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HATCHING A PLAN TOWARDS COMPREHENSIVE REGULATIONS IN EGG DONATION

INTRODUCTION

Assisted Reproductive Technologies (ART) provide thousands of infertile couples in the United States with the ability to conceive and raise a child of their own.¹ On the other side of ART lie the young women needed to provide oocytes, or eggs, to couples who cannot produce their own. Donors are often recruited by private fertility clinics and egg brokers hired by the recipient couples to locate donors with certain attributes who then refer donors to ART clinics where their eggs are retrieved.² There are rampant ethical concerns related to coercion in donor recruitment, commodification of body materials, and biases that can negatively influence risk disclosure and the medical retrieval of eggs. Despite these ethical concerns and inherent medical risks present in the donation process, the only federal laws concerning egg donation merely require reporting success rates of ART treatments and screening the eggs for communicable diseases, meaning that there are no federal regulations that operate to protect egg donors from the strong financial incentives within this multi-billion dollar private industry.³ Although fertility clinics and physicians are “self-regulated” under guidelines from professional societies, these guidelines are not mandatory and are hardly enforced.⁴ A minority of states that allow egg donation have made efforts to pass laws

1. Saswati Sunderam et al., *Assisted Reproductive Technology Surveillance—United States, 2010*, 62 MORBIDITY & MORTALITY WKLY. REP., Dec. 6, 2013, at 9.

2. See John A. Robertson, *Commerce and Regulation in the Assisted Reproduction Industry*, 85 TEX. L. REV. 665, 691–92 (2007) (reviewing DEBORA L. SPAR, *THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION* (2006)) (describing the business model of an embryo bank in San Antonio, Texas); Julie L. Sauer, *Competing Interests and Gamete Donation: The Case for Anonymity*, 39 SETON HALL L. REV. 919, 926 (2009).

3. Andrea Preisler, Student Article, *Assisted Reproductive Technology: The Dangers of an Unregulated Market and the Need for Reform*, 15 DEPAUL J. HEALTH CARE L. 213, 213 (2013); see Michelle Bercovici, *Biotechnology Beyond the Embryo: Science, Ethics, and Responsible Regulation of Egg Donation To Protect Women’s Rights*, 29 WOMEN’S RTS. L. REP. 193, 193 (2008); see also Lucy Frith & Eric Blyth, *Assisted Reproductive Technology in the USA: Is More Regulation Needed?*, 29 REPRODUCTIVE BIOMEDICINE ONLINE 516, 517 (2014) (arguing that more comprehensive oversight is needed); Brittany L. Marvin, Note, *Regulating the Procurement of Female Gametes: Donors’ Health and Safety*, 16 MICH. ST. U. J. MED. & L. 119 (2011).

4. Kitty L. Cone, Note, *Family Law—Egg Donation and Stem Cell Research—Eggs for Sale: The Scrambled State of Legislation in the Human Egg Market*, 35 U. ARK. LITTLE ROCK L. REV. 189, 191–92 (2012).

that help protect egg donors, but the majority of states fail to provide adequate safeguards and supervision in this unique industry.⁵

This Comment argues that the current federal laws are not only inadequate to supervise egg donation, but that they may contribute to the existing problems in the system's structure.⁶ Federal action is necessary for any reforms to occur in the United States. In the end, any solution to these issues must be balanced to account for the interests of all the parties involved in ART. By shifting the current incentive structure within the industry, which currently emphasizes successful pregnancies and accordingly preferential treatment of the recipient couple, greater emphasis could be placed on the well-being of the donor.⁷ This could be accomplished by increasing insurance coverage of ART, tying reimbursement to certification by either professional associations or state agencies, and compliance with new regulations.⁸ Expansion of the current reporting requirements to include more information on donors would aid in understanding risks in egg donation, the detection of unprofessional clinics, and forcing physicians to internalize their predatory and aggressive practices toward egg donors.⁹

Part II of this Comment provides a background of the ART industry and the risks it poses to egg donors.¹⁰ It further explains the current ART regulations in the United States at the federal and state levels.¹¹ Part III discusses the deficiencies in the current regulatory scheme and argues that the current federal reporting requirements not only fail to provide any protection for donors but also increase the ethical risks by incentivizing high fertility success rates.¹² This Comment argues that federal action is necessary to spur more states into regulating egg donation, and suggests a solution to these biases through increased insurance coverage of ART and expansions to the current federal reporting requirements.¹³ Section IV discusses the implications of these suggested changes and examines them in light of existing barriers to reforming ART regulation.¹⁴ Section V concludes that expanding the current federal reporting requirements and tying

5. See *infra* notes 125–38 and accompanying text, for a further discussion of state regulation of egg donations.

6. See *infra* notes 146–81 and accompanying text (discussing the lack of uniform regulation of ART in the United States).

7. See *infra* notes 182–84 and accompanying text.

8. See *infra* notes 185–89 and accompanying text.

9. See *infra* notes 192–200 and accompanying text.

10. See *infra* notes 17–99 and accompanying text.

11. See *infra* notes 100–44 and accompanying text.

12. See *infra* notes 146–201 and accompanying text.

13. See *infra* notes 182–201 and accompanying text.

14. See *infra* notes 210–50 and accompanying text.

insurance coverage to compliance with those requirements and professional standards would address the current ethical risks that exist in the industry in a balanced manner.¹⁵

II. BACKGROUND

This Part provides a background on ART generally and then moves to a discussion regarding the egg donation process and the medical risks of egg donation. An explanation of the structure of the ART industry and the parties involved is then discussed, leading to the ethical issues relating to egg donors presented by the industry and the regulations pertaining to ART in the United States. All of the issues presented *supra*¹⁶ have spawned from the emergence and proliferation of ART.

A. The ART Industry and Egg Donors

Sixty-two million U.S. women of childbearing age are infertile,¹⁷ and 12%, or 7.4 million, of those women will seek infertility services during their lives;¹⁸ consequently, ART represents a multi-billion dollar industry in the United States¹⁹ that has been steadily growing.²⁰ There are many parties holding stake in this lucrative private health sector: infertile couples who finance the procedures, fertility clinics who perform the ART procedures, egg brokers who seek out desirable gamete donors and connect them with infertile patients, pharmaceutical companies who manufacture the drugs needed for ovulation cycles, and, lastly, sperm or egg donors.²¹ Despite the inherent risks involved in the donation process, such as blood clots or future infertil-

15. See *infra* notes 251–258 and accompanying text.

16. *supra* notes 1–5 and accompanying text.

17. NAT'L CTRS. FOR DISEASE CONTROL & PREVENTION, 2012 ASSISTED REPRODUCTIVE TECHNOLOGY: FERTILITY CLINIC SUCCESS RATES REPORT 3 (2014) [hereinafter 2012 CLINIC SUCCESS RATES REPORT]. The American Society for Reproductive Medicine defines infertility as “the failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination.” Practice Comm. of the Am. Soc’y for Reproductive Med., *Definitions of Infertility and Recurrent Pregnancy Loss: A Committee Opinion*, 99 FERTILITY & STERILITY 63, 63 (2013) [hereinafter ASRM, *Definitions of Infertility*].

18. 2012 CLINIC SUCCESS RATES REPORT, *supra* note 17 at 3.

19. Marvin, *supra* note 3, at 120.

20. Sunderam et al., *supra* note 1, at 2.

21. See *infra* notes 82–99 and accompanying text (discussing the different roles and interests of these three parties, which interact to create conflicts of interests raising ethical concerns).

ity,²² millions of women donate their eggs each year for a cost of anywhere from \$5,000 up to \$20,000 per cycle.²³

ART is a general term that covers a variety of fertility treatments, and new cutting-edge treatments are being developed each year, which, in turn, introduce new issues of bioethics.²⁴ To understand the issues presented by ART and, specifically, egg donation, a general understanding of both is necessary. This subsection explains the basics of ART in general, the egg donation process, and the medical risks of egg donation.

1. *The ABCs of ART*

According to the U.S. Centers for Disease Control and Prevention (CDC), ART includes any fertility treatments in which either human eggs or embryos are handled.²⁵ Fertility treatments provide couples who are unable to conceive naturally with a potential means for achieving pregnancy.²⁶ The main ART procedure is in vitro fertilization (IVF).²⁷ IVF involves extracting the eggs from either a woman seeking infertility treatment or an egg donor, fertilizing the retrieved eggs in a laboratory, and then transferring the resulting embryos into

22. See Bercovici, *supra* note 3, at 195 (discussing ovarian hyperstimulation, which is the most prominent and threatening risk of hyperstimulation).

23. Although it is impossible to know exactly how much donors are compensated, most reports estimate average compensations between \$5,000 and \$10,000. See Marvin, *supra* note 3, at 128–30 (examining advertisements in newspapers or produced by fertility clinics).

24. See, e.g., Paul R. Brezina & Yulian Zhao, *The Ethical, Legal, and Social Issues Impacted by Modern Assisted Reproductive Technologies*, OBSTETRICS & GYNECOLOGY INT'L (2012); WORLD HEALTH ORG., CURRENT PRACTICES AND CONTROVERSIES IN ASSISTED REPRODUCTION (Effy Vayena et al. eds., 2002).

25. NAT'L CTRS. FOR DISEASE CONTROL & PREVENTION, 2013 ASSISTED REPRODUCTIVE TECHNOLOGY: FERTILITY CLINIC SUCCESS RATES REPORT 3 (2015) [hereinafter 2013 CLINIC SUCCESS RATES REPORT]. This is the definition employed by the CDC in its annual reports. See *id.* An egg is the female reproductive cell, also called an oocyte or ovum. *Id.* at 529.

26. Ethics Comm. of the Am. Soc'y for Reproductive Med., *Using Family Members as Gamete Donors or Surrogates*, 98 FERTILITY & STERILITY 797, 797 (2012). Couples often prefer ART over adoption due to their desire to have children possessing their own genetics. See generally Kenneth Baum, *Golden Eggs: Towards the Rational Regulation of Oocyte Donation*, 2001 B.Y.U. L. REV. 107, 115 (discussing that artificial insemination allows parents to maintain genetic and gestational ties to the offspring). In certain instances, adoption might even be more costly than utilizing infertility treatments. See Geoff Williams, *The Cost of Adoption*, U.S. NEWS: MONEY (Oct. 2, 2014, 9:38 AM), <http://money.usnews.com/money/personal-finance/articles/2014/10/02/the-cost-of-adoption>. Assisted reproductive technologies are also used to implant a couple's, or donor's, sperm, egg, or embryo into another woman as a surrogate. Ethics Comm. of the Am. Soc'y for Reproductive Med., *supra* note 26, at 797. Surrogacy and donor sperm, eggs, or embryos are often necessary for same-sex couples to have children with their own genetics. John A. Robertson, *Gay and Lesbian Access to Assisted Reproductive Technology*, 55 CASE W. RES. L. REV. 323, 324–25 (2004).

27. 2012 CLINIC SUCCESS RATES REPORT, *supra* note 18, at 3.

the uterus via the cervix of either the woman seeking treatment or a designated surrogate who will carry the fetus during the pregnancy.²⁸

A woman may use her own eggs for IVF treatments, but oftentimes infertility stems from issues with her own eggs, requiring her to obtain eggs from an oocyte donor.²⁹ These donors are generally young women because younger eggs have a higher chance of fertility.³⁰ Donors are often targeted from universities or selected based on personal traits, such as race, intelligence, height, or any type of preferred appearance.³¹ The potential of financial coercion, when combined with the large amounts of compensation offered, may raise ethical concerns regarding the commodification of body materials.³²

Women may also donate eggs to be used for stem cell research.³³ Due to the controversial nature of stem cell research, there are more laws and restrictions governing the retrieval, handling, and use of eggs

28. REPROD. HEALTH TECHNOLOGIES PROJECT, OVARIAN STIMULATION AND EGG RETRIEVAL: OVERVIEW & ISSUES TO CONSIDER 1–2 & tbl.1 (2009), <http://www.rhpt.org/fertility/assisted/documents/RHPT-OvarianStimulationandEggRetrievalPaperUpdated.pdf>. Although there are other popular ART treatments, IVF is used as the basis for this Comment. The discussions regarding egg donation for fertility treatment in this Comment are applicable to other ART treatments that require anonymous donors.

