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THE SCRAMBLE TO PROMOTE EGG DONATION THROUGH A MORE PROTECTIVE REGULATORY REGIME

JACOB RADECKI*

INTRODUCTION

Can we put a price on the human body? This is the uncomfortable and difficult question that the process of human oocyte (egg) donation presents to both the legislator and the cash-strapped college student sitting in her dorm room. It is important at the outset to recognize egg donation for what it often is: egg sales. Young women are solicited from college campuses to “donate” their eggs for dollar amounts that can reach the tens of thousands.¹ This is a burgeoning business; it is estimated that over 100,000 women have sold or donated eggs to clinics around the country.² Opposition to this process abounds. A range of scholarship argues that egg sales contribute to the greater commodification of women’s bodies and exploit the poor.³ The American Society for Reproductive Medicine, which promulgates compensation guidelines for egg donations, notes that a significant critique of market-based compensation is that such compensation turns the building blocks of human life into mere products.⁴

In addition to the ethical controversy over whether to allow egg sales due to the special nature of reproductive tissue in creating human life, there are significant risks to the women who sell their eggs. Egg extraction presents numerous serious health risks to those undergoing the process.⁵ More than one egg needs to be harvested, as in-vitro fertilization (IVF) is an im-

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1. Kari L. Karsjens, *Boutique Egg Donations: A New Form of Racism and Patriarchy*, 5 DEPAUL J. HEALTH CARE L. 57, 58 (2002).

2. W. Kramer et al., *US Oocyte Donors: A Retrospective Study of Medical and Psychosocial Issues*, 24 HUM. REPROD. 3144 (2009).

3. See Karsjens, *supra* note 1.

4. Ethics Comm. of the Amer. Soc’y for Reprod. Med., *Financial Compensation of Oocyte Donors*, 88 FERTILITY & STERILITY 305, 306 (2007), available at http://www.sart.org/uploadedFiles/ASRM_Content/News_and_Publications/Ethics_Committee_Reports_and_Statements/financial_incentives.pdf.

5. See Kramer et al., *supra* note 2, at 3145.

perfect process that requires more than one attempt in most cases. To accomplish this, doctors administer drugs to stimulate the ovaries. This process sometimes results in a condition called Ovarian Hyper-stimulation Syndrome (OHSS).⁶ Serious cases result in the enlargement of the ovaries⁷ and massive fluid build-up in the body, requiring intensive medical care.⁸ The rate of OHSS for those undergoing gonadotropin regimens, one of the most common methods of inducing stimulation, is around 0.3 to 5 percent, though due to the lack of available data and consistent definitions, that rate might be higher or lower.⁹ Anecdotal evidence has also shown that some frequent egg donors have contracted colon and other cancers thought to be a result of the process, though there is a dearth of statistical information precisely because of the lax regulatory environment.¹⁰

Critically, these potential harms are not addressed by any coherent, uniform system of regulation. There are presently no federal regulations on what risks clinics have to disclose to women.¹¹ Certain states, though few, have their own regulations. Louisiana explicitly prohibits the sale of eggs,¹² while Arizona, for example, permits egg donation but codified mandatory informed consent standards.¹³ While this Note argues that the compensation of egg donors should not be regulated, every state should adopt both advertising and informed consent requirements. Advertising requirements detailing the existence of potential harms may dissuade donors who are not well aware of the risk of injury from egg extraction. Additionally, informed consent requirements enable women to make the best choices for their own health and welfare while allowing them to retain their individual autonomy.

Additionally, no state requires that clinics pay the significant medical costs associated with serious conditions such as OHSS that can result from

6. See Kramer et al., *supra* note 2, at 3145–46.

7. Andrew Zacher, *Oocyte Donor Compensation for Embryonic Stem Cell Research: An Analysis of New York's "Payment for Eggs Program"*, 21 ALB. L.J. SCI. & TECH. 323, 335 (2011).

8. Justine Durrell, *Women's Eggs: Exceptional Endings*, 22 HASTINGS WOMEN'S L.J. 187, 195 (2011).

9. See *id.* at 195 n.57. Note that other studies have found a much higher rate of OHSS; the Kramer study referenced previously found that 30.3 percent of women experienced some degree of OHSS, while 11.6 percent experienced a severe enough case that required hospitalization. Kramer et al., *supra* note 2, at 3146.

10. See Kramer et al., *supra* note 2, at 3145 (noting that most IVF clinics do not keep in contact with former donors); see also Jennifer Schneider, *Case Report: Fatal Colon Cancer in a Young Egg Donor*, FERTILITY AND STERILITY 1.e1 (2008).

11. The FDA does register clinics that perform egg extractions and mandates testing for donors. *What You Should Know—Reproductive Tissue Donation*, FDA.GOV (Nov. 5, 2010), <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm232876.htm>.

12. See *infra* note 88.

13. See *infra* note 89.

the egg extraction process.¹⁴ This Note argues that clinics should provide insurance for women undergoing egg extraction or otherwise bear the cost of potential injuries. Requiring clinics to provide insurance for women who undergo these procedures places the financial burden on the shoulders of those who profit most from egg donation: the reproductive services industry. Further, placing the burden on the clinics reduces the potential that women who donate their eggs might be financially burdened by medical costs.

Presently, there is no registry recording the rates of harm occurring to the donors.¹⁵ In 1992, Congress passed an existing reporting requirement relating only to pregnancy success rates by individual ART programs and the names of the laboratories used.¹⁶ This statute required such reports to flow through the Centers for Disease Control.¹⁷ While not a perfectly analogous situation, such a reporting requirement serves as a model for a reporting requirement to evaluate the long-term effects of egg extraction on egg donors.¹⁸ This Note argues that, due to the yet unevaluated potential long-term risks of OHSS, such as cancer, Congress should create a similar reporting requirement for long-term side effects. Such a requirement can increase the ability of regulators to respond to the risks of egg donation as they become clearer.

Given the increasing demand for egg sales, the practice is likely to continue. Opponents of the for-profit reproductive industry regard the high compensation rates as commodification of the human body.¹⁹ Other arguments suggest that the process of recruiting financially vulnerable young women is a new form of exploitation.²⁰ Concededly, there may be elements of commodification and exploitation in the process. However, these concerns cannot override the important interest an individual has in choosing what is best for her, including what to do with her own body. This Note concludes that, given the prevalence of reproductive tissue sales in society and the likelihood that the demand for eggs will increase, a comprehensive regulatory regime would account for the problems inherent in the sale of reproductive tissue while preserving an individual's autonomy and complete right to her own body.

14. See *infra* notes 88–98.

15. *What is Assisted Reproductive Technology?*, CDC.GOV (Sept. 10, 2013), <http://www.cdc.gov/art/>.

16. 42 U.S.C. § 263a-1 (2013).

