NOTE

IN VITRO FERTILIZATION, FERTILITY FRUSTRATIONS, AND THE LACK OF REGULATION

I. INTRODUCTION

Airing from 2014 to 2019, The CW's *Jane the Virgin* depicted the life of a "young, devout Catholic woman" after she discovered she had been "mistakenly artificially inseminate[d]" by her doctor during a routine check-up.[1] Audiences watched as the heroine, Jane, navigated a relationship with the biological father of the baby.[2] The baby's biological father happened to be a married man, a former playboy, and Jane's boss.[3] Jane also had to balance this nuanced relationship with others, including the ones she maintained with her boyfriend and her involved and extremely invested family.[4] The series was nominated for four Golden Globes and won one over the course of its airing.[5] Critics hailed it as "a show that shouldn't be taken for granted."[6] While Jane's medical mix-up was literally made for television, such a shocking narrative is not unheard of in reality beyond broadcast entertainment.[7]

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1. *See generally Jane the Virgin*, IMDB, https://www.imdb.com/title/tt3566726 (last visited Feb. 8, 2021) [hereinafter *Jane the Virgin Description*] (providing a plot summary of the television series); *Jane the Virgin* (The CW television broadcast 2014). Another television broadcast that utilized artificial insemination to develop the show's plot is NBC's *The Office*, which depicted an erratic female character shocking her previous boyfriend when she revealed she had visited a sperm bank, unbeknownst to him, to pursue artificial insemination during the course of their relationship. *The Office: Goodbye, Toby* (NBC television broadcast May 15, 2008); *Season 4 – Episode 14 "Goodbye Toby,"* OFFICEQUOTES.NET, https://www.officequotes.net/no4-14.php (last visited Feb. 8, 2021).

2. *Jane the Virgin*, *supra* note 1.

3. *Jane the Virgin Description*, *supra* note 1.

4. *Id.*

5. *Winners & Nominees: Jane the Virgin*, HFPA, https://www.goldenglobes.com/tv-show/jane-virgin (last visited Feb. 8, 2021).

6. Alessandra Stanley, *'Jane the Virgin' Ends a Strong First Season*, N.Y. TIMES (May 10, 2015), https://www.nytimes.com/2015/05/11/arts/television/jane-the-virgin-ends-a-strong-first-season.html ("'Jane the Virgin' is an inspired swirl of Latin music, romance and telenovela kitsch that takes its ethnic identity as a given.").

7. *See* Kathianne Boniello, *Mom Whose Embryo Was Wrongly Implanted in Queens Woman*

Hopeful parents that have been tangled in medical mix-ups that involve their biological child being inadvertently birthed by an unintended woman have been left "hurt by these experiences in ways that haunt [the biological parent] every day."[8] While Jane's fictional story yielded a dramatic and enduring television series, pregnancies using the reproductive technology that inadvertently caused Jane's pregnancy have grown rapidly in reality and practice.[9] Preliminary data indicate that "the number of [in vitro fertilization] cycles increased by 21% in just one year, from 2012 to 2013."[10] In fact, over one million babies were born in the United States between 1987 and 2015 through the use of some reproductive technology, including assistance from a fertility doctor.[11]

The United States Centers for Disease Control and Prevention ("CDC") is responsible for reporting health information to the general public.[12] After compiling information regarding infertility in women, the CDC reported: "Of the approximately 61 million women aged 15-44 years in 2011-2015, more than 7 million, or 12%, had received any infertility services. Additionally, almost 7% of married women aged 15-44 years were unable to get pregnant after at least 12 consecutive months of trying."[13] Hopeful parents who would like to pursue a pregnancy aided by medical intervention have autonomy in choosing a

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Tells All, N.Y. POST (July 13, 2019, 7:04 PM), https://nypost.com/2019/07/13/mom-whose-embryo-was-wrongly-implanted-in-/queens-woman-tells-all (discussing a couple who was pursuing in vitro fertilization ("IVF") in California and the couple's resulting shock when they were informed by the fertility clinic that one of their embryos was wrongly implanted in a woman from New York, who had already given birth to the child).

8. Isaac Stanley-Becker & Michael Brice-Saddler, *They Thought Their Embryo Didn't Take. Then Their Son Was Born to a Stranger Across the Country, Lawsuit Claims*, WASH. POST (July 10, 2019, 6:41 PM), https://www.washingtonpost.com/nation/2019/07/10/they-thought-their-embryo-didnt-take-then-their-son-was-born-stranger-across-country-lawsuit-claims/?noredirect=on.

9. *Jane the Virgin Description*, *supra* note 1; Ellie Kincaid, *A Booming Medical Industry in the U.S. Is Almost Totally Unregulated*, BUS. INSIDER (July 7, 2015, 3:50 PM), https://www.businessinsider.com/assisted-reproduction-ivf-industry-regulation-2015-6.

10. Kincaid, *supra* note 9.

11. *IVF by the Numbers*, PENN MED.: FERTILITY BLOG (Mar. 14, 2018), https://www.pennmedicine.org/updates/blogs/fertility-blog/2018/march/ivf-by-the-numbers.

12. *Mission, Role and Pledge*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/about/organization/mission.htm (May 13, 2019).

13. CTRS. FOR DISEASE CONTROL & PREVENTION, 2017 ASSISTED REPRODUCTIVE TECHNOLOGY: FERTILITY CLINIC SUCCESS RATES REPORT 3 (2019), ftp://ftp.cdc.gov/pub/Publications/art/ART-2017-Clinic-Report-Full.pdf. For "many people who want to start a family, the dream of having a child is not easily realized." *Id.* at 1. "Infertility is 'the inability to conceive [a child] after 12 months of unprotected intercourse,'" or after six months if the woman is thirty-five years or older. *Defining Infertility*, AM. SOC'Y FOR REPROD. MED., https://www.reproductivefacts.org/news-and-publications/patient-fact-sheets-and-booklets/documents/fact-sheets-and-info-booklets/defining-infertility (last visited Feb. 8, 2021).

clinic and doctor that they trust to facilitate this process.[14] Many decisions go into choosing the doctors, researchers, and methods involved with such an intimate procedure.[15] The U.S. government has enacted a statute that intends to provide hopeful parents with information that can be useful in selecting a clinic to help propel a pregnancy.[16] This information can include data regarding the particular assisted reproductive method or methods employed at the clinic in question, the reasons for the usage of assisted reproductive technology ("ART") by a clinic's patients, and the success rate based on the service provided.[17] Therefore, although not required to do so, clinics have some incentive to provide the success rates of reproductive methods utilized by their practice over the previous year.[18] Even though the federally regulated data is useful and supports success rates, patients still cannot obtain all the information they need because of issues associated with transparency, or the lack thereof.[19]

Part II of this Note will begin by examining the history and background behind reproductive technologies, including one in particular: in vitro fertilization ("IVF").[20] Developments in reproductive technology and their related history were catalysts for the existing U.S.

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14. *See generally, e.g.*, Natalie Silverman, *Would You Go to IVF Bootcamp?*, THE FERTILITY PODCAST (Aug. 12, 2019) (downloaded using Apple Podcasts) (showcasing one conversation with a fertility clinician who offers intensive fertility treatment, colloquially known as "bootcamp"); *About Me*, THE FERTILITY PODCAST, https://www.thefertilitypodcast.com/about (last visited Feb. 8, 2021) (hosting fertility experts, medical directors, pharmacists, consultants, and celebrities as guest podcast panelists to discuss miscarriage and fertility treatments).

15. *See generally About Me*, *supra* note 14 (showcasing opportunities to hear and observe conversations regarding fertility treatment by experts in the field).

16. *See generally* Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (codified as amended at 42 U.S.C. §§ 263a-1–a-7) (setting forth required reporting statistics for embryo laboratories).

17. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13, at 13.

18. Laura Damiano, Note, *When Parents Can Choose to Have the "Perfect" Child: Why Fertility Clinics Should Be Required to Report Preimplantation Genetic Diagnosis Data*, 49 FAM. CT. REV. 846, 853-54 (2011) (arguing that clinics should be required to report details about their use of preimplantation genetic diagnosis, a procedure used to screen embryos for certain genetic conditions before implantation through in vitro fertilization). Preimplantation genetic diagnosis was originally "used to prevent the birth of children with deadly genetic disorders, but it is now used for more controversial reasons, such as to select for sex." *Id.* at 846.

19. *See* Ellen S. Fischer, Note, *The 'Wild West' of Medicine: An Argument for Adopting the United Kingdom's 'HFEA' Framework, to Improve the Market for Assisted Reproduction in the United States*, 39 NW. J. INT'L L. & BUS. 201, 204-05, 210 (2019) (arguing that the United States should adopt a scheme over the assisted reproduction market that is similar to that of the United Kingdom's Human Fertilisation and Embryology Act, which allows for a streamlined and authoritative approach with one governing body to license, oversee, and promulgate regulations in the IVF industry).

20. *See infra* Part II.

federal regulation governing the fertility industry.[21] An examination and comparison of the states' regulatory framework, along with an overview of the current fertility-related federal legislation, will also be included in Part II.[22] Part III will then call attention to the lack of uniform regulation surrounding misimplantations and provide examples of misimplantations that have occurred as of late.[23] Offering a solution, Part IV of this Note will propose that the current federal statute, the Fertility Clinic Success Rate and Certification Act ("FCSRCA"), be modified to require fertility clinics to report statistics regarding their error rates, specifically errors concerning instances of misimplantation.[24] This Note will argue that this solution is best suited to be implemented at a federal level, rather than on a state-by-state basis.[25] This Note takes this position because federal oversight will yield greater transparency in a shorter amount of time, promote uniformity, and decrease consumer confusion when prospective parents research and select an ART clinic.[26]

II. BABY STEPS: A WALK THROUGH ASSISTED REPRODUCTIVE TECHNOLOGY, INCLUDING IVF AND ITS RELATED LEGISLATION

Before examining the more compelling issues surrounding misimplantation of embryos into an unintended woman and legal issues inherent in such practices,[27] a basic review of the methods and technologies used in assisted reproduction is necessary.[28] Several notable public figures have taken advantage of varying reproductive technologies as of late,[29] increasing the discussion and coverage surrounding the technology relied upon in the fertility sphere.[30] In response to the increased use of reproductive technologies, federal and state legislation has been enacted with varying severity of regulation and enforcement.[31] With this foundational knowledge, the reader can better appreciate the legislative solution proposed in this Note, which aims to

21. David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 39 FAM. L.Q. 727, 728-29, 731 (2005) (arguing that regulation of the fertility field in the United States is fragmented but has become more unified in recent years).