29. NAT'L CTRS. FOR DISEASE CONTROL & PREVENTION, 2013 ASSISTED REPRODUCTIVE TECHNOLOGY: NATIONAL SUMMARY REPORT 12 (2015); N.Y. TASK FORCE ON LIFE & THE LAW, THINKING OF BECOMING AN EGG DONOR?: GET THE FACTS BEFORE YOU DECIDE 12 (Apr. 2009) [hereinafter N.Y. EGG DONOR FACTS], <http://www.health.ny.gov/publications/1127.pdf>. This Comment uses the term “donors” to refer to women who are donating eggs and are not the ones who ultimately will keep the child. This Comment uses the term “Recipients” to refer to the person who is financing the procedures to make a child, regardless of whether the recipient carries the child to birth or contracts a surrogate to do it.

30. Marvin, *supra* note 3, at 128 (estimating that 75% of all U.S. egg donors are college students). The typical donor age ranges from twenty-one to thirty-five. N.Y. EGG DONOR FACTS, *supra* note 29, at 5. The lower limit of eighteen represents the ability to legally contract for donation. *Id.* The upper limit of thirty-five is set due to increase risks involved in responses to the stimulation drugs. *Id.*

31. Marvin, *supra* note 3, at 128.

32. See Justine Durrell, *Women's Eggs: Exceptional Endings*, 22 HASTINGS WOMEN'S L.J. 187, 189 (2011) (“The issues of health risks and informed consent cannot be divorced from the concerns of financial compensation.”); Sauer, *supra* note 2, at 927 n.58 (citing Ethics Comm. of the Am Soc'y for Reprod. Med., *Financial Compensation of Oocyte Donors: A Committee Report*, 88 FERTILITY & STERILITY 305, 306 (2007)).

33. M. Elliot Neal, Note, *Protecting Women: Preserving Autonomy in the Commodification of Motherhood*, 17 WM. & MARY J. WOMEN & L. 611, 617 (2011). Stem cells are undifferentiated cells produced in the early stages of embryos that can multiply and produce specific differentiated cells. Stephen R. Munzer, *How To Integrate Administrative Law and Tort Law: The Regulation of Stem Cell Products*, 64 ADMIN. L. REV. 743, 746–77 (2012). These cells can be used in a variety of therapies and treatments, which ultimately end in the destruction of the embryos. Radhika Rao, *Coercion, Commercialization, and Commodification: The Ethics of Compensation for Egg Donors in Stem Cell Research*, 21 BERKELEY TECH. L.J. 1055, 1055 (2014).

when they are retrieved for stem cell research.³⁴ Almost every state has legislation concerning the donation and use of eggs when they are intended to create embryos for stem cell use.³⁵ Although the retrieval procedures and the eggs are virtually identical, the increased regulation of stem cell research provides donors with more protections and safeguards from predatory industry practices.³⁶ Despite the imbalance in regulation and discussion between the two uses of eggs, the majority of eggs donated in the United States are from anonymous donors who are compensated for their eggs.³⁷ Although egg donation is often required in ART treatments, it remains a time-intensive, invasive, and complicated process.

2. *The Egg Donation Process*

The ART treatments, including donation and implantation, are performed in cycles and are composed of several stages.³⁸ Donation cycles typically last three weeks and involve ovarian stimulation and surgical retrieval of the eggs,³⁹ a drug process carrying acute and long-term risks.⁴⁰

The donation process begins with the recruitment and selection of the donor.⁴¹ Donors are often recruited through online or print advertisements offering monetary compensation in exchange for their eggs.⁴² A fertility clinic or a third-party agency, generally referred to as an “egg broker” who matches the recipients and donors with the traits they seek and who facilitates parts of the transaction, conducts

34. See generally Neal, *supra* note 33 at 617–18 (discussing the controversy surrounding stem cell research).

35. Cone, *supra* note 4, at 217 app. A. Many states outright ban the use of embryos for stem cell research, and most states that do allow such research expressly ban compensating donors for donating eggs. Diana M. Santos, *Compensation for Egg Donations to Stem Cell Research: Coercion or Choice?*, 2 HEALTH L. & POL'Y BRIEF 82, 82 (2013); See Cone, *supra* note 4, at 217 app. A.; *Embryonic and Fetal Research Laws*, NAT'L CONF. ST. LEGISLATURES, <http://www.ncsl.org/research/health/embryonic-and-fetal-research-laws.aspx> (last updated Jan. 1, 2016);

36. Cone, *supra* note 4, at 208.

37. N.Y. EGG DONOR FACTS, *supra* note 29, at 13.

38. REPROD. HEALTH TECHNOLOGIES PROJECT, *supra* note 28, at 2.

39. *Id.*

40. *Id.* at 3–5. See *infra* notes 55–65 and accompanying text, for a discussion of the medical risks.

41. Baum, *supra* note 26, at 116.

42. Aaron D. Levine, *Self-Regulation, Compensation, and the Ethical Recruitment of Oocyte Donors*, HASTINGS CENTER REP., Mar.–Apr. 2010, at 29, 35. These advertisements often do not disclose risks involved in the donation process. Hillary B. Alberta et al., *Risk Disclosure and the Recruitment of Oocyte Donors: Are Advertisers Telling the Full Story?*, 42 J.L. MED. & ETHICS 232, 233–34.

the recruitment process.⁴³ The “egg market” has expanded online into the form of social databases akin to Facebook or dating websites that match donors and recipients.⁴⁴

Once the donors are selected, they are screened by a fertility clinic for medical risks, communicable diseases, and psychological risks.⁴⁵ According to the American Society for Reproductive Medicine (ASRM) and other professional guidelines, donors must go through the informed consent process and be made fully aware of the entire donation procedure, including the risks involved.⁴⁶ Once donors provide their informed consent and are properly screened and approved for donation, they begin the “controlled hyperstimulation” process of the cycle.⁴⁷

“Controlled hyperstimulation” involves a three-week cycle of hormone therapy whereby three sets of hormones are administered almost daily to stimulate the donor’s ovaries into producing many eggs at one time.⁴⁸ The ASRM estimates that the donor will spend almost

43. Kari L. Karsjens, *Boutique Egg Donations: A New Form of Racism and Patriarchy*, 5 DEPAUL J. HEALTH CARE L. 57, 65 (2002).

44. Bercovici, *supra* note 3, at 196–97; Sauer, *supra* note 2, at 951 n.202 (citing THE DONOR SIBLING REGISTRY, <http://www.donorsiblingregistry.com/> (last visited Mar. 12, 2016)).

45. N.Y. EGG DONOR FACTS, *supra* note 29, at 8–10. “Common complaints from donors during the donation process include hormone injections, egg retrieval pain, anxiety, and mood swings. Donors also reported worrying about potential medical and fertility consequences from their donations.” Durrell, *supra* note 32, at 203 (footnotes omitted).

46. Durrell, *supra* note 32, at 217. Although ASRM recommends that physicians disclose financial interests related to the donation process when eggs will be used for research purposes, they do not have similarly explicit recommendations when the eggs are being retrieved for ART purposes. Ethics Comm. of the Am. Soc’y for Reprod. Med., *Informed Consent and the Use of Gametes and Embryos for Research: A Committee Opinion*, 101 FERTILITY & STERILITY 332, 333 (2014) (“IVF facility and research investigators should disclose all conflicts of interests to the donors, including but not limited to financial conflicts of interest.”); Ethics Comm. of the Am. Soc’y for Reprod. Med., *Donating Embryos for Human Embryonic Stem Cell (hESC) Research: A Committee Opinion*, 100 FERTILITY & STERILITY 935, 935 (2013) (“Patients should be informed of financial incentives, if any, that the investigator/physician or the institution/organization has in the research.”). Financial interests can undermine informed consent. See, e.g., Valerie K. Blake et al., *Conflicts of Interest and Effective Oversight of Assisted Reproduction Using Donated Oocytes*, J.L. MED. & ETHICS 410, at 411 (2015); Durrell, *supra* note 32, at 215, 220–21; Sonia M. Suter, *Giving in to Baby Markets: Regulation Without Prohibition*, 16 MICH. J. GENDER & L. 217, 238–40 (2009); Cone, *supra* note 4, at 202.

47. See generally N.Y. EGG DONOR FACTS, *supra* note 29, at 15–16 (describing the process of controlled hyperstimulation).

48. REPROD. HEALTH TECHNOLOGIES PROJECT, *supra* note 28, at 2 & tbl.1. There are many different brands and types of hormone inducing drugs utilized in ovarian hyperstimulation. *Id.* at 2 tbl.1. The health care provider performing the retrieval usually selects which one to administer based on “various factors, including age, ovarian responsiveness and the purpose of the egg retrieval.” *Id.* at 2. There are three stages involved in hyperstimulation: (1) synthetic gonadotropin-releasing hormones are administered to temporarily suppress regular ovarian function in order to have the donor reach baseline hormone levels; (2) stimulate the pituitary gland to produce gonadotropins, which stimulate the ovaries to mature and release multiple follicles; and (3)

fifty-six hours in the clinic during the hyperstimulation process.⁴⁹ Although women may donate eggs without undergoing hyperstimulation by donating the one egg naturally released during a menstrual cycle,⁵⁰ it is preferable to both the women seeking fertility treatment and the fertility clinics to remove multiple eggs per cycle and implant as many eggs as possible due to the high costs and time commitment involved in each cycle.⁵¹ Despite fertility professionals' desires to maximize financial efficiency and increase the chances of fertility,⁵² the risks from donating increase exponentially when more eggs are retrieved.⁵³ Once the eggs are fully matured from the final hormone in the hyperstimulation process, they must be physically retrieved from the ovarian follicle within twenty-four to thirty-six hours using an ultrasound-guided needle.⁵⁴ Despite the proliferation of ART and egg donation, egg donation can present serious medical risks to egg donors.

3. *The Medical Risks*

It is well documented that there are risks involved in both the hyperstimulation and the surgical egg retrieval, yet there are no comprehensive studies detailing the likelihood of risks occurring because there is no source of objective data on the long-term risks and outcomes in egg donation.⁵⁵ While the physical extraction process of the eggs may seem extreme, it is minimally invasive compared to the intense and time-consuming hormone process.⁵⁶ Both procedures can

administer human gonadotropin to stimulate the final maturation of the egg triggering ovulation while simultaneously triggering progesterone after egg retrieval to prepare the uterus for implantation. *Id.*

49. *Id.* at 3.

50. *Id.* at 2–3.

51. *See id.* at 1–3.

52. Cone, *supra* note 4, at 202.

53. Am. Soc'y Reproductive Med., *Ovarian Hyperstimulation Syndrome*, 90 FERTILITY & STERILITY S118, S118 (2008); Sesh Kamal Sunkara et al., *Association Between The Number of Eggs and Live Birth in IVF Treatment: An Analysis of 400 135 Treatment Cycles*, HUM. REPROD.: ADVANCE ACCESS, at 1744, (May 10, 2011). Implanting multiple eggs into recipients may result in multiple simultaneous births, which can create extreme dangers in birthing. Practice Comm. of the Am. Soc'y for Reprod. Med. & Practice Comm. of the Soc'y for Assisted Reprod. Tech., *Criteria for a Number of Embryos to Transfer: A Committee Opinion*, 99 FERTILITY & STERILITY 44, 44 (2013) [hereinafter ASRM, *Criteria for a Number of Embryos to Transfer*].

54. REPROD. HEALTH TECHNOLOGIES PROJECT, *supra* note 28, at 3. "The process of egg extraction or 'harvesting' generally occurs when the woman is under light anesthesia." Bercovici, *supra* note 3, at 195.

55. *See* REPROD. HEALTH TECHNOLOGIES PROJECT, *supra* note 28, at 3, 7. Because clinics and physicians are not required to report any post-egg retrieval complications, or even follow up with donors at all, there is no data collected on post-donation complications. The only data on risks come from case studies or self-reported studies. *See infra* notes 192–200 and accompanying text, for an analysis on data and reporting.

