Authority ("HFEA") in the U.K. lists the best interests of the child as a paramount principle in regulating ART. *See* HUM. FERTILISATION & EMBRYOLOGY AUTHORITY, CODE OF PRACTICE § 1.2 (7th ed. 2008), *available at* http://cop.hfea.gov.uk/cop/pdf/CodeOfPracticeVR_4.pdf.

a cap on the number of embryos[230] or by refusing to fund treatments that do not comply with the policy.[231] Many countries have capped the number of embryos at three per transfer;[232] furthermore, Belgium, Sweden, the Netherlands, and Finland have shown increases in the use of single-embryo transfers ("SETs").[233]

In 1993, Swedish IVF clinics, concerned with the increasing rate of multiple births, voluntarily reduced the number of embryos that they transferred in each cycle from three to two.[234] While this practice reduced the number of triplets, it had little effect on the number of twins.[235] Following clinical studies that showed worse health outcomes for IVF children, mainly as a result of multiple gestation pregnancies, and randomized trials on SET, which showed that for patients younger than thirty-six, SET did not reduce pregnancy rates, the Swedish National Board of Health and Welfare released a guideline that all IVF treatments be SETs, except for patients with a low risk of twinning.[236] In 2004, Sweden reported that only 5.6% of all IVF births were multiples (compared with 35% in the United States).[237]

Belgium, on the other hand, chose to induce greater use of SET by offering greater insurance coverage for single-embryo IVF procedures. The law became effective in 2003.[238] It makes SET mandatory in the first IVF cycle for all women under thirty-six.[239] During the second IVF cycle, either one or two embryos can be transferred, depending on their quality. Thereafter, two embryos can be transferred without restriction.[240] For women between thirty-six and thirty-nine, two or three embryos can be transferred, and there are no restrictions on women over thirty-nine.[241] One Belgian study reports that after the introduction of the new law, 49% of all IVF cycles transferred a single embryo (compared with 14% beforehand), and the twinning rate was reduced from 19% to 3%.[242]

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[230] *See IFFS Surveillance 07, supra* note 221, at S20.

[231] In 2003, Belgium passed a law providing coverage for up to six transfers, provided that only one embryo be transferred on the first attempt. *See* Gordts et al., *supra* note 226, at 437.

[232] *See IFFS Surveillance 07, supra* note 221, at S20 (indicating, for example, Germany, Slovenia, Spain, and Switzerland).

[233] *See id.* at S19.

[234] Karlström & Bergh, *supra* note 11, at 2202.

[235] *Id.*

[236] *See* Pia Saldeen & Per Sundström, *Would Legislation Imposing Single Embryo Transfer Be a Feasible Way to Reduce the Rate of Multiple Pregnancies After IVF Treatment?*, 20 HUM. REPROD. 4, 4 (2005).

[237] *See* Nyboe Andersen, *supra* note 25, at 765.

[238] *See* Gordts et al., *supra* note 226, at 437.

[239] *Id.* at 437.

[240] *Id.*

[241] *See id.*

[242] *Id.* at 436.

## IV. Possible Regulation of ART to Prevent Multiple Gestation Pregnancies

The United States has yet to seriously consider government regulation of ART for a number of reasons. First, the issue of assisted reproduction is highly politically charged because of its entanglement with the abortion debate. Defenders of reproductive freedom want to preserve the right to make personal reproductive decisions, and fear that regulation of ART will infringe on their right to privacy.[243] Pro-life activists fear that any federal regulation of ART might give tacit approval to practices they find morally unacceptable.[244] This situation makes any attempt at federal regulation politically difficult.[245]

Second, the practice of medicine requires doctors to make complex judgment calls on a case-by-case basis.[246] Since legislators and government authorities generally lack medical expertise, the federal government is reluctant to regulate the medical profession.[247] At the same time, the United States Supreme Court has emphasized that every competent individual has a right to determine what shall be done with his own body.[248] The Court proclaimed that competent adults have both a constitutionally protected liberty interest to refuse unwanted medical treatment and a corollary right to consent to desired treatment.[249] Any legislation that limited treatment options in ART could violate the patient's protected right to consent to medical treatment as recognized in *Cruzan* (that a patient has the right to determine what will be done with his or her own body). However, the right to consent to medical treatment has not been interpreted as coextensive with the right to refuse medical treatment.[250]

Third, procreation and child rearing involve some of the most intimate aspects of human life and hence there is a strong presumption against government intrusion that can only be overcome by a compelling government interest.[251] While the Supreme Court has not recognized a constitutionally protected right to procreate, this is mainly because the government has not

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[243] President's Council on Bioethics, *supra* note 67, at 8.

