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## R-Egg-Ulation: A Call for Greater Regulation of the Big Business of Human Egg Harvesting

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R-EGG-ULATION:  
A CALL FOR GREATER REGULATION OF THE BIG  
BUSINESS OF HUMAN EGG HARVESTING

*Danielle A. Vera\**

ABSTRACT

*When it comes to young healthy women “donating” their eggs, America has a regulation problem. This Note explains the science behind the harvesting of human eggs, focusing on potential egg donors, and describes the specific factors that make egg donation a unique type of transaction. It describes the current regulatory status of the assisted reproductive technology industry in the United States and highlights the ways in which this scheme fails to protect egg “donors.” This Note concludes with a call for comprehensive regulation of the assisted reproductive technology industry.*

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\* Danielle A. Vera, J.D./M.B.A., University of Michigan 2015. I would like to particularly thank my Aunt, Kryisia Vandenbussche, for her help and support in crafting this Note. I also want to thank my parents for listening to my ideas on this topic for many months and Professor Edward Goldman for inspiring me in his course on Reproductive Justice. Thank you also to the staff of the *Michigan Journal of Gender & Law* for all of your assistance in bringing my initial draft to publication.

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## INTRODUCTION

### *A. Jessica Schneider’s Story*<sup>1</sup>

Jessica Schneider was an ideal egg donor: a Stanford University graduate, an elegant former model, and an artistic film producer.<sup>2</sup> She was musically inclined and a talented composer, singer, pianist, and guitar player.<sup>3</sup> And, at six feet tall, she was equally athletic.<sup>4</sup> When Schneider decided to become an egg donor, she was reassured by the fact that the in vitro fertili-

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1. Jennifer Schneider, *It’s Time for an Egg Donor Registry and Long-term Follow Up*, RECORD OF TESTIMONY AT A CONGRESSIONAL BRIEFING ON HUMAN EGG TRAFFICKING ON NOV. 14, 2007 (Mar. 3, 2008, 1:09 PM), <https://www.donor-siblingregistry.com/sites/default/files/images/docs/cgs.pdf>.

2. *Id.* at 1.

3. *Id.*

4. *Id.*

zation clinic she chose was well respected within the community.<sup>5</sup> In discussing her decision to donate, Schneider explained to her mother, “[t]here are some risks associated with the procedure, such as bleeding or infection, and that’s about it.”<sup>6</sup> After Schneider’s donated eggs resulted in a pregnancy, she became an even more desirable donor and was offered double the price to donate a second time.<sup>7</sup> Later, she completed a third and final donation cycle.<sup>8</sup>

While pursuing a master’s degree in filmmaking, Schneider developed abdominal pain.<sup>9</sup> Her doctors diagnosed advanced colon cancer, a rare affliction among twenty-nine year olds.<sup>10</sup> She dropped out of her graduate program to begin treatment for the cancer in her colon. It subsequently spread to her bones and brain, requiring chemotherapy, massive surgery, and radiation.<sup>11</sup> Ultimately, the cancer made its way to her lungs, resulting in a gradual loss of her ability to breathe.<sup>12</sup> After battling for two years, Schneider died of cancer at the young age of thirty-one.<sup>13</sup> In 2003, Jessica’s oncologist said there was no evidence to support a connection between ovarian hyper-stimulation and colon cancer.<sup>14</sup> Today, we know differently.<sup>15</sup>

Jessica Schneider was the victim of America’s failed regulatory scheme. She voluntarily became an egg donor, but she was denied the information and support structure she needed to make a reasoned decision. She had no access to studies evaluating the health risks of egg donation, and she engaged in a transaction where there was—and remains—little opportunity for true informed consent. Furthermore, she fell prey to coercive compensation and aggressive consumer marketing. The regulatory scheme that applies to egg donors in the United States does not protect vulnerable women like Jessica. It needs to change.

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5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

10. *Id.*

11. *Id.*

12. *Id.*

13. *Id.*

14. *Id.* at 2.

15. Jennifer H. Lin & Edward Giovannucci, *Sex Hormones and Colorectal Cancer: What Have We Learned So Far?*, 102 J. NAT’L CANCER INST. 1746, 1746 (2010) (“Patients who received treatment with gonadotropin-releasing hormone agonists or orchiectomy had a 30%–40% increased risk of developing colorectal cancer relative to those patients who did not have the therapies.”).

### B. Approach and Focus of This Note

According to the Center for Disease Control and Prevention (CDC), assisted reproductive technology (ART) “includes all fertility treatments in which both sperm and eggs are handled.”<sup>16</sup> Egg donation is not required in all forms of ART, but it is required for a subset of ART called “collaborative reproduction,” which is the focus of this Note. Collaborative reproduction is the use of “eggs, sperm, or embryos of a third party to create a child biologically unrelated to at least one intending parent.”<sup>17</sup> By definition, the donation of an egg, or sperm, or both, is needed for collaborative reproduction.<sup>18</sup> The most common type of ART is in vitro fertilization (IVF),<sup>19</sup> where the sperm fertilizes the egg outside of the womb, making an embryo; the embryo is then implanted into the womb.<sup>20</sup> When the egg or sperm or both come from a third party, the IVF is considered collaborative reproduction.

“Donor” nomenclature and variations of this term are standard within the ART field. However, this paper purposefully does not use this term as a call to scrutinize its use. Instead, this Note will use variations of the term “supplier” in order to more accurately describe the nature of a woman’s actions in what is commonly referred to as “egg donation.” In a minority of instances, third-party women provide human eggs without any kind of compensation or remuneration;<sup>21</sup> in those circumstances they are in fact “donors.” Yet in most circumstances, these women are not actually donors but instead are provided with compensation, either for their services or discomfort, or in direct payment for the eggs procured.<sup>22</sup> To put it accurately, then, these women are not “donors” in any sense of the word, but paid “suppliers” of eggs. It is important to acknowledge this distinction between donors and suppliers, because compensation fundamentally changes the na-

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16. *What is Assisted Reproductive Technology?*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/art/whatis.html> (last visited Nov. 14, 2014).

17. Helen M. Alvaré, *The Case for Regulating Collaborative Reproduction: A Children’s Rights Perspective*, 40 HARV. J. ON LEGIS. 1, 1 (2003).

18. *Id.*

19. NAT’L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, 2013 ASSISTED REPRODUCTIVE TECHNOLOGY FERTILITY CLINIC SUCCESS RATES REPORT 3 (2015), <http://www.cdc.gov/art/pdf/2013-report/art-2013-fertility-clinic-report.pdf> [hereinafter 2013 FERTILITY CLINIC SUCCESS RATES REPORT].

20. *In vitro fertilization (IVF)*, MAYO CLINIC, <http://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/home/ovc-20206838> (last visited Aug. 23, 2016).

21. See Jacoba Urist, *How Much Should a Woman Be Paid for Her Eggs?*, THE ATLANTIC (Nov. 4, 2015), <http://www.theatlantic.com/health/archive/2015/11/how-much-should-a-woman-be-paid-for-her-eggs/414142/>.

22. See *id.* (drawing attention to how there is little consensus over what the financial compensation is actually for).

ture of the transaction. The donor nomenclature hides the compensation element, which raises issues of societal distaste and significant ethical debate.<sup>23</sup>

Rather than propose specific legislative reforms needed in the ART industry, I will focus on the failures of the current regulatory scheme in the ART industry and how the unique characteristics of this field justify its further regulation. This Note will focus on the egg harvesting process from the perspective of female egg suppliers. By placing attention on prospective egg suppliers, I am concerned with those women who are unacquainted with the egg recipient and are not an intended parent of the resulting offspring.<sup>24</sup> There are other important interests involved in collaborative reproduction that will not be addressed here, such as those of the future offspring, the gamete recipient, and the general public.

This Note explains the science behind the harvesting of human eggs, focusing on the profile of potential egg suppliers, and details the specific factors that make egg harvesting a unique type of transaction. It also describes the current regulatory status of the assisted reproductive technology industry in the United States and highlights how this scheme has failed to protect egg suppliers. Taken together, this provides the justification for and a call for comprehensive regulation of the assisted reproductive technology industry.

## I. THE SCIENCE BEHIND EGG HARVESTING PROCEDURES

To fully appreciate why women providing eggs to others for reproduction should be regulated in ways that it currently is not, it is important to understand the medical procedures involved in such a decision. Once a woman decides to become an egg supplier, she undergoes a two-phase medical treatment that is completed over the course of a month.<sup>25</sup> The first stage

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23. See generally Kenneth Baum, *Golden Eggs: Towards the Rational Regulation of Oocyte Donation*, 2001 B.Y.U. L. REV. 107 (2001) (discussing the merits of regulating oocyte donor compensation); Michael Hiltzik, *Should We Pay Women to Donate Their Eggs for Research? No, and Here's Why*, L.A. TIMES (July 22, 2016), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-egg-donors-20160722-snap-story.html>.

24. The intention of individuals to be parents prior to the ART treatments is legally significant and helps to determine parental rights for the child later, at least in some states. See *Elisa B. v. Superior Court*, 117 P.3d 660, 668–70 (Cal. 2005). But see, *C. M. v. C. C.*, 377 A.2d 821 (Juv. & Dom. Rel. Ct. Cumberland Cnty, N.J. 1977) (granting visitation rights to plaintiff, biological father, who donated sperm to an unmarried woman).

25. Margaret R. Sobota, Note, *The Price of Life: \$50,000 for an Egg. Why Not \$1,500 for a Kidney? An Argument to Establish a Market for Organ Procurement Similar to the Current Market for Human Egg Procurement*, 82 WASH. U. L.Q. 1225, 1243 (2004).

is called ovarian hyper-stimulation or super-ovulation.<sup>26</sup> In this stage, the supplier takes a series of hormone medications, causing her body to deviate from the natural menstruation process that produces a single egg per cycle, and instead produces ten to twenty eggs in a single cycle.<sup>27</sup> Some of the hormone medications used in super-ovulation are administered through daily injections.<sup>28</sup> In the last five days of the hormonal treatments, the supplier is monitored with near-daily blood tests and ultrasounds to determine precisely when the eggs have matured.<sup>29</sup> A final injection of human chorionic gonadotropin (hCG) is administered and the second stage, called egg retrieval, begins in the following twenty-four to forty-eight hours.<sup>30</sup> The supplier undergoes transvaginal ultrasound aspiration, a surgical procedure in which the doctor removes the mature eggs from the supplier's body while she is under conscious sedation.<sup>31</sup> Guided by a transvaginal ultrasound, a doctor uses a suctioning needle to physically remove the oocytes from the follicles within her ovaries.<sup>32</sup>

#### A. Physical Health Risks of Egg Harvesting Procedures

The process of super-ovulation and egg retrieval is invasive. It is classified as a surgery<sup>33</sup> and carries concomitant health risks, only some of which are known. Mildred Cho, of the Stanford University Center for Biomedical Ethics in California, advocates for more research to uncover these risks, because it is "important for people to understand in the consent process that we don't know as much as we should about what those risks are."<sup>34</sup> Furthermore, Louise Brinton, of the U.S. National Cancer Institute, has completed preliminary studies of the associated cancer risks, but she is convinced that the risk analysis is incomplete.<sup>35</sup>

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26. Stanford University, *The Medical Procedure of Egg Donation*, THE EGG DONOR INFORMATION PROJECT, <http://www.stanford.edu/class/siw198q/websites/eggdonor/procedures.html> (last visited Aug. 23, 2016).

