The Children of ART (Assisted Reproductive Technology): Can the Law Protect Them from Harm?

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Jennifer L. Rosato*

I. INTRODUCTION

Assisted reproductive technology ("ART")¹ has been in existence for twenty-five years with very little oversight or regulation.² During this time, many infertile couples, gay and lesbian couples, and single parents have benefited from these procedures, which include in vitro fertilization ("IVF")³

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⁴IVF involves combining egg and sperm in a laboratory and then implanting the resulting pre-embryo in a woman’s uterus. See ROBERT BLANK & JANNA C. MERRICK, HUMAN REPRODUCTION, EMERGING TECHNOLOGIES, AND CONFLICTING RIGHTS 87–92 (1995); GODWIN I. MENIRU, CAMBRIDGE GUIDE TO INFERTILITY MANAGEMENT AND ASSISTED REPRODUCTION 117–52 (2001). The embryo can be carried to term by the intended mother or by a gestational surrogate. BLANK & MERRICK, supra, at 87–92.
and intracytoplasmic sperm injection ("ICSI"). In the year 2001, 107,587 ART cycles were reported, which represents a sixty-six percent increase from 1996. This number is likely to increase even further as more older couples try to conceive and more clinics begin to offer ART services. Consequently, fertility is one of the fastest growing areas of medicine.

When IVF is combined with more recent technologies, the probability of giving a healthy child to an infertile couple becomes even greater. Preimplantation genetic diagnosis ("PGD"), for example, allows parents to determine whether a genetic disease is present before the pre-embryo is implanted in a woman’s uterus. Pre-embryos have been screened for

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4ICSI is a “laboratory procedure developed to help infertile couples undergoing in vitro fertilization... due to male factor infertility” and “involves the injection of a single sperm directly into the cytoplasm of a mature egg (oocyte) using a glass needle (pipette).” Am. Soc’y for Reprod. Med., Patient’s Fact Sheet: Intracytoplasmic Sperm Injection (ICSI) (Aug. 2001), at http://www.asrm.org/Patients/FactSheets/ICSI-Fact.pdf (last visited Feb. 2, 2004). While ICSI “increases the likelihood of fertilization when there are abnormalities in the number, quality, or function of the sperm[,]” it is “generally unsuccessful when used to treat fertilization failures that are primarily due to poor egg quality.” Id.; see also Abi Berger, Science Commentary: What is Involved in Intracytoplasmic Sperm Injection?, 318 BMJ 705, 705 (1999) (“Intracytoplasmic sperm injection involves injecting a single sperm into the centre of an ovum using a fine glass needle (one fourteenth the size of a human hair).”).

5CDC REPORT 2001, supra note 1, at 13 fig.1, 52; see also Mary Duenwald, After 25 Years, New Ideas in the Frenatal Test Tube, N.Y. TIMES, July 15, 2003, at F5 (noting number of ART babies has increased from 260 born in 1985 to 35,025 born in 2000).

6Births to women over thirty-five have increased steadily over the past ten years. See Joyce A. Martin et al., Births: Final Data for 2001, 51 NAT'L VITAL STAT. REP. 6–7 (Dec. 18, 2002) [hereinafter Births 2001 Reports], available at http://www.cdc.gov/nchs/data/nvst/nvstr51/nvstr51_02.pdf. For example, the number of births to women thirty-five to thirty-nine years old has risen forty-two percent since 1990, and the number of births to women forty-five to forty-nine years old has tripled since 1990. Id. at 7; see also Noah, supra note 2, at 612 n.37 (explaining that “demographers have noted a trend of deferred childbearing”).

7See CDC REPORT 2001, supra note 1, at 13 fig.1 (noting that in 2001, there were 421 clinics with 384 clinics reporting); Ctrs. for Disease Control, Use of Assisted Reproductive Technology—United States, 1996 and 1998, 51 MORBIDITY & MORTALITY WkLY. REP. 97, 97 (2002) (stating from 1996 to 1998, number of ART clinics increased from 330 to 390).

8See ANDREWS, CLONE AGE, supra note 2, at 220 (discussing increased availability of fertility treatment since late 1970s); cf. Gina Kolota, Fertility Inc.: Clinics Race to Lure Clients, N.Y. TIMES, Jan. 1, 2001, at F1 (focusing on competitiveness among fertility practices).

9In this Article, the term “pre-embryo” refers to a fertilized zygote, frozen or fresh, that has not yet been implanted in a uterus. See Patricia A. Martin & Martin L. Lagod, The Human Preembryo, the Progenitors, and the State: Toward a Dynamic Theory of Status, Rights, and Research Policy, 5 HIGH TECH. L.J. 257, 258 (1990) (noting that phase “begins with the first cell division, continuing for some fourteen days after conception, and ending as the embryo appears and major body systems begin to form”); see also Davis v. Davis, 842 S.W.2d 588, 593 (Tenn. 1992) (noting that majority of expert scientific witnesses testified that pre-embryo refers to zygote immediately after division and up until fourteen days after fertilization); cf. John A. Robertson, In the Beginning: The Legal Status of Early Embryos, 76 VA. L. REV. 437, 437 & n.2 (1990) (referring to pre-embryos as “early embryo[s]”).

10See Richard J. Tasca & Michael E. McClure, The Emerging Technology and Application of Preimplantation Genetic Diagnosis, 26 J.L. MED. & ETHICS 7, 8 (1998); Am. Soc’y for
debilitating diseases such as Tay-Sachs,\textsuperscript{11} cystic fibrosis,\textsuperscript{12} sickle-cell anemia,\textsuperscript{13} and even early onset Alzheimer's disease,\textsuperscript{14} thus preventing the implantation of pre-embryos that would develop into seriously impaired children or adults. The extensive knowledge about our genetic makeup gained through the Human Genome Project\textsuperscript{15} will permit even more screening and, hopefully, more healthy children born to loving parents.

However, this positive portrayal of ART tells only half the story. The emerging reality is that children born using these technologies—the children of

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\textsuperscript{12} Alan H. Handyside et al., \textit{Birth of a Normal Girl After In Vitro Fertilization and Preimplantation Diagnostic Testing for Cystic Fibrosis}, 327 NEW ENG. J. MED. 905, 906 (1992).
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\textsuperscript{13} Kangpu Xu et al., \textit{First Unaffected Pregnancy Using Preimplantation Genetic Diagnosis for Sickle Cell Anemia}, 281 JAMA 1701, 1705 (1999).
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\textsuperscript{14} Yury Verlinsky et al., \textit{Preimplantation Diagnosis for Early-Onset Alzheimer Disease Caused by V717L Mutation}, 287 JAMA 1018, 1018–19 (2002) (describing experience of mother who had fetus tested to ensure that her child was free of early onset Alzheimer's disease because members of mother's family had been stricken by disease and mother, herself, had tested positive for disease).
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Ethical issues are particularly vexing in this context because early onset Alzheimer's disease does not appear until adulthood and, if the mother is afflicted with the disease, she is likely to die before the child reaches adulthood. See Dena Towner & Roberta Springer Loewy, \textit{Ethics of Preimplantation Diagnosis for a Woman Destined to Develop Early-Onset Alzheimer Disease}, 287 JAMA 1038, 1039 (2002) (questioning mother's decision to have child even though she would not be able to care for child until child reached adulthood); see also Faye Flam, \textit{A Birthing Success, an Ethical Debate}, PHILA. INQUIRER, Feb. 28, 2002, at A1 (discussing ethical implications of genetic screening for early-onset Alzheimer's).

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In the future, information gained through the Human Genome Project will be used, among other things, to create more effective treatments by matching drugs to a patient's genetic makeup. See, e.g., Josh Fischman, \textit{On Target: A New Generation of Drugs Offers Customized Cures}, U.S. NEWS & WORLD REP., Jan. 20, 2003, at 51, 52 (describing benefits of customized drug treatment resulting from knowledge of human genome); Andrew Pollack, \textit{Telling the Threatening Tumors from the Harmless Ones}, N.Y. TIMES, Apr. 9, 2002, at F1 (discussing contribution of completed human genome sequence to hope that cancer will one day be categorized by its genetic makeup).
ART—are at risk of serious harm. Studies show that these children are more likely to be born at low birth weight ("LBW") or very low birth weight ("VLBW"),\textsuperscript{16} and, as a result, these children have a greater probability of being born with serious birth defects.\textsuperscript{17} There is even evidence that IVF children born within normal weight range are more likely to be born with birth defects.\textsuperscript{18}

The risk of harm is exacerbated by the high rate of multiple births among the children of ART. The use of ovulation-stimulation hormones,\textsuperscript{19} a popular method for assisting infertile couples, creates a heightened risk of high-order multiples, ranging from triplets to septuplets, because the ovaries are stimulated to release multiple eggs at the same time.\textsuperscript{20} Similarly, within IVF,

\textsuperscript{16}See infra notes 138, 151–52 and accompanying text (citing medical studies about birth defects and their potential causes). LBW is defined as less than 2500 grams, and VLBW is less than 1500 grams. See Laura A. Schieve et al., Low and Very Low Birth Weight in Infants Conceived with Use of Assisted Reproductive Technology, 346 N. ENG. J. MED. 731, 731 (2002); see also Dennis P. Andruslis et al., SUNY Downstate Med. Center, Healthy Cities, Healthy Suburbs: Progress in Meeting Healthy People Goals for the Nation’s 100 Largest Cities and Their Suburbs, at 6 (Aug. 2002), at http://www.downstate.edu [hereinafter Andruslis, Healthy Report] (citing Centers for Disease Control definition of low birth weight).

\textsuperscript{17}See infra note 142 and accompanying text (discussing possible afflictions, such as cerebral palsy and learning disabilities).

\textsuperscript{18}See infra notes 142–45 and accompanying text (providing examples of ART singletons born with defects).

\textsuperscript{19}Ovulation-stimulation hormones are prescribed to cause the woman to create an excess of eggs that can be used for ART or simply enhance the probability of pregnancy through natural means. See Noah, supra note 2, at 610–12. There are a number of pharmaceuticals that can be prescribed. Id. They vary in a number of ways, including likelihood of success and side effects. Id. See generally THE STAFF OF RESOLVE, RESOLVING INFERTILITY 101–11 (1999) [hereinafter RESOLVE] (describing various medications and hormones used in ART).

\textsuperscript{20}See Am. Soc’y for Reprod. Med., Practice Committee Report: Multiple Pregnancy Associated with Infertility Treatment 1 (Nov. 2000), at http://www.asrm.org [hereinafter ASRM, Multiple Pregnancy Report] (noting that up to sixty-nine percent of triplet gestations and up to seventy-two percent of quadruplets and greater multiples were attributed to ovulation stimulation); see also Ctrs. for Disease Control, Contribution of Assisted Reproductive Technology and Ovulation-Inducing Drugs to Triplet and Higher-Order Multiple Births—United States, 1980–1997, 49 MORBIDITY & MORTALITY WKLY. REP. 535, 536 (2000) (estimating that forty percent of triplets and other higher-order multiples born between 1996 and 1997 were attributable to ovulation-inducing drugs without ART). Obtaining reliable information regarding the incidence of multiples through ovulation stimulation is difficult because reporting of the use of these hormones is not required. Id.

The most well-known septuplets born through ovulation stimulation are those that were born to Bobbi and Kenny McCaughhey in November 1997. See Septuplets’ Mother Holds Biggest Baby, Meet Media, L.A. TIMES, Nov. 22, 1997, at A22; see also Arlene Judith Klotzko, Medical Miracle or Medical Mischief?: The Saga of the McCaughhey Septuplets, HASTINGS CTR. REP., May–June 1998, at 5, 7–8 (recounting story of septuplets’ birth and moral issues arising therefrom). For many, their birth was considered a “miracle.” See Alexander Morgan Capron, Punishing Mothers, HASTINGS CTR. REP., Jan.–Feb. 1998, at 31, 31. Since their birth, however, that romantic sentiment has given way to reality. For example, two of the septuplets have serious, permanent physical disabilities and other septuplets have been afflicted with serious health problems, including seizures and digestive difficulties requiring years of tube feeding. See Kathryn Casey, A Houseful of Happiness, LADIES HOME J., Dec. 2002, at 108–12 (reporting
the accepted practice of implanting multiple pre-embryos at one time also significantly increases the likelihood of multiple births.\textsuperscript{21} It is well established that multiples have a greater risk of serious health problems that can cause lifelong impairments.\textsuperscript{22}

The emotional and physical risks to the children of ART are likely to increase: the number of multiples is still growing,\textsuperscript{23} human reproductive cloning ("HRC") may become a reality in the future,\textsuperscript{24} and gamete donors (especially egg donors) are becoming more plentiful.\textsuperscript{25} Yet, there is no regulatory framework in place to protect future children from the methods of assisted reproduction that might harm them.

This Article identifies the weaknesses of the current system and explores the reasons why regulation has been resisted.\textsuperscript{26} Those reasons include the motivations of parents and doctors, as well as the politically charged abortion debate that affects the creation of any public policy relating to pre-embryos.\textsuperscript{27}

\textsuperscript{21}See infra notes 133–34 and accompanying text (discussing increased rate of multiple births).
\textsuperscript{22}See infra notes 133–41 and accompanying text (discussing adverse health effects associated with multiples).
\textsuperscript{23}For example, the rate of twins increased three percent in 2001, constituting the first year in which twins exceeded three percent of all births in the United States. \textit{Births 2001 Reports}, supra note 6, at 4, 20–21. The study attributes the increase in the twin rate—as well as the increase in triplets and other super-multiples—to the use of procedures such as IVF and ovulation stimulation. \textit{Id.} at 21; \textit{cf.} CDC \textit{REPORT 2001}, supra note 1, at 57 fig.45 (noting rates of multiples increased slightly from 2000 to 2001, and overall rate remained stable since 1996); Thomas H. Maugh II, \textit{Infant Deaths Rise for 1st Time Since '58}, \texti{L.A. Times}, Feb. 12, 2004, at A14 (noting that U.S. infant mortality has increased, partly as result of multiple births caused by fertility treatments).
\textsuperscript{26}See infra Section II (discussing limits of existing regulation).
\textsuperscript{27}See infra Section II.C (examining barriers to regulation).
This Article then proposes a “double-decker” approach to regulation that combines both state and federal reform.\textsuperscript{28} Regulation should begin at the state level. The overall goal would be to provide the children of ART needed protection from known harms, consistent with the existing state of scientific knowledge.\textsuperscript{29} To that end, two specific changes are warranted. First, each state should impose a moratorium on HRC for four years and, at the same time, act to safeguard the rights of any cloned children who may be born in the United States or brought here from abroad.\textsuperscript{30} Second, states should take steps to prevent the birth of multiples by limiting the number of pre-embryos that can be implanted in one IVF cycle and by sanctioning doctors that cause the birth of super-multiples through ovulation induction.\textsuperscript{31} This Article also proposes regulation at the federal level, including creation of an agency that would oversee ART. The goal of this federal policymaking body should be primarily to protect vulnerable populations from harm.\textsuperscript{32}

The final Section of the Article articulates why the “double-decker” approach is unlikely to violate parents’ constitutional rights.\textsuperscript{33}

II. THE LIMITS OF EXISTING REGULATION

\textit{The market rules and no one in the entire contracting process speaks for the future child.}\textsuperscript{34}

In the United States, reproduction proceeds virtually unregulated, as it has for the past twenty-five years.\textsuperscript{35} Federal regulation does not control ART in any meaningful way, and state intervention is limited.\textsuperscript{36} Consequently, no comprehensive scheme currently exists to ensure that ART is safe and is conducted in an ethical manner. Although there is some self-regulation of

\textsuperscript{28}See infra Section III.B (explaining “double-decker” approach to regulation of ART).
\textsuperscript{29}See infra Section III.A (discussing evidence of harm caused by ART).
\textsuperscript{30}See infra Section III.B.1.(a) (providing specific reasons that support need to protect cloned children).
\textsuperscript{31}See infra Section III.B.1.(b) (advocating, at state level, bright-line standards in regulation of multiples).
\textsuperscript{32}See infra Section III.B.2 (proposing regulation at federal level).
\textsuperscript{33}See infra Section IV (arguing parental rights are not violated because proposed regulation of ART is limited to categorical conflict, specific view of harm, and to conduct of third parties).
\textsuperscript{35}See Andrews & Elster, \textit{supra} note 2, at 44 (“The United States notably lacks an adequate structural mechanism for assessing genetic and reproductive technologies.”); Noah, \textit{supra} note 2, at 648 (noting current lack of regulation in reproductive-technology field).
\textsuperscript{36}See Andrews & Elster, \textit{supra} note 2, at 44 (noting lack of federal regulation in United States); Noah, \textit{supra} note 2, at 648 (“[S]tates have not shown any real interest in exercising greater supervision of [ART].”).
fertility practices through professional medical organizations, the system is not well-equipped to curb harmful or unethical practices.\textsuperscript{37}

This Section describes the current state of existing law and self-regulation and considers why more meaningful self-regulation is unlikely to occur in the near future. At present, it seems that ART is bound only by the ethics of the fertility specialist and the financial and emotional limits of the infertile couple.\textsuperscript{38} As a result, the interests of the children of ART have not been given careful consideration.

