REGULATING MULTIPLE BIRTH PREGNANCIES: COMPARING THE UNITED KINGDOM'S COMPREHENSIVE REGULATORY SCHEME WITH THE UNITED STATES' PROGRESSIVE, INTIMATE DECISION-MAKING APPROACH

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INTRODUCTION

On January 26, 2009, Nadya Suleman made history by giving birth to the first set of *surviving* octuplets.[1] The proud staff at Kaiser Permanente Bellflower Medical Center in Bellflower, California announced the amazing news that the eight infants weighed between "1lb 8 ounces (820g) and 3lb

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1. *US Woman Gives Birth to Octuplets*, BBC NEWS, Jan. 27, 2009, http://news.bbc.co.uk/2/hi/americas/7852623.stm.

4oz (1.47kg)," and were "doing well."[2] However, public opinion quickly turned from joy to horror when it was revealed that Nadya Suleman was single, unemployed,[3] and living with her parents.[4] Furthermore, she already had six children conceived by in vitro fertilization ("IVF"), and several of them were disabled.[5] The American public was further outraged to learn Nadya supported her six children on food stamps and public assistance.[6] Nadya then dropped another bombshell: Doctor Michael Kamrava, who performed all of Nadya's IVF treatments, had implanted her with six embryos,[7] well above the American Society for Reproductive Medicine's ("ASRM") recommendation of one to two embryos for women under thirty-five.[8] Doctor Kamrava was then subject to an investigation by the Medical Board of California,[9] and he was expelled from ASRM for "repeatedly violat[ing] the group's standards [of care]."[10] Meanwhile, Nadya Suleman remains the mother and primary caretaker of fourteen IVF children.

The Octomom drama brought Assisted Reproductive Technology ("ART"), IVF, and the problem of multiple birth pregnancies to national attention. In contrast to most European countries, ART in the United States is subjected to *limited* state and federal regulations.[11] For years, some legal scholars have called for legislators to fill this regulatory void, and prevent desperate baby-obsessed parents and unethical physicians from harming

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2. *Id.*

3. *Octuplets' Mom "Obsessed" with Having Kids*, CBS NEWS, Jan. 31, 2009, http://www.cbsnews.com/stories/2009/01/31/earlyshow/health/main4766068.shtml.

4. *Octuplets' Family Facing Foreclosure Threat*, FOX NEWS, Feb. 19, 2009, http://www.foxnews.com/story/0,2933,496169,00.html.

5. *Id.*

6. *Id.*; *Accord Octuplet Mom Nadya Suleman Receives Death Threats, Los Angeles Police Investigating*, ASSOCIATED PRESS, Feb. 12, 2009, http://www.foxnews.com/story/0,2933,491806,00.html; *PR Firm Drop 'Octomom' Amid Death Threats, Others Not Interested*, ASSOCIATED PRESS, Feb. 18, 2009, http://www.foxnews.com/story/0,2933,495329,00.html; *Octuplets' Mom on Welfare, Spokesman Confirms*, FOX NEWS, Feb. 10, 2009, http://www.foxnews.com/story/0,2933,490269,00.html.

7. *Octuplet Birth Doctor Under Investigation*, ASSOCIATED PRESS, Feb. 7, 2009, http://www.usatoday.com/news/nation/2009-02-06-octuplets_N.htm.

8. ASRM PRACTICE COMMITTEE, GUIDELINES ON NUMBER OF EMBRYOS TRANSFERRED 1 (2009), *available at* http://www.asrm.org/Media/Practice/Guidelines_on_number_of_embryos.pdf [hereinafter GUIDELINES ON NUMBER OF EMBRYOS TRANSFERRED].

9. *Octuplet Birth Doctor Under Investigation*, *supra* note 7.

10. Nick Allen, *Octomom's Dr. Michael Kamrava Expelled from American Society for Reproductive Medicine*, TELEGRAPH, Oct. 19, 2009, http://www.telegraph.co.uk/news/newstopics/celebritynews/6380099/Octomoms-Dr-Michael-Kamrava-expelled-from-American-Society-for-Reproductive-Medicine.html; *see also* Press Release, American Society for Reproductive Medicine, ASRM Reacts to Latest News About California Octuplets (Feb. 9, 2009), *available at* http://www.asrm.org/news/article.aspx?id=628 [hereinafter ASRM Reacts to Latest News].

11. *See* Robert L. Stenger, *The Law and Assisted Reproduction in the United Kingdom and the United States*, 9 J.L. & HEALTH 135, 135–39(1995); *see also* Ouellette et al., *Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, 31 AM. J.L. & MED. 419, 419–35 (2005).

America's children and society at large. The Octomom media drama and backlash against Nadya and Doctor Kamrava has fueled renewed calls for regulation.[12] However, prior to calling for further regulation, submitting ad hoc proposals to regulate ART, or drafting a comprehensive regulatory scheme similar to the one adopted in the United Kingdom, scholars, legislators, and public policy groups need to distance themselves from the Octomom drama. The questions they should be asking themselves are: (1) what specific area of ART are they thinking about regulating; (2) is regulation necessary; and (3) what constitutional rights, if any, are affected by these proposed regulations?

This Note addresses regulations that seek to prevent multiple birth pregnancies by restricting the number of embryos implanted during IVF treatments. In addition, it focuses on the regulation of multiple birth pregnancies rather than the regulation of ART as a whole because each ART treatment presents its own set of risks, and moral and ethical concerns. Part I gives a brief summary of ART terminology, the increasing use of ART to conceive children in the United States, and the problems associated with multiple birth pregnancies. Part II addresses the history of IVF treatments in the United Kingdom, and its "Single Embryo Transfer" ("SET") policy. Part III discusses IVF regulations in the United States, self-regulation by medical societies, physicians, and patients, and the problems associated with regulating IVF treatments. Finally, Part IV concludes that even in the face an increasing demand for IVF treatments, the United States cannot and should not adopt the United Kingdom's SET policy because (1) the regulation of this medical treatment is unnecessary, as there are sufficient ethical, medical, and economic safeguards already in place to protect ART physicians, patients, and children; and (2) the regulation of this medical treatment affects a person's ability to have a child, and thus, it violates his or her fundamental right to procreate, which is protected by the Due Process Clause of the Fourteenth Amendment. In order to effectively reduce the rate of multiple birth pregnancies, I propose our resources would be better allocated if public funds were spent to raise awareness among patients and physicians about the dangers associated with multiple birth pregnancies, and to further research IVF treatments.

I. ART

A. Terminology

ART is defined by the Center for Disease Control and Prevention ("CDC") as "[a]ll treatments or procedures that involve surgically removing eggs from a woman's ovaries and combining the eggs with sperm to help a

12. *See* S.B. 169, 150th Gen. Assem., Reg. Sess. (Ga. 2009); *see also* H.B. 810, 95th Gen. Assem., 1st Reg. Sess. (Mo. 2009).

woman become pregnant."[13] These procedures include IVF, "[a]n ART procedure that involves removing eggs from a woman's ovaries and fertilizing them outside her body. The resulting embryos are then transferred into the woman's uterus through the cervix."[14] This Note will focus on IVF treatments using fresh, non-donor eggs. Fresh eggs are "[e]ggs . . . that have not been frozen."[15] Meanwhile, donor eggs are where "[a]n embryo is formed from the egg of one woman (the donor) and then transferred to another woman who is unable to use her own eggs (the recipient)."[16] Finally, a multiple birth pregnancy, or multiple-infant birth, is "a pregnancy that results in the birth of more than one infant."[17] Thus, this term encompasses pregnancies that result in twins, triplets, quadruplets, quintuplets, sextuplets, septuplets, and octuplets. Multiple birth pregnancies are more likely to occur where children are conceived using IVF treatments than by natural conception because of (1) the ovarian stimulation injections given to the mother so that the physician can retrieve several eggs, and (2) the implantation of multiple embryos into the mother's womb.[18]

B. Modern Statistics

The number of infants born who are conceived using ART, including IVF treatments, has steadily increased in the past decade. According to the CDC, "[t]he number of ART cycles performed in the United States has more than doubled, from 64,681 cycles in 1996 to 138,198 in 2006."[19] Furthermore, "[t]he number of live-birth deliveries in 2006 (41,343) was more than two and a half times higher than in 1996 (14,507)."[20]

In addition to tracking information about ART clinics and their success rates, the CDC also tracks information about the women using ART. The CDC reports "[t]he average age of women using ART services in 2006 was 36." [21] However, "[t]he largest group of women using ART services were women younger than 35, representing 39% of all ART cycles carried out in 2006."[22] American women increasingly choose to rely on ART in order to

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13. CENTERS FOR DISEASE CONTROL AND PREVENTION, ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES 525 (2006), *available at* http://www.cdc.gov/ART/ART2006/508PDF/2006ART.pdf [hereinafter 2006 ART REPORT].

14. *Id.* at 526.

15. *Id.* at 525.

16. *Id.*

17. *Id*. at 526.

18. Jennifer L. Rosato, *The Children of ART (Assisted Reproductive Technology): Should the Law Protect them from Harm?*, 2004 UTAH L. REV. 57, 60–61 (2004).

19. 2006 ART Report, *supra* note 13, at 61.

20. *Id.*

21. *Id.* at 15.