17. *Id.*

18. See *id.*

19. See Karsjens, *supra* note 1.

20. *Id.*

This Note is comprised of four parts. Part I outlines the present practice of egg harvesting and sale in the United States. Part II analyzes criticisms of the practice of reproductive tissue sales through the lens of both public policy and theory. Part III evaluates areas of risk and concern, examining the present regulatory regime surrounding egg donation, and finds this regime insufficient. Part IV provides several arguments. It argues that state regulations should mandate informed consent of risks before donations occur. Additionally, clinics that solicit women and extract their eggs should provide mandatory coverage for medical care in the event that a serious medical complication such as OHSS arises. Finally, a federal registry should be created to collect information about the long-term health effects of OHSS and other negative externalities.²¹

I. THE PROCESS

Typically, the process begins with the solicitation of eggs from a woman with desirable characteristics.²² These can include the ability to play a musical instrument; athletic achievement; superior academic performance, including high test scores on tests such as the SAT,²³ LSAT, or GMAT; college degrees; graduate school attendance; or professional degrees such as law degrees or degrees in medicine.²⁴ Given the significant debt incurred by attendees in those programs, it seems that the solicitations are specifically targeted toward the more educated or accomplished classes of women.²⁵ However, solicitations do not limit requirements to objective criteria such as scores or school attendance.²⁶ Some include ethnicity requirements and appearance requirements.²⁷

Advertisements commonly appear in student newspapers, targeting women who are most likely to fit the aforementioned criteria. A 2010 study

21. All of the above proposals should pertain as well to self-extraction and extraction without compensation (i.e., between friends or family members). In fact, disclosure and reporting requirements are arguably more pertinent since the altruistic may be less likely to engage in risk-reward balancing and an evaluation of potential harms.

22. Steven R. Lindheim et al., *Recruitment and Screening Policies and Procedures Used to Establish a Paid Donor Oocyte Registry*, 13 HUM. REPROD. 2020, 2021–22 (1998).

23. Rene Almeling, *Selling Genes, Selling Gender: Egg Agencies, Sperm Banks, and the Medical Market in Genetic Material*, 72 AMER. SOC. REV. 319, 326–29 (2007); see also *Genius Egg Donor Wanted*, STANFORD DAILY, May 18, 2012, at 7, available at <http://www.scribd.com/doc/94009954/DAILY-05-18-12>.

24. See, e.g., *For Donors*, APERFECTMATCH.COM, <http://www.aperfectmatch.com/fordonors.html> (last visited Feb. 13, 2015).

25. See Kramer et al., *supra* note 2 (stating that in 2004, around 1 percent of all U.S. infants born were conceived through IVF).

26. See Almeling, *supra* note 23, at 327.

27. *Id.*

by The Hastings Center for Bioethics and Public Policy sampled 105 such advertisements.²⁸ The study found that the majority of those advertisements were from agencies soliciting donations, and that most of the solicitations promised compensation between four and five thousand dollars.²⁹ The average compensation offered was \$9,190 dollars.³⁰ However, fifteen solicitations promised compensation between nineteen and twenty thousand dollars, and five offered thirty to forty thousand dollars.³¹

The entire process, from stimulation to harvesting, involves substantial burdens on the donor. When a woman agrees to have eggs harvested, she typically signs a contract including surrendering her parental rights to any offspring from her eggs.³² Contracting happens privately between an agency and the donor, establishing, among other things, payment terms and obligations of both parties.³³ However, given that there is little state regulation, there is generally no requirement that the donor obtains legal counsel.³⁴ For that reason, it is unclear whether the donor truly understands the legal and physical implications of permitting her eggs to be harvested for cash.

Even if she fits the requisite qualifications, however, the donor must submit to a series of genetic and blood tests to evaluate her suitability.³⁵ Frequently, the donor must meet with a mental health counselor as well.³⁶ Disqualifying characteristics can include a family history of mental disability or serious illness such as cancer.³⁷ The requirements are quite stringent; often, agencies request family information with great specificity, including a family medical history for at least two generations.³⁸

After a woman is recruited, medically tested, and approved, the process involved is both arduous and invasive, taking around six weeks.³⁹ The process involves three stages. First, the donor will be injected with hor-

28. Aaron D. Levine, *Self-Regulation, Compensation, and the Ethical Recruitment of Oocyte Donors*, 40 HASTINGS CENTER REP. 25, 29 (2010).

29. *Id.*

30. *Id.* at 28.

31. *Id.* at 29.

32. See AMER. SOC'Y FOR REPROD. MED., THIRD-PARTY REPRODUCTION: A GUIDE FOR PATIENTS 15–16 (2012).

33. *Id.* (noting that “many states allow for a declaration of parentage prior to the child’s birth”).

34. See, e.g., *infra* notes 88–98.

35. See AMER. SOC'Y FOR REPROD. MED., *supra* note 32, at 5–6.

36. *Id.* (Noting that the ASRM supports this particular requirement).

37. *Id.*

38. *Id.* at 10.

39. See Lynn M. Squillace, *Too Much of a Good Thing: Toward a Regulated Market in Human Eggs*, 1 J. HEALTH & BIOMEDICAL L. 135, 137 (2005).

mones that suppress ovulation in preparation for stimulation.⁴⁰ Lupron, one drug commonly used for that purpose, has side effects such as hot flashes, rashes, memory loss, chest pain, migraines, and dizziness, among others.⁴¹ Second, after hormone levels are suppressed, daily injections of either follicle stimulating hormone or human menopausal gonadotropin are administered. This stage encourages multiple follicles to develop so several mature eggs will simultaneously mature.⁴² Finally, once the eggs are mature, an injection of human chorionic gonadotropin triggers ovulation.⁴³ The eggs are typically retrieved about 36 hours after injection.⁴⁴

Numerous complications can arise from this process. Risks from the retrieval process include structural damage to organs close to the ovaries. Severe injury to the bladder, uterus, bowel, or other pelvic structures is possible.⁴⁵ Other risks include lacerations, infection, and hemorrhage.⁴⁶ As with any surgery, there are risks inherent in using an anesthetic.⁴⁷ However, OHSS is the most significant concern.⁴⁸ While the cause of OHSS is not fully understood, it is likely caused by ovarian blood vessels reacting abnormally to high level of human chorionic gonadotropin in the donor's body.⁴⁹ These blood vessels leak fluid.⁵⁰ Serious cases of OHSS involve blood clots, kidney failure, enlargement of the ovaries, and massive fluid build-up in the body, requiring intensive care treatment.⁵¹ The prevalence of OHSS in studies has ranged from 3 to 6 percent for moderate cases, while more severe cases occur in 0.3 to 5 percent of those undergoing the process, with the notable caveat that definitions of OHSS differ and that consistent data is hard to find.⁵² However, because of the lack of any reporting requirement and the relative novelty of the process in general, other

40. See Durrell, *supra* note 8 at 194. See also Mary Lyndon Shanley, *Collaboration and Commodification in Assisted Procreation: Reflections on an Open Market and Anonymous Donation in Human Sperm and Eggs*, 36 LAW & SOC'Y REV. (SPECIAL ISSUE ON NONBIOLOGICAL PARENTING) 257, 264 (2002).

41. Shanley, *supra* note 40, at 264.

42. *Id.*

43. Durrell, *supra* note 8, at 194.

44. *Id.*

45. *Id.* at 194-95.

46. *Id.*

47. *Id.*

48. Pratap Kumar et al., *Ovarian Hyperstimulation Syndrome*, 4 J. HUM. REPROD. SCI. 70 (2011).

49. See *id.*

50. *Id.*

51. *Id.*

52. See Durrell, *supra* note 8, as well as the note's discussion in its entirety. See also Kumar et al., *supra* note 48, where Kumar states that the rate of OHSS is between 0.1 percent and 3 percent. If anything, the variance between the statistics highlighted in these studies illustrates the need for further evaluation of the serious risk of OHSS.

problems may exist that have gone undiscovered. Further, anecdotal evidence exists that the long-term effects of egg extraction might not be so limited.⁵³ Several women have reported cancer diagnoses years later, which are thought to be a result of egg donation.⁵⁴

II. THE EXPLOITATION EXPECTATION

If there are significant health risks from egg donation, is the process too exploitative to continue? Much of the critical scholarship regarding egg donation states that, because the process is physically and financially exploitative, compensation should be severely limited.⁵⁵ Further, some arguments regard the risk of a potential “eugenic effect” as determinative. This reasoning suggests that the ability to select the most “preferable” types of genetic material might lead to a situation in which the rich and poor will literally have different appearances. However, the most significant concern raised is that of long-term physical harm and exploitation. Given the significant liberty interest at stake and the likelihood that the practice will continue in some form in the face of significant price regulations, what should be addressed is not the *monetary* price of the eggs, but rather the potential *physical* price that women might pay as a result.

