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# Women's Eggs: Exceptional Endings

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## I. INTRODUCTION

Over the last two decades women's eggs have become increasingly coveted by the fertility business and stem cell researchers.<sup>1</sup> This Article will show that while egg donation is generally marketed as a safe procedure, it has inherent risks, and unfortunately, many of those risks have not yet received sufficient scrutiny. Young healthy women subject themselves to high-potency drug regimens, surgery, and anesthesia to give another woman the promise of a baby, though the procedure they undergo has not been sufficiently researched to ensure its safety.

As shown below, many women pass through the rigors of egg donation with nothing more than minor discomfort, while others have lost their lives in the process; a whole host of problems exist between the two ends of this

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1. See DEBORA L. SPAR, *THE BABY BUSINESS*, 41–42 (2006) (indicating the market for eggs in the fertility industry emerged only in the early 1990s but rapidly became the most differentiated and competitive link in the supply chain); INST. OF MED. AND NAT'L RESEARCH COUNCIL, *ASSESSING THE MEDICAL RISKS OF HUMAN OOCYTE DONATION FOR STEM CELL RESEARCH*, WORKSHOP REPORT 10 (Linda Giudice et al., eds., 2007) [hereinafter IOM].

The major source of stem cells to date has been excess IVF embryos that are donated by couples who have completed their treatment for infertility. . . . If stem cells are to be made by IVF purely for research, however, and not as a part of infertility treatment, this would necessarily require the donation of eggs.

*Id.*; Jim Hopkins, *Egg-Donor Business Booms on Campus*, USA TODAY, Mar. 16, 2006, at 2A (discussing egg donor compensation to college and graduate students seeking to offset educational expenses); Diane Beeson & Abby Lippman, *Egg Harvesting for Stem Cell Research: Medical Risks and Ethical Problems*, REPRODUCTIVE BIOMED. ONLINE Aug. 14, 2006, <http://www.rbmonline.com/4DCGI/Article/Article?38?091?09=%202503%09> (describing use of "donation" terminology as euphemistic given payments to donors, and detailing the conflict of interest created when doctors soliciting donations are also seeking to use donated oocytes for their own research).

spectrum.<sup>2</sup> Currently, no state or federal regulations, or even industry guidelines require clinics to track egg donors' health after donation.

Many experts agree that more comprehensive long-term studies are needed.<sup>3</sup> The limited studies undertaken to date have not been able to clearly determine whether the hormone modulating drugs used to manipulate human egg production increase the risk of various cancers. For example, some studies have found associations between the use of the fertility drug Clomiphene and increased incidents of ovarian, endometrial and breast cancer.<sup>4</sup> Nevertheless studies to date have been flawed due to small sample pools,<sup>5</sup> failure to separate fertile from infertile women, and failure to follow test subjects to the age when their risk for cancer naturally rises.<sup>6</sup> Because of the lack of sufficient research to identify the short-term and long-term effects of hormone regulating drugs used in assisted reproductive technology (ART), the question remains as to whether a donor can truly give informed consent.<sup>7</sup> *Informed consent* is a legal and ethical

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2. See *infra* Section II.

3. See IOM, *supra* note 1, at 26–28 (suggesting that long-term studies would be helpful to determine the effects of ovarian stimulation drugs on donor fertility).

4. See, e.g., Ali Mahdavi et al., *Induction of Ovulation and Ovarian Cancer: A Critical Review of the Literature*, 85 FERTILITY & STERILITY 819, 825 (2006) (citing Alice S. Whittemore et al., *Characteristics Relating to Ovarian Cancer Risk: Collaborative Analysis of 12 US Case-Control Studies*, 136 AM. J. EPIDEMIOLOGY 1175, 1177 (1992)) (discussing study showing association between fertility medication and ovarian cancer); Mary Anne Rossing et al., *Ovarian Tumors in a Cohort of Infertile Women*, 331 NEW ENG. J. MED. 771, 773 (1994) (discussing study showing a 2.3 times higher risk of ovarian cancer with Cloiphene use than without); Louise A. Brinton et al., *Ovarian Cancer Risk After the Use of Ovulation-Stimulating Drugs*, 103 AM. C. OBSTETRICIANS & GYNECOLOGISTS 1194, 1194 (2004) (finding increased risk of ovarian cancer with twelve or more cycles of Clomiphene use) [hereinafter Brinton et al., *Ovarian Cancer*]; but see Louise A. Brinton et al., *Ovulation Induction and Cancer Risk*, 83 FERTILITY & STERILITY 261, 264–65 (2005) (finding no increased risk of ovarian cancer with ovarian inducing drugs but sustaining connection between infertility and ovarian cancer) [hereinafter Brinton et al., *Ovulation Induction*]. See also *infra* Section B.3.b. for more thorough discussion.

5. Mahdavi et al., *supra* note 4, at 825.

6. Brinton et al., *Ovulation Induction*, *supra* note 4, at 262.

7. The U.S. Centers for Disease Control and Prevention (CDC) defines assisted reproductive technology (ART) as all treatments or procedures that involve surgically removing eggs from a woman's ovaries and combining the eggs with sperm to help a woman become pregnant including in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), and zygote intrafallopian transfer (ZIFT). CTRS. FOR DISEASE CONTROL & PREVENTION, FAQs: 2005 ASSISTED REPRODUCTIVE TECHNOLOGY REPORT, FAQ #2 (2005), <http://www.cdc.gov/art/ART2006/faq.htm#2>; see also Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 608–09 (2003) [hereinafter Noah, *Pitfalls*]. Noah gives a more expansive definition. *Id.*

ART now encompasses several distinct methods, though they often are used in combination. Artificial insemination (AI), also referred to as intrauterine insemination (IUI), has the longest history and requires the least technological sophistication: the procedure introduces sperm . . . into the woman's uterus. GIFT, which delivers the sperm and harvested eggs . . . directly into the woman's fallopian tube, represents a more complicated method of insemination. . . . Some definitions of ART include only those

obligation in which doctors must explain to patients the potential adverse effects, positive outcomes as well as the side effects of a procedure prior to obtaining a patient's consent.<sup>8</sup> While informed consent should protect patients from unknowingly risking their health and to encourage trust between doctor and patient, it is questionable whether potential egg donors can truly give informed consent because insufficient research has been conducted into possible long-term risks.<sup>9</sup> For example, doctors and medical researchers should be able to answer the question whether ovarian stimulation through the use of fertility drugs increases a woman's lifetime risk of cancer before subjecting a healthy woman to the donor protocol.<sup>10</sup> In the absence of reasonable medical or scientific certainty as to a particular drug causing a particular injury, donor plaintiffs will also continue to have difficulty proving causation against their medical providers for failure to fully inform them of the risk of injury in donation.

The issues of health risks and informed consent cannot be divorced from the concerns of financial compensation. Originally characterized as a fee for "time and convenience," payment to egg donors has become widely accepted in the ART industry.<sup>11</sup> Over the years, many of the advertisements with monetary offers for egg donors have moved from quiet requests to help infertile couples, to elitist bids for eggs from well-educated, intelligent, and athletically-endowed donors.<sup>12</sup> The current demand for donated eggs for human Embryonic Stem (hES) cell research<sup>13</sup> highlights the debate over the potential commercialization and commodification of the human body through egg donation.<sup>14</sup> The

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techniques that involve the handling of oocytes or embryos outside of the body, which would encompass GIFT but not AI.

*Id.*

8. Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 365–66 (2002) [hereinafter Noah, *Informed Consent*].

9. Victoria Uroz and Lucia Guerra, *Donation of Eggs in Assisted Reproduction and Informed Consent*, 28 MED. & LAW 565, 574 (2009).

10. IOM, *supra* note 1, at 53.

11. SPAR, *supra* note 1, at 44–46 (discussing the increase in amounts paid to donors between 1990 to 2004 as the egg donation industry grew).

12. *Id.* (noting specific instances of extremely high payments offered to donors who could match very particular criteria in terms of age, race, health, and academic prowess).

13. IOM, *supra* note 1, at 1.

14. See Radhika Rao, *Symposium: California's Stem Cell Initiative: Converting the Legal and Policy Challenges: Coercion, Commercialization, and Commodification: The Ethics of Compensation for Egg Donors in Stem Cell Research*, 21 BERKELEY TECH. L.J. 1055, 1056 (2006). Rao argues that prohibitions on payments to donors for research purposes "implicitly invoke the rubric of privacy and reject propertization of the human body," and points out that no such prohibition on financial gain applies to donors for IVF, nor to the non-donor entities involved in stem cell research. *Id.* Rao contends that this contradiction undermines the anti-commodification purposes underlying the prohibition on payments in the stem cell context and begs the question of how well the guidelines protect the interests of donors. *Id.*

commercial value of women's eggs is undeniable<sup>15</sup> and this rightfully raises the question as to whether otherwise healthy young women are being financially coerced into subjecting themselves to risky and potentially life-altering procedures.

While the fertility industry has promulgated guidelines for compensating donors,<sup>16</sup> no federal regulations have been enacted. There is, however, a contrast between the way compensation for egg donation is addressed for reproductive purposes for stem cell research. For example, federal guidelines recommend that compensation for egg donors for stem cell research be limited to expenses, such as transportation, medical expenses, and lost wages.<sup>17</sup> Most states pursuing stem cell research have followed these federal guidelines. However, in 2009, New York became the first state to authorize payment to egg donors for embryonic stem cell research,<sup>18</sup> which may be the way of the future for other states. The practice of egg donation requires greater record keeping, more stringent research, and authentic public discourse on issues such as health risks, informed consent, legal compensation, tissue commercialization and commodification, and greater clarity regarding legal parentage of and access to information by donors' offspring.

Many issues are raised by egg donation and ART generally that are ripe for discussion. These include the physical, psychological, and legal ramifications for the recipients of the eggs and the offspring conceived therein; the social, racial and/or religious considerations of egg donation in ART; and the political implications of egg donation for hES cell research. This Article, however, is necessarily limited. Section II explains the donation process itself and the potential physical and psychological risks involved. This section also discusses the cost of egg donation in both money and time, in comparison with other types of tissue donations. The last part of the article is dedicated to an exploration of the law as it potentially might apply to egg donors. Because there are no reported cases specifically relating to damage claims by egg donors, cases that address the use of human tissue, fertility drugs, rights and remedies for research subjects, informed consent, conflicts of interest, and medical malpractice are examined as possibly legally analogous to egg donation.

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15. Hopkins, *supra* note 1, at 2A (describing an ad offering \$10,000 to UC Berkeley students for donated eggs, as well as figures estimating industry-wide spending on donated eggs alone at \$3 billion).

16. Soc'y for Reprod. Med., *Financial Compensation of Oocyte Donors*, 88 FERTILITY & STERILITY 305, 308 (2007) [hereinafter ASRM Ethics Committee].

17. NAT'L RESEARCH COUNCIL & INST. OF MED., GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH 87 (2005) [hereinafter NRCIM GUIDELINES].

18. See Rob Stein, *N.Y. Lets Tax Funds Pay Women for Eggs*, WASH. POST (reprinted in S.F. CHRON.), June 26, 2009, at A8.

## II. EGG DONATION IN ASSISTED REPRODUCTIVE TECHNOLOGY

### A. THE HUMAN EGG

Human cells are divided into two groups: eggs and sperm, the reproductive cells, are called *germ cells* or *gametes*; all other cells, including skin, muscle, and stem cells, are *somatic cells*.<sup>19</sup> The mammalian egg is often referred to as an oocyte, a general term used to describe all the stages of egg cell growth and maturation.<sup>20</sup> Human eggs are truly wondrous. In fact, the more we learn about them, the more extraordinary they seem. The egg is the largest cell in the human body, approximately 250 times the size of a somatic cell and 4,000 times the size of a sperm head.<sup>21</sup>

Female babies are born with approximately two million immature eggs in their ovaries, each encased in a protective covering called a follicle.<sup>22</sup> An unborn female fetus already carries the oocytes that have the potential to one day become her children.<sup>23</sup> At the time of a girl's first menstrual period, she has only 400,000 eggs containing follicles and incredibly, by the time a woman reaches menopause, almost all her eggs are gone.<sup>24</sup> Over the average four decades of a woman's monthly ovulatory cycles, only about 500 oocytes mature and are released during ovulation; the remainder are absorbed and/or discarded by the body.<sup>25</sup> The egg is very sophisticated, with a collection of enzymes and other molecules that enable it to completely remodel the sperm's chromosomes after fertilization.<sup>26</sup> The egg carries out a series of astounding duplications of both sets of chromosomes to generate new and exact copies and apportion them equally within new daughter, or divided cells.<sup>27</sup> This enzyme copying mechanism, which manifests the genetic code and forms the offspring's genotype, resides only within the egg and is not found within the sperm.<sup>28</sup>

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19. A germ cell is "[a] sperm or egg or a cell that can become a sperm or egg." NRCIM GUIDELINES, *supra* note 17, at 118. A gamete is "[a] mature male or female germ cell, that is, sperm or oocyte, respectively." *Id.* Somatic cells are "[a]ny cell of a plant or animal other than a germ cell or germ cell precursor." *Id.* at 119.

20. Ann A. Kiessling & Scott C. Anderson, HUMAN EMBRYONIC STEM CELLS 261, (2d ed., 2007).

21. Ann A. Kiessling, *What Is an Embryo?*, 36 CONN. L. REV. 1051, 1051 (2004).

22. IOM, *supra* note 1, at 14.

23. *See* NRCIM, GUIDELINES *supra* note 17, at 37.

24. IOM, *supra* note 1, at 14.

25. Kiessling, *supra* note 21, at 1055.

26. *See id.* at 1051-53.

27. *See* Kiessling, *supra* note 21, at 1051-53.

28. *See id.* at 1058.

## B. THE EGG DONATION PROCESS

The first birth from a human oocyte (egg) donation was announced in 1984.<sup>29</sup> Since then, demand for egg donations has increased dramatically.<sup>30</sup> The Centers for Disease Control and Prevention (CDC) receives information from fertility clinics and records the number and success of ART cycles performed annually. According to the 2006 CDC report, the number of ART cycles using donor eggs or embryos was approximately 16,976, or 12% of all ART cycles.<sup>31</sup> This is a three-fold increase over the 5,162 cycles using donor eggs in 1996, which represented 8% of all ART cycles that year.<sup>32</sup>

### 1. Selection

To be selected as an egg donor a woman must meet several criteria. First, she must be of legal age. Some clinics require donors be at least twenty-one years old, and generally do not accept prospective donors who are over thirty-five years old, since women over thirty-five have an increased risk of chromosomal anomalies.<sup>33</sup> A prospective donor's proven fertility is a plus, and women who have completed their childbearing are often considered better candidates.<sup>34</sup> Although short-term clinical studies suggest there is minimal to no risk of future infertility in egg donors,<sup>35</sup> no long-term studies have been conducted on the issue of how fertility drugs may affect egg donors' fertility and it remains one of many open questions regarding an egg donor's risks.<sup>36</sup>

A woman must complete several screening steps before she can be accepted as an egg donor. To be seriously considered a woman must sign an informed consent form which—although not standardized—generally

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29. John E. Buster, *Historical Evolution of Oocyte and Embryo Donation as a Treatment for Intractable Infertility*, in PRINCIPLES OF OOCYTE & EMBRYO DONATION 3, 3 (Mark V. Sauer, ed., 1998); see Peter Lutjen et al., *The Establishment and Maintenance of Pregnancy Using 'In Vitro' Fertilization and Embryo Donation in a Patient with Primary Ovarian Failure*, 307 NATURE 174, 174–75 (1984), available at <http://www.nature.com/nature/journal/v307/n5947/abs/307174a0.html>.