22. *Id.* The CDC further states, "Twenty-three percent of ART cycles were carried out among women aged 35–37, 19% among women aged 38–40, 10% among women aged 41–42, and 10% among women older than 42." *Id.*

conceive children even though there is no corresponding increase in the number of women being diagnosed as infertile.[23] The New York State Task Force on Life and the Law states there has been an increase in ART because

> (1) medical services for infertile couples are more widely available;
> (2) there are more women of reproductive age than in the past;
> (3) there is an ongoing trend toward delayed childbearing, particularly among professional and highly educated women;
> (4) important risk factors for infertility are increasing among younger women; and
> (5) adoption is no longer an easy method of family building.[24]

Furthermore, ART, and specifically IVF treatments, are very expensive. It has been estimated that patients pay out of pocket fees totaling $1.7 billion annually to conceive children using IVF treatments,[25] which costs roughly $12,400 per cycle.[26] Thus, IVF treatments are not readily available to the general public, and Nadya Suleman would not have been able to afford her IVF treatments had it not been for a small inheritance from her aunt and a $165,000 Workers Compensation award.[27]

C. Multiple Birth Pregnancies

With the increasing use of IVF treatments come new medical, moral, ethical, and legal concerns. Specifically, the problem of multiple birth pregnancies is one of the most hotly debated issues among legal scholars. Multiple birth pregnancies pose serious medical and psychological risks to both the mother and children conceived using IVF. Mothers are putting their health at risk by carrying multiple fetuses. They are more likely to develop hypertension, pre-eclampsia, hemorrhages, anemia, fluid overload, a myocardial infarction, and heart failure.[28] Multiple birth pregnancies have

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23. The CDC reports "about 12% of women of childbearing age in the United States have used an infertility service." *Id.* at 1. Meanwhile, the CDC reports, "Of the approximately 62 million women of reproductive age in 2002, about 1.2 million, or 2%, had had an infertility-related medical appointment within the previous year, and an additional 10% had received infertility services at some point in their lives." *Id.* at 3.

24. NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, ASSISTED REPRODUCTIVE TECHNOLOGIES: ANALYSIS AND RECOMMENDATIONS FOR PUBLIC POLICY 15–16 (1998).

25. Debora Spar & Anna M. Harrington, *Building A Better Baby Business*, 10 MINN. J.L. SCI. & TECH. 41, 47 (2009).

26. American Society for Reproductive Medicine, Frequently Asked Questions About Infertility, http://www.asrm.org/Patients/faqs.html (last visited Apr. 20, 2010).

27. *Suleman: Wages, Inheritance Paid for In Vitro*, ASSOCIATED PRESS, April 7, 2009, http://www.foxnews.com/wires/2009Apr07/0,4670,Octuplets,00.html.

28. Urska Velikonja, *The Costs of Multiple Gestation Pregnancies in Assisted Reproduction*, 32 HARV. J. L. & GENDER 463, 471–72 (2009).

also been linked to gestational diabetes.[29] Furthermore, mothers who have multiple birth pregnancies are "more likely to require long periods of bed rest, hospitalization, administration of medication to prevent pre-term labour, surgical procedures, such as emergency Cesarean section and . . . premature labor."[30] They are also more likely to require hysterectomies due to pregnancy complications.[31] Moreover, they suffer "higher rates of miscarriage," and "there is 2/25,000 risk of maternal mortality during twin pregnancy or birth" as compared with a "1/25,000 risk of maternal mortality during singleton pregnancy or birth."[32]

Multiple birth pregnancies also increase the infants' health risks. Children born in multiple birth pregnancies "are more likely to be born prematurely and with a low birth weight than babies from singleton pregnancies."[33] They are also "more likely to die within the first year of life than singletons."[34] Furthermore, IVF children often suffer from long-term medical problems, such as "cerebral palsy, delayed mental and language development, and motor and coordination difficulties."[35] Furthermore, they are more likely to suffer from respiratory distress[36] and congenital malformations,[37] and to have mental and physical disabilities.[38] In the case of Nadya Suleman, three of her previous six IVF children were registered as disabled with the State of California.[39] Finally, since they were born prematurely, children of multiple birth pregnancies are likely to spend at least their first month of life in neonatal care units.[40]

As witnessed in the Octomom drama, parents, children, relatives, and the community at large also suffer psychological and financial harm as a result of multiple birth pregnancies. Since it is more difficult to care for multiple infants, IVF patients may not be prepared to deal with the stress of being parents.[41] It was later reported that several months after delivering the

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29. One At A Time, Risks to the Mother, http://www.oneatatime.org.uk/367.htm (last visited Mar 23, 2010).

30. Velikonja, *supra* note 28, at 472.

31. *Id.*

32. Risks to the Mother, *supra* note 29.

33. Velikonja, *supra* note 28, at 472.

34. One At A Time, Risks to the Child, http://www.oneatatime.org.uk/368.htm (last visited Mar. 23, 2010); *see also* Stephanie Saul, *Grievous Choice on Risky Path to Parenthood*, N.Y. TIMES, Oct. 12, 2009, http://www.nytimes.com/2009/10/12/health/12fertility.html?_r=1&th&emc=th; *see generally The Risks of Multiple Births*, N.Y. TIMES, Oct. 11, 2009, http://www.nytimes.com/slideshow/2009/10/11/us/20091012IVF2_index.html.

35. Velikonja, *supra* note 28, at 473.

36. Risks to the Child, *supra* note 34.

37. *Id.*

38. Velikonja, *supra* note 28, at 474.

39. *Octuplets' Family Facing Foreclosure Threat*, *supra* note 4.

40. Risks to the Child, *supra* note 34.

41. Velikonja, *supra* note 28, at 475–78. "Multiple births have psychological consequences as well. These include a negative psychological impact on the mother, as

octuplets, Nadya said, "I screwed myself. I screwed up my life, I screwed up my kids' lives. . . . I have to put on this strong facade and I have to pretend like I don't regret it."[42] Moreover, "parents of multiples are seriously sleep deprived . . . and many become homebound and report feeling isolated."[43] Nadya Suleman seems to acknowledge her social isolation in that she has publicly stated, "I cannot maintain a social life and be a mother."[44] Having multiple birth infants can also cause problems with the children's parents, siblings, or other family relatives.[45] With regards to Nadya, her mother, Angela Suleman, publicly condemned her daughter's decision to have more children, but they later reconciled after Angela met her grandchildren.[46]

Finally, both the parents of multiple birth infants and society at large bear the financial costs of paying for the infants' delivery costs, and long-term medical problems.[47] The Associated Press reported the Bellflower hospital is seeking reimbursement from California's Medicaid program for an undisclosed amount to pay the octuplets' neonatal care.[48] Moreover, it will cost California taxpayers somewhere between $1.3 million to $2.7 million to support Nadya's fourteen IVF children from now until age seventeen.[49]

While Nadya Suleman's poor decision-making is self-evident, and the financial costs associated with her decision to have more children are astronomical, it is important that legislators, and the American public put the Octomom drama into perspective. In 2006, 11.1% of ART cycles using fresh nondonor eggs or embryos resulted in multiple-fetus pregnancies.[50] Furthermore, the CDC reports that of the 28,404 live births resulting from ART cycles using fresh non-donor eggs or embryos, 69.3% were singletons,

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indicated by higher rates of depression, drug and alcohol abuse, and divorce among mothers of multiples. Such negative impacts on the mother naturally have an adverse impact on the children as well, and higher rates of child abuse have been found in families of multiples." Catherine A. Clements, *What About the Children? A Call for Regulation of Assisted Reproductive Technology*, 84 IND. L.J. 331, 336 (2009).

42. *Octomom Says She 'Screwed Up' Her Life*, ASSOCIATED PRESS, June 4, 2009, http://www.foxnews.com/story/0,2933,525164,00.html.

43. Velikonja, *supra* note 28, at 477.

44. *Octomum: I've Not Had Sex for 8 Years*, THE SUN (London), Feb. 14, 2009, http://www.thesun.co.uk/sol/homepage/features/article2237580.ece.

45. Velikonja, *supra* note 28, at 478.

46. *Octuplets' Mother, Grandmother Feud in Video Posted on Gossip Web Site*, ASSOCIATED PRESS, Feb. 23, 2009, http://www.foxnews.com/story/0,2933,498965,00.html; *see also Octuplets' Grandma Ends Spat With Daughter, Will Help Raise Babies*, ASSOCIATED PRESS, Feb. 17, 2009, http://www.foxnews.com/story/0,2933,494224,00.html.

47. Velikonja, *supra* note 28, at 479–81.

48. *Octuplet Family Financial Burden May Fall of Taxpayers*, ASSOCIATED PRESS, Feb. 11, 2009, http://www.foxnews.com/story/0,2933,491204,00.html.

49. *Id.*

50. 2006 ART REPORT, *supra* note 13, at 20.

29% were twins, and about 2% were triplets or more.[51] Thus, the total multiple-infant live birth rate for 2006 was 31%.[52] This 31% figure seems large when compared to the 3% multiple-infant birth rate of naturally conceived children.[53] However, as noted above, only 2% of ART children are triplets or more — or 568 out of 28,404 children. Moreover, as ART live birth rates have increased,[54] the practice of transferring four or more embryos has decreased.[55] Interestingly, the CDC reports success rates have increased for ART cycles when one to three embryos are transferred, but success rates have decreased for transfers that involve four or more embryos.[56] Therefore, the Octomom drama is a psychological, ethical, and medical anomaly.

Despite the general trend in the United States, which indicates "multiple-infant live births decreased between 1996 and 2006 for women of all age groups,"[57] there have been increasing calls for regulating ART, and specifically IVF treatments.[58] In fact, many Western nations have enacted ART regulations in the last few decades,[59] and the United Kingdom, as part

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51. *Id.* at 22.

52. *Id.*

53. *Id.*

54. *Id.* at 68. "From 1996 through 2006, the percentage of transfers that resulted in live births for women younger than 35 increased 33%, from 34% in 1996 to 45% in 2006. Over the same period, the percentage of transfers that resulted in live births increased 28% for women 35–37, 24% for women 38–40, 31% for women 41–42, and 22% for women older than 42." *Id.*

55. *Id.* at 71. "In 1996, almost two-thirds (64%) of ART cycles involved the transfer of four or more embryos; 33%, three embryos; 3%, two embryos; and less than 1%, one embryo. . . . By 2006, four or more embryos were transferred in only 3% of cycles, three in 16% of cycles, two in 75% of cycles, and one in 7% of cycles." *Id.* "[I]n 2006, and cycles that involved the transfer of four or more embryos decreased from 62% in 1996 to 16% in 2006." *Id.* at 70.