A. Is Egg Donation Physically Exploitative? Examining the Organ Analogy

One critique of the egg extraction process likens the sale of human eggs to that of human organs. Looking at that example, however, the analogy does not fit for several reasons.

The United States bans the sale of organs and non-regenerative human tissue other than eggs.⁵⁶ The National Organ Transplantation Act of 1984 forbids the purchase and sale of human organs.⁵⁷ The logic is partly based on the premise that permitting the sale of organs such as kidneys is inherently damaging to the donor’s health. Kidneys and other organs do not regenerate, and permitting the sale of these tissues could result in greater risk of disease or other health externalities in the future than would otherwise exist. Therefore, banning the sale of non-regenerative organs has some merits. While this Note does not purport to discuss the organ trade at

53. See, e.g., Kramer et al., *supra* note 2, at 3145.

54. *Id.*

55. See Karsjens, *supra* note 1.

56. 42 U.S.C. § 274e (2013).

57. *Id.*

length, it is notable that this ban on organ sales creates a lack of available organs. As of this writing, the Department of Health & Human Services website, organdonor.gov, states that 123,655 people are waiting for an organ and that 18 people will die each day waiting for one.⁵⁸

The other part of the argument relates to exploitation. The assumption is that commodification of the human body disproportionately affects poor and underprivileged people and is generally deleterious to the fabric of society, emphasizing the binary between rich and poor. However, does the logic behind banning organ sales apply to egg sales? On the one hand, as reproductive tissue goes, egg and sperm sales cannot be equated. Women have a finite amount of eggs. Eggs are clearly not regenerative tissue in the same sense as sperm. The risks surrounding egg donation are also much greater than sperm donation, and the process inherent in harvesting them more arduous.

Yet neither can eggs be equated with organs. Eggs are plainly not essential to a woman's bodily integrity in the sense of a kidney or other major organ. A woman might choose to sell her eggs with absolutely no desire to later have children. In that case, eggs have zero future value, and a woman should be able to exploit that resource for whatever gain she can. Furthermore, should a woman desire to have children later in life, egg donation does not necessarily preclude that possibility, though it might affect the likelihood in some way.⁵⁹ Yet the United States does not, and should not, prevent women from having children later in life because of career or educational ambitions, mere circumstance, or simple desire. Neither does Congress ban women from having children after a certain age, despite considerably greater risks of birth defects.⁶⁰ Any paternalistic rationale for banning the sale of eggs should therefore be rejected.

Certainly there is a justifiable concern with the risks outlined above. The retrieval process is an inherently dangerous and invasive medical procedure. Further, the risk of OHSS includes the potential for immediate health effects such as stroke or future risk of cancer or infertility. These legitimate concerns support the need for health risk disclosure and other similar regulation. However, health risks are implicated in many elective medical procedures, such as plastic surgery. No other procedure also enables a woman to give a life to a childless couple or benefit in a financially

58. [ORGANDONOR.GOV](http://organdonor.gov), <http://organdonor.gov/index.html> (last visited Feb. 13, 2015). The number cited is current as of the access date.

59. See Kramer et al., *supra* note 2, at 3145.

60. See *Pregnancy After 35: Healthy Moms, Healthy Babies*, [MAYOCLINIC.COM](http://www.mayoclinic.com) (July 13, 2011), <http://www.mayoclinic.com/health/pregnancy/PR00115>.

significant way from the procedure. Rather than preventing a woman from profiting from this process, regulations should facilitate a safer environment for donors, one in which willing women are made to fully understand the risks before they donate, if they choose to do so.

B. Should Concerns about a Potential “Eugenic Effect” Preclude Compensation for Egg Donors?

The eugenic effect argument is a fear of something out of science fiction. In the movie *Gattaca*, the sale of designer reproductive tissue has proliferated to the extent that the few remaining “normal” people are precluded from life advancement.⁶¹ In *Star Trek: The Wrath of Khan*, the super-rich designed hyper-intelligent, human *ubermenschen* who wrought havoc on the rest of humanity.⁶² Luckily for critics of the process, the modern world has little to fear from the eugenic effect of egg donation.

First, as a practical matter, the science of intelligence and trait heritability likely precludes a significant eugenic effect. Recent studies have suggested that half of intelligence is heritable, while the remainder is environmental.⁶³ The very fact that humankind has yet to discern how intelligence is constituted in the human brain suggests that the supposed eugenic effect is overblown. Even if these somewhat reductive beliefs about the heritability of intelligence exist as motivating factors for the trade in eggs, any rationale for regulating genetic choice should not rest on concerns about what might happen based on private activities such as egg donation.

Second, a more pressing concern is the subtle issue of stigmatization and societal pressure to conform to aesthetic standards. If the process of egg extraction and donation proliferated, widespread implementation could theoretically result in a bifurcated society. Those with wealth and means would be able to select the most socially preferable genetic traits, such as skin or eye color, creating “designer babies.” However, given that the government does not intervene in people’s individual choice of mates, neither should the government regulate the decisions of individuals who wish for their children to have certain traits. Notably, given the varying likelihood of heritability for traits, there is no guarantee that the more “favored” traits will actually materialize. There are too many variables with respect to genetics for the offering of “preferable” eggs to dramatically affect societal

61. *GATTACA* (Columbia Pictures 1997).

62. *STAR TREK II: THE WRATH OF KHAN* (Paramount Pictures 1982).

63. See, e.g., Tia Ghose, *Heritability of Intelligence*, *SCIENTIST* (Aug. 9, 2011), <http://www.the-scientist.com/?articles.view/articleNo/31016/title/Heritability-of-Intelligence/>.

perceptions in ways more influential than present society has dreamed up on its own.

Additionally, the stigmatization rationale should only apply to restrict egg donations if it similarly applies to sperm donations. Sperm donors frequently are subjected to the same rigorous academic, physical, and frequently aesthetic requirements.⁶⁴ These aesthetic desires are holdovers from older societal perceptions of what kind of appearance is preferable. Thus the question becomes whether this kind of selectivity in traits is a symptom or a driver of the disease; it is far more likely, given the socialized nature of “attractiveness” and desirability, that such preferences fall into the former category. As previously mentioned, even if reproductive tissue donation eventually became more akin to a driver of such preferences, there is no reason that on its own, it would be more pervasive than the influences of myriad beauty products and commercial media existing presently.

Third, as a pragmatic issue closely related to that in the second point, genetic selection happens during mating on a large scale generally. The United States does not preclude couples from having children based on any trait except those in which the government has a significant interest, such as preventing inbreeding. Regulating mating choices smacks of government overreach and the very kind the Supreme Court rejected in *Loving v. Virginia*.⁶⁵ In overturning miscegenation laws, the Supreme Court in *Loving* stated that marriage was a fundamental right.⁶⁶ So too is the right to procreate. The opposite proposition permits a government to select with whom an individual can reproduce, and fundamentally violates the principle of individual liberty and autonomy at issue in *Loving*.

In addition, it is evident that individuals in the United States tend to self-select based on a variety of factors; most marriages are between members of the same race and educational background.⁶⁷ While much is made of the possible preference for blonde-haired, blue-eyed egg donors, a socially constructed preference should not impact the legality of a practice. Notably, the American Society for Reproductive Medicine (ASRM), which promulgates guidelines related to egg donation, prohibits member clinics

64. Almeling, *supra* note 23, at 325–27.

65. 388 U.S. 1 (1967).