56. Bercovici, *supra* note 3, at 195.

result in minor and severe complications that may arise acutely or develop over time.⁵⁷

One of the most common risks associated with egg donation is ovarian hyperstimulation syndrome (OHSS), which is an “exaggerated response” to the third step of controlled hyperstimulation in which the human hormone gonadotropin is administered to trigger the ovulation.⁵⁸ Most estimates suggest that a majority of women undergoing controlled hyperstimulation will experience some mild symptoms of OHSS.⁵⁹ Surgical egg retrieval carries risks common to most surgical procedures, such as bleeding, infection, complications, and adverse reactions to anesthetics.⁶⁰

Aside from egg retrieval’s acute risks that may develop, egg retrieval may carry serious long-term risks as well.⁶¹ The egg retrieval process is potentially associated with increased risks of breast, ovarian, and endometrial cancers, as well as infertility.⁶² Certain psychological risks may arise from the egg donation process, including, but not limited to: (1) second thoughts in donating; (2) the revelation of previously unknown medical conditions that disqualify them from donating; or (3) donors’ concerns about the future use of their eggs.⁶³

57. See *id.* at 194–95.

58. See REPROD. HEALTH TECHNOLOGIES PROJECT, *supra* note 28, at 3 (defining “OHSS” as “a condition following administration of human chorionic gonadotropin (hGC) to trigger ovulation”); Practice Comm. of the Am. Soc’y for Reprod. Med., *Ovarian Hyperstimulation Syndrome*, 90 FERTILITY & STERILITY S118, S118 (Supp. 2008) (defining “OHSS” as “an exaggerated response to ovulation induction therapy”). OHSS carries a variety of symptoms from swelling of the ovaries, mild to severe abdominal pain, vomiting, nausea, and dehydration. Bercovici, *supra* note 3, at 195. It can also cause very serious problems, including “clotting disorders, renal failure, and ovarian twisting.” REPROD. HEALTH TECHNOLOGIES PROJECT, *supra* note 28, at 3.

59. See, e.g., REPROD. HEALTH TECHNOLOGIES PROJECT, *supra* note 28, at 4 (citing LINDA GIUDICE ET AL., ASSESSING THE MEDICAL RISKS OF HUMAN OOCYTE DONATION FOR STEM CELL RESEARCH: WORKSHOP REPORT 18 (2007)). The exact rates of OHSS are impossible to know because all previous studies have utilized retrospective methods, and no follow up information was recorded on donors. One in ten women have been estimated to experience abdominal or pelvic pain. *Id.* OHSS can occur two to seven days after the third step of hyperstimulation or later (around twelve to seventeen days after the third stage). *Id.* Later occurrences tend to bring more severe complications. *Id.* Conservative estimates suggest that the morbidity rate of women who develop serious OHSS symptoms is one in every 500,000 egg donation cycles; however, data is vulnerable to confounding variables, because women who have their own eggs retrieved for their own IVF procedures subsequently become pregnant, which carries its own increased risks of blood clots. *Id.*

60. *The Medical Procedure of Egg Donation*, EGG DONOR INFO. PROJECT, <https://web.stanford.edu/class/siw198q/websites/eggdonor/procedures.html> (last updated June 5, 2002).

61. Amy L. Boutelle, *Donor Motivations, Associated Risks and Ethical Considerations of Oocyte Donation*, 18 NURSING FOR WOMEN’S HEALTH 112, 117–18 (2014).

62. *Id.*; Durrell, *supra* note 32, at 188; Cone, *supra* note 4, at 200–01.

63. LINDA GIUDICE ET AL., *supra* note 59 at 41–49.

The medical risks and compensation to egg donors underscore concerns that the industry's structure and relation of the parties involved may present conflicts of interests and biases that could cause egg donors to be exposed to subpar treatment from those parties, specifically physicians.

B. *System Structure, Interests, and Ethical Risks*

In the United States, there are three general parties involved in the ART and egg donation process: (1) recipients; (2) donors; and (3) those involved in the industry. Each of these parties has different interests and goals based on their roles and position in the structure of the U.S. egg market.⁶⁴ Donors have either financial or altruistic motivations in donating their eggs as well as concern with their own well-being.⁶⁵ Recipients will usually seek healthy donors with certain attributes and clinics with high fertility rates and competitive prices on fertility cycles.⁶⁶ There are two types of industry parties that interact with egg donors: those on the clinical side, such as fertility physicians and the clinics that employ them, and third-party recruiters and egg brokers.⁶⁷ The clinics want to attract recipients to their services, keep those recipients satisfied to retain their payments, and maximize and maintain the fertility success rates that attract future customers.⁶⁸

The different roles and interests of these three parties interact to create conflicts of interests that raise ethical concerns. Although ethical concerns arise in any commodification of bodily materials, they are amplified by the financial incentives and motives that drive the largely unsupervised side of the ART industry.⁶⁹ The following Section details the ethical concerns with egg donation generally, the increased risks of ethical issues presented by the industry's structure, and the incentives that drive the industry.

1. *The Ethical Risks Surrounding ART*

Almost every aspect of ART can be criticized on some sort of ethical ground,⁷⁰ but there are specific concerns that accompany the egg

64. Hereinafter, "egg market" refers to the market for ART rather than stem cells.

65. See Boutelle, *supra* note 61, at 115.

66. See *id.* at 114; Durrell, *supra* note 32, at 216 n.242; Preisler, *supra* note 3, at 226.

67. Blake et al., *supra* note 46, at 411; 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, 672 (2008).

68. Cone, *supra* note 4, at 202.

69. Blake et al., *supra* note 46; Reddix-Small, *supra* note 67, at 650 n.18.

70. Yehezkel Margalit et al., *The New Frontier of Advanced Reproductive Technology: Reevaluating Modern Legal Parenthood*, 37 HARV. J.L. & GENDER 108, 108-09 (2014).

donor's situation.⁷¹ Some scholars view the compensation that donors receive as a coercive monetary incentive.⁷² These concerns are amplified by the fact that the typical donor is a young woman in college who is likely in need of money.⁷³ This concern is evidenced by the fact that most countries engaging in ART typically ban any monetary compensation beyond direct costs.⁷⁴ However, these bans can force massive negative effects on the ART industry, such as severely reducing the supply of donor eggs, which can lead to black markets and stifled innovation.⁷⁵ The ASRM guidelines limit compensation, but much evidence suggests that the guidelines are not widely adhered to in many circumstances.⁷⁶

Another ethical concern in egg donation is whether physicians obtain informed consent from donors.⁷⁷ To attain proper informed consent, donors must be made fully aware of, and comprehend, all risks and procedures involved in egg donation, and they must give their consent to participate in these procedures.⁷⁸ Because informed con-

71. Ina N. Cholst, *Oocyte Donation and the Therapeutic Misconception*, 99 FERTILITY & STERILITY 1561, 1561–62 (2013). One of the biggest ethical dilemmas in egg donation, is the fact that no aspect of the entire procedure is medically necessary for the donors and, thus, the risks to the donor will always outweigh any medical benefit she may receive from the procedure. Marvin, *supra* note 3, at 127. Some advertisements have offered as much as \$50,000 to donors with specific physical, cultural, or personal characteristics; however, these are extremely rare. Ethics Comm. of the Am Soc'y for Reprod. Med., *supra* note 32, at 306.

72. See, e.g., Durrell, *supra* note 32, at 189–90; 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 399, 401–02 (2010); Rao, *supra* note 33, at 1058–60.

73. Bercovici, *supra* note 3, at 196.

74. Gaia Bernstein, *Regulating Reproductive Technologies: Timing, Uncertainty, and Donor Anonymity*, 90 B.U. L. REV. 89 (2010) (reviewing NAOMI R. CAHN, *TEST TUBE FAMILIES: WHY THE FERTILITY MARKET NEEDS LEGAL REGULATION* (2009)).

75. See *infra* notes 237–26 and accompanying text (discussing the consequences of increased regulation).

76. Ethics Comm. of the Am Soc'y for Reprod. Med., *supra* note 32, at 305–06 (explaining that some Internet advertisements have offered payments of \$5,000 or more). The guidelines recommend limiting donor compensation to \$5,000, with justifications for any amounts exceeding this; amounts over \$10,000 are inappropriate in all situations. *Id.*

77. See generally Am. Soc'y Reproductive Med., *Informed Consent and the Use of Gametes and Embryos for Research: A Committee Opinion*, 101 FERTILITY & STERILITY 332 (2014) [hereinafter ASRM, *Informed Consent*]; Margaret E. Swain, *The Essentials of Informed Consent*, FAMILY ADVOCATE, Fall 2011, at 18. Modern informed consent evolved from the common law tort of battery, as a means to refuse nonconsensual contact or, in the medical context: unwanted treatment or treatment that would be refused had the patient been fully informed. Barbera Atwell, *The Modern Age of Informed Consent*, 40 U RICHMOND L. REV. 591, 593–95 (2006). Informed consent promotes a patient's autonomy to make medical decisions. *Id.*

78. N.Y. EGG DONOR FACTS, *supra* note 29, at 19–20. Proper informed consent is a delicate and fluid process that can involve many aspects and mechanisms. See Swain, *supra* note 77, at 18.

sent is typically carried out through a release form that is signed by the donor, which indicates that she is fully aware of the risks and processes, it is difficult to know exactly how much information is given, how accurate the information is, and whether the donor has had the necessary time and opportunity to comprehend the risks and benefits associated with the procedures.⁷⁹ The ASRM publishes standards for informed consent and recommends that any advertisements recruiting donors that offer financial compensation must also disclose the risks and burdens of egg donation.⁸⁰ Even when proper risk disclosure is made, informed consent can be undermined and, thus, incomplete, when there are conflicts of interest between the egg donor and physician or clinic performing the retrieval.⁸¹ In addition to the traditional ethical issues presented by egg donation, other ethical concerns, such as conflicts of interest and biases, are presented by the current structure of the U.S. ART industry.

2. *Conflicts and Biases in the Egg Donation Process*

Conflicts of interest are inherent in the typical donation process and can introduce biases in the risk disclosure and retrieval processes.⁸² These conflicts of interest exist within the donation scheme because recipients are the “patient” in the sense that the aim of the whole process is to successfully impregnate them, and, even more so, because they are financing the entire procedure.⁸³ The high costs of IVF procedures usually limit the number of cycles a recipient can afford, putting pressure on the clinics and physicians to maximize the chance

79. Alberta, *supra* note 42, at 233–234; Swain, *supra* note 77, at 18.

80. See ASRM *Informed Consent*, *supra* note 77; Ethics Comm. of the Am Soc’y for Reprod. Med., *supra* note 32, at 306. Studies indicate that compliance with these recommendations is generally low. Alberta, *supra* note 42. California requires that recruitment advertisements to include risk disclosures. See *infra* note 134–135 and accompanying text (discussing California’s regulatory landscape).

81. Vanessa Gruben, *Women as Patients, Not Spare Parts: Examining the Relationship Between the Physician and Women Egg Providers*, 25 CAN. J. WOMEN & L. 249, 270 (2013).

82. *Id.*; Judith Daar, *Regulating the Fiction of Informed Consent in ART Medicine*, AM. J. BIOETHICS, Fall 2001, at 19; Gruben, *supra* note 81, at 270. Conflict of interest arises from the physician’s dual role of treating both donors and recipients as patients. The conflict is further intensified by the strong financial tie between the recipient and physician. Blake et al., *supra* note 46, at 416. This can cause the physician to prefer the medical and personal interests of the recipients, and disregard the interests of the donor, creating a bias favoring the recipients. *Id.*; Andrea L. Kalfoglou & Gail Geller, *Navigating Conflict of Interest in Oocyte Donation: An Analysis of Donors’ Experiences*, 10 WOMEN’S HEALTH ISSUES 226, 226–27 (2000).

83. Cone, *supra* note 4, at 202. This bias will likely increase as the cost of IVF cycles have steadily increased and the ART industry expands and becomes more competitive. Gruben, *supra* note 81, at 270; Sauer, *supra* note 2. There are also concerns about placing donors who were specifically picked because they were in good health but are now being subjected to risks without any chance of a medical benefit to them. Cone, *supra* note 4, at 190.

of obtaining pregnancies in the first cycle.⁸⁴ There may also be an incentive to retrieve as many eggs per donation cycle as possible because donors are compensated at a flat rate regardless of the number of eggs obtained.⁸⁵ Financial incentives can undermine informed consent because physicians could purposely or unintentionally omit or downplay descriptions of donation risks, ignore a donor's predisposing factors to OHSS, or make them reluctant to cancel or modify hyperstimulation cycles.⁸⁶

These biases also stem from the financial structure of the U.S. ART industry and the interaction of the parties involved.⁸⁷ Scholars note that the U.S. ART industry is one of the largest and most lucrative of all countries that utilize these procedures.⁸⁸ This may be due to the industry's private nature and structure, and the lack of enforceable laws regulating it.⁸⁹ There are several parties engaged in the ART industry aside from the donors and recipients.⁹⁰ The most involved are the professional parties, such as the fertility clinics who facilitate much of the process, physicians who perform the egg removal and embryo implantation procedures, egg brokers who locate and recruit egg donors, and pharmaceutical companies who manufacture drugs.⁹¹

Because fertility clinics are generally privately owned and derive their income from treating recipients, it is in their best interest to attract as many potential customers as possible.⁹² An important tool in attracting customers is a clinic's pregnancy success rates.⁹³ The physicians who perform the procedure likely have a financial stake in the clinic; thus, they are also incentivized to maximize successful outcomes by making risky choices for both the donor and the recipient.⁹⁴

84. Cone, *supra* note 4, at 202.

85. Judith Daar, *Federalizing Embryo Transfers: Taming the Wild West of Reproductive Medicine?*, 23 COLUM. J. GENDER & L. 257, 261 (2012).