56. *Id.* at 71. "From 1996 through 2006, the success rates tripled, from 14% to 42%, for ART cycles that involved the transfer of two embryos. The success rates also increased for ART cycles that involved the transfer of either one or three embryos; however, the success rates decreased 13%, from 32% to 28%, for ART cycles that involved the transfer of four or more embryos." *Id.*

57. *Id.* at 75. "In 1996, 43% of live-birth deliveries to women younger than 35 were multiple-infant births, compared with 34% in 2006. Among women older than 42, the percentages of multiple-infant live births decreased from 14% in 1996 to 9% in 2006." *Id.*

58. *See generally* THE PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION & RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 205–18 (2004), http://www.bioethics.gov/reports/reproductionandresponsibility/_pcbe_final_reproduction_and_responsibility.pdf; Naomi R. Cahn & Jennifer M. Collins, *Eight is Enough*, 103 NW. U. L. REV. COLLOQUY 501 (2009); Marsha Garrison, *Regulating Reproduction*, 76 GEO. WASH. L. REV. 1623 (2008); Rosato, *supra* note 18; Stenger, *supra* note 11, at 135; Clements, *supra* note 41; Velikonja, *supra* note 28.

59. The "One Child At A Time" report summarizes the laws for the following countries: Belgium: "Introduction of a reimbursement system that links funding for 6 IVF cycles per patient to the compulsory use of eSET in the first cycle in women < 36 years, use of eSET in follow-on cycles depends on age and embryo quality"; Finland: "No state regulation, but the sector has moved successfully to wide-spread use of eSET with follow-on

of its comprehensive regulatory scheme, has recently updated its federal regulations to include the "Single Embryo Transfer" policy in an effort to cap the number of embryos implanted into IVF patients.

II. UNITED KINGDOM

A. History

The Human Fertilisation and Embryology Authority ("HFEA") is the United Kingdom's regulatory agency that oversees "the use of gametes and embryos in fertility treatment and research."[60] British Parliament has given the HFEA broad regulatory powers, including the ability to set licensing guidelines for U.K. fertility clinics;[61] to interpret mandatory requirements as established by the "Human Fertilisation and Embryology Act 1990" and the "Human Fertilisation and Embryology Act 2008";[62] to construct a best-practice guide in order to help British clinics comply with these acts and its subsequent regulations;[63] and to gather data about fertility treatments in the United Kingdom.[64] In short, Parliament has given the HFEA the authority to regulate every aspect of ART, [65] including the authority to reduce the rates of multiple birth pregnancies in IVF treatments.[66]

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cryopreservation"; Sweden: "Regulation by the National Board on Health and Welfare states that in principle only one embryo should be replaced apart from exceptional circumstances, which seem to be loosely defined"; Norway and Denmark: "No state regulation, but the sector has moved to a substantial proportion of eSET cycles"; Netherlands: "Dutch fertility sector introduced eSET policies without state legislation"; Germany: "Embryo Protection Act 1990: No more than 3 oocytes can be cultured beyond the two-pronucleate stage, embryo selection practices disallowed, no cleavage stage embryos can be frozen, so all embryos need to be transferred"; and France, Spain, Portugal, and Greece: "No legislation or regulations on reducing numbers of multiples, no evidence of rising number of eSET cycles." PETER BRAUDE ET AL., REPORT OF THE EXPERT GROUP ON MULTIPLE BIRTHS AFTER IVF, HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY, ONE CHILD AT A TIME: REDUCING MULTIPLE BIRTHS AFTER IVF 18–20 http://www.hfea.gov.uk/docs/MBSET_report_Final_Dec_06.pdf.

60. Human Fertilisation & Embryology Authority, http://www.hfea.gov.uk/ (last visited Mar. 11, 2010).

61. Human Fertilisation & Embryology Authority, What We License, http://www.hfea.gov.uk/139.html (last visited Mar. 23, 2010).

62. Human Fertilisation & Embryology Authority, Our Role as Regulator, http://www.hfea.gov.uk/135.html (last visited Mar. 11, 2010).

63. Human Fertilisation & Embryology Authority, Our Role to Provide Guidance and Advice, http://www.hfea.gov.uk/136.html (last visited Mar. 11, 2010).

64. Human Fertilisation & Embryology Authority, Our Role as an Improved Information Provider, http://www.hfea.gov.uk/5443.html (last visited Mar. 11, 2010).

65. *See generally* HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY, CODE OF PRACTICE: 8TH EDITION (2009), http://www.hfea.gov.uk/docs/complete_CoP8.pdf.

66. HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY, MULTIPLE BIRTHS, http://www.hfea.gov.uk/docs/CoP8_section4_multiple_births.pdf [hereinafter MULTIPLE BIRTHS].

The United Kingdom's centralized approach to ART can be traced to the birth of Louise Joy Brown, the world's first test tube baby.[67] She was born on July 25, 1978, in the Oldham and General District Hospital in Lancashire.[68] Her parents decided to undergo IVF treatment, using their own eggs and sperm, after it was discovered that Louise's mother had blocked fallopian tubes.[69] Louise's successful delivery whipped up a frenzy among theologians, physicians, ethicists, social workers, scientists, philosophers, attorneys, church groups, medical societies, and public policy groups, who were concerned with everything from Louise's health to eugenics to possible governmental intrusion on an individual's right to procreate.[70] In response to this public outcry, the Committee of Inquiry into Human Fertilisation and Embryology was formed in 1982.[71] In 1984, the Committee published what later became known at the Warnock Report.[72] While the Warnock Report generally supported using ART to treat heterosexual couples with infertility,[73] it recognized a "need" for regulations. Specifically, the Committee states:

> [P]eople generally want *some principles or other* to govern the development and use of the new techniques. There must be *some* barriers that are not to be crossed, *some* limits fixed, beyond which people must not be allowed to go. Nor is such a wish for containment a mere whim or fancy. The very existence of morality depends on it. A society which had no inhibiting limits, especially in the areas with which we have been concerned, questions of birth and death, of the setting up of families, and the valuing of human life, would be a society without moral scruples. *And this nobody wants*.[74]

The Committee then proposes specific recommendations on a variety of issues, including the need to counsel couples using ART;[75] to have informed consent by both parties and for it to be in writing;[76] to establish legal

67. *See* Stenger, *supra* note 11, at 139–40.

68. *Id.* at 139. On December 20, 2007, Louise Brown, twenty-eight, made highline news again when she gave birth to a baby boy named Cameron. *See Baby Son Joy for Test-Tube Mother*, BBC NEWS, Jan. 14, 2007, http://news.bbc.co.uk/2/hi/uk_news/6260171.stm.

69. *1978: First 'Test Tube Baby' Born, BBC on This Day 1950-2005*, BBC NEWS, Jul. 25, 2009, http://news.bbc.co.uk/onthisday/hi/dates/stories/july/25/newsid_2499000/2499411.stm.

70. Stenger, *supra* note 11, at 140–41.

71. Human Fertilisation & Embryology Authority, Warnock Report, http://www.hfea.gov.uk/2068.html (last visited Mar. 23, 2010).

72. COMMITTEE OF INQUIRY INTO HUMAN FERTILISATION AND EMBRYOLOGY, WARNOCK REPORT (1984), *available at* http://www.hfea.gov.uk/docs/Warnock_Report_of_the_Committee_of_Inquiry_into_Human_Fertilisation_and_Embryology_1984.pdf [hereinafter WARNOCK REPORT].

73. *Id.* at 1–3.

74. *Id.* at 2 (emphasis in original).

75. *Id.* at 15–16.

76. *Id.* at 16, 25–26.

parentage;[77] to disclose the donor's ethic origins and medical information to ART children once they reach eighteen;[78] to limit the number of donations made by a single donor;[79] to outlaw commercial surrogacy;[80] to prevent children conceived posthumously from inheriting via intestate succession,[81] and to regulate the research,[82] storage, and disposal[83] of human embryos. Ultimately, the Committee calls for "the establishment of a new statutory licensing authority to regulate both research and those infertility services which we have recommended should be subject to control."[84]

The Committee's call for a new statutory licensing authority was answered in 1990, when the British Parliament passed the Human Fertilisation and Embryology Act 1990.[85] This Act was subsequently amended by the Human Fertilisation and Embryology Act 2008.[86] The 1990 Act sets up the HFEA's licensing authority, and its ability to regulate fertility clinics' administrative and medical procedures, as well as the legal and medical rights of ART patients and donors. Neither the Human Fertilisation and Embryology Act 1990 nor the Human Fertilisation and Embryology Act 2008[87] directly address the issue of multiple birth pregnancies. However, Section 8 of the 1990 Act gives the HFEA the general authority to:

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77. *Id.* at 25–26.
78. WARNOCK REPORT, *supra* note 72, at 24–25.
79. *Id.* at 26–27.
80. *Id.* at 42–47.
81. *Id.* at 55.
82. *See id.* at 58–79.
83. *Id.* at 56–57.
84. WARNOCK REPORT, *supra* note 72, at 75.
85. *See generally* Human Fertilisation and Embryology Act, 1990, c. 37 (Eng.), *available at* http://www.opsi.gov.uk/acts/acts1990/pdf/ukpga_19900037_en.pdf.
86. *See generally* Human Fertilisation and Embryology Act, 2008, c. 22 (Eng.), *available at* http://www.opsi.gov.uk/acts/acts2008/pdf/ukpga_20080022_en.pdf.
87. The main provisions of the 2008 act include: (1) "ensuring that the creation and use of all human embryos . . . are subject to regulation"; (2) "a ban on selecting the sex of the offspring for social reasons"; (3) "requiring that clinics take account of "the welfare of the child" when providing fertility treatment, and removing the previous requirement that they also take account of the child's "need for a father"; (4) "allowing for the recognition of both partners in a same-sex relationship as legal parents of children conceived through the use of donated sperm, eggs or embryos"; (5) "enabling people in same sex relationships and unmarried couples to apply for an order allowing for them to be treated as the parents of a child born using a surrogate"; (6) "changing restrictions on the use of data collected by the HFEA to make it easier to conduct research using this information"; and (7) "provisions clarifying the scope of legitimate embryo research activities, including regulation of 'human admixed embryos' (embryos combining both human and animal material)." Human Fertilisation and Embryology Authority, The HFE Act (and Other Legislation), http://www.hfea.gov.uk/134.html (last visited Apr. 20, 2010).