66. *Id.*

67. See Wendy Wang, *The Rise of Intermarriage*, PEW SOC. & DEMOGRAPHIC TRENDS 1, 48 (Feb. 16, 2012), <http://www.pewsocialtrends.org/files/2012/02/SDT-Intermarriage-II.pdf>. While the study’s summary appropriately lauds the recent increase in interracial marriage and acceptance thereof, it is clear that the majority of marriages are between people of the same race.

from advertising based on particular aesthetic traits.⁶⁸ However, clearly some people refuse to reproduce with individuals who are not of a particular category, including on the basis of physical traits or standards like educational background. Pursuant to the liberty interest noted above, the government would not attempt to impose mating selection on individuals as a general matter; so too should the government refuse to do so in the case of egg donation. Permitting compensation for egg donation actually conforms to this liberty interest in allowing individuals to choose the kind of genetic material that will constitute their future children.

C. Is Egg Donation Financially Exploitative?

A more significant argument against the sale of eggs is one of financial exploitation. It is true that those willing to subject themselves to the process of egg extraction are likely those in a difficult financial situation. However, it is not as if an egg from one woman is considered as valuable as an egg from another, unlike in the case of kidney sales. The women offered thousands of dollars for their eggs are college attendees or graduates, sometimes with (or in pursuit of) graduate degrees.⁶⁹ In other words, these women have the intellectual capacity to understand the risks and rewards.

Certainly there is a risk that these young women will not have the foresight to consider the risks to their future fertility or whether they will suffer emotionally from not knowing whether they have biological progeny. However, situations abound in which young women, above the age of eighteen, are considered responsible enough to make decisions that might affect their future health. Both men and women work in high-risk professions because they are accorded a significant liberty interest and right to contract. Take pornography as an example. This is a profession which many people consider exploitative to at least some degree. Yet society permits the profession to exist precisely because it implicates this liberty interest and right to contract. Rather than driving the practice underground, where exploitation will *certainly* occur, it is preferable to craft reasonable regulations to protect participants.

Further, as a basic matter, women should be given the full ability to deal with their bodies as they see fit. Restricting a woman's ability to sell her eggs harkens back to historical prohibitions against contraception and, ironically, norms of a woman's body as property (albeit in that case, her father's or husband's). An element of protectionism undeniably persists in

68. Ethics Committee of the Amer. Soc'y for Reprod. Med., *supra* note 4 at 307–08.

69. See *For Donors*, *supra* note 24.

society with respect to women's bodies. Denying women the agency to contract and presuming their inability to weigh the issue is further paternalism that serves a well-meaning, if ill-aimed, purpose. This historical trend has been tough to reverse, and it is certainly possible that a large part of the uncomfortableness with which people approach questions of reproductive rights stems precisely from this paternalistic background.

Yet it is true that there would be more cause for concern if those being targeted by advertisements were poor women, and they were targeted due to some drastic increase in the infertility of women generally. This is precisely the situation implicated in the now-illegal trade in organs. Still, as noted above, eggs are not analogous to organs. Though eggs are finite, they are not essential to a woman's life in the sense of a kidney, for example, which is required to filter waste. There are also obviously more eggs than organs, and the demand is different, given that not every couple wishes to have children, and most that do are capable of making use of their own reproductive material. However, even if poor women were being targeted by advertisements soliciting egg donations, that would still be insufficient justification to ban compensation. Rather, such an occurrence would actually support the need for regulations that increase disclosure of potential health risks, and protect the health of those who undergo these procedures. That type of regulatory regime does not exist now. This should be rectified going forward.

III. EXAMINING THE EXISTING REGULATORY REGIME

Given that there are significant health risks inherent in the egg donation process, strong regulatory mechanisms should exist to ensure that those women who choose to become donors have all the information available to them. Further, these regulations should prevent the financial exploitation that can occur as a result of potential medical issues. Finally, regulations should exist to facilitate the continued study of potential long-term harms such as cancer. This section evaluates existing guidelines and potential regulatory options. Unfortunately, the existing guidelines are frequently voluntary, and where states have created statutory regimes, they are frequently piecemeal and fail to address those longer-term issues.

A. While Private Organizations Like the ASRM Promulgate Regulations, the Lack of a Statutory Regime Precludes Meaningful Enforcement

While there are few government regulations controlling the use of this technology, the ASRM has issued guidelines in concert with the Society for Assisted Reproductive Technology (SART).⁷⁰ ASRM and SART are professional organizations that set standards for member-clinics to follow in the advertisement, compensation, and performance of egg donation. The ASRM ethics committee recommends limiting compensation for egg donation, stating sums of “\$5,000 or more require justification and sums above \$10,000 are not appropriate.”⁷¹ These guidelines attempt to restrain the potential for unbridled capitalism in the egg donation industry.⁷² And yet these guidelines are frequently, if not routinely, flouted. As noted above, the Hastings Center study indicated that over a quarter of solicitations exceeded the ASRM guidelines.⁷³ There is obviously no enforcement mechanism for these guidelines outside of the independent regulations adopted by the states.⁷⁴

SART offers advertising guidelines, but these mainly pertain to potential exploitation of recipients.⁷⁵ For example, SART’s advertising guidelines require that the advertisements comply with Federal Trade Commission (FTC) guidelines, the advertisements’ claims are supported by verifiable data, and the advertisements do not compare clinic-specific data such as success rates.⁷⁶ According to the guidelines, “live births must be reported if within the time frame” of the report in question, and all cycles within the period have to be reported.⁷⁷ While the SART advertising guidelines present a framework for potential future regulations, they do not directly address the issues in question here.⁷⁸

The ASRM also offers informed consent guidelines, requiring that clinics provide “all relevant information necessary to make an informed

70. Ethics Committee of the Amer. Soc’y for Reprod. Med., *supra* note 4.

71. *Id.* at 305.

72. *See id.*

73. Levine, *supra* note 28, at 26–27.

74. This Note does not argue that ASRM’s financial guidelines, or any financial limitations, should be placed on clinics or interested parties.

75. *See SART Newsletter*, SOC’Y FOR ASSISTED REPROD. TECH. 1, 3 (Fall 2011), available at http://www.sart.org/uploadedFiles/Affiliates/SART/SART_Links/SART%20Newsletter%20Summer-Fall%202011.pdf.

76. *Id.*

77. *Id.*

78. *See id.*

decision,” and that potential donors have the ability to ask questions in furtherance of their understanding.⁷⁹ Accordingly, all donors should be provided with comprehensive information concerning the benefits and risks.⁸⁰ These guidelines extend also to the recipient, who should be informed that there are alternative methods of rectifying infertility problems, including adoption.⁸¹ All of these communications should be recorded in medical records and written informed consent should be secured.⁸² Clinics should provide counseling prior to donations so donors understand the potential negative psychological effects,⁸³ such as that future desires to connect with their offspring might not be accommodated.

ASRM’s informed consent guidelines offer a model for states to follow in implementing mandatory informed consent. Independently, ASRM guidelines do not have any teeth; violations offer no detriment to the violator except potential expulsion from the ASRM. Thus, there is frequently little to no incentive for compliance. However, if these types of guidelines were backed by significant civil or even criminal penalties for violations, clinics and service providers would take notice and have greater incentive to comply.