27. Brittany L. Marvin, *Regulating the Procurement of Female Gametes: Donors' Health and Safety*, 16 MICH. ST. U. J. MED. & L. 117, 122 (2011).

28. *The Medical Procedure of Egg Donation*, *supra* note 26.

29. Sobota, *supra* note 25, at 1243.

30. Marvin, *supra* note 27, at 122.

31. *The Medical Procedure of Egg Donation*, *supra* note 26.

32. *Id.*

33. *Id.*; Hiltzik, *supra* note 23.

34. Helen Pearson, *Health Effects of Egg Donation May Take Decades to Emerge*, 422 NATURE 607 (2006), <http://www.nature.com/nature/journal/v442/n7103/full/442607a.html>.

35. *Id.*

Some known short-term effects from ovarian hyper-stimulation include swelling, bruising, and menopause-like symptoms.<sup>36</sup> Certain commonly used, FDA-approved fertility drugs reportedly cause a litany of side effects: rashes, burning sensations, tingling, migraines, hives, hair loss, severe joint pain, difficulty breathing, chest pain, nausea, depression, fainting, amnesia, hypertension, rapid heart rate, muscle pain, bone pain, abdominal pain, insomnia, chronic enlargement of the thyroid, liver function abnormality, anxiety, and vertigo.<sup>37</sup> Other complications include adnexal torsion, a condition where a drug-stimulated ovary changes its position in such a way that cuts off its blood supply.<sup>38</sup> This serious condition requires medical intervention to untwist or remove the affected ovary, thus affecting an egg supplier's fertility and ability to have her own children in the future.<sup>39</sup>

It is also possible for egg suppliers to contract ovarian hyper-stimulation syndrome (OHSS).<sup>40</sup> This syndrome may present symptoms ranging from mild to severe, commonly requiring hospitalization.<sup>41</sup> Symptoms include fluid build-up in the chest and abdomen, difficulty breathing, kidney damage, and blood clotting disorders, which can result in permanent injury or even death.<sup>42</sup> The risk of OHSS is positively correlated with higher doses of the hormonal injections,<sup>43</sup> which are critical to produce eggs ten to twenty times greater than the body's cycle would naturally produce; these risks increase for younger women.<sup>44</sup>

Increased risk for colon cancer has been conclusively linked to hormone therapies that include gonadotropin, a hormone used in the egg harvesting procedure to induce the expulsion of ovum in the final days of ovarian hyper-stimulation.<sup>45</sup> The use of this hormone increases the risk for colon cancer by thirty to forty percent compared to those patients who did

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36. *The Medical Procedure of Egg Donation*, *supra* note 26.

37. Judy Norsigian, *Egg Donation Dangers*, COUNCIL FOR RESPONSIBLE GENETICS, <http://www.councilforresponsiblegenetics.org/ViewPage.aspx?pageId=103> (last visited Sept. 12, 2016).

38. *The Medical Procedure of Egg Donation*, *supra* note 26.

39. *Id.*

40. *Id.*

41. Practice Comm., Am. Soc'y for Reprod. Med., *Ovarian Hyperstimulation Syndrome*, 90 FERTILITY & STERILITY S188, S188–89 (2008) [hereinafter *Ovarian Hyperstimulation Syndrome*].

42. Alison Motluk, *The Human Egg Trade: How Canada's Fertility Laws Are Failing Donors, Doctors, and Patients*, THE WALRUS, Apr. 12, 2010, at 35, <https://thewalrus.ca/the-human-egg-trade>.

43. *Ovarian Hyperstimulation Syndrome*, *supra* note 41, at S188.

44. *Id.* at S191.

45. *The Medical Procedure of Egg Donation*, *supra* note 26.



not have this type of hormone therapy.<sup>46</sup> Super-ovulation may also be correlated with ovarian cancer; the risk for a woman who undergoes ovarian stimulation is double that of a woman who does not.<sup>47</sup> The risk of ovarian cancer increases even more if a woman does not get pregnant,<sup>48</sup> and particularly if she uses certain fertility drugs for more than twelve months.<sup>49</sup> According to a 2003 study, ovarian hyper-stimulation may have the capacity to cause serious pulmonary, neurological and hematological complications.<sup>50</sup> This summarizes the *known* serious risks posed by the invasive procedure of egg harvesting; there may remain risks as yet unknown.

### B. Egg Supplier Profile

The ART industry revolves around the egg recipient, and therefore not a lot of information is collected about the egg suppliers.<sup>51</sup> However, we know that egg suppliers are generally young, healthy women.<sup>52</sup> The health and age of the supplier are significant factors in ensuring the health of the provided eggs.<sup>53</sup> In an effort to maintain some quality control, organizations that connect egg suppliers with fertility clinics will put potential donors

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46. Jennifer H. Lin & Edward Giovannucci, *Sex Hormones and Colorectal Cancer: What Have We Learned So Far?*, 102 J. NAT'L CANCER INST. 1746, 1746 (2010) ("Patients who received treatment with gonadotrophin-releasing hormone agonists or orchiectomy had a 30%–40% increased risk of developing colorectal cancer relative to those who did not have the therapies.").

47. John W. Malo, *Ovulation Induction and Cancer*, GA. REPROD. SPECIALISTS, <http://www.ivf.com/ovca.html> (last visited Sept. 13, 2016) (explaining that the incidence of ovarian cancer in the general population is low, typically 1–1.8%, while the lifetime risk is approximately 4–5% among women who have taken ovulation-inducing medications).

48. *Id.* (noting that pregnancy following ovarian stimulation seems to have ameliorating effects, and that those who are exposed to the fertility hormones but later get pregnant do not have the same risk multiplier).

49. *The Medical Procedure of Egg Donation*, *supra* note 26 (stating that women who use the non-naturally occurring fertility drug clomiphene for more than one year increase their risk of ovarian cancer).

50. Victoria Uroz & Lucia Guerra, *Donation of Eggs in Assisted Reproduction and Informed Consent*, 28 MED. & L. 565, 569 (2009).

51. See 2013 FERTILITY CLINIC SUCCESS RATES REPORT, *supra* note 19, at 8 (noting that the only information collected about egg suppliers is their age); Sarah B. Angel, *The Value of the Human Egg: An Analysis of Risk and Reward in Stem Cell Research*, 22 BERKLEY J. GENDER L. & JUST. 183, 199-200 (2013) (noting the scant information about egg suppliers).

52. EMILY GALPERN, ASSISTED REPRODUCTIVE TECHNOLOGIES: OVERVIEW AND PERSPECTIVE USING A REPRODUCTIVE JUSTICE FRAMEWORK 16 (2007) <http://www.geneticsandsociety.org/downloads/ART.pdf>.

53. *Id.*

through various screening tests prior to approving them for the process.<sup>54</sup> For example, these tests might include a fertility screening to check the health of the ovaries; medical screening for general health, blood type, infectious disease, and sexually transmitted infections; genetic screening for risks of hereditary or family disease; and psychological screening to ensure the egg provider is prepared to make her decision to become a supplier.<sup>55</sup>

The physiological reality is that fertility is related to age.<sup>56</sup> The peak of fertility generally occurs in women between the age of twenty-three and thirty-one.<sup>57</sup> At thirty-one, your fertility begins to decline quickly.<sup>58</sup> At thirty-nine, your chances of conceiving are half what they were at thirty-one, and by forty-two, they decrease by fifty percent again.<sup>59</sup> Modern medicine and technology have not been able to change this fact of nature.<sup>60</sup> In 2013, the average egg supplier was twenty-six years old.<sup>61</sup>

Beyond health and age, other important qualifications for an egg supplier are often egg recipient-specific.<sup>62</sup> Egg recipients tend to want children that will look like themselves.<sup>63</sup> Moreover, egg recipients are often willing to pay more for eggs from a supplier with specific traits, such as high SAT scores, athletic ability, etc.<sup>64</sup> Seventy-five percent of egg suppliers are college students, because they are “likely to be young, healthy, and in need of money.”<sup>65</sup> Furthermore, it is evident that there is a socioeconomic difference between the women who are receiving the eggs, who are affluent and

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54. *The Big Business of Egg Donation*, ABC NEWS, Nov. 6, 2015, <https://www.youtube.com/watch?v=8zV8SVLMP1w>.

55. See, e.g., *The Donation Process*, EGG DONOR AMERICA, <https://www.eggdonoramerica.com/become-egg-donor/the-donation-process> (last visited Aug. 25, 2016) (describing its egg supplier screening process); *The Big Business of Egg Donation*, *supra* note 54.

56. Christie Aschwanden, *Fertility 101*, WEBMD, <http://www.webmd.com/baby/features/fertility-101#1> (last visited Sept. 11, 2016).

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

61. 2013 FERTILITY CLINIC SUCCESS RATES REPORT, *supra* note 19, at, at 8.

62. See Sandra G. Boodman, *Egg Donation Demand Soars, but Many Long-Term Effects Unknown*, THE RUNDOWN (June 21, 2016), <http://www.pbs.org/newshour/run-down/egg-donation-demand-soars-but-many-long-term-effects-unknown/> (stating that people are willing to spend more money to find a donor with particular traits).

63. *The Big Business of Egg Donation*, *supra* note 54.

64. See, e.g., Gina Kolata, *\$50,000 Offered to Tall, Smart Egg Donor*, N.Y. TIMES (Mar. 3, 1999), [www.nytimes.com/1999/03/03/us/50000-offered-to-tall-smart-egg-donor.html](http://www.nytimes.com/1999/03/03/us/50000-offered-to-tall-smart-egg-donor.html).

65. GALPERN, *supra* note 52, at 16.

can afford to undergo costly, elective procedures, and the women who are supplying the eggs, who are often financially stressed.<sup>66</sup>

## II EGG HARVESTING IS A UNIQUE TRANSACTION THAT CANNOT COMPARE TO OTHER MEDICAL TREATMENTS

Unique attributes of ART create a high risk of undue influence on potential donors and justify a greater need for government intervention. The fertility clinics' opportunity for huge profits at the expense of egg suppliers, the conflict of interest that ART medical doctors face, and the romanticized rhetoric surrounding ART all contribute to an unusual and highly manipulative transactional environment.