> (a) keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and advise the Secretary of State . . .
> . . .
> (c) provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by this Act, or may wish to do so, and
> (d) perform such other functions as may be specified in regulations.[88]

Furthermore, Parliament gives the HFEA the authority to maintain a Code of Practice. The regulations included in this code must take into account the welfare of ART children, "and of other children who may be affected by such births."[89] Moreover, "[t]he code may also give guidance about the use of any technique involving the placing of sperm and eggs in a woman."[90] Finally, the HFEA's licensing committee is given the power to revoke a practitioner's license for failure to comply with the Code of Practice.[91] It is under the HFEA's authority to research fertility treatments, provide advice, take into account the welfare of the children, and regulate procedures under its Code of Practice that it adopted the "Single Embryo Transfer" policy.

B. The Single Embryo Transfer Policy

The HFEA's "Single Embryo Transfer" ("SET") policy is a product of several years of research, debate, and discussion. The first step toward the adoption of the SET policy occurred in September of 2006, when the HFEA set up the "Expert Group on Multiple Births after IVF" to research the problem of multiple birth pregnancies.[92] This expert group was composed of obstetricians, gynecologists, professors, medical directors, journalists, pediatricians, fertility specialists, embryologists, international monitors, and public health specialists.[93] In October 2007, the expert group issued the "One Child at a Time Report."[94] According to the Report, "1 in 4 IVF pregnancies [in the U.K.] leads to the birth of twins," which is "more than ten times higher than would be expected after spontaneous (natural)

88. Human Fertilisation and Embryology Act, 1990, c. 37, § 8 (Eng.), *available at* http://www.opsi.gov.uk/acts/acts1990/pdf/ukpga_19900037_en.pdf.
89. *Id.* § 25(2).
90. *Id.* § 25(3).
91. *Id.* § 25(6)(b).
92. Human Fertilisation and Embryology Authority, Timeline of Key Events, http://www.hfea.gov.uk/3121.html (last visited Apr. 10, 2010) [hereinafter Timeline of Key Events]; *see also* BRAUDE ET AL., *supra* note 59, at 1–105.
93. BRAUDE ET AL., *supra* note 59, at 4.
94. *See id.*

conception."[95] The Report focused on the United Kingdom's high twin rate because multiple birth pregnancies with three or more children are rare due to the United Kingdom's strict two-embryo policy.[96] The Report proceeded to address in great detail the serious health risks to women using and children conceived by IVF treatments when there are multiple birth pregnancies.[97] Given the numerous medical and psychological risks, as well as the increased financial burden on parents and society, the expert group stated, "A multiple pregnancy should not be regarded as the ideal outcome of IVF treatment."[98] Moreover, the Report stated, "The only way to reduce the multiple birth rate after IVF is to transfer only one embryo to those women at most risk of having twins. Overall, eSET [Elective Single Embryo Transfer] needs to be made the norm in IVF treatment."[99] In order to transition from a strict two-embryo transfer policy for women under forty and a three embryo transfer policy for women forty and above, the expert group made two recommendations. First, the HFEA should cap the number of multiple births at each clinic.[100] Second, the HFEA should develop the criteria to determine which group of women is more likely to produce multiples, and then this group would first be offered SET.[101]

During April of 2007 to May of 2008, the HFEA considered the expert group's recommendations.[102] It then enacted the SET policy, which went into effect on January 1, 2009.[103] The SET policy is being monitored by a "National Strategy Multiple Births Group."[104] There are four key elements under the SET policy. First, for the year 2009, "the maximum multiple birth rate for each [U.K.] clinic is [set at] 24%. In other words, all centres should ensure that their annual multiple birth rate does not exceed this figure."[105] The HFEA realized clinics may well be under or at this 24% cap. Therefore, these clinics can meet this requirement by working to lower their

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95. *Id.* at 8. Furthermore, the One Child at a Time Report states, "[T]he incidence of triplets has more than halved since the strict two embryo policy was introduced in 2003." *Id.* at 74.

96. Under the strict two-embryo policy, which was adopted in 2004, clinics were not allowed to implant more than two embryos in women under the age of forty, and there were no exceptions to this rule. Furthermore, a clinic was not allowed to implant more than three embryos in women age forty and above. Human Fertilisation & Embryology Authority, Embryo Transfer and Multiple Births, http://www.hfea.gov.uk/2587.html#3057 (last visited Apr. 10, 2010).

97. BRAUDE ET AL., *supra* note 59, at 24–26.

98. *Id.* at 9.

99. *Id.*

100. *Id*. at 10, 54–60.

101. *Id.* at 10.

102. Timeline of Key Events, *supra* note 92.

103. *Id.*

104. One At A Time, The Work of the National Strategy Multiple Births Stakeholder Group, http://www.oneatatime.org.uk/145.htm (last visited Mar. 23, 2010).

105. Human Fertilisation & Embryology Authority, CH(08)03, Sept. 30, 2008, http://www.hfea.gov.uk/489.html.

current multiple birth pregnancy rates.[106] Second, the HFEA's long-term goal is to set a maximum multiple birth rate of 10% for each U.K. clinic, and thus, it will gradually lower the maximum multiple birth rates to meet this goal.[107] The HFEA "will carefully monitor the impact of its policy, including any impact on fresh cycle pregnancy rates, to ensure that all rates are appropriate."[108] Third, all U.K. fertility clinics were instructed to come up with a "multiple births minimisation strategy (the strategy) which will set out how they intend to reduce their annual multiple birth rates and to ensure that they do not exceed [the] HFEA-set maximum figure."[109] Finally, the SET policy does not replace the strict two or three embryo policy, but "run[s] alongside it."[110]

In its Code of Practice, the HFEA sets out how a fertility clinic is supposed to come up with a strategy to reduce its multiple birth pregnancy rate. A clinic's strategy must determine "(a) how the centre aims to reduce the multiple birth rate . . . (b) the circumstances in which the person responsible would consider it appropriate to recommend single embryo transfer (SET) to a patient . . . [and] (c) the criteria for transferring eggs . . . ."[111] Furthermore, the clinic is required to audit its progress and, if necessary, revise its strategy.[112] Should a clinic transfer more than one embryo to a patient who meets its SET criteria, the clinic is required to explain why the SET policy was not applied, and it must prove that the patient was informed of the dangers of multiple birth pregnancies.[113] Finally, if a clinic should implant four eggs or three embryos as part of an IVF treatment, it is required to keep medical records that explain why so many eggs or embryos were transferred and "keep a summary log of every treatment cycle."[114] Surprisingly, these strict reporting requirements, and the overall implementation of the SET policy is supported by the major medical associations in the United Kingdom.[115] In contrast, in the United States, most physicians and medical associations staunchly oppose the

106. *Id*.
107. *Id*.
108. *Id*.
109. *Id*.
110. *Id*.
111. MULTIPLE BIRTHS, *supra* note 66, at 1.
112. *Id.*
113. *Id.* at 2.
114. *Id.* at 2.
115. The following organizations support the SET policy: "Association of Clinical Embryologists, British Fertility Society, British Infertility Counselling Association, Human Fertilisation and Embryology Authority, Infertility Network UK, Multiple Births Foundation, Royal College of Nursing, Royal College of Obstetricians and Gynaecologists, and the Royal College of Paediatrics and Child Health." Press Release, Human Fertilisation & Embryology Authority, HFEA Statement on Elective Single Embryo Transfer (eSET guidelines) (Sept. 3, 2008), *available at* http://www.hfea.gov.uk/405.html.

government's regulation of ART.[116] In fact, the Society for Assisted Reproductive Technology adopted the slogan "'prevention is the best medicine' with regard to government regulation."[117]

In conclusion, the United Kingdom has adopted a top down regulatory approach to IVF and the problem of multiple birth pregnancies. The United Kingdom has limited the number of embryos implanted in IVF to one embryo unless a clinic can justify implanting two or three embryos. Should a fertility clinic fail to comply with this numerical limit, it risks having its license revoked by the HFEA.

III. UNITED STATES

The United Kingdom's comprehensive regulatory approach is the antithesis of the United State's free market approach. In the United States, fertility clinics are subject to limited federal and state regulations. In lieu of extensive governmental regulation, fertility clinics are self-regulated by professional medical associations, such as SART, the Society for Assisted Reproductive Technology,[118] and ASRM, the American Society for Reproductive Medicine.[119]

A. Federal and State Regulations

The only federal law that directly regulates ART procedures in the United States is the Fertility Clinic Success Rate and Certification Act of 1992.[120] This Act has two primary components. First, it requires all fertility

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116. Most physicians believe the federal government's regulation of IVF is excessive because "every IVF procedure and its outcome must be reported to the federal government, [and] this is not true for any other medical procedure." Press Release, American Society for Reproductive Medicine, ASRM Responds to Incidents at IVF Clinic (Sept. 25, 2009), *available at* http://www.asrm.org/Washington/Bulletins/vol11no50.html. However, physicians may be moving towards the position further regulation may be necessary. In a recent ASRM bulletin, the executive director of ASRM wrote, "The time has come for policy makers to sit down with the leading experts in the field to explore ways we can codify our standards to give them additional regulatory teeth." *Id.*