B. Federal Regulations are Non-Existent, and the State Statutory Regimes are Piecemeal and Oftentimes Ineffective

There are no federal regulations regarding egg sales. This makes the United States somewhat exceptional among industrialized nations.⁸⁴ The result of this laissez-faire atmosphere is that the market tends to determine the price of eggs. As noted previously, though some donations are within the cautionary margin of above \$5,000 dollars and below \$10,000, a full quarter of the donations in one study did not adhere to the regulations.⁸⁵ Further, there are no specific regulations regarding the informed consent of egg donors. Nor are there any reporting requirements for negative health effects on donors, while there are for success rates of IVF.⁸⁶

79. ARSM PRACTICE COMMITTEE, *Revised Minimum Standards for Practices Offering Assisted Reproductive Technologies*, 90 FERTILITY & STERILITY 165, 168 (Nov. 2008), available at [http://www.sart.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Guidelines_and_Minimum_Standards/Revised_minimum_standards\(1\).pdf](http://www.sart.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Guidelines_and_Minimum_Standards/Revised_minimum_standards(1).pdf).

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.* at 167.

84. *See, e.g., infra* notes 101–105.

85. Levine, *supra* note 28, at 26–27.

86. *See What is Assisted Reproductive Technology?*, *supra* note 15.

Additionally, the majority of states do not have any regulations on egg sales.⁸⁷ Louisiana prohibits compensation of egg donors for any reason.⁸⁸ Arizona,⁸⁹ California,⁹⁰ Connecticut,⁹¹ Maryland,⁹² and Massachusetts⁹³ prohibit compensating egg donors for research purposes,⁹⁴ but do not prohibit the same for IVF. Arizona does have an informed consent statute, requiring doctors to describe the hormone regimen, for example, and possible physical effects.⁹⁵ Indiana permits compensation for egg harvesting for IVF purposes, limiting the amount to \$4,000 as compensation and expenses for earnings lost, travel, hospital and medical expenses.⁹⁶ New York allows compensation and expenses for both IVF and research.⁹⁷

In some cases, what little state regulation exists is almost completely toothless. California recently passed a law requiring health risk warnings for egg donations.⁹⁸ However, this law only requires including health warnings with those advertisements that do *not* fall within the ASRM's guidelines.⁹⁹ This seems counterintuitive given that the health risks inherent in the egg extraction process do not subside simply because compensation falls within the ASRM guidelines. Recently, California's Governor Jerry Brown also vetoed a bill that would have permitted compensation for egg donations for research as well.¹⁰⁰ Given this survey of state prohibitions and limitations, there remains a distinct lack of regulation with respect to the three issues of informed consent, healthcare costs, and evaluating long-term health effects.

87. See *infra* notes 88–98.

88. LA. REV. STAT. ANN. § 9:122 (2008) (stating that “[t]he sale of a human ovum, fertilized human ovum, or human embryo is expressly prohibited.”).

89. ARIZ. REV. STAT. ANN. § 36-1703 (West 2014).

90. CAL. HEALTH & SAFETY CODE § 125350 (West 2012).

91. CONN. GEN. STAT. § 19a-32d(c)(3) (West 2013) (stating in pertinent part, “[a] person who elects to donate for stem cell research purposes any human embryos or embryonic stem cells . . . shall not receive direct or indirect payment”).

92. MD. CODE ANN. ECON. DEV. § 10-439 (2008).

93. MASS. GEN. LAWS ANN. ch. 111L, § 8 (West 2003) (stating “[n]o person shall knowingly and for valuable consideration purchase, sell, transfer, or otherwise obtain human embryos . . . for research purposes.”).

94. ARIZ. REV. STAT. ANN. § 36-1703; CAL. HEALTH & SAFETY CODE § 125325; CONN. GEN. STAT. § 19a-32d(c)(3); MD. CODE ANN. ECON. DEV. § 10-439; MASS. GEN. LAWS ANN. ch. 111L, § 8.

95. ARIZ. REV. STAT. ANN. § 36-1702.

96. IND. CODE ANN. § 35-46-5-3 (West 2012).

97. N.Y. PUB. HEALTH LAW § 265-a (West 2012).

98. CAL. HEALTH & SAFETY CODE § 125325.

99. *Id.*

100. Marc Lifsher, *Egg Donor Payment Bill Vetoed by Brown*, L.A. TIMES, Aug. 18, 2013, <http://articles.latimes.com/2013/aug/18/business/la-fi-capitol-business-beat-20130819>.

*C. International Programs Might Provide a Model, but They
Frequently Proscribe Compensation*

Conversely, many other countries do not permit egg sales for any price. Great Britain, for example, follows the Human Fertilization and Embryology Act of 1990.¹⁰¹ The English regulatory agency, the Human Fertilization and Embryology Authority (HFEA), discourages clinics from using donors whom they suspect have been paid by the recipient.¹⁰² Under that law, egg donors can receive compensation for expenses up to 750 pounds.¹⁰³ Limited compensation for donors eliminates the financial incentive for donors, leaving solely an altruistic one. Many countries, such as Israel and Denmark, restrict egg donation to egg-sharing as a solution to the compensation problem.¹⁰⁴ Others, such as Germany, bar compensation outright.¹⁰⁵

Under the health system in England, couples are also offered free IVF treatment through the National Health Service's egg-sharing process.¹⁰⁶ During the egg donation process, there are frequently leftover eggs, which can be distributed to or "shared" with other interested parties.¹⁰⁷ This limits the risk of harm to fewer women, and further rejects the idea that egg donation should be targeted at those with the supposed ideal characteristics, which is the norm as exemplified by the solicitations described above. Additionally, egg-sharing reduces the cost of the IVF process; "appropriate" donors who conform to the desires of the individual recipients cannot be found since the very premise of egg-sharing is that the donors are anonymous.¹⁰⁸ In England, for example, recipients are not informed about the identities of their donors; however, individuals conceived after April 1,

101. See Human Fertilisation and Embryology Act, 2008, c. 22 (U.K.).

102. See Kamal K. Ahuja, et al., *Egg Sharing and Egg Donation: Attitudes of British Egg Donors and Recipients*, 12 HUM. REPROD. 2845, 2845 (1997).

103. *Egg Donation & Egg Sharing*, HUM. FERTILISATION & EMBRYOLOGY AUTH., <http://www.hfea.gov.uk/egg-donation-and-egg-sharing.html> (last updated Aug. 5, 2014).

104. K.K. Ahuja & E.G. Simons, *Cancer of the Colon in an Egg Donor: Policy Repercussions for Donor Recruitment*, 13 HUM. REPROD. 227, 229 (1998).

105. See Bonnie Steinbock, *Payment for Egg Donation and Surrogacy*, 71 MOUNT SINAI J. OF MED. 255, 256 (2004). According to the article, compensation is illegal in Norway, Sweden, and Japan as well. *Id.*

106. See *Can I get IVF treatment on the NHS?*, NHS (May 8, 2013), <http://www.nice.org.uk/guidance/cg156/resources/guidance-fertility-pdf>; see also NAT'L INST. FOR HEALTH & CARE EXCELLENCE, FERTILITY: ASSESSMENT AND TREATMENT FOR PEOPLE WITH FERTILITY PROBLEMS 42–43 (2013).

107. *Egg Share Programme*, UNIV. HOSPS. COVENTRY & WARWICKSHIRE, <http://www.uhew.nhs.uk/ivf/treatments/esp> (last visited Jan. 23, 2015).

108. See *If You Were Conceived after 1 April 2005*, HUM. FERTILISATION & EMBRYOLOGY AUTH., <http://www.hfea.gov.uk/5526.html> (last visited Jan. 23, 2015).

