ASSUMPTION OF WHAT? BUILDING BETTER MARKET ARCHITECTURE FOR EGG DONATION

WYNTER K. MILLER*

INTRODUCTION

In 2007, the Ethics Committee of the American Society for Reproductive Medicine (ASRM), in conjunction with its affiliate, the Society for Assisted Reproductive Technology (SART), released an opinion addressing the morality of monetary payment for oocyte donation. The opinion raised the following question: "[D]oes financial compensation devalue human life by treating oocytes as property or commodities?"[1] In a succinct four pages, the Committee answered

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* Wynter K. Miller received her J.D. from U.C. Davis School of Law. Her research focuses on reproductive law and ethics, with special emphasis on emerging reproductive technologies. She currently works for a health tech startup in San Francisco.

1. Ethics Comm. of the Am. Soc'y for Reprod. Med., *Financial Compensation of Oocyte Donors*, 88 FERTILITY & STERILITY 305, 305 (2007) [hereinafter ASRM, *Financial Compensation*], http://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/financial_compensation_of_oocyte_donors-pdfmembers.pdf.

with a qualified no.[2] The Committee acknowledged the potential concerns attached to egg donation. Women might, for example, suffer health and reproductive consequences as a result of the oocyte retrieval process.[3] Women might experience psychological side-effects.[4] Payment might encourage new forms of positive eugenics, or objectification of women and children, or commodification of human life. The Committee noted that state and federal law prohibits direct payment for human materials in other contexts (e.g., for organ and tissue transplants).[5] And then, the Committee reached its conclusion: not only is paying women for oocyte donation ethically defensible, failing to do so is to "demean their significant contribution."[6] The Committee determined that sums appropriately recognizing these types of contributions would generally fall below the five-thousand-dollar mark.[7] Payments exceeding five thousand would require justification, and sums over ten thousand would be inappropriate in every case.[8]

Four years after the ASRM issued its guidelines, Lindsay Kamakahi filed a class action lawsuit[9] on behalf of all women who "agree[d] to supply their own human eggs for assisted fertility and reproductive procedures."[10] The complaint, filed against ASRM and SART—the two Defendant organizations collectively responsible for setting reproductive policy in the United States[11]—explicitly alleged "naked price-fixing" and anticompetitive profits by the "[egg buyers']

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2. *Id.* at 306.

3. *Id.* The Committee specifically noted the following risks: unintentional pregnancy, increased risks of morbidity and remote risk of mortality from controlled ovarian stimulation and oocyte retrieval, future health risks associated with use of fertility drugs, and impaired fertility. *Id.*

4. *Id.* (noting that young women "may underestimate the psychologic and legal consequences of their agreement to forgo parental rights and future contact with children born to oocyte recipients").

5. *Id.*

6. *Id.* at 307.

7. *Id.* at 308.

8. *Id.*

9. Kamakahi v. Am. Soc'y for Reprod. Med., 305 F.R.D. 164, 171 (N.D. Cal. 2015).

10. First Amended Class Action Complaint at 1, Kamakahi v. Am. Soc'y for Reprod. Med., 305 F.R.D. 164 (N.D. Cal. 2015) (No. 3:11-CV-1781 SBA) [hereinafter First Amended Class Action Complaint].

11. *Id.* at 3 (describing the "promulgat[ion of] guidelines and standards to be followed by reproductive professionals" as "a central function of ASRM," and noting that SART controls more than 85% of assisted reproductive technology clinics in the United States). SART places its own membership estimate at "more than 90% of the ART clinics in our country." *What Is SART?*, SOC'Y FOR ASSISTED REPROD. MED., http://www.sart.org/patients/what-is-sart/ (last visited Oct. 20, 2018).

cartel" in violation of U.S. antitrust law.[12] Implicitly, this raised a more foundational question: are egg donors helped or harmed by policies designed to prevent their commodification?