117. Ouellette et al., *supra* note 11, at 443.

118. Society for Assisted Reproductive Technology, http://www.sart.org (last visited Mar. 23, 2010).

119. American Society for Reproductive Medicine, http://www.asrm.org (last visited Mar. 23, 2010).

120. Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a-1 (2009). Another statute that may indirectly regulate ART clinics is the Clinical Laboratories Improvement Amendments of 1988, 42 U.S.C. § 263a (2009). ART clinics are also loosely regulated by the FDA, which regulates the donation of human tissue. *See generally* FOOD AND DRUG ADMINISTRATION, U.S. DEP'T OF HEALTH AND HUMAN SERVS., GUIDANCE FOR INDUSTRY: ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCT (HCT/PS) (2007), *available at* http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.pdf. Finally, the FTC regulates deceptive advertisements involving

clinics in the United States to submit data to the CDC about their pregnancy success rates.[121] The CDC then publishes this information in its annual report.[122] The CDC and its data collection contractor primarily rely on SART to collect this information.[123] SART is an organization of medical professions, whose mission is "to set and help maintain the standards for ART in an effort to better serve our members and our patients."[124] It is made up of 392 practitioners, and 95% of all IVF clinics in the United States are SART members.[125] One of the weaknesses of the Fertility Clinic Success Rate and Certification Act is the CDC cannot issue sanctions against clinics that fail to report their pregnancy success rates. Fortunately, all SART members are required to impute their clinics' data into the SART system, or else risk being sanctioned by SART, and this data is subsequently passed onto the CDC's data collection contractor.[126] Moreover, while the act makes no mention of multiple birth pregnancies, SART's Quality Assurance Committee has independently adopted "[a] recent initiative in which programs with triplet rates . . . were formally contacted and asked to comment on their practice patterns and to formalize means by which changes would take place to lower these rates."[127]

The second part of the Fertility Clinic Success Rate and Certification Act requires the CDC "develop a model program for the certification of embryo laboratories to be carried out by the States."[128] No state has yet adopted the CDC's model certification program. In fact, on the state level, the regulation of ART varies dramatically with regards to access, permissible procedural and medical techniques, and licensing, safety, and reporting requirements. New Hampshire has adopted one of the most comprehensive regulatory schemes for IVF treatments.[129] New Hampshire requires IVF patients to be at least twenty-one years old, and medically fit to undergo IVF treatment.[130] Moreover, IVF patients and their spouses must undergo

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fertility clinics' pregnancy success rates. *See* Judith F. Daar, *Regulating Reproductive Technologies: Panacea or Paper Tiger?*, 34 HOUS. L. REV. 609, 613–14 (1997).

121. Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a-1 (2009).

122. *Id.*

123. Ouellette et al., *supra* note 11, at 424.

124. Society for Assisted Reproductive Technology, What is SART?, http://www.sart.org/WhatIsSART.html (last visited Mar. 23, 2010) [hereinafter What is SART?]. In order to active its mission, SART collects data from its program members, creates practice guidelines and standards of care for its membership, functions as "a governmental watchdog for ART," provides consultations to its membership to improve clinic's care, offers accreditation programs for embryology laboratories, and researches ART procedures. *Id.*

125. *Id.*

126. Ouellette et al., *supra* note 11, at 424–28.

127. What is SART?, *supra* note 124.

128. 42 U.S.C. § 263a-2 (a)(1) (2009).

129. *See generally* N.H. REV. STAT. ANN. § 168-B:13–B:15 (2009).

130. N.H. REV. STAT. ANN. § 168-B:13 (2009).

counseling, and if the IVF patient is married, her spouse must accept legal parentage prior to the IVF treatment.[131] New Hampshire's comprehensive regulations can be compared with more lax statutes in Louisiana or Pennsylvania. In Louisiana, fertility clinics are required to follow IVF guidelines established by the American Fertility Society (later renamed ASRM), and the American College of Obstetricians and Gynecologists.[132] Meanwhile, in Pennsylvania, fertility clinics must meet various reporting requirements.[133]

No state in the United States has adopted laws seeking to curtail multiple birth pregnancies. However, in the wake of the Octomom drama, two proposals were made attempting to limit the number of embryos transferred into IVF patients. In Georgia, the state Senate passed a bill entitled the "Ethical Treatment of Human Embryos Act," which makes it "unlawful for any person or entity to intentionally or knowingly create or attempt to create an in vitro human embryo by any means other than fertilization or intracytoplasmic sperm injection of a human egg by a human sperm."[134] Intracytoplasmic sperm injection ("ICSI") is "[a] procedure in which a single sperm is injected directly into an egg."[135] This bill was not voted on in the state's House,[136] and thus, the proposal is not the law in Georgia.

Furthermore, in Missouri, a somewhat less restrictive bill was proposed, which states, "When treating infertility, physicians within the state of Missouri shall not implant more embryos into a human than the current recommendations set forth by the American Society for Reproductive Medicine, or its successor."[137] This bill was passed in the Healthcare Transformation Committee, but was not voted on by the state House or Senate, and it is not currently on the calendar.[138] Thus, in the United States the problem of multiple birth pregnancies is not subject to federal or state regulation, but rather it is being addressed by self-regulation in the medical field.

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131. *Id.*

132. LA. REV. STAT. ANN. § 9:128 (2009).

133. 18 PA. CONS. STAT. § 3213(e) (2009). "All persons conducting . . . in vitro fertilization shall file quarterly reports with the department . . . containing the following information: (1) Names of all persons conducting or assisting in the fertilization or experimentation process; (2) Locations where the fertilization or experimentation is conducted; (3) Name and address of any person, facility, agency or organization sponsoring the fertilization or experimentation except that names of any persons who are donors or recipients of sperm or eggs shall not be disclosed; (4) Number of eggs fertilized; (5) Number of fertilized eggs destroyed or discarded; [and] (6) Number of women implanted with a fertilized egg." *Id.* Clinics that fail to keep records, fail to supply their reports, or submit false reports will be fined $50 per day. *Id.*

134. S.B. 169, 150th Gen. Assem., Reg. Sess. (Ga. 2009).

135. 2006 ART REPORT, *supra* note 13, at 526.

136. SB 169, 150th Gen. Assem., Reg. Sess. (Ga. 2009).

137. H.B. 810, 95th Gen. Assem., 1st Reg. Sess. (Mo. 2009).

138. *Id.*

B. Self-Regulation

In the United States, even in the absence of governmental regulation, professional medical associations, individual physicians, IVF patients, and the market are effectively addressing multiple birth pregnancies.[139] Often working in conjunction with SART, ASRM is the leading multidisciplinary medical organization that addresses the medical, procedural, and ethical concerns of using ART in order to protect patients, ART children, physicians, and society as a whole.[140] ASRM is "committed to facilitating and sponsoring educational activities for the lay public and continuing medical education activities for professionals who are engaged in the practice of and research in reproductive medicine."[141] Its members include medical professionals, such as obstetricians, gynecologists, reproductive endocrinologists, embryologists, mental health professionals, and pediatricians.[142] In addition to providing its members with continuing medical education,[143] ASRM publishes a peer-reviewed medical journal, *Fertility and Sterility*; two newsletters, *ASRM News* and *Menopausal Medicine*; ASRM's Ethics Committee reports; and ASRM's Practice Committee reports, which "provide assistance about diagnostic and therapeutic dilemmas."[144]

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139. The judiciary cannot effectively lower the multiple birth pregnancy rate. Malpractice litigation is not applicable to IVF treatments because (1) "most U.S. Courts 'will not entertain wrongful life suits'"; (2) "even in states that do allow wrongful life or wrongful birth claims, courts limit the damages that the parents or the children recover"; (3) "parental lawsuits 'may be barred by their prior consent'"; (4) "many states 'preclude finding negligence if a doctor's practices are widely shared with others in the field'"; and (5) "'most negligently injured patients do not sue.'" Velikonja, *supra* note 28, at 492–93.

140. *See* American Society for Reproductive Medicine, ASRM Mission Statement, http://www.asrm.org/detail.aspx?id=60 (last visited Mar. 21, 2010) [hereinafter ASRM Mission Statement]. "The American Society for Reproductive Medicine, founded in 1944, is an organization of more than 8,000 physicians, researchers, nurses, technicians and other professionals dedicated to advancing knowledge and expertise in reproductive biology. Affiliated societies include the Society for Assisted Reproductive Technology, the Society for Male Reproduction and Urology, the Society for Reproductive Endocrinology and Infertility and the Society of Reproductive Surgeons." ASRM Reacts to Latest News, *supra* note 10.

141. ASRM Mission Statement, *supra* note 140.

142. American Society for Reproductive Medicine, History and Purpose, http://www.asrm.org/detail.aspx?id=35 (last visited Mar. 20, 2010) [hereinafter History and Purpose].

143. ASRM Mission Statement, *supra* note 140.

144. History and Purpose, *supra* note 142. "Also published are the ASRM Patient Education Committee's Patient Information Series booklets and Patient Fact Sheets, which are designed to help the patient understand the complexities of reproductive disorders and their treatment." *Id.*

ASRM has directly addressed the problem of multiple birth pregnancies,[145] and it is instrumental in continuing to raise awareness about the dangers of multiple birth pregnancies,[146] and in lowering clinics' multiple pregnancy rates.[147] In 2008, ASRM's Practice Committee, in conjunction with the Practice Committee for SART, updated its guidelines on the number of embryos to be transferred to patients.[148] ASRM supports the continuing practice of allowing patients and their attending physicians to determine the number of embryos that will be transferred in IVF treatments.[149] Its "guidelines provide the flexibility to give each patient treatment individualized to her needs, and her best chance to become pregnant without risking high-order multiple pregnancy."[150]

In determining how many embryos to transfer, ASRM recommends physicians consider the patient's age, the patient's previous success with IVF, the quality of the embryos to be transferred, and whether the excess embryos are eligible for cryopreservation.[151] ASRM makes the following numerical recommendations:

> A. For patients under the age of 35 who have a more favorable prognosis, consideration should be given to transferring only a single embryo. [For all others in this group, n]o more than two embryos . . . should be transferred.
> B. For patients between 35 and 37 years of age who have a more favorable prognosis, no more than two . . . embryos should be transferred. All others in this age group should have no more than three . . . embryos transferred. . . .
> C. For patients between 38 and 40 years of age who have a more favorable prognosis, no more than three . . . embryos . . . should be transferred. All others in this age group should have no more than four . . . embryos . . . transferred.

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145. *See generally* American Society for Reproductive Medicine, ASRM Topic: Multiple Birth or Multiple Gestation, http://www.reproductivefacts.org/topics/detail.aspx?id=1611 (last visited Mar. 21, 2010).

