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ASSISTED REPRODUCTIVE TECHNOLOGY: THE DANGERS OF AN UNREGULATED MARKET AND THE NEED FOR REFORM

*Andrea Preisler**

I. INTRODUCTION

The last century has seen incredible advances in science never before imaginable. Identifying health concerns and curing diseases have given people new hope in science and its abilities. However, while these scientific and technological advances bring great joy and relief, they also prompt controversial debates. One such debate has surrounded assisted reproductive technology (“ART”). Ethical, social, and legal challenges surrounding this technology have plagued the United States. For many couples and women desperate to have a child, ART is seen as a magical cure to infertility. Others denounce it as a “new holy war against human nature.”¹ To them, it is morally repugnant to let science and technology intervene in the most sacred area of human life: procreation.

As society struggles to assess the ethical, cultural, legal, and religious dimensions of what this reproductive technological progress means for families and society, scientists continue to improve upon and advance ART.² Because of society’s struggle to come up with a cohesive consensus on ART, lawmakers have been slow to address this technology. This apprehension has left a gaping hole for a booming, unregulated market fraught with fraud and abuse. There are no rules and restrictions for ART providers or the intermediaries who have identified a wildly lucrative niche in the market; it is a lawless free-for-all where the most exploitive providers reign. Currently, ART cannot be explored solely through a legal framework simply because no such structure exists; instead, it first must be analyzed through an economic lens. One cannot formulate a comprehensive legal structure for the ART industry without understanding and accepting the economic realities of this science turned big business. “Buyers, sellers, supply and demand, and technological

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1. *Guiding Regulatory Reform in Reproduction and Genetics*, 120 HARV. L. REV. 574 (2006).

2. Lori B. Andrews & Nanette Elster, *Regulating Reproductive Technologies*, 21 J. LEGAL MED. 35 (2000).

advances all operate in a robust marketplace . . . with minimum state and federal regulatory control.”³ This lack of oversight has opened the floodgates to exploitation and commercialization of one of the most valued and personal aspects of society.⁴ Third parties have been quick to recognize that there is no profit ceiling given the lack of federal regulation and ineffective and unenforceable industry recommendations.

The absence of oversight and regulation combined with the high cost of fertility treatments created the perfect storm for the commercialization of procreation. While assisted reproductive technology has given infertile couples and individuals hope for a child, state legislatures and Congress have fundamentally failed to respond to this technology by promulgating shallow regulations that are nonbinding, unenforced, and inadequately funded thereby exposing consumers of the technology to safety hazards and financial exploitation. Technology that emerges as controversial and becomes so deeply rooted in society becomes difficult, if not impossible, to regulate.⁵ The regulatory history of reproductive technology, or lack thereof, “highlights the phenomenon that strong public acceptance and entrenched market forces surrounding new technologies often result in suboptimal safety standards.”⁶

In order to explore the legal implications of assisted reproductive technology, one must understand what it is. This article begins with a background in ART in Part II. Part III provides an overview of the history of regulation and its current state while outlining inadequacies. Part IV addresses concerns and possibilities for fraud and abuse in the reproductive technology industry, including abuses as they relate to providers of assisted reproductive technology and middlemen. Finally, Part V explores what is needed in a successful and effective regulatory framework, its aims, and how to implement new regulation.

II. WHAT IS ART?

Assisted reproductive technology (“ART”) is the general terminology used to define the process of conceiving a child through artificial or partially artificial means. It is typically viewed as a means of treating infertility. The Centers of Disease Control and Prevention (“CDC”), as a

3. Brenda Reddix-Small, *Assessing the Market for Human Reproductive Tissue Alienability: Why Can We Sell Our Eggs But Not Our Livers?*, 10 VAND. J. ENT. & TECH. L. 643 (2008).

4. Meena Lal, *The Role of the Federal Government in Assisted Reproductive Technologies*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 517, 518 (1997).

5. *Guiding Regulatory Reform in Reproduction and Genetics*, *supra* note 1, at 592.

6. *Id.* at 595.

result of the 1992 Fertility Clinic and Success Rate and Certification Act, defines ART as “all fertility treatments in which both eggs and sperm are handled. In general, ART procedures involve surgically removing eggs from a woman’s ovaries, combining them with sperm in the laboratory, and returning them to the woman’s body or donating them to another woman.”⁷ The acceptance and use of ART has been increasing rapidly from its inception in the 1970s.⁸ ART has spawned an industry that aids thousands of American couples and women with conceiving children despite the high out-of-pocket costs.⁹

ART encompasses several distinct methods of achieving pregnancy, and some methods may be combined and modified. Procedures of ART include artificial insemination, pre-implantation surgeries, surrogacy, and in vitro fertilization (“IVF”). This article primarily addresses IVF and the sperm bank intermediary in IVF and artificial insemination.

In vitro fertilization, the classic form of ART, was first accomplished in 1978 and the first American IVF birth took place in 1981.¹⁰ Since its inception, IVF has resulted in over two million births worldwide.¹¹ IVF is typically used after other infertility treatment options have been exhausted. It is accomplished by harvesting eggs from a female and mixing them with sperm from a male in a petri dish where fertilization occurs. One or more of the resulting embryos are then transferred back into the patient where they implant themselves in the uterine wall.¹² There are various methods of IVF given its use of gametes: the sperm and/or eggs may come from donors, the fertilized embryos may be transferred back into the woman who supplied the eggs or into an unrelated surrogate, and the embryos may be transferred into the woman’s uterus or, usually at an earlier period of embryonic development, into her fallopian tubes.¹³ The process of placing the embryo into the uterus or fallopian tube is accomplished using a tube called a cannula, just as sperm is in artificial insemination.¹⁴

7. 42 U.S.C. § 263(a) (2012).

8. John A. Robertson, *Commerce and Regulation in the Assisted Reproduction Industry*, 85 TEX. L. REV. 665 (2007).

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

10. Robertson, *supra* note 8 at 665.

11. *Id.*

12. Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 609 (2003).

13. *Id.*

14. Weldon E. Havins & James J. Dalessio, *The Ever-Widening Gap Between the Science of Artificial Reproductive Technology and the Laws Which Govern That Technology*, 48 DEPAUL. L. REV. 825, 834 (1999).

Artificial insemination is the placement of semen into the uterus opening.¹⁵ The sperm cells travel through the cervix and uterus and into the fallopian tube where they fertilize one or more eggs. The fertilized egg, which is now a zygote, moves back down the fallopian and into the uterus where it implants itself into the uterine wall.¹⁶ Artificial insemination is a particularly attractive ART option for a female who does not have a male partner or has a male partner who is sterile.