22. *See infra* Part II.D–E.

23. *See infra* Part III.

24. *See infra* Part IV.

25. *See infra* Part IV.B–D.

26. *See infra* Part IV.

27. *See infra* Part III.

28. *See infra* Part II.A.

29. *See infra* Part II.B.

30. *See infra* text accompanying notes 55-59.

31. *See infra* Part II.D–E.

better assist hopeful parents in choosing a competent fertility clinic provider.[32]

A. Learn to Crawl Before You Walk: Defining Assisted Reproductive Technology

ART generally includes "all fertility treatments in which both eggs and embryos are handled outside of the body."[33] ART treatments involve "removing mature eggs from a woman's ovaries using a needle, combining the eggs with sperm in the laboratory, and returning the embryos to the woman's body or donating them to another woman."[34] ART can involve the use of eggs from a woman who does not give birth to the resulting child.[35] ART methods are inclusive of other treatments beyond IVF, such as "zygote intrafallopian transfer, gamete intrafallopian transfer, and intracytoplasmic sperm injection," among others.[36] IVF, the most common and effective form of ART procedures, now assists in "1 to 2 percent of all U.S. births annually."[37]

IVF is a medical procedure that involves "administration of fertility drugs to the woman, surgical extraction of her eggs, fertilization in a laboratory, and surgical implantation of the resulting embryos into the woman's womb."[38] In some IVF procedures, fertilization involves a special technique known as intracytoplasmic sperm injection, where a single sperm is injected directly into a woman's egg.[39] Just one IVF

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32. *See infra* Part IV.

33. *Reproductive Health: Infertility FAQs*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/reproductivehealth/Infertility/index.htm (Jan. 16, 2019). Commentators have acknowledged that there is no single definition of the term "embryo," but in this Note, "embryo" will refer to "a human egg fertilized in vitro (outside the body) by human sperm, whose cell division is allowed to develop only up to a defined and limited period of time after fertilization." Susan L. Crockin, *The "Embryo" Wars: At the Epicenter of Science, Law, Religion, and Politics*, 39 FAM. L.Q. 599, 601 (2005).

34. *Reproductive Health: Infertility FAQs*, *supra* note 33.

35. *Id.*

36. 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, 194 (2012). Gamete intrafallopian transfer involves "using a fiber optic instrument called a laparoscope to guide the transfer of unfertilized eggs and sperm (gametes) into a woman's fallopian tubes through small incisions in her abdomen." CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13, at 3. Zygote intrafallopian transfer involves "fertilizing a woman's eggs in the laboratory and then using a laparoscope to guide the transfer of the fertilized eggs (zygotes) into a woman's fallopian tubes." *Id.*

37. *Reproductive Health: Infertility FAQs*, *supra* note 33; *IVF by the Numbers*, *supra* note 11.

38. Hall v. Nalco Co., 534 F.3d 644, 645 (7th Cir. 2008). In considering the issue and solution proposed by this Note, it is important to be cognizant of the fact that "infertility affects both men and women." *Id.*

39. *Reproductive Health: Infertility FAQs*, *supra* note 33.

treatment can take "weeks to complete, and multiple treatments are sometimes needed to achieve a successful pregnancy."[40] The national average cost of one IVF cycle is around $12,000, which does not include subsequent medications that can run up costs ranging from $3,000 to $5,000.[41]

B. Notable Instances of ART Usage

Sir Robert Edwards, a British embryologist, and Dr. Patrick Steptoe, a British gynecologist,[42] are responsible for the first successful instance of IVF in the world.[43] Dr. Steptoe had knowledge and experience in extracting eggs, while Sir Edwards was well-versed in fertilizing such eggs.[44] Their collective, successful efforts in retrieving both an egg from the eventual birth mother and sperm from her husband enabled the duo to mix the egg and sperm in a petri dish and implant the embryo in the mother's womb.[45] Their monumental work resulted in the 1978 birth of Louise Brown.[46] Sir Edwards was later "awarded the Nobel Prize in Physiology or Medicine 'for the development of in vitro fertilization.'"[47] The first infant conceived with the aid of ART in the United States followed shortly thereafter in 1981.[48] That year, after forty-one failed attempts at IVF, a Massachusetts-based couple finally gave birth to a baby that was genetically theirs.[49]

Notable celebrities have also taken advantage of ART options available to them.[50] Mariah Carey was able to give birth at the age of forty-one after receiving donor eggs that were successfully implanted in

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40. *Hall*, 534 F.3d at 645-46.

41. Jennifer Gerson Uffalussy, *The Cost of IVF: 4 Things I Learned While Battling Infertility*, FORBES (Feb. 6, 2014, 3:00 PM), https://www.forbes.com/sites/learnvest/2014/02/06/the-cost-of-ivf-4-things-i-learned-while-battling-infertility/#18dd1fa424dd (expanding upon the financial details of IVF). Because "few healthcare plans cover fertility treatments, IVF costs are primarily paid out-of-pocket, often making it 'too expensive for more than a single try,' increasing pressure on the physician or clinic to achieve a successful result." *See* Cone, *supra* note 36, at 202-03.

42. Andrew Danielson, *Patrick Christopher Steptoe (1913-1988)*, EMBRYO PROJECT ENCYC. (June 10, 2009), https://embryo.asu.edu/pages/patrick-christopher-steptoe-1913-1988.

43. Sinem Karipcin, *We've Come a Long Way, Baby: The History of IVF*, U.S. NEWS & WORLD REP. (July 26, 2018), https://health.usnews.com/health-care/for-better/articles/2018-07-26/weve-come-a-long-way-baby-the-history-of-ivf (examining the successes associated with IVF since the first successful "test tube baby" was born over forty years ago).

44. Danielson, *supra* note 42.

45. Karipcin, *supra* note 43.

46. Danielson, *supra* note 42.

47. Karipcin, *supra* note 43.

48. Cone, *supra* note 36, at 201.

49. Karipcin, *supra* note 43.

50. *Id.*

her.[51] Jimmy Fallon and Neil Patrick Harris both became fathers through the hiring of surrogates.[52] Chrissy Teigen and John Legend conceived two children utilizing IVF.[53] Teigen has been forthcoming in discussing her ART and IVF experiences, sharing with her Instagram followers that "people are just curious and I think hearing success stories gives people hope. I'm all for talking about IVF."[54]

As IVF becomes more mainstream through press coverage and celebrity influence, the accessibility of IVF knowledge to those without a public following has grown as well.[55] Clinics have attempted to respond to the consumers' twofold interest in the process: having a baby coupled with the financial concerns associated with ART procedures.[56] One option available through some IVF providers is a "money-back guarantee[]," where the patient pays a premium for a guarantee of successful pregnancy and birth, rather than paying per cycle.[57] Some clinics also offer financing for their patients' treatments with loans, graduated repayments, or outcome-based pricing models.[58] Nonetheless, costs associated with ART treatments, including IVF, continue to be a persisting issue.[59]

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51. *Id.*

52. *Id.*

53. Elise Solé, *Chrissy Teigen Shares Adorable Photo of Baby Miles, IVF Journey*, HUFFPOST (July 2, 2018), https://www.huffpost.com/entry/chrissy-teigen-shares-photo-of-baby-miles-ivf-journey-hearing-success-stories-gives-people-hope_n_5b33a4b2e4b0b5e692f3647d.

54. *Id.* Teigen has also been open with the media in sharing that her first attempt at IVF was unsuccessful, and that the experience was "devastating" for her and her family. Korin Miller, *Chrissy Teigen Says It Was 'Devastating' When Her First IVF Round Didn't Work*, SELF (Apr. 5, 2018), https://www.self.com/story/chrissy-teigen-first-ivf-round-didnt-work.

55. *See supra* notes 50-54 and accompanying text. *See generally* IVF Explained (@ivf_explained), INSTAGRAM, http://instagram.com/ivf_explained?igshid=elqjudoo769c (last visited Feb. 8, 2021) (explaining to its followers the concepts, science, and methods behind IVF); *see also* Modern Fertility (@modernfertility), INSTAGRAM, http://instagram.com/modernfertility?igshid=6p3m5hzrusn (last visited Feb. 8, 2021) (providing insight into fertility with digital tools including hormone, ovulation, and pregnancy tests).

56. *See* Megan Leonhardt, *Women Are Traveling Far and Wide for Affordable IVF—Here's Why It's So Expensive*, CNBC: MAKE IT (Aug. 13, 2019, 3:09 PM), https://www.cnbc.com/2019/08/13/women-are-traveling-far-and-wide-for-affordable-ivf.html (explaining that most insurance policies do not cover the costs of IVF, so clinics attempt to offer pricing packages to offset the costs and risks). In fact, only sixteen states, including California and New York, currently "require insurance companies to have some sort of coverage" for insureds seeking fertility treatments. *Id.*

57. *Id.* ("Patients pay more for the guarantee than they otherwise would if they were successful after just one IVF cycle."). A "cycle" is typically known as a multi-step treatment that can take multiple weeks "rather than a procedure at a single point in time." CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13, at 4.

58. Katie Young & Jessica Dickler, *Infertility Treatment Is Burying Families in Debt as They Choose to Have Children Later in Life*, CNBC (Apr. 28, 2019, 9:35 AM), https://www.cnbc.com/2019/04/26/infertility-treatment-is-putting-families-in-debt.html.

59. *See id.* (spotlighting one couple who has taken on more than $24,000 in debt over one

C. The Right to Procreate

The first iteration of international human rights as we know them today was set forth in the Universal Declaration of Human Rights ("UDHR") in December of 1948.[60] Since its drafting, the UDHR "has been translated into over 500 languages."[61] Article 1 of the UDHR begins by stating, "All human beings are born free and equal in dignity and rights."[62] The UDHR also guarantees "the right to marry and to found a family" under Article 16.[63]

Likewise, U.S. case law establishes the right to privacy and personhood.[64] This guarantee is expansive and includes the right of individuals to procreate, regardless of marital status.[65] The tension between parental and biological rights has even made its way to the Supreme Court of the United States.[66] Though the existing case law protects the right to procreate, scholars currently debate how the parameters of such a right will evolve in the context of ART, including IVF, paid surrogacy, and egg donation.[67]

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year, paying out-of-pocket for fertility treatments); *see also* Leonhardt, *supra* note 56 (highlighting another couple who could afford just one cycle of IVF treatment before going into debt).