[244] *Id.*

[245] *See id.*

[246] *Id.* at 9.

[247] *See id.* at 8–9.

[248] Cruzan v. Dir., Mo. Dep't Health, 497 U.S. 261, 269 (1990) (citing and endorsing Justice Cardozo's adoption of the informed consent doctrine in *Scholendorff*: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . ." Scholendorff v. Soc'y of N.Y. Hosp., 211 N.Y. 125, 129–30 (1914)).

[249] *Id.* at 269–70, *but see* notes 249–250 and accompanying text, *infra.*

[250] *See* Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695 (2007) (holding that terminally ill patients do not have a right to consent to treatment with experimental drugs). The right to refuse treatment, on the other hand, is virtually unlimited.

[251] *See* President's Council on Bioethics, *supra* note 67, at 10.

attempted to limit the ability of married couples to have children when they choose. The Court has, however, decided a number of disputes that suggest that any attempt aimed at interfering with procreative choices could be invalidated as interfering with fundamental rights.[252] In addition, U.S. law protects parenthood in particular, and considers parents "the principal protectors" of their children's well-being, including their future and potential children.[253] This presumption in favor of the parents is problematic in ART, since the interests of the parents may be inconsistent with the interests of their children.

The following sections explore the constitutional limitations on regulating ART in the United States, and what regulation might nevertheless be possible and desirable.

### *A. Constitutional Limitations of ART Regulation*

The U.S. Supreme Court has not recognized a fundamental right of access to IVF or ART more generally. The Court has, however, recognized a number of substantive due process rights from which a right to ART could be derived. In the following section, I first analyze whether there exists a fundamental right to ART and, if so, what standard of review would apply to governmental attempts to limit it. Then I analyze what limitations would probably survive a constitutional attack.

#### 1. *Fundamental Right to ART and the Standard of Review*

A number of commentators, most notably Professor John Robertson, have argued that the U.S. Constitution precludes most regulation of ART.[254] The argument is based on *Skinner v. Oklahoma*,[255] where the Supreme Court struck down a statute authorizing forcible sterilization of three-time offenders. Based on that decision and a number of other due process cases, Professor Robertson argues that any law restricting coital reproduction by a married couple would have to survive strict scrutiny review.[256] He further argues that if fertile persons possess a constitutional right to procreate, then infertile persons must also posses such a right, since the values and interests of both groups are the same.[257] Therefore, any restriction of the use of ART would have to withstand strict scrutiny. The state would have the burden of

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[252] *See* Judith F. Daar, *Regulating Reproductive Technologies: Panacea or Paper Tiger?*, 34 HOUS. L. REV. 609, 641–42 (1997).

[253] *See* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 67, at 10–11.

[254] *See* JOHN A. ROBERTSON, CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES 32 (1994).

[255] 316 U.S. 535 (1942).

[256] *See id.* at 36.

[257] *See id.* at 38.

showing a compelling state interest to restrict a specific practice.[258] Such strong justifications rarely exist; therefore, Robertson concludes that decisions about ART would virtually always be left to the individuals.[259]

Opponents of a broad right to procreative liberty argue that Robertson overstates his case and that the Supreme Court has never articulated such a restrictive standard for procreative liberty cases.[260] They point to laws on adoption, which are regulated both to protect the interests of the adoptive child and to protect the would-be adoptive parents. Similarly, ART could be regulated to protect these interests.[261]

In addition, ART could also be perceived as medical treatment and constitutionally protected as such.[262] Following this logic, the right to infertility treatment is a fundamental right that cannot be restricted absent a compelling state purpose. But not every court has found that all medical treatment is such a fundamental right. In fact, in 2007, the D.C. Circuit decided that there is no fundamental right of access to experimental drugs for the terminally ill.[263] It held that limiting access to drugs undergoing clinical trials is "consistent with our historical tradition of prohibiting the sale of unsafe drugs."[264] Similarly, it could be argued that Congress can regulate ARTs with the goal of preventing very serious side effects associated with those treatments, including multiple gestation pregnancies. If there is no right to potentially lifesaving experimental treatment, then, *a fortiori*, there is no fundamental right to ART.