III. HISTORY OF ART POLICIES AND GOVERNMENT INVOLVEMENT

In 1979, President Jimmy Carter appointed an Ethics Advisory Board ("EAB") to address research issues surrounding ART, specifically those relating to IVF, which experienced its first success a year earlier.¹⁷ Ultimately, the EAB issued a report stating it was "acceptable from an ethical standpoint to undertake and fund research involving human IVF and embryo transfer subject to various qualifications."¹⁸ While the EAB approved of continued research of IVF, it avoided the relevant ethical and legal questions regarding the morality of IVF or embryo research and how IVF technology and research fit into the United States legal regime. Despite the EAB's support for continued research of IVF, it intentionally circumvented the difficult issues that ART raised and continues to raise. Subsequently, the Carter, Reagan, and George H.W. Bush administrations denied funding for the EAB.¹⁹ Without federal funding and minimal authority, the EAB disappeared.

Lacking federal oversight or funding, ART research was privately funded in the 1980s. Private firms quickly discovered the earning potential of ART and began to dominate this area of science operating under a set of suggested guidelines with minimal oversight.²⁰ This allowed private researchers to push the limits of ART. The private industry's rapid advances coupled with the lack of regulation fueled the demand for this miracle technology. These circumstances exemplified the "ever-increasing gap between ART and the field of medical science, on the one

15. Michael J. Kirby, *Medical Technology and new Frontiers of Family Law*, 14 L. MED. & HEALTH CARE 113 (1986).

16. Havins & Dalessio, *supra* note 14, at 834.

17. Reddix-Small, *supra* note 3, at 654.

18. *Id.*

19. *Id.*

20. *Guiding Regulatory Reform in Reproduction and Genetics*, *supra* note 1, at 574.

hand, and the lack of any consistent regulation of that science, on the other.”²¹

IV. CURRENT LEGAL FRAMEWORK

Currently, the private sector continues to dominate ART research. Private firms, companies, and university medical facilities conduct ART research and operate by their own non-binding standards and guidelines outlined by several medical societies and associations.²² From the outset of the private sector developing ART technology, the government was apprehensive to get involved and formulate a cohesive legal framework of rules and regulations.²³ This initial apprehension of how to approach ART had the unfortunate and likely unintended consequence of opening up a burgeoning private assisted reproductive technology industry. The United States’ only policy on reproductive technologies is essentially a market-driven policy.²⁴

A. 1992 Fertility Clinic Success Rate and Certification Act

The oversight and policy of ART has largely been a story of self-regulation with little effort by state or federal government to formulate an enforceable policy. Legally, the right to oversee the reproductive technology industry has been assigned to the Department of Health and Human Services (“DHHS”).²⁵ In 1992 the DHHS delegated this oversight power to the Centers for Disease Control and Prevention (“CDC”) in the Fertility Clinic Success Rate and Certification Act (“FCSRCA”), which outlines critical components of ART regulation.²⁶ The Act promulgates a model program for the certification of embryo laboratories, which was to be adopted and carried out voluntarily by individual states.²⁷

The enactment of FCSRCA was largely driven by public policy concerns and the need to assure high standards of care within the assisted reproductive technology market.²⁸ The Act stated, “not later than 2 years

21. Havins & Dalessio, *supra* note 14, at 828.

22. Hecht, *supra* note 9, at 253.

23. *Id.* at 231.

24. Andrews & Elster, *supra* note 2, at 36.

25. Havins & Dalessio, *supra* note 14, at 843.

26. Yaniv Heled, *The Regulation of Genetic Aspects of Donated Reproductive Tissue—The Need for Federal Regulation*, 11 COLUM. SCI. & TECH. L. REV. 243, 250 (2010).

27. Implementation of the Fertility Clinic Success Rate and Certification Act of 1992—A Model Program for the Certification of Embryo Laboratories, 64, Fed. Reg., 39374 (21 July 1999).

28. Anne Drapkin Lyerly, *Marking the Fine Line: Ethics and the Regulation of Innovative Technologies in Human Reproduction*, 11 MINN. J. L. SCI. & TECH. 685, 701 (2010).

after October 24, 1992, the Secretary, through the Centers for Disease Control, shall develop a model program for the certification of embryo laboratories (referred to in this section as a “certification program”) to be carried out by the States.”²⁹

Section two of the FCSRCA required ART clinics and providers to report their pregnancy success rates to the CDC and all reporting standards were to be established by the CDC.³⁰ The statute required that the Secretary, through the CDC, define pregnancy success rates and mandate that each clinic report its success rates annually so that the CDC can make the findings publically available.³¹ This policy was intended to combat the problem of clinics exaggerating pregnancy success rates and to ensure that consumers are properly informed and knowledgeable about pregnancy success rates. Further, the policy would allow consumers to more accurately predict the chances of a live birth.³²

Section three of the FCSRCA required the CDC to develop a model program for the accreditation of IVF laboratories that was to be adopted by each state.³³ Again, the Secretary, through the CDC, was to “promulgate criteria and procedures for the approval of accreditation organizations to inspect and certify embryo laboratories.”³⁴ The Act briefly stated that certified laboratories were to meet certain criteria and procedures “as the Secretary . . . may require”³⁵ and that the performance of each accredited organization must be evaluated and inspected annually by such means “as the Secretary determines to be appropriate.”³⁶ In 1999, the CDC published the Model Program, which set forth a skeleton of a certification program for individual states to adopt, supplement, and implement. The Program included proposed definitions, administrative requirements, and laboratory standards.³⁷

Additionally, the Act instructed the Secretary of DHHS to annually publish pregnancy success rates as reported by ART programs.³⁸ It also instructed the Secretary to compile a list of noncompliant laboratories. However, the Act does not promulgate a means to shut down these noncompliant organizations, allowing them to continue to operate without

29. 42 U.S.C. § 263 a-2(a)(1) (2012).

30. Heled, *supra* note 26, at 250.

31. Havins & Dalessio, *supra* note 14, at 843.

32. *Id.*

33. Hecht, *supra* note 9, at 255.

34. 42 U.S.C. § 263a-3(a) (2012).

35. 42 U.S.C. § 263a-3(b)(1) (2012).

36. 42 U.S.C. § 263a-3(c)(2) (2012).

37. Heled, *supra* note 26, at 250.

38. 42 U.S.C. § 263a-5(1)(A) (2012).

meeting standards and consequently without sanctions.³⁹ Without teeth, the noncompliance list is virtually meaningless.