The most important difference between egg harvesting and other medical procedures is the unique circumstance wherein egg supplier patients receive, instead of remit, payments for a medical procedure. Whether the compensation is a "direct" payment for eggs or is limited to compensation commensurate with time and inconvenience, the financial aspect of this transaction fundamentally changes the assumptions we have about doctor-patient relationships. Third party egg donors are young, healthy women who are exposed to the physical and psychological risks of this procedure in exchange for money. The nature of the procedure is non-therapeutic; it confers no curative health benefit in exchange for exposure to risk. Instead, it confers risk in exchange for financial compensation. Super-ovulation and egg retrieval from egg suppliers are not the only non-therapeutic medical treatments, but they are the only treatments where patients actually earn income.<sup>67</sup>

As a result of this exposure to risk, suppliers also create an opportunity for fertility clinics to make large profits. There is a sizeable demand for ART services in the United States.<sup>68</sup> "Of the approximately 61 million women aged fifteen to forty-four in 2011–2013, about 6.9 million, or 11%, had

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66. EVELINA WEIDMAN STERLING & ELLEN SARASOHN GLAZER, *HAVING YOUR BABY THROUGH EGG DONATION* 291 (2nd ed.2013), [https://books.google.com/books?id=cownXvUUE0oC&pg=PA291&lpg=PA291&dq=socioeconomic+egg+donor&source=bl&ots=1xG0lscOIV&sig=i\\_b03gsRPPg-60j0n7Q8D4o8dYE&hl=en&sa=X&ved=0ahUKEwiQ-nw7NLOAhXCPB4KHdFACG4Q6AEISTAE#v=onepage&q=socioeconomic&f=false](https://books.google.com/books?id=cownXvUUE0oC&pg=PA291&lpg=PA291&dq=socioeconomic+egg+donor&source=bl&ots=1xG0lscOIV&sig=i_b03gsRPPg-60j0n7Q8D4o8dYE&hl=en&sa=X&ved=0ahUKEwiQ-nw7NLOAhXCPB4KHdFACG4Q6AEISTAE#v=onepage&q=socioeconomic&f=false).

67. Cf. Bridget J. Crawford, *Taxation, Pregnancy, and Privacy*, 16 WM. & MARY J. WOMEN & L. 327, 333 (2010) (arguing that replenishable bodily fluids like blood plasma and breast milk are ordinary assets for income tax purposes, while body parts such as kidneys and lungs may not be, because they are not replenishable. This analogy may extend to sperm and egg donations).

68. Justine Durrell, *Women's Eggs: Exceptional Endings*, 22 HASTINGS WOMEN'S L.J. 187, 216 (2011) ("demand far outstrips the current human egg supply").

received infertility services at some time in their lives.”<sup>69</sup> The CDC describes a woman as infertile when she has been unable to get pregnant in more than twelve months.<sup>70</sup> In 2010, about 1.5 million, or 12%, of married women between the ages fifteen and forty-four were infertile based on this definition.<sup>71</sup> According to the CDC, in 2014, 208,604 ART cycles were performed across 458 reporting clinics in the United States.<sup>72</sup> A 2014 study of the global market for ART services demonstrated that North America dominated the global market, and accounted for \$8.6 billion in revenue.<sup>73</sup> Furthermore, demand for ART services is expanding beyond just infertile women to include male homosexual couples.<sup>74</sup>

Access to the collaborative reproduction marketplace requires finding women willing to assume the risks associated with supplying their eggs in exchange for payment. Further limiting this group is the fact that ideal egg suppliers are between the ages of twenty-one and thirty-four years old.<sup>75</sup> This is important because diminished fertility is linked with advanced age.<sup>76</sup> During egg harvesting, clinicians seek to produce ten to twenty follicles in a single cycle.<sup>77</sup> On average, an ART cycle in the United States costs infertile couples \$12,400.<sup>78</sup> Some couples spend as much as \$100,000 before

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69. 2013 FERTILITY CLINIC SUCCESS RATES REPORT, *supra* note 19, at 3.

70. *Id.* at 528.

71. CTR. FOR DISEASE CONTROL & PREVENTION, 2011 FERTILITY CLINIC SUCCESS RATES REPORT 3 (2011) [hereinafter 2011 FERTILITY CLINIC SUCCESS RATES REPORT].

72. *ART Success Rates*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/art/artdata/index.html> (last updated June 21, 2006).

73. *Assisted Reproductive Technology (ART) Market Analysis By Procedures (Frozen Non-Donor, Frozen Donor, Fresh Donor, Fresh Non-Donor, Embryo/Egg Banking) And Segment Forecasts to 2022*, GRAND VIEW RESEARCH (2016), <http://www.grandviewresearch.com/industry-analysis/assisted-reproductive-technology-market>.

74. See Debora Spar, *Where Babies Come From: Supply and Demand in an Infant Marketplace*, HARV. BUS. REV. (2006), <https://hbr.org/2006/02/where-babies-come-from-supply-and-demand-in-an-infant-marketplace> (noting that homosexual couples interested in having offspring related to both parents would be in high demand of reproductive services).

75. Practice Comm., Am. Soc’y for Reprod. Med., *Recommendations for Gamete and Embryo Donation: A Committee Opinion*, 99 FERTILITY & STERILITY 47, 55 (2012) [hereinafter *Recommendations for Gamete and Embryo Donation*]. See *supra* Section I.B.

76. See Lisa M. Luetkemeyer, *Who’s Guarding the Henhouse and What Are They Doing with the Eggs (and Sperm)? A Call for Increased Regulation of Gamete Donation and Long-Term Tracking of Donor Gametes*, 3 ST. LOUIS U. J. HEALTH L. & POL’Y 397, 400 (2010).

77. Marvin, *supra* note 27, at 122.

78. *Frequently Asked Questions About Infertility Q06: Is Infertility Expensive?*, AM. SOC’Y FOR REPROD. MED., <https://www.asrm.org/awards/index.aspx?id=3012> (last visited Aug. 20, 2016).

conceiving or giving up.<sup>79</sup> Therefore, each time an egg supplier is approved, she represents an average of \$120,000–\$240,000 of potential gross income for a fertility clinic. Furthermore, the fertility industry has grown quickly during a short period of time. In 1986, there were only 100 fertility clinics in the United States, but in the last two decades, these clinics have more than quadrupled to 428 clinics.<sup>80</sup> In the same time period, their revenues have grown sixty fold, from \$41 million to almost \$3 billion.<sup>81</sup> In fact, the market is even larger than these statistics suggest because these values exclude payment to third party beneficiaries of the fertility market: attorneys, consultants, counselors, equipment manufacturers, and suppliers.<sup>82</sup> The fact that American health insurance companies largely consider infertility to be a socially-constructed need and IVF to be an experimental treatment<sup>83</sup> facilitates the growth of the industry's private players. These companies' profits are not restricted by insurance reimbursement rates or other regulatory price ceilings, so they can maximize profit potential based on demand.<sup>84</sup> The CDC reported that in 2011, the average egg supplier was twenty-eight years old,<sup>85</sup> and use of supplier eggs resulted in a pregnancy success rate of 54.8%.<sup>86</sup> Even in comparison to the most successful age group of patients who use their own eggs, supplier pregnancy success rates are at least eight percentage points higher.<sup>87</sup> This means that using third-party-supplier eggs is generally more successful than interested party eggs, and thus more profitable for fertility clinics. As a consequence, fertility clinics highly value the egg supplier market.

Arthur Caplan, director of the division of medical ethics at New York University's School of Medicine says that ART is "a field characterized by

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79. Kimberly D. Krawiec, *Altruism and Intermediation in the Market for Babies*, 66 WASH & LEE L. REV. 203, 213 (2009).

80. *Id.* at 212.

81. *Id.*

82. *See id.* at 212–13.

83. Ahmad O. Hammoud, M.D., et al., *In Vitro Fertilization Availability and Utilization in the United States: A Study of Demographic, Social, and Economic Factors*, 91 FERTILITY AND STERILITY 1630, 1634 (2009).

84. *See, e.g.*, ISLAT Working Group, *ART into Science: Regulation of Fertility Techniques*, 281 SCIENCE 651 (1998) (stating that the ART industry amasses over \$2 billion in the United States in annual revenue and has been accessed by infertile couples in the United States at a rate of 1 in 6, demonstrating the rapid growth of ART on a national scale).

85. 2011 FERTILITY CLINIC SUCCESS RATES REPORT, *supra* note 71, at 8.

86. *Id.* at 24. A pregnancy success rate indicates the percentage of embryo transfers resulting in live births.

87. *Id.* (demonstrating that the pregnancy success rate per transfer for women under thirty-five using their own eggs was 46.0% as compared to the 54.8% success rate when women use donor eggs).

strong anti-regulatory sentiment because it evolved as a business, not a research enterprise.”<sup>88</sup> Medical doctors working at a fertility clinic must navigate a conflict of interest between their employer and the egg supplier patient. They do not comfortably fit within the legal understanding of the physician-patient relationship, which assumes a context of neutrality, objectivity, and non-ideological motivation in furthering the patients’ best interests.<sup>89</sup> As employees of fertility clinics, the physicians’ compensation depends on the continued success of the clinic. The fertility clinic has much to gain financially by completing any given ART cycle, which creates an interest in harvesting as many third-party-supplier eggs as possible. Medical doctors take an oath to act in the best interests of their patients, the egg suppliers. Sometimes, because the ART cycles have significant health risks, it is in the patient’s best interest to terminate the cycle without reaching the egg retrieval stage. When that situation arises, it creates a direct conflict between the physician’s Hippocratic oath and the economic interests of the fertility clinic. Commenters highlight the need for short- and long-term clinical studies on the effects of ovarian hyper-stimulation and egg retrieval on egg suppliers.<sup>90</sup> This conflict of interest may account for the lack of scientific evidence available regarding the effects of or increased risks created by the egg harvesting procedures.<sup>91</sup> Considering that the first “test-tube” baby was born more than three decades ago in 1978,<sup>92</sup> it is tempting to explain the persisting dearth of research on health effects as neglect of patients in service of industry self-interest. It is plain that fertility clinics’ business model discourages the pursuit of long-term studies that may clarify and confirm the risks that they impose on their patients.<sup>93</sup>

Another characteristic that separates collaborative reproduction from other medical procedures is the romanticized rhetoric that follows the

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88. 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](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).

89. See Susan Stefan, *Leaving Civil Rights to the “Experts”: From Deference to Abdication Under the Professional Judgment Standard*, 102 YALE L.J. 639, 654–55 (1992).

90. See W. Kramer, J. Schneider, and N. Schultz, *U.S. Oocyte Donors: A Retrospective Study of Medical and Psychosocial Issues* 6 HUMAN REPROD. 3148–49 (2009), <http://humrep.oxfordjournals.org/content/21/6/1503.short>; Hiltzik, *supra* note 23.

91. COMM. ON ASSESSING THE MED. RISKS OF HUMAN OOCYTE DONATION FOR STEM CELL RESEARCH, WORKSHOP REPORT 4 (Linda Giudice, et al. eds., 2007), [http://www.nap.edu/openbook.php?record\\_id=11832&page=4](http://www.nap.edu/openbook.php?record_id=11832&page=4) (calling for the accumulation of extensive health data from women whose eggs are harvested and monitoring the long term effects of the procedure); Hiltzik, *supra* note 23.