30. See e.g. U.S. CTR. FOR DISEASE CONTROL AND PREVENTION, ASSISTED REPRODUCTIVE TECHNOLOGY (ART) REPORT: SECTION 4: ART CYCLES USING DONOR EGGS 61, available at <http://www.cdc.gov/ART/ART2006/508PDF/2006ART.pdf> (reporting donation and IVF cycle information compiled from 483 reporting fertility clinics) (describing the increase in donated eggs between 1996 and 2006) [hereinafter CDC 2006 REPORT].

31. *Id.* at 56.

32. U.S. CTR. FOR DISEASE CONTROL AND PREVENTION 1996 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: SECTION 4: ART CYCLES USING DONOR EGGS 22 (1996) [hereinafter CDC 1996 Report].

33. Marsha J. Gorrill, *Selection and Screening of Potential Oocyte Donors*, in PRINCIPLES OF OOCYTE AND EMBRYO DONATION 35, 38–40 (Mark V. Sauer ed., 1998).

34. *Id.* at 39–40.

35. IOM, *supra* note 1, at 26–28.

36. *Id.* at 28.

outlines the procedures, medications, risks (as recognized by the clinic at the time), and legal disposition of the eggs and embryos.<sup>37</sup> Most clinics require psychological testing and a psychological interview to evaluate a donor's emotional stability, life stresses, and coping skills.<sup>38</sup> The donor must also complete a screening health questionnaire, including an extensive family history detailing hereditary diseases.<sup>39</sup> She is further subjected to a thorough physical examination, including a transvaginal pelvic ultrasound to screen for pelvic pathology, and blood tests to check for infectious diseases and hormone levels.<sup>40</sup> If the results are all acceptable, the woman may be selected for donation. The Institute of Medical and National Research Council estimates that only about 12% of all applicants actually complete the screening and donation cycle.<sup>41</sup>

## 2. Preparation and Donation

Under nonclinical conditions, [during a regular monthly cycle], a woman generally produces one egg to maturation. This egg bursts from its follicle on one of the two ovaries, and then travels into the fallopian tube and down into the uterus.<sup>42</sup> For fertilization to occur, the egg must encounter sperm in the fallopian tube before it reaches the uterus. Egg retrieval is timed to catch the eggs shortly before they start this journey.<sup>43</sup> When a sperm succeeds in reaching and penetrating the egg, the fused cells form a *zygote*,<sup>44</sup> which travels to the uterus and implants in the uterine lining, where it will remain for nine months, as it develops into a full-term baby.

To be useful as a donor, a woman's cycle must be coordinated with the recipient's and the number of eggs reaching maturation during a single ovulation cycle must be vastly increased. The procedure begins with a ten-to twenty-one day regimen using a hormone such as Lupron to completely suppress ovulation and synchronize the donor's menstrual cycle with the cycle of the mother-to-be.<sup>45</sup> Following the initial qualifying ultrasound and blood tests, the donor undergoes a second round of ultrasound and blood

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37. Kari L. Karsjens, *Boutique Egg Donations: A New Form of Racism and Patriarchy*, 5 DEPAUL J. HEALTH CARE L. 57, 62–63 (2002).

38. Gorrill, *supra* note 33, at 44 (citing a 1992 study showing over three-quarters of clinics have this requirement).

39. *Id.* at 41–42.

40. *Id.* at 42.

41. IOM, *supra* note 1, at 42.

42. *Id.* at 31.

43. *Id.* at 31; Kenneth Baum, *Golden Eggs: Towards the Rational Regulation of Oocyte Donation*, 2001 BYU L. REV. 107, 118 (2001).

44. "Zygote: A cell formed by the union of male and female germ cells." NRCIM GUIDELINES, *supra* note 17, at 120.

45. See Baum, *supra* note 43, at 117–18; Karsjens, *supra* note 37, at 63; Michelle Bercovici, *Biotechnology Beyond the Embryo: Science, Ethics, and Responsible Regulations of Egg Donation to Protect Women's Rights*, 29 WOMEN'S RTS. L. REP. 193, 194–95 (2008).

tests ten to eleven days into the ovulation suppression process. Assuming her hormone levels are within the expected range and her ovaries appear normal, she then starts a seven- to twelve-day course of intramuscular self-injections of a relatively high dose of a follicle-stimulating hormone (FSH) taking her from no eggs to an abnormally large production, between ten and twenty.<sup>46</sup> Next, the clinic will check the donor's blood again for hormone levels and administer an ultrasound to measure the development of the eggs in her ovaries. Once the donor's oocytes have fully developed, she receives a final shot of a high-concentration of human chorionic gonadotropin (hCG), an ovarian-stimulating hormone that prepares her eggs for retrieval.<sup>47</sup>

Approximately thirty-six hours after administration of hCG, the donor is put under general anesthesia and a needle is inserted through her vagina into her ovaries where it suctions out the eggs.<sup>48</sup> Fertility doctors and the recipients paying for the eggs prefer the donor develop at least ten mature follicles per cycle.<sup>49</sup> The average number of mature follicles a donor may develop appears to be around thirteen, although some doctors indicate that some women on powerful fertility drugs can produce up to forty eggs in one cycle.<sup>50</sup> Immediately after the donor's eggs are retrieved, the eggs are inseminated in the laboratory. Within a couple of days a physician performs the embryo transfer, selecting several healthy-appearing embryos and transferring them into the waiting recipient.<sup>51</sup>

### C. RISKS OF DONATION

While the process of stimulating ovaries and retrieving eggs is represented to donors as generally safe, it carries associated complications, side effects, and risks. At the lower end of the risk spectrum are minor problems, such as: bruising from subcutaneous injections; hormonal side effects, including hot flashes, mood swings, vaginal dryness, and difficult or painful intercourse; and potential heavy bleeding due to estrogen withdrawal.<sup>52</sup> A more serious risk, also disclosed on informed consent

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46. Baum, *supra* note 43, at 118; Bercovici, *supra* note 45, at 195.

47. Baum, *supra* note 43 at 118; IOM, *supra* note 1, at 10–11.

48. Baum, *supra* note 43, at 118.

49. Jesse McKinley, *The Egg Woman*, N.Y. TIMES, May 17, 1998, at 7.

50. McKinley, *supra* note 49, at 7; see Bercovici, *supra* note 45, at 195, 29 WOMEN'S RIGHTS L. REP. 193, 195 (stating that hyperstimulation generally produces between ten and twenty eggs at once); see also Jodie Snyder, *Donating Eggs Creates Nest Egg*, ARIZ. REPUBLIC, May 30, 2006, at A6 (describing the experience of a woman who donated eggs five times over two years, producing between thirteen and twenty-three eggs per cycle); Hopkins, *supra* note 1, at 2A (describing typical egg production with ovarian stimulation hormones as between ten and fifteen eggs per cycle).

51. Baum, *supra* note 43, at 118.

52. Randy S. Morris, *Complications and Side Effects of Oocyte Donation*, in PRINCIPLES OF OOCYTE & EMBRYO DONATION 97, 98 (Mark V. Sauer ed., 1998).

forms, is complication during the egg harvesting surgery.<sup>53</sup> This procedure carries the danger of infection; use of anesthetic; hemorrhage and injury to adjacent structures like the ureter, bladder, and bowel; and pelvic scarring.<sup>54</sup> ART clinics typically do not keep statistics on these surgical complications, so it is difficult to quantify the extent or frequency of injuries caused during the retrieval process.<sup>55</sup> Furthermore because of the lack of longitudinal studies to determine the long-term effects of egg donation on a donor's health, there may be many possible risks and complications that cannot be taken into account prior to donating.

### 1. Ovarian Hyperstimulation Syndrome

Medical professionals generally regard ovarian hyperstimulation syndrome (OHSS) as the most serious complication of ovulation induction treatment.<sup>56</sup> Accordingly, it is included on informed consent forms.<sup>57</sup> While the syndrome is not yet completely understood, it is believed the gonadotropin stimulation of the ovaries caused by use of hGCs will generally trigger a massive fluid buildup in the abdomen.<sup>58</sup> This fluid build-up can lead to pressure on the diaphragm causing labored breathing and a decrease in blood volume. OHSS has been described as "the most serious iatrogenic complication of ovulation induction treatment,"<sup>59</sup> with higher doses of fertility drugs increasing the effectiveness of follicle development while simultaneously increasing the risk of adverse effects to the patient.<sup>60</sup>

OHSS cases are often categorized as moderate or severe, and most women who undergo ovarian stimulation will have at least some mild

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53. The ASRM Practice Committee recommends practitioners inform donors of the risks involved in egg harvesting surgery. ASRM Practice Committee, *Elements to be Considered in Obtaining Informed Consent for ART*, FERTILITY & STERILITY, S272, S273 (Nov. Suppl. 2006).

54. Morris, *supra* note 52, at 101–04.

55. IOM, *supra* note 1, at 32–33.

56. Yoram Abramov, Uriel Elchalal, & Joseph G. Schenker, *Pulmonary Manifestations of Severe Ovarian Hyperstimulation Syndrome: A Multicenter Study*, 71 FERTILITY & STERILITY 645, 645 (1999).

57. It is difficult to find consistent data on the incidence of OHSS, in part because practitioners use different definitions for what symptoms and degree of severity count as OHSS. Jayaprakasan et al., *Estimating the Risks of Ovarian Hyperstimulation Syndrome (OHSS): Implications for Egg Donation for Research*, 10 HUM. FERTILITY 183, 183 (2007). Although some estimate that severe OHSS presents in just 0.1% to 0.2% of women who undergo ovarian stimulation (IOM, *supra* note 1, at 29; Abramov, *supra* note 57, at 645), others estimate that between 0.3% and 5% or even up to 10% of such women experience severe OHSS. David Magnus & Mildred Cho, *Ethics: Issues in Oocyte Donation for Stem Cell Research*, 308 SCI. 1747, 1747 (2005).

58. Abramov, *supra* note 56, at 645.

59. *Id.* at 645. An "iatrogenic" disorder is one inadvertently induced by treatment for another disorder. MERRIAM-WEBSTER'S MEDICAL DESK DICTIONARY 379 (2005).

60. Noah, *Pitfalls*, *supra* note 7, at 628.

symptoms of hyperstimulation.<sup>61</sup> The more severe forms of OHSS may require hospitalization and surgery,<sup>62</sup> as this syndrome has also been known to cause liver dysfunction,<sup>63</sup> kidney failure, adult respiratory distress syndrome,<sup>64</sup> thrombosis,<sup>65</sup> thromboembolic pneumonia,<sup>66</sup> stroke,<sup>67</sup> central retinal artery occlusion,<sup>68</sup> ovarian torsion,<sup>69</sup> delirium,<sup>70</sup> and even death.<sup>71</sup>

Past studies have indicated that donors have a lower risk of developing OHSS than the infertile egg recipients because risk of OHSS associated with fertility drugs is higher in pregnant women.<sup>72</sup> Nevertheless, this risk to donors has still been considered significant enough to warrant serious

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61. IOM, *supra* note 1, at 18.

62. Morris, *supra* note 52, at 99; IOM, *supra* note 1, at 18–19.

63. Bogdan Obrzut et al., *Liver Dysfunction in Severe Ovarian Hyperstimulation Syndrome*, 21 GYNECOLOGICAL ENDOCRINOLOGY 45, 45–49 (2005) (reporting on a severe case of OHSS in a 32-year-old woman that resulted in severe liver dysfunction); Andrew J. Davis et al., *A Severe Case of Ovarian Hyperstimulation Syndrome with Liver Dysfunction and Malnutrition*, 14 EUR. J. OF GASTROENTEROLOGY & HEPATOLOGY 779, 779–82 (2002).

64. Fineschi Vittorio et al., *An Immunohistochemical Study in a Fatality Due to Ovarian Hyperstimulation Syndrome*, 120 INT'L J. LEGAL MED. 293 293–99 (2006).

65. Apurv Sinha et al., *Need for an Urgent Ultrasound Examination for Neck Lump*, 116 LARYNGOSCOPE 833, 833–34 (2006) (finding few cases of upper extremity thrombosis due to OHSS following IVF); Anjali K. Rao et al., *Subclavian Vein Thrombosis Following IVF and Ovarian Hyperstimulation: A Case Report*, 20 HUM. REPROD. 3307, 3307–12 (2005) (stating that approximately “one in 128 women with severe OHSS develops thromboembolism,” and 66% of cases of thromboembolism associated with ovulation induction were associated with IVF and 84% associated with pregnancy); Ramazan Akdemiret et al., *Acute Myocardial Infarction Secondary Thrombosis Associated with Ovarian Hyperstimulation Syndrome*, 83 INT'L J. OF CARDIOLOGY 187, 187–89 (2002); A. Mancini et al., *A Case of Forearm Amputation After Ovarian Stimulation for In Vitro Fertilization-Embryo Transfer*, 76 FERTILITY & STERILITY 198, 198–200 (2001); J.A. Stewart et al., *Thromboembolic Disease Associated with Ovarian Stimulation and Assisted Conception Techniques*, 12 HUM. REPROD. 2167, 2167–72 (1997).

66. Abramov, *supra* note 57, at 646.

67. Sandra Coney, *Auckland Inquest Into Death After IVF*, 345 LANCET 849 (1995) (reporting possibly the first case of death due to stroke following IVF treatment).

68. I.M. Turkistani et al., *Central Retinal Artery Occlusion Associated with Severe Ovarian Hyperstimulation Syndrome*, 11 EUR. J. OF OPHTHALMOLOGY 313, 313–15 (2001).

69. H. Gorkemliet et al., *Adnexal Torsion After Gonadotrophin Ovulation Induction for IVF or ICSI and Its Conservative Treatment*, 267 ARCHIVES GYNECOLOGY & OBSTETRICS 4, 4–6 (2002).

70. Sibel Mercanet et al., *Case Report: Delirium Associated with Ovarian Hyperstimulation Syndrome*, 10 REPROD. BIOMED. ONLINE 178, 178–81 (2005) (presenting the case of a thirty-year-old woman who developed OHSS following oocyte retrieval, resulting in delirium). “Delirium is a syndrome, not a disease, and has many causes . . . [d]elirium remains an under recognized and under-diagnosed clinical disorder.” *Id.*

71. Morris, *supra* note 52, at 100; see generally Alison Solomon, *Sometimes Perganol Kills*, in INFERTILITY: WOMEN SPEAK OUT ABOUT THEIR EXPERIENCES OF REPRODUCTIVE MEDICINE 46, 46–50 (Renate D. Klein, ed., 1989) (relating an interview with the husband of a woman who died of herniation of the brain following OHSS induced by IVF).

72. See Morris, *supra* note 52, at 100–101 (stating that in a study of 139 ART cycles, including seventy-two donors and sixty-seven IVF cycles (recipients), six IVF patients developed OHSS and no donors). Morris also states that no reports of donor OHSS were found in the literature at the time of publication. *Id.* at 100.

attention.<sup>73</sup> In contrast to the prior body of research suggesting low risk to donors, a recent study by the National Health Service in the United Kingdom has indicated that the risk to egg donors of developing OHSS is not eliminated by not becoming pregnant.<sup>74</sup> Rather, the researchers found that the risk of serious OHSS symptoms correlated with the development of greater than twenty egg follicles after injection with hCG.<sup>75</sup> Additionally, youth is considered a risk factor for OHSS because younger women tend to have a greater number of primordial follicles.<sup>76</sup> The implications of this study are very serious for egg donors, since youth is a requirement for egg donation; most clinics set an age range of eighteen to thirty years old for their donors.

