

What About the Children? A Call for Regulation of Assisted Reproductive Technology

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INTRODUCTION

Sitting in rush-hour traffic, I hear a radio commercial for a local hospital. Quadruplets were born, it says, premature, after the mother was on hospitalized bed rest for several weeks. The radio commercial urges listeners to visit the hospital's Web site to "see how the story turned out." A review of the Web site reveals that the quadruplets have survived and are developing well despite their prematurity.¹ Further investigation reveals that the quadruplets were born because their mother used fertility drugs.² Prematurity is one of the adverse outcomes that users of assisted reproductive technology (ART) might expect, and not all ART stories have happy endings.³

In 1978, the first "test-tube" baby was born.⁴ This birth, the first to result from the use of in vitro fertilization (IVF), ushered in an era of new reproductive choices for infertile parents. Since that first birth, the use of assisted reproduction has grown dramatically. In 2005, fertility clinics registered with the Centers for Disease Control and Prevention (CDC)⁵ performed 134,260 ART cycles,⁶ which resulted in 38,910 live

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1. The story of the quadruplets is labeled as a story of "tiny successes" on the St. Vincent Hospital Web site. *Mystory.St.Vincent.org—Tiny Successes Quad Story*, http://www.stvincent.org/MyStory/tinysuccesses/quad_story.htm; *see also* 4tunate: Everyday Adventures with Extraordinary Boys, <http://www.murraycrew.blogspot.com> (the weblog for the quadruplets).

2. Kristine Brite, *Party of Six*, HENDRICKS COUNTY FLYER, Mar. 16, 2007, *available at* http://www.flyergroup.com/local/local_story_075163531.html.

3. For a discussion of the risks of ART and multiple births, see *infra* Part I.

4. Carol Lawson, *Celebrated Birth Aside, Teen-Ager is Typical Now*, N.Y. TIMES, Oct. 4, 1993, at A18. Louise Brown, the first test-tube baby, was created using in vitro fertilization (IVF). *Id.* This technique involves a procedure in which doctors extract a woman's eggs, fertilize them in the laboratory, and then transfer the fertilized eggs back into the uterus. CTRS. FOR DISEASE CONTROL AND PREVENTION, U.S. DEP'T OF HEALTH AND HUMAN SERVS., 2005 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS, *available at* http://www.cdc.gov/ART/ART2005/508PDF/2005ART508Cover_National.pdf [hereinafter CDC 2005 ART REPORT].

5. Currently, there is no regulation of ART. Rather, fertility clinics can voluntarily report their success rates to the CDC. The system is voluntary, and even the CDC acknowledges that only 88.8% of clinics report to it. *See* CDC 2005 ART REPORT, *supra* note 4, app. C. In addition, no statistics are reported for experimental procedures. *See* FAQs: 2005 ART Report, <http://www.cdc.gov/art/ART2005/faq.htm#8>. There are no statistics on the clinics which choose not to report, and there is no information on practices that may be performed by family doctors, such as fertility drug use. CDC 2005 ART REPORT, *supra* note 4, at 3.

6. CDC 2005 ART REPORT, *supra* note 4, at 11. According to the CDC, an ART cycle

births and 52,041 infants.⁷

ART and fertility drugs provide something remarkable: an ability to control, or at least overcome, nature. For infertile couples,⁸ the ability to have a child is now within the reach of science. However, newfound scientific power often comes with substantial ethical and practical dilemmas, as seen in the current genetic cloning and embryonic stem cell research debates.⁹ Ethical and practical dilemmas swirl around ART. As the limits on the right to procreation remain undefined, scientific advances often harm the children eventually born, and the costs to the healthcare system go unchecked. Left unregulated, ART is subject only to market forces (guided by parents desperate to have children), the empty threat of tort liability, and the voluntary but self-interested guidelines of physicians (who have profit and experimentation in mind). These forces are not sufficient to safeguard society from the significant risks associated with the use of ART.

This Note calls for federal regulation of ART and highlights the distinct groups which have a stake in the ART process. These include the children eventually born using ART, the would-be parents, and the public.¹⁰ Children who are the products of ART often suffer the consequences of risky and irresponsible practices. Meanwhile, the fertility industry booms¹¹ and infertile parents go on a single-minded quest to have biologically-related children without regard to the risks and in preference to adoption.¹² Broad disagreement over the dimensions of the procreative right prevents the often-desperate, would-be parents from receiving meaningful guidance. Further, excessive and irresponsible use of ART harms the public health.¹³ This Note proposes an approach to regulation of ART that takes these interests into account.

starts when a woman starts taking drugs to stimulate egg production or begins ovarian monitoring in anticipation of embryo transfer. The ART cycle then continues over a period of about two weeks. *See id.* at 4.

7. *Id.* at 11. These infants accounted for more than one percent of U.S. births. CDC Reproductive Health: ART Surveillance System, <http://www.cdc.gov/ReproductiveHealth/DRH/activities/ART>.

8. Infertility is defined as lack of success after trying to conceive a child for one year. This condition affects about ten percent of the population. *See* Resolve: The National Infertility Association: What is Infertility?, http://www.resolve.org/site/PageServer?pagename=lrn_wii_home. The CDC estimates that “about 12% of women of childbearing age in the United States have used an infertility service.” CDC 2005 ART REPORT, *supra* note 4, at 1.

9. *See* Dena S. Davis, *The Puzzle of IVF*, 6 HOUS. J. HEALTH L. & POL’Y 275, 292 (2006); Janet L. Dolgin, *Embryonic Discourse: Abortion, Stem Cells, and Cloning*, 31 FLA. ST. U. L. REV. 101, 103 (2003).

10. *See, e.g.*, Jennifer L. Rosato, *The Children of ART (Assisted Reproductive Technology): Should the Law Protect Them from Harm?*, 2004 UTAH L. REV. 57 (2004); Helen M. Alvare, *The Case for Regulating Collaborative Reproduction: A Children’s Rights Perspective*, 40 HARV. J. ON LEGIS. 1 (2003); Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603 (2003); Lori B. Andrews & Nanette Elster, *Regulating Reproductive Technologies*, 21 J. LEGAL MED. 35 (2000).

11. Alexander N. Hecht, Comment, *The Wild Wild West: Inadequate Regulation of Assisted Reproductive Technology*, 1 HOUS. J. HEALTH L. & POL’Y 227, 229 (2001).

12. *See* MAURA A. RYAN, *THE ETHICS AND ECONOMICS OF ASSISTED REPRODUCTION: THE COST OF LONGING* 70–74 (2001).

13. *See infra* Part IV.

In order to introduce the issues and tensions inherent in any discussion of assisted reproduction, I will first provide an overview of assisted reproduction and its risks. Parts II, III, and IV will discuss how the use of ART affects the interests of the children, the parents, and the public. Finally, in Part V, I will discuss the current regulatory scheme for ART. I argue in this Note that federal regulation may be the only appropriate solution to the ethical dilemmas presented by the use of ART. Despite widespread debate on the extent of the right to reproduce,¹⁴ the harm caused to future children by risky ART practices is entirely preventable and should be avoided. The children born from the use of ART, their parents, and the public will benefit from a regulatory scheme that takes their interests into account.

I. OVERVIEW OF ASSISTED REPRODUCTION AND ITS RISKS¹⁵

Couples suffering from infertility have a wide variety of options if they choose to utilize ART. These include artificial insemination,¹⁶ fertility drugs,¹⁷ IVF,¹⁸ intracytoplasmic sperm injection (ICSI),¹⁹ gamete intrafallopian transfer (GIFT),²⁰ zygote intrafallopian transfer (ZIFT),²¹ use of a donor egg, or often a combination of techniques.²²

14. Compare John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J. L. & MED. 439, 447 (2003) (defining procreative liberty broadly), with Carter J. Dillard, *Rethinking the Procreative Right*, 10 YALE HUM. RTS. & DEV. L.J. 1, 63 (2007) (proposing a narrower definition of procreative liberty).

15. Infertile couples have many options for expanding their families in addition to assisted reproduction. Adoption, for example, is one viable way for couples to create a family. Many couples choose this method, and federal and state laws and regulations ensure careful screening of parents. Richard F. Storrow, *The Bioethics of Prospective Parenthood: In Pursuit of the Proper Standard for Gatekeeping in Infertility Clinics*, 28 CARDOZO L. REV. 2283, 2294 (2007). However, adoption is “considered a second-best alternative for intended parents who are left with no other choices.” Rosato, *supra* note 10, at 70. By contrast, ART is not regulated. Collaborative reproduction, another option for infertile couples, involves use of third-party genetic material. The Uniform Parentage Act has attempted to provide a guideline for dealing with the legal issues surrounding this type of reproduction. See generally UNIF. PARENTAGE ACT 9B U.L.A. (2000).

16. Artificial insemination involves the use of either the partner’s sperm or donor sperm that is injected into the woman in the hopes of becoming pregnant. ROBERT G. EDWARDS & STEVEN A. BRODY, *PRINCIPLES AND PRACTICE OF ASSISTED HUMAN REPRODUCTION* 13–15 (1995).