86. Cone, *supra* note 4, at 199.

87. Preisler, *supra* note 3, at 223–26.

88. See, e.g., Aaron D. Levine, *The Oversight and Practice of Oocyte Donation in the United States, United Kingdom, and Canada*, 23 HEC FORUM 15 (2011).

89. Cone, *supra* note 4, at 195.

90. Roberts, *supra* note 2.

91. *Id.*

92. Marvin, *supra* note 3, at 127.

93. Preisler, *supra* note 3, at 226. Although federal law requires these rates to be truthfully advertised, they are vulnerable to several methods of manipulation, such as clinics only taking recipients with high chances of pregnancy and turning away older clients, and may encourage clinics to transfer more embryos than is medically safe. See generally, *infra* notes 110–117 and accompanying text (discussing the purpose of federal regulation). Clinics may administer IVF to recipients early on before trying less expensive and potentially effective options, so some of these women could have gotten pregnant without IVF. Preisler, *supra* note 3, at 223.

94. See Durrell, *supra* note 32, at 221.

There are also egg brokers, or recruitment agencies who pair recipients with donors who have specific traits they desire.⁹⁵ This third-party service can be extremely lucrative, and brokers may facilitate egg transactions between parties in two different countries.⁹⁶ These services contribute to the phenomenon of reproductive tourism in which recipients seek ART treatments in other countries because they are unavailable or too expensive in their native area.⁹⁷ The parties likely holding the largest stake in the ART industry are the pharmaceutical companies that manufacture the drugs necessary for hyperstimulation and implantation.⁹⁸ Insurance companies are also involved in the ART industry, but to a much lesser extent than the others previously mentioned.⁹⁹ Because of the many conflicts and incentives in the industry as well as the medical nature of the process, there are some aspects of the egg donation that are regulated, while other aspects remain unregulated.

C. Regulation of ART in the United States

Opponents of the U.S. ART industry criticize it for being one of the least regulated of ART-involved countries.¹⁰⁰ This could stem from the dual nature in which egg donation is regulated as well as the lack of comprehensive or enforceable guidelines that cover donation for fertility treatments.¹⁰¹ At the state and federal levels, eggs that are retrieved for stem cell research are subject to more comprehensive regulations than those for fertility treatment.¹⁰² The egg donation industry for fertility purposes is largely left to professional self-regulation.¹⁰³ Although every state has laws concerning aspects related to ART, these laws usually concern parentage of the resulting children or ownership over embryos created for IVF, aspects of surrogacy con-

95. Kimberly D. Krawiec, *Altruism and Intermediation in the Market for Babies*, 66 WASH. & LEE L. REV. 203, 207, 234 (2009). These brokers are a large concern because they generally fall outside the few regulations in the industry. Cone, *supra* note 4, at 191.

96. Cone, *supra* note 4, at 191–93, 196.

97. J. Brad Reich & Dawn Swink, *You Can't Put the Genie Back in the Bottle: Potential Rights and Obligations of Egg Donors in the Cyberprocreation Era*, 20 ALB. L.J. SCI. & TECH. 1, 20 (2010).

98. Sandra T. Jimenez, "My Body, My Right": A Look Into IVF Regulation Through the Abortion Legal Framework, 33 WOMEN'S RTS. L. REP. 375, 383 (2012).

99. See *infra* notes 136–138 (discussing the role of insurance companies).

100. See, e.g., Durrell, *supra* note 32, at 188–90; Frith & Blyth, *supra* note 3, at 516–17; Jocelyn Sweet, *Safety and Access: Is the UK Regulatory Model Right for America?*, 4 HEALTH L. & POL'Y BRIEF 54, 54 (2010); Neal, *supra* note 33, at 615; Preisler, *supra* note 3, at 223, at 214.

101. See Cone, *supra* note 4, at 190; Marvin, *supra* note 3, at 129.

102. See Cone, *supra* note 4, at 189–92.

103. See *infra* notes 139–141 and accompanying text (discussing these professional societies).

tracts, or the use of eggs and embryos for stem cell research.¹⁰⁴ Although some states have regulations in place to protect egg donors, these regulations comprise only a patchwork of laws, and a majority of states have no regulations in place to protect egg donors.¹⁰⁵ The following section explains the regulations at the federal level and the various approaches implemented by the states.

1. Regulation at the Federal Level

The substantial revenues generated by this private industry certainly have some impact on the national economy, and thousands of egg donors and recipients are either positively or negatively affected by ART every year. Currently, the only federal laws related to egg donation control the screening and handling of donor gametes, truth in the advertising of fertility success rates, and the inability to compensate egg donors for eggs to be used in stem cell research.

The primary federal legislation governing ART in the United States is the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA).¹⁰⁶ The FCSRCA requires the Secretary of the U.S. Department of Health and Human Services (HHS) to annually collect data through the CDC from fertility clinics.¹⁰⁷ The FCSRCA also requires the Secretary to develop model certification guidelines for the states to certify fertility clinics inside their borders.¹⁰⁸ However, states are not required to adopt these model regulations or even create any of their own.¹⁰⁹ There are no current federal regulations directly supervising aspects of egg donation.

The main purpose of the FCSRCA was intended for the protection of consumers.¹¹⁰ The FCSRCA requires the CDC to collect information and data concerning the pregnancy success rates of clinics and compile this data in an annual report.¹¹¹ This report also lists which

104. Sweet, *supra* note 100, at 55; Cone, *supra* note 4, at 206; *see also* Marvin, *supra* note 3, at 133–34 (noting that state laws do not address the issues of the industry).

105. Kenneth Baum, *Golden Eggs: Towards the Rational Regulation of Oocyte Donation*, 2001 B.Y.U. L. REV. 107, 123–25; Cone, *supra* note 4, at 205; Marvin, *supra* note 3, at 129.

106. Pub. L. No. 102-493, 106 Stat. 3146 (codified as amended in scattered sections of 42 U.S.C.). The FCSRCA refers to clinics as “assisted reproductive technology programs.” 42 U.S.C. § 263a-1(a) (2012).

107. 42 U.S.C. § 263a-1(a)(1).

108. *Id.* § 263a-2(a)(1).

109. *See id.* § 263a-2(b).

110. Preisler, *supra* note 3, at 218.

111. 42 U.S.C. § 263a-5(1)(A). This data includes the number of cycles performed, the number of cycles that resulted in live births, the age of the recipients, the ages of donors, and the number of embryos transferred. Sunderam et al., *supra* note 1 at 6 fig.2. Although success rates are calculated in several ways, the primary method is the percentage of cycles that resulted in live births. *Id.* at 2. This information is collected by Westat, Inc., a statistical survey research

clinics have been certified by the CDC, state agencies, and professional associations as well as listing those that lack certification.¹¹² The FCSRCA does not require the CDC to collect any information on egg donors aside from their age, which is used to determine the effect of donor age on pregnancy outcomes and the outcomes of donor eggs in general.¹¹³ The purpose of collecting and publishing pregnancy success rates is to ensure that fertility clinics are truthfully advertising their success rates to recipients and to allow recipients to see which clinics are certified.¹¹⁴ However, reporting is not mandatory.¹¹⁵ The only consequence a clinic faces when failing to report the requested data is being “listed as a non-reporter in the CDC’s website.”¹¹⁶

The FCSRCA’s ability to protect egg donors is severely limited because its own terms prohibit the Secretary of HHS or individual states from establishing regulations, “which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs.”¹¹⁷ If states did develop their own regulations under the FCSRCA, they could not effectively regulate the necessary aspects of the donation process, such as screening, informed consent standards, or placing limits on the amount of eggs retrieved, because these regulations would amount to supervision of the medical process.¹¹⁸

As the primary ART legislation in the United States, the FCSRCA is far from comprehensive. The two main components of the FCSRCA are: (1) ensuring truthful advertising of pregnancy success rates to prospective recipient consumers and (2) improving the quality of IVF and other procedures.¹¹⁹ The only aspect concerning donors is reporting the number of embryos transferred to recipients created

organization contracted by CDC, which maintains a list of all U.S. ART clinics known to be in operation. *Id.* at 3. Clinics submit their data online to the National ART Surveillance System (NASS) operated by Westat who then relays the organized data to the CDC. *Id.* The CDC annually audits a sample of clinics to ensure that they are reporting accurately. *National ART Surveillance: Why Do We Monitor Assisted Reproductive Technology?*, CTDS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/art/nass/index.html>. (last updated Mar. 7, 2016).

112. 42 U.S.C. § 263a-5(1)(B).

113. See Frith & Blyth, *supra* note 3, at 518.

114. See Preisler, *supra* note 3, at 217–18.

115. Marvin, *supra* note 3, at 133.

116. *Id.*

117. 42 U.S.C. § 263a-2(i).

118. See Preisler, *supra* note 3, at 220. The U.S. Food and Drug Administration (FDA) regulates and sets standards for the screening and testing of donor biological materials. 21 C.F.R. § 1271 (2015). However, these regulations are designed to prevent the transfer of communicable diseases, namely to the donor. Frith & Blyth, *supra* note 3, at 518.

119. Judith Daar, *Federalizing Embryo Transfers: Taming the Wild West of Reproductive Medicine?*, 23 COLUM. J. GENDER & L. 257, 268 (2012); Preisler, *supra* note 3, at 218–19.

with donor eggs and the ages of the donors.¹²⁰ Clinic standards are supposed to be based on model guidelines created by the CDC, but states are free to develop their own programs.¹²¹ There is very little sanctioning power granted by the FCSRCA; the penalty for not reporting is being listed as a nonreporting clinic in the CDC's annual report.¹²² And although the FDA requires donor screening, this is only to prevent the spread of communicable diseases.¹²³

The FCSRCA does not require states to adopt the model regulations created under the FCSRCA or mandate that the states create regulations of their own.¹²⁴ Thus, federal regulations neither directly supervise aspects of egg donation nor require that states supervise egg donation on their own. However, states are allowed to regulate egg donation, although only a small minority of states have taken initiatives to do so.

2. *Regulation by the Individual States and Professional Associations*

The individual states are reserved implied police powers under the Tenth Amendment to “protect the general health and welfare” of their citizens.¹²⁵ This grants states the ability to control the conduct and morals of their citizens through means such as local law enforcement or professional licensure.¹²⁶ Despite their powers, few states have passed regulations to protect egg donors.¹²⁷ Most state laws regulating ART, when they exist, concern the disposition of donated gametes, stem cell research, human cloning, parentage, and aspects of surrogacy.¹²⁸ Despite states' inaction, there are some state laws that are designed to protect donors, or, at the very least, affect the donation process.¹²⁹

Some states, including Georgia and Louisiana, have chosen to ban the sale of human eggs altogether.¹³⁰ Other states have taken limited

120. See 21 C.F.R. § 1271.

121. 42 U.S.C. § 263a-2; Preisler, *supra* note 3, at 218.

122. Reddix-Small, *supra* note 67, at 659.

123. Frith & Blyth, *supra* note 3, at 518.

124. 42 U.S.C. § 263a-2(b).

125. Michelle N. Meyer, *States' Regulation of Assisted Reproductive Technologies: What Does the U.S. Constitution Allow?*, 5 & 16 n.9 (Nelson A. Rockefeller Inst. of Gov., Harvard Law Working Paper 2009), http://www.rockinst.org/pdf/health_care/2009-07-States_Regulation_ART.pdf.

126. See *id.* at 14.

127. See Cone, *supra* note 4, at 208.

128. *Id.* at 205, 208.