This Article explores and evaluates the issues raised by the *Kamakahi* litigation. Part I establishes a foundational background for evaluating U.S. reproductive law and policy. Section A provides a cursory overview of ART use internationally, positioning ART clinics and agencies as third-party facilitators of a truly unique market. Section B defines the critical terms and concepts implicated by discussions about assisted reproductive technology (ART). Section C describes the relevant participants in the ART process, with a focus on egg donors and donation recipients. Parts II and III identify the two dominant doctrinal approaches—free market commercialism and anti-commodification—guiding egg donation policy. Part II describes the domestic market, outlining the history of ART use in the U.S. and surveying the legal landscape across the states. It uses *Kamakahi v. American Society for Reproductive Medicine*, and its resolution, as an illustrative example of the United States' adoption of free market commercialism. Part III introduces Canada's 2004 Assisted Human Reproduction Act (AHRA) as representative of an anti-commodification approach and juxtaposes the Canadian model with the United States' free market model. Part IV opens a normative discussion of the ethical implications produced by the two approaches. It argues that while both approaches are necessary components of a broader discussion, both fail to allot appropriate attention to risk disclosure and risk assumption. Part V offers recommendations for moving toward an ethically sound and legally practicable model of egg donation. This Article concludes that current approaches are fragmented and should be replaced with policies built on accurate understandings of donors' motivations and appropriate consideration of the risks attendant to egg donation.

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12. Kamakahi's complaint quotes a commentator's observation that this type of price fixing is so unusual that "the most intriguing question it raises is not whether it violates the Sherman Act . . . [but] how, given the government's substantial enforcement resources and the presence of an active and entrepreneurial plaintiffs' bar, this buyers' cartel has managed to survive unchallenged since at least 2000." First Amended Class Action Complaint, *supra* note 10, at 16 (quoting Kimberly D. Krawiec, *Sunny Samaritans and Egomaniacs: Price-Fixing in the Gamete Market*, 72 L. & CONTEMP. PROBS. 59, 60 (2009) [hereinafter Krawiec, *Samaritans and Egomaniacs*]).

I. BACKGROUND: "A STRANGE ANIMAL"

If, when, and how to have children are no longer private decisions between intimate partners. Rather, procreation has become a highly collaborative process involving doctors, patients, donors, gestational carriers, governments—and in some cases airlines, insurance companies, marketing professionals, psychologists, and lawyers.[13] Indeed, "[p]regnancy separated from passion is a strange animal," allowing "every facet of the future child [to be] managed, scrutinized, valued and assessed."[14] Above all, procreation has become an industry facilitated by third parties: agencies and clinics and independent fertility providers.

A. The Fertility Industry

The rise and proliferation of ART services is apparent across all jurisdictions. That said, ART access, usage, and governance varies considerably. In the United States, the shift from private to commercial reproduction manifested with congressional codification of data collection requirements for ART providers. The first ART Success Rates Report was published in 1997 and collated data collected in 1995.[15] At that time, 263 fertility clinics were in operation.[16] By 2014, there were 498 operating ART clinics, cumulatively facilitating an estimated 2% of total U.S. births.[17] Today, the fertility industry generates an estimated four billion dollars in annual revenue in the United States alone[18]—and the domestic industry accounts for only 15% of the international market-share.[19] European nations are the primary purveyors of ART services and treatments. Women in Belgium and Denmark utilize ART in the

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13. Scott Carney, *It's Not Altruism, It's Selling*, PULITZER CTR. (Aug. 13, 2010), http://pulitzercenter.org/reporting/its-not-altruism-its-selling.

14. *Id.*

15. *Archived ART Reports and Spreadsheets,* CDC, https://www.cdc.gov/art/reports/archive.html (last updated Aug. 13, 2018).

16. CDC, 1995 CLINIC TABLES (1997), https://www.cdc.gov/art/reports/archive.html (select "1995").

17. CDC, 2014 ASSISTED REPRODUCTIVE TECHNOLOGY: NATIONAL SUMMARY REPORT 7 (2016) [hereinafter CDC, 2014 NATIONAL SUMMARY], https://www.cdc.gov/art/pdf/2014-report/art-2014-national-summary-report.pdf.