17. With use of drugs that boost egg production, a woman increases her chances of becoming pregnant. *Id.*

18. IVF is the classic “test-tube baby” procedure, in which a woman’s eggs are extracted, fertilized in the laboratory, and then transferred back into the uterus. CDC 2005 ART REPORT, *supra* note 4, at 3.

19. ICSI is a special technique used in IVF in which a single sperm is injected directly into the egg. *Id.*

20. GIFT involves transferring unfertilized eggs and sperm into the woman’s fallopian tubes through small incisions in the abdomen. *Id.*

21. ZIFT is performed in much the same way as GIFT, but in ZIFT the woman’s eggs are fertilized in the laboratory and then transferred into her fallopian tubes. *Id.*

22. EDWARDS & BRODY, *supra* note 16, at 13–15.

According to the CDC, which employs a limited definition of ART²³ and reports statistics on only those clinics participating in a voluntary reporting scheme,²⁴ the overall success rate²⁵ for couples using ART was less than fifty percent.²⁶

Assisted reproduction is risky, both for mothers-to-be and for their unborn children. Eighteen percent of ART-induced pregnancies have an adverse outcome such as miscarriage, abortion, or stillbirth.²⁷ Risks to the fetus include prematurity and birth defects.²⁸ Birth defects are roughly twice as prevalent among children born using ART than they are among naturally conceived children.²⁹ Children born from ART are at a greater risk for preterm birth than infants in the general population.³⁰ The risks of prematurity include mortality, mental retardation, visual and hearing impairments, learning disabilities, and behavioral and emotional problems throughout life.³¹ Additional risks of prematurity include neurological disorders such as cerebral palsy.³²

Pregnancy resulting in multiple births is also a common risk associated with the use of ART. Among clinics reporting to the CDC in 2005, approximately thirty-two percent of all ART-induced births resulted in multiple infants (twins, triplets, or more),³³ compared with a multiple-infant birth rate in the general U.S. population of just over three percent.³⁴ Multi-fetal pregnancy carries with it significant risks for newborns, including low birth weight and prematurity.³⁵ Multi-fetal pregnancy can

23. The CDC definition of ART only includes procedures in which both eggs and sperm are handled. CDC 2005 ART REPORT, *supra* note 4, at 3.

24. *Id.* at app. C.

25. The CDC defines success in six different ways, but each definition measures success in terms of rates of pregnancies or live births. *See id.* at 19.

26. *See id.* at 20. The overall clinical pregnancy rate for couples receiving treatment at CDC-reporting clinics was thirty-four percent.

27. *Id.* at 21.

28. Jane R. W. Fisher, Karin Hammarberg, & Gordon Baker, *Assisted Conception Is a Risk Factor for Postnatal Mood Disturbance and Early Parenting Difficulties*, 84 FERTILITY & STERILITY 426 (2005); Noah, *supra* note 10.

29. Michele Hansen, Jennifer J. Kurinczuk, Carol Bower, & Sandra Webb, *The Risk of Major Birth Defects After Intracytoplasmic Sperm Injection and in Vitro Fertilization*, 346 NEW ENG. J. MED. 725, 729 (2002).

30. According to the CDC, preterm birth occurs when a baby is born before thirty-seven weeks of pregnancy. CDC 2005 ART REPORT, *supra* note 4, at 23.

31. *Contribution of Assisted Reproductive Technology and Ovulation-Inducing Drugs to Triple and Higher-Order Multiple Births—United States, 1980–1997*, 49 MORBIDITY & MORTALITY WKLY. REP. 535, 536 (2000) [hereinafter *CDC: Contribution to Multiple Births*].

32. B. Stromberg, G. Dahlquist, A. Ericson, O. Finnstrom, M. Koster, & K. Stjernqvist, *Neurological Sequelae in Children Born After in-Vitro Fertilisation: A Population-Based Study*, 359 LANCET 461, 464 (2002).

33. *See* CDC 2005 ART REPORT, *supra* note 4, at 22.

34. *Id.* at 22. At least one study has found that ART contributed to approximately 43.3% of the triplet and higher-order multiple births in 1997. *CDC: Contribution to Multiple Births*, *supra* note 31, at 535.

35. Siddharth Khanijou, *Multifetal Reduction in Assisted Reproductive Technologies: A License to Kill?*, 8 DEPAUL J. HEALTH CARE L. 403, 408–09 (2005); *see also, e.g.*, Nanette Elster, *Less Is More: The Risks of Multiple Births*, 74 FERTILITY & STERILITY 617, 618 (2000) (detailing the medical complications that arise from the often-premature births of multiples).

also result in too many pregnancies to be viable,³⁶ leading some practitioners and patients to elect fetal reduction as a way to preserve the health of the mother and the remaining fetuses.³⁷ Some parents refuse to undergo this procedure, with mixed results.³⁸

The use of ovulation stimulation hormones is also associated with a higher rate of multiple pregnancies and the attendant serious complications.³⁹ One observational study concluded that while physicians have made inroads into controlling multiple births resulting from the use of IVF and GIFT, rates of multiples resulting from the use of ovulation stimulation drugs have remained the same.⁴⁰ Further, all physicians can prescribe fertility drugs—there are no restrictions.⁴¹ The use of fertility drugs is thus

36. Khanijou, *supra* note 35.

37. *Id.*

38. *Dateline: After 10 Years, New Adventures for Septuplets* (NBC television broadcast Dec. 12, 2007), <http://www.msnbc.msn.com/id/22223331/> [hereinafter *Dateline: McCaughey*]. Most famously, the parents of the McCaughey septuplets refused fetal reduction on religious grounds. The septuplets, born in 1997, survived and are now ten years old. *Id.* Before the McCaugheys, however, there were the Frustaci septuplets, whose parents also refused fetal reduction. GREGORY E. PENCE, *CLASSIC CASES IN MEDICAL ETHICS: ACCOUNTS OF THE CASES AND ISSUES THAT DEFINE MEDICAL ETHICS* 113 (5th ed. 2008). One of the seven babies was stillborn and three others died shortly after birth in 1987. The remaining three children were diagnosed with cerebral palsy and mental retardation. The Frustacis sued the fertility clinic and the maker of the fertility drug that they used and received a \$2.7 million settlement. *Septuplets Heartache: The Frustaci Story*, CNN.COM, Nov. 20, 1997, <http://www.cnn.com/US/9711/20/septuplets.frustaci/index.html>.

39. See Rosato, *supra* note 10, at 60; Noah, *supra* note 10, at 628–30. For example, one fertility drug, known as Repronex®, lists the risk of multiple pregnancy as a warning on its package insert. Ferring Pharmaceuticals, Repronex® Package Insert, http://www.ferringusa.com/fertility_products/insert_repronex.htm. The multiple births resulting from the use of fertility drugs are celebrated in the popular media. Recently, the front page of the *Indianapolis Star* celebrated the homecoming of the Manley quintuplets, born after their mother took fertility drugs. Dana Knight, *Five-Fold Blessing: Large, Well-Organized Church Family Is Gearing Up to Help Indianapolis Couple Care for Tiny Infants*, INDIANAPOLIS STAR, Jan. 5, 2008, at A1; see also *Dateline: McCaughey*, *supra* note 38 (discussing the McCaughey septuplets); Khanijou, *supra* note 35, at 404 (live multiple births are often given significant positive media attention, without much attention to negative outcomes that befall many of the babies born as multiples).

40. Mark I. Evans, Linda Littmann, Lori St. Louis, Laurie LeBlanc, Jeanne Addis, Mark Paul Johnson, & Kamran S. Moghissi, *Evolving Patterns of Iatrogenic Multifetal Pregnancy Generation: Implications for Aggressiveness of Infertility Treatments*, 172 AM. J. OBSTET. & GYNECOL. 1750 (1995) (“Nevertheless, it is also abundantly clear that for a small group of physicians and centers the use of ovulation-stimulating medications is very cavalier, with reduction seen as a relatively unimportant side effect of aggressive infertility therapy.”); see also Rick Lyman, *As Octuplets Remain in Peril, Ethics Questions Are Raised*, N.Y. TIMES, Dec. 22, 1998, at A22 (Issues of high-order multiple births “only come into play in procedures involving these fertility drugs. . . . In those cases where in-vitro fertilization is used, under 10 percent of all cases, the number of eggs implanted into the mother can be controlled.”).

41. Lyman, *supra* note 40, at A22 (quoting Dr. Alan Copperman, Director of Reproductive Endocrinology at Mt. Sinai-N.Y.U. Medical Center and Health System in New York). Indeed, because of the decline in multiple births due to IVF and other procedures that can be controlled, “gonadotropin stimulation is now a major cause of multiple gestation, especially high-order

much more difficult to control than is the use of ART procedures such as IVF and GIFT.