146. *See generally* AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, PATIENT'S FACT SHEET: CHALLENGES OF PARENTING MULTIPLES (2003), http://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/challenges.pdf; AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, PATIENT'S FACT SHEET: COMPLICATIONS AND PROBLEMS ASSOCIATED WITH MULTIPLE BIRTHS (2008), http://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/complications_multiplebirths.pdf; AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, PATIENT'S FACT SHEET: FERTILITY DRUGS AND THE RISK OF MULTIPLE BIRTHS (2008), http://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/fertilitydrugs_multiplebirths.pdf.

147. *See generally* ASRM Reacts to Latest News, *supra* note 10.

148. GUIDELINES ON NUMBER OF EMBRYOS TRANSFERRED, *supra* note 8, at 1.

149. *Id.*

150. ASRM Reacts to Latest News, *supra* note 10.

151. GUIDELINES ON NUMBER OF EMBRYOS TRANSFERRED, *supra* note 8, at 1.

> D. For patients [greater than 40] years of age, no more than five . . . embryos . . . should be transferred.[152]

ASRM also encourages patients and physicians to discuss the patient's individual circumstances, but it only recommends increasing the number of embryos to be transferred based the patient's circumstances if the patient has had two or more failed IVF treatments.[153] Cynics have criticized ASRM's self-regulation, since ASRM lacks enforcement mechanisms to ensure physicians adhere to its guidelines. However, physicians are taking the initiative and following ASRM's guidelines[154] because their primary concern is the health and safety of their patients, and they wish to bolster the reputation of their fertility clinic in this competitive market.

Furthermore, physicians have successfully lowered the rate of multiple birth pregnancies. As R. Dale McClure, President of ASRM, stated in an Octomom press release, ASRM began issuing guidelines about how many embryos to implant in IVF procedures in 1996, and saw almost immediate results.[155] "[I]n 1996, 7% of fresh, non-donor ART cycles . . . were triples or more" compared to just 2% in 2005.[156] McClure proudly stated, "This [decline in multiple birth pregnancies] was achieved without hurting the pregnancy rates for our patients. In fact, during the same period, the live birth rate from fresh non-donor embryo transfers increased from 28% in 1996 to 34.3% in 2005."[157]

In addition to physicians following ASRM's recommendations on how many embryos to implant in IVF patients, should multiple fetuses develop in a woman's womb, patients can elect to undergo selective reduction, or multiple pregnancy reduction.[158] Selective reduction is "[a] procedure to

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152. *Id.*

153. *Id.* at 1–2.

154. This fundamental concern with the health and safety of their patients is evidenced in the words of the Modern Hippocratic Oath, which medical students recite at graduation. "I swear to fulfill, to the best of my ability and judgment, this covenant . . . I will apply, for the benefit of the sick, all measures which are required, avoiding those twin traps of overtreatment and therapeutic nihilism. . . . I will remember that I remain a member of society, with special obligations to all my fellow human beings, those sound of mind and body as well as the infirm. If I do not violate this oath, may I enjoy life and art, respected while I live and remembered with affection thereafter. May I always act so as to preserve the finest traditions of my calling and may I long experience the joy of healing those who seek my help." John Hopkins University, Hippocratic Oath (Modern Version), http://guides.library.jhu.edu/content.php?pid=23699&sid=190964 (last visited Mar. 23, 2010).

155. ASRM Reacts to Latest News, *supra* note 10.

156. *Id.*

157. *Id.*

158. Conversely, a couple may choose not to undergo selective reproduction. The New York Times recently published the article about a couple that chose not to undergo selective reproduction, and the tragic results that ensued. *See* Stephanie Saul, *Grievous Choice on Risky Path to Parenthood*, N.Y. TIMES, Oct. 12, 2009, http://www.nytimes.com/2009/10/12/health/12fertility.html?_r=1&th&emc=th.

reduce the number of fetuses in the uterus."[159] It involves "inject[ing] potassium chloride into the fetus."[160] This procedure is performed to protect the health of the mother and "to prevent the entire pregnancy from aborting or delivering very prematurely."[161] Physicians perform selective reduction procedures in one to two percent of pregnancies.[162] Selective reduction procedures are "more likely to be performed when there are four or more fetuses present."[163] However, selective reduction results in miscarriages in four to five percent of cases.[164] While the CDC does not collect information on selective reduction, "[a]pproximately one-third of infertility patients would not consider selective reduction for religious or ethical reasons."[165] While some critics argue selective reduction is not an adequate or ethical solution to the problem of multiple birth pregnancies, selective reproduction procedures do address the underlying health risks to both the mother and her children.

Market forces also regulate the availability of IVF treatments, and influence patients' perceptions of multiple birth pregnancies. Since IVF treatments are expensive and usually not covered by insurance, patients may be delighted to conceive twins or triplets.[166] In order to combat the high costs of IVF treatments, some clinics have offered shared-risk or refund programs. Under shared-risk or refund programs, a patient will pay a high fee, and if the patient conceives, the fertility clinic keeps the money, and if the patient fails to conceive, "90 to 100% of the fee is returned."[167] Patients will not receive reimbursement for pretreatment screening costs or the cost of fertility drugs.[168] These programs give peace of mind to IVF patients who are concerned about the high costs of IVF, or have a "substantial risk of IVF failure."[169] These shared-risk plans can also reduce patients' desires

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159. AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, PATIENT'S FACT SHEET: FERTILITY DRUGS AND THE RISK OF MULTIPLE BIRTHS 13 (2004), http://www.asrm.org/Patients/patientbooklets/multiples.pdf [hereinafter FERTILITY DRUGS AND THE RISK OF MULTIPLE BIRTHS].

160. AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, PATIENT'S FACT SHEET: MULTIPLE GESTATION AND MULTIFETAL PREGNANCY REDUCTION 1 (1996), http://www.albanyivf.com/resources/docs/ASRMFactSheetMultipleGestationandMultifetalPreganancyReduction.pdf [hereinafter MULTIPLE GESTATION AND MULTIFETAL PREGNANCY REDUCTION].

161. FERTILITY DRUGS AND THE RISK OF MULTIPLE BIRTHS, *supra* note 159, at 13.

162. *Id.*

163. Multiple Gestation and Multifetal Pregnancy Reduction, *supra* note 160, at 1.

164. *Id.*

165. Amy B. Monahan, *Value-Based Mandated Health Benefits*, 80 U. COLO. L. REV. 127, 164 (2009).

166. *See* Velikonja, *supra* note 28, at 486–90.

167. ASRM ETHICS COMMITTEE, RISK-SHARING OR REFUND PROGRAMS IN ASSISTED REPRODUCTION 1 (2006), http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Ethics_Committee_Reports_and_Statements/sharedrisk.pdf.

168. *Id.*

169. *Id.*

for multiple birth pregnancies because patients can go through multiple unsuccessful IVF treatments without accruing too much debt, and thus, IVF patients are not economically pressured into having multiples.

Furthermore, even if a clinic does not offer shared-risk or refund programs, or IVF patients do not undergo multiple IVF treatments, an IVF patient's knowledge about the high costs of raising a child also acts as an economic deterrent to multiple birth pregnancies. The Department of Agriculture estimates the cost of raising a child from birth to age seventeen is between $221,190 and $366,660 for middle to wealthy income families.[170] This hefty price tag combined with high delivery costs,[171] and companies unwillingness to donate products to multiples — a result of the increase in the number of multiples birth pregnancies[172] — make multiple births less appealing to expectant parents.

To conclude, SART's and ASRM's efforts to reduce multiple birth pregnancies combined with selective reduction procedures and market pressures are effectively lowering fertility clinics' multiple birth pregnancy rates. Given the due diligence of America's medical societies, the comprehensiveness of their guidelines, and the advancements in the fertility field, the rate of multiple birth pregnancies will continue to decrease. Furthermore, with 95% of all IVF clinics in the United States complying with SART/ASRM's medical guidelines,[173] federal regulations are simply unnecessary, and redundant.

C. Problems with Regulating IVF treatments

Regulating IVF treatments in order to reduce the rate of multiple birth pregnancies raises a myriad of concerns, such as whether states or the federal government should enact regulations; whether IVF is covered under a person's fundamental right to procreate, or whether IVF is similar to adoption; whether regulations can be used as a stepping stone for the eugenics movement; whether regulations are necessary based on physicians'

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170. MARK LINO & ANDREA CARLSON, CTR. FOR NUTRITION POLICY & PROMOTION, U.S. DEPT. OF AGRICULTURE, EXPENDITURES ON CHILDREN BY FAMILIES, 20 (2009), *available at* http://www.cnpp.usda.gov/Publications/CRC/crc2008.pdf.

171. "For the year 2000, the projected costs of care for ART multiple births in the United States were $640 million, and $470 million for all IVF and ICSI cycles. The estimated costs for twins, triplets, and quadruplets were $377 million, $220 million, and $43 million, respectively." ASRM PRACTICE COMMITTEE, MULTIPLE PREGNANCY ASSOCIATED WITH INFERTILITY THERAPY 2 (2006), http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Educational_Bulletins/multiple_pregnancy_associated.pdf.

172. AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, PATIENT'S FACT SHEET: CHALLENGES OF PARENTING MULTIPLES 1 (2003), http://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/challenges.pdf.

173. What is SART?, *supra* note 124.

and patients' respective interests; whether IVF can withstand strict scrutiny; and whether regulations are obsolete in the face of fertility tourism.

1. Basic Principles in Family and Constitutional Law

First, family law is predominately regulated by state legislatures. Since each of the fifty states adopts different laws, there arises a so-called patchwork or "checkerboard"[174] of ART regulations. This checkerboard effect is not inherently bad. It does not "deny . . . equality before the law," or "send[] conflicting signal[s] that reduce the law's capacity to express and support underlying public values."[175] Instead, diversity among states allows for regulatory innovations. If one state system proves to be particularly effective, other states are free to adopt similar regulations. Furthermore, diversity among the states, and in particular the lack of ART restrictions, allows for medical innovation. Part of the thrust behind SART's campaign against government regulation is "fear [that] government regulation would limit their flexibility in utilizing innovative ART procedures and techniques, thereby compromising patient care and access."[176] These current, pressing concerns are assuaged by the states' general lack of regulation.