\textbf{A. ART Unlimited: Federal and State Law}

Federal law requires the dissemination of certain information related to ART on a yearly basis, but not much else. Under the 1992 Fertility Clinic Success Rate and Certification Act (the “Act”),\textsuperscript{39} fertility centers are required to provide information regarding their success rates, which are measured by the numbers of pregnancies and live births.\textsuperscript{40} The Centers for Disease Control (“CDC”) then reports these statistics, which are readily available to the public.\textsuperscript{41} The information serves a worthwhile consumer-oriented purpose: it allows intended parents to make knowledgeable choices about the fertility center they will use.\textsuperscript{42}

However, the Act itself does not clearly set forth what is prohibited and

\textsuperscript{37}See Noah, supra note 2, at 648 (“[P]rofessional self-regulation has failed to stem the tide of artificially-induced multiple births.”).

\textsuperscript{38}See infra Sections II.C.1 and II.C.2 (discussing decision making dynamics of parents and doctors).

\textsuperscript{39}Pub. L. No. 102-493, 106 Stat. 3146 (1992) (codified as amended at 42 U.S.C. § 263a-1 to -7 (2000)). Although the Act was enacted in 1992, it was not fully implemented until 1996, when CDC first collected complete data. See Laura A. Schieve et al., \textit{Live Birth Rates and Multiple-Birth Risk Using In Vitro Fertilization}, 282 JAMA 1832, 1833 (1999) (noting data collection of U.S. fertility clinics was initiated in 1996); cf. CDC REPORT 2001, supra note 1, at 52 (noting data was first collected in 1995, but data from clinics that were not members of Society for Assisted Reproductive Technology (“SART”) was not reported until 1996).

\textsuperscript{40}See 42 U.S.C. § 263a-1(b) (2000). ART success rates are measured six ways: by pregnancy per cycle rate, live births per cycle rate, live births per egg retrieval rate, live births per transfer rate, singleton live birth per cycle rates, and singleton live birth per transfer rates. CDC REPORT 2001, supra note 1, at 17. CDC began reporting singleton rates for the first time in 2003, because “[e]verybody agreed that was the ideal . . . .” Silvia Pagán Westphal, \textit{The BESST Way to Judge the Success of IVF Clinics}, NEW SCIENTIST, Jan. 17, 2004, at 7, 7 (quoting Joyce Zetzit).


\textsuperscript{42}See Implementation of the Fertility Clinic Success Rate and Certification Act of 1992—A Model Program for the Certification of Embryo Laboratories, 64 Fed. Reg. 39,374, 39,374 (July 21, 1999) (noting that the [Act] “was intended to provide the public with comparable information concerning the effectiveness of infertility services . . . .”).
what consequences follow if a program fails to comply. The practical consequences of this failure seem relatively minor: a program that fails to comply is published as non-reporting and cannot be a member of certain professional organizations. Yet, because such a program still can treat couples for infertility, the effect of this shaming technique is not clear.

State regulation of ART exists, but it is not comprehensive and varies considerably among the states. Most regulation of assisted reproduction at the state level seems focused on particular methods, such as sperm donation, surrogacy, HRC, or embryo donation. A few states have attempted to

47 For instance, in its 2000 report, CDC listed Genetics and IVF Institute as a non-reporting clinic, but the clinic continued to practice without governmental interference. See Nat’l Ctr. for Chronic Disease Prevention and Health Promotion, Ctrs. for Disease Control and Prevention, 2000 Assisted Reproductive Technology Success Rates: National Summary and Fertility Clinic Reports app. C, at http://www.cdc.gov/reproductivehealth/ART00/appixc_nonreport.htm (last visited Feb. 7, 2004); see also Tom Graham, Va. Clinic Is Mum on ‘Success’ Rate, Wash. Post, Dec. 4, 2001, at F6 (reporting that nationally recognized Genetics and IVF Institute failed to report as required by federal law). Genetics and IVF Institute is a state-of-the-art facility responsible for innovations in PGD, and it developed the “MicroSort” technique used for preconception gender selection. See Genetics and IVF Institute, at http://www.givf.com (last visited Mar. 4, 2004). Notably, in the 2001 report, the CDC did list the Genetics and IVF Institute as reporting, while naming thirty-seven other clinics as non-reporting. CDC Report 2001, supra note 1, at 498, app. C.
48 See, e.g., Cal. Fam. Code § 7613(a) (West 1994) (prohibiting parentage of sperm donor when recipient patient is not his wife); N.J. Stat. Ann. § 9:17-44(b) (West 2002) (declaring absent contract to contrary, semen donor is not treated as father unless recipient is his wife); N.Y. Dom. Rel. Law § 73(1) (McKinney 1999) (declaring if husband and wife provide written consent, child born to them by artificial insemination using another donor will be recognized as their child for all purposes); Ohio Rev. Code Ann. § 3111.93(A)(2)(a) (Anderson 2003) (requiring, upon request, donor’s disclosure of his blood relatives’ genetic information to recipient and husband); Or. Rev. Stat. § 109.239 (2001) (nullifying sperm donor’s parental right to child produced by artificial insemination).
(prescribing, inter alia, eligibility requirements for surrogacy including psychological and medical evaluations, mandatory terms and procedural requirements to form a binding contract, preauthorization hearing procedures, and damages for breach). In contrast to these approaches, California does not regulate surrogacy through legislation, and surrogacy contracts have not been held to violate public policy. See Johnson v. Calvert, 851 P.2d 776, 784–85 (Cal. 1993) (holding that public policy did not demand invalidation of gestational surrogacy contract because there was no financial coercion, all participants entered into contract voluntarily, and there were no demonstrably adverse social effects), cert. denied, 510 U.S. 874 (1993). See generally JANET L. DOLGIN, DEFINING THE FAMILY 76 n.16, 77 (1997) (citing various state approaches). “[T]he legislative response to surrogacy reflects the ambivalence of the society. Most state legislatures have failed to respond at all, and of those that have responded, the results are extraordinarily varied and generally fail to establish a broad regulatory system for handling surrogacy.” Id. at 77.


Although unclear in its precise contours, Virginia’s law proscribing human cloning may extend to therapeutic cloning. Virginia law defines human cloning as “the creation of or attempt to create a human being by transferring the nucleus from a human cell from whatever source into an oocyte” but fails to clarify the definition of “human being.” Va. Code Ann. §§ 32.1-162.21 to .22 (Michie 2001).

See Okla. Stat. Ann. tit. 10 § 556(A), (B), (C), (E) (West Supp. 2004) (requiring consent of donors, recipient couple, physician performing procedure, and judge with adoption jurisdiction; requiring such consent to be filed with court; designating resulting child as legal child of recipient couple; relieving donating parents of all rights and obligations to resulting child; and exempting such transfer and donation from penalties for trafficking in children).
regulate ART practices directly,\textsuperscript{52} but that approach is the exception rather than the rule. When issues arise that are not specifically addressed by existing law, more generally applicable laws have had to fill in the gaps. For example, some disputes have been resolved using the state’s family or contract law.\textsuperscript{53}

For the most part, the law has steered clear of interfering with the practices of assisted reproduction. While self-regulation has attempted to incorporate ethical principles to guide health-care providers, it has had only limited success.

\textbf{B. Self-Regulation}

Self-regulation of fertility centers, along with self-regulation of other health-care professionals who provide medical services to infertile couples, could be an effective way to limit unethical and harmful practices in the absence of positive legal restrictions. The American Society for Reproductive Medicine ("ASRM") is the primary professional organization that oversees the field of reproductive medicine,\textsuperscript{54} and the Society of Assisted Reproductive Technology ("SART"), an affiliated organization, specifically covers IVF programs, in addition to other types of ART programs.\textsuperscript{55}

According to ASRM's literature, its overall mission is to set forth standards for education, research, and practice in the field.\textsuperscript{56} Although not specifically mentioned in its mission statement, ASRM's goals include building healthy families.\textsuperscript{57} ASRM accomplishes its multifaceted mission a

\footnotesize\textsuperscript{52}See Noah, supra note 2, at 615, 615 nn.50–51 (noting that most states do not regulate fertility clinics, but few states have enacted legislation regulating fertility field). For examples of such provisions, see L.A. REV. STAT. ANN. § 9:128 (West 2000) (declaring that fertility clinics must adhere to professional standards); N.H. REV. STAT. ANN. § 168-B:13 (2001) (requiring IVF and pre-embryo transfer to be performed in accordance with "rules adopted by the department of health and human services . . ." ); 18 PA. CONS. STAT. ANN. § 3213(e) (West 2000) (requiring fertility clinics to report); VA. CODE ANN. § 54.1-2971.1 (Michie 2002) (requiring patients to sign disclosure form before undergoing certain types of infertility treatment).


\footnotesize\textsuperscript{55}See Council, March 7 Transcript, supra note 54 (statement of Dr. Carson); Soc’y for Assisted Reprod. Tech., FAQs, at http://www.sart.org/faq.html#member (last visited Feb. 20, 2004).


\footnotesize\textsuperscript{57}According to Dr. Sandra Carson, the president of ASRM, the “main concern in self-regulation is the goal of building healthy families.” Council, March 7 Transcript, supra note 54.
number of ways. It issues committee opinions, ethics committee reports, and technical and educational bulletins. According to ASRM’s president, members must comply with all ASRM and SART policies, which purportedly include the policies and standards that are issued by the committees. Standards have been issued on topics such as gamete donation, number of embryos to transfer in a cycle, and gender selection.

Compliance with these requirements is determined through an on-site validation process. These validations are conducted in conjunction with CDC to determine whether the clinic has accurately reported the data required for the yearly report to CDC, not necessarily to determine adherence to ASRM’s ethical standards. If a program is found to be noncompliant, it has one year to correct its mistake(s). After a year without remediation, the program loses its ASRM and SART memberships.

Self-regulation arguably has advantages over legal regulation in this context because it better protects patients’ privacy and autonomy and it can respond to issues in a flexible and innovative manner. The focus is “education and correction” rather than punishment. In the medical field, self-regulation facilitates development of innovative therapies for patients because there are fewer barriers to overcome.

The problem is that, in reality, the current system of self-regulation does not effectively curtail harmful and unethical ART practices. This problem is

59 See Council, March 7 Transcript, supra note 54 (statement of Dr. Carson).
63 See Council, March 7 Transcript, supra note 54 (statement of Dr. Carson).
64 See id.; Notice for the Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs, 65 Fed. Reg. 53,312-313 (Sept. 1, 2000); see also Soc’y for Assisted Reprod. Tech., FAQs, at http://www.sart.org/faq.html#validation (last visited Feb. 20, 2004) (“Validation is the process whereby, through random sampling, the veracity of the entire dataset to be published is established. This process is performed by the Validation Committee in conjunction with the CDC.”).
65 Council, March 7 Transcript, supra note 54 (statement of Dr. Carson).
66 Id.
67 See id. (“[S]elf-regulation is important in such a rapidly advancing field because it’s more adaptable in speed and innovation than government regulation.”).
68 Id.
69 See Annas, supra note 34, at 263–65; see also Noah, supra note 2, at 648 (stating self-regulation is not effective in limiting multiple births).
evidenced in several ways. First, existing enforcement mechanisms are ineffective. On-site validations of laboratories only occur every three years, which is too infrequent to assess practices in such a quickly evolving field. Further, compliance with the standards is voluntary and not every program is a member of ASRM. The penalty for noncompliance is removal from group membership, but violators are still free to offer services to willing parents. As a result, non-reporters can still build a lucrative fertility practice without any effective oversight.

Second, it is unclear how effectively ASRM can regulate standards other than those related to annual reporting. Some of the standards set forth in the committee reports are too vague to be enforceable. For example, the committee report that sets forth guidelines as to the number of embryos that should be transferred allows the individual program to define the number using its own data and variables. Further, even when the clinic does not generate its own data, it can make individual determinations as to the appropriate number. The report recommends a range from two to five embryos implanted per cycle, with the precise number depending on the likelihood that the female partner will become pregnant. The ineffectiveness of this discretionary approach is evidenced by the fact that, in 2001, nearly sixty-six percent of all ART cycles using fresh donor eggs involved the transfer of three or more embryos, and over ten percent involved five or more.

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70See Council, March 7 Transcript, supra note 54 (statement of Dr. Carson) (discussing on-site validation process).
72See supra note 47 and accompanying text (discussing one institute that continued to practice despite being listed as non-reporting).
73ASRM, Guidelines on Embryos Transferred, supra note 61.
74Id.
75Id.; see also Carson Strong, Too Many Twins, Triplets, Quadruplets, and so on: A Call for New Priorities, 31 J.L. MED. & ETHICS 272, 276 (2003) (ASRM's guidelines “are based on the idea that the worse the prognosis for pregnancy in a given case, the greater the number of preembryos it is permissible to transfer”).
76CDC REPORT 2001, supra note 1, at 34. Three or more embryos is considered a “higher-order embryo transfer” that is more likely to result in multiple births. See Meredith A. Reynolds et al., Does Insurance Coverage Decrease the Risk for Multiple Births Associated with Assisted Reproductive Technology?, 80 FERTILITY & STERILITY 16, 17 (2003).
77CDC REPORT 2001, supra note 1, at 34.
Third, and most importantly, the limited regulation in this area allows experimental procedures to be treated as clinical practice too quickly.\textsuperscript{78} This approach is more likely to put families at risk.\textsuperscript{79} One of the best examples of this “practice first, assess risk later” approach is the use of ICSI, the method by which a sperm is injected directly into the egg.\textsuperscript{80} ICSI was developed in 1992 to assist with male infertility,\textsuperscript{81} and became an acceptable clinical practice several years later.\textsuperscript{82} ICSI has been used in approximately thirty percent of all cycles\textsuperscript{83} and is regularly being used even when male infertility is not a factor.\textsuperscript{84} Yet, the safety of ICSI remains a serious question.\textsuperscript{85} ICSI has been associated with a risk of congenital abnormalities,\textsuperscript{86} chromosomal abnormalities (including inherited male infertility),\textsuperscript{87} and developmental delays.\textsuperscript{88} Research

\textsuperscript{78}See Erik Parens & Lori P. Knowles, Reprogenetics and Public Policy: Reflections and Recommendations, HASTINGS CTR. REP., July–Aug. 2003, at S1, S3, S6–7, S12 (Supp.) [hereinafter Reprogenetics Report] (noting researcher-clinician who referred to reprog enetics as “one big embryo experiment”).

\textsuperscript{79}See Anna, supra note 34, at 263–64; Noah, supra note 2, at 617–18.

\textsuperscript{80}See supra note 4 (defining ICSI).

\textsuperscript{81}See Álvaré, supra note 25, at 21.


\textsuperscript{83}See CDC REPORT 2001, supra note 1, at 38.

\textsuperscript{84}Id. at 38–39 (noting forty-two percent of ICSI cycles were performed for couples without diagnosed male factor infertility).

\textsuperscript{85}See ALASTAIR G. SUTCLIFFE, IVF CHILDREN: THE FIRST GENERATION—ASSISTED REPRODUCTION AND CHILD DEVELOPMENT 61 (2002) [hereinafter Sutcliffe, IVF Children] (“Unfortunately, because there was no animal model on which to test [ICSI] (i.e. no infertile primate similar to man), it was not possible to test the safety of this technique prior to its introduction.”); Herman J. Tournaye & André C. Van Steirteghem, Intracytoplasmic Sperm Injection: A Time Bomb?, in ASSISTED REPRODUCTIVE TECHNOLOGY: ACCOMPLISHMENTS AND NEW HORIZONS, supra note 71, at 397, 397 (“[O]ur basic understanding of both the fertilization processes after ICSI and the andrological problems that are being treated is still limited.”).


\textsuperscript{87}See ASRM, ICSI Risk Report, supra note 86; Tournaye & Van Steirteghem, supra note 85, at 401. One particular concern is that the chromosomal aberration in the father may be inherited by the son, causing the son to be infertile as well. See, e.g., Matthew G. Retzlaff & Mark D. Hornstein, Is Intracytoplasmic Sperm Injection Safe?, 80 FERTILITY & STERILITY 851, 852–54, 858 (2003) (discussing how gene-specific mutations underlying male infertility may be passed on to sons created by ICSI).