Multiple births have psychological consequences as well. These include a negative psychological impact on the mother, as indicated by higher rates of depression, drug and alcohol abuse, and divorce among mothers of multiples.⁴² Such negative impacts on the mother naturally have an adverse impact on the children as well, and higher rates of child abuse have been found in families of multiples.⁴³

The use of ART poses serious, long-term mental and physical risks to both mothers and children. Because the risks associated with ART are so significant, the government cannot continue to leave regulation up to general market forces and simple voluntary reporting requirements. In the discussion that follows, I outline three of the interests affected by the use of ART: those of the children born from it, their parents, and the public.

II. INTERESTS OF THE UNBORN CHILDREN

Children born through the use of ART are at risk of permanent health problems.⁴⁴ For the most part, however, scholars and courts have declined to see this possibility as harm that can be remedied through tort liability.⁴⁵ At the same time, states increasingly criminalize risky behavior by pregnant women.⁴⁶ While they classify risky behavior such as illicit drug use by pregnant women as harm,⁴⁷ policy makers and courts tend to take a much less definitive stance on harm when parents and physicians make a conscious decision to engage in risky ART procedures.⁴⁸ Meanwhile, fertility clinics freely flourish in a market-driven, unregulated system.⁴⁹ Although it is tempting to believe that this freedom stems from deference to reproductive rights, the lack of regulation in the fertility industry is probably due to the political influence of fertility

multiple gestation (i.e. with triplets or more).” Siladitya Bhattacharya & Allan Templeton, *In Treating Infertility, Are Multiple Pregnancies Unavoidable?*, 343 N. ENG. J. MED. 58, 58 (2000).

42. Khanijou, *supra* note 35, at 410.

43. See Antoinette Martin, *Multiple Births: A Wake-Up Call*, N.Y. TIMES, Feb. 8, 1996, at 1 (linking multiple births to increased rates of child abuse).

44. See Hansen et al., *supra* note 29, at 725; Noah, *supra* note 10, at 622–23. See generally Rosato, *supra* note 10, for an excellent discussion of the interests of the children born using ART.

45. See, e.g., CHARLES P. KINDREGAN, JR. & MAUREEN MCBRIEN, *ASSISTED REPRODUCTIVE TECHNOLOGY: A LAWYER’S GUIDE TO EMERGING LAW AND SCIENCE* 267–74 (2006) (outlining the current legal framework of harm cases); PAUL LAURITZEN, *PURSUING PARENTHOOD: ETHICAL ISSUES IN ASSISTED REPRODUCTION* 41 (1993) (explaining the “nonidentity problem” in conceptualizing procreative harm).

46. See Jean Reith Schroedel & Pamela Fiber, *Punitive Versus Public Health Oriented Responses to Drug Use by Pregnant Women*, 1 YALE J. HEALTH POL’Y L. & ETHICS 217, 220 (2001) (reviewing attempts by different states to criminalize risky behavior by pregnant women).

47. More than two-thirds of states have passed fetal protection statutes aimed at preventing the harms caused by prenatal drug exposure. *Id.*

48. Davis, *supra* note 9, at 288; Dolgin, *supra* note 9, at 109.

49. See Hecht, *supra* note 11, at 229.

physicians and their patients.⁵⁰ Tort liability remains the only check on fertility clinics' freedom to engage in risky practices. And this threat is not a viable means of deterring risky behavior on the part of ART physicians.

A. States "Protect" Unborn Children from Risky Behavior by Expectant Mothers

Legislative attempts to punish pregnant women for risky behaviors often have poor outcomes.⁵¹ Despite evidence that the legislature might discourage drug-addicted pregnant women from seeking treatment for fear of prosecution, statutes that punish such women represent part of a growing trend of punitive responses directed at pregnant women who engage in risky behavior.⁵² For example, Wisconsin enacted a civil commitment statute that allows pregnant women to be taken into custody for exhibiting a habitual lack of self-control with alcohol and controlled substances.⁵³ The implications for pregnant women under these statutes are frightening. Because pregnancy carries numerous risks, and because many behaviors on the part of the pregnant woman can result in risks to the fetus,⁵⁴ such statutes carry with them a risk of over-policing pregnant women to ensure that they only engage in the healthiest behaviors.⁵⁵

This legislative trend stands in stark contrast to the government's laissez-faire approach toward ART, which allows practitioners and patients to engage in risky

50. See Davis, *supra* note 9, at 288.

51. See Linda C. Fentiman, *The New "Fetal Protection": The Wrong Answer to the Crisis of Inadequate Health Care for Women and Children*, 84 DENV. U. L. REV. 537, 541 (2006). In *Ferguson v. City of Charleston*, the Supreme Court upheld a state hospital's procedure of turning over drug testing results of pregnant women to law enforcement officials. 528 U.S. 1187 (2000).

52. This is indeed a growing trend, with some kind of fetal protection statute on the books in at least two-thirds of states. Schroedel & Fiber, *supra* note 46, at 220. State legislative efforts to address prenatal drug abuse can be categorized as either punitive or public health oriented. *Id.*; see also Fentiman, *supra* note 51, at 594 (first arguing that punitive treatment of pregnant women does not solve the problems related to poor prenatal healthcare and then proposing solutions); Deanna Rae Reitman, Note, *The Collision Between the Rights of Women, the Rights of the Fetus and the Rights of the State: A Critical Analysis of the Criminal Prosecution of Drug Addicted Pregnant Women*, 16 ST. JOHN'S J. LEGAL COMMENT. 267, 301-02 (2002) (suggesting that criminal sanctions against pregnant women may result not only in subordination of women but in more harm to the fetus); Shawn N. Randolph, Note, *Pregnancy and the Criminalization of Perinatal Substance Abuse: Unethical, Unconstitutional and Poor Public Policy*, 2 S. CAL. REV. L. & WOMEN'S STUD. 375, 391 (1992) (arguing that criminalization laws are ineffective public policy); Robert Holland, Note, *Criminal Sanctions for Drug Abuse During Pregnancy: The Antithesis of Fetal Health*, 8 N.Y.L. SCH. J. HUM. RTS. 415, 458 (1991) (concluding that the threat of criminal sanctions defeats the goal of fetal health).

53. WIS. STAT. § 48.193 (1999). The Wisconsin statute is undeniably broad.

54. A cursory overview of pregnancy recommendations from the expectant mother's most popular guidebook includes prohibitions on such common-sense risks as alcohol, tobacco, and drugs, as well as prohibitions on less well-known risks such as changing cat litter and eating cold deli meat and peanuts. HEIDI MURKOFF, ARLENE EISENBERG & SANDEE HATHAWAY, *WHAT TO EXPECT WHEN YOU'RE EXPECTING* 56-63, 67, 151, 189 (3d ed. 2002).

55. Heather Flynn Bell, Comment, *In Utero Endangerment and Public Health: Prosecution vs. Treatment*, 36 TULSA L.J. 649, 671-72 (2001).

techniques that carry serious consequences of harm. Indeed, Texas's Prenatal Protection Act specifically exempts from prosecution harm inflicted by fertility treatments.⁵⁶ This Note does not argue that parents who use ART should be criminally penalized. It argues that punishing pregnant women who engage in risky behaviors that are indicative of poverty while refusing even to consider regulating the use of ART is inconsistent. Rather, both groups of women (those who engage in "wealthy" risky behaviors such as ART and those who engage in "poor" risky behaviors such as drug abuse) would benefit from a comprehensive approach to women's health. In particular, regulation of ART could improve outcomes for both the prospective mothers and their future children, while public health initiatives that offer treatment, not punishment, to drug-addicted pregnant women could likewise improve the outcomes for those mothers and their future children.

B. Courts Are Reluctant to Classify ART-Related Injury as Harm for the Purposes of Tort Liability

The most common barrier to characterizing injuries caused by ART as harm for the purposes of tort liability is the "nonidentity problem."⁵⁷ Simply, some commentators view it as a logical impossibility that a person in existence would be better off if he had never been born.⁵⁸ Under this view, a child born disabled due to complications of ART was not harmed. Rather than arguing "but for the use of ART, I would be better off," a child can only say, "but for the use of ART, I would not exist."⁵⁹ Courts have had great difficulty in classifying this type of "wrongful life" as harm.⁶⁰ Further, because

56. Michelle Haynes, Note, *Inner Turmoil: Redefining the Individual and the Conflict of Rights Between Woman and Fetus Created by the Prenatal Protection Act*, 11 TEX. WESLEYAN L. REV. 131, 146 (2004).

57. LAURITZEN, *supra* note 45, at 41 (explaining the "nonidentity problem" in conceptualizing procreative harm). *But see* Søren Holm, *Wrongful Life, the Welfare Principle and the Non-Identity Problem: Some Further Considerations*, in FIRST, DO NO HARM: LAW, ETHICS AND HEALTHCARE 407, 419 (Sheila A. M. McLean ed. 2006) (arguing that the nonidentity problem ignores questions of harm in the context of wrongful birth and wrongful life claims); M.A. Roberts, *Supernumerary Pregnancy, Collective Harm, and Two Forms of the Nonidentity Problem*, 34 J. L. MED. & ETHICS 776, 776 (2006) (proposing a theory of harm that includes children born from infertility treatment-induced supernumerary pregnancy); Rosato, *supra* note 10, at 75 (suggesting that the ten percent of babies born disabled due to complications of ART should be viewed as harmed by the procedures); Philip G. Peters, Jr., *Harming Future Persons: Obligations to the Children of Reproductive Technology*, 8 S. CAL. INTERDISC. L.J. 375, 384 (1999) (supporting a definition of harm that includes taking a risky course of action when a safer one was available); Joshua Kleinfeld, Comment, *Tort Law and In Vitro Fertilization: The Need for Legal Recognition of "Procreative Injury"*, 115 YALE L.J. 237, 244 (2005) (arguing that the law should recognize a new category of tort liability for procreative injury).