Theoretically, these provisions would maximize the quality of IVF procedures and ensure compliance with safety guidelines. They are neither difficult to comply with nor hinder clinic productivity. However, nearly all CDC efforts have been ineffective because of a lack of federal funding.⁴⁰ The 1992 FCSRCA did not receive federal funding for implementation until 1996 when the HHS allocated a meager \$1 million dollars to the CDC.⁴¹

The FCSRCA does not mandate states implement the certification program, aggravating its effectiveness.⁴² Therefore, Congress' establishment of a voluntary certification for embryo laboratories "fails to fulfill the existing need for clinics' standardization and internal control."⁴³ The director of the CDC claims 90% of clinics voluntarily report their success rates; however, without any audit mechanism or funding to devote to auditing, there is no way to confirm the accuracy of the reported data.⁴⁴ Further, because accreditation is voluntary, there is no system of determining exactly how many ART clinics currently offer laboratory services therefore making the director of CDC's claim unprovable.

On its face, the FCSRCA appears to be an appropriate regulatory measure because it provides guidelines and standards to assure consistent performance of procedures, quality control, and standard recordkeeping. However, there is neither inherent power to establish any regulation that has the effect of exercising supervision over the practice of ART programs nor any enforcement mechanism.⁴⁵ The FCSRCA only outlines the parameters of a much-needed comprehensive government regulation that tackles the problem of ensuring that ART patients are receiving quality medical care and forthright information. Further, it leaves the formulation and implementation of any regulation mirroring the Act solely up to the individual state legislatures and their pocketbooks. The FCSRCA "represents governmental regulation at its weakest."⁴⁶ "Existing controls

39. 42 U.S.C § 263a-4(b) (2012).

40. Hecht, *supra* note 9, at 255.

41. Havins & Dalessio, *supra* note 14, at 844.

42. Lal, *supra* note 4, at 533.

43. *Id.* at 534.

44. Havins & Dalessio, *supra* note 14, at 847.

45. Lal, *supra* note 4, at 534.

46. Reddix-Smalls, *supra* note 3, at 658.

are patchwork, and most decisions are left to individual providers and their patients.”⁴⁷

Federal regulation of ART is not only justifiable but also necessary. As “consumers” of ART technologies, couples are often so desperate for a biological child that they become too emotionally involved to maintain an objective stance toward the practices of ART providers.⁴⁸ All the federal government has done is issue voluntary guidelines for ART providers without any enforcement authority. No state department is authorized to punish a fertility clinic or practitioner for non-compliance with guidelines. The Act fails to provide noncompliant organizations with even a slap on the wrist. Consequently, ART providers and intermediaries are free to perform procedures for profit without government regulation.

B. Industry Self-Regulation

Because government regulation of reproductive medicine is minimal, ART providers operate under some form of self-regulation.⁴⁹ Providers utilizing exclusively private money to operate are largely free to develop their own rules and procedures governing reproductive technology.⁵⁰ Generally, providers are free to offer new, experimental infertility options, which are solely limited by the practitioners themselves or their supporting institutions.⁵¹

Industry leaders cite professional guidelines that may be helpful in industry self-regulation.⁵² Numerous medical societies and associations have published guidelines for ART providers.⁵³ The American Society for Reproductive Medicine (“ASRM”), a leading advocate for increased ART regulation, has issued a statement on ART and proposed guidelines.⁵⁴ The ASRM is the “leading market force in the field of reproductive medicine” representing individuals in law, bioethics, and reproductive medicine.⁵⁵ The organization reports on clinically relevant issues in reproductive

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

48. Lal, *supra* note 4, at 535.

49. *Guiding Regulatory Reform in Reproduction and Genetics*, *supra* note 1, at 578.

50. *Id.* at 587.

51. *Id.* at 578.

52. Lyerly, *supra* note 28, at 703.

53. See *Revised Minimum Standards for Practices Offering Assisted Reproductive Technologies*, AM. SOC'Y FOR REPROD. MED. (2008), available at [http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Guidelines_and_Minimum_Standards/Revised_minimum_standards\(1\).pdf](http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Guidelines_and_Minimum_Standards/Revised_minimum_standards(1).pdf).

54. Reddix-Small, *supra* note 3, at 673.

55. *Id.*

technology.⁵⁶ These reports propose industry guidelines and standards; however, “they fall short of providing adequate oversight for the protection of participants in innovative procedures.”⁵⁷ Following the guidelines is purely voluntary, and adherence to them is not required for professional certification, which itself is voluntary and does not hinder participation in the market.⁵⁸

The ASRM and the Society for Assisted Reproductive Technology (“SART”) created the Reproductive Laboratory Accreditation Program (“RLAP”).⁵⁹ The program established standards for accreditation.⁶⁰ According to SART, two-thirds of SART members are accredited through RLAP.⁶¹ As an accredited clinic, providers are required to comply with SART and ASRM guidelines. However, this accreditation is ultimately meaningless since neither the ASRM nor SART has the ability to enforce any requirements where even initial participation is voluntary.⁶² Furthermore, the associations do not have authority to sanction those ART providers in violation of the guidelines, nor do they have an independent auditing mechanism to detect such violations.⁶³

SART’s website lists its member companies, which include Bayer, Merck, Wyeth, Lilly, and Brown & Brown, meaning corporate giants are the entities making policy decisions in this market in the absence of federal oversight.⁶⁴ The ART industry’s mechanism of self-regulation is large, wealthy companies controlling the marketplace. The fertility provider’s alignment with the pharmaceutical and biological products industry may not be unethical or harmful; however, “groups like SART certainly cannot provide for sufficiently objective review of these clinics in light of their corporate relations.”⁶⁵

Professional organizations provide the most substantial guidelines for clinics, but these are either non-pervasive or not legally binding.⁶⁶ There is interplay of powerful, dominant participants in a market economy with unyielding demand. Self-regulation is insufficient for ensuring the health

56. Lyerly, *supra* note 28, at 702.

57. *Id.*

58. Lyerly, *supra* note 28, at 702.

59. Reddix-Small, *supra* note 3, at 673.

60. *Id.*

61. *Id.* at 673-74.

62. Lyerly, *supra* note 28, at 702.

63. *Id.* at 675.

64. Reddix-Small, *supra* note 3, at 675.

65. *Id.* at 676.

66. *Guiding Regulatory Reform in Reproduction and Genetics*, *supra* note 1, at 578.

and welfare of ART patients and resulting children.⁶⁷ The lack of oversight and regulation incentivizes abuse within the ART industry. There is minimal accountability, and providers are not shy to exploit the marketplace and play upon consumer emotions.