92. ‘Test-tube baby’ Brown Hails Pioneers on 35th Birthday, B.B.C. NEWS (Jul. 25, 2013), <http://www.bbc.co.uk/news/health-23448665>.

93. Durrell, *supra* note 68, at 220.

baby-making industry.<sup>94</sup> There is a trend demonstrated by different players involved in assisted reproductive technology to sentimentalize the industry. Suppliers, physicians, egg broker agencies and others across the industry exhibit a “pretense that profit-seeking and market forces are, at best, secondary considerations in matters so sacred as reproduction and parenthood.”<sup>95</sup> This is evidenced in the names of egg brokers and agencies: for example, “Creative Love Egg Donation,”<sup>96</sup> “Happy Beginnings,”<sup>97</sup> “First Smile Egg Donation Agency,”<sup>98</sup> and “Graceful Conception.”<sup>99</sup> They also use psychologically-manipulative marketing language such as: “Congratulations! You are taking the first step in creating a miracle. How often do you get to be a part of something so spectacular?;”<sup>100</sup> “Parenthood is magical, it is a gift, a miracle;”<sup>101</sup> “Sharing the gift of life.”<sup>102</sup> In the words of physicians at Boston IVF, “our greatest honor is knowing that at least one of our patients fulfills their dream of becoming a parent every day of every year.”<sup>103</sup> This romanticized rhetoric is reflected in the egg supplier psyche—altruism is one of the primary motivating factors potential egg suppliers profess in mental health pre-screenings.<sup>104</sup> They describe their feelings with statements such as, “I know somebody who can’t have a child. I want to help somebody.”<sup>105</sup> This sort of rhetoric pervades the ART industry marketing material and has the effect of diverting attention away from the financial incentives at work in the industry.

The industry targets healthy young women because they possess the only available source of eggs. Considering the huge market demand for such

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94. Melanie Thernstrom, *Meet the Twiblings*, N.Y. TIMES MAGAZINE (Dec. 29, 2010), <http://www.nytimes.com/2011/01/02/magazine/02babymaking-t.html> (commenting on how this romanticism sickened a woman seeking a donor).

95. Krawiec, *supra* note 79, at 213.

96. CREATIVE LOVE EGG DONOR & SURROGATE AGENCY, <http://www.cledp.com> (last visited Aug. 20, 2016).

97. HAPPY BEGININGS, LLC, <http://www.happybeginningseggdonation.com> (last visited Aug. 20, 2016).

98. FIRST SMILE EGG DONATION AGENCY, <https://firstsmileeggdonation.com> (last visited Aug. 20, 2016).

99. GRACEFUL CONCEPTION, <http://www.gracefulconception.com> (last visited Aug. 20, 2016).

100. *Egg Donor Program Introduction*, FERTILITY BRIDGES, <http://www.fertilitybridges.com/egg-donor-program/as-egg-donor/?gclid=CIK2leGAv7sCFUQ6Qgodj1wAfQ> (last visited Aug. 20, 2016).

101. CREATIVE LOVE EGG DONOR & SURROGATE AGENCY, *supra* note 96.

102. GRACEFUL CONCEPTION, *supra* note 99.

103. Krawiec, *supra* note 79, at 213.

104. COMM.ON ASSESSING THE MED. RISKS OF HUMAN OOCYTE DONATION FOR STEM CELL RESEARCH, WORKSHOP REPORT 43 (Linda Giudice, et al. eds., 2007), [http://www.nap.edu/openbook.php?record\\_id=11832&pager1](http://www.nap.edu/openbook.php?record_id=11832&pager1).

105. *Id.*

eggs, egg suppliers create the potential for enormous industry profits. These financial incentives, coupled with other conflicts of interest, an unregulated market, and a continuing refusal to commission long-term health studies, create a recipe for ART service providers to exert undue influence over vulnerable patients, which heightens the need for governmental intervention.

### III. THE CURRENT REGULATORY SCHEME COVERING THE EGG HARVESTING BUSINESS

The current ART regulatory scheme in the United States is “patchwork” at best.<sup>106</sup> George Annas, a notable bioethicist, professor at the Boston University School of Public Health, and board member of the Ethics Advisory Board of the Society for Assisted Reproductive Technology (SART) and the American Society of Reproductive Medicine (ASRM), refers to assisted reproductive technology as “the Wild West” of American medicine.<sup>107</sup>

In theory, the American regulatory scheme for ART runs the gamut from Food and Drug Administration (FDA) directives, the Federal Trade Commission (FTC) directives, state-level statutes, self-regulatory guidelines espoused by professional medical societies, and judicial involvement through tort claims. Given the limited scale of federal and state regulation, the reality is that the industry is mostly self-regulated. According to the CDC’s 2013 National Summary Report on Assisted Reproductive Technology, 190,773 ART cycles were performed across 467 reporting clinics in the United States during 2013.<sup>108</sup> Despite the fact that the ART industry constitutes a \$3 billion dollar industry and assists one million patients across a variety of services,<sup>109</sup> the United States government has taken a *laissez faire* approach to its regulation.<sup>110</sup>

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106. Helen M. Alvaré, *supra* note 17, at 26; Michelle Bercovici, *Biotechnology Beyond the Embryo: Science, Ethics, and Responsible Regulation of Egg Donation to Protect Women’s Rights*, 29 WOMEN’S RTS. L. REP. 193, 198 (2008); Marvin, *supra* note 27, at 129.

107. Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past—Present, and Future?*, 36 CONN. L. REV. 125, 179 (2003).

108. 2013 FERTILITY CLINIC SUCCESS RATES REPORT, *supra* note 19, at 3.

109. Krawiec, *supra* note 79, at 211 (discussing industry data from 2004).

110. *Ovarian Stimulation and Egg Retrieval: Overview & Issues to Consider*, REPROD. HEALTH TECH. PROJECT, <http://www.rhtp.org/fertility/assisted/documents/OvarianStimulationandEggRetrieval-Issues.pdf> (“little to no US government oversight and regulation”). See also Spar, *supra* note 74 (suggesting that this approach comes from America’s typical reluctance to regulate emerging markets combined with the fact that ART is closely connected to the divisive abortion debate in the US).



*A. Federal Regulations Govern ART Facilities With Limited Binding Authority*

Although you might expect the FDA to be the federal authority with jurisdiction over the ART industry, in reality, the agency imposes few binding standards.<sup>111</sup> The United States has a long regulatory history that respects the autonomy of the doctor-patient relationship.<sup>112</sup> The FDA's authority is limited by this principle and by Congressional admonition that it not directly interfere with the discretion of medical doctors.<sup>113</sup> Because medical practitioners both supervise and perform egg donation procedures, ART is largely beyond the direct reach of FDA regulation.<sup>114</sup> Congress' desire to maintain this regulatory "hands off" posture was made explicit in the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA): "In developing the certification program, the Secretary [of the Department of Health and Human Services] may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in an assisted reproductive technology program."<sup>115</sup>

ART clinics operate largely independently of public funding.<sup>116</sup> Legal precedent regarding the fundamental right of procreation, and the politically contentious nature of abortion laws, have in part impacted lawmakers' ability to regulate the ART industry more closely.<sup>117</sup> A limitation on federal funding for procreative exercise leaves IVF clinics separated not only from the Congressional purse but, notably, from the federal oversight that attaches to such Congressional funding.<sup>118</sup> As a result, federal regulations de-

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111. ASRM Practice Guidelines point to "FDA required" testing for the purposes of determining donor eligibility. However the FDA has merely provided guidelines, which are just one of many alternatives that can be chosen, so long as the procedures carried out "satisf[y] the applicable statutes and regulations." U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) 1 (2007), <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.pdf>.

112. Philip M. Rosoff & Doriane Lambelet Coleman, *The Case for Legal Regulation of Physicians' Off-Label Prescribing*, 86 NOTRE DAME L. REV. 649, 659 (2011) ("This society has a strong tradition of deference to physicians' autonomy and judgment in the context of the physician-patient relationship.").

113. See Michael J. Malinowski & Radhika Rao, *Legal Limitations on Genetic Research and the Commercialization of Its Results*, 54 AM. J. COMP. L. 45, 60 (2006).

114. *Id.*

115. 42 U.S.C.A. § 263a-2(i)(1)(2000) (Westlaw through Pub. L. No. 114-219).

116. In part, this is a result of American abortion law jurisprudence, a topic outside the scope of this paper. See ISLAT Working Group *supra* note 84, at 652.

117. Helen M. Alvaré, *Gonzales v. Carhart: Bringing Abortion Law Back into the Family Law Fold*, 69 MONT. L. REV. 409, 417 (2008); Spar, *supra* note 74.

118. ISLAT Working Group, *supra* note 84, at 651-52.

signed to protect women, such as those participating in research experiments,<sup>119</sup> have not been meaningfully applied to ART. For example, while the FCSRCA mandated a reporting system administered by the CDC, this system focuses on the success rate of ART rather than the health of egg suppliers.<sup>120</sup> The CDC is obligated to collect data and report on the success rates and live births produced by all fertility providers.<sup>121</sup> The data collected in these reports includes the egg recipients' "medical history (such as infertility diagnosis), clinical information pertaining to the ART procedure, and information on resulting pregnancies and births."<sup>122</sup> The only information the CDC report requires about egg suppliers is their age.<sup>123</sup>

The FDA is indirectly involved in ART through the labeling and distribution of the hormone injectable drugs used in ovarian hyper-stimulation.<sup>124</sup> However, the FDA has no oversight of the medical profession's use of the drugs.<sup>125</sup> In fact, it is commonplace and legal for physicians to prescribe "drugs for indications, in dosages, and following treatment protocols different from those expressly approved by the FDA."<sup>126</sup> This is known as off-label use.<sup>127</sup> Use of drugs such as FDA approved Lupron in super-ovulation protocols is considered off-label use.<sup>128</sup>

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119. Malinowski, *supra* note 107, at 198.

120. The act only requires ART programs to report "pregnancy success rates achieved by such program." Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C.A. § 263a-2 (Westlaw through Pub. L. No. 102-493).

121. TASK FORCE ON LIFE & THE LAW, N.Y. STATE DEP'T OF HEALTH, EXECUTIVE SUMMARY OF ASSISTED REPRODUCTIVE TECHNOLOGIES: ANALYSIS AND RECOMMENDATIONS FOR PUBLIC POLICY (2011), [http://www.health.ny.gov/regulations/task\\_force/reports\\_publications/exccsum.htm](http://www.health.ny.gov/regulations/task_force/reports_publications/exccsum.htm). Some commentators are skeptical about the accuracy of these reports, particularly because CDC site visits to verify the accuracy of the data are limited. *See, e.g.*, Malinowski, *supra* note 107, at 182. In 2011, only 35 of 451 reporting clinics were visited for a site check and data quality control. 2011 FERTILITY CLINIC SUCCESS RATES REPORT, *supra* note 71, at 6.