58. LAURITZEN, *supra* note 45.

59. *See id.*

60. KINDREGAN & MCBRIEN, *supra* note 45, at 270. However, as Philip G. Peters, Jr. notes, "[t]he nonexistence comparison is most vulnerable to criticism whenever injuries associated with a reproductive practice could be avoided by modifying that practice in a way that results in the birth of a different (healthy) child." Philip G. Peters, Jr., *Protecting the Unconceived*:

characterizing undesirable outcomes as harm means that parents and/or physicians would be responsible for the harm, attempts to do so have been infrequent.⁶¹ Indeed, if successful, these arguments would have “significant moral and legal implications,”⁶² such as a necessary re-evaluation of the procedures used in ART. The courts should not conduct such a re-evaluation, case by case, but rather, the legislature should enact principled regulation addressing the legitimate interests of the child in the ART process.

Tort liability alone is unlikely to produce adequate self-regulation. Although some commentators and courts have called for a new category of tort liability in the assisted reproduction context,⁶³ and a small number of courts have allowed children to sue their mothers for prenatal injury,⁶⁴ it remains difficult to prove harm under traditional tort definitions in the pregnancy/labor/delivery context.⁶⁵ The unregulated nature of the ART business has left the children born from ART unprotected from harm.⁶⁶ It is fairly clear, given the legal framework and the nonidentity problem discussed above, that children born severely harmed from their parents’ decision to undergo ART have a difficult time recovering damages through the legal system.

III. INTERESTS OF THE WOULD-BE PARENTS

Parents who seek treatment for infertility naturally have an interest in the process, and often the voices of the parents (who comprise the market for fertility services) are the only voices heard. Although some scholars call for unfettered access to ART,⁶⁷ there is no basis for treating the positive right to reproduce as fundamental.⁶⁸ Indeed,

Nonexistence, Avoidability, and Reproductive Technology, 31 ARIZ. L. REV. 487, 487 (1989).

61. See KINDREGAN & MCBRIEN, *supra* note 45, at 267 (stating that the case law dealing with wrongful life claims is “slight”); Roberts, *supra* note 57, at 778 (proposing a theory of harm that includes infertility treatment-induced supernumerary pregnancy); G.M. Adam, *Assisted Human Reproduction – Legal Rights of the Unborn in Respect of Avoidable Damage*, 26 MED. & L. 325, 336 (2007) (arguing that ART should be regulated to be consistent with the aims of the United Nations Convention on the Rights of the Child).

62. Roberts, *supra* note 57, at 776.

63. Kleinfeld, *supra* note 57; see also *Karlin v. IVF Am., Inc.*, 93 N.Y.2d 282 (N.Y. 1999) (allowing a complaint for false and misleading business practices against IVF clinic when plaintiffs failed to conceive).

64. See, e.g., *Nat’l Cas. Co. v. N. Trust Bank of Fla., N.A.*, 807 So. 2d 86, 87 (Fla. Dist. Ct. App. 2001) (allowing an insurance claim against a mother in the context of a motor vehicle accident); *Grodin v. Grodin*, 301 N.W.2d 869, 871 (Mich. Ct. App. 1980) (allowing a court to consider whether a mother’s ingestion of a drug while pregnant that discolored her son’s teeth was conduct rising to the level of tort liability); *Bonte v. Bonte*, 616 A.2d 464, 466 (N.H. 1992) (recognizing a cause of action by a child against a mother for negligently crossing the street while pregnant).

65. Noah, *supra* note 10, at 634.

66. Rosato, *supra* note 10, at 59–60 (arguing that children born from ART are at risk of serious harm). “The market rules and no one in the entire contracting process speaks for the future child.” *Id.* at 62 (quoting George J. Annas, *Human Cloning: A Choice or an Echo?*, 23 U. DAYTON L. REV. 247, 262 (1998)).

67. See, e.g., Judith F. Daar, *Accessing Reproductive Technologies: Invisible Barriers, Indelible Harms*, 23 BERKELEY J. GENDER L. & JUST. 18, 23 (2008); Robertson, *supra* note 14.

68. However, the negative right (the right not to reproduce) has been protected. See *Casey v. Planned Parenthood*, 505 U.S. 833 (1992); *Roe v. Wade*, 410 U.S. 113 (1973); *Eisenstadt v.*

the use of ART can be dangerous for the would-be parents, and the children eventually born.⁶⁹ However, the extent of procreative liberty is not well-defined,⁷⁰ and there is no unified feminist perspective on the use of ART.⁷¹ Finally, couples who seek out ART may eventually divorce. When this happens, their interests often conflict.⁷² With such disagreement and debate, the would-be parents are left with little guidance as they attempt to determine how best to achieve their dreams of having children.

A. The Unclear Dimensions of Procreative Liberty

The advent of ART has allowed many infertile couples to realize the dream of having their own biological children, but it has also sparked debates about how far the right to procreative freedom reaches. Espousing the modern traditionalist view of procreative liberty, Professor Robertson has defined it as “a liberty or claim-right to decide whether or not to reproduce. As such, it has two independently justified aspects: the liberty to avoid having offspring and the liberty to have offspring.”⁷³ Others have echoed this broad view of procreative liberty.⁷⁴ Robertson and other commentators base their views on the belief that a meaningful life depends on having one’s own biological children.⁷⁵ The medical establishment respects this view: “Couples suffering from infertility are continually reminded of their situation Simple tasks which we take for granted become painful—almost every shop is stocked with goods for the baby or young family; . . . the infertile couple is excluded from this ritual.”⁷⁶ As a legal matter, courts and legislators have yet to determine the reach of the procreative right. The Supreme Court has not considered a case in which the right to procreate via assisted reproduction was at issue. Court doctrine extending the substantive due process right of liberty to the reproductive context has thus far only addressed the right not to procreate⁷⁷ or the right to procreate in the face of prohibitive laws.⁷⁸ Legal commentators disagree as to whether the Supreme Court would ever include a right to procreate under its substantive due process doctrine.⁷⁹

Baird, 405 U.S. 438 (1972); *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992).

69. See *supra* Part I for a discussion of the risks associated with ART.

70. Compare Robertson, *supra* note 14, with Dillard, *supra* note 14.

71. Richard F. Storrow, *Quests for Conception: Fertility Tourists, Globalization and Feminist Legal Theory*, 57 HASTINGS L.J. 295, 308 (2005).

72. See *infra* Part III.C.

73. Robertson, *supra* note 14, at 447.

74. Daar, *supra* note 67, at 23 (advocating a view of procreation as a “basic human right”); Andrews & Elster, *supra* note 10, at 45 (stating that the “right to make reproductive decisions includes the right of an infertile couple to utilize medically assisted reproduction . . .”).

75. Robertson, *supra* note 14.

76. T. Appleton, *An Ethical Approach to Counselling*, in A TEXTBOOK OF ASSISTED REPRODUCTION AND IN VITRO FERTILIZATION 417, 417 (Peter R. Brinsden & Paul A. Rainsbury eds., 1992).

77. See *Casey v. Planned Parenthood*, 505 U.S. 833 (1992); *Roe v. Wade*, 410 U.S. 113 (1973); *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Griswold v. Connecticut*, 381 U.S. 479 (1965).

78. *Skinner v. Oklahoma*, 316 U.S. 535 (1942).

79. See Dillard, *supra* note 14, at 18–19 (arguing that the privacy/autonomy line of Supreme Court substantive due process precedent could not be used to justify a broad right to

Technology will continue to provide new and astounding ways for humans to reproduce. Advances in reproductive technology provide wonderful opportunities for prospective parents, but carry significant risks both to the mother and to the unborn child.⁸⁰ The procreative right, therefore, has costs. These risks and costs point to the need for some regulatory limits to ensure that science does not needlessly harm the children born through ART or burden the public health system.

B. The Fractured Feminist Perspective

The feminist perspective is fractured over the boundaries of the procreative right.⁸¹ Some feminists champion advances in reproductive technology because they provide additional choices to women seeking to become pregnant,⁸² while other feminists view the entire process of assisted reproduction as a means of placing additional reproductive burdens on women.⁸³ Additionally, because regulations on assisted reproduction vary widely around the world, the booming “fertility tourism” industry has the potential to harm women as their bodies become commodities in the fertility trade.⁸⁴ And finally, other women’s rights commentators are concerned with the advances in reproductive technology that allow for sex selection and sex-selective abortion.⁸⁵ The fractured nature of the feminist perspective on ART clouds debate over potential regulation.