129. See *infra* notes 131–35 and accompanying text (e.g., Arizona, California, & New York).

130. See, e.g., GA CODE ANN § 16-12-160 (2011); LA. STAT. ANN. § 9:122 (2008).

steps in mandating informed consent requirements.¹³¹ For example, Arizona has informed consent requirements and mandates that a physician-patient relationship exists between the doctor performing the egg retrieval and the donor.¹³² New York has taken the most active step in creating regulatory structures for the oversight of egg donation under its State Task Force on Life and the Law, which has a special advisory group for ART that creates guidelines for state clinics and releases information for prospective donors.¹³³ California is the only state to take an initiative in passing regulations designed to protect egg donors in a comprehensive manner, although its regulatory scheme falls short of being comprehensive.¹³⁴ California requires that any advertisements offering monetary compensation for egg donation disclose certain risks in the same advertisement.¹³⁵

States have also tied some regulations to insurance coverage.¹³⁶ Currently, seventeen states have some law that requires certain insurance plans to cover certain ART procedures.¹³⁷ For instance, Arkansas requires that clinics be licensed or certified by the Arkansas Department of Health and conform to the guidelines released by the American College of Obstetricians and Gynecologists to have the procedures covered by insurance.¹³⁸

Aside from New York and California, the few states that are highly involved in regulating ART, the last remaining safeguard between donors and the financial incentives of the industry comes from ASRM's self-regulating guidelines. Two national professional societies, ASRM and the Society for Assisted Reproductive Technology (SART), cer-

131. See, e.g., ARIZ. REV. STAT. § 36-1702 (2014) (stating that prior to a medical procedure, a physician must provide the donor with information such as a description of the hormones the egg donor will need to take, all procedures that will be performed, and any potential risks); CAL. HEALTH & SAFETY CODE § 125325 (West 2012) (if an entity advertises for egg donation, it must also provide a notice on the advertisement concerning medical risks and other information); N.Y. COMP. CODES R. & REGS. tit. 10, § 52-8.8 (2014) (requiring informed consent, which includes the donor acknowledging notice to information such as the donor's name and address, will remain on a file, genetic testing will be performed, and the donor has a right to withdraw her consent).

132. ARIZ. REV. STAT. § 36-1702.

133. N.Y. EGG DONOR FACTS, *supra* note 29, at 2, 5; Sweet, *supra* note 100, at 55 (2010).

134. Cone, *supra* note 4, at 192.

135. CAL. HEALTH & SAFETY CODE § 125325.

136. See Jim Hawkins, *Selling ART: An Empirical Assessment of Advertising on Fertility Clinics' Websites*, 88 IND. L.J. 1147, 1163-64, 1167 (2013).

137. *State Infertility Insurance Laws*, AM. SOC'Y FOR REPROD. MED., <http://www.asrm.org/insurance.aspx> (last updated Mar. 11, 2016, 12:22 PM) (listing fifteen states); *State Laws Related to Insurance Coverage for Infertility Treatments*, NAT'L CON. ST. LEGISLATURES, <http://www.ncsl.org/research/health/insurance-coverage-for-infertility-laws.aspx> (last updated June 2014) (listing seventeen states).

138. ARK. CODE ANN. §§ 23-85-137, 23-86-118 (2014).

tify and issue guidelines for fertility clinics.¹³⁹ ASRM issued guidance limiting donor compensation, suggesting standards for informed consent, discussing the disclosure of financial interests, and recommending the medical and psychological screening of donors.¹⁴⁰ Compliance with these guidelines is completely voluntary, and adhering to them is not required for professional certification, which is also voluntary and not required to work in the ART industry.¹⁴¹

There is almost no data on donor outcomes or their donation experiences.¹⁴² Because of this, it is unknown how many physicians and clinics operate outside the ASRM guidelines or engage in other unprofessional conduct with donors.¹⁴³ This absence of data stems from the limited oversight by most states and the federal reporting requirements being limited to pregnancy outcomes.¹⁴⁴

The lack of regulation and oversight regarding the egg donation process make the ethical issues surrounding egg donors even more concerning. None of the regulations at the federal level concern the egg donation process directly; self-regulation by professional societies is ineffective due to a lack of oversight and enforcement, and only a small minority of states that permit egg donation have laws designed to protect egg donors. Thus, uniform and comprehensive changes are necessary to ensure that egg donors are not exposed to unethical treatment from industry players. However, there are several potential explanations as to why egg donation has not received greater regulation in the United States.¹⁴⁵ Accordingly, any comprehensive reforms designed to protect egg donors must avoid these issues. Reforms with minimal administrative burdens that can shift the incentives within the egg donation process may be able to avoid these barriers while still protecting egg donors.

139. Levine, *supra* note 42, at 26; Marvin, *supra* note 3, at 136–47; Preisler, *supra* note 3, at 220–21. See, e.g., ASRM, *Informed Consent*, *supra* note 77; Ethics Comm. of the Am Soc’y for Reprod. Med., *supra* note 26; ASRM, *Definitions of Infertility*, *supra* note 17.

140. See, e.g., ASRM, *Criteria for a Number of Embryos to Transfer*, *supra* note 53; AM. SOC’Y REPRODUCTIVE MED., *Recommendations for Gamete and Embryo Donation: A Committee Opinion*, 99 FERTILITY & STERILITY 47, 47 (2013) [hereinafter ASRM, *Recommendations for Gamete and Embryo Donation*].

141. Preisler, *supra* note 3, at 221.

142. See Boutelle, *supra* note 61, at 116–17.

143. See Gruben, *supra* note 81, at 257–58.

144. See *id.* at 270.

145. See *supra* notes 210–50 and accompanying text (discussing the barriers to regulating ART and egg donation).

III. ANALYSIS

The general lack of uniform regulation of the U.S. ART industry is troubling¹⁴⁶—especially in light of the inherent risks in donation,¹⁴⁷ the coercively high compensation paid to donors,¹⁴⁸ and the billion dollar revenues the industry generates.¹⁴⁹ The actual interactions between donors and clinics are impossible to measure because this information is not reported.¹⁵⁰ Presumptively, the overwhelming majority of ART physicians and clinics, as in any medical practice area in the United States, are ethically sound doctors concerned for the safety and well being of both donors and recipients. Nevertheless, there are certainly unethical doctors in any practice, and without any federal laws requiring special standards for fertility physicians and clinics to follow, egg donors will likely remain vulnerable to coercive and predatory practices. Given the financial incentives competing in the privatized nature of the industry, driven by the increased emphasis on success rates from the FCSRCA reporting requirements, as well as the peculiar medical relationships and duties within the U.S. donor process, concerns of unprofessional conduct existing in this relatively unsupervised area of medicine are not unjustified.

The individual states, rather than the federal government, are more than capable, if not better positioned, to conduct the primary oversight and regulation of ART due to their reserved authority over medicine and health related areas.¹⁵¹ Furthermore, there are benefits in allowing the laboratory of the states to test different regulatory schemes of ART and to provide their residents with a choice.¹⁵² And, despite the fact that the regulation of medicine has traditionally been reserved to the states under their police powers and the fact that Congress's role in governing medicine was traditionally limited,¹⁵³ decisions upholding aspects of Patient Protection and Affordable Care Act (ACA)¹⁵⁴ suggest that Congress may have more authority than

146. Durrell, *supra* note 32, at 188; Neal, *supra* note 33, at 611–12; Preisler, *supra* note 3, at 214. See generally Frith & Blyth, *supra* note 3, at 517–19 (discussing the limitations of regulations);

147. See *supra* notes 55–62 and accompanying text (discussing the associated medical risks).

148. See *supra* notes 72–74 and accompanying text (discussing the associated ethical risks).

149. Marvin, *supra* note 3, at 120.

150. Boutelle, *supra* note 61, at 117; see *supra* notes 100–23 and accompanying text (discussing the lack of ART regulation and reporting standards in the United States).

151. Meyer, *supra* note 125, at 2.

152. *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

153. See Meyer, *supra* note 125, at 5.

154. Pub. L. No. 11-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 42 U.S.C.).

previously thought.¹⁵⁵ Although states are believed to be best suited to regulate aspects of egg donation,¹⁵⁶ only a few states have passed laws with the purpose or effect of protecting donors.¹⁵⁷ And, although Congress has typically been limited in its ability to regulate medicine, it may have a stronger ability to do so in the post-ACA regulatory jurisprudence.¹⁵⁸

It is unlikely that many states will heed the call for reforms from scholars,¹⁵⁹ and it is even more unlikely that the federal government will step up and begin tightly regulating and supervising the egg donation industry.¹⁶⁰ Therefore, it is necessary for the federal government to spur the states themselves into properly regulating egg donation under their police powers. This Part begins by proposing that the current federal reporting scheme not only fails to account for the safety of egg donors, but may even be further jeopardizing it by emphasizing high success rates. This Part then argues that federal action is necessary to incentivize states into regulating egg donation more closely, offering potential forms of supervision that could aid in counteracting the prorecipient biases through expanded insurance recovery to incentivize compliance with professional standards and a more robust federal reporting scheme to include information on egg donors.

A. *Regulatory Gaps Leave Donors Vulnerable to Biases and May Actually Increase Them*

Without any significant monitoring of egg donation or mandatory guidelines concerning their treatment, physicians and clinics are

155. See, e.g., *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2599 (2012) (upholding the individual mandate requires tax payers to purchase health insurance as a tax, thus suggesting that Congress has broader authority to regulate medicine than previously suggested). See generally ANNIE L. MACH & BERNADETTE FERNANDEZ, CONG. RESEARCH SERV., R42069, PRIVATE HEALTH INSURANCE MARKET REFORMS IN THE AFFORDABLE CARE ACT 1–2 (2014) (explaining that “[w]hile such market reforms may be new at the federal level,” the “ACA follows the model of federalism that has been employed in prior federal health insurance reform efforts”); Liz Festa, *State v. Federal Regulation Debate a ‘Relic,’ Says FIO Chief McRaith*, INS. J. (Feb. 6, 2014), <http://www.insurancejournal.com/news/national/2014/02/06/319683.htm> (arguing that the state versus federal oversight debate is no longer relevant).

156. Meyer, *supra* note 125, at 2.

157. See *supra* notes 129–35 and accompanying text.

158. See KATHLEEN S. SWENDIMAN, CONG. RESEARCH SERV., R40846, HEALTH CARE: CONSTITUTIONAL RIGHTS AND LEGISLATIVE POWERS (2012).

159. Michael Ollove, *States Not Eager To Regulate Fertility Industry*, PEW CHARITABLE TRUSTS: RESEARCH & ANALYSIS—STATELINE (Mar. 18, 2015), <http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/3/18/states-not-eager-to-regulate-fertility-industry>.

160. See *infra* notes 210–23 and accompanying text (discussing the issues related to federal oversight & federalism).

largely free to treat donors as they see fit.¹⁶¹ Although most physicians conform to professionally ethical practices, the financial incentives from the lucrative industry may bias their interactions with donors.¹⁶² Financial interests may bias clinics and physicians toward giving preferential consideration to the recipient, the party funding the entire treatment process, and the ART industry.¹⁶³

On an ethical level, a clinic's or physician's financial interest in treatment outcomes creates a conflict of interest that undermines the informed consent given to donors.¹⁶⁴ If the recipients have a particular egg donor in mind, the financial conflict of interest could cause clinics or their staff to ensure that the preferred donor goes through with the donation and that the recipients will retain the clinics services.¹⁶⁵ The person providing information to the donor for informed consent may unconsciously or purposely downplay or omit some of the risks and procedures accompanying egg donation to avoid scaring donors away from the procedure.¹⁶⁶ Clinics and their staff may also overlook certain characteristics in donors that predispose them or increase the likelihood of post donation complications, especially donors who have donated in the past.¹⁶⁷

These conflicts of interest also reach the medical aspects of the donation process. Physicians are not limited in their choice of what drugs to administer for the hormone stimulation or the type of procedure to remove the eggs; thus, the biases could cause physicians to choose removal methods or drugs that are not in the donor's best interests.¹⁶⁸ Physicians are also given discretion in the amount of eggs they can retrieve per donation cycle, although the ASRM has guidelines suggesting limits.¹⁶⁹ Complications, such as OHSS, significantly increase

161. Boutelle, *supra* note 61, at 114.

162. *See supra* notes 82–94 and accompanying text (discussing the biases in the donation process).

163. Cholst, *supra* note 71, at 1561; Gruben, *supra* note 81, at 270; Kalfoglou & Geller, *supra* note 82, at 226–27; Suter, *supra* note, 46 at 239; *see* Cone, *supra* note 4, at 202.

164. Gruben, *supra* note 81, at 270.

165. *See* Cone, *supra* note 4, at 196–97.

166. Gruben, *supra* note 81, at 270.

167. *Id.* at 268–69.