122. 2011 FERTILITY CLINIC SUCCESS RATES REPORT, *supra* note 71, at 4.

123. *Id.* at 8.

124. The FCSRCA requires ART programs to report "pregnancy success rates achieved by such program . . . ." 42 U.S.C.A. § 263a-1(a)(1)(1992) (Westlaw through Pub. L. No. 114-244).

125. *See* Monique C.M. Leahy, *Off-Label Use of Prescription Medications*, 124 AM. JUR. TRIALS 487 (2012).

126. *Id.* at § 1.

127. *See id.*

128. *See* Judy Norsigian, *Egg Donation Dangers*, COUNCIL FOR RESPONSIBLE GENETICS (2005), <http://www.councilforresponsiblegenetics.org/GeneWatch/GeneWatchPage.aspx?pageId=192> (last visited Sept. 25, 2016).

The FTC investigates deceptive claims made by healthcare providers engaged in interstate commerce, which includes ART providers.<sup>129</sup> The FTC has the specific authority to investigate claims made in promotional materials, advertisements, contracts, consent forms, and other point-of-sale materials.<sup>130</sup> In light of the industry's prevalent use of aggressive direct-to-consumer marketing tactics, this is an important role.<sup>131</sup> If the FTC can prove that there have been "unfair or deceptive practices," then it may issue cease-and-desist orders and impose civil penalties.<sup>132</sup> The FTC has entered into at least five cease-and-desist consent orders with ART providers following investigations uncovering inaccurate advertising claims, typically related to the providers' claims about the pregnancy success rates of a given fertility clinic.<sup>133</sup> However, given the size of the industry and the number of players, the FTC plays a minor role in impacting the industry's marketing practices.

*B. The State-by-State Experimental Approach to Gamete Donations Results  
In Meager Protection of Suppliers*

The void in binding federal directives regarding ART leaves industry regulation in the hands of individual state legislatures. Under the scheme developed by the FSCRCA, the CDC developed a model certification program to govern ART providers.<sup>134</sup> A prototype system was distributed to state legislatures for enactment at each state's discretion.<sup>135</sup> Not a single state has fully implemented the model program recommendation.<sup>136</sup> The CDC does not manage state implementation of its program; instead the CDC delegated its authority to the Society for Assisted Reproductive Technology (SART).<sup>137</sup> This delegation and optional certification program have rendered state implementation of the federal oversight plan feeble.<sup>138</sup>

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129. See PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 156 (2004), <http://bioethics.georgetown.edu/pcbe/reports/reproductionandresponsibility/index.html>.

130. See 15 U.S.C.A. § 45 (Westlaw through P.L. 114-219).

131. See *supra* Section II (discussing the romanticized marketing used in the industry).

132. See 15 U.S.C.A. § 45 (Westlaw through P.L. 114-219).

133. See TASK FORCE ON LIFE & THE LAW, *supra* note 121.

134. See Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs, 65 Fed. Reg. 53,310 (Aug. 28, 2000).

135. See Malinowski, *supra* note 107, at 182.

136. See *id.*

137. See *id.*

138. See *id.*

Independent of federal directives, state legislatures have variously protected egg suppliers<sup>139</sup> and ignored their interests.<sup>140</sup> Some states prescribe minimum information that must be provided to egg suppliers in order to constitute informed consent.<sup>141</sup> State statutes often declare that egg suppliers have no parental claims to the resulting offspring.<sup>142</sup> This protects egg suppliers from legal obligations that default parentage laws establish in coital offspring. The effect of the default rules is particularly important when gametes are provided to unacquainted recipients; in those situations, it seems evident that the intent of the ovarian stimulation and egg retrieval procedures is not to become pregnant.

At the time of this writing, the state of New York had the most comprehensive regulatory system for gamete donation and storage in the nation.<sup>143</sup> The New York State Task Force on Life and the Law provides the legislature with research and recommendations for guidelines and legislation, including, among other things, how to protect against the particular risks associated with ART.<sup>144</sup> Relevant recommendations deal with issues of gamete supplier informed consent, results of supplier screening, repeat suppliers, experimental procedures, payments for gametes, and parentage.<sup>145</sup>

There is a lower but varying degree of regulation by other states. Maryland prohibits posthumous tissue supply for the purposes of assisted reproduction; which protects the posthumous bodily integrity of a supplier.<sup>146</sup> Some states permit payment for gametes, while other states outlaw the practice,<sup>147</sup> but generally, supplier compensation for time and inconvenience is acceptable.<sup>148</sup> California requires the following language to be included

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139. See TEX. FAM. CODE ANN. § 160.704 (Westlaw through 2015 Legis. Sess.) (Texas exempts married women from a requirement that her husband consent to the procedure, if they are donating eggs for the purposes of assisted reproduction by another female).

140. For example, Louisiana prohibits the sale of ovum but does not address any further issues protecting egg suppliers. See LA. STAT. ANN § 9:122 (Westlaw through 2016 Legis. Sess.).

141. See, e.g., ARIZ. REV. STAT. ANN. § 36-1702 (2010); CAL. BUS. & PROF. CODE § 2260 (2005); N.Y. COMP. CODES R. & REGS. tit. 10, § 52-8.8 (2000); LA. STAT. ANN. § 14:101.2 (1999).

142. See, e.g., COLO. REV. STAT. ANN. § 19-4-106 (2009); CONN. GEN. STAT. ANN. § 45a-775 (2007); VA. CODE ANN. § 20-158 (2000); WASH. REV. CODE ANN. § 26.26.735 (2011) (donor may have rights if there is an explicit written agreement establishing the intent of the parties to impose parental rights and obligations on the egg donor).

143. See TASK FORCE ON LIFE & THE LAW, *supra* note 121.

144. *Id.*

145. *Id.*

146. MD. CODE ANN., Health-Gen. § 20-111 (2013).

147. TASK FORCE ON LIFE & THE LAW, *supra* note 121.

148. *Id.*

clearly and conspicuously in any advertisements seeking egg suppliers in exchange for compensation:

Egg donation involves a screening process. Not all potential egg donors are selected. Not all selected egg donors receive the monetary amounts or compensation advertised. As with any medical procedure, there may be risks associated with human egg donation. Before an egg donor agrees to begin the egg donation process, and signs a legally binding contract, she is required to receive specific information on the known risks of egg donation. Consultation with your doctor prior to entering into a donor contract is advised.<sup>149</sup>

This kind of regulation encourages donors to make informed choices, and, ideally, protects donors from aggressive promotional techniques.

A few state legislatures recognize a distinction between eggs harvested for collaborative reproduction and for medical research purposes, where compensation for eggs supplied to research is generally prohibited.<sup>150</sup> New York was the first state to allow compensation for supplying eggs for research purposes, including the use of government funds to do so.<sup>151</sup> The ethical debate about the effect that compensation has on egg suppliers is discussed below.<sup>152</sup>

The global trend against supplier anonymity (total or limited) has recently spread to the United States.<sup>153</sup> In 2011, Washington State became the first in the United States to eliminate the availability of an anonymous egg supply.<sup>154</sup> Washington now requires a minimum of non-identifying information to be available for future offspring,<sup>155</sup> though all other states allow suppliers to choose what kind of information and contact they want to provide for future offspring.

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149. CAL. HEALTH & SAFETY CODE § 125325 (2010).

150. California and Massachusetts explicitly ban compensation for egg donations that will be used for medical research purposes. *See id.*; MASS. GEN. LAWS ANN. ch. 111L, § 8 (2005).

151. Libby Nelson, *New York State Allows Payment for Egg Donations for Research*, N.Y. TIMES (June 26, 2009), [http://www.nytimes.com/2009/06/26/nyregion/26stemcell.html?\\_r=0](http://www.nytimes.com/2009/06/26/nyregion/26stemcell.html?_r=0).

152. *Infra* Section IV.C.1.

153. Gaia Bernstein, *Unintended Consequences: Prohibitions on Gamete Donor Anonymity and the Fragile Practice of Surrogacy*, 10 IND. HEALTH L. REV. 291, 292 (2013).

154. WASH. REV. CODE ANN. § 26.26.750 (2011).

155. *Id.*

State statutes also provide a range of supplier screening requirements; some defer to regulation from the Department of Health,<sup>156</sup> while others provide explicit statutory testing requirements for Human Immuno-deficiency Virus and other sexually transmitted infections.<sup>157</sup> Although these laws “include” and “cover” suppliers, they are not necessarily conceived to protect them, but rather are designed with egg recipients, future offspring, and society in mind. The purpose of supplier screening is to prohibit suppliers, through the ART community, from spreading communicable diseases.<sup>158</sup> Currently there are no state laws that regulate the number of eggs or cycles that each supplier is permitted to sell, nor do state laws restrict ways in which intending parents may choose among potential egg suppliers.<sup>159</sup> The loose web of state statutes demonstrates a shortage of political energy within state legislatures to protect egg suppliers and an absence of uniformity across states.

*C. Voluntary “Self-Regulation,” or Lack Thereof, by Professional Medical Societies Leaves Egg Suppliers Vulnerable*

Because of the gap in statutory and regulatory rules promulgated by the Federal and State governments, ART is characterized by a “self-regulatory” regime.<sup>160</sup> Like other medical fields, ART practice lies outside of the traditional “command-and-control regulatory authority” of the federal government,<sup>161</sup> and instead is largely guided through self-regulation by professional medical societies.<sup>162</sup> Where the law of contracts arose in response to commercial relationships between interested parties, professional relationships have long been considered “fundamentally different from commercial relationships.”<sup>163</sup> The doctor-patient relationship is a fiduciary relationship;

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156. N.H. REV. STAT. ANN. § 168-B:14 (2014).

157. *See, e.g.*, VA. CODE ANN. § 32.1-45.3 (2015); DEL. CODE ANN. tit. 16, § 2801 (1995); CAL. HEALTH & SAFETY CODE § 1644.5 (2016); OKLA. STAT. ANN. tit. 63, § 2151.1 (1988).

158. These statutes are often categorized in such a way as to make this apparent. For example, Virginia’s law is under “Article 3: Disease Control Measures” and Delaware’s law is under “Regulatory Provisions Concerning Public Health”. *See* VA. CODE ANN. § 32.1-45.3 (2015); DEL. CODE ANN. tit. 16, § 2801 (1995).

159. Helen M. Alvaré, *The Case for Regulating Collaborative Reproduction: A Children’s Rights Perspective*, 40 HARV. J. ON LEGIS. 1, 31 (2003).

160. *See supra* Sections III.A & III.B.

161. Timothy Stoltzfus Jost, *Health Law and Administrative Law: A Marriage Most Convenient*, 49 ST. LOUIS U. L.J. 1, 4 (2004).

162. *See* Malinowski, *supra* note 107, at 181-82.