\textsuperscript{88}Compare M. Bounduelle et al., Mental Development of 201 ICSI Children at 2 Years of Age, 351 LANCET 1553, 1553 (1998) (finding “no indication that [two-year-olds conceived by ICSI] have a slower mental development than the general population”) with Jennifer R. Bowen et al., Medical and Development Outcome at 1 Year for Children Conceived by Intracytoplasmic Sperm Injection, 351 LANCET 1529, 1532 (1998) (finding seventeen percent of one-year-olds conceived by ICSI showed delayed mental performance while only three percent of one-year-
into the safety of ICSI is being conducted, but its clinical use continues unabated.

For the reasons set forth above, it does not appear that self-regulation sufficiently protects children and is unlikely to do so in the near future. The profession’s goal of “building healthy families” has not been realized. In light of this gap in protection, it is time to contemplate legal regulation of fertility practices. However, a number of barriers will hinder any meaningful regulation of these practices. The following Section concludes that these nonlegal barriers are significant but not insurmountable.

C. Barriers to Regulation

The call for regulation of ART has never been stronger. It has been suggested by a number of influential sources, including The President’s Council on Bioethics and The Hastings Center.

At the same time, ART is an area where a lack of regulation has well-served the interests of the participants themselves: the fertility doctors and the intended parents. Their ultimate goal is to achieve a “take-home” pregnancy.

olds conceived naturally or by IVF showed delayed mental performance). However, a number of studies have shown no greater abnormalities in children who are a product of ICSI. See generally Sutcliffe, IVF Children, supra note 85, at 71–81 (concluding that ICSI children are as healthy as children conceived through other methods of ART); Jennifer J. Kurinczuk, Safety Issues in Assisted Reproductive Technology: From Theory to Reality—Just What Are the Data Telling Us About ICSI Offspring Health and Future Fertility and Should We Be Concerned?, 18 Hum. Reprod. 925, 928–29 (2003) (concluding that results of recent studies are mixed); Retzloff & Hornstein, supra note 87, at 852–58 (arguing that although no major problems are currently documented, more studies and patient education are needed).


See Tournaye & Van Steirteghem, supra note 85, at 398 (“For ICSI, the clinical phase is far ahead of the research phase.”).

See supra note 57 and accompanying text (discussing ASRM’s goal of promoting healthy families).


Reprogeneics Report, supra note 78, at S18–S21.

Melissa E. Fraser, Note, Gender Inequality in In Vitro Fertilization: Controlling Women’s Reproductive Autonomy, 2 N.Y. City L. Rev. 183, 192 (1998) (using term in reference to women’s goals).
as soon as possible, and together they work single-mindedly towards that goal. It would be in their self-interests to keep this area as free of regulation as possible.

1. The Parents

From the outset, parents of ART are likely to come to the process in an emotionally weakened state because they have already tried, unsuccessfully, to have a child. The realization that they cannot have a child on their own can be devastating. Labeled as an "infertile" couple, they may perceive themselves as failures at one of the most important tasks of adulthood: creating a child. This feeling of inferiority is fueled in part by the heavy societal pressure imposed on heterosexual, married couples to create a child that is genetically related to them. Adoption exists, but it is considered a second-best alternative for intended parents who are left with no other choices.

Consumed with a desire to create a child that is biologically related to them, these intended parents aggressively pursue the most effective methods they can afford. Most intended parents pay out-of-pocket for ART; in most states, expensive fertility treatments, such as IVF, are not covered by

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95 Others may use fertility services by choice, such as single mothers or lesbian/gay couples. The focus of this Article, however, is the use of ART by married, heterosexual couples who use the services of a fertility specialist because of their inability to conceive by natural means.


97 The commonly understood clinical definition of infertility is a couple who has tried to conceive a child naturally for a year or more. See Am. Soc'y for Reprod. Med., Practice Committee Opinion: Definition of Infertility, at http://www.asrm.org/Links/Practice/opinion_infertility.html (1993) (source available to members only); see also GARY S. BERGER & MARC GOLDSTEIN, THE COUPLE'S GUIDE TO FERTILITY 51 (3d ed. 2001) (defining infertile as individuals who unsuccessfully attempt to become pregnant or fail to carry pregnancy to term); RESOLVE, supra note 19, at 5 (defining infertile as "individuals who try for more than one year to become pregnant without success and those unable to carry a pregnancy to term because of miscarriage").


100 BARTHOLET, supra note 99, at 24–25.
insurance. Each IVF cycle costs approximately $10,000, even without PGD. For less affluent couples, ART is beyond reach and infertility is a reality that they simply have to accept. Other couples deplete their savings and risk losing their homes just for the chance to have a baby of their own.

Because of these economic constraints, parents have an incentive to get pregnant as quickly as possible. In this state of mind, parents may take some unnecessary risks, such as allowing and encouraging the doctors to implant as many embryos as possible, or allowing an overstimulated follicle to release many eggs at one time. According to one source, “[i]nfertile women will often opt for any treatment option presented, regardless of the physical, psychological, or financial price.”

Yet, parents cannot act on their own. Their dreams for a child become reality through the efforts of their doctors, who are not necessarily looking out for the welfare of the children they help bring into this world.

2. The Doctors

Fertility doctors also are motivated to give couples a “take-home” pregnancy as quickly as possible, but for different reasons than the parents. The fertility field is extremely competitive and profitable, constituting a

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102 See, e.g., Jain et al., supra note 101, at 661 (reporting cost of one IVF cycle ranges from $7000 to $11,000); see also RICKI LEWIS, HUMAN GENETICS: CONCEPTS AND APPLICATIONS 432 (5th ed. 2003) (noting IVF costs from $8000 to $15,000 per cycle). PGD adds approximately $2500 to the cost of IVF. See ASRM, PGD Report, supra note 10, at 3.

103 See Liza Mundy, A Special Kind of Poverty, WASH. POST MAG., April 20, 2003, at W8.

104 See id.

105 See Reynolds et al., supra note 76, at 17 (“The assumption is that patients who pay out of pocket for ART are less willing to risk a failed procedure and are therefore more likely to elect to transfer a higher number of embryos so as to maximize their chances of a live birth.”); Anne Adams Lang, Doctors Are Second-Guessing the ‘Miracle’ of Multiple Births, N.Y. TIMES, June 13, 1999, § 15, at 4. See generally Howard W. Jones, Jr. & John A. Schnorr, Multiple Pregnancies: A Call for Action, 75 FERTILITY & STERILITY 11, 12 (2001) (discussing rapid increase in multiple pregnancy coupled with patients’ intense desire to become pregnant).

106 Waldman, supra note 96, at 923; see also Rebecca Skloot, Sally Has 2 Mommies + 1 Daddy, and Other Side Effects of Experimentation on Unborn Children in the Underregulated World of High-Tech Fertility Treatments, POPULAR SCIENCE, March 2003, at 72, 103 (quoting one ART father as saying: “Is there a possibility of long-term effects? Yeah, there is. And that worries us. But even if we’d found the kids would be at higher risk, we would have still done it all.”).
multibillion-dollar industry.\(^{107}\) The profitability of a particular practice depends on its success, which in turn is measured by the number of pregnancies and live births.\(^{108}\) The more successful a practice, the more patients who will come for treatment and the more profitable the practice will become. Given this business structure, there is intense pressure on doctors to maximize their success rates.\(^{109}\) It is not surprising then that the fertility field is considered by many to be the “Wild West” of medicine, with fertility doctors as its cowboys.\(^{110}\)

Doctors, however, are not just concerned about their bottom line. They are also deeply concerned about their patients. Some of these patients ask their doctors to take risks to help them have a baby quickly by, for example, implanting too many pre-embryos at one time.\(^{111}\) Doctors feel the obligation, supported by the ethic of patient autonomy,\(^{112}\) to accede to the strong desires of their patients.\(^{113}\)

As scientists, doctors want to be able to use the most advanced technology available to achieve their medical objectives. Yet, because federally funded experimentation on embryos is not permitted,\(^{114}\) any risks of new methods must be borne by the infertile couples and their future children. For example, cytoplasmic transfer\(^{115}\) was developed at fertility clinics without the benefit of clinical trials or other governmental oversight.\(^{116}\) Cytoplasmic transfer involves injecting cytoplasm from a donor into the genetic mother’s egg.\(^{117}\) This method

\(^{107}\)See ANDREWS, CLONE AGE, supra note 2, at 220 (stating that ART industry generates annual revenue of $2 billion).

\(^{108}\)See supra notes 39–42 and accompanying text (detailing CDC success rates).

\(^{109}\)See, e.g., Jones & Schnorr, supra note 105, at 12 (discussing incentive to achieve high pregnancy rate); Noah, supra note 2, at 626 n.97 (describing pressure to maximize success).


\(^{111}\)See Alison Murdoch, Triplets and Embryo Transfer Policy, 12 HUM. REPROD. 88, 92 (1997).

\(^{112}\)Frank A. Chervenak et al., Ethical Dimensions of the Number of Embryos to be Transferred in In Vitro Fertilization, 18 J. ASSISTED REPROD. & GENETICS 583, 585–86 (2001).

\(^{113}\)See Noah, supra note 2, at 629–30; Strong, supra note 75, at 277–78 (detailing pressure on doctors to take risks).

\(^{114}\)See Annas, supra note 34, at 263; see also Reprogenetics Report, supra note 78, at S11–S12 (proposing ban on embryo research be lifted).


\(^{116}\)At St. Barnabas, institutional review boards (“IRBs”) were involved in supervising the protocols. Cytoplasmic Transfer, supra note 115.

\(^{117}\)See Barritt et al., supra note 115, at 513; Skloot, supra note 106, at 77–78.
is used when the mother’s egg needs an energy “boost” to allow the embryo to develop successfully.118 Cytoplasmic transfer always has been a controversial procedure because the risk to the child is unknown, especially the risk of the child inheriting some mitochondrial DNA from the cytoplasm donor.119 In 2001, the Food and Drug Administration (“FDA”) asserted jurisdiction over this method and imposed significant restrictions on its development,120 but this occurred only after the method had been used numerous times and children had been born through its use.121

Ultimately, even if the doctors and patients were amenable to regulation, it still might be difficult. The effects of the abortion debate serve as a strong social barrier to any principled regulation in this area.

3. Other Nonlegal Barriers: The Effects of the Abortion Debate

The politics of abortion exert a powerful influence over this area of the law, which further prevents meaningful regulation. Disagreement over the right to an abortion (and the permissible limitations on that right) has become increasingly polarized in the years since Roe v. Wade122 was decided. The differences between the “pro-life” and “pro-choice” perspectives now appear to be irreconcilable.123 There is no consensus regarding the status of

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119 Specifically, evidence exists that the mitochondrial DNA of some of the donors has been passed on to the children. See Barritt et al., supra note 115, at 513; Skloot, supra note 106, at 77; Winston & Hardy, supra note 118, at S18.

120 See Letter from U.S. Food & Drug Admin. to Sponsors/Researchers, Human Cells Used in Therapy Involving the Transfer of Genetic Material By Means Other than the Union of Gamete Nuclei (July 6, 2001), at www.fda.gov/cber/letters.htm. Although the FDA did not completely ban the transfer of genetic material, it concluded that the method was a “clinical investigation” requiring, among other things, submission of an Investigative New Drug (IND) application. Id. Instead of proceeding with INDs, practitioners “halted the procedure altogether.” Council, Reproduction Report, supra note 45, at ch. 2.

121 See Skloot, supra note 106, at 77 (“[C]ytoplasmic transfer led to seventeen babies at St. Barnabas (and several at other clinics).”); Cytoplasmic Transfer, supra note 115 (noting sixteen babies have been born using this procedure). The method is limited in other countries as well. IFFS Report 2001, supra note 10, at S19–S21.

122 410 U.S. 113 (1973).

embryos,\textsuperscript{124} even though such a determination would bring needed coherence to much of the law affecting them.

As a result of this ideological divide, any efforts to regulate in areas related to the unborn are likely to fail. Every issue becomes a battleground about the rights of the embryo, including fetal homicide statutes,\textsuperscript{125} federal judicial nominations,\textsuperscript{126} and guardianship.\textsuperscript{127} One of the most active battlegrounds at the national and international levels is the cloning issue. For two years, Congress has been unable to agree to a ban on cloning,\textsuperscript{128} even


\textsuperscript{125}Unborn Victims of Violence Act of 2004 (Laci and Conner’s Law), Pub. L. No. 108-212, 118 Stat. 568 (Apr. 1, 2004). This legislation, which makes killing a fetus a separate crime under federal law, recently was signed into law. Amy Goldstein, *Bush Signed Unborn Victims Act: Federal Law Establishes 2 Crimes Against Pregnant Women, WASH. POST,* Apr. 2, 2004, at A4. In light of the murder of Laci Peterson and her unborn fetus, the House Bill was renamed “Laci and Conner’s Law” in a successful effort to pass the bill. Although the statute is narrow because of its limited federal scope, it is also broad because it gives pre-embryos the status of a person for purposes of the statute. Pub. L. No. 108-212 (“As used in this section, the term ‘unborn child’ means a child in utero, and the term ‘child in utero’ or ‘child, who is in utero’ means a member of the species homo sapiens, at any stage of development, who is carried in the womb.”).

\textsuperscript{126}The current controversy over potential judicial nominations to the Supreme Court seems to be related to a nominee’s stance on abortion rights. Jeffrey Toobin, *Advice and Dissent: The Fight over the President’s Judicial Nominations,* NEW YORKER, May 26, 2003, at 42–48. For example, the polarization of views on the abortion issue quickly surfaced at the hearings of judicial nominees for federal circuit courts, including those of Miguel Estrada and William Pryor. David L. Greene, *Partisan Reigns in Battle over Courts, BALT. SUN,* June 15, 2003, at 1C; Toobin, *supra,* at 46–47. Senators have been willing to let candidates rise and fall based on their views on certain social issues, especially abortion. Greene, *supra,* at 1C (discussing role of political ideologies in judicial appointment process).

\textsuperscript{127}Recently, for example, Florida Governor Jeb Bush sought to appoint a guardian for a fetus, but the court refused to grant the request. *In re Guardianship of J.D.S.,* No. 5D03-1921, 2004 WL 42619, at *4 (Fla. Dist. Ct. App. Jan. 9, 2004). Under federal law, such appointments are improper. See Doe v. Shalala, 862 F. Supp. 1421, 1426–27 (D. Md. 1994) (reasoning that because “fetus” is not “person” under Fourteenth Amendment, appointment of guardian is improper). However, state law is in disagreement on this issue. *Compare In re D.K.,* 497 A.2d 1298, 1301–09 (N.J. Super. Ct. Ch. Div. 1985) (reasoning that because “fetus” is not “person” appointment of guardian ad litem is improper), with *In re Anonymous,* 720 So. 2d 497, 500–01 (Ala. Civ. App. 1998) (Hooper, C.J., concurring specially in part and dissenting in part) (concluding appointment of guardian for unborn fetus was proper pursuant to ALA. R. CIV. P. 17(c)).

\textsuperscript{128}Although most members of Congress agree that HRC should be banned, strong disagreement in the Senate on whether such a ban should extend to therapeutic cloning has prevented decisive action. In July 2001, the House of Representatives passed a measure that would have prohibited both forms of cloning, H.R. 2505, 107th Cong. (2001), but the Senate could not reach consensus and the measure died along with several contending Senate bills. See, e.g., S. 790, 107th Cong. (2001) (prohibiting reproductive and therapeutic cloning referred to Senate Judiciary Committee with no further action taken); S. 1758, 107th Cong. (2001)
though a ban on HRC enjoys overwhelming support. It is likely that this ideological stalemate also would hinder legislation regarding ART.

III. REGULATING ON BEHALF OF THE CHILDREN OF ART

Reports of a treatment that leaves almost 10% of children handicapped in some way must not be dismissed as a mere substantial quirk.

Notwithstanding the obstacles described above, some regulation now seems inevitable. One reason is that there is a growing body of evidence that the practices of ART may be harmful to children and regulation may be the only way to prevent this harm.

(prohibiting reproductive cloning but permitting therapeutic cloning, referred to Senate Judiciary Committee with no subsequent action).

This dispute in the Senate appears likely to prevent passage of legislation in the current congressional session as well. Despite swift House approval of another comprehensive ban in February 2003, H.R. 534, 108th Cong. (2003), the Senate has yet to act on this measure or a number of competing Senate proposals.