168. *Id.* at 263. Physicians choose the drugs and removal methods. *Id.* at 258. There are also of financial conflicts of interests between clinics, physicians, and the donor. *Id.* at 267; Blake et al., *supra* note 46, at 411, 416; Durrell, *supra* note 32, at 220–21; Gruben, *supra* note 81, at 268; Kalfoglou & Geller, *supra* note 163, at 226–27 (discussing the pressures on doctors to favor the recipients); Suter, *supra* note 46, at 238–40.

169. Gruben, *supra* note 81, at 258 n.54 (“For example, the ASRM does not set a limit on the number of eggs per retrieval.”); ASRM, *Recommendations for Gamete and Embryo Donation*, *supra* note 140, at 53 (suggesting that a single donor should be limited to no more than twenty-five births in a population of 800,000).

when more eggs are retrieved.¹⁷⁰ Yet, there is an incentive to remove as many eggs as possible per donation cycle because the treatment expenses and compensation are not changed by the amount of eggs retrieved.¹⁷¹

Even if a majority of clinics and physicians remain unbiased from the financial pressures of the industry, there are some fertility professionals who will subject donors to unjustified risks to further their own financial interests. Possibly the greatest threat to donors is the potential lack of recourse when they suffer complications, whether those risks result from risks inherent in the donation process or from less-than best physician practices.¹⁷² It is difficult to determine the amount of negligent practice that occurs in the U.S. ART industry.¹⁷³ This could indicate overall adherence to professional standards and unbiased treatment of donors. But, there could also be difficulties in donors holding clinics accountable for unprofessional conduct.¹⁷⁴

170. Gruben, *supra* note 81, at 175.

171. *Id.* at 269.

172. Daar, *supra* note 85, at 278 (arguing that claims are seldom brought and those that are brought are usually unsuccessful).

173. The ASRM does not publish disciplinary actions. See E-mail from Sean Tipton, Chief Policy, Advocacy and Development Officer, Am. Society for Reproductive Medicine, to author (May 31, 2016, 10:05 AM) (on file with author). One source of information concerning misconduct are state medical licensing boards, but getting the necessary information would require sorting through all reported actions. FED'N OF STATE MED. BDS., U.S. MEDICAL REGULATORY TRENDS AND ACTIONS, 7–10, 18–20 (2014) [hereinafter FSMB REGULATORY TRENDS AND ACTIONS]; *Links to State Medical Boards*, AM. MED. ASS'N, <http://www.ama-assn.org/ama/pub/education-careers/becoming-physician/medical-licensure/state-medical-boards.page> (last visited May 17, 2016). The main resource for issues between donors and unprofessional clinics is, presumably, the ASRM, who directs the allegedly wronged donor to the particular state medical board or other licensing authority. AM. SOC'Y FOR REPRODUCTIVE MED., OVERSIGHT OF ASSISTED REPRODUCTIVE TECHNOLOGY 3, 5, 10 (2010) [hereinafter OVERSIGHT OF ART]. Every state has some licensing authority that handles disciplinary conduct of physicians. See, e.g. FSMB REGULATORY TRENDS AND ACTIONS, *supra* note 173; *Links to State Medical Boards*, AM. MED. ASS'N, *supra* note 173. Depending on the circumstances, nonadherence to ASRM guidelines, such as retrieving too many eggs, could lead to disciplinary actions from the licensing board, as well as any criminal liability for sever violations. See OVERSIGHT OF ART, *supra* note 173, at 5.

174. Daar, *supra* note 85, at 311, 313; Durrell, *supra* note 32, at 222 (arguing that a court could find that no patient–physician relationship existed); Jacob Radecki, Note, *The Scramble to Promote Egg Donation Through a More Protective Regulatory Regime*, 90 CHI.-KENT L. REV 729, 752 (2015) (arguing that some typical malpractice coverage is insufficient to protect donors). It is unclear whether certain unprofessional conduct would be actionable. Gross medical negligence would be disciplined by the state licensing board and governed by state tort law, but complications resulting from nonadherence to ASRM guidelines may not be fully reprehensible by state boards if clinics and doctors are not bound by them. *But see* Daar, *supra* note 85, at 271–72 (noting that Dr. Michael Kamrava disregarded the established guidelines and although a court was not willing to suspend his license, on further review the state medical board suspended his license because he failed to adhere to the voluntary guidelines). It may be difficult for donors to bring suit because they may have waived their rights through contracts with the fertility

Without the collection and recording of the drugs administered to donors for ovarian stimulation by a regulatory body or professional association, similar to the records kept by SART and the CDC on embryo transfers and outcomes, there is no way to track and study the side effects and long-term risks of those drugs; and, there are no current guidelines covering the amount or type of fertility drugs administered aside from the requirement that they obtain FDA approval.¹⁷⁵ Further, there are no mandatory laws limiting the amount of eggs retrieved in the United States.¹⁷⁶ Under the current regulatory laws, doctors are afforded great discretion in the donation process, leaving them free to compete with other clinics with maximized efficiency in egg retrieval and transfer and experimenting with new procedures and techniques.¹⁷⁷ The lack of any binding standards regulating the medical aspect stems from the FCSRCA's prohibition on HHS "exercising supervision or control over the practice of medicine in [ART] programs."¹⁷⁸

Good fertility rates are extremely valuable to fertility clinics, but because the FCSRCA holds success rates as the sole and primary measure distinguishing the efficacy of fertility clinics, these clinics must strive harder to keep their rates competitively high.¹⁷⁹ Although the reasons behind the FCSRCA's reporting requirement to ensure truthfully advertised success rates were well intentioned,¹⁸⁰ they may empower the recipient-preferential bias. Clinics will sometimes skew their definitions of pregnancies or terminate those unlikely to result in live birth to boost their success rates.¹⁸¹ The success rates place such a large emphasis on achieving pregnancy that they are incentivized to attain pregnancies at all costs and retain the recipient's business by making them happy. Although success rates were important in the past, under the current federal regulations, they are now the primary goal of fertility clinics. Because the current regulatory scheme has substantial gaps regarding the well-being of egg donors, more robust regulation and oversight is necessary to ensure that donors are insulated from potentially unethical treatment.

clinic or they may not be able to state a claim for a lack of informed consent due to the lack of a doctor-patient relationship between them and the physician. Durrell, *supra* note 32, at 222-23.

175. Judy Norsigian, *Egg Donation for IVF and Stem Cell Research: Time to Weigh the Risks to Women's Health*, DIFFERENT TAKES 33, Spring 2005, at 1, 2 (Spring 2005).

176. Gruben, *supra* note 81, at 258.

177. Reddix-Small, *supra* note 67, at 672.

178. 42 U.S.C. § 263a-2(i)(1) (2012).

179. Blake et al., *supra* note 46, at 416; Durrell, *supra* note 32, at 216.

180. See Reddix-Small, *supra* note 67, at 659.

181. See Durrell, *supra* note 32, at 216.

B. *Setting Limits and Shifting Incentives To Protect Donors*

This Section proposes two regulatory changes to protect egg donors. The first is a structural change at the federal level that encourages states to regulate ART more closely, to follow the example of some states by mandating insurance coverage for ART,¹⁸² and tie reimbursement to compliance with state or professional association guidelines and expanded reporting requirements.¹⁸³ The second substantively broadens the current federal reporting requirements to cover donor information and clinical aspects of the donation process, providing valuable insight into the outcomes of egg donation as well as opportunities to detect unprofessional clinics and doctors, and to allow donors to hold them accountable.¹⁸⁴

1. *Tying Insurance Coverage to Compliance with State or Federal Certification*

The current regulatory scheme in the United States lacks enforceable standards at the federal level and only has very few at the state level. Increasing insurance coverage of fertility treatments and tying reimbursement to clinic compliance with state or professional certification would greatly increase oversight and subsequently help donors.¹⁸⁵ This could be done by requiring states to either require fertility services as “essential health benefits”¹⁸⁶ or ban egg donation in their state. Standard fertility treatments would remain legal, but states that desire to allow egg donation must take some steps to regulate it and require insurance coverage for eligible couples.¹⁸⁷

182. See *infra* notes 185–86 and accompanying text (arguing that states should either require fertility services as “essential health benefits” or ban egg donation in their state).

183. See *infra* notes 188–89 and accompanying text (arguing that states that do choose to permit ART treatments and compensation for eggs should be required to create some oversight structure that could be tailored within certain regulatory limits).

184. See *infra* notes 192–201 and accompanying text (arguing that collecting information on the donor and the donation process could help curb unprofessional conduct).

185. Daar, *supra* note 85, at 323 (“While the problems with clinical guidelines would remain a provision that mandated reporting . . . combined with a penalty for false reporting — could act as an incentive for adherence. Knowing that [reports] could trigger provider scrutiny, ART doctors would take care to follow and accurately report clinical practices.”); OVERSIGHT OF ART, *supra* note 173, at 10.

186. See *The Affordable Care Act and Infertility*, NAT’L INFERTILITY ASS’N, <http://www.resolve.org//the-center-for-infertility-justice/public-policy/-care-act-and-infertility.html?print=t%201/5> (last updated Feb. 17, 2014).

187. Although there may be potential counterarguments that couples who are too poor to afford insurance would be disadvantaged in seeking egg donation and IVF, out of pocket costs for such procedures are extremely high to begin with; and additionally, studies have confirmed that increased insurance coverage for infertility treatments increases access. See OVERSIGHT OF ART, *supra* note 173, at 10; Barton H. Hamilton & Brian McManus, *The Effects of Insurance*

States that do choose to permit ART treatments and compensation for eggs should be required to create some structure of oversight that can be tailored to fit within certain regulatory limits or, at the very least, set regulations based on the ASRM guidelines. Upper limits should be set for the number of eggs retrieved from donors,¹⁸⁸ screening standards should automatically exclude donors with certain risk factors, uniform informed consent guidelines should be mandated with some form of ensuring compliance,¹⁸⁹ reporting should be expanded, and postdonation follow-ups should be required.

These limits should not be hard lines, and violations should not automatically bring punishment. Doctors should be allowed to go outside the limits when providing treatment, such as taking eggs or implanting embryos, above the guideline limits.¹⁹⁰ But, because this information will be reported under the new regulatory scheme, doctors should give some explanation for the exception. In addition to some of the incentives produced from increased insurance coverage, mandating physicians and clinics to report more information concerning the donor may also help balance the prorecipient incentives that exist within the privatized industry structure and possibly strengthened by the current reporting scheme.¹⁹¹

Mandates on Choices and Outcomes in Infertility Treatment Markets; 21 H. ECON. 994, 1009 (2012); J. Ryan Martin et al., *Insurance Coverage and In Vitro Fertilization Outcomes: A U.S. Perspective*, 95 FERTILITY & STERILITY 964, 968 (2011) (“It is also recognized that insurance coverage would provide access to infertility treatment for those who previously could not afford it.”).

188. ASRM, *Recommendations for Gamete and Embryo Donation*, *supra* note 140, at 53.

189. This could be accomplished through a detailed and comprehensive informed consent form approved by the state regulatory body.

190. See David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 39 FAM. L.Q. 727, 738 (2005); OVERSIGHT OF ART, *supra* note 173, at 11. Although transferring multiple embryos is almost always risky, the ASRM believes that doctors should be able to use their professional judgment to render different types of care in different circumstances:

a simple legal restriction on the number of embryos transferred would not be desirable. It is preferable that the clinical judgment of highly trained specialty physicians, brought to bear on the particular circumstances of each case and made with evidence-based national guidelines in mind, determine the course of treatment. While properly crafted language in a widely adopted medical practice act requiring specialists in ART to follow ASRM guidelines unless otherwise indicated might improve the uniformity of practice nationwide, it is important to recognize that ART is already one of most highly regulated of all medical practices in the United States.

OVERSIGHT OF ART, *supra* note 173, at 11.

191. The ASRM has acknowledged that increased insurance coverage may allow physicians to make the most medically appropriate decisions and would help eliminate financial pressures. OVERSIGHT OF ART, *supra* note 173, at 10. ASRM also suggests that states and insurers could tie coverage and reimbursement to adherence to the ASRM’s guidelines. *Id.*; Marvin, *supra* note 3, at 133–34. Additionally, studies have shown that states that implemented insurance coverage for ART had a lower number of multiple embryo transfers than states without insurance

2. *Expand Reporting Requirements and Follow-Up*

Under the current reporting scheme, the only information reported concerns the accurate advertising of pregnancy success rates, thus furthering the already strong incentive to achieve maximum pregnancy rates. Collecting information on the donor and the donation process could help curb unprofessional conduct. The limit to this is that doctors are not likely to explicitly report their unprofessional conduct. Requiring doctors to report more information on the donation process may cause them to internalize some of the aggressive retrieval methods or unprofessional conduct to which donors are subjected.