V. ABUSES AND CONCERNS

The fertility marketplace operates in stark contrast to most enterprises within the United States. It “operates without scrutiny from the usual regulatory oversight of enterprises that affect the health of citizens.”⁶⁸ There has been little effort for federal oversight of the fertility market, and a general lack of recognition of the need to regulate.⁶⁹ This produces the opportunity for industry actors to continue the unethical practices that have become characteristic of the ART market.⁷⁰

ART has spawned an industry that helps thousands of American couples and women in conceiving and has only increased in popularity.⁷¹ About 7.1% or 2.1 million married couples are infertile.⁷² Infertility is a natural consequence of aging and as individuals choose to bear children later in life they increasingly turn to fertility treatments as a solution to infertility.⁷³ In addition, ART provides a remedy for women seeking to bear and raise children on their own and same-sex couples desperate for children.

More than 11,000 physicians provide fertility services to an estimated 172,000 women each year.⁷⁴ And, while it has become an increasingly popular medical intervention, ART also has become a flourishing industry.⁷⁵ “Lack of national policy has resulted in the existence of exploitation and commercialization of one of the most valued and personal aspects of our society.”⁷⁶ Due to recent advancements in technology and the availability of ART procedures, the private infertility marketplace has exploded into a vibrant, free market.⁷⁷ The exchange of money for reproductive services brings a commercial element, but it does not change

67. Heled, *supra* note 26, at 276.

68. Reddix-Small, *supra* note 3, at 679.

69. Lal, *supra* note 4, at 533.

70. *Id.*

71. Hecht, *supra* note 9, at 227.

72. Judith F. Daar, *Accessing Reproductive Technologies: Invisible Barriers, Indelible Harms*, 23 BERKELEY J. GENDER L. & JUST. 18, 24 (2008).

73. Noah, *supra* note 12, at 612.

74. Hecht, *supra* note 9, at 230.

75. Noah, *supra* note 12, at 614.

76. Lal, *supra* note 4, at 518.

77. Reddix-Small, *supra* note 3, at 677.

the nature of the private and intimate act of reproduction.⁷⁸ This free market has prompted the ART industry to evolve into a moneymaking machine, incentivizing fraud and abuse to make a profit.

A. Big Business and Market Forces

Over the past few decades, advances in reproductive technology have created a market for babies “in which parents choose traits, clinics woo clients, and specialized providers earn millions of dollars a year.”⁷⁹ The fertility market has turned into interplay between powerful market participants and the economics of supply and demand.⁸⁰ “The dominant market forces in ART include the fertility clinics, the physicians, the pharmaceutical companies, the suppliers, the representative organizations, the embryo laboratories, the gamete middlemen and brokers, and the infertile consumer.”⁸¹

It is estimated that today’s ART industry reaps annual revenues of nearly seven billion dollars, and that figure continues to grow as the use of reproductive technology skyrockets.⁸² While the majority of the roughly 400 fertility clinics in the United States today operate for profit, some clinics are free-standing entrepreneurial facilities, and other clinics are housed within larger health care institutions.⁸³ Additionally, the international sperm supply industry is particularly concentrated in the United States with four of the five largest sperm banks based in the United States.⁸⁴ These four banks control about 65% of the international sperm market, an industry estimated to be worth between \$50 million and \$100 million dollars.⁸⁵

“Much like other fee-for-service operations such as elective cosmetic surgery, hospitals may establish fertility clinics as lucrative profit centers.”⁸⁶ A single IVF cycle may cost anywhere from \$10,000 to \$20,000, and, because couples may have to undergo many cycles in order to achieve a successful pregnancy, couples invest upwards of \$200,000 for a single pregnancy.⁸⁷ There has been no uniform pricing or price

78. Andrews & Elster, *supra* note 2, at 40.

79. Robertson, *supra* note 8, at 668.

80. Reddix-Smalls, *supra* note 3, at 676.

81. *Id.* at 681.

82. Daar, *supra* note 72, at 25.

83. Noah, *supra* note 12, at 614.

84. Buck Wolf, *Sending Sperm Abroad*, ABC NEWS (Dec. 16, 2005), at <http://abcnews.go.com/US/Sex/story?id=93277&page=1>.

85. *Id.*

86. Noah, *supra* note 12, at 614.

87. Hecht, *supra* note 9, at 229.

resolutions proposed to curb the commodification of these procedures.⁸⁸ Furthermore, because profitability is a function of the number of cycles performed, clinics have an incentive to utilize IVF prematurely before exploring cheaper, potentially effective options. The high demand for these innovative fertility treatments coupled with a void in federal regulation has helped to make reproductive medicine a lucrative business first and a medical undertaking second.⁸⁹ The commercial-minded actors in this business have little interest in proper record keeping and questioning the safety of medical practices as these exercises may greatly harm the earning power of their business.⁹⁰

Exacerbating the issue of lack of oversight is that ART procedures are rarely covered by insurance.⁹¹ “The result is that any role insurance might play in encouraging evidence-based practice is minimized in the context of ARTs.”⁹² Although, in 1992, the American Fertility Society and The American College of Obstetricians and Gynecologists recognized that infertility is a disease stemming from the abnormal function of the reproductive system.⁹³ Despite this recognition, there has been a general lack of willingness to include infertility treatment in health insurance policies. And, while some states have elected to enact legislation that requires health insurance companies cover at least a portion of infertility treatments,⁹⁴ Congress has not acted to mandate funding of treatment under health insurance policies.⁹⁵ Treating infertility like any other disease thus implicating health care coverage would impact the way fertility treatments are provided.⁹⁶ However, “limited insurance coverage contributes to the tendency for fertility care to operate more as a business than other areas of medicine, with market forces instead of regulatory oversight shaping the parameters of practice.”⁹⁷

The absence of insurance coverage in the ART business has a two-fold effect. First, because health insurers rarely cover the cost of ART,

88. Anetta Pietrzak, *The Price of Sperm: An Economic Analysis of the Current Regulations Surrounding the Gamete Donation Industry*, 14 J. L. & FAM. STUD. 121, 131 (2012).

89. Lyerly, *supra* note 28, at 696.

90. Lyerly, *supra* note 28, at 697.

91. *Id.*

92. *Id.*

93. Jessica Hawkins, *Separating Fact from Fiction: Mandated Insurance Coverage of Infertility Treatments*, 23 WASH. U. J.L. & POL'Y 203, 204 (2007).

94. *State Laws Related to Insurance Coverage for Infertility Treatment*, (Mar. 2012), at <http://www.ncsl.org/issues-research/health/insurance-coverage-for-infertility-laws.aspx>.