## 2. Women's Hormone Use and Cancer

Prescriptions for ovulation-inducing drugs nearly doubled between 1973 and 1991.<sup>77</sup> By 2006, estimated annual U.S. spending on fertility drugs was \$1.3 billion.<sup>78</sup> This demand for fertility drugs seems likely to continue since some projections suggest that between 5.4 million and 7.7 million women aged fifteen to forty-four will be diagnosed with some form of infertility by 2025.<sup>79</sup> The most alarming consideration regarding an increase in fertility drug usage is the absence of definitive long-term studies to rule out the possibility of increased cancer risks for women using these pharmaceuticals.<sup>80</sup>

This is particularly troubling given a historical pattern of experimenting with synthetic hormone treatments on women without sufficient research or investigation to establish safety.<sup>81</sup> The widespread prescription of diethylstilbestrol (DES) to pregnant women starting in 1947,<sup>82</sup> and the more recent vigorously marketed hormone replacement therapy (HRT) to menopausal women, were both somewhat experimental

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73. See IOM, *supra* note 1, at 29; Magnus et al., *supra* note 57, at 1747–48, *Ethics: Issues in Oocyte Donation for Stem Cell Research*, 308 SCI. 1747, 1747–48 (2005).

74. See Jayaprakasan et al., *supra* note 57, at 183–87.

75. *Id.* “[T]he presence of  $\geq 20$  follicles identified 99.96% of women who developed significant clinical symptoms or biochemical features of OHSS requiring hospital admission.” *Id.* at 185.

76. IOM, *supra* note 1, at 21.

77. Brinton et al., *Ovulation Induction*, *supra* note 4, at 261.

78. Hopkins, *supra* note 1, at 2A.

79. Brinton et al., *Ovulation Induction*, *supra* note 4, at 261.

80. See, e.g., Brinton et al., *Ovulation Induction*, *supra* note 4, at 262.

81. Speaking of unknown long-term effects on women taking hormones, the FDA has given approval to an oral contraceptive that stops a woman's monthly period indefinitely. See Associated Press, *Agency Approves a Birth Control Pill Halting Periods Indefinitely*, N.Y. TIMES, May 23, 2007, at C1.

82. Beeson & Lippman, *supra* note 1, at 575.

and created serious health problems for women.<sup>83</sup> DES, a potent estrogen initially prescribed to pregnant women in 1938 for the prevention of miscarriage and premature birth<sup>84</sup> was the first synthetic estrogen to be discovered.<sup>85</sup> Between 1950 and 1952, some 1,000 women unknowingly became part of an experiment conducted by the University of Chicago and Eli Lilly & Company as part of a double-blind study to determine the value of this synthetic estrogen in preventing miscarriages.<sup>86</sup> In 1971, the Food and Drug Administration eventually banned prescribing DES to pregnant women after research linked DES to a rare vaginal cancer, clear cell adenocarcinoma, in those women's female children.<sup>87</sup> Despite this discovery, the women in the experiment were neither informed that they had taken the drug, nor of the possible link between DES and abnormal conditions in their daughters' genital tracts until late 1975 or 1976.<sup>88</sup> Moreover, DES was still prescribed to women outside the United States after 1971 without any tracking data to describe where, when, or in what form or quantities it is being sold.<sup>89</sup> Some commentators have pointed out that it was somewhat fortuitous that DES was shown to cause a rare cancer, for had it been breast or uterine cancer, its carcinogenicity may never have been discovered and it might still be prescribed today.<sup>90</sup>

Even before DES was taken off the market, hormone replacement therapy was promoted as the answer to an aging woman's problems. Starting in the 1950s, Ayerst Laboratories began aggressive marketing of a hormone replacement pill to menopausal women.<sup>91</sup> The pill was Premarin, which was created with extracted estrogen from pregnant mares.<sup>92</sup> Robert Wilson's *Feminine Forever*, which had Ayerst's financial backing and advertised the benefits of HRT, was published in 1966 and further boosted hormone replacement sales.<sup>93</sup> By 1975, Premarin was administered to approximately six million women, making it the number one dispensed

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83. Beeson & Lippman, *supra* note 1, at 575; see also Davis et al., *Postmenopausal Hormone Therapy: From Monkey Glands to Transdermal Patches*, 185 J. OF ENDOCRINOLOGY 207, 213–15 (2005) (discussing risks of hormone replacement therapy).

84. Mike Mitka, *CDC Resource Focuses on DES Exposure*, 289 J. AM. MED. ASS'N 1624, 1624 (2003).

85. CTRS. FOR DISEASE CONTROL, DES: PHARMACOLOGY, DATA INDICATING LACK OF EFFICACY FOR PREVENTION OF MISCARRIAGE, CLINICAL INDICATIONS, AND CURRENT USES, <http://www.cdc.gov/des/hcp/pharmacology/index.html> (last visited Apr. 21, 2009) [hereinafter, CDC DES].

86. *Mink v. Univ. of Chi.*, 460 F.Supp.713, 715 (N.D. Ill. 1978).

87. Mitka, *supra* note 84, at 1624 (citing Arthur L. Herbst et al., 284 NEW ENG. J. MED. 878, 878–91 (1971)).

88. *Mink*, 460 F. Supp. at 715.

89. CDC DES, *supra* note 85.

90. GENA COREA, THE MOTHER MACHINE, REPRODUCTIVE TECHNOLOGIES FROM ARTIFICIAL INSEMINATION TO ARTIFICIAL WOMB 149 (1985).

91. Davis et al., *supra* note 83, at 210.

92. *Id.*

93. *Id.*

drug in the United States.<sup>94</sup> In the mid-1970s, an increased risk for invasive and non-invasive endometrial cancer was demonstrated by using estrogen unopposed by progesterone, causing the use of Premarin and other estrogens to dramatically fall.<sup>95</sup>

In the 1980s and 1990s, pharmaceutical companies marketed a new kind of HRT which used both estrogen and progesterone, which appeared to offer improved menopause health without the adverse effects of Premarin-style estrogen only treatment.<sup>96</sup> Although earlier studies observed an elevated risk of breast cancer in postmenopausal women who either took estrogen alone or both estrogen and progestin,<sup>97</sup> it was not until 2002 that a trial of estrogen plus progesterone, undertaken by the Women's Health Initiative (WHI) was stopped due to the discovery of the increased risk of adverse health effects associated with its use, including invasive breast cancer and coronary heart disease.<sup>98</sup>

After the trial was halted and the women ceased taking the hormones, the researchers conducted a three-year follow-up study.<sup>99</sup> This study observed a 27% increased risk for breast cancer and a 24% increased risk of development of any form of cancer in the treatment group compared to the rate in women randomized to placebo therapy.<sup>100</sup> While the study has attracted widespread debate and criticism,<sup>101</sup> it is important to follow those who take hormones, even after they stop.

Additionally, several studies found an association between long-term use of estrogen and an increased risk of ovarian cancer.<sup>102</sup> More research is

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94. Davis et al., *supra* note 83, at 210.

95. *Id.* at 211.

96. *Id.*

97. Graham A. Codlitz et al., *The Use of Estrogens and Progestins and the Risk of Breast Cancer in Postmenopausal Women*, 332 *NEW ENG. J. MED.* 1589, 1591 (1995). Progestin is a natural or synthetic hormone that mimics progesterone, a sex hormone produced by the ovaries. *MERRIAM-WEBSTER'S MEDICAL DESK DICTIONARY* 671 (2005).

98. Jacques E. Rossouw et al., *Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women, Principal Results From the Women's Health Initiative Randomized Controlled Trial*, 288 *J. AM. MED. ASS'N* 321, 330 (2002).

99. Gerardo Heiss et al., *Health Risks and Benefits 3 Years After Stopping Randomized Treatment With Estrogen and Progestin*, 299 *J. AM. MED. ASS'N* 1036, 1036 (2008); Press Release, Nat'l Inst. of Health, WHI Follow-Up Study Confirms Health Risks of Long-Term Combination Hormone Therapy Outweigh Benefits for Postmenopausal Women (Mar. 4, 2008), <http://www.nih.gov/news/health/mar2008/nhlbi-04.htm> [hereinafter Press Release, NIH].

100. See Press Release, NIH, *supra* note 99.

101. Davis et al., *supra* note 83, at 212.

102. James V. Lacey, Jr. et al., *Menopausal Hormone Replacement Therapy and Risk of Ovarian Cancer*, 288 *J. AM. MED. ASS'N* 334, 339 (2002); Carmen Rodriguez, Alpa V. Patel, Eugenia E. Calle, Eric J. Jacob, Michael J. Thun, *Estrogen Replacement Therapy and Ovarian Cancer Mortality in a Large Prospective Study of US Women*, 285 *J. AM. MED. ASS'N*, 1460, 1463 (2001); U.S. NAT'L INST. OF HEALTH, NATIONAL CANCER INSTITUTE FACT SHEET: MENOPAUSAL HORMONE REPLACEMENT THERAPY USE AND CANCER: QUESTIONS AND ANSWERS, Question 7 (last visited Oct. 5, 2007); *Study Cites Hormones as Cancer Risks*, *N.Y. TIMES*, July 15, 2009, at A13.

underway to invent new drugs<sup>103</sup> to alleviate the pain and suffering of a woman's passage into menopause, which for some is good news and for others is frightening, considering the "widespread exposure of healthy women to incompletely assessed drug interventions."<sup>104</sup>

### 3. Ovarian Hyperstimulation and Cancer

According to Louise Brinton et al., there are three areas raising concern for the potential effects of ovulation-inducing drugs on cancer risk.<sup>105</sup>

First, the most commonly used medications, clomiphene citrate and gonadotropins, are effective for stimulating ovulation, a factor implicated in the etiology of both breast and ovarian cancers. Second, these drugs raise both E2 and P levels, hormones that are recognized as affecting the development and growth of breast and gynecologic cancers as well as some other cancers. Finally, as elaborated below, some clinical and epidemiological studies have linked use of these drugs with an increased incidence of various cancers.<sup>106</sup>

A study reported in 1992 in the *American Journal of Epidemiology* found an association between fertility medications and ovarian cancer in twelve U.S. case-controlled studies.<sup>107</sup> Two years later in 1994, a reported Seattle-based cohort study concluded that Clomiphene use (for stimulating the ovaries) was associated with a 2.3-fold increased risk for ovarian cancer.<sup>108</sup> Several studies since then have found ovulation-inducing drugs to have no effect on ovarian cancer risk,<sup>109</sup> but these studies confirmed previous findings that infertility increases the overall risk of ovarian cancer.<sup>110</sup> Brinton, through an extensive analysis of previous studies, found a modest increase in risks for ovarian cancer among women with twelve or more cycles of use (or fifteen or more years since follow-up) and in nulligravid (never-pregnant) women.<sup>111</sup> However, all of this warrants further research as most of the studies were relatively small and/or had

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103. See Davis et al., *supra* note 83, at 216–218.

104. Beeson & Lippman, *supra* note 1, at 575 (describing experimental use of HRT and DES on unwitting patients, and arguing that "[p]olicy makers have an obligation to protect non-patient 'donors' from the possible threat of irreversible harm by insisting that prevention take precedence over everything else").

105. Brinton et al., *Ovulation Induction*, *supra* note 4, at 261; see IOM, *supra* note 1, at 22–26.

106. Brinton et al., *Ovulation Induction*, *supra* note 4, at 261.

107. Mahdavi et al., *supra* note 4, at 825.

108. Rossing et al., *supra* note 4, at 773.

109. Brinton et al., *Ovulation Induction*, *supra* note 4, at 264–65.

110. Roberta B. Ness et al., *Infertility, Fertility Drugs, and Ovarian Cancer: A Pooled Analysis of Case-Control Studies*, 155 AM J. EPIDEMIOLOGY 217, 222 (2002).

111. Brinton et al., *Ovulation Induction*, *supra* note 4, at 264–65 (2005).

short-term follow-up.<sup>112</sup> As Brinton has so acutely observed, “[g]iven that clomiphene was first approved for clinical use in 1967 and gonadotrophins in 1969, the women who first used these drugs during their late 20s and early 30s have only recently reached the age when hormonally related cancers are common.”<sup>113</sup> In a later critical review of the literature it was noted that the epidemiological studies on fertility drug use and risk of ovarian cancer were hampered by methodological problems, such as small study size, short follow-up time, and low prevalence of infertility and fertility drug use.<sup>114</sup> As a result, some commentators have concluded that it is possible the effect of fertility drug use on ovarian cancer risk has been underestimated.<sup>115</sup>

Findings for breast, uterine, endometrial, and other cancers are similarly inconclusive. However, one study focusing on women using Clomiphene found that as time elapsed since treatment, there was an increase in the risk for breast, ovarian, and endometrial cancers, with the highest risks for endometrial cancers.<sup>116</sup> In a more recent study conducted at Hadassah-Hebrew University in Jerusalem, researchers reported three times the incidence of uterine cancer in women who had been given ovulation-inducing fertility drugs and subsequently gave birth.<sup>117</sup> For women who took Clomiphene, the risk was over four times that of women who did not take drugs.<sup>118</sup> The researchers also reported a smaller, but significant, increase in breast cancer and malignant melanoma associated with Clomiphene use,<sup>119</sup> and an increase in non-Hodgkin’s lymphoma associated with taking ovulation induction drugs.<sup>120</sup> Interestingly, no increased hazard of developing ovarian cancer was observed in connection with either regimen.<sup>121</sup>

Thus far, all of the studies exploring a possible association between fertility drugs and cancer have been conducted on the “egg recipients” or infertile women, and none of the studies have focused on healthy oocyte donors.<sup>122</sup> To date, investigations have failed to account for previous use of hormones (e.g., use of birth control pills or HRT) or genetic predisposition

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112. Brinton et al., *Ovarian Cancer*, *supra* note 4, at 1201.

113. *Id.* at 1200.

114. Mahdavi et al., *supra* note 4, at 825.

115. *Id.*

116. IOM, *supra* note 1, at 26.

117. R. Calderon-Margalit et al., *Cancer Risk After Exposure to Treatments for Ovulation Induction*, 169 AM. J. EPIDEMIOLOGY 365, 368 (2009), available at <http://aje.oxfordjournals.org/cgi/content/abstract/169/3/365>; see Alison Motluk & Celeste Biever, *Fertility Drugs Increase Cancer Risk*, NEW SCIENTIST, Dec. 13, 2008, at 14.

118. Calderon-Margalit et al., *supra* note 117, at 368.

119. *Id.* at 370.

120. *Id.* at 368.

121. *Id.* at 368–70.

122. Catherine Elton, *As Egg Donations Mount, So Do Health Care Concerns*, TIME, Mar. 31, 2009, available at <http://www.time.com/time/health/article/0,8599,1888459-1,00.html>.

in that they have not controlled for these factors in their examinations.<sup>123</sup> According to Brinton, other factors of concern include the current trend in ART of using higher levels of gonadotropins for stimulation and a luteal<sup>124</sup> phase support for several weeks with supplemental progestins, as these agents have been linked to increases in breast cancer risk.<sup>125</sup> This story may sound familiar in what appears to be a pattern of experimenting with the use of hormone drugs on women without definitive studies warranting their safety.