C. Conflicting Parental Interests

The most common legal treatment of ART concerns divorce disputes over frozen embryos.⁸⁶ When a couple has used IVF, successfully or unsuccessfully, they often

procreate because that right must be balanced against the rights of the unborn children); Rosato, *supra* note 10, at 97–98 (arguing that medically assisted procreation is not a constitutionally protected right). *But see* Note, *Assessing the Viability of a Substantive Due Process Right to In Vitro Fertilization*, 118 HARV. L. REV. 2792, 2813 (2005) (arguing that extending substantive due process to include a right to in vitro fertilization would be logical based on prior Supreme Court doctrine).

80. See *supra* Part I for a discussion of the risks associated with ART.

81. Storrow, *supra* note 71, at 308–09.

82. *Id.* at 309–10.

83. *Id.* at 308–09; Michele Goodwin, *Assisted Reproductive Technology and the Double Bind: The Illusory Choice of Motherhood*, 9 J. GENDER RACE & JUST. 1, 53–54 (2005) (arguing that IVF and assisted reproduction are illusory choices foisted on women who are forced to delay childbearing until later in life so that they can fit into the male-dominated workforce); Melissa E. Fraser, Note, *Gender Inequality in In Vitro Fertilization: Controlling Women’s Reproductive Autonomy*, 2 N.Y. CITY L. REV. 183, 194 (1998) (stating that IVF deepens the reproductive inequality between men and women and furthers attempts to control women’s reproductive freedom).

84. See Storrow, *supra* note 71, at 328.

85. See April L. Cherry, *Choosing Substantive Justice: A Discussion of “Choice,” “Rights” and the New Reproductive Technologies*, 11 WIS. WOMEN’S L.J. 431, 435–36 (1997).

86. KINDREGAN & MCBRIEN, *supra* note 45, at 94–100; Helene S. Shapo, *Assisted Reproduction and the Law: Disharmony on a Divisive Social Issue*, 100 NW. U. L. REV. 465, 465 (2006).

choose to keep leftover frozen embryos in storage for potential future use.⁸⁷ When such a couple divorces, the partners sometimes disagree on how those embryos should be used. Here, the courts have used different models to resolve the disputes. Most courts have used a contract model,⁸⁸ but when the contract is not clear, courts have ruled in favor of the partner opposing use of the embryos for procreation.⁸⁹ This highlights a limited vision of the procreative right: it is a right not to procreate.

ART's unregulated status has left would-be parents without guidance amid conflicting interests. The procreative right remains largely undefined, feminists cannot agree on the proper way to view assisted reproduction, and the only real legal guidance exists in the disposition of frozen embryos of divorced couples. This leaves the parents who wish to use ART with only their desires to have children and profitable fertility clinics that are more than willing to help them in their quest.⁹⁰ This state of affairs is unconscionable when babies are born severely harmed due to irresponsible practices on the part of parents and their physicians. Regulation of the most risky ART practices could prevent most of this needless pain.

IV. PUBLIC HEALTH PERSPECTIVES

The increase in premature births caused by assisted reproduction techniques is surely a public health concern.⁹¹ Discussion of the general public good involves different considerations than discussion of the parental interest or the interests of the unborn children. The costs of assisted reproduction are high, not only for treatment of the infertile parents⁹² but for treatment of the children eventually born.⁹³ These high costs, both to individuals and to society, foster bioethical perspectives that suggest limiting the procreative right.⁹⁴ In addition, infertility treatment is often only available to the wealthy due to high costs and lack of insurance coverage,⁹⁵ and fertility clinics

87. See Angela K. Upchurch, *A Postmodern Deconstruction of Frozen Embryo Disputes*, 39 CONN. L. REV. 2107, 2110–11 (2007).

88. Under a contract model, couples who divorce must abide by the terms of their embryo storage contract. See, e.g., *Kass v. Kass*, 696 N.E.2d 174 (N.Y. 1998).

89. See, e.g., *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992); *In re Witten*, 672 N.W.2d 768 (Iowa 2003).

90. See *Developments in the Law—Medical Technology and the Law*, 103 HARV. L. REV. 1519, 1541 (1990); Hecht, *supra* note 11, at 261.

91. ROBERT BLANK & JANNA MERRICK, HUMAN REPRODUCTION, EMERGING TECHNOLOGIES, AND CONFLICTING RIGHTS 213 (1995). Healthcare costs of premature infants constitute “a major financial drain” on employers who fund health insurance plans. March of Dimes, *The Cost to Business*, http://www.marchofdimes.com/prematurity/21198_15349.asp; see also Noah, *supra* note 10, at 620 (discussing the high costs of caring for infants born as a result of ART).

92. Elizabeth Heitman, *Infertility as a Public Health Problem: Why Assisted Reproductive Technologies Are Not the Answer*, 6 STAN. L. & POL’Y REV. 89, 95 (1995); Noah, *supra* note 10.

93. Noah, *supra* note 10; Heitman, *supra* note 92, at 95.

94. Dillard, *supra* note 14, at 63 (proposing a narrow definition of the procreative right that considers the public good).

95. See Elizabeth A. Pendo, *The Politics of Infertility: Recognizing Coverage Exclusions as Discrimination*, 11 CONN. INS. L.J. 293, 300–01 (2005) (making the case that coverage exclusions for fertility treatments should be seen as discriminatory). “Estimates for IVF range from \$8000 to \$10,000 per procedure, and patients often undergo multiple procedures.” *Id.* at

are not limited in the types of gate-keeping practices they can employ.⁹⁶ Such barriers to access lead to concerns of discriminatory practices by the fertility industry.

A. *The High Cost of ART*

The poor outcomes caused by ART result in expense and stress on the public health system as a whole.⁹⁷ Because the use of ART contributes significantly to multiple births,⁹⁸ and because multiples are at increased risk of preterm birth and low birth weight,⁹⁹ a discussion of the public health risks of ART must include the long-term costs of preterm birth. The March of Dimes estimates that preterm birth cost the United States at least \$26.2 billion in 2005.¹⁰⁰ In addition, because babies born prematurely often have low birth weight, they are at higher risk of death and disability.¹⁰¹ Further, multiple-gestation pregnancies “result in substantially increased hospital charges for both mothers and neonates” when compared with singleton pregnancies.¹⁰² And a substantial proportion of multiple-gestation pregnancies are the result of fertility treatments.¹⁰³ Even singleton babies conceived through the use of ART are more likely to be born with low birth weight, adding to the public health risks associated with fertility treatments.¹⁰⁴

Multiple births are associated with a host of problems for both parents and children.¹⁰⁵ These include dramatically increased healthcare costs, use of educational resources, and social services.¹⁰⁶ When lost parental productivity and the costs of

301.

96. Storrow, *supra* note 15, at 2287, 2318 (arguing that minimal gate-keeping standards should be used in fertility clinics to avoid discriminatory practices); Pendo, *supra* note 95, at 344 (making the case that coverage exclusions for fertility treatments should be seen as discriminatory).

97. “Multiples are much more prone to premature birth, a situation that can produce a whopping first-year health-care tab—more than \$1 billion for all low-birth-weight multiples, 35 percent of it borne by Medicare and Medicaid.” Antoinette Martin, *Multiple Births: A Wake-Up Call*, N.Y. TIMES, Feb. 8, 1996, at C1.

98. ART is a major cause of increasing multiple-birth rates. See *supra* Part I for a discussion of ART’s contribution to the risk of multiple births.

99. A leading cause of the recent increase in premature births is an increase in multiple births. See MARCH OF DIMES, THE GROWING PROBLEM OF PREMATURITY (2005), available at http://www.marchofdimes.com/files/Prem_Fact_Sheet_10-05_press_kit.pdf.

100. March of Dimes, The Economic Costs, http://www.marchofdimes.com/prematurity/21198_10734.asp.

101. Nigel S. Paneth, *The Problem of Low Birth Weight*, THE FUTURE OF CHILDREN, Spring 1995, at 19, 19.

102. Tamara L. Callahan, Janet E. Hall, Susan L. Ettner, Cindy L. Christiansen, Michael F. Greene, & William F. Crowley, *The Economic Impact of Multiple-Gestation Pregnancies and the Contribution of Assisted-Reproduction Techniques to Their Incidence*, 331 NEW ENG. J. MED. 244 (1994), available at <http://content.nejm.org/cgi/content/full/331/4/244>.

103. *Id.*

104. See Georgina M. Chambers, Michael G. Chapman, Narelle Grayson, Marian Shanahan, & Elizabeth A. Sullivan, *Babies Born After ART Treatment Cost More Than Non-ART Babies: A Cost Analysis of Inpatient Birth-Admission Costs of Singleton and Multiple Gestation Pregnancies*, 22 HUMAN REPROD. 3108, 3110 (2007).