95. Lal, *supra* note 4, at 531-32.

96. Lyerly, *supra* note 28, at 696-97.

97. *Id.* at 697.

individuals pay the expenses directly and in full.⁹⁸ Second, the providers play off the emotional desperation of these patients for the full, out-of-pocket payment. They utilize aggressive marketing techniques in hope of luring desperate and vulnerable patients into their facilities, and “clinics are not shy about relying on the emotional desperation of childless couples to inflate asking price.”⁹⁹

Providers are free to operate in a laissez-faire climate.¹⁰⁰ The dominant social value in the United States can be described as “show me the money.”¹⁰¹ Providers offer experimental technology and buy and sell genetic material outside the regulatory system of the United States; “they operate in the purest model of a free-market enterprise.”¹⁰² The only oversight is provided by organizations such as ASRM and SART, which, as mentioned previously, are ruled by dominant industry leaders, which appear to operate as lobbying groups to keep the status quo of self-regulation.¹⁰³ These groups can exert a disproportionate influence over the regulatory process.

The winners in the fertility industry include providers, pharmaceutical companies, and technological providers. These actors capitalize on fragmented regulatory structure in order to reap the biggest monetary benefits out of the consumer-patients, who, because of the nature of this market, are provided with an imperfect amount of information.¹⁰⁴

The mixture of dominant industry forces and the endless supply and demand for ART creates an incentive to avoid regulation. While large lobbying forces hinder government intervention, private clinics and providers are free to exploit consumers through the market forces in the ART vacuum.

B. Inflated Success Rates

Infertility is a source of great personal suffering, and can be especially traumatic and emotional for the spouse who feels he or she is being replaced because of his or her inability to perform a natural biological function.¹⁰⁵ Couples and individuals willingly expend tens, if

98. Noah, *supra* note 12, at 616.

99. Lal, *supra* note 4, at 530.

100. Reddix-Small, *supra* note 3, at 645.

101. Andrews & Elster, *supra* note 2, at 45.

102. Reddix-Small, *supra* note 3, at 672.

103. *Id.*

104. *Id.* at 679.

105. Andrews & Elster, *supra* note 2, at 50.

not hundreds of thousands of dollars in their desperate quest for a child.¹⁰⁶ ART providers understand and exploit the common consumer belief that no price is too high to pay for a child. “Certainly the price incentives are sufficient to make the ‘ART baby business’ a lucrative one.”¹⁰⁷ This makes consumers vulnerable to the profit-driven providers that overlay success and efficacy of their procedures.¹⁰⁸

In a deregulated market driven by profit, fraudulently exaggerating success rates is commonplace, and providers who choose not to “play the game,” cannot meaningfully participate in this competitive industry. Reporting success rates is purely voluntary; however, there is a market incentive to not only provide such rates but also exaggerate them in the absence of regulation.¹⁰⁹

In such a large and competitive industry, questions arise about the accuracy of promotional claims made by fertility clinics, particularly pregnancy success rates.¹¹⁰ And, although the FCSRCA dictates that clinics report their success rates, such reports are voluntary and often fraudulent.¹¹¹ However, without an independent audit, there is no way of verifying the accuracy of such claims.¹¹² “Methods of reporting significantly influence the derivation of the actual success rate.”¹¹³

Many fertility clinics have different definitions of IVF successes, enabling them to manipulate success rates.¹¹⁴ Some clinics may label unsuccessful cycles, particularly those with older patients who are likely to have more difficulty becoming pregnant, as “research” and not count them in their overall success rates.¹¹⁵ Additionally, clinics may inflate success rates by taking advantage of the lack of definitions. Some clinics statistically manipulate success rates by reporting the rate of pregnancy instead of the successful live birth rate.¹¹⁶

Clinics may try maintaining a higher success rate by turning patients away.¹¹⁷ Clinics with a high number of difficult patients, such as older

106. Lal, *supra* note 4, at 530.

107. Reddix-Small, *supra* note 3, at 654.

108. Robertson, *supra* note 8, at 674.

109. Hecht, *supra* note 9, at 254.

110. Noah, *supra* note 12, at 614.

111. Riley & Merrill, *supra* note 47, at 5.

112. Hecht, *supra* note 9, at 254.

113. Lal, *supra* note 4, at 529.

114. *Id.*

115. Burt Littman, *IVF Success Rates*, THE CTR. FOR REPROD. MED. (2012), at www.marylanderm.com/ivfsuccess.html.

116. *Id.*

117. *Center for Reproductive Medicine – Success Rates*, WAKE FOREST BAPTIST HEALTH (Aug. 2012), at <http://www.wakehealth.edu/IVF/Center-for-Reproductive-Medicine---Success-Rates.htm>.

patients and patients with previous IVF failure, will have lower pregnancy rates.¹¹⁸ Clinics may refuse to provide treatment to couples over a certain age who, because of their age, have decreased chances of IVF success.¹¹⁹

Additionally, philosophies and practices of different providers can significantly affect the program's purported success rates.¹²⁰ Clinics may report higher rates because they transfer more embryos, which leads to a much higher incidence of multiple gestation.¹²¹ Multiple gestation may be very dangerous and pose a health risk to the mother and surviving babies. In such circumstances, "the risk of premature birth increases dramatically, resulting in a significant risk to the health and survival of the infants."¹²² In addition to multiple gestation increasing the risk for premature birth, studies have linked multi-fetal pregnancy with low birth weight and birth defects.¹²³ CDC researchers "estimate[d] that more than 3 percent of the low-birth-weight infants and more than 4 percent of the very-low-birth-weight infants born in 1997 were conceived with [ART]-six times the proportions that would be expected on the basis of the frequency of these procedures."¹²⁴

Another practice clinics utilize is liberally cancelling cycles prior to retrieval when there is a low response to stimulation.¹²⁵ Moreover, clinics have monetary and reporting incentives to utilize IVF early in the course of therapy rather than exploring less expensive and potentially effective options.¹²⁶ In doing this, they inflate rates by including patients who would have gotten pregnant without IVF.¹²⁷

However, despite their potentially manipulative, unethical, and unsafe practices, clinics are free to publish such rates. "The variance in success rates lure hopeful women to the IVF institutions and encourages extensive financial and emotional investments in programs with questionable credibility."¹²⁸

118. *Id.*

119. Littman, *supra* note 115.

120. WAKE FOREST BAPTIST HEALTH, *supra* note 117.

121. *Id.*

122. Littman, *supra* note 115.

123. Noah, *supra* note 12, at 622-23.

124. Laura A. Schieve et al., *Low and Very Low Birth Weight in Infants Conceived with Use of Assisted Reproductive Technology*, 346 NEW ENG. J. MED. 731, 736 (2002).