One Senate measure, a companion bill to H.R. 534, supra note 128, would prohibit both HRC and therapeutic cloning, while an alternative bill would prohibit HRC but permit therapeutic cloning. Compare S. 245, 108th Cong. (2003) (proscribing any asexual nuclear transfer for purposes of creating living organism at any stage of development), with S. 303, 108th Cong. (2003) (banning implantation of blastocyst into uterus or equivalent but permitting creation and maintenance of unfertilized blastocyst for up to fourteen days).


See, e.g., Hecht, supra note 110, at 234 ("[A] factor in the slow development of ART regulation is the deep moral divide among Americans over abortion."); Naomi D. Johnson, Note, Excess Embryos: Is Embryo Adoption a New Solution or a Temporary Fix?, 68 BROOK. L. REV. 853, 878 (2003) (arguing that different ideological groups favor or disfavor regulation of ART based on views of abortion and procreative rights). See generally Alvaré, supra note 25, at 32–33 ("It is . . . possible that the nation’s ongoing struggles with abortion have dampened legislators’ will to regulate the new reproductive technologies."); Annas, supra note 34, at 272 (blaming lack of needed regulation on “divisive and narrow abortion debate”).

Winston & Hardy, supra note 118, at S14.
A. Evidence of Harm

At this time, it appears that the risk of harm to the children of ART is neither remote nor insignificant. Up to ten percent of this population may be adversely affected, which means upwards of 4000 children in 2001 alone.\footnote{CDC REPORT 2001, supra note 1, 13 fig.1 (noting approximately 40,000 live babies born in 2001 as result of ART).} Such a potential impact at least warrants monitoring of the problem.

The greatest harm to the children of ART is posed by the probability that they will be born a multiple.\footnote{See F. Olivennes et al., Perinatal Outcome and Developmental Studies on Children Born After IVF, 8 HUM. REPROD. UPDATE 117, 117–25 (2002); Schieve et al., supra note 39, at 1837 (“Adverse fetal and infant outcomes associated with multiple pregnancy and birth have been identified as the greatest potential hazard associated with IVF therapies.”).} Approximately thirty-six percent of all births resulting from IVF and ICSI are multiples,\footnote{See supra note 23 (citing three percent increase in rate of twins in 2001); see also Jones & Schnorr, supra note 105, at 11 (“Since 1980, twin births have risen fifty-two percent . . . and the number of triplet and higher order gestations has quadrupled.”); Strong, supra note 75, at 272–73 (detailing rate of increase of multiples since 1980). Tarum Jaim et al., Trends in Embryo-Transfer Practice and in Outcomes of the Use of Assisted Reproductive Technology in the United States, 350 NEW ENG. J. MED. 1639 (2004) (twin rate has remained constant, but rate of other high-order multiples has declined, following decrease in number of embryos transferred per cycle).} and the numbers continue to grow.\footnote{See, e.g., Francois Olivennes, Double Trouble: Yes a Twin Pregnancy Is an Adverse Outcome, 15 HUM. REPROD. 1663, 1663 (2000) (Correspondence) (“Triplet pregnancies (or pregnancies of higher order) are clearly considered as the major adverse outcome of [ART].”); Gladys B. White & Steven R. Leuthner, Infertility Treatment and Neonatal Care: The Ethical Obligation to Transcend Specialty Practice in the Interest of Reducing Multiple Births, 12 J. CLINICAL ETHICS 223, 223 (2001) (“Multiple births, and particularly the birth of three or more infants, are an unacceptable hazard of successful treatment of infertility.”).} Multiples generally are considered a necessary side effect of existing ART practices.\footnote{See, e.g., ASRM, Multiple Pregnancy Report, supra note 20, at 2 (“Prematurity accounts for most of the excess perinatal morbidity and mortality with multiple gestations.”); Nanette Elster, Less Is More: The Risks of Multiple Births, 74 Fertility & Sterility 617, 618 (2000) (“Many medical complications result from the fact that multiples are often born prematurely.”); see also White & Leuthner, supra note 136, at 225 (detailing risks of premature births).}

It is well-established that multiple births cause serious health problems. Multiples are more likely to be born prematurely\footnote{See, e.g., Elster, supra note 137, at 618 (“On average, the birth weight of a triplet is only half that of a singleton.”).} and at LBW.\footnote{See, e.g., Elster, supra note 137, at 618 (“On average, the birth weight of a triplet is only half that of a singleton.”).} The mortality rates for multiples are significantly higher than for singletons: for triplets, it is thirteen times that of singletons, and for twins, it is five times
higher.\textsuperscript{139} Even if they survive, multiples (including twins) are more likely to suffer serious physical and mental handicaps, such as cerebral palsy.\textsuperscript{140} In light of this evidence, one noted commentator has wondered why the widespread creation of multiples through ART has not been considered a "public health problem."\textsuperscript{141}

The findings as to singletons of ART are less conclusive. Some recent studies suggest that IVF singletons have a greater risk of serious impairment than naturally conceived singletons. For example, a study published in March 2002\textsuperscript{142} concluded that infants conceived through ART\textsuperscript{143} were more than twice as likely to have major birth defects in the first year of life and were more likely to have "multiple major defects."\textsuperscript{144} Specifically, children born with the assistance of IVF (including singletons) had greater frequencies of cardiovascular, urogenital, and musculoskeletal defects.\textsuperscript{145} The incidence of these defects was approximately nine percent, more than twice the percentage as children naturally conceived.\textsuperscript{146}

\textsuperscript{139} Schievé et al., supra note 39, at 1832; see also ASRM, Multiple Pregnancy Report, supra note 20, at 2 (noting that fetal deaths for singletons are 4.3 per 1000 births and twenty-one per 1000 for triplets).

\textsuperscript{140} See, e.g., Elster, supra note 137, at 618 (outlining risks of harm to multiples, including low birth weight and handicaps); Noah, supra note 2, at 619–20 (describing developmental harms in multiples); Olivennes, supra note 136, at 1663–64 (stating that twins are at greater risk of prematurity, LBW and VLBW, and handicaps including cerebral palsy); Strong, supra note 75, at 273–74 (detailing serious complications suffered by multiples).

Even the annual CDC report notes the risks of multiples. See CDC REPORT 2001, supra note 1, at 17, 20, 35, 50, 54, 56, 57 (highlighting negative consequences of prematurity, LBW, and disability). See generally Council, Reproduction Report, supra note 45, at ch. 2 (setting forth "adverse impact" of multiple births, including "blindness, respiratory dysfunction, and brain damage").

\textsuperscript{141} ANDREWS, CLONE AGE, supra note 2, at 53; see also Olivennes et al., supra note 133, at 118 ("Multiple pregnancies are a significant public health problem considering the medical, social and financial consequences of their perinatal complications."); cf Patricia Katz et al., The Economic Impact of Assisted Reproductive Technologies, 4 NATURE CELL BIOLOGY & NATURE MED. FERTILITY SUPP. S29, S30–S32 (2002), available at www.nature.com/fertility ("Rarely addressed are the increased costs related to long-term complications.").

\textsuperscript{142} Michele Hansen et al., The Risk of Major Birth Defects after Intracytoplasmic Sperm Injection and in Vitro Fertilization, 346 NEW ENGL. J. MED. 725 (2002).

\textsuperscript{143} The researchers compared the frequency of defects among children conceived by ICSI, IVF, and those conceived naturally. Id. at 725–26.

\textsuperscript{144} Id. at 726–30 (defining "multiple major defects" as "two or more defects affecting different systems").


\textsuperscript{146} Hansen et al., supra note 142, at 726–30.
Certain diseases have been associated with the use of ART. Beckwith-Weidemann Syndrome, for example, is characterized by bigger-than-average size, midline abdominal wall defects, and a greater incidence of childhood cancer.\textsuperscript{147} ICSI, in particular, has been associated with the existence of hypospadias, an incomplete development of the anterior urethra in males.\textsuperscript{148} Although hypospadias may be considered a minor defect that can be corrected surgically in most cases,\textsuperscript{149} the harm actually may be more serious in the long-term because the defect may indicate future male infertility.\textsuperscript{150} Through ICSI, parents inadvertently may be passing on infertility from one generation to another. It is too early to tell the long-term effects.

Singleton children of ART not only may have more defects, they also may have a higher rate of premature birth and LBW.\textsuperscript{151} This data is important because if babies are born prematurely or at LBW (regardless of the reason), they are more likely to suffer from other serious afflictions, such as cerebral palsy and learning disabilities.\textsuperscript{152}

\textsuperscript{147}See Michael R. Debaun et al., Association of In Vitro Fertilization with Beckwith-Weidemann Syndrome and Epigenetic Alterations of LIT1 and H19, 72 AM. J. HUM. GENETICS 156, 156 (2003); Roger Gosden et al., Rare Congenital Disorders, Imprinted Genes, and Assisted Reproductive Technology, 361 LANCET 1975, 1975–77 (2003) (reviewing studies that found greater incidence of Beckwith-Weidemann Syndrome among IVF and ICSI children); see also Suz Redfearn, A Reality Check on Assisted Reproduction, WASH. POST, NOV. 4, 2003, at F1 (listing features of Beckwith-Weidemann Syndrome).


\textsuperscript{150}See Reztloff & Hornstein, supra note 87, at 854 (detailing how genetic mutations underlying male infertility may be passed on to sons through ICSI).


\textsuperscript{152}See, e.g., Adnan T. Bhutta et al., Cognitive and Behavioral Outcomes of School-Aged Children Who Were Born Preterm, 288 JAMA 728, 728 (2002) (noting children born preterm
Other studies have found that singletons of ART have no greater health problems than children who are naturally conceived.\textsuperscript{153} And even if a greater frequency of harm were associated with ART, it does not mean that ART actually caused the harm.\textsuperscript{154} Further research is necessary to determine a causal relationship between the method and the child's resulting condition.\textsuperscript{155}

In the meantime, some intervention will be needed. The following Section outlines the laws that should be promulgated to benefit the children of ART.

\textbf{B. A "Double-Decker" Approach to Regulation}

In light of the tentativeness of the empirical evidence and the nonlegal barriers to regulation set forth above,\textsuperscript{156} any regulation should be principled and focused. This Section proposes a "double-decker" or two-tiered approach to regulation. Under the first tier, state law adapts to eradicate the greatest dangers to these children. Under the second tier, a federal system of oversight is created to prevent future harm to vulnerable populations, especially children. This approach will adequately protect children while respecting the parents' rights, and it is consistent with the philosophy that it is best for families to govern themselves, with as little interference by the State as possible. Ultimately, by limiting its scope to the protection of children from harm—an area already regulated extensively—this approach will avoid legislating any particular view of morality.

\footnotesize{(younger than thirty-seven weeks) had more cognitive deficits and behavioral problems). See also supra notes 137–38 (discussing LBW and prematurity in multiples).

\textsuperscript{153}See generally Redfearn, supra note 147, at F1 (noting conflicting evidence with "a few studies show[ing] an association between assisted reproductive technology and a higher risk of cancer, birth defects, and genetic diseases").

\textsuperscript{154}See, e.g., Hansen et al., supra note 142, at 729–30 (describing study that possibly shows increase in medical problems in children of ART); Schieve et al., supra note 16, at 731 ("[I]t remains unclear whether the risk of low birth weight among singleton infants concerned with [ART] is a direct effect of the procedure involving such technology."). The harm could be caused by the IVF process itself, or other variables such as the characteristics of the female partner. Olivennes et al., supra note 133, at 122–25 (discussing patient-related risk factors). See generally George Kovalovsky et al., Do Assisted Reproductive Technologies Cause Adverse Outcomes?, 79 FERTILITY & STERILITY 1270, 1270–72 (2003) (critiquing recent studies finding negative effects of ART and emphasizing that results only show associations).

\textsuperscript{155}Such research is ongoing. See Redfearn, supra note 147, at F1 (discussing founding of center to objectively analyze IVF technologies); Press Release, Effects of ART, supra note 89 (announcing formation of ART Children's Health Panel to report on health effects).

\textsuperscript{156}See supra Sections II.B and II.C (examining limits to existing regulation of ART stemming from ineffective self-regulation and nonlegal barriers, such as conflicting interests of parents, doctors, and third parties).}
1. Regulation at the State Level

States should consider enacting legislation that would curb, based on the existing scientific evidence, the practices that pose the greatest threat to the welfare of the children of ART. Specifically, states should ban HRC and enact laws that would reduce the numbers of multiples born as a result of ART.

(a) Cloning: Hope for the Best but Prepare for the Worst

At this time, HRC poses grave health risks to children who might be born using this technology. If this method were allowed, it is feared that many children would be sacrificed as guinea pigs: many would die before birth, others would be born defective, and even more would suffer from latent defects that may not be detectable until later in life.\(^\text{157}\)

This prediction is based on what has already happened to cloned animals. Animal cloning has resulted in a significant number of miscarriages and stillborn births,\(^\text{158}\) animals born with serious defects,\(^\text{159}\) and development of serious ailments in adult animal clones.\(^\text{160}\)

Because cloned children may suffer fates similar to those of their animal counterparts, states need to step in and enact a four-year moratorium on HRC.\(^\text{161}\) These statutes should carefully define HRC,\(^\text{162}\) clearly ban the practice

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\(^{158}\)See NAS, Cloning Report, supra note 157, at 40–41.

\(^{159}\)Id.; see also Cloned Asian Cattle Is Put to Death Because of Size, Wash. Post, Apr. 10, 2003, at A19 (reporting that calf born abnormally large was euthanized).

\(^{160}\)See, e.g., First Cloned Sheep Dolly Dies at 6 (Feb. 14, 2003), at http://www.cnn.com/2003/WORLD/europe/02/14/cloned.dolly.dies (reporting Dolly was afflicted with premature arthritis and died young); cf. Carl T. Hall, 'Huge' Genetic Defects Discovered in Mice Cloned from Stem Cells, S.F. Chron., July 6, 2001, at A1 (reporting on study of genetic defects not manifest at birth in cloned mice).

Thus far no primates have been successfully cloned. See Calvin Simerly et al., Molecular Correlates of Primate Nuclear Transfer Failures, 300 Science 297, 297 (2003); Gretchen Vogel, Misguided Chromosomes Foil Primate Cloning, 300 Science 225, 225 (2003); see also Rick Weiss, Study Shows Problems in Cloning People, Wash. Post, Apr. 11, 2003, at A12 (discussing failed attempts at cloning primates).

\(^{161}\)Accord NBAC, Cloning Report, supra note 157, at 108–09 (suggesting three- to five-year moratorium on HRC).

\(^{162}\)See, e.g., supra note 50 (providing examples of state statutes regulating cloning); see also Human Cloning Ban and Stem Cell Research Protection Act, S. 303, 108th Cong., 1st Sess.
for this fixed period, and impose severe criminal penalties on anyone who violates the ban.\(^{163}\)

A moratorium would be preferable to an outright ban on cloning, because it would require legislatures to revisit the issue after allowing the methods to develop in animal studies or abroad. It is possible that in a few years the method may become safe enough to be used as a means of assisted reproduction. Then, it should be permitted to proceed, albeit with some regulatory oversight.\(^{164}\)

Even if these state moratoria are enacted expeditiously, they may not be completely effective, so additional safeguards will be necessary. Some states may fail to enact limits, or cloned children may be “imported” from other countries.\(^{165}\) Once the cloned child is living within the borders of the state, the focus should shift from preventing harm to ensuring that the resulting child is treated under the law as any other child, regardless of the manner of conception.\(^{166}\) Cloned children must not be treated as subhuman (as some have feared)\(^{167}\) or only given the “special respect” that has been given to pre-embryos.\(^{168}\)

(2003) (“‘Human cloning’ means implanting or attempting to implant the product of nuclear transplantation into a uterus or the functional equivalent of a uterus.”).

\(^{163}\) See, e.g., CAL. HEALTH & SAFETY CODE § 24187 (West Supp. 2004) (levying fines of up to $1 million for violating cloning ban); see also S. 303, supra note 162 (imposing imprisonment of up to ten years and substantial fines).

\(^{164}\) See generally infra Section III.B.2 (arguing new model of federal regulation is needed to protect children of ART).

\(^{165}\) See generally Maxwell J. Mehlman & Kirsten M. Rabe, Any DNA to Declare? Regulating Offshore Access to Genetic Enhancement, 28 AM. J.L. & MED. 179, 185–86 (2002) (arguing United States must strive to regulate cloning abroad because of threats cloning presents to society). For example, a cloned embryo could be created and implanted in the gestational mother while in another country. The “illegal” embryo could be brought into the United States in utero, or the resulting child brought in after his or her birth.