163. Andrew Fichter, *The Law of Doctoring: A Study of the Codification of Medical Professionalism*, 19 HEALTH MATRIX 317, 321 (2009).

thus, the medical profession is characterized by trust, disinterestedness, specialization, and self-regulation.<sup>164</sup>

Currently, ART industry practices are guided by the Society for Assisted Reproductive Technologies (SART) and the American Society of Reproductive Medicine (ASRM).

These societies are dedicated to the practice of reproductive medicine for the benefit of patients, suppliers, and society.<sup>165</sup> Both strive to determine best practices, to educate, and to advocate on behalf of patients and suppliers.<sup>166</sup> SART was commissioned by the CDC to collect data and implement mandatory reporting requirements regarding fertility success rates under the Fertility Clinic Success Rate and Certification Act of 1992. Ninety percent of the fertility clinics in the United States are SART members.<sup>167</sup> With the cooperation of SART, the CDC published the first annual *Assisted Reproductive Technology Success Rates Report* in 1997, which provided pregnancy success rates statistics from 1995.<sup>168</sup> ASRM's Ethics Committee and Practice Committee publish documents that embody the official guidelines for medical professionals and suppliers working with ART. These guides are comprehensive and address a wide range of issues. Topics relevant for this discussion include gamete supplier rights and obligations;<sup>169</sup> fertility program obligations;<sup>170</sup> supplier health and psychological screening, gamete testing, and supplier selection;<sup>171</sup> fertility program obligations for record keeping and informed consent;<sup>172</sup> multiple supplier compensation schemes;<sup>173</sup> and concerns about limitations on repeat suppliers.<sup>174</sup>

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164. *See id.* at 321, 335.

165. They do not have a mission statement that includes any concern for egg providers. *See Mission Statement, SOC'Y OF ASSISTED REPROD. TECH.*, [http://www.sart.org/Mission\\_Statement/](http://www.sart.org/Mission_Statement/) (last visited Sept. 25, 2016); *Mission Statement, AM. SOC'Y FOR REPROD. MED.*, <http://www.asrm.org/mission/> (last visited Sept. 25, 2016).

166. *See id.*

167. *What is SART?*, SOC'Y OF ASSISTED REPROD. TECH., [http://www.sart.org/What\\_is\\_SART/](http://www.sart.org/What_is_SART/) (last visited Aug. 20, 2016).

168. *See Archived ART Reports and Spreadsheets*, CENTER FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/art/reports/archive.html> (last visited Aug. 20, 2016).

169. Ethics Comm., Am. Soc'y for Reprod. Med., *Interests, Obligations, and Rights of the Donor in Gamete Donation*, 91 FERTILITY AND STERILITY 22, 22 (2009).

170. *Id.*

171. *Recommendations for Gamete and Embryo Donation*, *supra* note 75, at 47.

172. *Id.*

173. Ethics Comm., Am. Soc'y for Reprod. Med., *Financial Compensation of Oocyte Donors*, 88 FERTILITY & STERILITY 305 (2007) [hereinafter *Financial Compensation of Oocyte Donors*].

174. Practice Comm., Am. Soc'y for Reprod. Med., *Repetitive Oocyte Donation*, 90 FERTILITY & STERILITY S194, S194–95 (2008).

The problem with ASRM guidelines is not necessarily that they embody bad policy, but rather, that compliance is strictly optional and the guidelines are easily ignored.<sup>175</sup> These publications are available at SART's website with the following disclaimer:

[The ASRM guidelines] are not intended to be a protocol to be applied in all situations, and cannot substitute for the individual judgment of the treating physicians based on their knowledge of their patients and specific circumstances. The recommendations in these guidelines may not be the most appropriate approach for all patients. Medical science and ethics are constantly changing, and clinicians should not rely solely on these guidelines.<sup>176</sup>

SART publishes guidelines that, by its own admission, are neither comprehensive nor suitable for total reliance. Therefore, it is no surprise that the guidelines ineffectively constrain the industry.

Supplier compensation is a good example of an aspect of the industry rife with ASRM guideline violations. The guidelines regarding supplier compensation state, “[t]otal payments to [suppliers] in excess of \$5,000 require justification and sums above \$10,000 are not appropriate.”<sup>177</sup> Furthermore the guidelines indicate that:

To avoid putting a price on human gametes or selectively valuing particular human traits, compensation should not vary according to the planned use of the oocytes (e.g., research or clinical care), the number or quality of oocytes retrieved, the outcome of prior supplier cycles, or the supplier's ethnic or other personal characteristics.<sup>178</sup>

Whether these guidelines embody the appropriate policies is debatable. Regardless, studies indicate that these voluntary guidelines go unheeded. In 2010, a study of supplier-seeking advertisements in newspapers on university campuses across the country demonstrated that in almost a quarter of the advertisements the offered compensation exceeded the maximum ASRM guideline.<sup>179</sup> Furthermore, an increase of an egg supplier's SAT score

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175. Hiltzik, *supra* note 23.

176. *Practice Committee Documents*, AM. SOC'Y FOR REPROD. MED, <http://www.asrm.org/Guidelines/> (last visited Jan. 15, 2015).

177. *Financial Compensation of Oocyte Donors*, *supra* note 173, at 305.

178. *Id.*

179. AARON D. LEVINE, HASTINGS CTR., SELF-REGULATION, COMPENSATION, AND THE ETHICAL RECRUITMENT OF OOCYTE DONORS 25, 31 (2010).



by 100 points was linked to an increase in compensation of \$2,350.<sup>180</sup> In 2012, another study exploring IVF clinic and agency compliance found that “considerable numbers were noncompliant with ASRM’s guidelines that prohibit varying compensation based on a supplier’s traits (thirty-four percent), and recommend an age of twenty-one years or older (forty-one percent), and presentation of risks alongside compensation (fifty-six percent).”<sup>181</sup> These rates of violation clearly demonstrate that attempts to self-regulate are not successful.

*D. Negligible Effect of Judicial Enforcement Through Egg Supplier Tort Claims*

Since the federal government takes a hands-off position in its regulation of the practice of medicine, the professional medical community is permitted to establish its own standard of care.<sup>182</sup> Medical malpractice claims, under the province of state law, are brought in actions for negligence. Instead of relying on the “reasonably prudent person” standard, as is typical in negligence claims, a medical doctor is measured against a standard established by his/her peers within the medical community. “As long as a doctor follows the medical standard or custom, he/she is not negligent, regardless of how risky the custom or how unnecessary.”<sup>183</sup> Doctors owe their patients a duty that comports with the minimum standard of care. When this duty is breached and patient harm results, patients can maintain a cause of action in state court for damages.<sup>184</sup> State laws typically govern these medical malpractice actions.<sup>185</sup>

Egg suppliers harmed by fertility treatments have brought surprisingly few tort actions. Given the health risks involved in the medical procedures, and the volume of procedures, one would expect to find more medical malpractice cases brought against doctors and more products liability actions against fertility drug manufacturers. There are many cases involving determinations of parental rights for children as a result of assisted reproduc-

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180. *Id.*

181. Jason Keehn et al., *Recruiting Egg Donors Online: An Analysis of In Vitro Fertilization Clinic and Agency Websites’ Adherence to American Society for Reproductive Medicine Guidelines*, 98 FERTILITY & STERILITY 995, 995 (2012).

182. Philip M. Rosoff & Doriane Lambelet Coleman, *supra* note 112, at 666.

183. *Id.* at 666 n.63.

184. E.H. Schopler, Annotation, *Statute of Limitations Applicable to Malpractice Action Against Physician, Surgeon, Dentist, or Similar Practitioner*, 80 A.L.R.2D 320 (1961).

185. William M. Sage, *The Role of Medicare in Medical Malpractice Reform*, 9 J. HEALTH CARE L. & POL’Y 217, 219 (2006) (“Malpractice [historically] has been a state law issue, while health care is governed increasingly by federal law.”).

tion,<sup>186</sup> often involving the disposition of frozen embryos in cases of separated parents,<sup>187</sup> as well as suits determining the liability of health insurance companies related to assisted reproductive technology expenses<sup>188</sup> and civil actions for loss of cryopreserved genetic tissue.<sup>189</sup> However, as of this writing, only a few on-point cases with egg supplier plaintiffs exist.<sup>190</sup>

One such on-point case is *Steinmann v. Doyle*, which involved a medical malpractice action filed in 2011 against fertility clinic doctors for harm suffered by the plaintiff from ovarian hyper-stimulation.<sup>191</sup> Although she lived in Florida, Amanda Steinmann traveled to Connecticut to undergo ovarian stimulation and egg retrieval procedures at the Connecticut Fertility Associates (CFA).<sup>192</sup> She intended to supply her eggs to CFA for use in third party fertility treatments.<sup>193</sup> Six days into the hormonal treatment, Steinmann presented with symptoms of ovarian hyper-stimulation syndrome, complaining of pain in her “lower right quadrant.”<sup>194</sup> She was admitted to the emergency room and stayed overnight. The hospital’s physician found “significantly enlarged ovaries and a suspected ruptured ovarian cyst,” but determined that there was “no obvious source for her problem” and that she

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186. See, e.g., *D.M.T. v. T.M.H.*, 38 Fla. L. Weekly S812 (Fla. 2013) (the egg donor in a same-sex relationship did not waive her parental rights by signing a standard consent form, where the couple intended to raise the child as their own); *A.A.B. v. B.O.C.*, 112 So. 3d 761 (Fla. Dist. Ct. App. 2013) (the father was a sperm donor under the statute and had no parental rights for the offspring that resulted from artificial insemination); *K.M. v. E.G.*, 117 P.3d 673 (Cal. 2005) (court held that statute severing the parental rights of a sperm donor did not apply to an egg donor providing an egg to her lesbian partner even when the petition was filed after the domestic partnership ended).
187. See e.g., *Szafranski v. Dunston*, 993 N.E.2d 502 (Ill. App. Ct. 2013) (custody of pre-embryos should be determined by the agreement that reflects the intention of parties), *appeal denied* 996 N.E.2d 24 (Ill. 2013); *Kass v. Kass*, 696 N.E.2d 174 (N.Y. 1998) (ex-wife filed action for sole custody of five frozen pre-zygotes created during the marriage, Judge held that agreements between progenitors are presumptively valid, and the agreement here required the embryos to be donated to research).
188. See, e.g., *New Life Agency, Inc. v. Beitler Servs., Inc.*, No. B224724, 2012 WL 593142 (Cal. Ct. App. Feb. 23, 2012) (dispute between two insurance companies over liability in relation to coverage of medical expenses of a surrogacy contract); *Northrup v. Blue Cross & Blue Shield of Utica-Watertown Inc.*, 652 N.Y.S.2d 902, 903 (N.Y. App. Div. 1997).
189. See, e.g., *Jeter v. Mayo Clinic Arizona*, 121 P.3d 1256 (Ariz. Ct. App. 2005); *Witt v. Yale-New Haven Hosp.*, 977 A.2d 779 (Conn. Super. Ct. 2008).
190. Durrell, *supra* note 68, at 190 (“[T]here are no reported cases specifically relating to damage claims by egg donors[.]”).
191. *Steinmann v. Doyle*, No. CV 116017158S, 2011 WL 2436698, at \*1 (Conn. Super. Ct. May 24, 2011) (unpublished opinion).
192. *Steinmann*, 2011 WL 2436698, at \*1.
193. *Steinmann*, 2011 WL 2436698, at \*1.
194. *Steinmann*, 2011 WL 2436698, at \*1.