105. See *supra* Part I.

106. S. Petrou, T. Sach & L. Davidson, *The Long-Term Costs of Preterm Birth and Low*

treating lifelong disabilities are taken into account, the costs associated with preterm birth are astronomical.¹⁰⁷ Further, although advances in neonatal technology have drastically reduced mortality in premature infants,¹⁰⁸ such infants still face a significant risk of cognitive and neurological disorders.¹⁰⁹ Indeed, at school age, children who were born preterm have significantly lower cognitive test scores and face a significantly greater risk of suffering from attention deficit-hyperactivity disorder (ADHD).¹¹⁰ Impairment follows these children into young adulthood.¹¹¹

B. Public Health Concerns Mandate Limits on the Procreative Right

As a public health concern, ART's high costs must be considered when determining the scope of the procreative right.¹¹² A recently proposed, public-health-oriented definition of the procreative right casts it narrowly: "The right to procreate, correctly defined, is a right at least to replace oneself, and at most to procreate up to a point that optimizes the public good."¹¹³ This restrictive view of procreative liberty considers the public good and the burden that ART-related care places on the healthcare system as a whole.¹¹⁴

Parents and physicians may not consider the broader impact of their drive to "cure" infertility.¹¹⁵ Because the desire to procreate is a basic biological drive, parents who are unable to do so without assistance often become desperate, willing to try anything that provides a marginal chance of success.¹¹⁶ This desperation, combined with profit-focused fertility clinics, can have disastrous consequences. In the currently unregulated

Birth Weight: Results of a Systematic Review, 27 CHILD CARE, HEALTH & DEV. 97, 107–10 (2000).

107. One estimate puts the annual total cost of preterm birth at \$50 billion. Spencer E. Ante, *Million-Dollar Babies*, BUSINESS WEEK, June 23, 2008, at 46. A more modest estimate, calculated based on hospital and medical costs for the first five years of life, is \$26 billion per year. *Id.*

108. Although preterm infant mortality rates have declined, prematurity is still "the leading cause of neonatal mortality." Rebecca B. Russell, Nancy S. Green, Claudia A. Steiner, Susan Meikle, Jennifer L. Howse, Karalee Poschman, Todd Dias, Lisa Potetz, Michael J. Davidoff, Karla Damus & Joann R. Petrini, *Cost of Hospitalization for Preterm and Low Birth Weight Infants in the United States*, 120 PEDIATRICS e1, e2 (2007).

109. See Martin J.K. de Kleine, A. Lya den Ouden, Louis A.A. Kollée, Anneloes van Baar, Maria W.G. Nijhuis-van der Sanden, Adri Ilsen, Ronald Brand, & S. Pauline Verloove-Vanhorick, *Outcome of Perinatal Care for Very Preterm Infants at 5 Years of Age: A Comparison Between 1983 and 1993*, 21 PAEDIATRIC AND PERINATAL EPIDEMIOLOGY 26, 31 (2007).

110. Adnan T. Bhutta, Mario A. Cleves, Patrick H. Casey, Mary M. Craddock & K.J.S. Anand, *Cognitive and Behavioral Outcomes of School-Aged Children Who Were Born Preterm*, 288 J. AM. MED. ASS'N 728, 736 (2002). Prematurity is also "associated with up to one half of all pediatric neurodevelopmental disorders." Russell et al., *supra* note 108, at e2.

111. See Karolina Lindström, Birger Winbladh, Bengt Haglund & Anders Hjern, *Preterm Infants as Young Adults: A Swedish National Cohort Study*, 120 PEDIATRICS 70, 76 (2007).

112. See Heitman, *supra* note 92, at 89 (arguing that more attention to the public health perspective is warranted in the area of infertility).

113. Dillard, *supra* note 14, at 63.

114. See *id.*

115. See Rosato, *supra* note 10, at 70–71.

116. Heitman, *supra* note 92, at 95–96.

realm of fertility medicine, fertility clinics are free to employ screening measures designed to enhance profits rather than protect the welfare of their patients.

C. Currently Unregulated, Gate-keeping in Fertility Clinics Fosters Discrimination

In addition to healthcare costs, private costs to infertile parents often make the use of ART prohibitively expensive. Patients must undergo rounds of testing and usually take prescription drugs. One cycle of IVF alone can cost \$10,000,¹¹⁷ and couples may spend anywhere between \$44,000 and \$200,000 for a single pregnancy.¹¹⁸ These calculations often do not include the costs required to monitor high-risk pregnancies or to treat premature newborns.¹¹⁹ Most private insurers do not cover infertility treatments, meaning that many patients must use their own resources to pay for the expensive procedures.¹²⁰ Indeed, the high cost of fertility treatments, usually not covered by health insurance, drives some couples to engage in riskier techniques.¹²¹ This state of affairs means that ART, and especially lower-risk ART procedures, are only available to wealthy patients.¹²²

The science behind ART allows its own form of gate-keeping. ART patients may choose to use preimplantation genetic diagnosis (PGD) as one possible method to ensure that implanted embryos are free from serious genetic disorders.¹²³ In addition, some patients use controversial ART procedures to assist them in choosing the gender of their babies.¹²⁴ The science that makes ART possible also makes other even more controversial techniques a possibility, such as screening for non-serious genetic conditions or even cloning.¹²⁵ Discussion of these more controversial topics usually

117. Noah, *supra* note 10, at 616.

118. Lori B. Andrews, *Reproductive Technology Comes of Age*, 21 WHITTIER L. REV. 375, 382 (1999).

119. Heitman, *supra* note 92, at 95.

120. Pendo, *supra* note 95, at 344 (arguing that infertility treatments should be covered by medical insurance). Some, but not all, states have enacted statutes requiring private insurers to pay for infertility treatment. *Id.* at 308.

121. Amy Dockser Marcus, *Fertility Clinics Try New Way to Curb Risky Multiple Births*, WALL ST. J., January 22, 2003, available at http://online.wsj.com/article_email/article_print/SB1043179505382111184-.html (stating that some couples want an “instant family” and opt for riskier techniques to avoid the costs of repeated procedures).

122. KINDREGAN & MCBRIEN, *supra* note 45, at 263–64; Fraser, *supra* note 83, at 194–95.

123. EDWARDS & BRODY, *supra* note 16, at 521–28. See generally Rosamund Scott, Clare Williams, Kathryn Ehrich, & Bobbie Farsides, *The Appropriate Extent of Pre-Implantation Genetic Diagnosis: Health Professionals’ and Scientists’ Views on the Requirement for a “Significant Risk of a Serious Genetic Condition”*, 15 MED. L. REV. 320 (2007) (discussing PGD in general and the threshold for “serious genetic disorder”).

124. J.A. Nisker & M. Jones, *The Ethics of Sex Selection*, in ETHICAL DILEMMAS IN ASSISTED REPRODUCTION 41 (F. Shenfield & C. Sureau eds., 1997).

125. Guido de Wert & Joep P.M. Geraedts, *Preimplantation Genetic Diagnosis for Hereditary Disorders that Do Not Show a Simple Mendelian Pattern: An Ethical Exploration*, in CONTEMPORARY ETHICAL DILEMMAS IN ASSISTED REPRODUCTION 85, 95–96 (Francoise Shenfield & Claude Sureau eds., 2006); Dolgin, *supra* note 9, at 103.

emphasizes the debate over reproductive rights such as abortion, which often preempts thorough consideration of the ethical issues surrounding traditional use of ART.¹²⁶

The lessons learned from the early twentieth century eugenics movement can inform discussions of limits on the procreative right.¹²⁷ Gate-keeping in fertility clinics raises concerns about possible attempts to control the genetic features of the children created. Any such attempts could lead to discrimination.¹²⁸ Federal law does not subject fertility clinics to regulation, and the gate-keeping methods clinics used in screening potential clients vary widely.¹²⁹ While screening for adoptive parents is comprehensive and rigorous,¹³⁰ parents who use ART face poorly defined and inconsistent scrutiny.¹³¹ The most alarming aspect of the gate-keeping ability of fertility clinics is the cost of such treatments and the ability of the fertility clinics to make their own rules about whom they treat.¹³² The result is that often only wealthy parents are assured good ART outcomes.¹³³ Inconsistent gate-keeping practices affect not just parents, but the children eventually born. A revamped federal reporting and regulation scheme would bring consistency to this process.

Because so many interests intersect in this consideration, regulation of ART cannot be left to the fertility clinics (who have profit in mind)¹³⁴ or parents (who are on a single-minded quest to reproduce).¹³⁵ Rather, the federal government must provide consistent regulatory guidance to ensure that the interests of the children born using ART are not neglected.

V. REGULATION OF ASSISTED REPRODUCTION

Physicians and parents working alone cannot adequately safeguard children from the risks inherent in the use of ART, and more government involvement is mandated. Specifically, the government should provide more specific and mandatory guidelines for responsible use of IVF and associated procedures, and the FDA should more rigorously regulate the dosing and use of fertility drugs. This Part outlines the current state of ART regulation in the United States (Part V.A), then discusses and critiques some of the current scholarly proposals for regulating ART (Part V.B), and outlines some interesting regulation techniques employed in Europe (Part V.C). Finally, Part V.D provides recommendations for federal regulation of ART.