Because of its controversial nature, a resolution that sought to protect the rights of any live born human clones never made it before the ABA House of Delegates. See www.abanet.org/family/council/minutesSeattle2003.pdf, at 7 (reporting minutes from ABA Council meeting reveal that resolution withdrawn and requested to be considered at 2004 annual meeting). See Section of Family Law, ABA, Minutes: Council Meeting (Oct. 18, 2003) (reporting that cloning resolution was withdrawn and would be reconsidered at 2004 Annual Meeting) (on file with author).

\(^{167}\) ABA Report, supra note 166, at 3–4 (expressing concern that cloned child may be viewed as “not really a human being” and could thus be destroyed). The ABA recommendations
Each state should take steps, preferably through legislation, to protect cloned children from discrimination based on the manner of their creation. States might be able to protect this subclass of children by adapting their general discrimination laws\textsuperscript{169} or, even more appropriately, by using their genetic discrimination laws.\textsuperscript{170} If states are already protecting against discrimination based on genetic predisposition, then discrimination based on the child’s “method of creation” also should be covered. Passage of some clarifying language may be necessary so that it is evident that cloned children are in the protected class. It does not make sense to deny the possibilities that cloned children may live among us in the future and that they may be mistreated by others.

For that reason, cloned children should be allowed to integrate into their families and communities to the same extent as naturally conceived children. Even though their means of creation may have been unlawful, the children should not suffer for the sins of their parents. This means that the State should not be able to intrude into the privacy of a family simply because the child was conceived through a cloning technique. Specifically, the child’s method of creation should not be a sufficient basis for finding that a child has been abused or neglected.\textsuperscript{171}

It is my view that the harm caused by removing a cloned child from her loving parents would exceed any harm the child might incur from living with

\textsuperscript{168} See supra Section II.C.3 (noting ongoing controversy over legal status of embryos).

\textsuperscript{169} See, e.g., 775 ILL. COMP. STAT. § 5/1-103 (2001) (“Handicap’ means a determinable physical or mental characteristic of a person . . . the history of such characteristic, or the perception of such characteristic complained against, which may result from disease, injury, congenital condition of birth or functional disorder . . . .’’); S.D. CODIFIED LAWS § 20-13-1(4) (Michie 1995) (defining “[d]isability” as “a physical or mental impairment of a person resulting from disease, injury, congenital condition of birth or functional disorder which substantially limits one or more of a person’s major life functions; a record of having such impairment; or being regarded as having such an impairment . . . .’’); cf. 42 U.S.C. § 12102 (2)(A)—(C) (2000) (defining “disability” as person with one or more physical or mental impairments that substantially limits him or her in major life activity, person with record of such impairment, or person who is regarded as having such an impairment).


\textsuperscript{171} Such an attempt was made in the case of Baby Eve. See Head of Clonaid Ordered to Appear in Court Next Week (Jan. 22, 2003); at http://www.cnn.com/2003/LAW/01/22/clonaid.court. Clonaid announced the birth of the first cloned child, who was purportedly named Eve. Id. Soon thereafter, a lawyer tried to get himself appointed guardian for Baby Eve, so that she could be under the state’s jurisdiction as a child at risk of harm. See Attorney Wants Guardian Appointed for Alleged Human Clone (Dec. 21, 2002), at http://www.cnn.com/2002/LAW/12/31/human.cloning.guardian/index.html.
those parents, who admittedly were willing to put the child’s health at risk to create her. The cloning decision occurs preimplantation, during the period when intended parents are not likely to be thinking about the child’s welfare (and are not encouraged to do so). Once the child is born, and those emotional factors are absent, it is less likely that the parents would take risks with the child’s life. In fact, the opposite could be true: by going to such lengths to have a child, the parents presumably would do everything in their power to keep the child safe and healthy. Unless there is reason other than the child’s method of creation to suspect the cloned child is at risk of serious harm, his or her parents should be entitled to the same zone of privacy as other parents.

One area where State intervention may be necessary is to ensure the cloned child’s parentage. Who is a clone’s legal parent? Is it the intended parent(s), the donor of the somatic cell who provided the clone’s DNA, the donor’s parents, or the gestational mother and her husband? Although a state need not have a parentage law specifically addressing cloned children, each state legislature should examine its existing laws to ensure that they would adequately resolve any parentage disputes that might arise. As with other children of ART, parentage could be based on principles of intent.


\[173\] See supra Section II.C.1 (discussing how parents’ obsession with birth may cause them to overlook quality of life for children they are creating).

\[174\] See John A. Robertson, Human Cloning and the Challenge of Regulation, 339 NEW ENG. J. MED. 119, 121 (1998) (“What counts is how a child is treated after birth. Self-interested motives for having children do not prevent parents from loving children for themselves once they are born.”). This rationale may not extend to situations in which the child was conceived in order to replace a dead child or relative, or to serve as a donor for a family member. See generally Julia Sommerfeld, Coveting a Clone, at http://www.msnbc.msn.com/id/3076918/ (last visited Mar. 1, 2004) (profiling persons who seek to clone and discussing underlying reasons).

\[175\] For example, if the parents are not tending to the child’s physical needs.

\[176\] See ABA Report, supra note 166, at 3–4 (outlining anticipated parentage problems of cloned child).

\[177\] See COUNCIL, CLONING REPORT, supra note 157, at 102–03 (discussing cloned child’s possible confusion over identity of parents); see also Anthony Miller, Baseline, Bright-Line, Best Interests: A Pragmatic Approach for California to Provide Certainty in Determining Parentage, 34 McGeorge L. Rev. 637, 680 (2003) (identifying possible parents of clone as: donor of cell nucleus, donor’s biological parents, donor of enucleated egg, gestational mother and her husband, and intended parents) (citing Nanette Elster, Who Is the Parent in Cloning?, 27 Hofstra L. Rev. 533, 536 (1999)).

\[178\] See ABA Report, supra note 166, at 3–4 (discussing potential parentage disputes).

\[179\] See, e.g., UNIF. PARENTAGE ACT § 703 (amended 2002), 9B U.L.A. 33 (Supp. 2003) (mandating determination of paternity if consent plus intent); In re Marriage of Buzzanca, 72 Cal. Rptr. 2d 280, 280 (Cal. Ct. App. 1998) (holding that man who intended to be father of embryo implanted in surrogate was father even though he had no biological ties to child); Richard F. Storrow, Parenthood by Pure Intention: Assisted Reproduction and the Functional
genetics,\textsuperscript{180} gestation (to determine motherhood),\textsuperscript{181} or relationship with the child.\textsuperscript{182}

(b) Multiples: Time for a Bright Line

As previously discussed, the greatest danger to the children of ART is the likelihood of being born a multiple.\textsuperscript{183} Thus far, self-regulation has done little to reduce the number of multiples.\textsuperscript{184} Because no limits currently exist and because the number of embryos implanted ultimately depends on a variety of factors, it is not surprising that the rate of multiples has remained essentially the same.\textsuperscript{185} This rate is simply too high. Therefore, in their role as parens patriae,\textsuperscript{186} states need to act expeditiously to protect these at-risk children.\textsuperscript{187}

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\textsuperscript{181}See, e.g., Larkey, supra note 179, at 625–26 (citing laws of North Dakota and Arizona).


\textsuperscript{183}See supra Section III.A (discussing increased health risks to multiples).

\textsuperscript{184}See supra Section II.B (describing how current system of self-regulation has not curtailed harmful or unethical ART practices, including multiple births). But see Jain, supra note 135 (concluding that, in light of recent trends, professional self-regulation preferred over legislation).

\textsuperscript{185}See CDC REPORT 2001, supra note 1, at 57 fig.45 (concluding overall rate stable since 1996).


\textsuperscript{187}See infra Section IV.A.2 (contrasting constitutional rights of parents with risk of harm to children of ART); see also Strong, supra note 75, at 277 (arguing that laws need to prioritize children over desperate parents).
Admittedly, reducing the number of multiples through regulation will not be easy. Two different kinds of technology cause multiples: IVF, which is usually practiced by a specially trained fertility doctor; and ovulation stimulation, which can be administered by reproductive endocrinologists, ob-gyns, or general practitioners.\textsuperscript{188} The first kind of technology is easier to regulate than the second. Not only is little known about existing ovulation-stimulation practices,\textsuperscript{189} but it is easier to set a limit on the number of embryo implantations per cycle (as in IVF) than it is to control whether (or when) fertilization will occur or whether selective reduction will be chosen.\textsuperscript{190} Consequently, these different methods will need different regulatory responses to achieve the same goal of reducing the number of multiples.

To reduce the number of multiples born as a result of IVF, I propose that states limit the number of pre-embryos implanted to no more than three per cycle. An exception could be created for extraordinary circumstances—a determination that would need to be made by a third party, such as a licensing board. Although implantation of three pre-embryos still might result in a number of multiples,\textsuperscript{191} it would diminish the likelihood of super-multiples, which cause the highest levels of morbidity and the most severe disabilities.\textsuperscript{192}

This proposal is consistent with the approach of other countries that have affirmatively limited the number of implantations because of concern about the number of multiples. For example, Germany, Sweden, Denmark, and Switzerland limit implantations to three pre-embryos, at most, per cycle.\textsuperscript{193} The

\textsuperscript{188}See supra note 19 and accompanying text (describing use of ovulation-stimulation drugs and related increase in births of high-order multiples).

\textsuperscript{189}See supra note 20 (noting difficulty of obtaining information on ovulation stimulation).

\textsuperscript{190}Selective reduction is a technique used to decrease the incidence of preterm delivery in a multiple gestation (usually triplets or above) by reducing the number of fetuses. See Joanne Stone et al., \textit{A Single Center Experience with 1000 Consecutive Cases of Multi-Fetal Pregnancy Reduction}, 187 AM. J. OBSTETRICS & GYNECOLOGY 1163, 1163 (2002). One or more of the fetuses is aborted, and the others are allowed to develop to term. See Stacey Pinchuk, \textit{A Difficult Choice in a Different Voice: Multiple Births, Selective Reduction, and Abortion}, 7 DUKE J. GENDER L. & POL’Y 29, 30 (2000). Because the couple has tried so hard to conceive, and may lose all the embryos as a result of the procedure, they may be reluctant to proceed even if it means that the remaining children would be healthier. See ASRM, \textit{Multiple Pregnancy Report, supra note 20}, at 5; Comm. on Ethics, Am. Coll. of Obstetricians & Gynecologists, \textit{Nonselective Embryo Reduction: Ethical Guidance for the Obstetrician-Gynecologist}, 65 INT’L J. GYNECOLOGY & OBSTETRICS 216 (1999) (arguing “for . . . patients who may have achieved pregnancy after lengthy infertility treatment, [selective reduction] may be the least desirable”); Strong, supra note 75, at 275 (identifying reasons why reduction is unsatisfactory solution).


\textsuperscript{192}See supra notes 19–22 and accompanying text (discussing serious health problems caused by multiples).

\textsuperscript{193}IFFS \textit{Report 2001, supra note 10}, at S12 & tbl.3 (reviewing and discussing international survey regarding number of pre-embryos to transfer). For some, implantation of one embryo is the desired goal. See Lars Hamberger & John Hazekamp, \textit{Towards Single Embryo Transfer in
United Kingdom had imposed a limit of three pre-embryos until recently, when it decreased the limit to two.\textsuperscript{194} Although no strict limits on the numbers of implantations currently exist in the United States, they have been proposed by critics of the current system.\textsuperscript{195}

This bright-line limitation is likely to be vociferously opposed by patients and doctors alike. The patients will argue that their rights to procreate and to parent are being infringed.\textsuperscript{196} The doctors will argue that such a limitation is too restrictive and prevents them from making an informed medical determination based on a myriad of factors that sometime warrant implantation of more than three embryos.\textsuperscript{197} The limit is also subject to additional criticisms; for instance, that it is not based on empirical evidence and, more generally, that lawmakers should not be in the practice of legislating medicine.

In the end, however, none of these arguments should be considered persuasive enough to outweigh the interests of the children of ART. The harm caused by multiples is well-documented, and self-regulation has been ineffective in reducing the number of multiples caused by ART. The limit of three is based on sound public policy and is already being modeled by countries that have shown their commitment to reducing multiples. Further, as the next Section demonstrates, such a restriction does not violate the parents' constitutional rights.\textsuperscript{198}

\textit{IVF,} 55 J. REPROD. IMMUN. 141, 145–47 (2002) (urging standard of one-embryo transfer for health of children and quality of life for family); cf. Westphal, supra note 40, at 7 (stating certain Australian doctors are using new measure of success—"BESST" rate, based on birth of single, full-term babies). See generally Jain, supra note 135 (observing that "many countries . . . have enacted strict laws limiting the number of embryos (from two to four) that can be transferred per cycle").


\textsuperscript{195} See ISLAT WORKING GROUP, ART INTO SCIENCE: REGULATION OF FERTILITY TECHNIQUES, 281 SCIENCE 651, 652 (1998) (proposing limit of four embryos); Patricia K. Jennings & Joan C. Callahan, Multiple Gestations: Some Public Policy Issues, 9 HEALTH CARE ANALYSIS 167, 172 (2001) (arguing for maximum of four embryos per cycle); cf. N.Y. STATE TASK FORCE, ANALYSIS, supra note 96, at 169–70 (recognizing harm caused by multiples but declining to recommend limit on number of implantations); Christopher J. DeJonge & Don P. Wolf, Embryo Number for Transfer Should Be Regulated, 68 FERTILITY & STERILITY 784, 785–86 (1997) (recommending self-regulation); Strong, supra note 75, at 279 (same).

\textsuperscript{196} See infra Sections IV.A.1 and IV.A.2 (discussing constitutional dimensions of right to procreate and right to parent).

\textsuperscript{197} See supra Section II.C.2 (discussing doctors' incentives); cf. Mina Alikani & Klaus Wiemer, Embryo Number for Transfer Should Not Be Strictly Regulated, 68 FERTILITY & STERILITY 782, 782 (1997) ("[E]nforcing these regulations and the rather arbitrary choice of such a number is not only ineffective in significantly reducing multiple pregnancy rates but is also overly simplistic.").

\textsuperscript{198} See infra Section IV (discussing constitutional rights implicated under proposed "double-decker" approach and why such rights are not violated).
A bright-line approach will not work for regulating ovulation stimulation. However, some action must be initiated by the states because stimulation is the method that poses the greatest risk of super-multiples. For example, any doctor prescribing substances used to stimulate ovulation should be required to report the birth of multiples. When the rate of triplets or other super-multiples exceeds a certain percentage, the provider should be investigated by a licensing body.

Specifically, the provider should be sanctioned when it appears that all reasonable precautions to prevent multiples have not been taken (including using informed consent, preventing fertilization of multiple eggs, and encouraging selective reduction). Fertility doctors, ob-gyns, and general practitioners who are engaged in these high-risk practices need to understand that, by risking the welfare of future children, the doctors themselves face serious consequences. An existing accrediting organization or licensing board should take on the responsibility of overseeing these limits on a state-by-state basis. Although the logistics of regulating this practice may be difficult, it is well worth the cost.

2. Regulation at the Federal Level

Because it is unlikely that state regulation will be sufficient to protect the children of ART in the long-term, federal oversight will be necessary. Intervention at the federal level would permit a comprehensive, thoughtful approach that is long overdue. It would prevent intended parents from shopping for the most favorable laws among the states, as is currently possible. It also would be consistent with other areas where federal regulation already exists, including regulation of drugs and gene therapy.

Oversight of ART probably will require creation of a new entity or entities, as no existing federal agency is prepared to regulate the field at this time. For instance, the CDC currently is responsible for regularly disseminating information regarding success rates and overseeing model

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199 See supra notes 19–22 and accompanying text (defining ovulation-stimulation method and resulting risk of multiples).

200 In the surrogacy and adoption contexts, for example, attorneys currently specialize in finding states with the most favorable laws. See, e.g., Lisa Behm, Legal, Moral and International Perspectives on Surrogate Motherhood: The Call for a Uniform Regulatory Scheme in the United States, 2 DePaul J. Health Care L. 557, 586 (1999) (“In the absence of a uniform standard at the federal level, certain states may have become havens for couples who wish to have children through surrogacy arrangements.”); Hecht, supra note 110, at 235 (posing surrogacy practice involves shopping for most favorable state laws).
The CDC does not, however, specialize in reproductive technology issues or ethics, and its resources are limited.\textsuperscript{202}

The FDA is an equally unsuitable choice to regulate ART. The FDA’s main objective is to ensure the safety and efficacy of food, drugs, and biologics, which include vaccines and gene therapy.\textsuperscript{203} The FDA has recently sought to expand this objective by asserting its jurisdiction over certain aspects of ART, specifically HRC\textsuperscript{204} and the transfer of genetic material.\textsuperscript{205} Yet, even if the FDA were permitted to regulate these discrete aspects of ART,\textsuperscript{206} it is unlikely that the FDA would have the power to regulate the entire field of reproductive medicine. Indeed, many ART practices do not use drugs or biologics, or result in the creation of a product subject to the FDA’s jurisdiction.\textsuperscript{207}

Even if the FDA had the power to regulate ART, FDA regulation would not be recommended because the FDA’s primary concerns are the safety and efficacy of a product, which do not relate to broad ethical issues as a matter of course.\textsuperscript{208} The FDA does address a narrow range of ethical issues in clinical

\textsuperscript{201} See supra notes 40–42 (explaining CDC’s information dissemination role under federal law).