60. Lauren B. Paulk, *Embryonic Personhood: Implications for Assisted Reproductive Technology in International Human Rights Law*, 22 AM. U. J. GENDER, SOC. POL'Y & L. 781, 783, 796-97 (2014) (analyzing the "legal personification of embryos . . . through the lens of human rights treaties").

61. *Universal Declaration of Human Rights*, UNITED NATIONS, https://www.un.org/en/universal-declaration-human-rights (last visited Feb. 8, 2021) ("[T]he Declaration was proclaimed by the United Nations General Assembly . . . as a common standard of achievements for all peoples and all nations.").

62. G.A. Res. 217 (III) A, Universal Declaration of Human Rights, art. 1 (Dec. 10, 1948).

63. *Id.* at art. 16.

64. *See* Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 851 (1992) (holding that "[o]ur law affords constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing, and education"); Skinner v. Oklahoma, 316 U.S. 535, 541 (1942) (protecting the "basic civil rights of man," including marriage and procreation).

65. *See* Eisenstadt v. Baird, 405 U.S. 438, 453 (1972) ("If the right of privacy means anything, it is the right of the *individual*, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.").

66. *See* Michael H. v. Gerald D., 491 U.S. 110, 121, 124 (1989) (plurality opinion) (holding that the biological father did not have a liberty interest traditionally protected by society that would give rise to a substantive due process claim).

67. *See supra* notes 64-66 and accompanying text; *see also* Carl H. Coleman, *Assisted Reproductive Technologies and the Constitution*, 30 FORDHAM URB. L.J. 57, 59-60, 62 (2002) (discussing the basic questions society must confront when allocating greater social oversight of ART); John A. Robertson, *Assisting Reproduction, Choosing Genes, and the Scope of Reproductive Freedom*, 76 GEO. WASH. L. REV. 1490, 1497, 1503 (2008) ("[I]t is not a stretch to think that a future Supreme Court majority would allow states to protect human life from fertilization onward, whether the entity at stake is inside or outside the body.").

Professor Coleman, Associate Professor and Associate Director of the Health Law and Policy Program at Seton Hall Law School, argues that the aforementioned parameters will be determined by how "the principle of procreative liberty is interpreted by the Supreme Court" and whether the Court decides that ART technologies are entitled to "special constitutional protection."[68] Professor Rao, Associate Professor at the University of California, Hastings College of Law, argues that the "discrete acts involved in procreation," including those involved with assisted reproduction, are protected by "the rights of privacy, bodily autonomy, and equal protection work[ing] together."[69] In making this argument, Professor Rao suggests that the right to enter the reproductive commerce market is not *automatically* constitutionally protected because the "activities do not implicate private relationships," and instead, the right only attaches when procreation occurs "within the confines of a close personal association."[70] On the other hand, John Robertson, Vinson and Elkins Chair in Law at the University of Texas School of Law, argues that the principle of procreative liberty protects the individual's freedom to have a child biologically related to the parent.[71] Ann Massie, Associate Professor at the Washington and Lee University School of Law, pushes back against Robertson's theory.[72] Professor Massie contends that ART techniques used to have children do not implicate the same values that are protected by the privacy cases under constitutional law, such as marital intimacy or integrity of the family unit.[73]

Views on the use and accessibility of ART procedures are now being weighed in the confirmation process of federal judges in the

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68. *See* Coleman, *supra* note 67, at 60. Professor Coleman acknowledges that forecasting the constitutional analysis of this issue involves some degree of speculation: "Like all questions about the scope of substantive due process protections, the concept of procreative liberty is susceptible to multiple interpretations, depending on the level of generality at which the principle is defined." *Id.* at 68.

69. Radhika Rao, *Reconceiving Privacy: Relationships and Reproductive Technology*, 45 UCLA L. REV. 1077, 1079-80 (1998).

70. *Id.* at 1079. Privacy is a "structural right that protects private relationships as a mechanism to check excessive governmental power." *Id.* at 1104.

71. John A. Robertson, *Two Models of Human Cloning*, 27 HOFSTRA L. REV. 609, 618-19 (1999). Robertson makes this argument in the context of human cloning, where he argues that this right should only be denied if substantial harm from having a child via cloning could be shown. *Id.*

72. *See* Ann MacLean Massie, *Regulating Choice: A Constitutional Law Response to Professor John A. Robertson's* Children of Choice, 52 WASH. & LEE L. REV. 135, 144 (1995). Professor Massie urges that the issue with Robertson's approach "is that it ignores both the manner in which constitutional interpretation comes about and the underlying reasons for the way in which the Supreme Court approaches constitutional questions." *Id.*

73. *Id.* at 162 ("The clear message is that not all procreative behavior is subject to the heightened protection of the constitutional right of privacy.").

United States.[74] In 2019, the Senate weighed then nominee Sarah Pitlyk's views regarding protection for frozen embryos and the right to utilize fertility procedures or surrogacy when considering her appointment to the United States District Court for the Eastern District of Missouri.[75] Pitlyk has written that "surrogacy 'is harmful to mothers and children,'" and has also argued that frozen embryos should be protected under the law as human beings.[76] Despite the controversy surrounding then President Trump's decision to nominate Pitlyk for the lifetime position, including Pitlyk's unanimous rating as "Not Qualified" by the American Bar Association, the Republican-controlled Senate confirmed Pitlyk to the judiciary by a 49-44 vote.[77]

D. Federal Regulation of ART

In response to the increased usage of ART, Congress enacted the FCSRCA in 1992.[78] This law is sometimes referred to as "the Wyden Law."[79] The FCSRCA requires clinics that utilize ART methods to annually report their success rates to the CDC.[80] The CDC then consolidates, organizes, and publishes this information in a report that the general population can access.[81] The report is organized alphabetically by state.[82] Included within the report is an appendix that lists the current names and addresses of all reporting clinics, along with

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74. *See* Mark Joseph Stern, *Senate Confirms Trump Judicial Nominee Who Fought Against Abortion, Surrogacy, and Fertility Treatment*, SLATE (Dec. 4, 2019, 3:02 PM), https://slate.com/news-and-politics/2019/12/sarah-pitlyk-trump-judge-ivf-abortion.html.

75. *Id.*

76. *Id.* Pitlyk has also opined that destroying frozen embryos equated to "children" being "killed." *Id.*

77. *Id.*

78. Adamson, *supra* note 21, at 731; Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (codified as amended at 42 U.S.C. §§ 263a-1–a-7).

79. Adamson, *supra* note 21, at 731. Then Congressman Wyden felt that a reporting system would be valuable to hopeful parents when choosing between different Assisted Reproductive Technology ("ART") providers. *Id.*

80. Ima E. Nsien, *Navigating the Federal Regulatory Structure of Assisted Reproduction Technology Clinics*, A.B.A. (Nov. 1, 2017), https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2016-2017/nove mber2017/reproduction (reviewing the history and status of regulation of reproductive technology in the United States and suggesting a more comprehensive regulatory model).

81. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13, at 1. The latest report was published in 2019 but is based on data from 2017 because the earliest possible date for clinics to report complete annual data is nine months after the end of the reporting year, as all births from the year in question have then occurred. *Id.* at 4. Data is then sent to, prepared by, and verified by the CDC, resulting in a delay of publication. *Id.*

82. *See generally id.* at 25-522 (starting with clinics located in Alabama and ending with clinics located in Wisconsin).

a list of clinics known to be in operation in 2017 that did not report their data to the CDC as required by law.[83]

Although the FCSRCA requires the CDC to develop and distribute a model certification program for laboratory standards, states are not statutorily required to adopt this model certification program.[84] In fact, the FCSRCA specifically states that there cannot be any "regulation, standard, or requirement" established that would have "the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs."[85] The most recently published report notes that the CDC does not oversee nonfederal clinic accreditation programs.[86] Instead, clinics can be accredited "by one of the three nonfederal laboratory accreditation [p]rograms."[87] Under the FCSRCA, the only definitive federal repercussion for accredited clinics that do not report their success rates is a notation in the CDC's published report.[88]

In response to the passage of the FCSRCA, the Department of Health and Human Services ("DHHS") released a notice that "sets forth the model certification program requirements."[89] Within this notice, the CDC has pledged to distribute the model program to relevant state officials outlined in the FCSRCA and will encourage such officials to

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83. *Id.* app. C. The "clinics listed below provided ART services and were in operation as of January 1, 2017 and accordingly were required to submit ART cycle data under the provisions of the Fertility Clinic Success Rate and Certification Act passed by the US Congress." *Id.* app. C at 575.

84. 42 U.S.C. § 263a-2(b). What the Fertility Clinic Success Rate and Certification Act ("FCSRCA") "lacks, however, is any mechanism for prodding clinics to share their information directly with patients and, more importantly, any means of penalizing those clinics that do not report." Debora Spar & Anna M. Harrington, *Building a Better Baby Business*, 10 MINN. J.L. SCI. & TECH. 41, 63 (2009).

85. § 263a-2(i)(1).

86. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13, at 20. The accreditation standards will vary depending on the organization, but may include "components for personnel, quality control and quality assurance, specimen tracking, results reporting, or the performance of technical procedures." *Id.* at 21.

87. *Assisted Reproductive Technology (ART): Policy Documents*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/art/nass/policy.html (Feb. 8, 2017).

88. *See* Damiano, *supra* note 18, app. C at 851. *But see* CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13, at 575 (calling for "consumers who are aware of a clinic . . . in operation . . . but . . . not included in [the] report's lists of either reporting or nonreporting clinics" to contact the CDC with the name, address, and telephone number of the nonreporting clinic, in order for it to be included in future reports).