“would continue on the ovarian stimulation protocol.”<sup>195</sup> After being discharged from the hospital, Steinmann returned to CFA for monitoring, which showed that her estrogen levels were elevated. The ovarian hyper-stimulation stage was completed when hCG was administered two days after her discharge, and a successful surgical egg retrieval procedure followed.<sup>196</sup> Shortly after Steinmann’s return to Florida, she suffered severe pain; a physical examination demonstrated that her ovaries were “severely enlarged and otherwise damaged.”<sup>197</sup>

Of the five named defendants, one has been dismissed on settlement terms not publicly available.<sup>198</sup> If the four remaining defendants do not settle the claim, this would be the first adjudication of a claim brought by an egg supplier plaintiff regarding sub-standard medical treatment based on a conflict of interest in connection with her ovarian hyper-stimulation and egg retrieval procedure.<sup>199</sup>

While courts are authorized to hear personal injury claims to protect egg suppliers, as of this writing, there is no judicial opinion that deals precisely with the physical and psychological harms caused to third party egg suppliers.<sup>200</sup> The absence of case law has not been explained. At least one barrier is the dearth of long-term scientific studies that confirm the health risks of ovarian hyper-stimulation,<sup>201</sup> which may present extreme difficulty in establishing causation, a necessary element of a plaintiff’s case at trial.<sup>202</sup>

There may also be personal reasons an egg supplier is uninterested in pursuing a public trial or initiating a lawsuit available for public inspection. Given the private nature of the decision to be an egg supplier and to participate in collaborative reproduction, egg suppliers may wish to keep their remedial pursuits out of public view. Waiver documents and misinformation from clinics about the health risks of the procedure may also deter potential plaintiffs with valid claims from approaching an attorney in the first instance. For example, an egg supplier who has suffered from medical

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195. *Steinmann*, 2011 WL 2436698, at \*1.

196. *Steinmann*, 2011 WL 2436698, at \*1–2.

197. *Steinmann*, 2011 WL 2436698, at \*2.

198. *Steinmann*, 2011 WL 2436698, at \*2.

199. *See generally* Options Nat’l Fertility Registry v. Am. Soc’y for Reprod. Med., No. C 07-5238 JF (HRL), 2009 WL 4572769 (N.D. Cal. Dec. 4, 2009) (an egg donor plaintiff alleged a policy of “egg-sharing” without the consent of egg donors, but the case was fraught with procedural problems and dismissed on those grounds).

200. Durrell, *supra* note 68, at 190 (“there are no reported cases specifically relating to damage claims by egg donors”). The author’s research did not demonstrate any relevant briefs, pleadings or motions either.

201. *See* discussion *infra* Section IV.A.

202. *See* discussion *infra* Section IV.A (the benefit to industry defendants of that research deficiency presents an unfortunate incentive).

complications, but who signed the clinic's disclaimer of liability, may feel she has no legal recourse. In addition, the fact that clinics do not always share the whole truth about the health risks involved means that an egg supplier may not associate the egg harvesting procedure with her symptoms. Egg suppliers may also be deterred from legal action by feelings of regret and shame that may follow supplying eggs.<sup>203</sup> Regardless of the underlying reasons, regulation of the assisted reproductive technology industry has not come through judicial intervention.

#### IV. MAJOR FAILURES OF THE CURRENT REGULATORY REGIME OVER THE ART INDUSTRY

Jessica Schneider, a young, healthy, Stanford graduate was caught undergoing a non-therapeutic procedure without knowing the life-threatening risks because the United States regulatory scheme was unsuccessful. This system failed to provide her with the requisite information to make a sound decision and failed to protect her against the overbearing techniques of the industry. These failures directly resulted in her premature death at thirty-one years old. The patchwork of regulatory devices in the United States has largely left the ART industry to engage in self-regulation. The failures of self-regulation create a regulatory void, and as a result, the industry has been able to selfishly pursue profits without restraint. Unfortunately, this comes with a price, and egg suppliers are bearing the cost. The current system has failed to monitor the short- and long-term risks of egg harvesting, failed to establish the opportunity for informed consent, and failed to protect against the coercive pressures of aggressive marketing techniques.

##### *A. No Long-term Studies Substantiate the Safety Claims of Superovulation and the Egg Retrieval Procedure*

The medical risks of the procedures required to provide eggs are largely unknown, and they are borne exclusively by egg suppliers. The lack of studies is most probably the result of the conflict of interest of ART clinics, which creates a need for the government to step in and fund these studies for the protection of egg suppliers.

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203. See, e.g., COMM. ON ASSESSING THE MED. RISKS OF HUMAN OOCYTE DONATION FOR STEM CELL RESEARCH, WORKSHOP REPORT 45–46 (Linda Guidice et al. eds., 2007), <https://www.nap.edu/read/11832/chapter/1>; Leah Campbell, *Why I Regret Donating My Eggs*, YAHOO! NEWS (Dec. 12, 2015), <https://www.yahoo.com/news/why-i-regret-donating-my-1319025848811574.html?ref=GS>; Boodman, *supra* note 62; Katie O'Reilly, *I Wish I Hadn't Donated My Eggs*, BUZZFEED NEWS (June 30, 2015, 9:20 PM), [https://www.buzzfeed.com/katieoreilly/i-wish-i-hadnt-donated-my-eggs?utm\\_term=.ggvkvBDw#.afYLDQmxa](https://www.buzzfeed.com/katieoreilly/i-wish-i-hadnt-donated-my-eggs?utm_term=.ggvkvBDw#.afYLDQmxa).

Despite the fact that the first successful IVF birth occurred more than thirty-five years ago, only limited scientific data is available regarding the superovulation and egg retrieval process that makes IVF possible.<sup>204</sup> Many have commented on the concerns caused by this absence.<sup>205</sup> Even the ASRM spokesperson, Sean Tipton, admits that there are no specific studies of the long-term effects on egg suppliers.<sup>206</sup> In particular, no long-term study definitively demonstrates that super-ovulation and egg retrieval are safe for egg suppliers. Dr. Suzanne Parisian, a former Chief Medical Officer of the FDA, has stated: “Pharmaceutical firms have not been required by either the government or physicians to collect safety data for IVF drugs regarding risk of cancer or other serious health conditions despite the drugs having been available in the United States for several decades.”<sup>207</sup>

Despite this dearth of scientific data, many publications deceptively declare the relative safety of the procedure.<sup>208</sup> Even the ASRM acknowledges this: “Currently, there are no clearly documented long-term risks associated with oocyte donation, and as such, no definitive data upon which to base absolute recommendations.”<sup>209</sup> These admissions by industry regulators are disturbing. Egg suppliers have been providing eggs and supporting the growth of the industry without being monitored for long-term health risks for many years.

Conflicts of interest account, at least in part, for the failure to comprehensively track and study egg suppliers.<sup>210</sup> As the gatekeepers to the limited supply of eggs, potential egg suppliers have been shielded from information revealing the health risks of egg harvesting because it could diminish fertility clinics’ egg supply.<sup>211</sup> Diane Tober of the University of California, San Francisco, is conducting a study of egg suppliers and has found that most egg suppliers are told that the chances of complications are under one percent.<sup>212</sup> However, her study is showing that complications requiring bed rest

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204. See, e.g., Kramer et al., *supra* note 90, at 3144–45.

205. See Hiltzik, *supra* note 23.

206. *Id.*

207. Michelle Bercovici, *Biotechnology Beyond the Embryo: Science, Ethics, and Responsible Regulation of Egg Donation to Protect Women’s Rights*, 29 WOMEN’S RTS. L. REP. 193, 195 (2008).

208. See, e.g., PRESIDENT’S COUNCIL ON BIOETHICS, *supra* note 129, at 25 (describes the ovarian stimulation and egg retrieval producers as “[r]isks and complications are low”); Durrell, *supra* note 68, at 187 (“generally marketed as a safe procedure”); Robert Klitzman & Mark V. Sauer, *Payment of Egg Donors in Stem Cell Research in the USA*, 18 REPROD. BIOMED. ONLINE 603, 604 (2009).

209. *Ovarian Hyperstimulation Syndrome*, *supra* note 41, at S195.

210. Hiltzik, *supra* note 23.

211. See *id.*

212. *Id.*

and inpatient hospital admission are closer to thirty percent.<sup>213</sup> Another survey evaluating egg donors retrospectively showed results where thirty percent of egg donors had some OHSS following donation, and eleven and a half percent had complications that included paracentesis and/or hospitalization.<sup>214</sup> Given the seriousness of the health risks that may be substantiated by these studies, government intervention is not only warranted but critical. These studies will provide much needed information to ensure that ART protocols are safe for all involved parties, particularly for egg suppliers who are vulnerable to both commercial influence and abuse by those tempted to overuse the technology.<sup>215</sup>

The absence of research to inform the policy and protocols in this field is a critical failure. The government should initiate a change through investing in the studies necessary to fill in the gaps of scientific knowledge. ART industry players' failure to proactively generate these studies comes at the expense of all patients involved.

*B. Egg Suppliers Cannot Provide Informed Consent to Egg Harvesting*

“[K]nowledgeable decisions on reproducing and having children, whether technology is involved or not, can and should be made by the people and the families immediately affected by such decisions.”<sup>216</sup> Comprehensive information is a prerequisite for autonomous decision-making. Parties involved in ART may be getting *accurate* information, but without long-term and comprehensive studies they may not have access to *complete* information. This is the difference between “no known evidence” and “no evidence.”<sup>217</sup> Nevertheless, physicians have a legal obligation to obtain informed consent prior to treatment.<sup>218</sup>

Informed consent is a legal doctrine that stems from a fundamental right recognized in the American legal system that, “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body . . . .”<sup>219</sup> Because the doctor-patient relationship is characterized by fiduciary responsibilities, there is a heavy burden on the physician to ensure that informed consent is meaningfully obtained.<sup>220</sup> “True

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213. *Id.*

214. Kramer et al., *supra* note 92, at 3146.

215. See Malinowski, *supra* note 107, at 199 [citation omitted].

216. Robert P.S. Jansen, *Evidence-based Ethics and the Regulation of Reproduction*, 12 HUMAN REPROD. 2068, 2074 (1997).

217. Kramer et al., *supra* note 90, at 3144.

218. See 22 AM. JUR. 2D *Proof of Facts* § 721, Westlaw (database updated 2016).

219. *Schloendorff v. Soc’y of New York Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

220. See *supra* note 218.

consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each."<sup>221</sup> In some circumstances, a physician may be justified in withholding information from the patient about the risks of a particular treatment based on the concern that a patient will be adversely affected by the specific disclosure.<sup>222</sup> This exception is known as the "therapeutic privilege."<sup>223</sup>

However, in the context of egg donation or any other elective procedure, by definition, this privilege cannot be invoked.<sup>224</sup> On the contrary, "[i]n cases of elective medical treatment of any sort, full disclosure of the risks must be made because the patient's medical condition would not be jeopardized by taking no action at all."<sup>225</sup> Furthermore, a physician has a duty to disclose "personal interests unrelated to the patient's health, whether research-related or economic, if these interests may affect the physician's professional judgment, and a doctor's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent."<sup>226</sup>

The New York State Life and Law Task Force's extensive research on ART found that "[t]he process of obtaining informed consent to assisted reproduction is seriously deficient. There is considerable evidence that physicians provide incomplete or misleading information about benefits and risks."<sup>227</sup> As a result of this research, the Task Force received a grant to create literature for both practitioners and consumers "in order to address the conflicting information that is often provided in regards to the technology."<sup>228</sup>

Informed consent has not sufficiently protected egg suppliers against the conflict of interest raised by fertility clinics that manipulate the system by withholding important facts from patients who believe they are getting complete information.<sup>229</sup> The common misperception of the risks of the procedures required by egg donation is evidence of a failure to achieve meaningful informed consent despite written and signed consent forms.<sup>230</sup> A 2010 study of egg suppliers found that an alarming twenty percent did

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221. See *Canterbury v. Spence*, 464 F.2d 772, 780–81 (D.C. Cir. 1972).