126. Dolgin, *supra* note 9, at 103; Noah, *supra* note 10, at 605.

127. Robertson, *supra* note 14, at 441.

128. Lori B. Andrews & Lisa Douglass, *Alternative Reproduction*, 65 S. CAL. L. REV. 623, 633 (1992); Storrow, *supra* note 15, at 2288–89 (arguing that clinics should use only clinical gate-keeping rather than substantive judgments about the parental fitness of the prospective parents).

129. Storrow, *supra* note 15, at 2288.

130. *Id.* at 2294.

131. *Id.* at 2288.

132. Fraser, *supra* note 83, at 194–95; Heitman, *supra* note 92, at 93–94.

133. Daar, *supra* note 67, at 37–38.

134. Hecht, *supra* note 11, at 242–43; Rosato, *supra* note 10, at 71–72.

135. Rosato, *supra* note 10, at 70–71.

A. ART Is Unregulated in the United States

In 1992, Congress passed the Fertility Clinic Success Rate and Certification Act, a law requiring the CDC to publish a yearly report on the fertility clinics that participate in a voluntary reporting system.¹³⁶ This yearly report must include success rates for these fertility clinics. However, the success rates include only statistics for assisted reproductive techniques which involve the handling of both eggs and sperm.¹³⁷ Thus, the CDC's definition of ART includes IVF,¹³⁸ ICSI,¹³⁹ GIFT,¹⁴⁰ ZIFT,¹⁴¹ and use of donor eggs or embryos.¹⁴²

Notably, the CDC's definition of ART does not include procedures that involve only sperm, such as artificial insemination,¹⁴³ or only eggs, such as the use of ovulation stimulation hormones.¹⁴⁴ As a result, the CDC report does not include success rates or statistics on these procedures.¹⁴⁵ Other sources, however, such as medical texts,¹⁴⁶ popular fertility resources,¹⁴⁷ and legal scholars,¹⁴⁸ include ovulation stimulation and artificial insemination in the definition of assisted reproduction. Despite the CDC's failure to report on the use of fertility drugs, most of the ART procedures outlined in the CDC report use these drugs to enhance their rates of success.¹⁴⁹ Family practitioners or standard obstetricians often prescribe this treatment¹⁵⁰ and are not subject to the voluntary reporting requirements that apply to ART treatments.¹⁵¹ Because the CDC's reporting system includes only a limited definition of ART,¹⁵² provides only limited statistical information,¹⁵³ and is completely

136. 42 U.S.C. § 263a-1 (2000).

137. See 42 U.S.C. § 263a-7(a) (2000), which defines ART as "all treatments or procedures which include the handling of human oocytes or embryos." See also CDC 2005 ART REPORT, *supra* note 4, at 3 ("ART includes all fertility treatments in which both eggs and sperm are handled.").

138. See CDC 2005 ART REPORT, *supra* note 4, at 3.

139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.* at 4.

143. EDWARDS & BRODY, *supra* note 16, at 13–15 (1995).

144. *Id.*

145. See CDC 2005 ART REPORT, *supra* note 4, at 3.

146. EDWARDS & BRODY, *supra* note 16 (assisted reproduction includes ovulation stimulation and artificial insemination).

147. Popular fertility treatment Web sites include artificial insemination and fertility drugs among assisted reproductive treatments. See Fertility Treatment: Your Options at a Glance, BabyCenter, http://www.babycenter.com/0_fertility-treatment-your-options-at-a-glance_1228997.bc.

148. Noah, *supra* note 10.

149. *Id.* at 608–11.

150. Because ovulation stimulation is not included in the CDC's definition of ART, there are no readily available statistics on the use of fertility drugs. However, all physicians can prescribe such treatments (there are no restrictions), indicating that use of fertility drugs is probably under-reported. Lyman, *supra* note 40.

151. CDC: Contribution to Multiple Births, *supra* note 31, at 536.

152. CDC 2005 ART REPORT, *supra* note 4, at 3.

153. *Id.*

voluntary,¹⁵⁴ it cannot be viewed as an adequate quality control mechanism for the ART industry. Further, the “success rate” statistics reported by the CDC do not accurately reflect the risks inherent in ART, such as eventual complications caused by premature and multiple births.¹⁵⁵ The medical community cannot continue to rely on voluntary participation in the CDC reporting system as a viable means of regulation, despite calls by medical ethicists for physicians to bear more responsibility for ART outcomes.¹⁵⁶

Some states have laws affecting assisted reproduction. However, these laws are not comprehensive, and “[m]ost regulation of assisted reproduction at the state level seems focused on particular methods, such as sperm donation, surrogacy, human reproductive cloning, or embryo donation.”¹⁵⁷ Even among the few states that have enacted statutes directly regulating the fertility industry, there is no law requiring that fertility clinics conduct their practices in a way to avoid harm to the future children.¹⁵⁸ ART’s “wild west” status is particularly evident when a review of a local fertility clinic Web site proclaims proudly on its banner: “Expect a Miracle!”¹⁵⁹ Despite examples of such advertising that might give false hope to infertility patients, some insist that the industry can police itself.¹⁶⁰ Nonetheless, many scholars and at least one federal government panel agree on the necessity of further federal regulation of ART.¹⁶¹

B. Governmental and Scholarly Proposals for ART Regulation Do Not Go Far Enough

The President’s Council on Bioethics issued its recommendations for ART, including continued industry self-regulation and federally funded longitudinal studies.¹⁶² Unfortunately, these recommendations do not go far enough to avoid the heartbreaking and physically devastating outcomes of unprincipled uses of ART. In

154. *Id.*

155. *See generally id.*

156. Francoise Shenfield & Claude Sureau, *The Welfare of the Child: Whose Responsibility?*, in CONTEMPORARY ETHICAL DILEMMAS IN ASSISTED REPRODUCTION 73, 81 (Francoise Shenfield & Claude Sureau eds. 2006).

157. Rosato, *supra* note 10, at 63–65 (providing an excellent review of the currently limited state regulatory regimes).

158. Noah, *supra* note 10, at 648; Hecht, *supra* note 11, at 228.

159. The Follas Center for Reproductive Medicine, www.follascenter.com.

160. PRESIDENT’S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES (2002), available at http://www.bioethics.gov/reports/reproductionandresponsibility/_pcbe_final_reproduction_and_responsibility.pdf [hereinafter REPRODUCTION AND RESPONSIBILITY].

161. *See id.* at 206 (recommending enhanced voluntary reporting and self-regulation of ART); Michael J. Malinowski, *A Law-Policy Proposal to Know Where Babies Come From During the Reproduction Revolution*, 9 J. GENDER RACE & JUST. 549, 568 (2006) (proposing a comprehensive national licensing requirement for fertility clinics); Hecht, *supra* note 11, at 256–57 (outlining recommended features of a regulatory scheme for use of ART); Victoria Clay Wright, Laura A. Schieve, Meredith A. Reynolds, Gary Jeng & Dmitry Kissin, *Assisted Reproductive Technology Surveillance—United States, 2001*, 53 MORBIDITY & MORTALITY WEEKLY REPORT SURVEILLANCE SUMMARIES 1, 18 (2004).

162. REPRODUCTION AND RESPONSIBILITY, *supra* note 160, at 215.

addition, the American Society for Reproductive Medicine, a so-called “self-regulating” group of physicians, issued guidelines for the number of embryos transferred. These guidelines, which are completely voluntary and allow for physicians and their patients to make their own determinations within or outside the guidelines, recommend limiting the number of embryos transferred.¹⁶³

There are currently two proposed model acts governing ART. The first, the Model Assisted Reproductive Technology Act, is an attempt to propose regulations (including licensing requirements for clinics) on the use of ART.¹⁶⁴ This proposed regulation does not go far enough, however, as it fails to mention limits or safeguards to prevent or limit multiple births.¹⁶⁵ The most recent proposed model act was put forth by the American Bar Association (ABA).¹⁶⁶ The ABA Model Act’s proposed regulations focus on such issues as collaborative reproduction,¹⁶⁷ informed consent,¹⁶⁸ and disposition of frozen embryos.¹⁶⁹ Because the ABA Model Act does not mention ways to limit multiple births, it does not address the issues raised by this Note. Any future regulation of assisted reproduction must take into account the grave risks and societal costs of needlessly creating multifetal pregnancies.

Finally, Professor Rosato has proposed a “double-decker” approach to regulation that would similarly fall short of the need to protect the children eventually born from ART.¹⁷⁰ Her proposal includes continued state regulation with some federal oversight.¹⁷¹ Although her call for a “bright-line” rule limiting the number of multiple births is a good one, it is unclear how continued state regulation could accomplish this goal.¹⁷² Comprehensive federal regulation, involving agencies such as the Food and Drug Administration (FDA), is needed. Her approach for limiting the number of embryos transferred to three is likewise unlikely to stem the tide of multiples born as a result of IVF.¹⁷³ The number should be limited even further for younger women who have a good chance of becoming pregnant with one embryo transferred.¹⁷⁴ Further, her proposal to limit the number of multiples born from the use of ovulation stimulation

163. The Practice Comm. of the Soc’y for Assisted Reprod. Tech. & the Practice Comm. of the Am. Soc’y for Reproductive Med., *Guidelines on Number of Embryos Transferred*, 86 FERTILITY & STERILITY S51 (2006) [hereinafter ASRM Practice Committee].