Below are two anecdotal reports of deaths of oocyte donors from colon cancer following cycles of egg donation.<sup>126</sup> While anecdotal reports cannot replace in-depth investigation into the potential risks of a procedure, because those tests have not been conducted and because there is no long-term tracking of egg donor health by clinics or the Federal Drug Administration (FDA), there is no hard data showing the safety or danger of egg donation. Further, until such systematic data gathering is conducted, stories like these women's should be highlighted to illustrate the need for further research.

The most recent case involved a young egg donor who went through three egg-retrieval cycles in a few months.<sup>127</sup> Four years later she displayed widespread colon cancer, which had metastasized to her ovaries and later spread to her brain and bones.<sup>128</sup> After two years of treatment, she died at the age of thirty-one.<sup>129</sup> Subsequent DNA testing of her tissue revealed no genetic predisposition to colon cancer.<sup>130</sup>

In an earlier case, a donor went through two cycles to provide oocytes for her sister.<sup>131</sup> Four years later she had a tumor removed from her bowel.<sup>132</sup> One year later a metastasis eroded the base of her skull and she died shortly thereafter at age thirty-nine.<sup>133</sup> Other family members were screened showing no hereditary evidence of disease.<sup>134</sup>

Even the reporting of two colon cancer incidents to the medical community was to some extent serendipitous; one was reported because her

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123. Brinton et al., *Ovulation Induction*, *supra* note 4, at 271–72.

124. The luteal phase is the period between ovulation and menstruation. MERRIAM-WEBSTER'S MEDICAL DESK DICTIONARY 466 (2005).

125. Brinton et al., *Ovulation Induction*, *supra* note 4, at 271.

126. Jennifer Schneider, *Fatal Colon Cancer in a Young Egg Donor: A Physician Mother's Call for Follow-Up and Research on the Long-Term Risks of Ovarian Stimulation*, 90 FERTILITY & STERILITY 2016, 2016.e1–2016.e5 (2008); see K.K. Ahuja & E.G. Simons, *Cancer of the Colon in an Egg Donor: Policy Repercussions for Donor Recruitment*, 13 HUM. REPROD. 227, 227–28 (1998).

127. Schneider, *supra* note 126.

128. *Id.*

129. *Id.*

130. *Id.*

131. Ahuja & Simons, *supra* note 126, at 227–228.

132. *Id.* at 228.

133. *Id.*

134. *Id.* at 228.

mother was a physician and the other because the clinic had followed up with the sister regarding the disposition of the frozen embryos and thereby learned of the donor's death.<sup>135</sup> As pointed out by Dr. Schneider in her article documenting the death of her oocyte-donating-daughter, "[t]here has been no systematic study of the long-term risk of cancer or other adverse outcomes in healthy egg donors." At present, potential egg donors cannot give truly informed consent because insufficient information exists about their long-term risks.<sup>136</sup>

#### 4. The Psychology of Donation

There are only a few small studies assessing the psychological aspects of oocyte donation.<sup>137</sup> Common complaints from donors during the donation process include hormone injections, egg retrieval pain, anxiety, and mood swings.<sup>138</sup> Donors also reported worrying about potential medical and fertility consequences from their donations.<sup>139</sup> In a small study of thirty-two women, 50% reported concerns about never knowing if a child resulted from the donation.<sup>140</sup> Based on the current research it appears that women primarily donate eggs for altruistic reasons and financial compensation.<sup>141</sup> It is interesting to note that in a small study of the attitudes of oocyte donors in a university-based IVF program toward oocyte/embryo disposition, the donors' attitudes changed following donation. While 97% of participants said they would donate again, as donors became more knowledgeable about the process, they became more assertive about stating their attitudes about the process and expressed more concern for the future of their eggs.<sup>142</sup>

#### D. THE ISSUES OF MONEY AND TIME

##### 1. Supply and Demand

Since the first oocyte donation resulted in a live birth in 1984, demand for young women's eggs has risen. Not only are more women seeking the assistance of reproductive technology, but the number of attempts required for successful pregnancy supports the need as well; in 2007 only 27% of

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135. Schneider, *supra* note 126, at 2016.e1–2016.e5; Ahuja & Simons, *supra* note 126, at 228.

136. Schneider, *supra* note 126, at 2016.e1–2016.e5.

137. IOM, *supra* note 1, at 41.

138. *See id.* at 44–45.

139. IOM, *supra* note 1, at 45–46.

140. Nancy J. Kenney & Michele L. McGowan, *Looking Back: Egg Donors' Retrospective Evaluations of Their Motivations, Expectations, and Experiences During Their First Donation Cycle*, FERTILITY & STERILITY, doi:10.1016/j.fertnstert.2008.09.081, at 4–5 (published online Nov. 19, 2008).

141. Kenney & McGowan, *supra* note 140, at 4–5.

142. *See* Julianne E. Zweifel et al., *Comparative Assessment of Pre- and Post-Donation Attitudes Towards Potential Oocyte and Embryo Disposition and Management Among Ovum Donors in an Oocyte Donation Programme*, 21 HUM. REPROD 1325, 1327 (2006).

the ART attempts resulted in a baby.<sup>143</sup> In the United States, unlike many other countries, women donating eggs for assisted reproductive medicine can legally receive compensation, and no federal legislation in the United States regulates oocyte donations.<sup>144</sup>

Hundreds of internet sites advertise egg donors' profiles to hopeful parents. For example, Egg Donation, Inc., claims to be the world's oldest and largest program with "over 600 of the most exceptional and diverse donors available anywhere."<sup>145</sup> The Egg Donor Program claims it has "the most beautiful and accomplished donors in the country."<sup>146</sup> In fact, the whole business transaction can take place over the internet.<sup>147</sup>

Clinics and websites characterize payments to donors as compensation for the time spent in the clinical setting (approximately fifty-six hours<sup>148</sup>) and not for the eggs themselves.<sup>149</sup> However, this seems disingenuous in view of ads placed in Ivy League school papers. For example, as much as \$100,000 has been offered to entice women from the country's best schools to donate eggs.<sup>150</sup> Not surprisingly, the higher-priced ads seek donors with exceptional intelligence and athletic ability. Hundreds of attorneys, agencies, and fertility clinics have sprung up to serve as brokers for egg transactions.<sup>151</sup> Southern California attorney Thomas M. Pinkerton has made offers in the *Stanford Daily* to pay \$50,000 for egg donors.<sup>152</sup> On his website Mr. Pinkerton offers helpful legal information regarding surrogacy and egg and embryo donation.<sup>153</sup> Perhaps even more astonishing than an offer of \$100,000 for eggs is Ron's Angels' auction website initiated in

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143. SPAR, *supra* note 1, at 53–55.

144. Baum, *supra* note 43, at 128. For further discussion on oocyte regulations in various countries outside the U.S., *see id.*, at 128–29.

145. Egg Donation Inc. *About Us*, <http://eggdonor.com/?section=aboutus> (last visited Apr. 24, 2009).

146. Welcome to the Egg Donor Program, <http://www.eggdonation.com/> (last visited Apr. 24, 2009).

147. *See* Lindsey Arent, *Serving Up Eggs on the Web*, WIRED, Aug. 26, 1999, available at <http://www.wired.com/techbiz/media/news/1999/08/21413>.

148. The actual time involved includes eight to ten hours for application completion; physician interview; examination and screening; psychological testing and interview; instructions; and cycle initiation. The initial down-regulation phase involves two to three weeks of time and the ovarian stimulation requires an average of ten days, including four thirty minute office visits. The egg retrieval requires another day and there is a follow-up appointment of approximately thirty minutes. Gorrill, *supra* note 33, at 38 tbl. 4.3.

149. Kenney & McGowan, *supra* note 140, at 4–5.

150. *See* Joan O'C Hamilton, *What Are the Costs*, Stanford Magazine, 55 (Nov./Dec.2000) (advertisements in student newspapers such as Harvard, Yale, and UCLA had promised \$100,000 to Caucasian women under the age of 30 who are willing to donate their eggs); *see* TRANSPLANT NEWS, TRANSPLANT COMM, INFERTILE COUPLE OFFERING \$100,000 TO 'VERY SPECIAL DONOR' WITH 'ATHLETIC ABILITY' TO DONATE EGGS (2000).

151. SPAR, *supra* note 1.

152. Hamilton, *supra* note 150, at 55.

153. *See* Welcome to the National Fertility Law Center, NAT'L FERTILITY L. CTR., <http://www.nationalfertilitylaw.com/> (last visited Apr. 24, 2009).

October 1999 by Ron Harris, a *Playboy* photographer and erotic website owner.<sup>154</sup> His idea was to play on wealthy people's desire for beautiful children.<sup>155</sup> For a fee, buyers can browse through model pictures and personal biographies and bid on eggs in thousand-dollar increments with the bids starting around \$30,000.<sup>156</sup> At [www.ronsangels.com](http://www.ronsangels.com), auction bids can be made for eggs and sperm acquired from "beautiful" models.<sup>157</sup> With hundreds of ads and websites now available for egg shopping and no direct regulation, ethical issues abound.<sup>158</sup>

In an attempt to curb the auction-like atmosphere of egg donation, the Ethics Committee of the American Society for Reproductive Medicine (ASRM Ethics Committee) recommended in 2007 that total payments to donors in excess of \$5,000 required justification, and that none should surpass \$10,000.<sup>159</sup> The Committee reasoned that lower amounts did not pose a risk of undue allurements for financially-strapped women.<sup>160</sup> A follow-up report released by the ASRM in May 2007 indicated that a study of reproductive clinics throughout the United States showed that in over half of SART (Society for Assisted Reproductive Technologies) programs the standard compensation for egg donors was approximately \$4,200.<sup>161</sup>

## 2. Comparing Egg and Sperm Donations

The term "donor" may be a misnomer in the context of egg and sperm offerings, as more often than not money is given in exchange for the tissue. As noted above, this compensation is characterized as payment for the donor's time, not the gametes. No matter how it is represented, there is no

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154. See Baum, *supra* note 43, at 109.

155. *Id.*

156. *Id.*

157. Judith F. Daar, Op-Ed., *Physical Beauty Is Only Egg Deep Infertility: We May Be Shocked by the Crassness of Auctioning Off Models' Eggs, But Good Looks Always Have Been Prized*, L.A. TIMES, Oct. 28, 1999, at B11.

158. Daar, *supra* note 157, at B11. California recently passed a law requiring advertisements, offering cash to egg donors, to include a reference to the health risks posed by the procedure. See Marcy Darnovsky *California Warning Labels: "Donating" Eggs May be Hazardous to Your Health*, BIOPOLITICAL TIMES (Oct. 13, 2009) <http://www.biopoliticaltimes.org/article.php?id=4946>. This new law is the first of its kind in the country and takes an important step towards raising the awareness of young women contemplating donation. Catherine Elton, *As Egg Donations Mount, So Do Health Concerns*, TIME.COM, Mar. 31, 2009, <http://www.time.com/time/health/article/>. The state representative who sponsored the bill, Assemblyman Marty Block, initially contemplated introducing legislation to establish a statewide egg-donor registry. *Id.* He realized, however, that such a costly endeavor would have little success with California's current budget woes. *Id.* 0,8599,1888459-1,00.html.

159. Ethics Committee of the American Society for Reproductive Medicine, *Financial Compensation of Oocyte Donors*, 88 FERTILITY & STERILITY 305, 308 (2007) [hereinafter ASRM Ethics Committee].

160. *Id.*

161. Sharon N. Covington & William E. Gibbons, *What's Happening to the Price of Eggs?* Editor Corner, FERTILITY & STERILITY, 1001, 1003 (2007).

prohibition under United States federal law against paying sperm and egg donors for their contributions for ART.<sup>162</sup> It appears that part of the reasoning for allowing compensation for sperm and blood is that these tissues are regenerative. There are, however, legal prohibitions against paying donors for organs and other non-generative tissues.<sup>163</sup>

When comparing the minimal risk and time involved in sperm and blood donation to the rigorous courses of hormones and invasive procedures women endure for egg donation, it may be argued that egg donation belongs in a separate category.<sup>164</sup> Unlike sperm, women's eggs do not actually regenerate.<sup>165</sup> A woman's egg production is vastly different from a man's production of sperm; in contrast to the long and involved process of oocyte harvesting, sperm are easy to obtain and plentiful. For instance, following puberty, men generally produce anywhere from an average of 50 million to 500 million sperm per day.<sup>166</sup>

There is no federal law regulating compensation for oocyte donation for assisted reproductive technology and only a few states currently address it.<sup>167</sup> Louisiana explicitly prohibits the sale of human oocytes.<sup>168</sup> Virginia, on the other hand, authorizes the sale of human oocytes by explicitly exempting ova from the general ban on the sale of body parts.<sup>169</sup> Florida limits compensation to donors of eggs, sperm, and preembryos to what is "reasonable" but gives no further guidelines as to what that constitutes.<sup>170</sup>

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162. However, it is a different situation for sperm and egg donors for stem cell research in most states. For instance, New York has become the first state to authorize payment to egg donors for embryonic stem cell research. See Rob Stein, *N.Y. Lets Tax Funds Pay Women for Eggs*, WASH. POST (reprinted in S.F. CHRON.), June 26, 2009, at A8.

163. Currently there are strong arguments for allowing compensation for organ donations at death, and for kidney donations while alive. See generally Patrick D. Carlson, *The 2004 Organ Donation Recovery and Improvement Act: How Congress Missed an Opportunity to Say "yes" to Financial Incentives for Organ Donation*, 23 J CONTEMP. HEALTH L. & POL'Y 136 (2006) (discussing Pennsylvania's proposed use of incentives such as funeral benefits to donor family members to increase cadaveric organ donation); see also Curtis E. Harris & Stephen P. Alcorn, *To Solve a Deadly Shortage: Economic Incentives for Human Organ Donation*, 16 ISSUES L. & MED. 213 (2001) ("propos[ing] a governmentally regulated, posthumous organ market in which licensed brokerage houses operate under the oversight of the Food and Drug Administration"); Steve P. Calandrillo, *Cash for Kidneys? Utilizing Incentives to End America's Organ Shortage*, 13 GEO. MASON L. REV. 69 (2004) (discussing monetary incentives such as tax deductions for donors and non-monetary incentives such as "paired organ exchanges").

164. See, e.g., SPAR, *supra* note 1, at 43.

165. See, e.g., Kiessling, *supra* note 21, at 1055.

166. *Id.*

167. Robert Steinbrook, *Egg Donation and Human Embryonic Stem-Cell Research*, 354 NEW ENG. J. MED. 324, 325-26 (Jan. 26, 2006).

168. LA. REV. STAT. ANN. § 9:122 (2008) (Ovum, oocyte and egg are often used interchangeably to refer to the female reproductive cell.); see CHARLES P. KINDREGAN, JR. & MAUREEN MCBRIEN, *ASSISTED REPRODUCTIVE TECHNOLOGY: A LAWYER'S GUIDE TO EMERGING LAW AND SCIENCE* 324 (2006).