89. Implementation of the Fertility Clinic Success Rate and Certification Act of 1992—A Model Program for the Certification of Embryo Laboratories, 64 Fed. Reg. 39,374, 39,374 (July 21, 1999). This notice also incorporates comments that the CDC received from professional organizations, a consumer advocacy group, a manufacturer, and "individuals employed in embryo laboratories or . . . clinics[]." *Id.* at 39,375. Responses to each comment are included in the notice as well. *Id.* at 39,376-82.

have their state adopt the model program.[90] However, the CDC cautioned that "the model certification program for embryo laboratories does not provide for a [f]ederal oversight role."[91] One provision of the model certification program requires a quality management program both "to assure the quality of . . . services provided and to identify failures . . . as they occur."[92] Nonetheless, the model program does not impose a mandate to disclose these instances of misimplantation to the CDC or to the public at large.[93]

E. State Regulation of ART

Each state can decide to enforce the FCSRCA penalties—or not—under the police powers ensured to the states via the Tenth Amendment.[94] The FCSRCA respects the states' regulatory and enforcement jurisdiction by leaving the penalties for noncompliance to be decided by the states.[95] The legislation stipulates that the certifications will be issued "by the [s]tate or by accreditation organizations."[96] Suspensions or revocations of such accreditation may be based on a "state or organizations[']" finding that the owner, operator, or employee of the laboratory "failed to comply with any standards . . . applicable to the certification."[97]

States also have exclusive jurisdiction to regulate insurance coverage of fertility treatments, which has produced a variety of coverage relating to ART procedures throughout the country.[98] As of November 2019, only nine states required IVF to be covered by insurers in some form, but even in these states, the requirements to receive even

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90. *Id.* at 39,382. The model program calls for personnel qualifications and responsibilities and quality management, among other requirements. *Id.* at 39,386, 39,388. The model program also requires specific hours of documented training for laboratory directors, supervisors, or reproductive biologists in such clinics. *Id.* at 39,379.

91. *Id.* at 39,382.

92. *Id.* at 39,386. The model program also requires that "necessary corrective actions are taken, documented and reviewed for effectiveness whenever failures in quality are identified." *Id.* The laboratory must also retain records of the policies and procedures implemented for ten years, or the length of time set forth by federal, state, or local law, whichever is later. *Id.* at 39,391.

93. *See generally id.* at 39,374-75 (setting forth the model certification requirements, which do not include a duty to disclose such errors).

94. Nsien, *supra* note 80.

95. *Id.* ("[T]here is no enforcement mechanism provided for in the [FCSCRA] so it is unclear how the CDC ensures that all ART programs remain in compliance.").

96. 42 U.S.C. § 263a-2(f)–(g)(1).

97. *Id.* § 263a-4(a).

98. Alison Motluk, *A State-by-State Guide to Where Your Fertility Is Covered—and Where It Isn't*, N.Y. TIMES MAG., Nov. 10, 2019, at 5 (comparing, in detail, the coverage requirements of seventeen different states and the coverage requirements, on a general level, of the United States as a whole).

the minimal coverage due can be burdensome.[99] The vast majority of states either have no mandate to cover fertility treatments, including IVF, or alternatively, mandate that insurance providers cover or offer fertility treatment, but not necessarily IVF.[100]

1. New York: A Highly Regulated ART State

New York has used its state police powers to regulate medicine very stringently, specifically prohibiting any "person or other entity [from] . . . request[ing], accept[ing], receiv[ing], pay[ing] or giv[ing] any fee[s]" to, or compensating "in connection with any surrogate parenting contract," with limited exceptions.[101] These exceptions include payments made "in connection with the adoption of a child" or payments "for reasonable and actual medical fees and hospital expenses for artificial insemination or in vitro fertilization services incurred by the mother in connection with the birth of the child."[102] Under New York law, a "person or entity who . . . arranges or . . . assists in the formation of a surrogate parenting contract for a fee . . . [is] subject to a civil penalty not to exceed ten thousand dollars and forfeiture to the [S]tate of any such fee" for the first offense, and is subject to a felony conviction for a second offense.[103] A bill legalizing the practice of paid surrogacy is currently backed by the Governor of New York, Andrew Cuomo.[104] The efforts to overturn the ban on paid surrogacy recognize that "reproductive technology has completely changed" as commercial surrogacy increases in popularity across America.[105] New York is currently one of just three states that ban paid surrogacy contracts.[106]

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99. *Id.* (discussing New York's requirement that hopeful parents must wait a year without conceiving before gaining coverage, unless the woman is thirty-five or older, in which case she must wait six months, along with the limitations of Illinois' coverage, including an insurance allowance for just four completed egg retrievals, and then two more toward another child in the event of a live birth).

100. *See generally id.* (displaying a visual representation of state-by-state fertility coverage, or lack thereof, with a map).

101. N.Y. DOM. REL. LAW § 123 (McKinney 2020).

102. *Id.* § 123(1)(a)–(b).

103. *Id.* § 123(2)(b).

104. Elizabeth Chuck, *The Long Wait for Legalized Surrogacy May Soon End in New York*, NBC NEWS (Feb. 7, 2019, 4:25 AM), https://www.nbcnews.com/news/us-news/long-wait-legalized-surrogacy-may-soon-end-new-york-n968541 (discussing a New York couple who missed the early birth of their children after being forced to hire an out-of-state surrogate due to New York's ban on surrogacy for hire).

105. *Id.*

106. *Id.* A surrogacy contract is designed to protect the intended parents, the surrogate mother, and the baby. *Intended Parents: Understanding Surrogacy Contracts*, SURROGATE.COM, https://surrogate.com/intended-parents/surrogacy-laws-and-legal-information/understanding-surrogacy-contracts (last visited Feb. 8, 2021). Fee contracts for surrogacy usually outline the base payment to be made to the surrogate mother, along with fees should more than one child be born; additional

New York has a history of exercising its regulatory jurisdiction in ART-specific contexts.[107] In 1985,[108] New York created a "State Task Force on Life and the Law," which is responsible for developing recommendations and policy in the ART industry.[109] New York's Commissioner of Health is the chairman of the Task Force, and its other members are comprised of "Governor-appointed volunteer experts" of varying fields, including "law, medicine, nursing, and bioethics."[110] The task force created a list of factors it considered important to the "protection of procreative freedom," which are:

> Bodily integrity, [m]arital intimacy, [t]he relationship between coital reproduction and sexual intimacy, [t]he importance of being a parent and raising a child, [t]he importance of carrying on a genetic line, [t]he religious dimensions of decisions about procreation and child rearing, [t]he woman's interest in carrying a fetus and giving birth, [t]he intrusiveness of attempts to enforce laws limiting decisions about procreation, [and t]he danger that placing control of reproduction in the hands of the [S]tate will lead to eugenic policies.[111]

The working group concluded "the constitutional protection afforded [to] particular forms of [ART] should be based on the degree to which the procedure at issue implicates" the above-listed factors.[112] Commentators have noted that under such an approach, ART methods involving a married couple using their own sperm and egg may be afforded greater protections than an unmarried person using trait selection technologies.[113]

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payment, should a caesarian section be warranted; lost wages due to the birth of the child; and provisions regarding health insurance costs and coverage. *See generally Surrogate Mother Costs*, WEST COAST SURROGACY INC., https://www.westcoastsurrogacy.com/surrogate-program-for-intended-parents/surrogate-mother-cost (last visited Feb. 8, 2021) (outlining the 2020 schedule of fees and costs at a California surrogacy center).

107. Yaniv Heled, *The Regulation of Genetic Aspects of Donated Reproductive Tissue—The Need for Federal Regulation*, 11 COLUM. SCI. & TECH. L. REV. 243, 255, 257-58 (2010).

108. *About the Task Force on Life and the Law*, N.Y. STATE DEP'T OF HEALTH, https://www.health.ny.gov/regulations/task_force/about.htm (last visited Feb. 8, 2021).

109. *Id.*; Coleman, *supra* note 67, at 64. As part of its ART project, the "Task Force convened a special working group to consider the constitutional issues surrounding the use of ARTs." Coleman, *supra* note 67, at 64.

110. *About the Task Force on Life and the Law*, *supra* note 108.

111. Coleman, *supra* note 67, at 64-65.

112. *Id.* at 65.

113. *Id.* ("The Task Force specifically rejected the broad interpretation of procreative liberty advocated by . . . commentators.").

2. California: A Loosely Regulated ART State

California, on the other hand, has very limited regulation surrounding gestational contracts.[114] Parties to such a contract need only stipulate the date the agreement was executed; the "persons from which the gametes originated, unless donated gametes were used"; the "identity of the intended parent or parents"; and a "disclosure of how the intended parents will cover the medical expenses of the gestational carrier and of the newborn or newborns."[115] Parties to such an agreement "shall not undergo an embryo transfer procedure . . . until the . . . agreement for gestational carriers has been fully executed."[116] An agreement executed in accordance with this statute is "presumptively valid" and cannot "be rescinded or revoked without a court order."[117] This lower standard of protection surrounding ART procedures in California has been criticized, as argued by newly-confirmed District Court Judge for the Eastern District of Missouri, Sarah Pitlyk, in an amicus brief to the Supreme Court: "[T]he practice of surrogacy has grave effects on society, such as diminished respect for motherhood and the unique mother-child bond."[118]

Because California loosely regulates gestational contracts, it has developed into a worldwide destination for hopeful parents who seek fertility treatment.[119] California's proximity to Silicon Valley and tourist destinations offer hopeful parents the ability to leverage a clinic's access to cutting-edge technology with the added benefit of making a vacation out of their trip to the state.[120] "[O]f the fifty busiest IVF clinics in the United States," ten call California home.[121] Part of this popularity may be attributed to California's policy prohibiting discrimination against people choosing to pursue IVF on the basis of "age, ancestry, color,

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114. *See generally* CAL. FAM. CODE § 7962 (West 2020) (outlining the elements that a gestational agreement must contain).

115. *Id.* § 7962(a)(1)–(4).

116. *Id.* § 7962(d).

117. *Id.* § 7962(i).

118. *See supra* notes 74-76 and accompanying text; *see also* Motion and Brief of American Association of Pro-Life Obstetricians & Gynecologists et al. as Amici Curiae in Support of Petitioner at 3, M.C. v. C.M., 138 S. Ct. 239 (2017) (No. 17-129), https://www.thomasmoresociety.org/wp-content/uploads/2017/08/Amicus-Brief-in-M.C.-v.-C.M..pdf.

119. *See* Jancee Dunn, *How California Became the World's Fertility Treatment Destination*, VOGUE (Mar. 13, 2019), https://www.vogue.com/article/california-worlds-fertility-treatment-destination (discussing the relationship between California's technology industry and the state's burgeoning IVF industry).