164. Sara Cotton, Sara Hill, Anna F. Hirstein, Jessica L. James, Alissa D. Klein, Elizabeth A. Klotzer, Jamie Lai, Robert A. Lawler, Debra Fischer Leege, Kristofer J. Lyons, Malinda Morain, Michelle J. Roddy, Matthew M. Rice, Rhonda Stout, Katherine Stroebel & Lisa C. Williams, *Model Assisted Reproductive Technology Act: Examining the Legal, Ethical and Medical Issues of Assisted Reproductive Technologies*, 9 J. GENDER RACE & JUST. 55 (2005).

165. *Id.*

166. ABA MODEL ACT GOVERNING ASSISTED REPROD. TECH. (2008), available at <http://www.abanet.org/family/committees/artmodelact.pdf>.

167. *Id.* arts. 8, 10.

168. *Id.* art. 2.

169. *Id.* art. 5.

170. Rosato, *supra* note 10, at 80.

171. *Id.*

172. *Id.* at 84–86.

173. *Id.* at 85.

174. See ASRM Practice Committee, *supra* note 163, at S51 (indicating that in women younger than thirty-five a single embryo can be transferred without reducing the chance of success).

hormones is too modest (requiring physicians to report triplet and higher-order multiples born and then “investigating” them).¹⁷⁵ It is possible that these drugs should be banned altogether or their use strictly limited by the FDA.¹⁷⁶ Mere reporting and investigation will not suffice.

C. European Models Can Provide Guidance for the Regulation of ART in the United States

European models demonstrate that comprehensive regulation of ART is possible.¹⁷⁷ In the United Kingdom, for example, an independent government agency (the Human Fertilisation and Embryology Authority (HFEA)) grants licenses for all types of fertility treatment and research.¹⁷⁸ The HFEA has broad discretion to set the conditions for licensing and provides guidelines for practice.¹⁷⁹ These guidelines include limits on the number of embryos that can be transferred during IVF.¹⁸⁰ Similarly, in France, the Ministry of Health grants licenses to physicians to practice reproductive medicine.¹⁸¹ Belgium has managed to simultaneously address the problem of ART-associated multiple births and lack of access to fertility treatments. In 2002 the Belgian government instituted a policy to provide national health insurance coverage for fertility treatments.¹⁸² The country proposed to cover the additional costs of covering fertility treatments by making a concerted effort to reduce multiple births, thus reducing overall healthcare costs.¹⁸³ The first prong of this strategy has been successful: multiple births as a result of IVF have been reduced.¹⁸⁴ The next prong is to reduce multiple births associated with the use of fertility drugs.¹⁸⁵

175. Rosato, *supra* note 10, at 87.

176. Noah, *supra* note 10, at 628–29.

177. Alicia Ouellette, Arthur Caplan, Kelly Carroll, James W. Fossett, Dyrleif Bjarnadottir, Darren Shickle & Glenn McGee, *Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, 31 AM. J. L. & MED. 419, 434 (2005) (detailing the problems that could be resolved by adopting a regulatory framework for ART in the United States).

178. Margaret Foster Riley & Richard A. Merrill, *Regulating Reproductive Genetics: A Review of American Bioethics Commissions and Comparison to the British Human Fertilisation and Embryology Authority*, 6 COLUM. SCI. & TECH. L. REV. 1, 2 (2004).

179. *Id.* at 53–54.

180. See Ouellette et al., *supra* note 177, at 442–43. The HFEA limits the number of embryos transferred to two for women under forty years of age and three for women over the age of forty. See HUMAN FERTILIZATION AND EMBRYOLOGY AUTH., CODE OF PRACTICE § G.8.5.1 (7th ed., 2008), available at http://cop.hfea.gov.uk/cop/pdf/CodeOfPracticeVR_4.pdf.

181. See J. McGregor & F. Dreifuss-Netter, *France and the United States: The Legal and Ethical Differences in Assisted Reproductive Technology (ART)*, 26 MED. & L. 117, 119 (2007). Notably, surrogacy is illegal in France. *Id.* at 120.

182. See William Ombet, *Access to Assisted Reproduction Services and Infertility Treatment in Belgium in the Context of the European Countries*, 9 PHARMACEUTICALS POL'Y & L. 189, 194–95 (2007).

183. See *id.*

184. See *id.* at 195–96.

185. See *id.* at 197.

D. Recommendations for Regulation of ART

Although U.S. physicians would surely oppose licensing requirements for clinical practice,¹⁸⁶ the HFEA's guidelines and the Belgian project might be instructive as a model for U.S. regulatory requirements. As a primary matter, regulation should include limits on the numbers of embryos transferred during IVF, GIFT, and ZIFT. Guidelines limiting the number of embryos transferred during these procedures should be mandatory.

Finally, a principled regulatory framework must include guidelines for fertility drug use. The risks associated with the use of fertility drugs are so serious, in fact, that at least one legal scholar has called for the FDA to restrict or withdraw its approval for their use.¹⁸⁷ Perhaps the FDA could get involved, providing adverse event reporting on multiple pregnancies and reevaluating the approval of these drugs. Notably, even the voluntary reporting framework created by the Fertility Clinic Success Rate and Certification Act of 1992 does not include any provisions for reporting on the use of fertility drugs.¹⁸⁸ Use of these drugs carries serious risks,¹⁸⁹ and any proposed regulation of assisted reproduction must consider these serious risks and attempt to promote only responsible use of these drugs. That the 1992 Act excluded use of fertility drugs from its definition of ART is unfortunate for the people who are adversely affected by their use.¹⁹⁰ One such proposal for responsible use of fertility drugs includes, at the very least, "discourage[ing] aggressive ovarian stimulation in favor of either intrauterine insemination alone or in vitro fertilization with the transfer of no more than one or two embryos at one time."¹⁹¹ In addition, conservative use of ovarian stimulating drugs lessens the risk of high-order multiple pregnancies.¹⁹²

Putting these simple safeguards into place would allow parents and physicians the freedom they need to pursue parenthood without burdening the children eventually born. Those children should not be forced to suffer the consequences of poor decision making on the part of parents and physicians.

CONCLUSION

Assisted Reproductive Technology has flourished unregulated in the United States. Despite its unregulated status, ART is hardly a routine area of medicine that impacts only the immediate patient. Rather, availability and use of ART has the potential to

186. Riley & Merrill, *supra* note 178, at 2–63.

187. See Noah, *supra* note 10, at 648.

188. See 42 U.S.C. § 263a-7(1) (2000).

189. See Noah, *supra* note 10, at 607–08.

190. See *id.* at 628–29. Indeed, the FDA's review of fertility drugs indicates an astoundingly high rate of multiple pregnancies. It is unclear why these drugs are still widely available. Cf. SHELLEY R. SLAUGHTER, FOOD AND DRUG ADMIN., HUMAN GONADOTROPINS: A REGULATORY PERSPECTIVE, http://www.fda.gov/ohrms/dockets/ac/03/briefing/3985B1_04_Backgrounder-Human%20Gonadotropins.ppt.

191. Bhattacharya & Templeton, *supra* note 41, at 60.

192. Norbert Gleicher, Denise M. Oleske, Ilan Tur-Kaspa, Andrea Vidali & Vishvanath Karande, *Reducing the Risk of High-Order Multiple Pregnancy After Ovarian Stimulation with Gonadotropins*, 343 NEW ENG. J. MED. 2, 6 (2000).

profoundly impact the lives of parents, the children born from its use, and the healthcare system as a whole. The children have not had a voice in the debate.

It should be noted that any discussion of regulation of ART also raises the specter of regulation of other reproductive rights, such as abortion.¹⁹³ However, regulation of ART need not implicate the right to abortion. In consciously choosing to undergo invasive medical procedures to overcome their natural infertility, parents who use ART and the physicians who assist them undertake a grave responsibility—the responsibility to behave ethically and to safely bring a healthy child into the world. The simple safeguards that this Note recommends would greatly reduce the likelihood of injury to the children eventually born.

There are many barriers to the regulation of ART. In particular, even scholarly treatment of the issues associated with ART is sometimes blinded by emotion.¹⁹⁴ Any regulation of ART must take into account the interests of the future children. In doing so, it must restrict the use of practices which increase the risk for multiple births while preserving reproductive freedom for the would-be parents. Regulation to promote these goals would be relatively easy to implement and would not unduly burden the procreative liberty of the parents.

193. Cf. Dolgin, *supra* note 9, at 101–03.

194. For example, Lori B. Andrews and Lisa Douglass proclaim that “[i]n developing a framework for policy in this area, we need to go beyond emotional responses.” Andrews & Douglass, *supra* note 128, at 625 (1992). Three pages later in the same article, however, they plead that “it seems unfair to demand that the infertile provide greater justification for their desire to reproduce than we require of the fertile population.” *Id.* at 628.