222. 15 AM. JUR. 2D *Proof of Facts* § 711, Westlaw (database updated 2016).

223. *Id.*

224. See *supra* note 218.

225. *Id.*

226. *Supra* note 222.

227. See TASK FORCE ON LIFE & THE LAW, *supra* note 121.

228. *Id.*

229. See Barbara L. Atwell, *The Modern Age of Informed Consent*, 40 U. RICH. L. REV. 591, 607 (2006).

230. See *e.g.*, Boodman, *supra* note 62.

not know about the health risks involved.<sup>231</sup> The lack of research data with which to accurately determine health risks for egg donors casts serious doubt on whether informed consent can be achieved in this context.<sup>232</sup> However, even with the information currently available, additional safeguards are needed to protect the egg donor's autonomous choice, particularly against abuses by interested third parties at fertility clinics.<sup>233</sup>

### *C. Potential Egg Suppliers are Burdened by Aggressive Direct Marketing Techniques*

The ART industry uses aggressive marketing techniques to convert potential egg suppliers into actual egg suppliers and to satisfy the strong market demand for oocytes.

#### 1. Potential Egg Suppliers Face Strong Financial Incentives to Become Suppliers

The debate over whether egg donor compensation should be permitted at all, or to what extent, includes perspectives arguing for a wide range of compensation levels.<sup>234</sup> Advocates against compensation, like the Canadian legislature<sup>235</sup> and major scientific institutions,<sup>236</sup> are concerned by the vulnerability of women in financial hardship.<sup>237</sup> Egg brokers notoriously target women in financial stress, most notably graduate and undergraduate students studying at universities across the country.<sup>238</sup> Financial incentives are sometimes shockingly high, up to \$50,000 when egg brokers seek suppliers with specific traits such as an Ivy League education or a specific height, eye color, and ethnicity, etc.<sup>239</sup> This degree of financial

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231. *Id.*

232. Kramer et al., *supra* note 90, at 3145.

233. *Id.*

234. Hiltzik, *supra* note 23.

235. Alison Motluk, *The Human Egg Trade: How Canada's fertility laws are failing donors, doctors, and parents*, THE WALRUS (April 12, 2010), <https://thewalrus.ca/the-human-egg-trade/>.

236. Including the National Academy of Sciences and the California Institute for Regenerative Medicine. Hiltzik, *supra* note 23.

237. See Hiltzik, *supra* note 23; Motluk, *supra* note 235.

238. Michelle Bercovici, *Biotechnology Beyond the Embryo: Science, Ethics, and Responsible Regulation of Egg Donation to Protect Women's Rights*, 29 WOMEN'S RTS. L. REP. 193, 196 (2008); Carlene Hempel, *Golden Eggs: Drowning in credit-card debt and student loans, young women are selling their eggs for big payoffs. But can they really make the right medical and moral decisions when they're tempted with \$15,000?*, BOS. GLOBE (June 25, 2006), [http://archive.boston.com/news/globe/magazine/articles/2006/06/25/golden\\_eggs/](http://archive.boston.com/news/globe/magazine/articles/2006/06/25/golden_eggs/).

239. See Kolata, *supra* note 64; Ken Schwartz, *Ivy Eggs*, BUS. TODAY, Aug. 5, 2006 at 1.



compensation is a tempting lure to potential egg suppliers, and thus a significant concern. This amount of money encourages a person to disregard the risks of the procedure, particularly a person in financial stress.<sup>240</sup>

Most states prohibit compensation for eggs that are used for research purposes.<sup>241</sup> For example, Florida's Attorney General suggested a state constitutional amendment to allow stem cell research, "if and only, under conditions that satisfy applicable requirements for informed consent and do not involve financial inducement to any [supplier]."<sup>242</sup> Some have proffered that the concern for vulnerable donors is higher for research eggs because scientists in that context are not worried about "quality" but simply "quantity."<sup>243</sup> Yet the medical procedure is the same regardless of the purpose the harvested eggs are to serve, and this inequity does not seem justified.<sup>244</sup>

The ASRM guidelines suggest that \$5,000 is reasonable compensation; payment from \$5,001 to \$10,000 should be justified with receipts for expenses; anything above \$10,000 is inappropriate.<sup>245</sup> The ASRM did not provide a rationale to justify these values, but since they are official guidelines they certainly demonstrate that compensation of \$35,000 or \$50,000 grossly exceeds recommended practice.<sup>246</sup> Additional studies are needed to consider the impact of compensation on potential egg supplier behavior.<sup>247</sup> Compensation for time, expenses, inconvenience, and exposure to known and unknown health risks should be reasonably limited with well-structured regulation.

## 2. Coercive Pressure is Exacerbated With Appeals to Emotion

The aggressive marketing tactics of the industry contribute to an environment of coercion. Collectively, the fertility industry vigorously targets

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240. DEBORA L. SPAR, *THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION* 44 (2006); Marvin, *supra* note 27, at 127–131.

241. Diane Tober, *The Politics of Women's Eggs*, UN DARK (June 10, 2016), <http://undark.org/article/the-price-and-politics-of-womens-eggs/>.

242. Advisory Opinion to Attorney Gen. re Funding of Embryonic Stem Cell Research, 959 So. 2d 195 (Fla. 2007).

243. See, e.g., Naomi Cahn & June Carbone, *Leveling the field for human egg donors*, L.A. TIMES (July 13, 2013), <http://articles.latimes.com/2013/jul/13/opinion/la-oe-cahn-egg-donation-california-20130714>.

244. Klitzman & Sauer, *supra* note 208, at 603–08.

245. *Financial Compensation of Oocyte Donors*, *supra* note 173, at 308.

246. *Id.*

247. Klitzman & Sauer, *supra* note 208, 603–08 (2009).

eligible women to convert them into egg suppliers.<sup>248</sup> Advertisements and websites are created to manipulate maternal instincts and create the warm fuzzy feelings that will convince potential suppliers into becoming suppliers.<sup>249</sup> This appeal to altruism is reflected in egg supplier's motivation, as surveys show that this was the primary stated reason for interest in becoming an egg supplier.<sup>250</sup> Websites commonly emphasize how suppliers give the gift of life.<sup>251</sup> Egg Donation, Inc., "the oldest and largest egg donation agency," prominently displays their corporate tag line, "Where Dreams Come True," on the upper left heading of their website.<sup>252</sup> This romanticizes the baby-making business, and it is another tool used to lure egg suppliers. An attempt to curb the effect of this practice should come from regulation requiring conspicuous language on supplier-seeking advertisements even more stringent than what was passed in California.<sup>253</sup>

### CONCLUSION

The ART industry needs more regulation. Human egg harvesting is a unique sort of transaction, one that does not fit into a standard mold. As a

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248. These agencies target college students in particular. See Carlene Hempel, *Golden Eggs*, BOS. GLOBE (June 25, 2006), [http://archive.boston.com/news/globe/magazine/articles/2006/06/25/golden\\_eggs/](http://archive.boston.com/news/globe/magazine/articles/2006/06/25/golden_eggs/).

249. This is evidenced in the names of some of the egg brokers and agencies: "Creative Love Egg Donation," "Happy Beginnings," "First Smile Egg Donation Agency," and "Graceful Conception." CREATIVE LOVE EGG DONOR & SURROGATE AGENCY, *supra* note 96; HAPPY BEGINNINGS, LLC, *supra* note 97; FIRST SMILE EGG DONATION AGENCY, *supra* note 98; GRACEFUL CONCEPTION, *supra* note 99.

250. COMM. ON ASSESSING THE MED. RISKS OF HUMAN OOCYTE DONATION FOR STEM CELL RESEARCH, ASSESSING THE MEDICAL RISKS OF HUMAN OOCYTE DONATION FOR STEM CELL RESEARCH: WORKSHOP REPORT, 43 (Linda Giudice, et al. eds., 2007), [http://www.nap.edu/openbook.php?record\\_id=11832&page=R1](http://www.nap.edu/openbook.php?record_id=11832&page=R1).

251. See FERTILITY BRIDGES, <http://fertilitybridges.com/egg-donor-program/as-egg-donor> (last visited Sept. 11, 2016) ("Congratulations! You are taking the first step in creating a miracle. How often do you get to be a part of something so spectacular?"); see also CREATIVE LOVE EGG DONATION, <http://www.cledp.com> (last visited Sept. 11, 2016) ("Parenthood is magical, it is a gift, a miracle!"); GRACEFUL CONCEPTION, <http://www.gracefulconception.com> (last visited Sept. 11, 2016) ("Sharing the gift of life").

252. EGG DONOR INC., <https://www.eggdonor.com> (last visited Sept. 11, 2016).

253. See CAL. HEALTH & SAFETY CODE § 125325 (2010) (requiring the following notice to be included in egg donation advertisements: "Egg donation involves a screening process. Not all potential egg donors are selected. Not all selected egg donors receive the monetary amounts or compensation advertised. As with any medical procedure, there may be risks associated with human egg donation. Before an egg donor agrees to begin the egg donation process, and signs a legally binding contract, she is required to receive specific information on the known risks of egg donation. Consultation with your doctor prior to entering into a donor contract is advised.").

result, the standard regulatory scheme does not protect egg suppliers. Egg suppliers in the United States should function within a framework of safety and information. Unfortunately, the system in place does not provide either of those things, and egg suppliers bear the risks and costs of this failure. This is unacceptable exploitation. The substantive justifications described by this Note compel significant changes in the regulation of egg harvesting. We must have changes in the law to protect both a woman's choice and her health. ❀