\textsuperscript{202} See Council, Reproduction Report, supra note 45, at ch. 10 (recommending additional resources be awarded to CDC for additional disclosure requirements).


\textsuperscript{205} See supra notes 115–20 and accompanying text (discussing FDA regulation of cytoplasmic transfer).

\textsuperscript{206} See Dresser, supra note 203, at 7–8 (discussing problems with FDA regulating cloning).

\textsuperscript{207} George J. Annas, Why We Should Ban Human Cloning, 339 NEW ENG. J. MED. 122, 125 (1998) (“The FDA has no jurisdiction over either the practice of medicine or human replication and is far too narrowly constituted to represent the public [in the area of cloning].”); Gregory J. Rokosz, Human Cloning: Is the Reach of FDA Authority Too Far a Stretch?, 30 SETON HALL L. REV. 464, 512–13 (2000) (discussing why FDA authority might not extend to cloning). One notable exception may be ovulation stimulation, because this method involves prescribing pharmaceuticals. See Noah, supra note 2, at 610–12, 652–53 (suggesting that FDA “enjoys clear authority to regulate fertility drugs”).

\textsuperscript{208} See Council, Reproduction Report, supra note 45, at ch. 2; cf. Sec’y’s Advisory Comm. on Genetic Testing, Nat’l Insts. of Health, Enhancing the Oversight of Genetic Tests: Recommendations of the SAGCT Issue 5 (2000), at http://www4.od.nih.gov/oba/sagct/reports/oversight_report.htm (“Because FDA’s review [of genetic tests] will focus on assuring the analytical and clinical validity of a test, the agency’s capacity to assess the ethical and social implications of a test may not be sufficient.”).

In the context of gene therapy, the Recombinant DNA Advisory Comm. (“the RAC”) provides a public forum to examine novel or controversial gene-therapy trials. See Recombinant
trials that relate primarily to informed consent of the subject and protection of vulnerable populations. However, comprehensive regulation of ART would require greater consideration of the ethics of certain practices, and such consideration is beyond the FDA's expertise. A new model of regulation is needed that focuses on protecting vulnerable populations from harm, which would integrate ethical considerations to achieve that objective.

Recently, two visions of federal regulation have been proposed: one by The President's Council on Bioethics ("Council"); and another by Erik Parens and Lori Knowles of The Hastings Center. Although both proposals are extremely thoughtful, they go further than necessary and ultimately will lead to overregulation of ART. This is particularly true of the Council's recommendations. In the end, this Article concludes that The Hasting Center's Reprogenetics Report provides a workable framework for federal regulation, but its scope needs to be narrowed.

(a) Council Recommendations

To its credit, the Council has made the regulation of ART one of its priorities. Early in its deliberations, members realized that the lack of regulation was a problem that needed to be addressed. After issuing a report on cloning, the Council began considering the broader implications of ART.


See generally 21 C.F.R. §§ 56.111 (a)(3), (b) (requiring consideration of vulnerable populations when selecting subjects and designing study). Provisions specifically dealing with protection of children are located at §§ 50.50 to .56.


Reprogenetics Report, supra note 78.

The majority's policy recommendation in Human Cloning and Human Dignity: An Ethical Inquiry called for "a federal review of current and projected practices of human embryo research, pre-implantation genetic diagnosis, genetic modification of human embryos and gametes, and related matters, with a view to recommending and shaping ethically sound policies for the entire field." COUNCIL, CLONING REPORT, supra note 157, at 11; see also Council, Reproduction Report, supra note 45, at ch. 1 ("Three months following the release of [the cloning] report, the Council decided to undertake a thoroughgoing inquiry into the current regulation of those biotechnologies that touch human reproduction.").

Recently, it issued a report with recommendations that would encourage federal involvement in ART practices. Although some federal intervention is warranted, the Council's approach is problematic in a number of respects.

The recommendation section of the report consists of three parts. In the first part, the Council urges greater oversight of ART through: a longitudinal study of the children of ART, federally funded studies to ascertain the effects of ART on the health of women and children, and enhanced reporting by the CDC.

In the second part, the Council recommends that professional societies improve on self-regulation by, inter alia, improving the informed consent process, taking "concrete steps" to reduce the number of multiple births, improving enforcement of the organizations' existing guidelines, and ensuring protection for human subjects involved in experimental ART protocols (including embryos).

In the third part, the Council suggests that Congress pass legislation to curtail "certain particularly questionable practices." Specifically, it proposes that Congress enact specific moratoria that would be guided by four principles: (1) "Preserving a Reasonable Boundary between the Human and the Non-Human (or, between the Human and the Animal) in Human Procreation"; (2) "Respect for Women and Human Pregnancy, Preventing Certain Exploitative and Degrading Practices"; (3) "Respect for Children Conceived with the Aid of Assisted Reproductive Technologies, Securing for Them the Same Rights and Human Attachments Naturally Available to Children Conceived In Vivo"; and (4) "Setting Some Agreed-Upon Boundaries on How Embryos May Be Used and Treated."

I share the Council's concern about the welfare of children born using ART. The Council articulates this deep concern at various points in the document. For example, the Council states that "[a]mong the ethical issues


216 Id.
217 Id.
218 Id.
220 Id.
221 Id.
222 Id. Notably, the previous version eliminated "respect for early stages of nascent human life." Council, Draft Recommendations, supra note 219.
223 See supra Section III.A (examining evidence of harm to children of ART).
224 Council, Reproduction Report, supra note 45.
raised by the use of assisted reproductive technologies, the concern for the safety and well-being of children conceived through these technologies seems the one most in need of greater attention."225

Specifically, I concur in the Council’s recommendation to include children of ART in the National Children’s Study beginning in 2005, which would allow researchers to observe the impact of ART and other factors at regular intervals in the children’s lives.226 I also agree with the Council that federal funding should be used for comprehensive studies of practices (such as PGD), which would determine the effects these practices have on children, and report any adverse effects on children that may be caused by the technology.227

However, I disagree with a Council recommendation that does not go far enough. In the second part of its recommendations, the Council asks professional societies to better monitor and enforce the development of ART, which is essential to effective self-regulation.228 Yet, the Council does not take a strong enough stance against multiple births. It “strongly endorses a very specific substantive recommendation” to reduce multiple births through multiple embryo transfer; however, it does not actually propose a presumptive limit on the number of implantations per cycle with serious consequences for those providers who exceed the limit.229 Leaving this issue to professional organizations—with no more than a strong endorsement from the Council—puts too many children at risk.

In other respects, the Council’s recommendations seem to go too far. The Council purports to recommend proposals only where there is “fairly broad assent”230 or “widely shared goals,”231 but such agreement is not likely in this field. Even if we could agree to treat the child as a “relevant patient” in ART,232 we might disagree on how to implement goals. We might not agree, for example, that respect for children requires legislation be passed ensuring that all children have “a natural connection to two human genetic parents.”233

In addition, the Council seems distracted by concerns with certain “rogue” scientific practices that might only affect a few children or may never be developed; for instance, using gametes from a human fetus or fusing two blastomeres.234 These should not be the concerns occupying Congress at it begins to regulate ART.

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225 Id. at ch. 9.
226 Id.
227 Id.
228 See supra Section II.B (describing limits of existing self-regulation).
229 Council, Reproduction Report, supra note 45, at ch. 10.
230 Id.
231 Id.
232 Id.
233 Id.
234 Id.
Even more significantly, we as a society may not be able to agree on the underlying principles that guide regulation. Although the final versions of the report eliminate the references to protect the “dignity of human procreation,” and to show “respect for the early stages of nascent human life,” these values still seem to drive portions of the report. This moral perspective may not be shared by a majority of the citizenry, and could lead to more restrictive regulation. Finally, it is not clear that Congress is best-equipped to legislate proactively in this area, particularly since it cannot even enact a ban on HRC.

(b) Reprogenetics Report

The Reprogenetics Report proposes a useful framework for regulating ART at the federal level. The authors, Parens and Knowles, begin by articulating the guiding principles for any regulation: to promote “human well-being,” justice, and liberty. They emphasize that regulation must do more than simply protect against harm—it also should further core ethical concerns, such as the reduction of commodification and exploitation. Specifically, the authors are concerned about the health of children, as well as the injustice that may occur by practices such as the enhancement of traits.

To accomplish these goals, the Reprogenetics Report makes a number of specific suggestions: lift the current ban on embryo research and create a commission that would propose legislation for Congress to consider. This commission, the Reprogenetics Technologies Advisory Commission (“RTAC”), would consider the creation of a policymaking and license-granting body, called the Reprogenetics Technologies Board (“RTB”). The RTB would serve a number of important functions: “[G]rant licenses, monitor and inspect facilities, create a code of practice, consult with the public, and keep an information registry.”

I agree that there should be an expert commission, such as the RTAC, which would be able to consider the state of science and to carefully balance competing interests. Its mission should be to protect vulnerable populations from the effects of reproductive technologies. One of the greatest benefits of

236 Id. As discussed previously, the status of the embryo is one of the most contentious ethical and political issues. See supra Section II.C.3 (discussing effects of abortion debate on existing regulation of ART).
237 Reprogenetics Report, supra note 78, at S3–S7.
238 Id. at S7.
239 Id. at S3.
240 Id. at S18–S20. Unlike the Council, Reproduction Report, supra note 45, no specific legislation is recommended. Reprogenetics Report, supra note 78, at S18–S20.
241 Id. at S18.
242 Id. at S19.
such a commission would be to gather additional information necessary to inform legislation relating to ART. For example, more information is needed about: the well-being of multiples and singletons of ART, both at birth and at later stages in their lives;\textsuperscript{243} the use of selective reduction procedures;\textsuperscript{244} and the effectiveness of informed consent, especially as it relates to the risks to future children.\textsuperscript{245}

Creation of an entity such as the RTB would be useful in developing policies as science develops and as new ART methods are introduced. Safety and ethical concerns can be considered together in order to provide answers to questions, such as: Should a child be conceived for the purpose of being a donor for another?\textsuperscript{246} Should sex selection be permitted?\textsuperscript{247} Should parents be permitted to choose embryos with certain characteristics or "engineer" pre-embryos with certain traits?\textsuperscript{248} These concerns could be reflected in policymaking and the resulting code of practice in particular.

Although I favor the creation of an RTB, I am concerned about the scope of its power as set forth in the Reprogenetics Report. Two aspects of the report are troublesome. First, and the most troublesome, the RTB would be authorized to consider the well-being of society in addition to considering the

\textsuperscript{243}For example, initial reporting could include gestational age at birth, birth weight, any major birth defects, and a record of time spent in the Newborn Intensive Care Unit. Other indicators of health, such as medical history and enrollment in special education programs, could be used to measure the children's well-being as they grow.

\textsuperscript{244}Complete understanding of the severity of the multiples problem depends on how frequently multiples are reduced and whether they are reduced to triplets, twins, or singletons. See Mark I. Evans et al., Improvement in Outcomes of Multifetal Pregnancy Reduction with Increased Experience, 184 AM. J. OBSTETRICS & GYNECOLOGY 97, 102 (2001) (suggesting few studies have reported reliable data on risks and benefits of selective reduction).

\textsuperscript{245}Although this information would be the most difficult to obtain, the extent to which parents understand and appreciate the risks of ART should be studied and documented. Are parents warned about the risks of multiples or major defects? To what extent? In written or oral form? By the doctor or someone else? Without this information it is difficult to determine the effectiveness of this process, and the degree to which more protective intervention is necessary to protect the children of ART.

\textsuperscript{246}This was squarely posed in the case of Molly Nash, a child with Fanconi's anemia whose brother was conceived and selected to provide her with matched stem cells. See Lisa Belkin, The Made To Order Savior, N.Y. TIMES, July 1, 2001, § 6 (Magazine), at 36; see also Jim Ritter, Chicago Lab Helps Couples Create Made-to-Order Babies, CHI. SUN-TIMES, May 5, 2004, available at http://www.suntimes.com/output/health/cst-nws-baby05.html.


safety and well-being of children. The RTB should not be able to decide what is good for society because reaching a consensus on such ideals and how they should be furthered is unlikely; and intervening to preserve these ideals is likely to run afoul of the intended parents’ constitutional rights.

My second concern is the power that would be given to the RTB to grant or deny licenses to individual clinics. This power should remain with the licensing authorities that currently exist, based on the requirements of the applicable state law and professional organizations.

The RTB’s power should be limited to articulating and implementing broad policies in those areas of this field where there appears to be moral consensus as to harm; for example, to ban or limit a particular method, such as PGD, ICSI, or sex selection. This authority would be modeled after the RAC, which articulates policies and recommendations in the field of gene therapy but does not pass on particular clinical trials.

In the end, entities such as the RTAC and the RTB should be created at the federal level, but their mission should be limited to the protection of vulnerable populations from harm. This focused, principled framework for federal intervention not only furthers public policy, but also is consistent with parents’ constitutional rights.

IV. NO CONSTITUTIONAL BARRIERS TO DOUBLE-DECKER REGULATION

Procreative liberty is a bounded freedom, not an unbridled right. . . .
The reproductive interests of those who are subfertile must be weighed against the harm and wrong that fulfilling those interests might do to the resulting children, to third party participants, to these persons themselves, and to society.

Whenever regulation is proposed, particularly in an area that has not been extensively regulated previously, it is important to determine whether such

249 Reprogenetics Report, supra note 78, at S19–S20.
250 See infra Section IV.A (presenting parents’ rights potentially implicated by regulatory action).
251 Reprogenetics Report, supra note 78, at S20.
253 See Recombinant DNA, supra note 208 (discussing the RAC).
254 Cohen, supra note 71, at 359–60.
regulation would be constitutional. Specifically, it is important to analyze whether the double-decker approach to regulating ART\textsuperscript{255} would violate the intended parents' right to procreate or right to parent. This Part discusses the scope of these rights in the context of ART and articulates why the double-decker approach would not violate either right.

\textit{A. Constitutional Rights Implicated}

Most of the discussion of constitutional rights in this area has focused on whether a particular intervention or limitation violates the parents' right to procreate.\textsuperscript{256} This Section articulates why this right may not extend to certain ART decisions, and why the right to parent deserves greater consideration in this context.

\textit{1. The Right to Procreate}

The United States Supreme Court has recognized the right to procreate as a liberty interest protected by the United States Constitution.\textsuperscript{257} The Court has defined a liberty interest fairly broadly: "At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State."\textsuperscript{258} These matters include those "so fundamentally affecting a person as the decision whether to bear or beget a child."\textsuperscript{259} Although most cases before the Court have involved the "constitutional right \textit{not} to procreate,"\textsuperscript{260} it is understood that the right

\textsuperscript{255}See supra Section III.B (describing double-decker approach).
\textsuperscript{256}See Roger H. Taylor, Article, The Fear of Drawing the Line at Cloning, 9 B.U. J. SCI. & TECH. L. 379, 393 (2003) (noting lines have been drawn to protect individual right from statutory sterilization, right to be informed about and use contraception, and right not to carry fetus to term).
\textsuperscript{258}Lawrence, 123 S. Ct. at 2481 (quoting Casey, 505 U.S. at 851).
\textsuperscript{259}Eisenstadt v. Baird, 405 U.S. 438, 453 (1972); see also Skinner, 316 U.S. at 541 ("Marriage and procreation are fundamental to the very existence and survival of the race.").
extends to situations involving the right to procreate as well. See Carl H. Coleman, Assisted Reproductive Technologies and the Constitution, 30 Fordham Urb. L.J. 57, 61 (2002) (suggesting most commentators agree that Supreme Court, if called upon, would recognize constitutional right to reproduce through sexual intercourse); Judith F. Daar, The Prospect of Human Cloning: Improving Nature or Dooming the Species?, 33 Seton Hall L. Rev. 511, 546 (2003) [hereinafter Daar, Species] (noting that it is widely accepted that traditional coital reproduction is protected against governmental interference); John Robertson, Procreative Liberty in the Era of Genomics, 29 Am. J.L. & Med. 439, 453 (2003) (stating line of Supreme Court cases can be read to establish broad principle of negative reproductive freedom that encompasses right to avoid and engage in reproduction without State interference); cf. Elizabeth Price Foley, Human Cloning and the Right to Reproduce, 65 Alb. L. Rev. 625, 627 (2002) [hereinafter Foley, Right to Reproduce] (“Whether the Constitution also provides an affirmative, or positive, right to reproduce is less clear because the government has rarely acted to prevent individuals from procreating; hence, there has not been much litigation directly on point.”).