125. WAKE FOREST BAPTIST HEALTH, *supra* note 117.

126. *Id.*

127. *Id.*

128. Lal, *supra* note 4, at 529.

C. False Representations

Not only do IVF providers have ample opportunity to defraud consumer patients, sperm banks have the opportunity as well. “A sperm bank exemplifies the classic third party intermediary.”¹²⁹ Third parties involved in this moneymaking enterprise seek to gain profits from the commercialization of procreation.¹³⁰ For some couples and single women, obtaining a viable sperm from an outside donor is necessary to carry out the procedure.¹³¹ Sperm banks have been quick to capitalize on the market demand; sperm banking is a multi-million dollar industry that is responsible for about 30,000 births each year.¹³² Yet, despite their increased use and acceptance, sperm banks have remained “enveloped in secrecy and lacking comprehensive regulation.”¹³³ Without regulation imposing lawful duties, sperm banks are free to exploit consumers through fraudulent misrepresentation without liability.

The 2006 controversy involving five children born with a serious gene defect highlighted the fraudulent practices in sperm banks. The children, fathered by a sperm donor, were born with a gene defect that resulted in a blood disease that greatly increases their risk for leukemia and requires daily shots of an expensive drug to prevent infections.¹³⁴ There is a 50% chance that an affected child will pass the disorder onto his or her offspring.¹³⁵ Their father, sperm donor no. F827, passed this genetic disorder onto five of his eleven children conceived through the use of his sperm deposits to a Michigan sperm bank throughout the 1990s.¹³⁶ Doctors determined it was the sperm donor father who was responsible for passing on the genetic disorder; however, doctors could not confirm this because they could not locate donor no. F827 and could not test the remaining samples without his consent.¹³⁷ Exacerbating the issue was the fact that the sperm bank that collected donor no. F827’s sperm did not contact other recipients of his sperm to tell them that their children may have this genetic disorder because they had no legal duty to do so.¹³⁸

129. Havins & Dalessio, *supra* note 14, at 835.

130. Lal, *supra* note 4, at 518.

131. Chung, *supra* note 84, at 263.

132. Jennifer M. Vagle, *Putting the “Product” in Reproduction: The Viability of a Products Liability Action for Genetically Defective Sperm*, 38 PEPP. L. REV. 1175, 1177 (2011).

133. *Id.*

134. Denise Grady, *As the Use of Donor Sperm Increases, Secrecy Can Be a Health Hazard*, N.Y. TIMES, June 6, 2006, at F5.

135. Vagle, *supra* note 132, at 1176.

136. Grady, *supra* note 134, at F5.

137. Grady, *supra* note 134, at F5.

138. *Id.*

The 2009 case of *Donovan v. Idant Laboratories* illustrates the difficulty in holding a sperm bank liable for misrepresentation when the legislature imposes no duties on it.¹³⁹ In *Donovan*, the district court, applying New York law, held that claims of strict liability and third-party beneficiary breach of warranty claims “are properly termed claims of ‘wrongful life,’” which New York does not recognize.¹⁴⁰ Brittany Donovan, a mentally disabled child, sought to recover based on theory of products liability due to a genetic defect inherited from her sperm donor father, donor G738.¹⁴¹ In 1994, Donna Donovan, Brittany’s mother, entered into a contract with Idant to purchase semen for use in artificial insemination.¹⁴² In the contract, Idant made representations about its product, the semen, including a claim that the donor went through an extensive and thorough screening process to ensure he had no genetic abnormalities.¹⁴³ The semen was subsequently used in Ms. Donovan’s artificial insemination and Brittany was born in 1996.¹⁴⁴

After her pediatrician noticed developmental abnormalities, Brittany underwent testing and was diagnosed as a Fragile X carrier.¹⁴⁵ After confirming that she did not carry the disease, Ms. Donovan filed a complaint, on Brittany’s behalf, against Idant alleging “negligence, breach of contract, third-party beneficiary breach of contract, breach of the express warranty of merchantability, breach of implied warranty of merchantability, negligent misrepresentation, strict products liability and negligent infliction of emotional distress” due to G738’s “defective sperm.”¹⁴⁶

The court found that Ms. Donovan’s claims were time-barred given the relevant statute of limitations.¹⁴⁷ However, Brittany’s claims of negligence and negligent misrepresentation were not time-barred. Despite this, the court found that these causes of action constituted claims for wrongful life, which New York does not recognize, and dismissed both for failure to state a claim.¹⁴⁸

139. *Donovan v. Idant Labs.*, 625 F. Supp. 2d 256, 275 (E.D. Pa. 2009) *aff’d sub nom.* D.D. v. Idant Labs., 374 F. App’x 319 (3d Cir. 2010).

140. *Id.* at 271.

141. *Id.* at 262.

142. *Id.*

143. *Id.*

144. *Id.*

145. *Id.* at 263.

146. *Donovan* at 274.

147. *Id.* at 266.

148. *Id.* at 265.

Donovan highlights the present impossibility of holding sperm banks liable under nearly any cause of action due to lack of regulation. Though the decision opens up the possibility of treating these cases as products liability issues, the decision fundamentally fails to recognize a duty on the part of sperm banks to substantively ascertain the accuracy of representative claims and screen donors in the first place. While the court's decision was the right one given that it cannot make up a legal fantasy (i.e. duty) not in place to hold the sperm bank liable, *Donovan*—a Michigan case—and others cases like it, should prompt state legislatures to finally address the fraudulent practices rampant in sperm banks.

Despite recipients receiving the wrong sperm, contracting HIV¹⁴⁹ and children inheriting genetic diseases from ill-screened and misrepresented anonymous donors, the use of donor sperm from sperm banks continues to be a popular practice.¹⁵⁰ The government must address these issues in order to protect desperate consumer-patients from the abuses carried out by lazy or exploitive sperm banks. “Increased regulation is needed to reduce the repeated and much-publicized abuse in sperm banks.”¹⁵¹ Without regulation and minimal recordkeeping, sperm banks are free to misappropriate vital information, in particular, donor characteristics.¹⁵² Sperm bank liability is almost non-existent and donors are anonymous and surrounded by confidentiality provisions and contracts that make truthfulness and accountability unrealistic in the current regulatory regime.¹⁵³ Because of this policy of secrecy and anonymity, few sperm banks maintain donor records and many even destroy donor records once the supply has been depleted.¹⁵⁴ “The wall of confidentiality and privacy, which has a solid justification, also screens the entire assisted reproductive process.”¹⁵⁵ Due to the lack of regulation, no duty of care is imposed upon sperm banks; thus, sperm banks are free to perpetuate the exploitation rampant in the ART industry.¹⁵⁶

There is no limit to donor compensation in the United States. When individual patients select a donor who would not otherwise be available,

149. Heather J. Blum, *Liability as the Result of the Transmission of HIV Through Artificial Insemination by Donor*, 4 ALB. L.J. SCI. & TECH. 333 (1994).