2005, are able to inquire to the HFEA regarding identifying information about their biological parents.¹⁰⁹

Egg-sharing provides a viable alternative for those couples who lack a specific genetic desire for their progeny or the funding to be more selective. However, egg-sharing does not eliminate the market for more selective alternatives. Additionally, egg-sharing is arguably more coercive in some ways. Egg-sharing regimes require couples to give up the ability to choose their offspring's genetic origins. Significantly, this is the other end of the spectrum from the "eugenic effect" noted above that is feared by some. Couples should have some ability to choose the genetic origins of their children. Defaulting to a system in which egg-sharing is the only option implicates this significant liberty interest and might also drive more selective-minded couples to countries with a more permissive regulatory environment.

D. The FTC has Power to Penalize Those Who Issue False and Misleading Advertisements, but cannot Address the Significant Deficits in Information Given to Donors

While there are no federal regulations directly relating to advertisements soliciting egg donors, the FTC has brought suit against advertisers for false and misleading claims related to in-vitro fertilization success rates.¹¹⁰ For example, in 1995, the FTC reached a consent agreement with the Arizona Institute of Reproductive Medicine (AIRM) with respect to fabricated success rates.¹¹¹ AIRM counted multiple births (e.g., twins or triplets) as multiple deliveries, raising their in-vitro success rates.¹¹² In their advertisements, AIRM compared their success rates favorably to those collected and published by SART, which reports such multiple births as single deliveries.¹¹³ Finally, AIRM reported the national average incorrectly; while SART reported the national average as around 17 percent, AIRM stated that it was 14 percent.¹¹⁴ In either case, had AIRM counted multiple

109. *Id.*

110. Press Release, Federal Trade Commission, FYI: FTC Gives Final Approval to Consent Agreement with Arizona Institute of Reproductive Medicine, Ltd. (Oct. 3, 1995), available at <http://www.ftc.gov/news-events/press-releases/1995/10/fyi-ftc-gives-final-approval-consent-agreement-arizona-institute>.

111. *Id.*

112. *Id.*

113. *Id.*

114. *Id.*

births as single deliveries, AIRM's numbers would have been lower than the national average.¹¹⁵

While the FTC retains the power to address false and misleading claims in solicitations for egg donors, the FTC does not monitor compliance with advertising requirements, though it could if they were adopted, as proposed by this Note. Additionally, the FTC's present powers enable the organization to assign relatively minor civil penalties for those false and misleading claims. As noted in the consent agreement with the AIRM detailed above, a consent agreement "does not constitute admission of a law violation."¹¹⁶ Subsequent violations of orders can result in civil penalties up to \$10,000.¹¹⁷ Given the extent of the trade at issue, and the sizeable sums involved in the purchase and sale, these types of civil penalties are unlikely to have a significant deterrent effect. Stronger advertising requirements should be adopted, both by the FTC independently and with the assistance of Congress.

E. While the FDA could Choose to Evaluate the Risks of Drugs Used in Egg Extraction, They have Failed to do so Thus Far

The U.S. Food and Drug Administration (FDA) has previously evaluated Lupron, though not for its common use in the egg donation process.¹¹⁸ Off-label use of drugs like Lupron is not illegal, and is in fact quite common. Thus, while the FDA has noted potential risks for Lupron use in specific contexts, the FDA has yet to evaluate whether Lupron presents different risks when used for egg extraction.

Lupron functions by shutting down testosterone production in men and estrogen production in women.¹¹⁹ Lupron was originally developed to treat hormone-responsive cancers such as prostate cancer.¹²⁰ The drug is FDA-approved for that purpose, as well as more recently for endometriosis and fibroids.¹²¹ However, off-label uses are common; as noted above, Lu-

115. *Id.*

116. *Id.*

117. *Id.*

118. See *FDA Drug Safety Communication: Ongoing Safety Review of GnRH Agonists and Possible Increased Risk of Diabetes and Certain Cardiovascular Diseases*, U.S. FOOD & DRUG ADMIN. available at

<http://>

www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm209842.htm#table (last visited Feb. 13, 2015) [hereinafter *FDA Drug Safety Communication*].

119. *Lupron Depot*, U.S. FOOD & DRUG ADMIN. 5,

http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020011s0401b1.pdf (last updated Jan. 2012).

120. *FDA Drug Safety Communication*, *supra* note 118.

121. *Id.*

pron is one drug frequently used in the first stages of the stimulation process necessary for multiple-egg extraction.¹²² The FDA has not evaluated the safety or effectiveness of Lupron when used in the context of the egg donation process.¹²³

Significant risks exist even when Lupron is used in approved ways.¹²⁴ According to the FDA, hyperglycemia, increased risk of diabetes, and increased risk of heart attack and stroke have all been reported by men taking Lupron as treatment for prostate cancer.¹²⁵ Lupron's prescribing information notes that women have reported hot flashes, headaches, mood swings, myalgia, and a decrease in bone density.¹²⁶ As noted previously, the full effects of Lupron on women who undergo the egg donation process are not yet known due to this off-label usage.¹²⁷

Since it is clear that the FDA has not evaluated the risks of Lupron in a way useful to consumers for the purposes of this article, the question then becomes whether FDA regulations of other risky drugs present a viable, existing alternative. For example, the sedative thalidomide is known to cause a high rate of severe birth defects when administered to pregnant women.¹²⁸ The solid work of FDA physicians kept the drug from the American market in the mid-1960s, and the drug was only approved in 1998 for treatment of leprosy¹²⁹ and in 2013 for multiple myeloma.¹³⁰ When thalidomide was approved for leprosy, the FDA implemented a strict regulation system.¹³¹ Pharmacists must register with the manufacturing Celgene Corporation, patients must fill out surveys regarding their use of the drug, and women using thalidomide must take two forms of birth control and undergo pregnancy tests.¹³² This program is called the "System for Thalidomide Education and Prescribing Safety," or "S.T.E.P.S."¹³³

122. See, e.g., Cathy L. Brizek, et al., *Increased Incidence of Aberrant Morphological Phenotypes in Human Embryogenesis*, 12 J. OF ASSISTED REPROD. & GENETICS 106, 107 (1995).

123. *FDA Drug Safety Communication*, *supra* note 118.

124. *Id.*

125. *Id.*

126. *Lupron Depot*, *supra* note 119, at 8.

127. *Id.*

128. *Proposed Changes to Approved Thalidomid Package Insert*, U.S. FOOD & DRUG ADMIN. 1 http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021430s000,020785s0311bl.pdf (last visited Feb. 13, 2015).

129. Jerome B. Zeldis et al., *S.T.E.P.S.: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide*, 21 CLINICAL THERAPEUTICS 319, 320 (1999).

130. *Proposed Changes to Approved Thalidomid Package Insert*, *supra* note 128, at 10.

131. *Id.*

132. *Id.* at 325–28.

133. *Id.* at 320.

Certainly such a program would address critics' concerns that Lupron is not being monitored properly with respect to usage in the egg extraction process. But the first step, prior to any form of requirements, is to evaluate the safety of Lupron for egg extraction and the long-term effects of the process on women's health. This requires the FDA to oversee the use of Lupron for such ends, which the FDA has thus far failed to do. While thalidomide might provide an example of how Lupron can be monitored in the future, the problems with the egg extraction process are more multifaceted and the dangers less obvious due to the length of time at issue. The FDA should first evaluate the effects of Lupron on women who undergo the egg extraction process. Subsequent to a determination about the health effects, a policy determination can be made. However, the FDA requires assistance in determining the effects of egg extraction, given that the individuals who undergo the process are so geographically disparate and the process is presently unregulated in most states. This leads to the necessity of reporting requirements, which will be discussed further in this Note.