Furthermore, in *Planned Parenthood v. Casey*[265] and in *Gonzales v. Carhart*,[266] the U.S. Supreme Court cut back on the standard of review, making the fundamental right to reproductive freedom somewhat less fundamen-

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[258] *See* John A. Robertson, *Procreative Liberty and the Control of Conception, Pregnancy, and Childbirth*, 69 VA. L. REV. 405, 429 (1983).

[259] *See Skinner*, 316 U.S. at 40.

[260] *See* Marsha Garrison, *Regulating Reproduction*, 76 GEO. WASH. L. REV. 1623, 1625–26 (2008).

[261] *See id.* at 1627. U.S. law does distinguish between the interests of a fetus and those of a child. While a child enjoys full constitutional protections, subject to her parents' authority, the U.S. Supreme Court has recognized only limited protections that apply to a fetus, such as those in abortion cases. At the time ART is performed, neither a fetus nor a child exists. But, decisions about ART affect the future child, and thus that potential child, like the fetus in *Gonzalez v. Carhart* or *Planned Parenthood v. Casey*, enjoys some constitutional protections, including the right to life.

[262] While no case has clearly articulated a fundamental right to some medical treatment, there is little doubt that—if challenged—the Supreme Court would find that such a right exists. This does not, however, imply that individuals have a right to a particular treatment. "[T]he right to privacy does not include the right to select a *particular* medical treatment that the government reasonably has prohibited." Mitchell v. Clayton, 1992 U.S. App. LEXIS 11400, at *4 (7th Cir. 1992) (emphasis added).

[263] *See* Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 697 (2007), *cert. denied*, Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 128 S. Ct. 1069 (2008).

[264] *Id.* at 706.

[265] 505 U.S. 833 (1992).

[266] 550 U.S. 124 (2007).

tal. It suggested that it would apply an intermediate scrutiny standard of review in procreative liberty cases and strike down regulations only when they impose an "undue burden" on the woman's ability to choose.[267] Under the intermediate scrutiny standard, the Court is free to balance the private and state interests involved.[268]

In addition, if procreative liberty provides the same level of protection for coital and noncoital reproduction, as Robertson argues, then infertile patients do not have a right to options unavailable to individuals who are able to procreate coitally, such as the ability to choose the child's gender or hair color.[269] Since fertile couples cannot choose to conceive twins or triplets, infertile couples do not have a constitutionally protected right to deliberately have multiple children at once either. However, twins and higher-order pregnancies do occur naturally, so penalizing all infertile parents who conceive multiples with the help of ART or prohibiting all techniques that carry a remote risk of resulting in a multiple gestation pregnancy would violate procreative liberty. Nevertheless, the government's interest in reducing multiple gestation pregnancies would not impose an undue burden on procreative liberty as long as it does not punish conduct (like procedures that have a small chance of leading to multiple births) the equivalent of which is permissible to fertile couples.

Finally, the Supreme Court has declared that states may limit a parent's right to direct the upbringing and education of their children "if it appears that parental decisions will jeopardize the health or safety of the child, or have a potential for significant social burdens."[270] Because multiple gestation pregnancies may harm the health of the children and impose burdens on society, regulation aimed at reducing it should be permissible.

Whether the right is construed broadly or narrowly, commentators agree that "reproductive rights, like all rights, are not absolute and can be restricted or limited for good cause."[271] What they disagree about is what counts as sufficient justification for state regulation of ART.