120. *Id.* Dr. Boostanfar, a fertility doctor, fondly refers to the IVF process in California as a "fertilization vacation," where patients come to receive fertility treatment, but stay for the sunsets and beaches alike. *Id.*

121. *See id.*

disability, domestic-partner status, gender, gender expression, gender identity, genetic information, marital status, national origin, race, religion, sex, or sexual orientation."[122]

The growing popularity of IVF in California can also be attributed to the termination of China's one-child policy, which has caused the fertility market demand in China to grow exponentially.[123] By 2022, it is anticipated that China's market for fertility services will more than double the amount of money generated by the industry in 2016.[124] Kyle Francis, CEO of the Southern California Reproduction Center, partially attributes the rise in "medical touris[ts]" from China to strong Chinese cultural values that include extending the bloodline, along with growing acceptance of treatment to address infertility.[125]

Despite the increase of IVF popularity in China, China's population is still projected to *decrease* by approximately two percent by 2050.[126] The projected decrease in population is likely due to a number of factors, including "the cost of having children, housing availability and nationwide economic stress—especially worrying given the rapidly aging population."[127] In order to avoid long wait times, limited clinics, and excess demand for fertility treatment, hopeful Chinese parents have been taking their business abroad to other countries, including Singapore, Thailand, South Korea, and the United States.[128]

III. AN INCONCEIVABLE ISSUE: PERTINENT EXAMPLES OF MISIMPLANTATION TODAY AND THE ABSENCE OF REGULATION SURROUNDING THESE INSTANCES

In order to gain a functional understanding of the issue posed by the current ART regulations, this Part will begin by providing examples of hopeful parents who have been impacted by mistakes attributable to their

122. Motluk, *supra* note 98.

123. *Chinese Women Are Driving a Global Fertility Industry Boom*, BLOOMBERG (Sept. 17, 2018, 3:10 AM), https://www.bloomberg.com/news/articles/2018-09-16/chinese-women-are-driving-a-global-fertility-industry-boom.

124. *Id.*

125. Robert Blain, *More Chinese Seek IVF Abroad*, CHINADAILY.COM.CN (Feb. 21, 2018, 11:20 AM), http://www.chinadaily.com.cn/a/201802/21/WS5a8ce57ca3106e7dcc13d31d.html. Mr. Francis also acknowledges the increasing number of late marriages due to career expansion for women. *Id.*

126. Debbie Ponchner, *A Global Look at Fertility*, N.Y. TIMES MAG., Nov. 10, 2019, at 8.

127. *Id.*

128. Blain, *supra* note 125. Access to fertility clinics in other countries varies based on cultural differences. *See* Jessica Grose, *Access Is Everything: A Truth for All Ages*, N.Y. TIMES MAG., Nov. 10, 2019, at 2. In France, lesbian and single mothers must seek fertility treatment in another country in the European Union. *Id.*

fertility clinic.[129] Next, this Note will examine an individual state's autonomy in regulating medicine in the ART field.[130] An exploration of self-regulation in this industry will follow.[131] Finally, this Part will conclude by offering a guided analysis of the federal regulation and legislation surrounding ART.[132]

A. Scrambled Eggs: Uncommon Mix-Ups that Commonly Appear in the News Cycle

In April 1998, Deborah Perry-Rogers and her partner, Robert Rogers, began an IVF treatment program at a New York-based clinic.[133] During the couple's IVF treatment process, an embryo made of their genetic material was "mistakenly implanted into the uterus of defendant Donna Fasano, along with embryos from Ms. Fasano's and her husband's genetic material."[134] Ms. Fasano gave birth to two babies in December of 1998, and genetic tests following the birth confirmed that one of the babies was the Rogers' biological child.[135] The Rogerses sued the Fasanos, seeking a "declaratory judgement declaring the rights, obligations and relationships of the parties concerning [the Rogers' biological child]."[136] The Rogerses also sued the clinic, "alleg[ing] medical malpractice and breach of contract."[137]

The Rogerses have not been the only family to experience the unique heartache associated with a genetic child inadvertently being born to incorrect parents.[138] "About a decade ago, [Mr. and Mrs.] Manukyan . . . [stored] their embryos" at CHA Fertility Center in Los Angeles, California.[139] In 2018, they returned to CHA Fertility Center to

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129. *See infra* Part III.A.

130. *See infra* Part III.B.

131. *See infra* Part III.C.

132. *See infra* Part III.D.

133. Perry-Rogers v. Fasano, 715 N.Y.S.2d 19, 21 (App. Div. 2000).

134. *Id.* A troublesome legal dilemma has arisen with this technology: "When one woman's fertilized eggs are implanted in another, which woman is the child's 'natural' mother?" *Id.* at 24.

135. *Id.* at 22.

136. *Id.*

137. *Id.*

138. *See* Isaac Stanley-Becker, *She Gave Birth to Twins Through IVF. But the Babies Weren't Hers, a Lawsuit Alleges*, WASH. POST (July 8, 2019, 5:22 AM), https://www.washingtonpost.com/nation/2019/07/08/twins-ivf-birth-lawsuit. An anonymous couple became suspicious that something had gone awry after the expecting mother's first sonogram suggested she was carrying twin boys because she was previously informed that only *one* of the couple's embryos was a boy and it was not even intended to be used in the IVF transfer in question. *Id.*

139. Stanley-Becker & Brice-Saddler, *supra* note 8. The couple hails from Glendale, California. *Id.*

attempt an initial round of IVF with their previously-stored embryos.[140] Following multiple unsuccessful rounds of IVF, the Manukyans were informed in the spring of 2019 that one of their embryos had actually been implanted in the uterus of another woman in New York.[141] The Manukyans were not informed of this development until after the child in question had already been born.[142] The lawsuit filed by the Manukyans' attorney claimed that "[the Manukyans'] son had been stolen from them when he was still an embryo and implanted into a stranger that later became his birth mother."[143] After being informed of the mix-up, the unidentified birth mother and her husband sued CHA Fertility Center and the center's co-owners and directors, alleging "medical malpractice, negligence, battery and intentional infliction of emotional distress."[144] The Queens couple claimed to have "paid more than $100,000 for facility fees, medication, laboratory expenses, travel [expenses] and other costs" in an attempt to conceive a child that was genetically theirs via IVF.[145] The Manukyans also sued CHA Fertility Center and filed a habeas corpus petition in order to gain custody of the baby.[146] Today, the Manukyans still do not know what became of the other embryo that was intended to be used in their ART procedure.[147] "It means that we live with the uncertainty that another embryo of ours may be born to someone else," Mrs. Manukyan said.[148]

Instances of embryo mix-ups have not been limited to hopeful parents living in the United States.[149] In 2015, a London-based couple utilized the Connecticut-based CT Fertility P.C. clinic for IVF

140. *Id.*

141. *Id.*

142. *Id.*

143. *Id.*

144. Stanley-Becker, *supra* note 138.

145. *Id.*

146. Stanley-Becker & Brice-Saddler, *supra* note 8. Their petition was successful under the theory that the surrogacy had been unintended, and the Manukyans were able to fly home to California with their son eleven days after learning of the misimplantation. *Id.* Their attorney, Eric Wrubel, cited the sealed courtroom proceedings as among "'the most emotional scenes [he] ha[d] seen in [his] 25 years' of practicing law." *Id.*

147. *Id.* Mrs. Manukyan has stated that she "will never be the same person anywhere again in [her] life." *Id.* She further states that "CHA robbed [her] of [her] ability to carry [her] own child, to be with him in the first couple moments of his life, to nurse him, to just do skin on skin contact. Just be a mom to him." Eric Levenson & Cheri Mossburg, *This Couple Got a Stranger's Embryo in an IVF Mixup, and Someone Else Gave Birth to Their Baby*, CNN (July 10, 2019, 7:07 PM), https://www.cnn.com/2019/07/10/us/ivf-mixup-couple-lawsuit/index.html.

148. Levenson & Mossburg, *supra* note 147.

149. Daniel Tepfer, *Couple Claims Trumbull Clinic Switched Their Embryos*, CTPOST (Apr. 22, 2019, 4:09 PM), https://www.ctpost.com/local/article/Couple-claims-Trumbull-clinic-switched-their-13786141.php (explaining the lawsuit filed by the unnamed British couple against the fertility center at which they stored their embryos).

treatment.[150] CT Fertility used the "husband's sperm and embryos from a known donor."[151] The couple gave birth to their first child in April of 2016.[152] One year later, "the couple underwent a second IVF treatment at CT Fertility with the [clinic] representing [that it was] using the embryo from the known donor that was [allegedly] in storage at the clinic and the husband's sperm."[153] According to the lawsuit, the treatments undertaken by the couple cost approximately $200,000.[154] The second round of IVF was also successful in that it resulted in the couple giving birth to a second child.[155] However, "their second child appeared to have a much darker skin pigmentation then [sic] either the father, the genetic mother[,] or their first child[,] which was extremely unexpected and perplexing as the children were supposed to have the same genetic makeup."[156] A DNA test revealed that the two children were not genetically related to one another.[157] After receiving the news that their children were unrelated, the couple developed an unwavering "fear" that the embryo that was intended to be their second child had been wrongfully transferred to another patient.[158] CT Fertility has since closed,[159] and the "couple . . . seek[s] damages in excess of $15,000."[160] Jury selection is scheduled to begin in 2021.[161]

B. The State's Autonomy in Regulating Medicine

Neither the relatively deregulated state of California, nor the highly regulated state of New York, has enacted legislation requiring clinics to

150. *Id.*
151. *Id.*
152. *Id.*
153. *Id.*
154. Rich Scinto, *CT Fertility Clinic Mixed Up Embryos: Lawsuit*, PATCH (Dec. 18, 2019, 11:53 AM), https://patch.com/connecticut/trumbull/ct-fertility-clinic-mixed-embryos-lawsuit.
155. Tepfer, *supra* note 149.
156. *Id.*
157. *Id.* A DNA test is used to determine the genetic material of a person's deoxyribonucleic acids, which is unique to every person. *DNA Science Explained*, DNA DIAGNOSTICS CTR., https://dnacenter.com/the-science-explained (last visited Feb. 8, 2021) (discussing the "numerous techniques" that have been developed "to learn more about how living things function and solve genetic questions"). The DNA collected can be used for "relationship analysis," including that relationship between siblings. *Id.* Commercial DNA testing kits have helped to expose a medical ethical violation known as "fertility fraud," where fertility doctors lie to patients about the source of the donor sperm. Adam Liptak, *Fighting Fertility Fraud*, N.Y. TIMES MAG., Nov. 10, 2019, at 9.
158. Tepfer, *supra* note 149 ("While the plaintiff's second son is loved in every aspect[,] the plaintiffs live in constant, nagging, debilitating fear that the person whose genetic material was used will realize, as they did, that the defendants negligently mixed up their genetic material.").
159. *Id.*
160. Scinto, *supra* note 154.
161. *Id.*

report instances of implantation mix-ups, whether to the CDC or to the State itself, for publication.[162] As states are called on to "oversee medical licensing, educational requirements and discipline for physician misconduct," they have the legal power to revoke such a license.[163] The states "have largely abdicated that responsibility when it comes to ART, failing to implement safety standards or model programs for IVF clinics."[164] Marcy Darnovsky, Executive Director for the Center for Genetics and Society, points to the controversies that surround ART as the reason for state lawmakers' hesitation in attempting to regulate the industry.[165] Darnovsky specifically cites to the politically-charged topic of abortion, "which touches on conception[,] . . . embryos," and stem cell research, in defending this position.[166]