It is nearly impossible to obtain confident estimates on the actual risk outcomes of egg donation in the United States¹⁹² and the amount of unprofessional conduct performed by clinics and physicians.¹⁹³ There is no adequate data on risk outcomes because there is no information on post-donation outcomes reported,¹⁹⁴ further, there are no mandatory requirements to follow-up with donors.¹⁹⁵ Clinics should be required by law to collect and report information on donors' backgrounds and standard medical information, such as age, height, weight, average blood pressure, and any other factors that could affect a donor's predisposition to poor donation outcomes, such as previous donation.¹⁹⁶

coverage. Tarun Jain et al., *Insurance Coverage and Outcomes of In Vitro Fertilization*, 347 N. ENG. J. MED 661, 664–66 (2002); Martin et al., *supra* note 187, at 967–68.

192. Bercovici, *supra* note 3, at 199; Durrell, *supra* note 32, at 188; Cone, *supra* note 4, at 200; Marvin, *supra* note 3, at 123.

193. For purposes of this Comment, “unprofessional conduct” refers to any aspect of donor treatment when the donors’ best interests are ignored in favor of financial motivations or other forms of conflict. Defining unprofessional conduct is difficult in the United States because it may be based on ethical or practice standards imposed by state medical boards or professional societies such as the ASRM, or from the standard of care established for medical malpractice claims. Marvin, *supra* note 3, at 131–34; OVERSIGHT OF ART, *supra* note 173, at 4–5, 9, 11. Aside from gross negligence or criminal violations common to any type of doctor, there are few binding regulations on fertility doctors other than those imposed by state medical boards or individual requirements imposed by states with broader regulation of the ART industry. Luetkemeyer, *supra* note 72, at 412; Marvin, *supra* note 3, at 131–34 (“[V]ery few states have laws that genuinely address the issues within the ART industry.”).

194. Although some studies have been conducted, they are either severely limited in sample size or self-reported questionnaires. Boutelle, *supra* note 61, at 117.

195. *Id.*

196. See ASRM, *Recommendations for Gamete and Embryo Donation*, *supra* note 140, at 53–58 (listing the criteria for screening requirements); Kayla Mossien, *The Importance of Surrogate's and Egg Donor's Body Mass Index (BMI)*, CIRCLE SURROGACY, <http://www.circlesurrogacy.com/blog/2015/06/25/the-importance-of-body-mass-index/> (June 25, 2015) (“Egg donors are required to be of proportionate height and weight, as being overweight may affect egg quality, as well as necessitate higher doses of stimulation drugs to create follicles.”); *Egg Donor Screening*, EGG DONOR INFO. PROJECT, <https://web.stanford.edu/class/siw198q/websites/eggdonor/screening.html> (last updated June 5, 2002)

Doctors should also be required to report clinical aspects of the donation, such as the type and amount of drugs used for ovarian hyperstimulation, the length and timing of the cycle, and the type of removal procedure used. Reporting this information would allow long-term and comprehensive tracking of outcomes with certain drugs and egg removal methods. The most crucial piece of information would be the amount of eggs removed, which is generally proportional to the type of hyperstimulation drugs administered.¹⁹⁷ This would also help detect physicians who seek more eggs than they should or choose hyperstimulation regimes that place donors at risk.¹⁹⁸

Due to the lack of binding regulations concerning the donation process, certain treatments are left to the doctor's discretion, such as the type and amount of drugs to administer for ovarian stimulation, the approval of donors for donation in screening, informed consent process and methods, the amount of eggs retrieved, and whether to follow up with the donor.¹⁹⁹ It is within this range of discretion in which doctors are able to make decisions that may not be in the best interest of the donor. Because there is a general desire to keep the practice of medicine flexible and not constrain medical decisions with strict laws, regulations setting strict limits on these discretionary aspects should be avoided.²⁰⁰ Monitoring these aspects could help deter unprofessional conduct without unduly constraining the practice of medicine in ART.

By reporting aspects of the donor's relevant medical information that should be included in most screenings, certain predisposing risk factors leading to poor outcomes could be identified.²⁰¹ This information could also identify clinics retrieving eggs from women who may not be particularly suited for donation. The last aspect of reporting, and the most critical, would be a requirement to follow-up with donors. Requiring clinics to contact donors one to two weeks after donation would ensure that both valuable information on donation outcomes are collected and help provide donors with recourse in the event of post-donation complications.²⁰²

197. Gruben, *supra* note 81, at 175; .

198. See Blake et al., *supra* note 46, at 421–22; OVERSIGHT OF ART, *supra* note 173, at 10–11.

199. *Id.* at 258; Blake et al., *supra* note 46, at 421–22.

200. See, e.g., OVERSIGHT OF ART, *supra* note 173, at 11 (arguing that a strict restriction on the number of embryos that can be transferred is not desirable).

201. See ASRM, *Recommendations for Gamete and Embryo Donation*, *supra* note 140, at 55.

202. See Cone, *supra* note 4, at 214–15 (“Often, clinics do not keep donors’ medical records, making it difficult for donors to seek recourse if they experience complications and making it impossible for researchers to effectively monitor donors for long-term side effects such as infertility and increased risk of cancer.”) (citing Sunni Yeun, *An Information Privacy Approach to*

Mandating broader insurance coverage of ART, along with expanded reporting requirements, may help shift the incentives currently present in the egg donation process and lead to greater adherence to professional standards. These regulations would not necessitate large regulatory bodies, although they may be best despite the administrative and financial burdens on the federal and state governments, and the tradeoff between expanded insurance generating greater revenues for the ART industry would counteract fears of increased oversight from those involved.

Once states are required to cover infertility treatments as essential health benefits, the insurers will have to tie reimbursement to adherence with some set of professional and clinical standards.²⁰³ Insurers could either create their own standards or adopt those from the ASRM and SART.²⁰⁴ This may not cure all issues associated with the current incentive scheme in the donation process, the fear of losing reimbursement for potential violations, or false reporting may incentivize adherence.²⁰⁵ Finally, these expanded reporting requirements could be included within the current regime created under the FCSRCA²⁰⁶ or could also go through the existing structures of insurance companies for reviewing submissions for reimbursement.²⁰⁷ Research on the effect of insurance mandates providing coverage for infertility treatments on multiple birth rates indicates that insurance coverage may be an effective form of enforcing professional standards.²⁰⁸ And just like the cost savings to the health care industry from fewer multiple births, fewer instances of OHSS or other poor outcomes from donation could create cost savings as well.²⁰⁹

Regulating the Middlemen in the Lucrative Gametes Market, 29 U. PA. J. INT'L L. 527, 550 (2007)).

203. See Baum, *supra* note 26, at 125; Daar, *supra* note 85, at 323; Marvin, *supra* note 3, at 133–34.

204. OVERSIGHT OF ART, *supra* note 173, at 10–11; Daar, *supra* note 85, at 323; Marvin, *supra* note 3, at 134.

205. Blake et al., *supra* note 46, at 421–22; Daar, *supra* note 85, at 324.

206. Blake et al., *supra* note 46, at 421–22.

207. Baum, *supra* note 26, at 125; Daar, *supra* note 85, at 324; Marvin, *supra* note 3, at 134.

208. See OVERSIGHT OF ART, *supra* note 173, at 10; Daar, *supra* note 85, at 323–24; Jain et al., *supra* note 191, at 664–66; Martin et al., *supra* note 187, at 967–68. However, researchers attribute this success in reducing multiple births to changes in economic interests, namely that generous insurance coverage reduces the burden on achieving a successful pregnancy from one cycle, as opposed to utilizing aggressive treatments to maximizing chances of success. See OVERSIGHT OF ART, *supra* note 173, at 10; Martin et al., *supra* note 187, at 967–68. Some also attribute it to changes in characteristics of patients pursuing treatment once coverage is available. Jain & et al., *supra* note 191, at 664–66; Martin et al., *supra* note 187, at 968. However, regardless of the exact mechanism for achieving reduced multiple births, it has the effect of encouraging greater adherence to professional standards. Martin et al., *supra* note 187, at 968.

209. See Martin et al., *supra* note 187, at 968.

However, there have been several explanations as to why ART and egg donation specifically have not received greater regulation in the United States. Accordingly, the reforms suggested by this Comment must navigate the barriers that have prevented earlier reforms.

IV. IMPACT

There are several potential explanations for the lack of comprehensive federal ART regulation in the United States. By analyzing these barriers in light of previously proposed reforms as well as the insurance and reporting regulations suggested in this Comment, insight can be gained as to how to best solve these issues in the current industry structure. Some of the most oft-cited barriers to regulation include: (1) the administrative burdens of expanding federal regulations and oversight; (2) the argument that the federal government does not have the constitutional authority to regulate areas so closely related to medicine, procreation, and privacy interests; (3) opposition from the industry and religious groups; and (4) feared negative consequences of over-regulating ART and egg donation.

1. *Issues Related to Expanded Federal Oversight*

The United States' regulatory structure differs from those of other developed nations that have significant demand for ART and donor eggs.²¹⁰ In the United Kingdom, ART is directly regulated by the Human Fertilisation and Embryology Authority (HFEA), which controls the licensing and inspection of facilities performing ART procedures, such as IVF, or conducting research on human embryos.²¹¹ Canada also has a national oversight committee.²¹² These countries monitor and regulate the practice of ART more closely than the United States and also limit the amount of compensation donors may receive for eggs or ban anonymous donations.²¹³

Similar oversight and regulation in the United States would help prevent some of the biases and issues present in the ART industry.²¹⁴ Nevertheless, the increased regulations in these countries have negatively impacted their industries and could be disastrous for the U.S.

210. Levine, *supra* note 88, at 16–20 (examining the oversight structure of ART in the United Kingdom, Canada, and the United States).

211. *See id.* at 16–17.

212. *See id.* at 18 (noting that Canada relies on Assisted Human Reproduction Canada, a central oversight agency).

213. *Id.* at 20, 22 tbl.1.

214. Sweet, *supra* note 100, at 62 (arguing for a model similar to the United Kingdom's).

industry.²¹⁵ Thus, any regulation must balance the interests at stake.²¹⁶ Some have proposed the creation of a federal agency or authority charged with regulating and monitoring the ART industry, such as the United Kingdom's HFEA.²¹⁷ The changes proposed by this Comment would not require the creation of a federal oversight authority, and they could be implemented within existing regulatory structures.

2. Federalism Issues

The FCSRCA is self-limiting in the sense that it specifically prohibits the Secretary of HHS from passing regulations with the “effect of exercising supervision or control over the practice of medicine in [ART] programs.”²¹⁸ However, there may have been concerns of Federalism when the legislatures passed the FCSRCA in 1991.²¹⁹

States are typically reserved the authority to regulate and “protect the health, safety, and welfare of their citizens.”²²⁰ These “police powers” have typically reserved the regulation of medicine to the states, allowing them to control the licensure of doctors and hospitals as well as setting certain standards.²²¹ Thus, individual states are free to regulate ART in any way they see fit, as illustrated by the variety of ART regulations throughout the several states.²²² This reservation of police powers to states is an implied denial to the federal government to regulate these areas, and federal regulations infringing on these areas are vulnerable to constitutional challenges.²²³ However, the federal government is allowed to set certain standards in these reserved areas, specifically requirements for insurance coverage, as shown through the decisions upholding many portions of the Affordable

215. See *infra* notes 237–43 and accompanying text (noting some of the consequences the United Kingdom has experienced in their oversight of ART).

216. See Daar, *supra* note 85, at 292 (discouraging distasteful or invasive measures).

217. See, e.g., *id.* at 286 n.119, 287.

218. 42 U.S.C. § 263a-2 (2012).

219. See Meyer, *supra* note 125, at 2 (arguing that, in generally, the governmental interest in procreation belong to the states). Federalism is the principle that authority to regulate specific areas of the United States be distributed between the federal government, and those of the several states. See *id.* at 5 (noting that our constitutional framework requires the states to regulate certain interests, but other interests belong to the federal government).

220. *Id.* at 1.

221. *Id.* at 14.

222. See *supra* notes 126–36 and accompanying text (discussing several states' differing regulatory approaches). States may choose to mandate informed consent, control advertising, and regulate in almost any way they see fit. Meyer, *supra* note 125, at 14.

223. Meyer, *supra* note 125, at 5.

Care Act and its essential benefits requirements.²²⁴ Further, just because the FCSRCA does not authorize supervisory regulations under its authority, does not mean that Congress cannot take other legislative actions to regulate ART.