### 2. *Limitations of the Right to ART*

Unlike most medical procedures, where only the health of the patient is implicated, ART involves the well-being of the children born using the new technologies. The risks to the children would ordinarily not occur without

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[267] *Casey*, 505 U.S. at 874 (joint opinion of O'Connor, Kennedy, and Souter, JJ.). Intermediate scrutiny in other contexts, such as gender discrimination, has been defined somewhat differently. The government cannot discriminate on the basis of gender unless discrimination serves "important government objectives," provided that the government's act is "substantially related to achievement of those objectives." *See* Craig v. Boren, 429 U.S. 190, 197 (1976).

[268] *See* Note, *supra* note 29, at 2808.

[269] *See* Garrison, *supra* note 260, at 1627.

[270] *See* Wisconsin v. Yoder, 406 U.S. 205, 234 (1972).

[271] Robertson, *supra* note 27, at 20; *see also* Garrison, *supra* note 260, at 1627.

ART, but any argument against the use of ART techniques presents an ethical paradox. While it is true that the use of some techniques may lead to worse medical outcomes for the child, the only way to avoid the adverse effects is not to use ART; however, without ART, the child would not be born at all.[272] And being born, even with disabilities, is almost always preferable to not being born.[273] This is the famous philosophical problem that Derek Parfit calls "the non-identity problem": the person protected by laws limiting or prohibiting certain ART methods can never benefit because she is never born.[274]

Regulation to prevent multiple gestation pregnancies is less logically problematic than regulation preventing ART altogether, because there exists clear medical evidence "that some children who are born would have been better off if fewer siblings had been born."[275] "The total number of fetuses threatens the well-being of all," and by transferring fewer embryos, the welfare of those born would be enhanced without reducing the welfare of those not transferred, from a constitutional perspective, because embryos, as opposed to fetuses, do not have any constitutionally protected interests.[276]

But policies designed to prevent twins, such as SET, may reduce the chances of success in a given cycle and therefore may unduly burden the woman's procreative liberty. Any restriction will need to carefully balance the interests of a woman to conceive in a particular cycle with the interests of potential children and the costs to society. The right balance may be difficult to strike in practice. For example, for women under thirty-five with more than one embryo available for transfer, SET reduces success rates per transfer by 10%, from 52.8% to 43.3%, and the rate of a multiple gestation pregnancy from 38.6% to 1.9%.[277] Does a 95% reduction in the rate of multiple gestation pregnancies and their attendant costs justify requiring SET for younger women, despite the reduction in pregnancy rates? I would argue that it does, but it is also easy to conceive a counterargument that a 10% decrease in success rates may make it impossible for some women to have children, impermissibly burdening their procreative liberty.

If a restrictive ART policy were challenged, the Court would have to balance the private and state interests involved. On the private side, individuals have a strong interest in being free to decide whether or not to have children. In *Casey*, the Court found that this right lies at the center of "the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life."[278] Testimonials by infertile patients

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[272] Robertson, *supra* note 27, at 8.
[273] *See id.* at 14.
[274] *Id.*
[275] *Id.* at 15.
[276] *See id.*
[277] *See* CDC, 2005 ART REPORT, *supra* note 6, at 45 fig.33.
[278] Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 851 (1992).

demonstrate just how important it is for them to have biologically related children.[279]

The state, on the other hand, has a strong interest in the public health. The Court has traditionally given states great deference in regulations on public health concerns.[280] In addition, a parental decision to have a multiple gestation pregnancy creates excess costs for the American public, both through higher insurance premiums, as well as through higher spending on special programs designed for disabled children (e.g., special education).

Furthermore, the state could regulate in its role as *parens patriae* when the parents possess a conflict of interest that might impair their ability to look out for the best interests of their children.[281] Infertile would-be parents who have elected to undergo ART are "categorically conflicted," and they have usually undergone ART at considerable financial, emotional, and physical cost, in order to have a genetically related child.[282] Limited financial resources cap the number of shots at pregnancy that they can afford. As a result, they are necessarily balancing the risks to the future child and to themselves differently than would an impartial observer concerned with the child's welfare.[283] Many are, knowingly or unknowingly, willing to risk having a child with disabilities if that increases the chance of having a child. The fact that a child may not have suffered a legally cognizable injury by being born a multiple does not mean that the government cannot regulate.[284] The government regulates a wide array of harms that would not be actionable by individuals, such as workplace safety and environmental hazards.[285] Therefore, limited state regulation, combined with improved monitoring, would likely survive a constitutional attack.