18. JUDITH DAAR, THE NEW EUGENICS: SELECTIVE BREEDING IN AN ERA OF REPRODUCTIVE TECHNOLOGIES 55 (2017).

19. Patrick Präg & Melinda C. Mills, *Assisted Reproductive Technology in Europe: Usage and Regulation in the Context of Cross-Border Reproductive Care*, 43 FAMILIES & SOC'YS 1, 3 (2015).

highest numbers, followed by Iceland, Sweden, and Slovenia.[20] In a 2015 comparative study, researchers Patrick Präg and Melinda Mills found evidence linking ART use to economic and social factors. For example, cultural assumptions about the appropriate age to bear children influence usage rates.[21] ART clinics are more widely available in countries with higher (socially-determined) age "deadlines" for parenthood.[22] With respect to economic factors, affordability (calculated in terms of ART cost as a percentage of average disposable income) is also significant.[23] Affordability might explain Belgium and Denmark's high usage rates; both countries are known for having generous ART reimbursement policies, at levels upward of 75%.[24] By contrast, in the United Kingdom and Portugal, countries which both fall in the lower half of the usage distribution, reimbursement is more limited, especially in private settings.[25] In the United States, reimbursement is largely unavailable, with some estimates placing insurance coverage of in vitro fertilization (IVF) costs at only 15%.[26]

In addition to usage discrepancies, there is also variation in the types of services used. In the United States, procedures using donor eggs are common, comprising 12% percent of all ART procedures.[27] Internationally, however, egg donation is controversial. Austria and Germany explicitly prohibit it.[28] In 2010, Italy reported zero cases of egg donation; Slovenia and Denmark reported less than 2%; and the United Kingdom and Belgium reported 3% and 9%, respectively.[29] The highest rates of egg donor use in Europe occurred in the Czech Republic (9.7%) and Spain (22%).[30]

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20. *Id*. at 6.
21. *Id.*
22. *Id.*
23. *Id.*
24. *See Research & Education: Policy of Reimbursement*, IVF-WORLDWIDE, http://www.ivf-worldwide.com/education/introduction/ivf-costs-worldwide/policy-of-reimbursement.html (last visited Oct. 11, 2018).
25. *Id.*
26. DAAR, *supra* note 18, at 55; *see also* Michelle J. Bayefsky et al., *Compensation for Egg Donation: A Zero-Sum Game*, 105 FERTILITY & STERILITY 1153, 1153–54 (2016) ("Fertility treatment in the United States is largely uncovered by health insurance, meaning that couples must pay out of pocket more than $12,000, on average, for a single fresh cycle of IVF (including medications). Insurance coverage for fertility treatment is mandated in 15 states, but coverage in most of these states excludes IVF.").
27. DAAR, *supra* note 18, at 61.
28. Präg & Mills, *supra* note 19, at 14, 17.
29. *Id.* at 9.
30. *Id.*

Like all markets, the egg market is composed of buyers and sellers. But in the United States, unlike in other markets, the fertility industry does not recognize buyers and sellers as such. Instead, buyers are "donation recipients" and sellers are "donors."[31] The goods are not "products" but "gifts."[32] Clinics and agencies devote significant time and energy to screening donor candidates and using "gendered coaching strategies" to "produce calibrated distances between [ART] participants."[33] Market rhetoric and industry nomenclature are carefully designed to ensure alignment with the appropriate narrative. Clinics manipulate donor profiles to sell altruism, and reject prospective donors for expressing "too much interest in financial compensation" or for perceived deficiencies in charitable motivation.[34] The intent of this artful deception is, of course, to distance egg donation from standard commercial industries—to "hide[] the compensation element, which raises issues of social distaste and significant ethical debate."[35]

B. Defining Terms, Describing Processes

Assisted reproductive technology is the broad term used to refer to "any procedure that entails the handling of both eggs and sperm or of embryos for the purpose of establishing a pregnancy."[36] The U.S. Centers for Disease Control (CDC) utilizes a definition that specifically includes IVF, gamete intrafallopian transfer, and zygote intrafallopian transfer,[37] and specifically excludes treatments involving only sperm (e.g., artificial insemination) and treatments that stimulate egg production in women for purposes other than egg

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31. Krawiec, *Samaritans and Egomaniacs*, *supra* note 12, at 63 (noting that "[t]he phrase 'egg donation' is largely a misnomer"); Danielle A. Vera, *R-Egg-ulation: A Call for Greater Regulation of the Big Business of Human Egg Harvesting*, 23 MICH. J. GENDER & L. 391, 394 (2016) (discussing use of "'donor' nomenclature").