150. Vagle, *supra* note 132, at 1212-13.

151. Hecht, *supra* note 9, at 241.

152. *Id.* at 243.

153. Phillip C. Cato, *The Hidden Costs of Fertility*, 20 ST. JOHN'S J. LEGAL COMMENTAR 45, 46 (2005).

154. Lisa M. Luetkemeyer, *Who's Guarding the Henhouse and What Are They Doing with the Eggs (And Sperm)? A Call for Increased Regulation of Gamete Donation and Long-Term Tracking of Donor Gametes*, 3 ST. LOUIS U. J. HEALTH L. & POL'Y 397, 405 (2010).

155. Cato, *supra* at 48.

156. Heled, *supra* note 26, at 260-61.

compensation is practically unlimited.¹⁵⁷ However, typically a sperm donor receives an average of thirty-four to forty-four dollars in compensation per visit directly from the sperm bank.¹⁵⁸ In turn, sperm banks significantly mark up the cost and sell the sperm vial to fertility clinics for about \$275-\$400 per vial.¹⁵⁹ Further, sperm banks face no shortage of willing donors because donating sperm is relatively straightforward and quick.¹⁶⁰ Additionally, men do not need to undergo painful hormone injections unlike their female counterparts.¹⁶¹

Because of the large profit margin within the sperm bank industry, these intermediaries face stiff competition with one another to sell their “superior” sperm. Competing sperm banks use puffery to attract business. And, while puffery tends to be a given in commercial enterprises, sperm banks distort the line between advertisement and medical guarantee. With the lack of regulation, sperm banks are free to misappropriate donor characteristics in order to claim a more attractive donor pool.¹⁶² Typically, sperm banks fraudulently exaggerate or misrepresent donor characteristics such as height, hair color, disposition, and education. In this competitive industry, one must wonder whether “Mr. Perfect” truly exists.¹⁶³

Further, many sperm banks deem it unnecessary to test “quality” individuals such as medical students.¹⁶⁴ To them, a cursory glance for intelligence and good looks is a sufficient screening mechanism.¹⁶⁵ “For the first record artificial insemination by donor, in 1984, a physician impregnated a patient with ‘fresh semen from the best-looking member of the class.’”¹⁶⁶ It is thoughtless to assume that a superficial selection of the most well-educated and good-looking donors necessarily means the safest donors. Until physicians in the sperm banks realize that the “best” donor does not automatically mean the best looking, but rather the most thoroughly tested, patients cannot be assured they are receiving the proper care.

Not only do sperm banks misappropriate information because of a lack of reporting requirements and a veil of secrecy, they also opt out of donor screening and testing procedures, which saves about \$800-\$900 per

157. Chung, *supra* note 130, at 294.

158. Hecht, *supra* note 9, at 242.

159. Reddix-Small, *supra* note 3, at 653.

160. Chung, *supra* note 130, at 268.

161. *Id.* at 269.

162. Hecht, *supra* note 9, at 243.

163. *Id.*

164. *Id.* at 239.

165. *Id.*

166. *Id.*

screening.¹⁶⁷ Donor screening amounts to nothing more than a superficial, cursory glance. A study conducted at the University of North Carolina found that the majority of sperm donors tested do not recognize a genetic problem in their family history, and sperm banks refusing to perform genetic testing makes it impossible to determine whether these males are carriers of serious genetic disorders.¹⁶⁸ “It is often easier to learn whether a perspective donor plays the cello than whether he has a family history of Huntington’s Disease.”¹⁶⁹ And, while associations such as ASRM and SART urge sperm banks to properly screen donors, they amount to nothing more than suggestions.¹⁷⁰

VI. HOW TO BEGIN REGULATING

Regulation reform of assisted reproductive technology is the only viable solution to the appalling abuses committed by providers and intermediaries that are allowed to occur within the current system.¹⁷¹ Dwelling on whether society has proceeded too quickly in accepting technological control over conception is not productive.¹⁷² When initially suspect technology is established as an ordinary part of modern culture, regulators must be quick to alleviate concerns associated with the new technologies.¹⁷³ However, they must also be cautious of over-detering or stifling new research.¹⁷⁴ Regulators must alleviate public concern while being careful to avoid a lost opportunity; therefore, regulators must be wary of aligning regulations so closely with public opinion. “The problem of premature entrenchment of a new technology might be lessened by tailoring regulation to minimize the most difficult ethical problems.”¹⁷⁵

A. Balancing Act

Although ART originated as a means to overcome infertility and provide the ultimate joy of parenthood to thousands of individuals and families throughout the United States, the fundamental failure of the government to enact sufficient regulatory barriers and guidelines has led to

167. Hecht, *supra* note 9, at 243.

168. *Id.* at 239.

169. *Id.* at 243; Jeff Stryker, *The Complex Questions Raised by Sperm Banking*, S.F. EXAM’R, Oct. 8, 1993, at A23.

170. Cato, *supra* note 153, at 48-49.

171. Lal, *supra* note 4, at 542.

172. Robertson, *supra* note 8, at 666.

173. Note, *supra* note 1, at 592.

174. *Id.*

175. *Guiding Regulatory Reform in Reproduction and Genetics*, *supra* note 1, at 594-95.

medical irresponsibility where providers are rewarded not by providing the best patient-centered care but by aggressive marketing tactics and fraudulent behavior.

Regulatory reform is not an easy feat, and there is no perfect regulatory structure. Guidelines and laws affecting the right to family and privacy are challenging and controversial; however, in this context they are undoubtedly necessary. A regulatory structure must balance the right to familial autonomy and privacy with the need to assure patients are receiving safe medical care.