### *B. Possible Regulatory Solutions to Reduce the Number of Multiple Births from ART*

As discussed above, ART poses significant risks to children that could be reduced through sensible and balanced regulation. As some commenta-

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[279] *See, e.g.*, Crozer Reprod. Endocrinology & Fertility Ctr., Testimonials, http://www.crozerfertility.com/testimonial.asp (last visited Apr. 16, 2009) ("Just at the point when we were trying to decide whether or not the only way for us to have our own child was to have a surrogate carry it for us, we decided to get a second opinion. . . . After frequent morning temperatures, painful procedures, pseudo-spontaneous calendar orchestrated sex, and even surgery we realized that IVF was the only option for having our own child. So with a blind will, we persevered.").

[280] *See, e.g.*, Jacobson v. Mass., 197 U.S. 11, 30 (1905) (upholding Massachusetts's smallpox vaccination law, noting that the state legislature "could not properly abdicate its function to guard the public health and safety").

[281] *See* Rosato, *supra* note 139, at 104.

[282] *Id.* at 105–06.

[283] *Id.*

[284] *See* Garrison, *supra* note 260.

[285] *Id.* at 1643 (noting that workplace safety would not be actionable because of the doctrine of assumption of risk, while environmental hazards, such as air pollution, would not be actionable without a personal injury).

tors have suggested, because courts will likely employ the intermediate scrutiny standard, and not strict scrutiny, judges probably will not require that regulation reduce multiple pregnancy rates without any reduction in success rates.[286] Possible regulation, to be viable, will still need to balance the interests of all involved parties and avoid regulating access to ARTs. It could include more strictly enforced embryo transfer policies, punishment of clinics with excessive multiple pregnancy rates, changed reporting under the Fertility Clinic Success Rate and Certification Act, and improved disclosure of risks and costs to infertile patients.

One potential approach is to give the existing ASRM guidelines teeth, by states or the federal government requiring fertility clinics to comply with the guidelines to obtain and maintain their license to operate. In addition, states could provide for penalties for clinics that fail to comply with the guidelines.

States that already mandate health insurance for infertility treatment could provide financial incentives to patients who choose safer treatment options (e.g., SET), or to clinics that lower multiple pregnancy rates. Guidelines should also be reviewed and amended frequently, since success rates keep improving, particularly SET success rates. Requiring clinics to use a procedure that marginally reduces success rates, but significantly reduces multiple pregnancy rates (such as SET for women below thirty-five), would probably survive a constitutional attack. A general SET policy for all first IVF attempts, however, might reduce the already low odds of women in their forties conceiving to virtually zero, and would probably fail.[287]

In hormonal treatment, it is more difficult, but not impossible, to control the number of eggs that are fertilized.[288] With careful monitoring and individualized treatment, fertility doctors can reduce overall rates of multiple gestation pregnancies.[289] Instead of controlling how many embryos can implant in each cycle, regulation could provide for penalties for clinics with rates of multiple gestation pregnancies that exceed a certain percentage (e.g. 10%).[290]

Doctors and patients should also be informed that the infertile would-be parents do not have a right to intentionally conceive multiple children, regardless of how much they may desire twins or triplets. Some doctors report

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[286] *See* discussion *supra* Section IV.A.i.

[287] *Cf.* Garrison, *supra* note 260, at 1626 ("Although a complete ban on access to reproductive technology would be constitutionally suspect, there is no obvious reason why a regulatory scheme like the U.K.'s would not pass constitutional muster under the 'undue burden' standard."). HFEA, the U.K. regulatory agency, has imposed restrictions on embryo transfers: women under forty and those using donor eggs can have no more than two embryos transferred at a time, and women over forty no more than three. HFEA Frequently Asked Questions About Treatment, Treatment Options and Risks, http://www.hfea.gov.uk/en/979.html#twins_trips/ (last visited Apr. 16, 2009).

[288] *See* Adashi et al., *supra* note 35, at 534 (listing techniques that doctors can use to reduce multiple gestation pregnancies in women not using IVF).