3. *Opposition from Industry and Religious Groups*

Two strong parties with very separate agendas are typically strong opponents to most laws concerning ART. The first, religious persons or groups with strong pro-life beliefs, strongly oppose the use of embryonic stem cells for research use because the procedures destroy the embryos.²²⁵ These groups believe that human life, or at least its potential, begins at conception; accordingly, the destruction of embryos is the destruction of human life.²²⁶ These core beliefs may justify their opposition to IVF and other ART treatments not only because of the traditional ethical objections to creating sacred human life, but because excess embryos taken for IVF may be destroyed if not handled properly or if a recipient does not wish for others to use her embryos.²²⁷ This religious opposition is likely fueled by the strong emotions attached to the abortion debate.²²⁸ Unfortunately, any regulations short of bans on IVF or embryo destruction would likely be opposed by these groups.²²⁹ Thus, it is likely that any regulations designed to protect egg donors would experience this opposition.²³⁰

The second group likely opposed to broader supervision and regulation of ART is that of parties directly involved in the ART industry, although they are likely opposed for different reasons than the religious groups.²³¹ Unlike the first group, industry parties typically oppose regulations controlling the use of ART or stem cell research.²³²

224. Daar, *supra* note 85, at 321–24; Swendiman, *supra* note 158, at 6–15; *see supra* notes 153–56 and accompanying text.

225. *See* Robertson, *supra* note 2, at 697–98.

226. Specifically, the “majority of the Religious Right views an embryo as a living human being, and thus . . . the destruction of embryos [is] murder.” Bercovici, *supra* note 3, at 198.

227. *See* Robertson, *supra* note 2, at 697–98.

228. Helen M. Alvaré, *The Case for Regulating Collaborative Reproduction: A Children’s Rights Perspective*, 40 HARV. J. ON LEGIS. 1, 32–33 (2003); Bercovici, *supra* note 3, at 193; Jody Lyneé Madeira, *Woman Scorned?: Resurrecting Infertile Women’s Decision-making Autonomy*, 71 MD. L. REV. 339, 342 n. 9 (2012); Note, *Guiding Regulatory Reform in Reproduction and Genetics*, 120 HARV. L. REV. 574, 582–84 (2006).

229. John A. Robertson, *Conflicting Interests in Reproductive Autonomy and Their Impact on New Technologies: The Personal Right Privacy, Property, or Child?: Assisting Reproduction, Choosing Genes, and the Scope of Reproductive Freedom*, 76 GEO. WASH. L. REV. 1490, 1494–95 (2008).

230. *Id.* at 1490; Marvin, *supra* note 3, at 142; Note, *supra* note 228, at 583.

231. Reddix-Small, *supra* note 67, at 672–73; Preisler, *supra* note 3, at 225.

232. Preisler, *supra* note 3, at 225.

The most influential groups are the most organized, such as the professional associations ASRM and SART,²³³ or the most financially powerful, like fertility clinics and pharmaceutical companies who manufacture fertility drugs and hormone stimulation.²³⁴ Both professional societies and private industry parties want to ensure that the practice of ART is permitted in the United States and not unduly regulated, with ASRM seeking some regulations while businesses involved in ART prefer looser regulations.²³⁵ There are also smaller business interests, like egg brokers, clinics, and physicians performing ART or stem cell research, who also desire a generally unregulated industry.²³⁶

Although the changes suggested by this Comment could face opposition by both groups, these proposals are relatively modest. For one, religious groups typically oppose any legislation concerning ART short of definitive bans, and industry parties will fight any regulations that attempt to restrict or hinder their practice. Although industry parties may object to the increased oversight, the expansion of insurance will likely increase their customer base and, accordingly, attract their support.

4. *Consequences of Over-Regulation*

A less direct barrier to regulating ART is the fear of consequences of over-regulation, which includes restricted access to ART, the stifling of industry innovation and restriction of commerce, and the creation of a black market for eggs and reproductive tourism. These consequences have been felt by some of the countries that regulate ART more actively than the United States, particularly the United Kingdom.²³⁷ After the United Kingdom limited compensation to direct costs incurred and created a national donor registry that effectively eliminated donor anonymity, it experienced heavy reduction in the supply of egg donor.²³⁸ The number of women who donated dropped significantly to the point where there is currently a four-year

233. ASRM is not opposed to all legislation and typically advocates for certain laws. It also is conscious of consequences of over regulation and wants to ensure that the practice of ART can still freely operate within the bounds of medical guidelines. See OVERSIGHT OF ART, *supra* note 173, at 11.

234. Reddix-Small, *supra* note 67, at 672.

235. Jiminez, *supra* note 98, at 395; Reddix-Small, *supra* note 67 at 672–77.

236. See Krawiec, *supra* note 95, at 213–14.

237. Levine, *supra* note 88, at 27.

238. *Id.* at 25.

waiting list to obtain donor eggs.²³⁹ This has led to the emergence of black markets for donor eggs and increased reproductive tourism.²⁴⁰

The United Kingdom's decreased supply of donor eggs caused by its bans on compensation and anonymity resulted in recipients seeking more affordable treatments and eggs outside of regulatory oversight, thus being able to offer any compensation necessary to obtain the donor eggs they want.²⁴¹ This is clearly troublesome because it leads to ART being performed outside regulated facilities²⁴² or even outside the country to escape the prohibitory laws.²⁴³ This concept of going to different countries or jurisdictions to obtain cheaper or otherwise unavailable ART treatments is known as reproductive tourism, and it has been a particular issue within European countries.²⁴⁴

Although the changes proposed by this Comment will expand regulation and oversight beyond its current status, they are far from complete bans on compensation or anonymity. Further, although enforceable limits to compensation may act to "price out" some donors who demand a greater reimbursement for their time and eggs, the majority of donors are paid well within the current limits suggested by ASRM. And, even if the expanded reporting collects some information on donors, it does not require the disclosure of a donor's identity to the offspring created from their eggs, nor any other personally identifying information.

There are several constitutional concerns related to the feared effects of over-regulation detailed *supra*.²⁴⁵ One concern is that of reproductive rights and equal protection and treatment of citizens.²⁴⁶

239. *Id.* at 23 (citing Sam Lister, *Five-Year Waits in IVF Postcode Lottery*, TIMES (UK NEWS), May 24, 2005, <http://www.thetimes.co.uk/tto/news/uk/article1933345.ece>.)

240. *Id.* at 25.

241. *Id.*

242. *Id.*

243. Levine, *supra* note 88, at 25.

244. *What Is Reproductive Tourism?*, LA JOLLA IVF (Apr. 13, 2012), <http://www.lajollaivf.com/what-is-reproductive-tourism/>.

245. Although a detailed analysis of these potential challenges goes well beyond the scope of this Comment and may not all concern egg donors, the basic principles are still relevant. Although not particularly strong arguments, bans on donor compensation could be challenged as infringing ones' economic liberties, Daar, *supra* note 85, but this would likely survive constitutional challenges since various state laws ban compensation for all bodily substances except for sperm, eggs, and hair. See generally Baum, *supra* note 26, at 126 n.54 (examining the various state laws). The ART industry as a whole may have a stronger economic argument against over-regulation due to its financial stake in the billion dollar industry. Preisler, *supra* note 3, at 225; Reddix-Small, *supra* note 67, at 672; 681-88. Similarly, bans on donor anonymity could raise rather weak claims regarding privacy rights, but this would likely only be a strong argument from those who have relied on their anonymity in making the donation. Sauer, *supra* note 2, at 947-50.

246. Meyer, *supra* note 125, at 2-3, 7.

The U.S. Supreme Court has identified certain procreative rights, although they are rather limited.²⁴⁷ These rights have certainly not been extended access to ART, but when tied to concerns for the equal treatment of persons, limiting access to some groups but not others could on infringe certain individual rights.²⁴⁸ Even though a nationwide ban of ART may be vulnerable to challenges as limiting access to procreation, laws preventing or limiting access to ART by same-sex couples or persons of a particular race would face even stronger challenges.²⁴⁹ Unequal access or imbalanced use of certain offspring traits also raises ethical eugenics concerns.²⁵⁰

Although states can set restrictions on who may obtain insurance for ART treatments, the general mandate proposed in this Comment would not differentiate or set requirements for insurance coverage. Thus, although individual utilization of insurance expansion by individual states could be restricted to certain gender and relationship qualifications, the mandate this Comment proposed is neutral.

Because the reforms proposed by this Comment avoid the pitfalls related to other alternative regulations and those related to regulating ART generally, the reforms proposed by this Comment can operate to help safeguard egg donors from potentially unethical treatment and still have a chance to be implemented.

V. CONCLUSION

It is important to be mindful of the conflicting interests and forces involved in proposing any ART regulation. One of the strongest interests is that of the clinics, pharmaceutical companies, and third parties involved in the ART industry whose million dollars of annual revenues likely generate strong lobbying interest. Another interest is that of the millions of recipients who are willing to pay thousands of dollars to become pregnant with or without donor eggs.²⁵¹

247. *See id.* at 3–6.

248. *See* Valarie Blake, *It's an ART not a Science: State-Mandated Insurance Coverage of Assisted Reproductive Technologies and Legal Implications for Gay and Unmarried Persons*, 12 MINN. J.L. SCI. & TECH. 651, 678 (2011) (arguing that “implicit exclusion of gay, unmarried, and medico-structurally infertile persons from state-mandated insurance coverage of ART” would raise legal challenges). This is particularly relevant regarding access for same-sex couples who inherently require one donor gamete. *Id.* And, while the U.S. Supreme Court has not explicitly identified homosexuals as a protected class, any laws that specifically restrict access to same-sex couples but grant it for heterosexual couples could be extremely vulnerable to constitutional attacks. *Id.*

249. *Id.*

250. *See* Krawiec, *supra* note 95, at 219.

251. *See* Baum, *supra* note 26, at 149.

It may be best to heed the ASRM's advice and avoid passing strict standards at the federal level.²⁵² This would respect the interests of certain groups opposed to ART and preserve the benefits cited of the laboratory of the states as well as federalism principles of preserving the regulation of medicine to the states. It would also be preferable to fit the new regulatory scheme within existing structures and resources to reduce costs and quell political opposition to funding ART.

Tying insurance reimbursement for infertility services to the regulations that are implemented *supra* would modify the existing financial incentives to ensure professional conduct and proper donor treatment rather than achieving high pregnancy success rates and the negative consequences produced by these goals.²⁵³ The ART industry would be free to operate in its private free-market nature, and high pregnancy success rates would still be a goal, but compliance with expanded regulations and according eligibility for insurance coverage would be an equally important factor for potential recipient-consumers.²⁵⁴ Furthermore, several sources indicate that insurance coverage alone improves professional conduct and deters unprofessional acts.²⁵⁵ Insurance coverage may force physicians to make more medically appropriate judgments.²⁵⁶ Switching a clinic's end goal of achieving high pregnancy success rates to strict adherence of the expanded regulations listed *supra* would likely create better protections for egg donors.²⁵⁷ Monitoring compliance would be rather simple for insurance companies within the current regulatory structure because they could easily see which clinics are reporting to the

252. See OVERSIGHT OF ART, *supra* note 173, at 11.

253. See *supra* notes 146–209 and accompanying text (arguing that federal action is necessary to incentivize states into regulating egg donation more closely, offering potential forms of supervision that could aid in counteracting the prorecipient biases through expanded insurance).

254. See generally Alberta, *supra* note 42 (discussing the risks to both parties involved in an IVF procedure and the need for regulation in light of these concerns).

255. See OVERSIGHT OF ART, *supra* note 173, at 10–11 (citing Tarun Jian et al., *Insurance Coverage and Outcomes of In Vitro Fertilization*, 347 N. ENG. J. MED. 661 (2002); Soc'y for Assisted Reprod. Tech. & the Am. Soc'y for Reprod. Med., *Assisted Reproductive Technology in the United States: 1999 Results Generated from the American Society for Assisted Reproductive Technology Registry*, 78 FERTILITY & STERILITY 918 (2002)).

256. See *id.* at 10.

257. *Supra* notes 182–201 and accompanying text.

CDC²⁵⁸ and which are in compliance with either state or professional standards.

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258. See generally 2012 CLINIC SUCCESS RATES REPORT, *supra* note 18, at app. C, 535–576 (listing the reporting clinics as of 2013); Daar, *supra* note 85, at 323–24; *supra* notes 202–09 and accompanying text.

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