With virtually no regulation in this area, there has been little to challenge in the lower courts. Some lower court cases support the conclusion that the right to procreate extends to ART decisions. See Foley, Constitutional Implications, supra note 260, at 691–95. For example, the district court in Lifchez v. Hartigan appeared to extend the right to procreate to decisions involving ART. 735 F. Supp. 1361, 1376 (N.D. Ill. 1990), aff’d, 914 F.2d 260 (7th Cir. 1990), cert. denied, 498 U.S. 1069 (1991). The court found a statute limiting embryo experimentation unconstitutional in part because limiting certain procedures, such as embryo transfer and chorionic villi sampling, would interfere with the “zone of privacy” that includes “the right to submit to a medical procedure that may bring about . . . pregnancy.” Id. at 1377. I have serious reservations as to whether the United States Supreme Court would extend the right to procreate this broadly. The Lifchez court applied a broader definition of rights that existed before Casey was decided, and the Court used a definition of harm that is not widely accepted. See infra Section IV.B.2.(a) (arguing that Professor John Robertson’s definition of harm, cited with approval in Lifchez, does not sufficiently protect children).

See Foley, supra note 261, at 61 (discussing Court’s precedent relating to right to procreate); see also Foley, Right to Reproduce, supra note 261, at 630 (posing that whether right to reproduce extends to IVF and other ARTs “is a matter of conjecture to which one can only make an educated guess”).

There are a number of reasons to doubt whether the right to procreate extends far enough to encompass ART decisions. First, ART does not affect the right to bodily integrity. The right to procreate is strongest when it involves invasions of bodily integrity, not simply interference with private decision making. For example, a woman’s right to obtain an abortion is grounded in a serious concern that, if this right were denied, a woman would be forced to carry a child to term against her will. In contrast, most ART decisions are...
made before the pre-embryo is ever implanted in a woman’s uterus.\textsuperscript{264}

Second, ART does not involve a right that has been traditionally protected. ART has existed for only twenty-five years.\textsuperscript{265} Moreover, ART often occurs outside the traditional marital unit of husband and wife and frequently involves third parties, such as gamete donors or surrogates, who are not members of the family.\textsuperscript{266} Therefore, if tradition were considered essential to recognizing a constitutional right to privacy (which the Court has suggested),\textsuperscript{267} then ART would either not be protected at all, or only protected in limited circumstances—such as when technology is used to assist a married couple in doing what they could not do naturally: engage in coital reproduction.\textsuperscript{268}

\textsuperscript{264}See Judith F. Daar, Assisted Reproductive Technologies and the Pregnancy Process: Developing an Equality Model to Protect Reproductive Liberties, 25 AM. J.L. & MED. 455, 466 (1999) (discussing courts’ willingness to override reproductive rights of infertile women whose embryos are conceived in vitro, because such women lack direct physical relationships with their developing or cryopreserved embryos); Radhika Rao, Reconceiving Privacy: Relationships and Reproductive Technology, 45 UCLA L. REV. 1077, 1112 (1998) (stating that “[b]odily integrity does not guarantee infertile persons the right to conceive with the assistance of reproductive technologies and reproductive collaborators because such procedures do not prevent any invasion of the body”); cf. Thomas Stuart Patterson, Note, The Outer Limits of Human Genetic Engineering: A Constitutional Examination of Parents’ Procreative Liberty to Genetically Enhance Their Offspring, 26 HASTINGS CONST. L.Q. 913, 928 (1999) (concluding that bodily integrity plays no role in genetic engineering and that personal autonomy of women will not be affected by inability to genetically engineer children).

The first baby born using in vitro fertilization was Louise Brown in 1978. See Duenwald, supra note 5, at F5.

Single mothers and gay and lesbian couples have increasingly been resorting to reproductive technology to have children of their own. See James Arth, Responding to the Trend: Representing Same Sex Couples and Sperm Donors in Assisted Conception, TEXAS LAWYER, July 22, 2002, at 23; Eilis Lotozo, Gay and Lesbian Parents Fueling a ‘Gayby Boom’, PHILA. INQUIRER, June 29, 2003, at A01.


\textsuperscript{265}See Massie, supra note 267, at 162 (“[A]ssisted reproduction does not directly implicate the values—bodily integrity, marital intimacy, or integrity of the family unit—that are central to the privacy cases.”). But see Coleman, supra note 261, at 65–66 (finding it likely that Court would extend right to procreate to some forms of ARTs, particularly those that enable married couples to reproduce using their own gametes); Robertson, supra note 261, at 454 (asserting Court would likely grant protection to some reproductive and genetic technologies, if such cases involving them arose); Sunstein, supra note 267, at 992 (stating good reasons exist to question whether tradition should be exclusive basis for special protection).
Notwithstanding these arguments, the Court could conclude that the right to privacy extends to ART, reasoning that the Constitution protects any reproductive decision making and recognizes rights that are not traditional. Under this reasoning, the Constitution also should protect any couples who are trying to create a family and are unable to do so on their own.

Yet, even if the Court extended the right to procreate to ART, it is unclear what level of scrutiny would apply. Some commentators have concluded that the Court would permit the state to regulate ART as long as it did not “unduly burden” the right to procreate—an approach consistent with Planned Parenthood v. Casey. Others have concluded that the Court would allow the state to interfere in the parents’ decisions only if the strict scrutiny standard is satisfied: the state must possess a compelling state interest and only use means narrowly tailored to further that interest. Under this standard, the Constitution would probably tolerate some limited regulation of ART. Even if the right to procreate were not a significant barrier to regulating ART—

269 See Daar, Species, supra note 261, at 546 (noting there is some indication that courts would view certain forms of assisted reproduction on equal footing with traditional reproduction); see also David Orentlicher, Cloning and the Preservation of Family Integrity, 59 La. L. Rev. 1019, 1036–37 (1999) (arguing tradition is not final test because rights, such as abortion and contraception, which are not deeply rooted in tradition, are protected and suggesting absence of traditional opposition by state and federal government counteracts tradition argument of ban on asexual reproduction).


271 See Coleman, supra note 261, at 66, 67 (arguing that “the Court’s prior decisions have emphasized the importance of decisions about having and raising children, not the relationship between reproduction and sexual intimacy”). The Court has applied the standard of undue burden in other cases involving abortion rights. See Stenberg v. Carhart, 530 U.S. 914, 938–46 (2000) (applying undue burden standard in finding partial birth abortion statute unconstitutional).

There is also support for applying an intermediate level of scrutiny to ART decisions. See Foley, Right to Reproduce, supra note 261, at 645–46 (considering multi-tiered approach that would permit some regulation of ART); Sunstein, supra note 267, at 995 (noting lower level of scrutiny warranted for regulation other than ban).

272 See ROBERTSON, CHILDREN OF CHOICE, supra note 270, at 36–37; see also Foley, Constitutional Implications, supra note 260, at 719, 721–26 (explaining why “a law that banned all human cloning would . . . fail strict scrutiny”); Stephanie J. Hong, And ‘Cloning’ Makes Three: A Constitutional Comparison Between Cloning and Other Assisted Reproductive Technologies, 26 Hastings Const. L.Q. 741, 754, 761 (1999) (arguing that ARTs are “likely constitutionally protected forms of reproduction which may only be infringed upon with a showing of compelling state interest”).

For a discussion of Professor Robertson’s view of strict scrutiny, see infra Section IV.B.2(a); see also Sunstein, supra note 267, at 994–95 (suggesting that strict scrutiny should apply to limits on practices that would resemble ban on assisted reproduction, cutting off all realistic means to procreate).

273 See infra Section IV.A.2 (analyzing parental rights under strict scrutiny standard); see also Massie, supra note 267, at 159–70 (arguing that any procreative liberty interest that might exist would be outweighed by child’s best interests, broadly defined).
either because the right does not exist or because it could be overcome by a sufficiently strong state interest—the right to parent would impede regulation. For the reasons that follow, the right to parent actually may be the stronger of the two rights in this context.

2. *The Right to Parent*

It is well established that parents possess the constitutionally protected right to the care, custody, and control of their children. This right allows parents to make decisions on behalf of their children until they reach the age of majority, with few exceptions. This fundamental right was recognized even before the right to procreate—in fact, the right to procreate, first articulated in *Griswold v. Connecticut*, is derived from the earlier parental rights cases of *Meyer v. Nebraska* and *Pierce v. Society of Sisters*. Integral to the strength of this right is the presumption that parents act in their child’s best interests. The State can interfere with parental decisions only when it has a compelling interest and the regulation is narrowly tailored to serve that interest.

Decisions in the context of ART are as much parental as they are procreative; perhaps, even more so, as technology gives parents greater control over their children’s lives before they are born. When children are conceived through ART—especially when IVF is used together with PGD—the intended parents are not just making decisions about “whether to bear or beget a child.” Rather, they are making parenting decisions about the kind of family they will create and the quality of life their children will lead. For example, by consenting to IVF through implantation of two or more pre-embryos or consenting to ovulation stimulation where the likelihood of multiples is high, the intended parents are expressing their willingness to raise multiples, with the added expense and energy necessary to raise two or more children of the same age. The intended parents also are presumed to express a willingness to

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275 381 U.S. 479, 484 (1965).

276 262 U.S. 390, 400–01 (1923).


280 See supra notes 20 and 247 and accompanying text (discussing preconception gender selection and noting physical disabilities and health problems that sometimes result from ART).

281 Out of all live births that resulted from ART in 2001 (as defined by CDC to include IVF and ICSI), thirty-five percent resulted in multiple-infant live births. CDC REPORT 2001, supra note 1, at 20 (using fresh, non-donor eggs). See infra notes 311–17 (discussing risk of multiples).

282 See, e.g., Elster, supra note 137, at 619 (discussing difficulties associated with multiple births); I. Nisand & F. Shenfield, *Multiple Pregnancies and Embryo Reduction: Ethical and
care for children with special needs, as it is more likely that the children of ART (whether singletons or multiples) will be born at LBW or with congenital abnormalities that require treatment.283

With advancing technology, parents’ pre-birth decisions increasingly impact the child’s future and quality of life. By using IVF and PGD together, for example, intended parents can select pre-embryos with traits that inexorably will affect the child’s identity, such as: whether the child will be born disabled;284 whether the child is likely to develop a debilitating disease later in life;285 whether the child will be a boy or a girl;286 or whether the child will be born with a certain eye, hair, or skin color.287

Because decisions made in the context of ART are crucial for determining the quality of life for the children who are ultimately created, it is appropriate to categorize these decisions as parental. In addition, as the decision making process becomes less about choosing whether to have a child at all and more about deciding what kind of child the couple will have, guiding principles will be needed that are broad enough to apply to all of these decisions and to evaluate regulations in this area. The parental rights doctrine, a subset of the family law paradigm, provides these guiding principles.

According to the parental-rights doctrine, parents deserve deference in decisions made on behalf of their children, and the government (state or federal) is limited in its ability to interfere with these decisions. Parental rights are not absolute, as the government can issue narrowly tailored regulations that further a compelling interest.288 Preventing harm to children is one of the few interests recognized as sufficiently compelling.289

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283 See infra notes 315–18 and accompanying text (discussing studies that demonstrate harm caused by ART). See generally White & Leuthner, supra note 136, at 226 (“Parents are faced with the unusual demands of raising a large number of same-age siblings, some of whom may present special developmental challenges as a result of prematurity.”).

284 See supra notes 9–16 (discussing IVF and PGD technological abilities to determine genetic diseases in pre-embryos before implantation occurs and thereby avoiding birthing impaired or disabled children).

285 See supra notes 11–14 and accompanying text (discussing use of ART to screen embryos for debilitating diseases).


287 See Silver, supra note 99, at 83 (relating future scenario of parents choosing appearance of their daughter). See generally supra note 248 (discussing ability to “engineer” pre-embryos in order to achieve certain traits).

288 See supra notes 271–72 and accompanying text (discussing standard).

289 See infra notes 290–93 and accompanying text (discussing state’s justified interference when safety of children is at stake).
However, to interfere with parental decision making, it is not enough for the government simply to recite the mantra of preventing harm to children. The child must actually be suffering from serious physical or emotional harm—fear of harm is not enough and neither is minor harm. The State must assess the harm to each child individually.

It is well-established that the government can interfere with parental rights when necessary to protect children from serious physical and emotional harm. The State accomplishes this goal primarily through its child abuse and neglect laws, augmented by laws relating to adoption, custody, and child support. In general, the harm must be both serious and imminent before intervention is permitted: for example, a child may be removed when parents have physically injured the child and it appears that they are likely to do so again.

However, if the perceived harm is improbable or minor, intervention is unwarranted. Moreover, the State generally cannot interfere to prevent future harm. For example, even though Christian Science parents do not believe in giving traditional medical care to their children, the State ordinarily does not intervene until the child has already become ill, medical care has been denied, and the child’s condition has become serious (life-threatening). Because of the parental rights doctrine, our society is willing to tolerate even fatalities that the State might have prevented if it had intervened earlier. Although it is

290 See Rosato, Using Bioethics, supra note 274, at 8; see also In re Tara Cabrera, 552 A.2d 1114, 1120 (Pa. Super. Ct. 1989) (holding state’s interest in protecting children from possible death overrode parents’ religious objections to their child’s blood transfusions). See generally Prince v. Massachusetts, 321 U.S. 158, 170 (1944) (stating that although parents are given substantial rights to rear their children, they are not permitted to make “martyrs” out of them).
292 See id. § 9.4 (discussing child abuse and neglect).
295 See supra Section IV.A.2 (discussing parental rights doctrine).
296 Parents have been prosecuted after a sick child’s death. Walker v. Superior Court, 47 Cal. 3d 112, 139–41 (1988) (affirming conviction of involuntary manslaughter and child endangerment charges resulting from death of four-year-old daughter due to meningitis when parents substituted modern medicine for spiritual healing due to membership in Church of Christ, Scientist), cert. denied, 491 U.S. 905 (1989); State v. Hays, 964 P.2d 1042, 1045–47 (Or. Ct. App. 1998) (affirming conviction of criminal negligent homicide when father failed to treat
often said that the State protects the "best interests of the child," that is not true when the child has parents who speak for him or her. The State can act only to prevent infliction of serious harm.

The government is even more reluctant to intervene in parental decisions before the child is born, even though some intervention probably would improve the child's welfare. Courts have refused to order cesarean sections against a pregnant mother's will, even if needed to protect the future child's health.298 Courts also have been reluctant to intervene in cases involving mothers who take drugs while they are pregnant,299 although courts are less reluctant to protect the child once she is born.300

This reluctance to interfere with pre-birth decisions is attributable to a number of reasons: even if the fetus is considered viable, it is usually not

his son for leukemia due to his membership in Church of First Born), cert. denied, 527 U.S. 1006 (1999).

298 See In re A.C., 573 A.2d 1235, 1237 (D.C. 1990) (holding that patient who is near death with viable fetus is entitled to make all medical decisions regarding herself and her baby, unless patient is incompetent); In re Baby Boy Doe, 632 N.E.2d 326, 326 (Ill. App. Ct. 1994) (honoring woman's choice not to undergo cesarean section, although refusal might result in harm to the fetus). But see Pemberton v. Tallahassee Mem'l Reg'l Med. Ctr., Inc., 66 F. Supp. 2d 1247, 1254 (N.D. Fla. 1999) (holding mother's constitutional rights not violated when court order granted hospital petition to perform cesarean section in interest of unborn child).

Recently, a woman was charged with murder for failing to undergo a cesarean section. Prosecutors argued the cesarean section could have prevented the stillborn death of one of her twins. Pamela Manson, Mother is Charged in Stillborn Son's Death, SALT LAKE TRIB., Mar. 12, 2004, at A1. The state agency had determined it lacked jurisdiction before the twins' birth. Id.

299 See In re Unborn Child of Starks, 2001 OK 6, ¶ 19, 18 P.3d 342, 348 (Okla. 2001) (holding state statute inapplicable to fetus and thus that state could not regulate mother's prenatal conduct).


considered a “person” under the law;\textsuperscript{301} it is difficult to determine how the pregnant mother’s decisions will affect the child; and, during pregnancy, the mother’s right to bodily integrity is strong.\textsuperscript{302}

Although ordinarily the government is not permitted to intervene in parental decisions unless serious harm actually has occurred or is imminent, in narrow circumstances it can protect a group of at-risk children from future harm. One of these circumstances is when parents possess a conflict of interest that might impair their ability to look out for the child’s best interests. The rationale behind this categorical conflict exception\textsuperscript{303} is that the conflicted parents are unable to put their children’s needs above their own so that the presumption in favor of parental decisions can no longer apply.\textsuperscript{304} The parents are essentially disqualified from acting as primary decision makers, and the State, then, can act to protect this group of at-risk children from harm.