169. See VA. CODE ANN. § 32.1-291.16 (2008).

170. FLA. STAT. § 742.14 (2009).

In a related Florida statute prohibiting the advertising or sale of human embryos, “valuable consideration” is clarified as excluding the reasonable costs associated with its removal, storage, and transportation.<sup>171</sup>

There are other state and federal statutes that address gamete donations—both egg and sperm—but only collaterally through IVF regulations.<sup>172</sup> Kenneth Baum divided these regulations into three categories: donor medical screening guidelines, clinic success rate reporting, and insurance coverage.<sup>173</sup> The majority of clinics performing ART comply voluntarily with the guidelines set forth in the American College of Obstetrics and Gynecology and/or the American Society for Reproductive Medicine. The only federal regulation is the U.S. Fertility Clinic Success Rate and Certification Act of 1992.<sup>174</sup> This Act mandates that infertility clinics submit ART success rate data to the CDC annually.<sup>175</sup> The CDC then publishes annual success rates for pregnancies achieved via ART technology as well as develops a model program for licensing embryo laboratories.<sup>176</sup> However, the Act falls short of giving the CDC, or any other entity, the authority to enforce the data-reporting requirement.<sup>177</sup>

According to the CDC’s latest report, the number of ART cycles performed in the United States between 1996 and 2006 more than doubled, going from 64,681 cycles to 138,198.<sup>178</sup> Although the total number of cycles doubled in this ten-year period, the number of cycles using donor eggs and embryos tripled in the same ten-year period.<sup>179</sup>

There are no apparent signs of the industry slowing. In an article published in *USA Today* in 2006, the estimated annual spending by the various level consumers in the fertility business was \$1.3 billion for fertility drugs, \$1 billion for fertility clinic services, \$375 million for diagnostic tests, \$74 million for sperm donor fees, \$38 million for egg donor fees, and \$27 million for surrogate birth mothers.<sup>180</sup>

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171. FLA. STAT. § 873.05 (2009).

172. Baum, *supra* note 43, at 123.

173. *Id.* at 123–24. Also, a few states mandate insurance coverage for ART, including AK, HI, MD, IL, NJ, and TX.

174. 42 U.S.C. §§ 263a-1–7 (2006); see Alicia Ouellete et al., *Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, 31 AM. J.L. & MED. 419, 422 (2005).

175. See § 263a-1(a)(1).

176. See §§ 263a-1(a)(1), (c).

177. Ouellete et al., *supra* note 174, at 422–23.

178. CDC 2006 REPORT, *supra* note 30, at 69.

179. For example, in 1996, 8% of ART participants (5,162 cycles) used donor eggs, and in 2006, 12% used donor eggs (16,976 cycles). See *id.* at section 4, figs.44–48; see also CDC 2006 REPORT, *supra* note 30; see also CDC 1996 Report, *supra* note 32, at 22.

180. Hopkins, *supra* note 1, at 2A.

### III. REMEDIES FOR EGG DONORS

As discussed in Section B above, adverse health effects, primarily OHSS, have been a part of the history of women using ART over the past twenty-plus years. However, no reported United States legal case relating specifically to egg donor injuries could be found. This author is concerned that some of the dearth of cases could be related to informed consent contracts, waiver agreements, and the lack of scientific investigation into the association between fertility drug use and long-term consequences. Contracts and agreements may require the donor to waive her "right to sue the program for medical malpractice, pain and suffering, or any other expenses resulting from complications."<sup>181</sup> While most waivers cannot usurp the donor's right to sue for negligence by the fertility program,<sup>182</sup> in most acute situations contracts provide that medical needs or complications of the donor are handled by the program or whatever insurance has been put in place for the donor by the clinic. However, long-term problems and/or latent injuries are a different matter. As the market grows, it is probable that more egg donors will become injured and legal practitioners will be required to look at analogous areas of law for guidance.<sup>183</sup>

#### A. CIVIL ACTIONS INVOLVING FERTILITY DRUGS USED IN ART

As described in Section B 2, above, pharmaceutical drugs are used to stop a woman's normal cycle, to stimulate increased egg production, and to prepare eggs for retrieval. The FDA has approved several of these drugs for the treatment of infertility.<sup>184</sup> Considering the dangers known about other experimental hormonal drugs the lack of court decisions regarding the liability of fertility drug manufacturers, clinics or individual doctors due to the administration of Lupron, Clomid or other ART drugs is somewhat astonishing.<sup>185</sup> This may be an area of increased litigation in the future as the dangers become fully known.

##### 1. Lupron Related Cases

Lupron is one particular drug which has been in use in ART for several decades but has never been approved by the FDA specifically for such

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181. For an example of an agreement *see* N.Y. STATE TASK FORCE ON LIFE AND THE LAW, THINKING OF BECOMING AN EGG DONOR? GET THE FACTS BEFORE YOU DECIDE 23 (2002).

182. *Id.*

183. *See, e.g.,* Justine Durrell, *Can the Law Handle Human Cloning?*, 38 TRIAL 24, 24 (2002).

184. *See* Noah, *Pitfalls*, *supra* note 7, at 611–12. The FDA has approved the following products for use in treating infertility: clomiphene citrate (brand names Clomid and Serophene), human menopausal gonadotropins (hMG), also known as menotropins (sold under brand names Pergonal and Humegon), urofollitropin (brand names Fertinex and Metrodin), hCG (brand names Pergonyl and A.P.L.) and GnRH agonists (brand name Antagon). *Id.*

185. *Id.*, at 635.

treatment.<sup>186</sup> Leuprolide acetate—commonly known as Lupron—was originally developed for prostate cancer patients, but is now commonly used to treat women with endometriosis, fibroids, and in ART to stop the woman's normal cycle before ovulatory stimulation begins.<sup>187</sup> Lupron is a synthetic gonadotropin-releasing hormone (GnRH) which shuts down the pituitary gland, thereby reducing the amount of testosterone and estrogen produced by the body.<sup>188</sup>

Since 1999 the FDA has received adverse drug reports about Lupron from 4,228 women and 2,943 men.<sup>189</sup> Complaints of side effects included: tingling, itching, headache and migraine, dizziness, severe joint pain, difficulty breathing, chest pain, nausea, depression, emotional instability, dimness of vision, fainting, weakness, amnesia, hypertension, muscular pain, bone pain, nausea/vomiting, asthma, abdominal pain, insomnia, chronic enlargement of the thyroid, liver function abnormality, vision abnormality, and anxiety.<sup>190</sup> Moreover, 325 women required hospitalization and twenty-five women died.<sup>191</sup>

Still, the impact of Lupron on some women has been so profound that the National Women's Health Network, in conjunction with the Center for Medical Consumers, the Endometriosis Association, and Our Bodies Ourselves have formed *The Informed Rx Decision-Making Consortium*, which strives to educate women about prescription drugs, including Lupron.<sup>192</sup> Of three product liability cases against TAP Pharmaceuticals, Inc., for injuries allegedly related to the use of Lupron,<sup>193</sup> two were dismissed under the "Learned Intermediary" doctrine. This provision allowed the courts to determine if the package insert had adequately warned the physician of the types of injuries about which the women

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186. Judy Norsigian, *Egg Donation for IVF and Stem Cell Research, Time to Weigh the Risks to Women's Health*, DIFFERENT TAKES, Spring 2005 at 1, [http://popdev.hampshire.edu/sites/popdev/files/uploads/dt/DifferenTakes\\_33.pdf](http://popdev.hampshire.edu/sites/popdev/files/uploads/dt/DifferenTakes_33.pdf) (Spring 2005).

187. Susan F. Flinn, *Lupron®—If It Kills Prostate Cancer, What Does It Do to Women's Health?*, WOMEN'S ACTIVIST HEALTH NEWSL., Sept./Oct. 2008, [http://nwhn.org/newsletter\\_2008](http://nwhn.org/newsletter_2008) (select "Lupron®—What Does It Do To Women's Health?").

188. Flinn, *supra* note 187.

189. *Id.*

190. *Id.*

191. *Id.*; see also Judy Norsigian, Editorial, *Risks to Women in Embryo Cloning*, BOS. GLOBE, Feb. 25, 2005, at A13 (discussing adverse health effects for women using Lupron, such as depression, memory loss, liver disorders, bone loss, and severe muscle, joint, and bone pain); Hamilton, *supra* note 150 (discussing the death of a woman using Lupron; it is unknown if this case was reported to the FDA.).

192. Flinn, *supra* note 187. The National Women's Health Network promises that more information about *The Informed Rx Decision-Making Consortium* will appear in future months on its website <http://www.nwhn.org/>.

193. *Carter v. TAP Pharms., Inc.*, 2004 U.S. Dist. LEXIS 22741 (W.D. Tex. Nov. 10, 2004); *De Souza v. TAP Pharms., Inc.*, 2006 U.S. Dist. LEXIS 28943 (D. Conn. Jan. 3, 2006); *Saraney v. TAP Pharm. Prods.*, 2007 U.S. Dist. LEXIS 3113 (N.D. Ohio Jan. 16, 2007).

complained.<sup>194</sup> However, in the third case, *De Souza v. TAP Pharmaceuticals, Inc.*, the U.S. District Court for the District of Connecticut held that the warning label was very broad and did not adequately warn a prescribing physician of the potential risk of the adverse reactions from which that particular plaintiff claims to have suffered.<sup>195</sup> Therefore, Tap's motion for summary judgment was denied.<sup>196</sup>

## 2. Clomiphene-Related Cases

Clomid, or Clomiphene, has been in regular use since 1962.<sup>197</sup> Clomiphene tricks the body into making extra eggs by blocking estrogen receptors.<sup>198</sup> The use of clomiphene since the 1960s, may partly why the drug has shown up in many of the long-term studies linking various types of cancer hormone use.<sup>199</sup> However, no reported cases were found alleging direct injuries to the user. Only cases involving birth defects and multiple births were found.<sup>200</sup>

## 3. A Tragic Pergonal Case

In a tragic case which garnered national publicity, a woman who had received Pergonal treatment and declined selective reduction of her septuplet pregnancy delivered six premature infants, three of whom died shortly after birth while the other three are living with long-term disabilities.<sup>201</sup> She filed a medical malpractice lawsuit against her doctor and fertility clinic for administering an excessive dose of Pergonal and failing to detect by ultrasound an excessive number of maturing follicles before proceeding with the fertility treatment.<sup>202</sup> The parents, Sam and

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194. See *Carter*, 2004 U.S. Dist. LEXIS at \*6-7; *Saraney*, 2007 U.S. Dist. LEXIS at \*14-15.

195. See *De Souza*, 2006 U.S. Dist. LEXIS at \* 3-5.

196. *Id.*

197. Noah, *Pitfalls*, *supra* note 7, at 611 n.30.

198. Motluk & Biever, *supra* note 117, at 14.

199. Calderon-Margalit et al., *supra* note 117, at 365.

200. In *Lust v. Merrell Dow Pharmaceuticals, Inc.*, the plaintiff brought a product liability action against Dow alleging his birth defect was caused by his mother's ingestion of Clomid. The U.S. Court of Appeals for the Ninth Circuit excluded the plaintiff's expert witness, determining his scientific opinion was not reliably based on scientific knowledge and evidence. As plaintiff had no evidence on causation other than his expert, Dow prevailed on its motion for summary judgment. *Lust v. Merrell Dow Pharms.*, 89 F.3d 594, 595 (9th Cir. 1996). In *Morgan v. Christman*, a set of quadruplets contended in a medical malpractice case that their mother's doctor prescribed Clomid without properly advising their parents of the possibility of multiple pregnancies. The children alleged the fertility drug caused a multiple pregnancy with premature births resulting in their physical and mental defects. The causes of action—negligence, lack of informed consent, and negligent misrepresentation—all survived defendant's motion for summary judgment. The defendant, Dr. Christman reportedly settled the case for \$2.1 million. *Morgan v. Christman*, 1990 U.S. Dist. LEXIS 12179, at \*1 (D.Kan. July 20, 1990).

201. Marcia Chambers, *\$3.2 Million Suit by Parents of Septuplets Focusing on Ultrasound Screening*, N.Y. TIMES, Dec. 4, 1985, at A20.

202. Chambers, *supra* note 201, at A20.

Patti Frustaci, received a \$6.2 million settlement from the fertility doctor and Westwood, California clinic that treated her.<sup>203</sup> At the age of two, the surviving infants were determined to have cerebral palsy and one year later were diagnosed as developmentally disabled.<sup>204</sup>

In addition to the unquantifiable danger to women who donate their eggs, a recent study funded by the Centers for Disease Control and Prevention concluded that some birth defects occur more often among infants conceived with ART, although the mechanism for such structural injuries was not clear.<sup>205</sup> The authors of the study recommended that “couples considering ART should be informed of all potential risks and benefits.”<sup>206</sup> Further research findings have also indicated that children conceived through ART have higher risks for birth defects.<sup>207</sup>

## B. INFORMED CONSENT

### 1. Donor Consent in ART

Informed consent means that a participant fully understands the process and has voluntarily agreed to it.<sup>208</sup> The doctrine of informed consent emerged from the intentional tort of battery and with time has become rooted in the law of negligence.<sup>209</sup> The “duty to secure informed consent reflects a commitment to patient autonomy and self-determination.”<sup>210</sup>

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203. Noah, *Pitfalls*, *supra* note 7, at 633; *e.g.*, Chambers, *supra* note 201, at A20; Nancy Hill-Holtzman, *Frustaci Settle Suit over Birth of Septuplets*, L.A. TIMES, JULY 11, 1990, at A1.

204. CNN.com, *Septuplets Heartache: The Frustaci Story* (Nov. 20, 1997), <http://www.cnn.com/US/9711/20/septuplets.8pm/>.

205. J. Reefhuis et al., *Assisted Reproductive Technology and Major Structural Birth Defects in the United States*, 24 HUM. REPROD. 360, 361–62 (Nov. 14, 2008), available at <http://humrep.oxfordjournals.org/cgi/reprint/24/2/360>; see also Elizabeth Fernandez, *Higher Birth Defect Rate With Fertility Treatments*, S.F. CHRON., Nov. 18, 2008, at A4 (claiming that “[i]nfants conceived as a result of infertility treatments are two to four times more likely to have certain types of birth defects than children conceived naturally”).

206. Reefhuis, *supra* note 205, at 360, 365.

207. Gina Kolata, *Picture Emerging on Genetic Risks of IVF*, N.Y. TIMES, Feb. 17, 2009, at D1.

208. *Salgo v. Stanford Univ.*, 154 Cal. App. 2d 560, 578 (1957).

209. Noah, *Informed Consent*, *supra* note 8, at 364. Today, courts generally recognize a battery cause of action only on a limited basis where, for example, there is a complete lack of consent, a procedure is substantially different from that to which the patient consented, or when a doctor substitutes another doctor to perform a surgical procedure without informing the patient. See E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOUS. J. HEALTH L. & POL’Y 1, 56–57 n.280 (2003); see also *Mink*, 460 F. Supp. at 718–719 (finding battery where doctors gave DES to pregnant women without their knowledge or consent); *Pizzalotto v. Wilson*, 437 So.2d 859, 865 (La. 1983) (finding battery where a patient agreed to conservative surgery to preserve her fertility, yet the doctor performed a full hysterectomy); *Perna v. Pirozzi*, 457 A.2d 431, 438–39 (N.J. 1983) (finding battery where patient consented to surgery performed by a specific surgeon, however, another surgeon performed surgery without his knowledge or consent).