Second, if the federal legislature were to regulate ART and IVF treatments, it would have to do so under one of its enumerated Constitutional powers, such as the Commerce Clause, which has been liberally construed by the courts. Congress's mere desire to create uniformity does not give it the power to trample on state sovereignty, or an area of the law that is and has historically been under the exclusive control of state governments. Third, should a state adopt a measure similar to the U.K. SET policy, and the Supreme Court declare it unconstitutional, the Court's actions are not likely to prevent states from adopting different regulations, nor would it give the federal government the authority to preemptively regulate ART and IVF treatments. Fourth, should states begin to regulate ART, a regulatory gap will emerge between new ART procedures and current regulation. This gap is evident in other areas of family law,[177] and it is subsequently filled by common law doctrines and public policy arguments.[178]

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174. Garrison, *supra* note 58, at 1630–31.

175. *Id.* at 1630.

176. Ouellette et al., *supra* note 11, at 433.

177. There are gaps in family law with regards to recognizing legal parentage, granting visitation rights, and establishing intestate succession for non-traditional families and family members, i.e. for unmarried heterosexual couples like Brangelina, or for LGBTQAA couples, or for third parties, such as grandparents. *See generally* Troxel v. Granville, 530 U.S. 57 (2000); Michael H. v. Gerald D., 491 U.S. 110 (1989); Stanley v. Ill., 405 U.S. 645 (1972); O'Neal v. Wilkes, 439 S.E.2d 490 (Ga. 1994); Adoption of Tammy, 619 N.E.2d 315 (Mass. 1993); In re Alison D. v. Virginia M, 572 N.E.2d 27 (N.Y. 1991).

178. *See* CHARLES P. KINDREGAN, JR. & MAUREEN MCBRIEN, ASSISTED REPRODUCTIVE TECHNOLOGY: A LAWYER'S GUIDE TO EMERGING LAW AND SCIENCE 25

Finally, ART and IVF treatments are fundamentally different from adoption.[179] Adoption is both a public act, and a statutory right. Each state is free to set different criteria for adoptions,[180] and there is no fundamental right to adoption.[181] In the adoption context, states can intrude into the otherwise protected realm of family privacy because the state is acting *in loco parentis*, meaning the state is stepping into the shoes of the parent, and assuming the fundamental parental rights of care, custody, and control.[182] The state only assumes this responsibility after proving by clear and convincing evidence that the child's legal parents are unfit, and a court subsequently terminates parental rights.[183] Courts apply the amorphous "best interests of the child" standard to determine a legal parent's fitness.[184]

When states regulate ART, states are not acting *in loco parentis* or assuming parental responsibility because a living child has yet to be born. Instead, the legislature is dealing with eggs, sperm, and embryos. Moreover, when ART disputes arise before a child is conceived, courts are unlikely to apply the "best interests of the child" standard, and even after a child is born, courts often rely on an "intent" standard in lieu of the "best interests of the child" standard.[185] Furthermore, prior to the birth of the child, ART parents are not legal parents, but prospective legal parents. These prospective legal parents are in the same situation as prospective legal parents who conceive naturally.[186] States do not license people to be parents, whether the children are conceived naturally or using IVF. However, should a state apply the adoption approach to IVF treatments and adopt an SET policy, states will effectively be licensing parentage, as limiting the number of embryos to implant will affect some women's ability to conceive a child.

(2006). "[I]t is unlikely that widespread enactment of uniform laws will be forthcoming in the foreseeable future except possibly in regard to the status of children conceived by ART. The issues involved are politically controversial and often mixed with religious, moral, medical, political, social, and legal disagreement. This makes it too difficult for the political branches of government to develop a consensus as to how to regulate assisted reproduction. . . . Thus it is likely that for many years lawyers and judges will have to struggle with these issues on a common-law or equitable basis and evolve solution on a case-by-case basis." *Id.*

179. *See* Cahn & Collins, *supra* note 58, at 512–13.

180. States' unlimited ability to regulate adoption permits discriminatory bars on adoption by LGBTQAA couples. *See generally* Lofton v. Sec'y of the Dep't of Children and Family Servs., 377 F.3d 1275 (11th Cir. 2004).

181. *Id.*

182. *Id.*

183. Santosky v. Kramer, 455 U.S. 745, 767–70 (1982).

184. *Id.* at 745–63.

185. *See generally* Kass v. Kass, 696 N.E.2d 174 (N.Y. 1998); Davis v. Davis, 842 S.W.2d 588 (Tenn. 1992); In re Marriage of Buzzanca, 72 Cal.Rptr.2d 280 (Cal. Ct. App. 1998).

186. *See* Radhika Rao, *Equal Liberty: Assisted Reproductive Technology and Reproductive Equality*, 76 GEO. WASH. L. REV. 1457, 1460 (2008).

2. Eugenics

Regulating IVF and the potential restrictions on IVF procedures creates concerns about eugenics — the idea that governments can use selective breeding to create ideal citizens. The eugenics movement targets homosexuals, the handicapped, the poor, the mentally ill, Jews, Roma, and other minority groups. Supporters of IVF regulation argue eugenics concerns are inapplicable to the regulation of IVF procedures. After all, they argue regulating procedures do not determine who can and cannot conceive children. Yet in May of 2004, the FDA adopted guidelines that ban "[m]en who have had sex with another man in the preceding 5 years" from being anonymous sperm donors.[187] This regulation was adopted under the guise of wanting to prohibit the spread of HIV infections.[188] Yet it ignores the fact that sperm can easily and accurately tested for HIV, that "women with HIV may soon outnumber men with HIV,"[189] and that "[e]ven though blacks (including African Americans) account for about 13% of the U.S. population, they account for about half (49%) of the people who get HIV and AIDS."[190] Given this blatant refusal to recognize the reliability of HIV testing, or statistical data showing that HIV/AIDS is not a disease that exclusively affects men in the LGBTQAA community, this *procedural* regulation prohibits gay men from anonymously donating sperm, and passing on their genes to future generations. Thus, concerns about how eugenics will influence the regulation of IVF, if more procedural regulations are adopted, are valid.

3. Social Contract Theory

Supporters of IVF regulation write their proposed regulations knowing their place in society, and whether or not they will likely be subject to their own regulations. If they were a legislator blindly writing IVF regulations, not knowing whether they would be an IVF physician, a patient, or a child conceived using IVF, they may not be so quick to jump to the conclusion that America's self-regulation is inadequate. A woman seeking IVF treatments at a fertility clinic and her physician do not view her IVF

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187. FOOD AND DRUG ADMINISTRATION, *supra* note 120, at 14.

188. Gardiner Harris, *F.D.A. to Limit Sperm Donors*, N.Y. TIMES, May 20, 2004, http://www.nytimes.com/2004/05/20/health/20organ.html. "New York State already bars gay men from donating sperm anonymously, and most of the nation's sperm banks have similar restrictions because of concerns over transmission of H.I.V., the virus that causes AIDS." *Id.*

189. Centers for Disease Control and Prevention, *HIV/AIDS and Women*, http://www.cdc.gov/hiv/topics/women/index.htm (last visited Mar. 20, 2010).

190. Centers for Disease Control and Prevention, *HIV/AIDS and African Americans*, http://www.cdc.gov/hiv/topics/aa/index.htm (last visited Mar. 20, 2010).

treatment as creating a "baby market"[191] or "treat[ing] something integral to ourselves as a commodity, i.e. as separate and fungible,"[192] but instead view it as a woman conceiving her first child. A couple who seeks IVF after failing to conceive, or suffering a miscarriage does not conceive of themselves being in a "synergistic 'economic and emotional' vortex" that "causes them to obsess about conceiving . . . [and to] risk the lives of their future children."[193] Instead, this couple sees the woman's IVF treatment as a step toward building a family together. Furthermore, the attending physicians, who practice in fertility clinics and help patients bring children into this world, do not consider themselves to be cowboys operating in the "'Wild West' of medicine."[194] Nor would a conscientious physician, who cares about the health and safety of her patients, "feel the obligation, supported by the ethical patient autonomy, to accede to the strong desires of their patients"[195] when the procedure is not in her patient's best interests. Finally, where physicians own their own fertility clinics, the desire to maximize their clinics' baby take-home rate[196] will not compromise patient care if the physicians comply with the ASRM's guidelines, and their clinics measure success based on singleton births. In conclusion, since the underlying assumptions made by supporters of regulation are far-fetched, and easily rebutted by the concerns of both the physicians and the patients, proposals asking states to apply the adoption model to IVF treatments, to adopt a comprehensive regulatory scheme, or to place strict limitations on the number of embryos implanted in patients are paternalistic, and place unnecessary restrictions on others' procreative rights.

4. Due Process and IVF Regulations

If states rely upon an adoption approach to IVF treatments, ignore concerns about how cultural biases, stereotypes, and eugenics will influence ART regulations, adopt fanciful presumptions about IVF physicians and patients, and pass a law similar to the U.K. SET policy, limiting the number of embryos to be implanted in an IVF patient, the next question to ask is what level of scrutiny will the Supreme Court apply when determining the constitutionality of these regulations? Proponents of protecting individual, intimate decision-making, and thus, allowing for wide, unencumbered access to IVF treatments, will argue ART is a part of an individual's fundamental right to procreate. Therefore, they argue IVF treatments are

191. Sonia M. Suter, *Giving in to Baby Markets: Regulation Without Prohibition*, 16 MICH. J. GENDER & L 217, 232–34 (2009).

192. *Id.* at 222.

193. Rosato, *supra* note 18, at 104–05.

194. *Id.* at 73.