When a categorical conflict exists, courts give greater protection to every child within the category and do not require the State to consider the individual child’s circumstances.\textsuperscript{305} For example, parents are limited in their ability to volunteer their children as organ donors\textsuperscript{306} or research subjects,\textsuperscript{307} or to provide consent for their daughters’ involuntary sterilizations.\textsuperscript{308} The overriding concern in these types of cases is that the parental decision makers may be concerned about something or someone else besides the subject child; for example, in donation, parents might prioritize the needs of other children; in research, they might be lured by compensation; or in sterilization, they might want to act to lessen their burden of caring for a handicapped or seriously ill child.\textsuperscript{309}

\textsuperscript{301}See supra notes 124–27 and accompanying text (discussing status of fetus, within context of abortion debate).
\textsuperscript{302}See supra notes 257–64 (discussing strength of right to procreate when it involves invasions of bodily integrity rather than mere private decision making).
\textsuperscript{303}I have previously designated categorical conflicts as types of cases where the risk of a family member’s conflict of interest, when decision making, is so high that court intervention is necessary. See Rosato, Using Bioethics, supra note 274, at 43–46. A situational conflict, which is fact-based, arises when the decision maker’s ability to decide the patient’s best interests has been impaired severely in a particular case. Id. A situational conflict can be emotional, value-based, or financial. Id.
\textsuperscript{304}See id. at 43 (explaining rationale for conflict of interest exception).
\textsuperscript{305}Id.
\textsuperscript{306}See id. at 57–58, 58 nn.345 & 348–50.
\textsuperscript{308}See Rosato, Using Bioethics, supra note 274, at 58–60 (discussing parents’ conflict in forced sterilization context).
\textsuperscript{309}Id. at 59 n.355 (citing cases).
Where a categorical conflict of interest is identified, the State can limit the parents’ decision making powers in ways not otherwise tolerated. The State may disqualify the parent from making the decision at all, or may require the parent to seek approval of a neutral party before making a decision.

B. Why Constitutional Rights Are Not Violated

The double-decker approach to regulation is crafted carefully to ensure protection of the parents’ constitutional rights. The proposal is limited in a variety of ways: a categorical conflict must exist; probability of serious harm must be shown; and the conduct of third parties, not parents, is circumscribed. These limitations help to ensure that strict scrutiny is satisfied and that regulation is focused on protecting vulnerable populations.

1. Limited to Categorical Conflict

One fear of regulation has been that, if the State begins to regulate ART, it may subject many decisions of future parents to governmental scrutiny. For example, could carriers of cystic fibrosis be prevented from having a child because of the risk of having a child afflicted with the disease? Could the State penalize a mother over fifty years old for having a child, because the risk of defects is significantly higher when mothers are older? Would the State require a mother of a severely handicapped child to abort? The answer to these questions is no. These parents are not inherently conflicted and no third parties are involved; thus, the State cannot step in and prevent the children from future harm.

In contrast, intended parents engaged in the process of ART—whether IVF, ICSI, or ovulation stimulation—are categorically conflicted. The “emotional vortex” experienced by the parents causes them to obsess about conceiving, rather than carefully considering the quality of life of the children.

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310See id. at 20–22 (precluding parents from making most treatment decisions for critically ill newborns). Recently, however, courts increasingly hear cases dealing with a hospital’s refusal to follow parents’ wishes regarding their critically ill newborns. See Megan Anne Jellinek, Note, Disease Prevention and the Genetic Revolution: Defining a Parental Right to Protect the Bodily Integrity of Future Children, 27 HASTINGS CONST. L.Q. 369, 385 n.103 (2000) (noting that there has been increased judicial support for parental decision making, especially in cases where hospital’s resuscitation severely compromises bodily integrity of infant); cf. HCA, Inc. v. Miller, 36 S.W.3d 187, 187 (Tex. App. 2000) (reasoning that it cannot recognize exception to general rule imposing liability on physician for treating disabled infant without consent when determination of health of child not made until after child’s birth or if child born in emergent circumstances), aff’d, 118 S.W.3d 758 (Tex. 2003).

311See generally Rosato, Using Bioethics, supra note 274, at 58–60 (discussing court approvals required for involuntary sterilizations).

312Waldman, supra note 96, at 923.
they are creating.\textsuperscript{313} "The power of wishful thinking obscures rational deliberation."\textsuperscript{314} This conflict is exacerbated by the fertility doctors, who are looking out for their own interests rather than those of the children. As a result of this synergistic "economic and emotional vortex," the parents inadvertently may risk the lives of their future children.

Specifically, parents may make high-risk decisions they would not otherwise have made. They may use ovulation stimulation, which is more likely to produce super-multiples,\textsuperscript{315} agree to implant more than three embryos in one IVF cycle, proceed with ICSI even when chromosomal abnormalities are found in the father’s sperm,\textsuperscript{316} or refuse to selectively reduce the number of implanted embryos even though it would enhance the well-being of the remaining embryos.\textsuperscript{317}

The health-care provider likely will not alleviate this parental conflict. As previously discussed,\textsuperscript{318} the provider is in a vortex of its own creation, primarily concerned with the success rates of its program. In this position, providers are more likely to take unwarranted risks and the industry is likely to continue resisting regulation of its practices.

Because intended parents possess a categorical conflict when making ART decisions, the State may justifiably regulate to prevent harm before it occurs. At the same time, because of the risk of infringing on parental rights, the State must take care to define "harm" in a manner that adequately protects the children of ART but also respects the rights of the parents.

2. Limited Definition of Harm

Even when a categorical conflict exists, harm should justify intervention only when a method or application of a method would result in a significant risk of serious physical or emotional harm. This definition is satisfied at the state level by limiting practices that have been shown to harm children or to

\textsuperscript{313} See \textit{id.} (reporting infertile couples' experience with ART as "profoundly disorienting and wrenching"). See \textit{generally} Council, \textit{Reproduction Report}, supra note 45, at ch. 2 (pointing out that interests of parent and future child are not co-extensive, and that existing ASRM guidelines "make no allowance for any conflict of interest in this regard").

\textsuperscript{314} \textit{Id.} at 923–24.

\textsuperscript{315} See supra notes 281–82 and accompanying text (discussing risk of multiples).

\textsuperscript{316} See J.C. Giltay et al., Subfertile Men with Constitutive Chromosome Abnormalities Do Not Necessarily Refrain from Intracytoplasmic Sperm Injection Treatment: A Follow-Up Study on 75 Dutch Patients, 14 HUM. REPROD. 318, 319–20 (1999) (reporting that all seventy-five couples whose ICSI resulted in abnormal children had been counseled about increased risk).

\textsuperscript{317} See supra note 190 (describing technique of selective reduction and parents' reluctance to reduce).

\textsuperscript{318} See supra note 312 and accompanying text (discussing "emotional vortex" and doctors' conflicts of interest).
have a significant probability of harming children seriously, such as causing them to be born as a clone or as a multiple.

\(\text{(a) The "Rights-based" View of Harm: Too Narrow}\)

The "rights based" view of harm, articulated by Professor John Robertson, is insufficiently protective of children's welfare. Professor Robertson consistently has expressed the view that the right to procreative liberty is quite strong (even when assisted reproduction is used), and therefore governmental intervention in ART decisions should be strictly limited\(^{319}\) to situations where there is tangible harm to the interest of others.\(^{320}\) For harm to children to be sufficiently tangible, he believes that there must be proof of harm, and it appears that the harm must be physical.\(^{321}\) It further appears that merely a probability of harm (even to a group of children) would not be enough.\(^{322}\) Therefore, in most instances, the parents' decisions must be respected—even if they choose HRC as an ART.\(^{323}\)

I consider the tangible harm standard, which Professor Robertson proposes, to be insufficiently protective of children's interests. Because of children's vulnerability and the State's important role as parens patriae, waiting until a track record of harm exists is too late for intervention when a conflict of interest already exists. As long as there is a significant likelihood of harm, some intervention should be justified. Moreover, the harm can be physical or emotional.

\(^{319}\)See supra notes 258–68 and accompanying text (discussing strength of right to procreate); see also John A. Robertson, The Question of Human Cloning, in ETHICAL ISSUES IN HUMAN CLONING 207, 211, 221–22 (Michael C. Brannigan ed., 2001) [hereinafter Robertson, Question of Cloning] (arguing that regulation of ART decisions should be subject to strict scrutiny).


\(^{321}\)Robertson, Question of Cloning, supra note 319, at 220–21. Psychological or social harm does not rise to the level of harm worthy of government interference, but prenatal alcohol, drug, and tobacco abuse does. ROBERTSON, CHILDREN OF CHOICE, supra note 270, at 121–22.

\(^{322}\)Id.

\(^{323}\)Professor Robertson's view is exemplified by his qualified support for HRC. See, e.g., Robertson, Two Models, supra note 320, at 618–27 (arguing for procreative freedom to extend to reproductive cloning absent showing of substantial harm). He views cloning as an infertility treatment, at least for some couples, and considers the articulated risks to children to be speculative. Robertson, Question of Cloning, supra note 319, at 217–18. He seems to have faith that children, once born, will be loved by the families, regardless of how they were conceived. Id.; Robertson, Two Models, supra note 320, at 623–24. He seems skeptical about the projected psychological risks to cloned children, including fears of insecurity and confusion over their identities. Robertson, Question of Cloning, supra note 319, at 217–18; Robertson, Two Models, supra note 320, at 622–23.
(b) The “Open Future” View of Harm: Too Broad

The “open future” view of harm, on the other hand, is too broad. Essentially, to limit a child’s open future is to limit a child’s autonomy by limiting the paths she can choose before reaching adulthood. Under this theory, parental decision making should be limited whenever it would “substantially and irrevocably” limit the “child’s right to an open future.”

Professor Dena Davis has applied this definition in the context of ART. She conceptualizes genetic decisions that parents must make (including ART and the genetic testing of children) as a conflict “between parental autonomy and the child’s potential autonomy.” When the child’s right to an open future is threatened by these decisions, parental autonomy must yield to the child’s autonomy. For example, deaf parents should not be able to choose to have a deaf child, because it denies the child the ability to function in a hearing world, and parents should not be able to choose the sex of their child because they are limiting their child’s choices through gendered expectations.

Although well-intentioned and child-centered, Professor Davis’ view is inconsistent with the realities of parent-child relationships and the existing family law paradigm. Parents have the right to limit their children’s right to an open future in a myriad of ways deeply embedded in constitutional and family law. For example, parents are permitted to raise their children in insular religious communities—whether Christian Scientist or Amish—even though

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325 Id. at 561–67.

326 Dena S. Davis, Genetic Dilemmas: Reproductive Technology, Parental Choices, and Children’s Futures 32 (2001) [hereinafter Davis, Genetic Dilemmas]; see also Davis, Open Future, supra note 324, at 567.

Professor Lori Andrews seems to use a similar rationale to justify a ban on cloning. Andrews & Elster, supra note 2, at 63. In her view, cloning would expose the child to “limited experiences and limited opportunities.” Id. This is a different kind of harm than the tangible, physical harm that Professor Robertson refers to, because the situations that Professor Andrews seems concerned about might not cause tangible harm to the child but would lead to “[a]buses of power” by parents over their children. Id. at 63–64 (quoting Francis C. Pizzuli, Note, Asexual Reproduction and Genetic Engineering: A Constitutional Assessment of the Technology of Cloning, 47 S. Cal. L. Rev. 476, 497 (1974) (internal quotation marks omitted)).

In my view, to allow intervention to prevent an abuse of power is vague and not sufficiently respectful of the parental interests implicated. There is a risk of abuse of power inherent in any parent-child relationship, but the risk is usually diminished by the belief that, in the end, parents will act out of love for their children and will consistently do what is best for them. See supra note 278 (citing sources discussing presumption that parents act in their children’s best interests).

327 Davis, Genetic Dilemmas, supra note 326, at 23; see also Davis, Open Future, supra note 324, at 563 (positing that parents can violate children’s rights by cutting off opportunity to exercise those rights in future).

328 See Davis, Genetic Dilemmas, supra note 326, at 65, 105–06; Davis, Open Future, supra note 324, at 591.
such an upbringing is likely to limit their children’s life choices outside those communities.\textsuperscript{329} Parents are also permitted to make their children into athletes and actors (early in life) to the exclusion of all other opportunities.\textsuperscript{330}

Limiting choices in this way may be undesirable, but it is not unlawful. Our legal system is founded on the premise that parents make the best decisions on behalf of their children, and they must be given a protected zone of privacy to make those decisions. Recent proposals to regulate ART seem to be based on a broad view of harm—the Reprogenetics Report includes proposals to further children’s and societal “well-being,”\textsuperscript{331} and the Council has proposed recommendations intended to satisfy broad principles.\textsuperscript{332} Both efforts go further than needed to prevent harm to children and, thus, would result in excessive intrusion into the family.

(c) A “Significant Risk” View of Harm: Just Right

Ultimately, the definition of harm in this context must strike a delicate balance by protecting children while respecting the parents’ decision making authority. Existing abuse and neglect laws reflect this balanced approach. Actual harm usually must be shown, unless the parents possess a conflict of interest. If a conflict exists, then a lesser showing is permitted: state intervention is justified if the parental decision would pose a significant risk of serious physical or emotional harm.

Although the risk of harm need not be imminent, it should be at least significant and serious. An undefined fear, or one that would not result in serious injury, is insufficient.\textsuperscript{333} Based on the available medical literature, some

\textsuperscript{329}See Wisconsin v. Yoder, 406 U.S. 205, 229–31 (1972) (holding state cannot force Amish parents to send their children to high school).

\textsuperscript{330}See, e.g., TONY CASTRO, MICKEY MANTLE: AMERICA’S PRODIGAL SON 13–14, 18 (2002) (stating that after naming him after baseball hall-of-famer, Mantle’s father taught him to switch-hit as toddler and directed him in his career); Greg Couch, Just Blame Trend on 2 Fanatic Fathers: Woods and Williams Give New Meaning to Parental Pressure, CHI. SUN-TIMES, June 20, 2002, at 119 (reporting that fathers of Tiger Woods and Serena and Venus Williams had their children practicing their future professional sport at three and one-half and four years of age, respectively); Whatever It Takes: In Pursuit of the Perfect 10, at http://www.cnn.com/CNN/Programs/presents/index.perfect.10.html (last visited Mar. 3, 2004) (reporting that preparation for competitive gymnastics begins with girls as young as two years old and becomes focus of young woman’s life); see also Bruce Gierson, Spellbound, N.Y. TIMES, Sept. 1, 2002, § 6 (Magazine), at 48 (relating story about parents preparing their children for spelling bee competitions, to exclusion of other experiences).

\textsuperscript{331}Reprogenetics Report, supra note 78, at S3–S7.

\textsuperscript{332}See supra Section III.B.2.(a) (discussing Council’s recommendations).

children of ART are likely to suffer serious physical harm as a result of their parents' decisions.\textsuperscript{334}

3. Regulation Limited to Third Parties

The final limitation to prevent a slippery slope is to focus any regulation or oversight on third parties. By focusing on the health-care provider's methods rather than the parents' decisions, the risk of infringement is lessened considerably.

The proposed statewide bans on cloning are intended to prevent providers from making this method available to parents altogether, and the limitation on the number of implantations also constrains the doctor's conduct: doctors will not be able to give parents the option of implanting more than three pre-embryos, except in exceptional circumstances. Any federal legislation proposed by the RTAC or policies articulated by the RTB will focus on restricting the fertility industry with direct prohibitions on parental choices as the last resort.

Also, the double-decker approach is narrowly focused on the harm to vulnerable populations, thus permitting most infertile couples to take full opportunity of the available methods. The federal constitution does not give every couple an unfettered right to procreate. Considered along with the more balanced definition of harm set forth above, any infringement on parental rights is unlikely.

V. CONCLUSION

The objective of this Article has not been to make the case that ART should be banned. Many healthy children have been born to loving families using these methods. However, these important decisions must be made more responsibly than in the past to ensure the safety and well-being of future children. Focused state regulation and federal oversight of developing technologies are central to remedying the problems created by the lack of regulation over the last twenty-five years.

\textsuperscript{334}\textit{See supra} Section III.A (offering evidence of harm caused by ART).