210. Noah, *Informed Consent*, *supra* note 8, at 364.

The Practice Committees for the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology (SART) recommend that all informed consents be in writing, signed by all participating parties, and properly witnessed.<sup>211</sup> In addition to information about success and financial commitments, oocyte donors should be informed about 1) a description of the procedure, 2) potential risks and discomforts, 3) special considerations, and 4) legal issues.<sup>212</sup> While the category of potential risks is to include “[o]vulation induction agents including allergic reactions, hyperstimulation . . . and the association with ovarian cancer,”<sup>213</sup> it does not include a list of various conditions associated with ovarian hyperstimulation nor does it mention the possible association with cancers other than ovarian.<sup>214</sup>

A recent retrospective evaluation of eighty egg donors’ motivations, expectations, and experiences during their first donation cycle found that while most surveyed donors were aware of some physical risks associated with egg donation, a disturbing 20% reported being unaware of any possible physical risks.<sup>215</sup> Further, the study found the potential risks the donors acknowledged before donation, did not match the physical side effects actually experienced following donation.<sup>216</sup> While none of the eighty women surveyed in the study reported having cancer only 11.2% of those surveyed reported being aware of an increased risk of ovarian and/or uterine cancer from egg donation.<sup>217</sup> In fact a significant minority of surveyed donors reported some serious physical conditions, including impaired fertility, ovarian cyst fibroids, and chronic pelvic pain which they attributed to having donated their eggs.<sup>218</sup>

As Sonia M. Suter so succinctly states,

[E]xisting informed consent law cannot achieve the goals of full informed consent . . . for two reasons: (1) it only requires the

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211. The Practice Comm. of the Am. Soc’y for Reprod. Med. & the Practice Comm. of the Soc’y for Assisted Reprod. Techn., *Elements to be Considered in Obtaining Informed Consent for ART*, 86 FERTILITY & STERILITY S.272, S.272 (Nov. 2006).

212. *Id.* at S.272–73.

213. The Practice Comm. of the Am. Soc’y for Reprod. Med., *supra* note 211 at S.272.

214. *See* IOM, *supra* note 1, at 22 (According to Professor Roberta Ness, “There are three types of cancer that would seem to have a plausible biological link to the hormone regimens used in ovarian stimulation: breast, ovarian, and endometrial cancers.”). *Id.* *See also* Laura Shanner, Letter to the Editor, *Informed Consent and Inadequate Medical Information*, 346 LANCET 251 (July 22, 1995) (alleging that the lack of adequate studies, long-term assessments, and complete reporting may lead clinicians to deliver information required for informed consent in a undeservedly positive light).

215. *See* Kenney & McGowan, *supra* note 140, at 1, 5–6.

216. *Id.*

217. *Id.* at 1, 5–6. The survey was administered to women donating in the early 2000s. *Id.*

218. *Id.* at 1, 6–7.

disclosure of a limited range of information and (2) it goes only so far in ensuring full comprehension of risks and benefits.<sup>219</sup>

In addition to the moderate—or even undisclosed—warning about the controversial increased risk of cancer associated with fertility drug use and its unknown long-term risks, Suter raises two other substantive issues which rarely make it to the informed consent forms: psychological harm from selling one's reproductive material and legal ramifications.<sup>220</sup>

## 2. Informed Consent and Non-Therapeutic Research

Research using federal funds is subject to regulations under the Department of Health and Human Services known as the “common rule”<sup>221</sup> and regulations by the Food and Drug Administration.<sup>222</sup> These regulations require, among other things, that an institutional review board (IRB) confirm that human research subjects' informed consent has been obtained by the researcher.<sup>223</sup> Even if the research does not receive federal funding and therefore technically falls outside the reach of the “common rule,” many research institutions voluntarily require that all human subject research conducted at the institution abide by federal requirements.<sup>224</sup> This primarily includes IRB review and the need for documented voluntary informed consent.<sup>225</sup>

The following case law discussion raises the possibility that a heightened duty in the form of a special relationship, and heightened duty, may arise between egg donors and their physicians even in the context of nontherapeutic donations (in which category all ART and human Embryonic Stem Cell (hES) donations fall). Donations made for ART, however, are not considered scientific research, unlike egg donations for hES cell research. Following the logic of this case, hES egg donors could find themselves offered protections withheld from ART donors. The women who are being sought out for egg donation are, because of their youth, less likely than older adults to think in terms of long-term consequences. Further, both because of their age and the health requirements for egg donors, they may be unable to conceive of the potential consequences of an adverse reaction because they are unlikely to

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219. Sonia M. Suter, *Giving in to Baby Markets: Regulation Without Prohibition*, 16 MICH. J. GENDER & L 217, 244 (2009).

220. *Id.* at 242–48.

221. 45 C.F.R. § 46.116 (2009) (listing the general requirements for informed consent). For a more in-depth discussion of the federal regulatory guidelines on informed consent, see Noah, *Informed Consent*, *supra* note 8, at 364; see also Lori A. Alvino, *Who's Watching the Watchdogs? Responding to the Erosion of Research Ethics by Enforcing Promises*, 103 COLUM. L. REV. 893, 918–24 (2003).

222. 21 C.F.R. § 50.25 (2009) (listing the elements of informed consent).

223. See 45 C.F.R. §§ 46.116(c)–(d) (2009); 21 C.F.R. §§ 50.25(a)(1)–(8) (2009).

224. NRCIM GUIDELINES, *supra* note 17, at 83; CAL. CODE REGS. tit. 17, § 100100 (2009).

225. *Id.*

have context for what it means to have a serious illness or injury. Finally, the women for whom egg donation may be most appealing, and who are often sought out by advertisements seeking donors are college and graduate students, who are often in temporary but serious financial straits. These factors would suggest a higher duty of care than what a physician generally owes an adult participant in a non-therapeutic clinical setting.<sup>226</sup>

In *Grimes*, the Maryland Court of Appeals vacated the lower court's ruling granting defendants' motions for summary judgment, providing numerous theories upon which defendants' liability could be predicated. Minor plaintiffs had been the subject of nontherapeutic research conducted by a prestigious research institute associated with Johns Hopkins University, the Kennedy Krieger Institute, Inc. (KKI), to determine the effectiveness of varying degrees of lead paint abatement procedures.<sup>227</sup> The subject children were encouraged to reside homes containing lead so the lead dust content of their blood could be compared to the lead dust levels in the houses over a two-year period.<sup>228</sup> This was done to help the researchers determine the extent to which various partial abatement methods worked.<sup>229</sup> The research was approved by the Institutional Review Boards, which apparently encouraged the researchers to misrepresent the research as "therapeutic," thereby lowering the safety standard required by regulation.<sup>230</sup>

In beginning its analysis the Court held that "nontherapeutic scientific research on human subjects can, and normally will, create *special relationships* out of which duties arise."<sup>231</sup> The Court found that informed consent was lacking in these cases because it was reasonably foreseeable, and even anticipated by the KKI, that the children's blood would be contaminated by lead, the risk or likelihood of which was not disclosed to the consenting parents.<sup>232</sup> The Court opined that otherwise healthy children should not be the subjects of nontherapeutic experimentation that is potentially harmful.<sup>233</sup> Further, the Court found that neither the consent of the parents<sup>234</sup> nor the IRB approval extinguished the researcher's duty to the research subject.<sup>235</sup>

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226. See *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 815 n.6 (Md. 2001).

227. *Id.* at 811–12.

228. *Id.*

229. *Id.*

230. *Id.* at 817.

231. *Id.* at 834–35 (emphasis added); see also *Lenahan v. Univ. of Chi.*, 348 Ill. App. 3d 155, 163–64 (Ill. App. Ct. 2004) (finding a special relationship existed between the sponsor, principal investigator of experimental cancer protocol, and the decedent even in absence of any meetings between the physician and patient).

232. See *Grimes*, 782 A.2d at 848.

233. *Id.*

234. *Id.* at 850 ("Consent of parents can never relieve the researcher of this duty.").

235. *Id.* at 858 (holding that "governmental regulations can create duties on the part of researchers towards human subjects out of which 'special relationships' can arise").

*Whitlock*, a North Carolina case, involved a healthy experienced diver who consented to participate in research of simulated deep dives intended to study high pressure nervous syndrome.<sup>236</sup> Mr. Whitlock claimed that he suffered permanent organic brain damage as a result of his world record-setting simulated dive of 2,250 feet as part of the study.<sup>237</sup> The Court clearly distinguished between informed consent as it applies to nontherapeutic human experimentation and therapeutic experimentation in which the goal is to provide some direct benefit to the subject-patient.<sup>238</sup> Analyzing informed consent in the nontherapeutic context consistent with Section 46.116 of Title 45 of the Code of Federal Regulations,<sup>239</sup> the Court concluded there is a heightened duty of disclosure for foreseeable risks in the nontherapeutic context.<sup>240</sup> However, finding no evidence that defendants were aware of any foreseeable risk of organic brain damage resulting for the research dives, the Court granted defendants' motions for summary judgment on plaintiff's causes of action for fraud, breach of fiduciary duty, intentional infliction of emotional distress, breach of Section 46.116 of Title 45 of the Code of Federal Regulations, and strict liability, leaving plaintiff without remedy.<sup>241</sup> This case illustrates the current predicament of egg donors. While a court may find a heightened duty of disclosure for foreseeable risks given women's nontherapeutic donation, as in *Whitlock*, the court is likely to find the risks complained of were not foreseeable because compelling scientific research has not been done in this area.

### 3. Potential Conflicts of Interest Involving Egg Donors

In obtaining informed consent from egg donors, there are several potential conflicts of interest which may arise, both as to health risks and financial interests. A fertility business must have successful pregnancy rates to stay competitive.<sup>242</sup> Because of improved technology, and other factors including, an escalating international trade (due to legal restrictions in other industrialized countries),<sup>243</sup> and human embryonic stem cell

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236. *Whitlock v. Duke Univ.*, 637 F. Supp. 1463, 1466 (M.D.N.C. 1986).

237. *Id.* at 1466.

238. *Id.* at 1467.

239. 45 C.F.R. § 46.116(a)(2) (2009) (requiring that informed consent contain a "description of any reasonably foreseeable risks or discomforts . . .").

240. *Whitlock*, 637 F. Supp. at 1471.

241. *Id.* at 1473–76.

242. ART clinics are generally for-profit institutions that compete with one another for clientele based on representations of their ability to help infertile couples conceive. Prior success is a significant part of demonstrating this ability to clients with the resources to choose from clinics around the country, or in the case of metropolitan areas, to choose between several options within driving distance.

243. *See SPAR, supra* note 1, at 46.

research, the demand for eggs has risen dramatically over the last ten years.<sup>244</sup> This demand far outstrips the current human egg supply.<sup>245</sup>

In its infancy, beginning in 1978 with the birth of Louise Brown, the fertility industry maintained low success rates and questionable practices.<sup>246</sup> As the industry grew, concerns were raised regarding whether prospective parents were being truthfully informed about the success rates. In response to this concern and in an effort to protect consumers, Congress passed the Fertility Clinic Success Rate and Certification Act in 1992, which directed the Centers for Disease Control to collect and publish information regarding fertility center success rates.<sup>247</sup> However, what appears to be true is that success-rate reporting, if anything has made this multi-billion dollar industry<sup>248</sup> more competitive.<sup>249</sup> For example, some clinics report embryos which have only briefly implanted and then are reabsorbed as pregnancies.<sup>250</sup> Some clinics increase use of fertility drugs and multiple embryos to inflate their pregnancy rates.<sup>251</sup> Often couples or others paying for the ART cycles will request a high number of embryos to be transferred, hoping to avoid the costs of multiple attempts.<sup>252</sup> In 1986, the price for an in vitro fertilization cycle was roughly \$5,000 to \$6,000 at a private clinic and by 2003 the average price was \$12,400.<sup>253</sup> This highlights the tension for doctors. They have to choose the appropriate dose of fertility drugs to be administered and the right number of embryos to be transferred for implantation to respond to the desires of their patients and keep their success rate high.<sup>254</sup> Unfortunately, competition may lead them to ignore considerations like the health of the donor, the mother and the offspring.<sup>255</sup>

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244. See CDC 2006 Report, *supra* note 30 and CDC 1996 Report, *supra* note 32 showing a three-fold increase in use of donor eggs over a ten-year period of 1996–2006; SPAR, *supra* note 1, at 43 indicating demand for donor eggs grew steadily during the 1990s.

245. SPAR, *supra* note 1, at 43.

246. See generally Solomon, *supra* note 71, at 47–49 (discussing the adverse effects and subsequent death of a woman undergoing Pergonal treatment); Corea, *supra* note 90, at 144–59. (describing the adverse health effects associated with in vitro fertilization and other ART methods).

247. Noah, *Pitfalls*, *supra* note 7, at 615.

248. See SPAR, *supra* note 1, at 3.

249. See, e.g., Lori B. Andrews, *Eighteenth Annual Health Law Symposium: Reproductive Technology Comes of Age*, 21 WHITTIER L. REV. 375, 383 (1999).

250. *Id.*

251. *Id.* at 383–84.

252. See generally Siddharth Khanijou, *Multifetal Pregnancy Reduction in Assisted Reproductive Technologies: A License to Kill?*, 8 DEPAUL J. HEALTH CARE L. 403, 406–07 (2005) (contending that the trend of delaying childbearing, the use of ovarian stimulation, and the use of in vitro fertilization have all contributed to the increase in multiple births).

253. SPAR, *supra* note 1, at 33.

254. See Noah, *Pitfalls*, *supra* note 7, at 628–69.

255. See, e.g. Beeson & Lippman, *supra* note 1 (discussing a Korean case in which a doctor induced women to donate eggs for cloning research with false information and promoted his work with false results).

#### 4. The Donor, the Doctor and the Patient's Best Interests

"[A]s a practical matter, the federal government has made little attempt to provide true regulation of assistive reproductive technology in the United States."<sup>256</sup> The Ethics Committee of the American Society for Reproductive Medicine (ASRM) promotes the idea that egg donation is a "safe" procedure, and has various guidelines to help safeguard the donor, including recommending that she be fully respected by receiving her own physician:

Once the donation process begins, oocyte donors become patients owed the same duties present in the ordinary physician-patient relationship. Programs should ensure that every donor has a physician whose primary responsibility is caring for the donor. Oocyte donor program staff should recognize that physicians providing services to both donors and recipients could encounter conflicts in promoting the best interest of both parties and should create mechanisms ensuring equitable and fair provision of services.<sup>257</sup>

Nevertheless, the question must be asked, is it medical malpractice for a physician to prescribe synthetic hormones to a woman and then harvest her eggs in a procedure that has no therapeutic purpose for her? The harvest is performed as a "gift" to another woman so the recipient can give birth. In the case of human Embryonic Stem (hES) cell research, the purpose of the harvest is even more removed from the donor. The eggs are to be used for therapeutic cloning,<sup>258</sup> a field of research which has yet to be mastered in humans.<sup>259</sup>

The shield, or defense, against malpractice for the doctor or facility lies in the informed consent form.<sup>260</sup> Informed consent is a standard to ensure that patients understand the risks and benefits of a procedure before they consent to it.<sup>261</sup> It can also stand between an egg donor and access to

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256. KINDREGAN, JR. & MCBRIEN, *supra* note 168, at 197.

257. ASRM Ethics Committee, *supra* note 16, at 308–09.

258. As stated by Ann A. Kiessling, "The clear limit imposed on human reproduction is the human egg. Few in number, powerful in nature, the human egg is at the heart of the controversy surrounding human embryo research, human cloning, and the derivation of human embryonic stem cells for therapeutic purposes." Kiessling, *supra* note 21, at 1087.

259. Evan Y. Snyder, Jeanne F. Loring, *Beyond Fraud: Stem-Cell Research Continues*, NEW ENG. J. MED., 321, 322 (Jan. 26, 2006); NRCIM GUIDELINES, *supra* note 17, at 34–35. Stem cell research has shown some progression in areas of adult stem cell research, induced pluripotent stem cells (iPSC) and stem cell lines derived from discarded embryos. For more information on current research see The NIH Resource for Stem Cell Research website on Stem Cell Information at <http://stemcells.nih.gov/research/scilit/highlights/>.