195. *Id.*

196. *Id.* at 72–73.

protected by the Due Process Clause of the U.S. Constitution, and IVF regulations are subject to strict scrutiny.[197]

The Due Process Clause in the Fifth Amendment states, "[n]o person shall . . . be deprived of life, liberty, or property, without due process of law."[198] The Due Process Clause applies to the states under the Fourteenth Amendment.[199] The Due Process Clause incorporates restrictions that are not enumerated in text of the Constitution,[200] and it generally protects an individual's right to privacy.[201] Supreme Court precedent establishes that individuals have a fundamental right to procreation.[202] The Supreme Court has previously stated, "The decision whether or not to beget or bear a child is at the very heart of . . . constitutionally protected choices."[203] It is "one of the basic civil rights of man."[204] Furthermore, "the rights of personal intimacy, of marriage, of sex, of family, of procreation . . . are fundamental rights protected by both the federal and the state Constitutions . . . ."[205]

This fundamental right to procreation gives individuals the broad right to make intimate decisions about procreation.[206] In *Griswold v. Connecticut*, the Court held a law that made it illegal to give information to married couples about contraception violated Due Process.[207] Thus, the Court establishes that married couples have the right to use contraception. An individual's fundamental right to procreation is expanded in *Roe v. Wade*, which establishes that a woman's right to procreation includes her unfettered right to choose up until the viability of the fetus. The Court analysis is further elaborated upon in *Planned Parenthood of Southeastern Pa. v. Casey*, which establishes that states may regulate abortions before the

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197. *See* John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U.L. REV. 421, 426–28 (1996) (arguing since there is a fundamental right to choose whether or not to be a parent, regulations that restrict access to PGD information, which can influence this decision, are unconstitutional unless the state meets strict scrutiny).

198. U.S. CONST. amend. V.

199. U.S. CONST. amend. XIV § 1.

200. *See* Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 877 (1992).

201. *See* Griswold v. Conn., 381 U.S. 479, 483–86 (1965).

202. *See generally* Skinner v. Okla., 316 U.S. 535 (1942) (holding that an Oklahoma law requiring the forced sterilization of habitual criminals violates the 14th Amendment on Equal Protection grounds). "Oklahoma deprives certain individuals of a right which is basic to the perpetuation of a race—the right to have offspring." *Id.* at 536. "And so I think the real question we have to consider is not one of equal protection, but whether the wholesale condemnation of a class to such an invasion of personal liberty, without opportunity to any individual to show that his is not the type of case which would justify resort to it, satisfies the demands of due process." *Id.* at 544 (Stone, C.J. concurring).

203. Carey v. Population Servs. Int'l, 431 U.S. 678, 685 (1977).

204. Skinner, 316 U.S. at 541.

205. In re Matter of Baby M., 537 A.2d 1227, 1253 (N.J. 1988).

206. "Regulations imposing a burden on a decision as fundamental as whether to bear or beget a child may be justified only by compelling state interests, and must be narrowly drawn to express only those interests." Carey, 431 U.S. at 678.

207. Griswold, 381 U.S. at 485–86. This holding was later extended to unmarried couples in Eisenstadt v. Baird. *See generally* Eisenstadt v. Baird, 405 U.S. 438 (1972).

fetus attains viability, so long as they do not place an undue burden on a woman's right to choose. An undue burden has been defined as having "the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus."[208] If an undue burden is established, the state must then justify this undue burden and the court will apply the strict scrutiny test. Supporters of regulating IVF treatments have argued the United Kingdom's regulations would pass the Court's "undue burden" standard, or, alternatively, they would meet strict scrutiny.[209] This conclusions are false.

Limiting the number of embryos that can be implanted in an IVF patient would place an undue burden on a woman seeking to exercise her reproductive choices. After all, under the current ASRM guidelines, it may be appropriate for a doctor to implant up to five embryos in a patient, and in determining how many embryos to implant, doctors can consider the patient's circumstances if the patient has failed to conceive.[210] Thus, limiting physician-patient discretion may very well prevent a woman from conceiving all together. Since limiting the number of embryos that may be implanted creates an undue burden, the state's justification must then meet strict scrutiny.

In order to meet strict scrutiny, the government must have a compelling government interest, and the law must be narrowly tailored to achieve that compelling government interest.[211] A state may argue it has a compelling interest in protecting the health and safety of both the mother and the IVF child by limiting the number of multiples. Yet a state lacks a *compelling* interest in regulating the number of embryos to implant in a patient because it is not protecting a child, but is in fact addressing embryos that have yet to be implanted in a woman. Moreover, there is no guarantee of a health risk for either the mother or the children, as the IVF treatment might fail, the mother may elect to undergo selective reduction, or the children may be twins or triplets and be born healthy. Also, there is no guarantee that families with multiples will place financial burdens on the state.[212] Furthermore, a law limiting the number of embryos implanted would fail the narrow tailoring prong, as a numerical limit will likely prevent

208. Planned Parenthood of Southeastern Pa., 505 U.S. at 877.

209. Garrison, *supra* note 58, at 1626–28; *see also* Rosato, *supra* note 18, at 95–109.

210. GUIDELINES ON NUMBER OF EMBRYOS TRANSFERRED, *supra* note 8, at 1.

211. Carey, 431 U.S. at 678.

212. After all, Jon and Kate Gosselin, who have twins and a set of sextupletsconceived by artificial insemination, supported their children from the proceeds of the Jon and Kate Plus 8 television show, book deals, and various speaking engagements. *See* Lahle Wolfe, *Biography of Kate Gosselin*, ABOUT.COM, http://womeninbusiness.about.com/od/famouswomenentrepreneurs/p/Kate-Gosselin.htm (last visited Mar. 27, 2010); *see also* Alan Duke, *Jon Gosselin's Epiphany: Reality TV Not Good for My Kids,* CNN, Oct. 2, 2009, http://www.cnn.com/2009/SHOWBIZ/TV/10/02/lkl.jon.gosselin/index.html ("Gosselin revealed to King that the family was paid $22,500 per episode, with none of the money specifically designated for the eight children.").

reproduction in older woman. Again, ASRM guidelines suggest implanting as many as two to five embryos per IVF treatment. Also, numerical limits on IVF transfers will not prevent multiple birth pregnancies that occur due to ovarian stimulation injections. Additionally, there is no history of regulation with regards to the number of embryos implanted in a woman, and "there is no state statutory regulation of in vitro fertilization that restricts or controls choices made by medical personnel, patients, or donors."[213] Therefore, if state governments adopt a SET policy, these statutes would fail strict scrutiny, and be declared unconstitutional based on the Fourteenth Amendment.

5. Fertility Tourism

Capping the number of embryos implanted during IVF treatments, or imposing a comprehensive regulatory scheme on fertility clinics, will result in "fertility tourism," meaning couples will travel outside the United States to receive fertility treatments. Fertility tourism is not only a problem because it defeats the goal of the regulations, but it also leads to the "relocation of skilled doctors," and "significant concentrations of those professionals in minimally regulated areas."[214] Fertility tourism is popular among British citizens, who frequently come to the United States to take advantage of its progressive laws.[215] They also travel to other less regulated countries, such as Spain and the Czech Republic.[216] Fertility tourism affects women in other heavily regulated nations like Italy, France, the Netherlands, and Germany. [217] "Italian women are crossing the border in droves following tough legal restrictions on IVF imposed in 2004, while large numbers of gay French women bypass a ban by seeking treatment in Belgium."[218] Yet British women can be distinguished from their European counterparts. According to a study conducted by the European Society for

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213. KINDREGAN & MCBRIEN, *supra* note 178, at 78.

214. Aaron R. Fahrenkrog, *A Comparison of International Regulation of Preimplantation Genetic Diagnosis and A Regulatory Suggestion for the United States*, 15 TRANSNAT'L & CONTEMP. PROBS. 757, 770–71 (2006).

215. One of the most publicized downsides of the United Kingdom's system is fertility tourism between the United Kingdom and the United States has grown, since English citizens are traveling United States to take advantage of its progressive laws. *See* Jon di Paolo, *UK Couples 'Forced to go Abroad for IVF'*, SKY NEWS, July 31, 2009, http://news.sky.com/skynews/Home/UK-News/IVF-Tourism-More-Couples-Being-Forced-To-Go-Abroad-By-NHS-Postcode-Lottery/Article/200907415350053; *see also Increase in IVF Tourism for UK & European Couples Due to U.S. Economy & Progressive Laws*, REUTERS, June 23, 2009, http://www.reuters.com/article/pressRelease/idUS127254+23-Jun-2009+BW20090623?sp=true.

216. Sarah Bosely, *NHS Restrictions Prompt Fertility Tourism Boom*, THE GUARDIAN, June 30, 2009, http://www.guardian.co.uk/society/2009/jun/29/women-over-40-fertility-tourism.

217. *Id.*

218. *Id.*

Human Reproduction and Embryology in Amsterdam, "Although 80 per cent of German women, 70 per cent of Italians and 65 per cent of French women who traveled abroad for IVF cited legal restrictions at home, British women were the most likely to cite *access* difficulties as their main reason for seeking help in mainland Europe."[219] Furthermore, "63.5% of the British patients were over 40."[220] It is worthy to note that patients who are forty and over are more likely to be affected by the SET policy, and its concurrent strict two or three embryo policy. Therefore, not only would a SET policy fail strict scrutiny in the United States, if U.S. states adopt SET policies in the interim, these statutes would simply force older women to seek treatment overseas.

CONCLUSION

In order to avoid imposing unnecessary and unconstitutional regulations upon an individual's right to procreate, legislators, scholars, and public policy groups concerned with the problem of multiple birth pregnancies should focus their energies on educating health care professionals and IVF patients about the dangers of multiple birth pregnancies, educating infertile couples about alternative options to IVF treatments, such as adoption or surrogacy, and educating physicians on the latest breakthrough ART techniques, which increase their patients' success rates without leading to multiple birth pregnancies. These goals can be simply and cheaply achieved by increasing funding for ASRM's and SART's existing research and educational programs. Funding awareness and research into fertility treatments will lower the rate of multiple birth pregnancies in the United States, and IVF patients and their offspring, such as Nadya Suleman and her children Noah, Maliyah, Isaiah, Nariyah, Makai, Josiah, Jeremiah, Jonah, Elijah, Amira, Joshua, Aidan, Calissa, and Caleb, will be regarded as merely a blurb in a medical history book.

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219. Steve Connor, *Women Over 40 Fuel Boom in European 'IVF tourism'*, THE INDEP., June 30, 2009, http://www.independent.co.uk/life-style/health-and-families/health-news/women-over-40-fuel-boom-in-european-ivf-tourism-1724463.html.

220. *Id.*