The CDC itself states that adopting the model certification program is entirely voluntary, and has deferred approval and monitoring of laboratory accreditation to the states.[167] In the language that introduces the FCSRCA's model certification program, the CDC recognizes the state's autonomy in regulation, defining "State" as inclusive of "expressly delegated powers to [a] political subdivision sufficient to authorize the political subdivision to act for the State in enforcing requirements equal to or more stringent than the model certification program."[168] The CDC implicitly acknowledges the states' autonomy in this field by informing one commenter that if a state were to adopt its

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162. *See generally* CAL. FAM. CODE § 7962 (West 2020) (including no such requirement); N.Y. DOM. REL. LAW § 123 (McKinney 2020) (including no such requirement).

163. Kerry Breen, *Lack of Oversight and Regulations May Lead to IVF Mishaps*, TODAY (July 9, 2019, 3:24 PM), https://www.today.com/health/lack-oversight-regulations-may-lead-ivf-mishaps-t157872 ("There's no federal law, no state law, no enforced professional guideline that enforces requirements, that licenses these facilities in the way that they label or diagnose or handle sperm, eggs and embryos, that result in the creation of people.").

164. Fischer, *supra* note 19, at 212. An "ideal framework of ART regulation will be independent, will take into account patients, providers, and the public, and will be free from political, religious, or moral agendas." *Id.* at 222.

165. *See* Michael Ollove, *States Not Eager to Regulate Fertility Industry*, PEW: STATELINE (Mar. 18, 2015), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/3/18/states-not-eager-to-regulate-fertility-industry (discussing the Utah State legislature's decision to provide children conceived via sperm donation access to their biological father's medical history, and the general hesitancy of states to regulate the fertility industry).

166. *Id.* Darnovsky's opinion that legislatures are hesitant to regulate ART because of the ART industry's surrounding controversial spheres is shared by other critics: "It is unregulated because it touches on two, 'third-rail' issues . . . . It touches on abortion and also the creation of embryos, which politicians run away from because too many people still disagree about the right to use reproductive technologies, particularly who should pay for them and how much." *Id.*

167. Implementation of the Fertility Clinic Success Rate and Certification Act of 1992—A Model Program for the Certification of Embryo Laboratories, 64 Fed. Reg. 39,374, 39,377 (July 21, 1999).

168. *Id.* at 39,383.

model program, it would be left to that state to determine fees associated with certification.[169] The federal government has covered costs for implementing the FCSRCA, including the development of the model certification program and the publication of the annual report.[170]

C. Self-Regulation

Two prominent professional organizations in the medical field "develop and practice ethical guidelines and programs for laboratory accreditation."[171] These groups are the American Society for Reproductive Medicine ("ASRM") and the Society for Assisted Reproductive Technology ("SART").[172] SART is an affiliated society of ASRM,[173] and is "an organization of ART providers . . . [that] has been collecting data and publishing annual reports . . . for fertility clinics in the United States and Canada since 1989."[174] The CDC contracted with SART to use its "clinic specific database" in order to collect pregnancy data from clinics.[175] Before the enactment of the FCSRCA, SART's registry system was voluntary.[176] However, after the legislation was passed, it became mandatory for clinics performing ART procedures to submit their data to SART, who then forwards it to the CDC for compilation and publication.[177] SART member clinics "perform more than 95% of the [ART] cycles in the United States."[178] ASRM and SART publish guidelines covering "specific ART practice issues, such as the number of embryos to be transferred in an ART procedure."[179] A

169. *Id.* at 39,377.

170. *Id.* at 39,377-78.

171. Breen, *supra* note 163.

172. *Id.*

173. *Latest Data from SART Show Increasing Use of Cryopreservation for Fertility Preservation*, SOC'Y FOR ASSISTED REPROD. TECH. (Apr. 5, 2019), https://www.sart.org/news-and-publications/news-and-research/press-releases-and-bulletins/latest-data-from-sart-show-increasing-use-of-cryopreservation-for-fertility-preservation. The Society for Assisted Reproductive Technology ("SART") assisted then Congressman Wyden in developing the FCSRCA requirements. Adamson, *supra* note 21, at 732.

174. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13, at 1.

175. Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs, 65 Fed. Reg. 53,310, 53,312 (Sept. 1, 2000).

176. *Id.*

177. *Id.*

178. *Latest Data from SART Show Increasing Use of Cryopreservation for Fertility Preservation*, *supra* note 173.

179. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13, at 7. The year-by-year SART's National Summary Report gives "patients, professionals and the public the big picture view of the improvements and advances that have occurred in ART over the decades." *Latest Data from SART Show Increasing Use of Cryopreservation for Fertility Preservation*, *supra* note 173. Both the American Society for Reproductive Medicine ("ASRM") and SART have worked in collaboration

published ethics committee opinion by ASRM recommends guidelines to avoid mishandling embryos and includes suggestions such as self-implementing written procedures to prevent such an error in the first instance.[180] ASRM implores physicians to implement "rigorous procedures" in doing so.[181] ASRM has attempted to guide such "rigorous procedures" by stipulating:

> To prepare for the possibility that errors may occur despite these procedures, programs should foster an environment of truth telling that will allow prompt identification and disclosure of errors to patients. It is recommended that clinics have written policies and procedures that outline how to reduce and disclose medical errors.[182]

Sean Tipton, chief lobbyist for ASRM, challenges the view that reproductive medicine is unregulated, asserting that the field is "one of the most heavily regulated fields of medicine in the [United States]."[183] In support of this position, Tipton points to federal regulation of drugs and medical devices as evidence of components of ART that are regulated by the federal government.[184] It is true that ASRM issues guidelines to encourage self-regulation.[185] However, no sanction arises when practitioners or clinics violate the guidelines.[186] Arthur Caplan, Director of the Division of Medical Ethics at New York University's School of Medicine, asserts that the field will continue to be lightly regulated because it has evolved as a business, rather than a "research enterprise."[187] Some industry experts agree with Caplan's

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with the CDC to report success rates in the annual FCSRCA report. *National ART Surveillance*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/art/nass/index.html (Jan. 27, 2021).

180. Am. Soc'y for Reprod. Med., *Disclosure of Medical Errors Involving Gametes and Embryos: An Ethics Committee Opinion*, 106 FERTILITY & STERILITY 59, 62 (2016). When errors are "clinically relevant, fairness to patients, protection from harm, and respect for patient autonomy require open and honest disclosure of errors immediately upon recognition, even though disclosure may be difficult for clinicians." *Id.* at 59-60.

181. *Id.* at 59.

182. *Id.* at 62.

183. Michael Ollove, *Lightly Regulated In Vitro Fertilization Yields Thousands of Babies Annually*, WASH. POST (Apr. 13, 2015), https://www.washingtonpost.com/national/health-science/lightly-regulated-in-vitro-fertilization-yields-thousands-of-babies-annually/2015/04/13/f1f3fa36-d8a2-11e4-8103-fa84725dbf9d_story.html.

184. *Id.*

185. *See* Am. Soc'y for Reprod. Med., *supra* note 180, at 59 (outlining suggestions to prevent and disclose errors related to handling embryos). *But see* Ollove, *supra* note 183 (discussing critics' argument that ASRM works to "advance the business interests of its members, [unrestrained] by government regulation").

186. Ollove, *supra* note 183.

187. *Id.* The lack of regulation surrounding ART is cited as a benefit in some instances, such as those that involve same-sex couples or single parents as they avoid facing "built-in barriers" in

characterization, pointing to congressional hesitation to regulate on an issue that implicates abortion.[188] The current scheme has been criticized, as practitioners are relied on to comply with self-adopted standards and self-reporting guidelines while still participating in an economically competitive market that disincentivizes voluntary disclosure.[189]

D. The Absence of Federal Regulation

The Secretary of the DHHS is required to publish the names of laboratories that have not complied with FCSRCA's reporting standards.[190] Though this may sound like a compelling deterrent, laboratories that do not comply with reporting requirements are not subject to any sanctions imposed by the CDC.[191] If and when a state chooses to adopt the model certification program set forth by the FCSRCA, its laboratories become subject to inspection by the state or DHHS Secretary.[192] So far, no states have required their laboratories to opt into the model program.[193] In the published 2017 ART Fertility Clinic Success Rates Report, each non-reporting clinic had an entire page dedicated to it.[194] In this report, there were fifty clinics that did not report their yearly data.[195] The clinic's name and city are listed on an individual page devoted to each non-reporting clinic,[196] along with the following provision:

> This clinic provided ART services during 2017 and is therefore required to submit ART cycle data under the provisions of the Fertility Clinic Success Rate and Certification Act. This clinic either did not submit 2017 ART cycle data or the clinic's Medical Director did not approve the clinic's 2017 ART cycle data for inclusion in this report.[197]

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utilizing ART methods to conceive. *Id*. Same-sex couples have faced barriers in seeking out fertility treatment centers in developed countries in the European Union. Grose, *supra* note 128, at 2.

188. Ollove, *supra* note 183.

189. Heled, *supra* note 107, at 277-78.

190. 42 U.S.C. § 263a-5.

191. Jaime King, *Predicting Probability: Regulating the Future of Preimplantation Genetic Screening*, 8 YALE J. HEALTH POL'Y L. & ETHICS 283, 334 (2008).

192. § 263a-2(g)(1), (h)(1).