260. Barbara L. Atwell, *The Modern Age of Informed Consent*, 40 U. RICH. L. REV. 591, 597 (2006).

261. *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972).

remedies for injuries caused by the donation procedure.<sup>262</sup> For example, a young woman who claims injuries from an egg donation process is likely to be met in court with a signed consent form outlining the risks for treatment, making the claim difficult to win.<sup>263</sup>

Hundreds of women have complained over the years about Lupron, and extended studies have shown an association between an increased risk of various cancers, not just ovarian, from the use of Clomiphene.<sup>264</sup> Additionally there are the anecdotal reports of permanent injuries from OHSS and donor death from colon cancer, discussed previously. Informed consent forms and health care providers do not impart all of this information to the donors.<sup>265</sup> “In the absence of conclusive studies confirming safety and efficacy clinicians talking to patients must be explicit about what is unknown.”<sup>266</sup> This is particularly important as young women may sign broad consent forms, trusting their doctors to tell them if the procedure is unsafe.<sup>267</sup>

Not all clinics follow the ASRM guidelines and provide women their own physicians. The following two donor cases illustrate the importance of deciding if a patient-physician relationship exists when suing for medical malpractice or negligence in nontherapeutic cases. In *Delcambre v. Blood Systems, Inc.*, a blood donor went to the United Blood Services office in 1999 to gratuitously donate blood.<sup>268</sup> The phlebotomist inserted a needle too deep into Delcambre's arm, injuring him so that he required surgery, which resulted in potentially permanent impairment of his arm. Delcambre filed suit for negligence.<sup>269</sup> The issue was whether he was a

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The root premise is the concept, fundamental in American jurisprudence, that ‘every human being of adult years and sound mind has a right to determine what shall be done with his own body. . . .’ True 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.

*Id.* (citing *Schloendorff v. Society of New York Hospital*, 105 N.E. 92, 93 (1914)).

262. Atwell, *supra* note 260, at 597.

263. *Id.* Atwell recommends the use of a patient advocate to help in the informed consent process, especially with young women who are enticed by the \$5,000 or more, offered for the egg donation. *Id.* at 607.

264. See discussion *supra* Part II.C.2. regarding hormone use and cancer.

265. ASRM Practice Committee, *Elements to be Considered in Obtaining Informed Consent for ART, FERTILITY & STERILITY*, S272, S273 (Nov. Suppl. 2006). See, e.g., Atwell, *supra* note 260, at 597–98, 608.

266. Laura Shanner, *Informed Consent and Inadequate Medical Information*, LANCET, 251, 251 (1995).

267. See, e.g., Robert Gatter, *Human Subjects Research and Conflicts of Interest: Walking the Talk of Trust in Human Subjects Research: The Challenge of Regulating Financial Conflicts of Interest*, 52 EMORY L.J. 327, 355 (“[A] prospective human subject who has been referred to a study by a trusted physician might not take seriously any warning about a financial conflict of interest.”).

268. *Delcambre v. Blood Sys.*, 893 So. 2d 23 (La. 2005).

269. *Id.* at 25.

patient of the blood bank and therefore initially required to follow the procedures under the Medical Malpractice Act before filing suit.<sup>270</sup> The Louisiana Supreme Court held that since Delcambre was neither receiving medical care, being treated, nor being confined at the time of his blood donation, he was not a “patient” as defined in the Act.<sup>271</sup> Here, this was beneficial to Delcambre, as it meant he could sue directly for negligence instead of suing for medical malpractice in which case he would be subject to the state’s restrictive cap on damages.

In the case of *Montalto v. Stoff*, both a kidney transplant recipient and her donor filed suit against two doctors.<sup>272</sup> Relevant questions raised in the case were a) whether defendant doctor had a physician-patient relationship with the donor such that he owed him a duty, and b) whether the donor was properly informed of the risk that the recipient did not in fact need a kidney transplant in the first place. The Massachusetts Superior Court denied the doctor’s motion for summary judgment stating, “where a physician improperly advised a patient that she needs a kidney transplant, and a donor known to the physician relies on that advice and needlessly donates a kidney, there is a sufficient physician-patient relationship, based on which that donor is entitled to recover for medical malpractice.”<sup>273</sup> Unlike the donor in Delcambre who was not considered a “patient,” the donor in *Montalto* was seen as a patient.

#### 5. Disclosure of Health Risks

Experts have unequivocally stated that the potential risk of cancer, long-term fertility, and other risks to women taking fertility drugs are unknown and more studies need to be done.<sup>274</sup>

One of the most striking facts about in vitro fertilization (IVF) . . . is just how little is known for sure about the long-term health outcomes for the women—and men—who undergo the procedures. Although more than a million IVF cycles have been performed in the United States over the past 20 years, and although there are registries that keep track of the various reproductive outcomes, such as the number of eggs retrieved and the number of children born, *there are no registries that track the health of the people who have taken part.*<sup>275</sup>

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270. *Delcambre*, 893 So. 2d at 27–28.

271. *Id.* at 29–30.

272. *Montalto v. Stoff*, 2007 WL 3013204, \*1 (Mass. Super. Ct. 2007).

273. *Id.* at \*5.

274. *See* IOM, *supra* note 1, at 22–30 (discussing the adverse health effects associated with taking fertility drugs). *See also id.* at 51–54 (addressing the need for more complete studies on those women whom have taken fertility drugs).

275. *Id.* at 51 (emphasis added).

Because there are only a few long-term studies regarding cancer risk, concern has been raised by one study which focused just on women taking Clomiphene.

It found that as time elapsed since the treatment, there did seem to be an increase in risk for breast, ovarian, and endometrial cancers. This is of particular concern . . . because it raises the possibility that many studies have missed the increased cancer risk because they haven't followed their subjects for enough years.<sup>276</sup>

The deficiency in studies on both short-term and long-term consequences means clinicians may present treatment options in an overly optimistic view, leading women to take risks they might not tolerate if they had clear information on the proven and unproven risks.<sup>277</sup> Even with this information, the California Institute for Regenerative Medicine's recommendations regarding informed consent disclosures for stem cell research require no mention of potential association with an increased risk of cancer.<sup>278</sup> Without any definitive long-term studies on women oocyte donors, full disclosure may remain a moving target for a process in which the "best interests of the patient" are already being put aside. Women continue to be one of the most vulnerable populations subject to experimentation.<sup>279</sup>

#### 6. Disclosure of Financial Interests

In the context of the fertility business there are potential conflicts of interest in the administration of fertility drugs. The phrase, "conflict of interest" is defined as "a set of conditions in which professional judgment concerning a primary interest . . . tends to be unduly influenced by a secondary interest."<sup>280</sup> The same clinic may provide treatment to the infertile woman as well as the oocyte donor. The clinic is a business,

276. IOM, *supra* note 1, at 26.

277. See Laura Shanner, *Informed Consent and Inadequate Medical Information*, LANCET 346, 346; see also Sandra Coney, *Long-term effects of Assisted Conception*, 345 LANCET 976, 976 (1995) (contending that "little systematic study has been made of the long-term health effects on women, children, men, and families."); Marsden Wagner, *Techniques of Assisted Reproduction*, 350 LANCET 1559, 1559-60 (1997) (claiming a lack of long-term follow-up of women at risk for ovarian cancer).

278. See CODE REGS. § 100100(b)(3)(A).

279. See *Grimes*, 782 A.2d. at 815 n.6.

Indeed, the literature on the law and ethics of human experimentation is replete with warnings that all subjects, but especially vulnerable subjects, are at risk of abuse by inclusion . . . . Those vulnerable subjects included prisoners, who are subject to coercion; children and the elderly . . . and racial minorities, ethnic minorities, and women . . . .

*Id.* (citing R. Alta Charo, *Protecting us to Death: Women, Pregnancy and Clinical Research Trials*, 28 ST. LOUIS U. L.J. 135, 135 (1993) (internal citations omitted)).

280. Gatter, *supra* note 267, at 340-41.

concerned with keeping its success rate competitive.<sup>281</sup> Even if the physician administering fertility drugs to the donor and extracting the eggs is not part of the same clinic where the recipient is receiving care, that physician undoubtedly has some type of agreement with the fertility clinic to provide eggs, and of course, the more eggs the better.<sup>282</sup>

Ovarian hyperstimulation syndrome can range from a relatively benign condition to a life-threatening one.<sup>283</sup> As threshold symptoms of OHSS may occur, the best medical course may be to cancel the administration of ovary stimulating drugs to the donor. The woman's immediate and future health may depend on that decision. However, stopping the drugs early, almost always results in a lost cycle and hence, a loss of eggs, income, and financial investment.

Additional potential conflicts arise when an egg donor is asked to provide eggs for more than one cycle.<sup>284</sup> If a donor agrees to more than one cycle at her first donation cycle, this saves the clinic time and money in screening,<sup>285</sup> but is this an appropriate question to be put to the donor when she is first accepted into the program? The request may place pressure on the woman to donate for additional cycles before she has actually completed her first donation.<sup>286</sup> Once she knows how her body reacts to the fertility drugs and has some distance from the procedure, she is in a much better position to provide informed consent for a potential additional cycle.<sup>287</sup> Without question, the issue of informed consent for egg donors is without precedent and, as a result, is potentially vulnerable to attack. If there is a failure to fully disclose, and the egg donor actually has her own physician, in some states the donor may be able to pursue a breach of fiduciary duty or lack of informed consent for failures to disclose conflicts of interest.<sup>288</sup>

### C. MEDICAL MALPRACTICE AND EGG DONATION

The previous subsection showed that lack of informed consent may be a form of medical malpractice, research malpractice, and/or negligence. In addition to this issue, there are other forms of breach of duty which may

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281. See discussion *supra* at III.B.3. regarding conflict of interest.

282. See Noah, *Pitfalls*, *supra* note 7, at 628; Judy Norsigian, *Egg Donation for IVF and Stem Cell Research, Time to Weigh the Risks to Women's Health*, Center for Genetics and Society (Spring 2005) available at <http://www.geneticsandsociety.rsvpl.com/article.php?id=1972&&pri>.

283. See IOM, *supra* note 1, at 18–19.

284. See Jesse McKinley, *The Egg Woman*, N.Y. TIMES, Archives, May 17, 1998, at 8 of 10, available at [nytimes.com/.../the-egg-woman.html](http://nytimes.com/.../the-egg-woman.html).

285. N.Y. STATE TASK FORCE, *supra* note 181, at 24.

286. McKinley, *supra* note 284, at 8 of 10.

287. N.Y. STATE TASK FORCE, *supra* note 181, at 24.

288. See, e.g., *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 131–32 (1990) (finding breach of fiduciary trust where researchers patented a patient's genetic material and used it without his knowledge or mission to develop lucrative medical advances).

arise in the context of egg donation. This section will address a few of these issues, specifically: breach of standard of care in failure to perform adequate diagnostic tests; use of waivers to relinquish the right to sue; and performance of tests or procedures that have no medical or therapeutic value to the subject. This section will then draw some distinctions between medical and research negligence, and explore the problems such distinctions may pose for injured egg donors.

### 1. Potential Application to ART Egg Donors

A medical malpractice suit in the context of egg donation would be an issue of first impression; however, the following three cases may apply to such a case by way of analogy. In the case of *Gardner v. Pawliw*, the plaintiff alleged medical malpractice following the death of her nearly full-term fetus.<sup>289</sup> The plaintiff alleged that the obstetrician breached the standard of care because he failed to administer diagnostic tests indicated by her preexisting condition.<sup>290</sup> The court's discussion focused on the threshold testimony required of the plaintiffs' expert, and determined that the testimony raised a sufficient issue of fact to survive a motion to dismiss.<sup>291</sup> The Court determined the plaintiffs' burden was not to show that the tests would have revealed abnormalities; rather, plaintiffs' burden was to show the doctor's failure to perform the tests increased the risk that the fetus would die *in utero*.<sup>292</sup>

This case would be analogous to an egg donation malpractice suit where a doctor failed to perform adequate diagnostic tests before or during the donation process, resulting in increased risks to the patient. For example, a claim may arise for medical malpractice if during a woman's ovarian stimulation phase she begins to exhibit symptoms of OHSS and her attending physician fails to test and stop the ovary stimulating drugs, and the donor suffers significant injuries.

As previously seen in the *Delcambre* case above,<sup>293</sup> because an egg donor is not seeking treatment or care for a health problem, a court may find that no patient-physician relationship exists. In some instances this will benefit the donor pursuing an ordinary negligence claim. This principle is demonstrated in the case of *Weldon v. Universal Reagents, Inc.* (URI).<sup>294</sup> In *Weldon* a woman volunteered to donate red blood cells for a federally licensed program in which URI immunized plasma donors and potential plasma donors with human red blood cell antigens to increase the level of

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289. *Gardner v. Pawliw*, 696 A.2d 599, 601 (N.J. 1997).

290. *Id.* at 601.

291. *Id.* at 615–16.

292. *Gardner*, 696 A.2d at 615.

293. *See Delcambre*, 893 So. 2d at 29–30.

294. *Weldon v. Universal Reagents, Inc.*, 714 N.E.2d 1104 (Ind. Ct. App. 1999).

Rho(D) antibody in the donor's blood as part of a study.<sup>295</sup> Weldon became ill when she was immunized with the antigens.<sup>296</sup> In the ensuing lawsuit, the Indiana Appellate Court held there were no facts demonstrating either that Weldon suffered from any medical condition or that she went to URI in search of medical treatment or care, and the process of injecting antigens into her body to induce it to produce antibodies was not a procedure that benefited her.<sup>297</sup> The Court concluded that, because of her volunteer status, Weldon was not a patient for purposes of the Indiana Medical Malpractice Act.<sup>298</sup> This was to Weldon's advantage because it meant she was not required to follow the required Medical Malpractice Act procedures, and allowed her to proceed with a civil suit for negligence.<sup>299</sup>

Even after the malpractice hurdle, waivers of the right to sue may pose an obstacle for oocyte donors attempting to pursue a cause of action for injuries. However, actual negligence of the fertility clinic generally cannot be waived. In *Boll v. Sharp & Dohme, Inc.*, the court addressed the competency of informed consent forms to waive rights to sue, in the context of a blood donation made at defendant's drug manufacturing corporation.<sup>300</sup> Prior to donating blood, which he had done before, plaintiff signed a covenant not to sue.<sup>301</sup> Then during, or just after, the blood extraction, he fainted and fell, incurring serious and permanent injuries.<sup>302</sup> The court held that the contract did not exempt defendant from the exercise of due care in its procedures.<sup>303</sup>

## 2. Research Egg Donors

Liability for research missteps is still a shifting field with some courts applying a simple negligence standard and others a medical malpractice standard. In *Craft v. Vanderbilt University*, patients sued the university for violating their civil rights during a study conducted beginning in 1945.<sup>304</sup> In the study pregnant women were given a radioactive iron isotope "cocktail" drink so the scientists could track iron absorption.<sup>305</sup> The researchers failed to disclose the radioactive nature of the iron solution at the time or during follow up contacts, despite the high incidence of cancer among the participants.<sup>306</sup> Ruling favorably for the women and the children they were carrying at the time, the District Court concluded that

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295. *Weldon*, 714 N.E.2d at 1105–06.

296. *Id.*

297. *Id.* at 1109–10.

298. *Id.* at 1110.

299. *Id.*

300. *Boll v. Sharp & Dohme*, 281 A.D. 568 (N.Y. App. Div. 1953).

301. *Id.* at 569–70.