To some, fertility treatments constitute unethical medical experimentation on human beings in direct contrast to how countless infertile couples feel, which makes politicians apprehensive to confront this lightning rod issue via regulation. Governmental agencies in the fertility industry have received very little help from Congress on how to regulate.¹⁷⁶ Therefore, regulatory agencies, such as the CDC and DHHS, “are free to develop close and collaborative relationships with the market stakeholders.”¹⁷⁷ This has led to a series of inadequate compromises, such as industry self-regulation.¹⁷⁸ The question of how to regulate assisted reproductive technology has mirrored the abortion debate.¹⁷⁹ The initially strong connection between abortion and reproductive services created an early regulatory deadlock that unexpectedly accelerated the development and broad availability of ART.¹⁸⁰

In order to achieve reform, the government must address the market-driven nature of the fertility market, which provides economic incentives for providers to skirt ethical standards and put profits before public health.¹⁸¹ There are industry giants strongly tied to the interests of the market who work to prevent legislation to continue exploiting consumer-patients. The market forces undermine any opportunity to assess the current state of deregulation. These successful attempts to stop legislation are harmful to the integrity of the medical industry, and they are deadly to patients. The initial public acceptance and use of this technology coupled with the imbedded market forces in the industry are the roadblocks to substantive regulation.

Successful regulation will be a balancing act. It will account for entrenched market-forces and religious considerations. It will be

176. Reddix-Small, *supra* note 3, at 682.

177. Reddix-Small, *supra* note 3, at 682-83.

178. *Guiding Regulatory Reform in Reproduction and Genetics*, *supra* note 1, at 584.

179. *Id.*

180. *Id.*

181. *Guiding Regulatory Reform in Reproduction and Genetics*, *supra* note 1, at 579.

comprehensive and thoughtful but not burdensome. Reform should place a premium on patient safety and health with all other considerations secondary. Legislatures should not stifle the voices of interest groups and religious branches; however, it should be careful not to consider prospective regulation as a fully economic or a fully religious issue. This is a medical and ethical issue. Scientific progress and innovation hinge on the government's ability to successfully implement ART policy. The legislature must stop promulgating empty regulation; it must place itself in the center of the regulation ART demands.

B. Federal Regulatory Framework—The Rebirth of the FCSRCA

I am not proposing that a regulatory framework be created from scratch. My proposals are based off the 1992 FCSRCA. The FCSRCA provides an excellent starting point for comprehensive regulation.

The Act requires the HHS to delegate to the CDC a model program for the certification of ART laboratories to be adopted and carried out voluntarily by individual states.¹⁸²

This certification program should be extended to all fertility providers, including IVF clinics and sperm banks and based off of an adopted code of medical ethics. In addition, the CDC should make adoption of the certification program a federal program mandating that states abide by the certification program by a specific date. The federal government should incentivize states to speed up their compliance by offering incentive payments to eligible professionals and providers who adopt, implement, and demonstrate meaningful compliance with the certification program and the adopted code of medical ethics. This ensures patients are receiving uniform and proper care throughout the United States. Further, it would be easier for the federal government to regulate one policy that reaches across all states rather than leave it up to each individual state to adopt patchwork standards.

Such certification would not impede clinics' and sperm banks' abilities to participate in the market; it merely weeds out the clinics that are committing egregiously unethical practices such as not reporting and collecting data regarding clinical practices and outcomes, not properly screening sperm donors, and implementing dangerous practices such as multiple gestation. The CDC should publicize the clinics and sperm banks that are properly certified, and uncertified providers should be banned from the market with monetary sanctions.

182. 42 U.S.C. § 263a-2(a)(2) (2006).

Sanctions must be adopted with the appropriate corresponding enforcement mechanism. Such sanctions should include the ability to revoke a clinic certification. Further, the act should make practicing without the proper certification a criminal offense. Sanctions should impose a variety of charges, fines, and prison terms where appropriate.

Further, by making proper reporting and data collection mandatory under the certification program, the government will be able to not only ensure compliance with regulatory standards but also will be provided with needed information. The data may be synthesized to identify health implications of various practices and procedures in order to help the government ensure the mandatory standards are appropriate and highlight areas that may need more regulatory. It can be used to show areas that may need expanded requirements and also give providers and patients more information on long-term health outcomes for them and their children.

Certification should be extended to the providers in ART facilities as well. A licensing board should (1) properly license providers, (2) require that the facility reports a sufficient level of background information for all employees and staff, and (3) continually monitor staff and staff activities and practices.

In addition, medical definitions must be uniformly defined and adopted. Clinics should not be able to manipulate medical terminology and phrases, such as “pregnancy success rate.” Definitions must be clear and strict.

However, no regulation would be effective without an enforcement mechanism. It is paramount that the government recognizes the need for this legislation and devotes resources to the program. Ingenuously budgeting \$1 million a year to such an immense undertaking is wholly inadequate, and history has proved this. The DHHS and CDC must allocate sufficient federal funding for the proper oversight of providers and the collection of information from providers by a government-run oversight body, not the providers themselves. Therefore, the budget must account for extensive and annual audits of these ART providers.

In addition, going further than the FCSRCA, the DHHS should require each patient, prior to undergoing any procedure, to partake in a consultation with the provider where they thoroughly go over the proposed procedure and alternatives. Additionally, the provider must be required to review the relevant statistics reports compiled by the licensing committee and notify patients of counseling options while they undergo the ART process.

Further, the DHHS would be wise to implement a center where consumer-patients focus their complaints, concerns, and ask questions. This would not only help guide patients through the process, but also, it may help the DHHS to identify potentially noncompliant facilities and providers.

This reform must be undertaken with the cooperation of numerous groups with the proper knowledge and know-how. Consumer groups and medical professions with the appropriate expertise should be the leading consultants of ART legislation. The government should expend money and resources to formulate a board and focus groups under the direction of the CDC to identify problems in the industry and devise solutions targeted at those issues that can be realistically and successfully implemented. The leading consultants should be from the ASRM, practicing ART physicians and providers, scientists, and business advisors. The ART world is currently veiled in secrecy with wealthy, educated patients simply not knowing the right questions to ask. Therefore, medical professionals driving this regulation will be a preemptive shield from fraud and abuse within the market where providers seize the opportunity to take advantage of patient emotions and pocketbooks.

VII. CONCLUSION

The evolution and use of assisted reproductive technology has raised serious questions and implications for this generation and those to come. Assisted reproductive technology has advanced and flourished in the unregulated market in which it operates. It is responsible for the births of thousands of children and has brought joy to many families. However, in the process of giving the joy of a child, clinics and providers have played upon patients blinded by emotion and exploited their willingness to achieve pregnancy at any cost. The great potential for abuse within the market must be curbed by comprehensive and centralized legislation. Great abuses cannot continue simply because legislatures struggle with redefining family in the 21st century. Congress must create a national policy that forces it to think critically about the social implications of such technology, which already is entrenched deeply in our nation. Only then, after a mandated code of ethics and enforceable regulatory structure have been adopted, can American families utilizing assisted reproductive technology be confident that their health care is being delivered in the safest and most cost-effective way.