IV. TOWARD A MORE PROTECTIVE REGULATORY REGIME

Due to the significant interests in protecting the health and safety of donors outlined above, it is clear that the United States requires a stronger regulatory regime. While the argument that compensation should be nominal should be rejected, due to the individual right to contract, the circumstances under which women enter into donation contracts can be regulated. There is a significant state interest in protecting the lives and livelihoods of donors. At present, regulations are insufficient to protect the women who undergo these procedures. Without such regulation, financial and physical exploitation is likely to continue. However, there are three areas in which substantial improvement and greater regulation can occur.

First, with respect to informed consent, states should adopt requirements mandating that agencies describe the potential health risks of egg extraction in their solicitations. This requirement should also extend to the actual clinics that participate in the extraction process, along the lines of Arizona's law mandating informed consent standards.¹³⁴ Second, clinics should be obligated to pay health coverage for the negative health effects resulting from OHSS. Statutes could compel clinics to purchase short-term insurance policies covering these ill effects. Women suffering from serious medical problems as a result of OHSS should not be required to pay for procedures, which, in many occasions, exceed the dollar amount of their

134. ARIZ. REV. STAT. ANN. § 36-1702 (West 2014).

compensation. Finally, a federal reporting requirement should exist to document the long-term health effects of OHSS and egg extractions. As noted above, there is a significant lack of information about the prevalence of these conditions, particularly pertaining to the long-term health effects. While individuals obviously cannot be required to report their medical conditions, clinics performing these procedures can report the rates of OHSS and attempt to collect information on the long-term effects of this procedure through their access to former donors.

*A. States should Develop and Mandate Informed Consent
Requirements for Egg Donations*

While many egg extraction clinics do provide information about potential health risks and side effects,¹³⁵ states should adopt statutes mandating that such information be provided. First, each advertisement, irrespective of whether it conforms to ASRM guidelines, should note the potential health effects. Second, all clinics should outline in detail each negative health ramification that could result, including rare but serious effects such as OHSS and possibly even cancer.

However, regulations should not restrict advertising content, whether that relates to the type of individual solicited or the amount of money to be paid. For example, an advertisement that states that “[w]e are an Ivy League couple . . . seeking the help of a special woman who is a healthy, Caucasian, with highest percentile ACT/SAT scores . . . tall, slender, dark to light blonde hair, blue eyes, and under the age of 28” should not be altered for that content, however questionable.¹³⁶ However, each advertisement should be required to divulge the most relevant potential health risks. For instance, the above advertisement should include reference to the potential harms that arise from OHSS. They should note, at the least, that severe instances of disease occur in 0.3 to 5 percent of cases, and that the most severe cases result in sterility.¹³⁷

At a bare minimum, states should adopt ASRM guidelines and require that clinics conform with respect to informed consent and disclosure. While clinics frequently disclose the extent of the risk to some degree, a more full

135. See, e.g., *Egg Donation Risks and Side Effects*, TINY TREASURES L.L.C., <http://www.tinytreasuresagency.com/donors/risks/> (last visited Feb. 13, 2015).

136. Melinda Henneberger, *The Ultimate Easter Egg Hunt: 'Ivy League Couple' Seeks Donor with 'Highest Scores'*, WASH. POST (Mar. 21, 2013), <http://www.washingtonpost.com/blogs/she-the-people/wp/2013/03/21/the-ultimate-easter-egg-hunt-ivy-league-couple-seeks-donor-with-highest-percentile-scores/>.

137. Durrell, *supra* note 9.

explanation, both of the potential long-term effects and the short-term consequences, should be required. In particular, each individual should, in accordance with ASRM disclosure guidelines, undergo mandatory counseling prior to donation.¹³⁸ This practice would minimize criticism that young women are less aware of the psychological effects of having offspring by ensuring that they are fully briefed on the consequences of egg extraction.

Additionally, advertisements should at the very least note that the long-term effects of OHSS have not been fully explored. While anecdotal evidence indicates that some long-term risk of cancer exists, the evidence is yet equivocal.¹³⁹ In a sense, this follows the regulation of any medication. Everyone is accustomed to hearing the list of side effects at the end of a commercial for one medication or another. Mandating that advertisements include reasonable warnings does not impose an inappropriate burden on agencies that seek out young women as donors. Rather, such warnings adequately address the significant concern that young women in need of money might be exploited by overly optimistic representations of the difficult process which they will face if they choose to become donors.

Further, and perhaps more importantly, each clinic which performs the egg extraction procedure should be required to provide certain information relating to informed consent. New York, for example, requires that information surrounding the risks of use of hormones be described to the donor.¹⁴⁰ A sample form states:

The possible risks and complications from retrieval of eggs from my ovaries and the prolonged use of hormones has been explained to me and I understand these risks and complications. I understand my failure to comply with instructions given by, or to appear for appointments with, [name of laboratory or institution] may negatively impact my health. In addition, I understand that [I] shall be responsible for the cost of any medical treatment of complications arising from my donation.¹⁴¹

Similarly, Arizona has led the way in requiring that the adverse potential from egg donations be described to donors.¹⁴² In many ways, Arizona's description could serve as a model for federal or further state regulation. The statute requires, in part:

2. A description of all procedures to be performed on the egg donor, including the purpose, duration and estimated recovery time for each procedure.

138. See ARSM PRACTICE COMMITTEE, *supra* note 79, at 165–68.

139. See Kramer et al., *supra* note 2, at 3145.

140. N.Y. COMP. CODES R. & REGS. tit. 10, § 52-8.8 (2008).

141. 12A NEW YORK FORMS: LEGAL AND BUSINESS ch. 28B:26 (West, Westlaw updated through 2014).

142. ARIZ. REV. STAT. ANN. § 36-1702 (West 2014).

3. Medically accurate disclosures concerning all potential risks of egg donation that a reasonable patient would consider material to the decision of whether to undergo the procedure, including the medical risks associated with the surgical procedure and the drugs, medications and hormones prescribed for ovarian stimulation during the process.
4. A description of the effects that the surgical procedure and the drugs, medications and hormones may have on future attempts of the egg donor to become pregnant.
5. Notice that the egg donor cannot be completely informed of all potential risks or effects because all potential risks or effects and the magnitude of those risks or effects may not be known.¹⁴³

The benefit of presenting the risks to potential donors far outweighs the incidental cost of some women refusing to donate. In fact, mandating universal disclosure requirements would only enable women to better weigh costs and benefits of undergoing an egg extraction. At present, the majority of states lack any mandated requirement to inform women of the risks.¹⁴⁴ Providing such information ensures that those going through the procedure understand the risks, and thus might be better for the industry in the long run, given the potential harm of lawsuits or reputational harm that a lack of information might promote.

However, nothing in these requirements or disclosures should enable clinics to escape financial liability for resultant harms. Rather, by requiring that clinics affirmatively address these harms, states can ensure that women make the best possible decision for their *physical*, rather than *financial*, health in choosing to undergo egg donation. Disclosure does not necessarily impute comprehension; further, enabling clinics to escape liability simply by virtue of laying out potential harms defeats the purpose of shifting the burdens on the clinics. Therefore, disclosure should be conceptualized as relating to the risk of physical harm. Then, if physical harm occurs, clinics can still alleviate what would otherwise be a potentially crippling financial burden if laid on the women themselves.