[289] *See* Adashi et al., *supra* note 35, at 534.

[290] *See* Rosato, *supra* note 139, at 62.

experience with patients who are eager to conceive multiples and hesitant to undergo single embryo transfers,[291] and they should be made aware of the fact that procreative liberty does not include the right to twins. The duty to inform patients about their rights and about the risks of multiple gestation pregnancies could be imposed without additional regulatory changes, perhaps as a first step before determining whether more restrictive regulation is necessary.[292]

In addition to limiting the number of embryos transferred per cycle, and penalizing clinics with excessive multiple pregnancy rates, Congress could amend the Fertility Clinic Success Rate and Certification Act to require clinics to report success rates per embryo transferred (instead of per cycle),[293] and to report the number of multiples as an adverse outcome.[294] Changed reporting and limiting the number of embryos per transfer might generate the kind of competition among clinics that will lead to improved singleton pregnancy rates, just as reporting success rates has led to improved success rates, albeit with multiple gestation pregnancies.

In order to protect patients as consumers, "regulation should also require ART programs to give patients considering treatment adequate information about the likelihood of success, the risks of the procedure to themselves and their children, and the likely cost."[295] Instead of an impersonal consent form, an in-person consultation should be recommended, where a trained professional would explain the risks of the procedure in lay terms. The delivery of the message often affects its impact more than the substance of the message. Instead of stating, for example, that "twins have a four-fold increase in morbidity," the doctor or nurse could state that "twins have a much higher risk of being disabled and requiring long-term care."[296] In addition, the consent consultation could include a description of alternatives to ART, including adoption. This is particularly important because many parents may be under-informed about the costs and benefits of adoption as an alternative.[297] Although patients undergoing infertility treatment usually desire a biological child, it is likely that adoption might be a reasonable alternative for some.[298]

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[291] *See, e.g.*, Stillman, *supra* note 53, at 858.

[292] For example, HFEA and a number of other organizations in the United Kingdom support an informational website called One at a Time. The website includes information about the risks of multiple gestation pregnancies for both patients and doctors. *See* One at a Time, http://www.oneatatime.org.uk/ (last visited Apr. 16, 2009).

[293] *See* 42 U.S.C. § 263a-1(b)(2) (2006) (defining success rates as the number of live births over the number of treatment cycles performed).

[294] *See* June Carbone, *If I Say "Yes" to Regulation Today, Will You Still Respect Me in the Morning?*, 76 GEO. WASH. L. REV. 1747, 1753 (2008).

[295] Moriarty, *supra* note 21, at 517.

[296] Alper, *supra* note 149, at 514.

[297] *See e.g.*, BARTHOLET, *supra* note 11, at 213–14.

[298] Already, some couples adopt after several failed IVF attempts. *See e.g.*, *Beyond Infertility* (FOX 11 television broadcast Nov. 9, 2007), *available at* http://www.myfoxla.com/dpp/news/Beyond_Infertility_Part_Two.

Finally, regulation could fund a comprehensive study regarding the costs of multiple pregnancies for the parents, the children, and society. The study could provide accurate (or, at the least, better) information on the additional costs generated by multiple pregnancies for the insurers, the states, and the federal government, in order to be able to better understand how best to address these costs.

## V. Conclusion

The United States, unlike most developed countries, does not regulate its fertility industry. Rather, it vests control over the industry to professional organizations and to market forces. While lack of regulation has produced a vibrant market for ART services, it has also produced an undesirable consequence: a high rate of multiple gestation pregnancies. This Article summarizes the data on the medical, psychological, and financial costs associated with multiple pregnancies to the parents, the children, and American society. It suggests that the current U.S. regulatory regime has not only failed to address these costs as they surfaced but may also have aggravated the problem. It compares the U.S. regime to approaches taken in Europe to reduce the rate of multiple gestation pregnancies and suggests that governmental intervention may be necessary. Finally, it proposes that regulation to improve reporting, disclosure, and clinic supervision, combined with more strictly enforced embryo transfer practices, would reduce the costs of multiple births without impermissibly burdening the freedom to procreate. This proposed regulation is not only desirable, but it would also likely pass constitutional muster.