193. King, *supra* note 191, at 330.

194. *See, e.g.*, CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13, at 63, 158 (revealing clinics in Glendale, California, and Lutz, Florida, that were required to report ART cycle data under the FCSRCA but failed to do so).

195. *Id.* at 575-77.

196. *See, e.g.*, *id.* at 158 (showing one non-reporting clinic's individualized entry in the report).

197. *Id.* The same provision is listed on other non-reporting clinics' individualized entries in the report. *See, e.g.*, *id.* at 159, 213, 237.

An example of a non-reporting clinic found in the 2017 report is Braverman Reproductive Immunology, PC, located in Woodbury, New York.[198] Of the fifty non-reporting clinics noted in the 2017 report, thirteen have closed since January 1, 2017.[199]

While the FCSRCA mandates that clinics report their *success* rates to the CDC for annual publication, the FCSRCA fails to set forth statistical reporting and publishing requirements governing the rate in which the clinics *err*.[200] Commentators have pointed to other notable omissions in the reporting requirements set forth by the FCSRCA and CDC.[201] Ima Nsien, an attorney working with the California-based ADLI Law Group notes:

> [T]here is no state regulation of the number of children that may be conceived by an individual donor, no rules regarding the types of medical information and updates that must be supplied by young donors as they age, no standards regarding genetic testing on embryos, no limits on the age of donors, and virtually no regulation of the gametic material market.[202]

Further, states have not elected to develop their certification programs based on the model program outlined by the FCSRCA.[203] States that wish to provide patients with embryo misimplantation rates can instead require disclosure under state law.[204] This piecemeal approach has left gaps in the legislation surrounding the fertility industry.[205] As "states have done very little to fill the void left by the lack of federal legislation," most clinics have only a low-threshold duty to comply with the federal reporting standard as imposed by the FCSRCA requirements.[206]

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198. *Id.* at 367. There are four New York-based clinics that are listed as having provided ART services in 2017, and thus were required to submit ART cycle data under the FCSRCA, but instead failed to report. *Id.* at 577.

199. *Id.* at 575-77.

200. Nsien, *supra* note 80 (noting that clinics must report birth rates and other factors, such as demographic information, but not error rates).

201. Lynn D. Wardle, *Global Perspective on Procreation and Parentage by Assisted Reproduction*, 35 CAP. U. L. REV. 413, 419 (2006) (pointing to criticism the FCSRCA has faced, including the principal finding of the President's Council on Bioethics after its 2004 study of ART regulation: "There is no uniform, comprehensive, enforceable system of data collection, monitoring, or oversight for the biotechnologies affecting human reproduction."). *But see* Adamson, *supra* note 21, at 732 (stating that "the FCSRCA has been considered a success by physicians, patients and the government").

202. Nsien, *supra* note 80.

203. Adamson, *supra* note 21, at 732.

204. *See* Ollove, *supra* note 165 ("[A]spects of ART are simply unaddressed by the states.").

205. *See* CHARLES P. KINDREGAN, JR. & MAUREEN MCBRIEN, ASSISTED REPRODUCTIVE TECHNOLOGY: A LAWYER'S GUIDE TO EMERGING LAW AND SCIENCE 31-32 (2d ed. 2011).

206. *See* Nsien, *supra* note 80.

IV. BABY PROOFED: A STATISTIC INDICATING OCCURRENCES OF MISIMPLANTATION SHOULD BE ADDED TO THE FCSRCA REPORTING REQUIREMENTS

This Note's proposed solution is best explained by first examining the legislation's current required reporting statistics.[207] Next, the offered changes to the reporting requirements and statutory definitions will be set forth.[208] This Part will also argue that the proposed changes to the FCSRCA are an ideal solution because states will retain their enforcement abilities guaranteed to them under the Tenth Amendment and currently set forth in the existing FCSRCA legislation.[209] Furthermore, potential patients, hopeful parents, and the general public will continue to enjoy access to transparent information when considering clinics in the United States, while benefiting from a heightened standard of reporting requirements.[210] This Part will also demonstrate that this proposed solution can be explored, questioned, and considered by experts in the industry and the general public in a manner consistent with the modifications to the FCSRCA that the CDC is currently considering.[211]

A. The Legislation as It Currently Stands

The current FCSRCA legislation outlines the figures that clinics must report to the CDC for publication in its annual report and mandates:

> (a) In general: Effective 2 years after October 24, 1992, each assisted reproductive technology (as defined in section 263a-7 of this title) program shall annually report to the Secretary through the Centers for Disease Control—
> (1) pregnancy success rates achieved by such program through each assisted reproductive technology, and
> (2) the identity of each embryo laboratory (as defined in section 263a-7 of this title) used by such program and whether the laboratory is certified under section 263a-2 of this title or has applied for such certification.[212]

207. *See infra* Part IV.A.
208. *See infra* Part IV.B.
209. *See infra* Part IV.C.
210. *See infra* Part IV.D.
211. *See infra* Part IV.D.
212. 42 U.S.C. § 263a-1(a).

The FCSRCA, as currently compiled, continues on to define which subfactors must be included in the live birth rate, including the age, diagnosis, and other significant factors concerning the genetic parent:

> (b) Pregnancy success rates
> (1) In general: For purposes of subsection (a)(1), the Secretary shall, in consultation with the organizations referenced in subsection (c), define pregnancy success rates and shall make public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency) during its development.
> (2) Definition: In developing the definition of pregnancy success rates, the Secretary shall take into account the effect on success rates of age, diagnosis, and other significant factors and shall include in such rates—
> (A) the basic live birth rate calculated for each assisted reproductive technology performed by an assisted reproductive technology program by dividing the number of pregnancies which result in live births by the number of ovarian stimulation procedures attempted by such program, and
> (B) the live birth rate per successful oocyte retrieval procedure calculated for each assisted reproductive technology performed by an assisted reproductive technology program by dividing the number of pregnancies which result in live births by the number of successful oocyte retrieval procedures performed by such program.[213]

The FCSRCA also includes a generalized definition section, which currently sets forth three definitions for the purposes of the legislation as a whole:

> For purposes of sections 263a-1 to 263a-7 of this title:
> (1) Assisted reproductive technology
> The term "assisted reproductive technology" means all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency).
> (2) Embryo laboratory
> The term "embryo laboratory" means a facility in which human oocytes are subject to assisted reproductive technology treatment or procedures based on manipulation of oocytes or embryos which are subject to implantation.

213. *Id.* § 263a-1(b).

> (3) Secretary
> The term "Secretary" means the Secretary of Health and Human Services.[214]

Despite setting forth general parameters surrounding ART, the FCSRCA, as currently written, is silent as to the obligation of a clinic to report misimplantation or instances of human error in fertilization or implantation.[215]

B. Proposed Additions to the FCSRCA's Reporting Requirements and Definitions Sections

This proposed addition to the legislation preserves the law's reporting requirements as they currently stand, but calls for an *additional* statistic to be included in the general reporting requirements of section 263a-1, which would then read "each assisted reproductive technology program (as defined in section 263a-7 of this title) shall annually report to the Secretary through the Centers for Disease Control *known laboratory misimplantation instances per year*."[216] As previously explored, definitions relevant to the FCSRCA are included in section 263a-7.[217] This portion of the legislation should be amended to include a definition of "known misimplantation," so that the owner or operator of the laboratory responsible for reporting correct annual information to the CDC knows what "known misimplantation" would encompass, and when it must be reported.[218] This Note proposes that "known misimplantation" should be defined as "instances where an embryo was implanted in an unintended patient," and that this definition be included in the aforementioned reproduced section, following the preexisting definitions included in the FCSRCA.[219]

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214. *Id.* § 263a-7.

215. *See generally id.* § 263a-1(a) (stipulating that only the success rate of each ART method employed by such a clinic must be reported, along with the identity and certification status of the reporting clinic).

216. *See id.* § 263a-1(a).

217. *See generally id.* § 263a-7 (defining "assisted reproductive technology," "embryo laboratory," and "secretary").

218. *See generally id.* (including the three existing definitions that will be retained). One commentator has referred to instances of misimplantation as a subset of laboratory "mix-ups," which include instances of "mishandling sperm, eggs, or embryos," or "fertilizing eggs with [a] stranger['s] sperm," or "implanting embryos into the wrong person." Fischer, *supra* note 19, at 207. Defining "misimplantation" will also preserve the stated goal of the ART reporting system: to provide information related to ART treatment and success rates. *See generally* CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13, at 1.

219. *See* § 263a-7.

C. States Will Retain Their Enforcement Abilities

States have enforcement power over clinics that either fail to report or misrepresent their clinics' data.[220] Section 263a-4 of the FCSRCA outlines certification revocation and suspension of embryo laboratories, and mandates:

> (a) In general: A certification issued by a State or an accreditation organization for an embryo laboratory shall be revoked or suspended if the State or organization finds, on the basis of inspections and after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that the owner or operator or any employee of the laboratory—
> (1) has been guilty of misrepresentation in obtaining the certification,
> (2) has failed to comply with any standards under 263a-2 of this title applicable to the certification, or
> (3) has refused a request of the State or accreditation organization for permission to inspect the laboratory, its operations, and records.[221]

The changes proposed here will not impact the state's ability to issue certification or the state's authority to delegate such responsibility to the accreditation organization.[222] By solely incorporating the proposed reporting statistic of the known misimplantation instances, the certification program standards would remain voluntary.[223] Though the required reporting statistics would be enhanced, states would continue to have the choice as to whether to opt into the CDC's model certification program.[224] Likewise, states would continue to control the general practice of medicine within their state, which would include licensing and regulatory governance.[225]

Moreover, the State or relevant accreditation organization would continue to have the power to revoke a laboratory's license should the laboratory fail to comply with the standards, which would now include misreporting or failing to report the misimplantation rate.[226] The current legislation mandates that the DHHS Secretary "may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted

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220. *See supra* Part II.E.
221. § 263a-4.
222. *See id.*; *see also supra* Part IV.B.
223. Implementation of the Fertility Clinic Success Rate and Certification Act of 1992—A Model Program for the Certification of Embryo Laboratories, 64 Fed. Reg. 39,374, 39,374, 39,377 (July 21, 1999).
224. *Id.*
225. King, *supra* note 191, at 329.
226. § 263a-4.

reproductive technology programs."[227] This proposed solution does not have the effect of control over the practice of medicine, as this requirement would not impact a clinic's ability to conduct business in the industry and is similar to the currently required annual reporting statistics called for in section 263a-1.[228]

D. Patients Will Retain Their Ability to Access This Report with Enhanced Information Included in the CDC's Publication

In requiring a misimplantation statistic to be reported to and published by the CDC, the statute's goal of helping patients "make informed decisions about ART" by providing them with heightened information will not change.[229] The CDC's annual report currently aims to help hopeful parents find an ART clinic in their desired geographic area, which, in turn, allows the parents and providers to meet and discuss the individual's medical situation, needs, and likelihood of reproductive success.[230] The report will still be accessible to and used by the general public by being presented in "an easily understandable form."[231]

The FCSRCA was intended to enable consumer-patients exploring clinics within the United States to make more informed decisions about the ART options available to them by arming the public with information related to each clinic's success rate, while simultaneously incorporating a model certification program that the states could choose to adopt.[232] Providing the public with known misimplantation statistics will not derail the intent of the FCSRCA, but instead will enhance it, as the statute will continue to require "[s]tates and accreditation organizations to include the necessary explanatory information for the public" to use in interpreting the findings.[233] The CDC currently provides literature regarding the access of the annual report to aid the public in better understanding the information provided.[234] The CDC provides certain resources and poses considerations if the consumer is

227. § 263a-2(i)(1).