In sum, an informed consent requirement in both advertisements and prior to procedures would enable the industry to protect itself from liability while ensuring that women are cognizant of all the potential harms that might result. Equal information protects the liberty interest of women in availing themselves of egg donation, while simultaneously protecting those women, as members of the public, from physical exploitation. While some might argue that these regulations would reduce the availability of eggs, this is not a negative effect: women who would not donate if knowledgeable-

143. *Id.*

144. *See supra* notes 88–98.

ble of the risks should not be donating in any case. Providing information ensures that both parties are willing to incur the relative costs and benefits, and protects both parties from the former.

B. Clinics should Bear the Financial Burden for Negative Health Effects on Donors

As noted previously, OHSS can have severe health effects such as stroke or even infertility.¹⁴⁵ Though the incidence of severe OHSS is relatively rare, when it occurs, donors can be left with significant health care costs far exceeding their monetary compensation. Therefore, states should require clinics to pay the healthcare costs of women who undergo egg extraction and suffer from health problems such as severe OHSS. Requiring that clinics purchase short-term health insurance for donors could suffice, assuming such insurance covered OHSS. While some might contend that this requirement will lower the compensation for egg donors, the benefit of protecting donors far outweighs the potential costs.

Presently, most compensation for injuries suffered during medical procedures relies on malpractice claims. As a general matter, this obviously requires there to be some misdeed by the physician in the process of the procedure. Yet malpractice coverage is insufficient for the kind of harms at issue here. OHSS is not always a result of malpractice; the syndrome can occur in between 0.3 to 5 percent of cases where the drug regimen is administered properly.¹⁴⁶ Therefore, the issue is not one of malpractice, but of inherent risk. And the potential harm is great; the most severe cases of OHSS can result in life-threatening complications.¹⁴⁷ Typical malpractice recovery would not account for such injuries.

However, these medical costs also should not be placed on the soliciting couples. Loss-spreading is best practiced when there is a wider base upon which the harm will lie. This soft-landing approach of requiring clinics to pay medical costs also achieves the same goal that targeting couples would; those benefiting most from the egg extraction process are the ones who should compensate donors for their harms. It is the clinics, rather than the couples, who possess a primarily financial motive. Additionally, these clinics provide services to many individuals, and have the financial capacity to account for the harms inherent in their work. While this loss-spreading might lead to slightly higher costs to couples, or slightly lower compensa-

145. See Kramer et al., *supra* note 2, at 3145.

146. Durrell, *supra* note 9. See also the discussion at *supra* note 9.

147. *Id.* at 221.

tion for donors, it is better to share the effects of the harms up-front than cripple, financially and physically, donors who are relative neophytes to this specific market.

Next, requiring couples to pay for the sometimes-staggering cost of medical care resulting from egg extraction could have a dissuasive effect. This dissuasive effect should not be favored as it implicates a risk alluded to at the outset of this Note; where couples are dissuaded from engaging in egg donation in a jurisdiction, they are likely to merely change forums. The regulatory regime with the greatest utility provides donors with information sufficient to reach a conclusion about the risk to their health and healthcare coverage to prevent financial harm while still providing a favorable environment for soliciting couples who have an understandable desire to reproduce.

Given that one of the most salient concerns of the entire egg donation process is the exploitation of the women who donate, payment of medical expenses mitigates a significant potential harm. Requiring that clinics pay for short-term health insurance, or medical bills in the case of severe medical issues arising from the procedure, ensures that such exploitation will not occur. Certainly, agencies often target women who have significant amounts of student loans and other debt.¹⁴⁸ Providing that these women do not have to pay for medical care resulting from severe OHSS and other illnesses would ensure that they are not making a choice that will further cripple them financially. It is obvious that potential physical harms cannot always be mitigated. Yet society must help balance the interest in protecting these donors and facilitating their liberty interest. Mandating that clinics provide health coverage for this condition provides an adequate balance between the interest of donors in their own health, and the interest of recipients and clinics in finding such donors.

C. Congress should Create a Reporting Requirement Regarding the Long-Term Effects of Egg Extraction

Finally, Congress should require that clinics which perform egg extractions attempt to retrieve periodic information about former donors. This proposal stems from the relative novelty of the procedure and the prominent concern among some advocates that egg extraction can result in cancer or other long-term risks to a woman's health. This is not a radical suggestion, but one inspired by existing law.¹⁴⁹ The 1992 Fertility Clinic Success

148. Levine, *supra* note 28, at 35.

149. *What is Assisted Reproductive Technology?*, *supra* note 15.

Rate and Certification Act, for example, requires fertility clinics which perform IVF to provide data for all procedures performed to the Centers for Disease Control and Prevention (CDC).¹⁵⁰ The CDC then provides annual reports on success rates and monitors all clinics for compliance with the standards included in the Act.¹⁵¹

While not perfectly analogous circumstances, a similar requirement for periodic monitoring and reporting would provide the CDC and the government the ability to evaluate the long-term risks inherent in the egg extraction process and guide future regulation of the industry. Certainly a requirement to monitor former patients for a period would involve clinics committing more resources than when they merely reported their own success rates. However, clinics presumably retain the contact information of donors, and requesting change-of-address notification and distributing periodic health feedback forms would not represent an insurmountable administrative burden or financial cost on these profitable institutions. Additionally, while feedback response by former donors would be voluntary, such a program could provide valuable information.

Specifically, the Act has enabled a large amount of scholarship on the efficacy of IVF and encouraged various non-governmental organizations to provide information about clinics and their relative success rates.¹⁵² For example, the SART's website has an interactive map where potential parents can seek out clinics in their area, and look at the efficacy of each one.¹⁵³ One can imagine a future in which donors might be able to look at a similar map for clinics to donate, looking at their rates of OHSS and potentially evaluating their accreditation, if legislation included that standard.¹⁵⁴

Key within this proposal would be the information-gathering about future health effects, however. In the presently unregulated field of egg extraction, women cannot properly weigh the risks and rewards of donating eggs. More information is needed for individuals to make informed decisions. Given the significant and yet-unevaluated long-term risk of cancer inherent in the egg extraction process, more information is needed to guide future regulations. Collecting information from this largely unregulated industry, across fifty disparate states, suggests the need for creation of such a reporting requirement. While reporting requirements are rare, they are not

150. *Id.*

151. *Id.*

152. *See, e.g.,* SOC'Y FOR ASSISTED REPROD. TECH., <http://www.sart.org/> (last visited Feb. 13, 2015).

153. *IVF Success Rates*, SOC'Y FOR ASSISTED REPROD. TECH., http://www.sart.org/find_frm.html (last visited Feb. 13, 2015).

154. *See id.*

unheard of in nascent industries that present potential long-term issues or significant risk of harm, as was the motivation behind the 1992 Act dealing with in-vitro fertilization.¹⁵⁵

Proponents of the egg donation industry should be sympathetic to this proposal as well, as a substantial amount of criticism of the egg extraction process stems from accusations of opaqueness and consequent exploitation. Providing more information to the scientific community enables legislators to decide how to further regulate the egg extraction industry. Perhaps most importantly, providing women with adequate information that has implications for their future health is the best way to promote responsible donations, whereas clouding the process in secrecy encourages skepticism and more criticism.

CONCLUSION

With the proliferation of assisted reproductive technology, both supply of and demand for these services is bound to increase. While some seek to curtail compensation for donors, the truly problematic aspect of the egg donation process lies with a poor regulatory environment. Advertising and informed consent requirements enable young women to make reasoned, independent decisions about medicine and their own bodies. Requiring health coverage protects the physical and financial health of donors. A federal reporting requirement ensures that the long-term risks that are yet unknown will not stay unknown forever. Together, these regulations can provide that egg donation serves not only the interests of the industry, but also the women who are so intimately involved in it.

155. *What is Assisted Reproductive Technology?*, *supra* note 15.