302. *Id.*

303. *Id.* at 572.

304. *Craft v. Vanderbilt Univ.*, 18 F. Supp. 2d 786, 789 (M.D. Tenn. 1998).

305. *Id.*

306. *Id.* at 789.

Vanderbilt's (and Rockefeller Foundation's) experiments did not constitute medical care and provided no therapeutic benefit to the experimental subjects.<sup>307</sup> Therefore, defendants' attempts to dismiss the action as untimely based upon Tennessee's three-year medical malpractice statute, were denied.<sup>308</sup>

In the following two research cases, the courts interpreted their findings based on medical malpractice rules. They present facts distinguishable from *Craft*, in that the plaintiffs were in situations requiring medical treatment and the research protocols implemented were to some degree an attempt at therapy. The case of *Kernke v. Menninger Clinic, Inc.* involved a diagnosed schizophrenic who consented to participate in a clinical study of a new investigational drug for schizophrenia by Hoechst Marion Roussel, Inc., the predecessor of Aventis Pharmaceutical, Inc.<sup>309</sup> Kenneth Kernke, a schizophrenic, voluntarily admitted himself as an inpatient to Hope Unit, one of the numerous sites testing the drug.<sup>310</sup> During a two-week period where all prior medications were flushed out of his system, Kernke began experiencing a decline in his condition with deepening depression and an increase in psychosis.<sup>311</sup> He repeatedly informed the staff he wanted to return home and approximately two months after admission he went missing.<sup>312</sup> A short search returned no results and two months later his body was found in a wooded area about one mile away where he had died from exposure.<sup>313</sup> In a complaint for wrongful death, the court determined that plaintiffs had offered sufficient evidence to survive defendants' motions for summary judgment on both the issue of duty and proximate cause.<sup>314</sup>

In *Burton v. Brooklyn Doctors Hospital*,<sup>315</sup> infant and plaintiff Daniel Burton had been born premature and was included, without his parents' consent, in a study investigating the role of oxygen administration in the development of Retrolental Fibroplasia (RLF), a disease causing blindness in premature infants. One out of every three premature infants born in the hospital, including the plaintiff, was chosen to be placed in an increased oxygen environment and went blind as a result of the treatment.<sup>316</sup> The Court of Appeals affirmed judgment against the hospital and the research

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307. *Craft*, 18 F. Supp. 2d at 796–98.

308. *Id.*

309. *Kernke v. Menninger Clinic, Inc.*, 172 F. Supp. 2d 1347 (D. Kan. 2001).

310. *Id.* at 1350. The caretaker for Kernke was seeking a inpatient facility as he could no longer take care of him and Kernke's physician referred him to the Hope Unit and the drug protocol. *Id.*

311. *Id.* at 1350.

312. *Id.* at 1350–51.

313. *Id.* at 1351.

314. *Id.* at 1352–53.

315. *Burton v. Brooklyn Doctors' Hosp.*, 88 A.D.2d 217 (N.Y. App. Div. 1st Dep't 1982).

316. *Id.* at 220.

doctor for medical malpractice, stating “we find it difficult to believe that any reputable institution would permit two out of three of its patients to receive unusual treatment, which might result in death or brain damage.”<sup>317</sup> As the cases above illustrate, individuals cannot necessarily expect researchers to exercise sound judgment for their well-being. In fact, the goal of research is not to benefit any specific individual, but to advance some benefit for the greater good of certain populations.<sup>318</sup> It is worthwhile to keep this in mind as young women are being asked to donate their eggs for stem cell research. Under federal regulations (e.g., the Common Rule), the institutional review boards are required to weigh the risks to the subjects versus the anticipated benefits.<sup>319</sup> Further, the Belmont Report,<sup>320</sup> which significantly influenced the codification of the Common Rule,<sup>321</sup> set forth basic ethical principles for the protection of human research subjects including respect for persons, beneficence, and justice. The two rules formulating the expression of beneficent action are 1) do not harm and 2) maximize possible benefits and minimize possible harms.<sup>322</sup>

These ethical principles seem to contradict the request for women to become part of the research on stem cell research, where they must put themselves at considerable risk for a yet unproven benefit. The institutions, researchers, and physicians involved need to scrutinize this closely, as do the courts should cases end up there.

While some commentators argue that ordinary negligence is too lenient a standard for research mishaps,<sup>323</sup> still other advocates, caught up in the new exciting research in stem cells, propose stem cell treatments (when, and if, they commence) should be granted special protection from tort liability.<sup>324</sup> To suggest that, new stem cell therapies should not be subject

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317. *Burton*, 88 A.D.2d at 224.

318. *See Morreim*, *supra* note 209, at 15.

319. 45 C.F.R. § 46.111(a)(2) (2009).

320. THE NAT'L COMM'N FOR THE PROTECTION OF HUM. SUBJECTS OF BIOMED. AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH (Apr. 18, 1979), *available at* <http://ohsr.od.nih.gov/guidelines/belmont.html> [hereinafter BELMONT REPORT].

321. *See Alvino*, *supra* note 221, at 898–99.

322. BELMONT REPORT, *supra* note 320, at B.2.

323. *See Morreim*, *supra* note 209, at 28–30; *Alvino*, *supra* note 221, at 910–12; *see also* Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229, 255–263 (2003) (providing an in-depth discussion regarding how an injured research subjects can successfully bring a negligence cause of action against researchers for malpractice).

324. RUSSELL KOROBKIN & STEPHEN R. MUNZER, *STEM CELL CENTURY: LAW AND POLICY FOR A BREAKTHROUGH TECHNOLOGY* 253–57 (2007); *see also, e.g.*, James M. Wood et al., *Product Liability Protection for Stem Cell Research and Therapies: A Proposal*, 18 HEALTH LAW. 1 (2005) (explaining public policy rationales that support extending liability protection for stem cell research).

to tort law advances a society which exalts individualistic scientific experimentation over the common good.<sup>325</sup>

#### D. OTHER POTENTIALLY RELEVANT CASE LAW<sup>326</sup>

##### 1. Property

Property law is perhaps one of the least obvious remedies to pursue in cases relating to egg donation. However, it may be where certain treatments or drugs have been administered without disclosure and the true consequences are not discovered until long after the statute of limitations has expired. This occurred in the case of *In re Cincinnati Radiation Litigation*, wherein it was alleged that defendants administered massive full-body doses of radiation to unwitting terminal cancer patients, who were predominantly African American.<sup>327</sup> The experiments took place between 1960 and 1972, and because the Ohio statute of limitations for wrongful death was two years, defendants moved to dismiss plaintiffs' claims.<sup>328</sup> Plaintiffs argued that because defendants had fraudulently concealed the facts, they had lost a property right without due process, i.e., their ability to pursue a wrongful death claim.<sup>329</sup> The U.S. District Court for the Southern District of Ohio agreed, stating, "[b]ecause a cause of action is a species of property protected by the Fourteenth Amendment, any state action that substantially interferes with an individual's claims or precludes his or her opportunity to be heard, violates procedural due process."<sup>330</sup>

The Second Circuit found a similar property interest in a lawsuit. In *Barrett v. United States of America*, the estate of a New York State Psychiatric Institute patient filed a lawsuit primarily under the Federal Tort Claims Act and the civil rights provisions of Section 1983 of Title 42 of the United States Code for administration of experimental lethal chemical injections of mescaline derivatives without his consent.<sup>331</sup> An earlier wrongful death suit for medical malpractice had been settled in 1955 for \$18,000, but critical facts concerning causation were not known or discoverable until the Army made its disclosure in 1975.<sup>332</sup> In allowing plaintiffs to proceed with a claim under Section 1983 of Title 42 of the

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325. "In every age, morality has a bias. It is obvious to those who come after, but history shows us how hard even the most astute people find it to detect where the bias of our own age lies." MARY MIDGLEY, *EVOLUTION AS A RELIGION* 164 (2002).

326. In presenting this section of the paper, recognition and gratitude are extended to E. Haavi Morreim, whose writing and research were both thorough and innovative. See, e.g., Morreim, *supra* note 209, at 56–57 n.280.

327. *In re: Cincinnati Radiation Litig.*, 874 F. Supp. 796, 800 (S.D. Ohio 1995).

328. *Id.* at 825 n.26.

329. *Id.* at 825.

330. *Id.*

331. *Barrett v. United States*, 689 F.2d 324 (2d Cir. N.Y. 1982).

332. *Id.* at 328–29.

United States Code, the Court indicated that defendants' obstruction of justice had deprived plaintiffs, not of their entire constitutionally protected property consisting of the lawsuit, but only part of that protected property right.<sup>333</sup> "Statutory or common law entitlement to be fully compensated through a lawsuit for one's injuries should be considered a species of property for the same reason that statutory entitlement to bring such a lawsuit at all is so considered."<sup>334</sup>

## 2. Contracts

In *Grimes v. Kennedy Krieger Institute, Inc.*, the court found a special relationship existed between a corporation conducting research and the children it used in the nontherapeutic study on lead paint.<sup>335</sup> The parents had signed consent forms for their children to participate with the expectation they would be compensated.<sup>336</sup> In addition to the duties that flowed from the special relationship, the court found the research arrangement had all the elements of contract law present, holding that "[r]esearcher/subject consent in nontherapeutic research can, and in this case did, create a contract."<sup>337</sup>

At least one commentator has suggested that research subjects might be able to maintain an action against a research institution as a third-party beneficiary.<sup>338</sup> The proposal is based on the fact that, in exchange for federal funding, a research facility must submit a Federal Wide Assurance,<sup>339</sup> this creates a contract by which the facility promises to abide by the Federal Common Rule for all its research involving human subjects.<sup>340</sup>

## 3. Fraud

Fraudulent concealment is often appropriate for use in tolling the statute of limitations.<sup>341</sup> In *Mink v. University of Chicago* the women who were given diethylstilbestrol (DES) were able to toll the statute of limitations based upon defendants' fraudulent concealment.<sup>342</sup> The drugs were administered as part of an experiment conducted by the University of Chicago and Eli Lilly & Co. between 1950 and 1952 to determine the

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333. *Barrett*, 689 F.2d at 332.

334. *Id.*

335. *Grimes*, 782 A.2d. at 101.

336. *Id.* at 88–89, note 34.

337. *Id.* at 89–90.

338. *See* Alvino, *supra* note 221, at 918–24.

339. Federal Wide Assurance is a contract in which the research facility promises to abide by the Common Rule for all of its research that involves human subjects, whether it is privately or federally funded. *Id.* at 894.

340. *See id.* at 894.

341. *See* Morreim, *supra* note 209, at 68 n.317.

342. *Mink*, 460 F.Supp. at 721.

drug's efficacy at preventing miscarriage.<sup>343</sup> It was administered at the university's hospital during prenatal care as part of a double blind study to determine its efficacy in preventing miscarriages.<sup>344</sup> The women were not told they were being used for experiments nor were they told what drug they were being given.<sup>345</sup> The complaint alleged that as a result of having taken DES, their daughters developed abnormal cervical cellular formations and were exposed to an increased risk of vaginal or cervical cancer.<sup>346</sup> The women also alleged that they and their sons suffered reproductive tract and other abnormalities and incurred an increased risk of cancer.<sup>347</sup> The Court held that defendants' intentional concealment of the known circumstances of the experiment from 1950 to 1978 exceeded mere silence and approached affirmative action, thereby tolling the statute of limitations which allowed the women to proceed on their cause of action for battery.<sup>348</sup>

The statute of limitations will remain an issue for any woman who may discover in ten or fifteen years after treatment that the hormones she took to suppress or stimulate her ovaries have caused cancer. Of course, not only is the statute of limitations a problem, but proving causation remains a major obstacle, unless and until medical and scientific research demonstrate an association between fertility drug use and the increased risk of cancer.

#### IV. CONCLUSION

In 1978, in creating the first "test tube" baby, the doctors "waited until one of [the] mother's eggs had ripened, collected it, [and then] fertilized it . . . with her husband's sperm before replacing it in the womb."<sup>349</sup> Since then, the use of fertility drugs in artificial reproductive technology has grown increasingly aggressive; a single cycle may involve the production of one or two dozen eggs at once.<sup>350</sup> Any risks in this procedure are likewise increased for women undergoing multiple such cycles. While clinicians are making inroads by advocating for a milder treatment of hormones to both decrease the risk to women and the incidents of multiple

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343. *Mink*, 460 F.Supp. 715.

344. *Id.*

345. *Id.*

346. *Id.*

347. *Id.*

348. *Id.* at 721; see also discussion *supra* Part III.C.2. In *Craft*, pregnant women were given radioactive iron isotopes to track iron absorption but were not told of its radioactive nature, highlighting the vulnerability of women as a class. The Court determined the defendants had taken sufficient affirmative steps to apply the doctrine of fraudulent concealment. *Craft*, 18 F. Supp. 2d 786.

349. Olga Craig, *IVF 30 Years On*, TELEGRAPH.CO.UK, June 16, 2008, <http://www.telegraph.co.uk/education/3356528/IVF-30-years-on.html> (emphasis added).

350. *Id.*

births, the current profit margin for the companies supplying these drugs is so great it is hard to imagine a substantial decrease in their use anytime soon.<sup>351</sup> In fact, additional lucrative markets will open up if women begin to donate eggs for stem cell research.

Nontherapeutic use of hormone modulating drugs creates risks for the user. Informed consent exists to some extent as both a sham and a shield for the fertility business, which lacks any incentive to explore the actual risks involved and track the percentage of donors who suffer irreversible harm. Once the eggs are out of the womb they are not likely to be put back.

Donors need to be fully informed of all known and unquantifiable risks, in a true patient-physician relationship. The donor's physician must look out for the patient's best interest, which means giving weighty consideration to recommendations against the donation procedure. If the physician lacks the time or inclination to provide informed consent, then clinics should provide patient advocates to help young women, enticed by a few thousand dollars, understand both the known and unknown risks. A national register should be implemented to track donors for both short-term and long-term health effects. Agreeing to register should be part of the contract to donate. Money and energy must be allocated towards comprehensive studies on the impact of the fertility hormones on women's bodies, for the good of both the donors and the women attempting to get pregnant with the donated eggs. Federal regulations could mandate some small percentage of the profits from the sale of fertility drugs be earmarked for this.

Finally, as a society we must evaluate our craving for reproductive self-determination and scientific dominance. There are no easy answers to the multitude of questions raised by the various interests involved in egg donation. But at a minimum, we owe full disclosure to those donating and full compensation under the law when they are injured as a result of gratuitously undergoing this non-therapeutic procedure.

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351. Esther M. Heijnen, et al., *A Mild Treatment Strategy for In-Vitro Fertilisation: A Randomised Non-Inferiority Trial*, 369 LANCET 743, 743 (Mar. 3, 2007); F. Ubaldi, et al., *Hopes and Facts about Mild Ovarian Stimulation*, 14 REPROD. BIOMED. ONLINE 675, 679 (June 1007); C. De Klerk, et al., *The Psychological Impact of IVF Failure After Two or More Cycles of IVF with a Mild Versus Standard Treatment Strategy*, 22 HUM. REPROD. 2554, 2554–55 (Sept. 2007); Ragni Guido, et al., *Preventing High-Order Multiple Pregnancies During Controlled Ovarian Hyperstimulation and Intrauterine Insemination: 3 Years' Experience Using Low-Dose Recombinant Follicle-Stimulating Hormone and Gonadotropin-Releasing Hormone Antagonists*, 85 FERTILITY & STERILITY 619, 623 (Mar. 2006).

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