228. *See generally* § 263a-1 (stipulating the annual reporting statistics currently required).

229. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13, at 1.

230. *Id.* at 5.

231. *Id.* at 1. Likewise, this report will continue to be "informative and helpful to [those] considering an ART procedure" at a particular clinic. *Id.*

232. Adamson, *supra* note 21, at 731.

233. Implementation of the Fertility Clinic Success Rate and Certification Act of 1992—A Model Program for the Certification of Embryo Laboratories, 64 Fed. Reg. 39,374, 39,378 (July 21, 1999).

234. *Tutorial for Using the ART Report*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/art/patientResources/using.html (Feb. 17, 2017) (outlining, for the general public, what information is included in the report and the relevant "hints" to reviewing the report).

planning to use donor eggs or embryos, along with varying recommendations if the hopeful parent plans to use their own eggs.[235] The CDC also breaks down the tutorial into five different sections to guide users in finding the answers to questions they may have when seeking out information included in the report.[236] None of these suggestions, resources, or recommendations would need to be modified if the proposed changes to the legislation were incorporated, meaning this valuable consumer resource will not be rendered inoperable upon adoption of the above-mentioned proposed changes.[237]

Currently, the CDC is considering adding more required reporting statistics to the FCSRCA, along with expanding the required reporting laboratories.[238] The following provisions are under consideration for addition to the FCSRCA: reporting of a patient's demographic information where the patient is using donor eggs but does *not* carry the pregnancy; reporting of oocyte source and carrier information such as height, weight, smoking history, prior ART cycles, and pregnancy history; and requiring clinics that are under contract with external ART laboratories to report their data.[239] To this end, the CDC is currently seeking written comments on the proposed additions or modifications from any interested persons or organizations, which would be included in the public record and subject to review and consideration by the CDC.[240]

The CDC's attempt to seek comment on these modifications is consistent with the responsibility set forth in section 263a-1 of the FCSRCA, which states that the DHHS Secretary, who oversees the CDC, shall "consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with assisted reproductive technologies."[241] The CDC will respond to the recent comments in a manner similar to that in which it responded to comments

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235. *See id.* (suggesting that patients using donor eggs and embryos should focus on sections one and four of the report, while those using their own eggs should concentrate on sections one and two of the report).

236. *See id.* (denoting section one as an overview, section two as concerning ART cycles using fresh nondonor eggs or embryos, section three as concerning ART cycles using frozen nondonor eggs or embryos, section four as concerning ART cycles using donor eggs, and section five as concerning ART trends).

237. *See id.*

238. Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs; Proposed Additional Data Collection Fields; Request for Comment, 84 Fed. Reg. 59,814, 59,814-15 (Nov. 6, 2019).

239. *Id.*

240. *Id.* at 59,814.

241. *See* 42 U.S.C. § 263a-1(c).

prior to the initial implementation of the FCSRCA.[242] The amendment proposed in this Note could also be subject to notice-and-comment.[243]

V. CONCLUSION

Fertility treatments involving ART have quickly increased in popularity in the United States over the past forty years.[244] Many public figures have taken advantage of the medical advancements surrounding fertility,[245] with IVF being the most popular and widely used ART method as of today.[246] Despite the popularity of IVF, its long-term effects on women who undergo the treatment are still unknown.[247] The increased usage of IVF has unfortunately resulted in life-changing errors that have affected both the birth and genetic parents and will inevitably impact the children derived from misimplantation.[248]

After the federal government first responded to the increased use of ART technology by enacting the FCSRCA,[249] state legislatures were left to fill in the gaps with a varying patchwork approach.[250] As a result, this industry is governed with an uneven hand throughout the United States.[251] Some commentators have considered the FCSRCA and supplemental legislation or self-regulation to be an overall success,[252] while others remain critical of the collective shortcomings.[253] It is

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242. *See* Implementation of the Fertility Clinic Success Rate and Certification Act of 1992—A Model Program for the Certification of Embryo Laboratories, 64 Fed. Reg. 39,374, 39,376-82 (July 21, 1999) (including a summary of comments the CDC received from interested individuals and organizations and the CDC's accompanying response to each comment).

243. *See generally* Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs; Proposed Additional Data Collection Fields; Request for Comment, 84 Fed. Reg. at 59,814 (broadcasting the CDC's desire to obtain comments and reviews of proposed data collection fields and the modification of ART programs); *see also National ART Surveillance*, *supra* note 179 (outlining the CDC's ongoing partnership with ASRM and SART in producing the yearly FCSRCA report and facilitating public health communication).

244. *See supra* Part II.A. This popularity can also be observed in what is now colloquially known as "Cocktails and Cryo" parties, which are hosted by clinics in an effort to attract new business and normalize the process of patients freezing their eggs for later use in conceiving a child. Grose, *supra* note 128, at 2.

245. *See supra* Part II.B.

246. *See supra* note 36 and accompanying text.

247. *See* Maya Dusenbery, *What We Don't Know – And Why*, N.Y. TIMES MAG., Nov. 10, 2019, at 11 ("[I]t's all but impossible to know which observed health risks are due to the fertility treatments and which are a result of the underlying cause of the infertility itself.").

248. *See supra* Part III.A.

249. *See supra* Part II.D.

250. *See supra* Part II.E.

251. *See supra* Part III.D.

252. *See* Ollove, *supra* note 183 (featuring ASRM lobbyist Sean Tipton, who characterizes the industry as heavily regulated).

253. *See* Fischer, *supra* note 19, at 202 ("[T]he current state of legislative redundancy and gaps

undisputed, however, that there is currently no definite way for potential parents to know if the clinic they are considering has previously caused an embryo's misimplantation because the industry is allowed to rely on a clinic's voluntary compliance with the FCSRCA standards[254] and self-regulation.[255] The ability of clinics to rely on best practices, self-regulation, and self-reporting has earned the United States' fertility industry a reputation comparable to the "wild west."[256] Dov Fox, Professor of Law at the University of San Diego, describes unregulated misimplantation occurrences succinctly: "We really have no idea how often this sort of thing happens where sperm fertilizes the wrong egg or embryos are switched. But cases that appear in courts and reports suggest that it happens a whole lot more often than you might think."[257]

As such, the FCSCRA should be revitalized and amended to require clinics operating within the United States to report statistics that disclose these grave, life-changing errors.[258] Incorporating the proposed requirement will ensure the states retain their police powers, guaranteed under the Tenth Amendment,[259] and will likewise empower the general public by providing hopeful ART consumers with access to more transparent information needed to make decisions regarding their future children and family planning.[260] The intentions of the FCSRCA, as it was originally enacted, will be preserved,[261] but the access of the end users—hopeful parents—will be enhanced, thereby improving the increasingly popular ART field as a whole.[262]

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creates negative incentives for assisted reproduction providers and poses risks for their customers of their services."). *See also* Breen, *supra* note 163 (explaining that fertility centers in the United States "operate free of almost any regulation at all").

254. *See supra* Part III.B.

255. *See supra* Part III.C. Additionally, the industry relies on patients who have been victimized by misimplantation to come forward to the press. *See supra* Part III.A.

256. *See* Fischer, *supra* note 19, at 202.

257. Breen, *supra* note 163.

258. *See supra* Part IV.B. This solution will be a step forward in strengthening the ART industry by realigning the United States' standard slightly closer to that of the United Kingdom model cited as "the forefront of the ART field." Fischer, *supra* note 19, at 217.

259. *See supra* Part IV.C.

260. *See supra* Part IV.D. The report will continue to be "a helpful starting point for consumers to obtain information and consider their options." CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 13, at 5.

261. *See supra* Part IV.D.

262. *See supra* Part IV.

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* J.D. Candidate 2021, Maurice A. Deane School of Law at Hofstra University; B.S., *summa cum laude*, Commerce and Business Administration, 2016, University of Alabama. A warm thank you to my wonderful Notes Editor, Rebecca Marks, who was correct when she told me that writing a Note would be a labor of love. Kelly McKinney, Matthew Hauszpigel, Kristina Sgambati, and the Volume 49 *Hofstra Law Review* Staff also contributed invaluable efforts toward the publication of this Note, of which I am always grateful. I would be remiss if I did not thank my Faculty Advisor, Professor Juliana Campagna, for the outpouring of commitment and knowledge she devotes to each of her students, including myself, who was fortunate to have crossed paths with her. An immeasurable debt of gratitude is owed to my fellow Volume 49 Managing Editors, Leanne Bernhard and Robert Levinson, for their unwavering dedication to a largely thankless role, and during a global pandemic no less. Undeservingly so, I was privileged to have been surrounded by many admirable and bright women throughout the drafting and publication of this Note, including Katherine Cappeller and Nicole Kelly (both of whom are future legal trailblazers), Paige Illiano (who deserves endless credit for the puniness included herein), Savannah Droxler, Alexandra Foshee, Alanna Jackson, Natalie Kain, and Jill Mullane. My great friend, Cole Howie, is likewise overdue many thanks for always laughing with me. Finally, I owe everything and more to my mom, Dee; my dad, Eric; my brother, Zack; and my new sister, Amanda, for their unmatched support and love, no matter the day. Thank you, a million times over.