32. Krawiec, *Samaritans and Egomaniacs*, *supra* note 12, at 60.

33. Lisa C. Ikemoto, *Egg Freezing, Stratified Reproduction and the Logic of Not*, 1 J.L. & BIOSCIENCES 112, 116 (2015) [hereinafter Ikemoto, *Logic of Not*].

34. *See* Rene Almeling, '*Why Do You Want to Be a Donor?': Gender and the Production of Altruism in Egg and Sperm Donation*, 25 NEW GENETICS & SOC'Y 143, 148–51 (2006) [hereinafter Almeling, *Production of Altruism*].

35. Vera, *supra* note 31, at 395.

36. Meredith A. Reynolds et al., *Trends in Multiple Births Conceived Using Assisted Reproductive Technology, United States, 1997–2000*, 111 PEDIATRICS 1159, 1159 (2003).

37. Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, § 8, 106 Stat. 3146, 3151 (1992).

retrieval.[38] ART treatments are generally classified by egg origin (donor or non-donor) and egg type (frozen or fresh). Procedures involving fresh embryos from non-donor eggs are the most common.[39] According to data compiled in the CDC's 2015 National Summary, roughly 50% of women undergoing ART procedures use fresh embryos from non-donor eggs.[40] Roughly 38% of ART procedures utilize frozen embryos from non-donor eggs.[41] Put another way, roughly 88% of women employing ART use their own eggs, making procedures using donor eggs the least common. Nevertheless, the percentage of ART procedures using donor eggs is steadily increasing. In 2015, donor-facilitated procedures comprised about 12% of total ART procedures in the United States,[42] up from 8% in 1995.[43]

Logistically, an ART cycle using donor eggs is divisible into five discrete phases: (1) stimulation and monitoring, (2) egg retrieval, (3) fertilization and transfer, (4) pregnancy, and (5) live-birth delivery.[44] The first phase aims to synchronize the donor's and recipient's menstrual cycles. To achieve synchronization, facilities prescribe a three-drug regimen for donors. Initially, donors self-administer daily injections of gonadotropin-releasing hormones for two to three weeks.[45] Leuoprolide acetate, commercially known as Lupron, is the most commonly used form of gonadotropin[46] and triggers artificial

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38. *What Is Assisted Reproductive Technology?*, CDC, https://www.cdc.gov/art/whatis.html (last updated Feb. 7, 2017).

39. *ART National Data, 2015: Patient Characteristics–What Are the Categories of ART Cycles?*, CDC, https://nccd.cdc.gov/drh_art/rdPage.aspx?rdReport=DRH_ART.ClinicInfo&ClinicId=9999&ShowNational=1 (last visited Oct. 11, 2018).

40. *Id.*

41. *Id.*

42. *Id.*

43. Nancy J. Kenney & Michelle L. McGowan, *Egg Donation Compensation: Ethical and Legal Challenges*, 2014 MEDICOLEGAL & BIOETHICS 15, 15 (2014).

44. CDC, 2014 NATIONAL SUMMARY, *supra* note 17, at 12.

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

46. *See, e.g.*, *Egg Donation for Beginners*, FERTILITY SOURCE COMPANIES, https://www.fertilitysourcecompanies.com/egg-donation/egg-donation-process/ (last visited Oct. 11, 2018) (noting that "the first phrase involves a medication called Lupron"); *Egg Donation Process*, EGG DONATION INC., http://www.eggdonor.com:80/egg-donation-process/egg-donor-follicle-stimulation [https://web.archive.org/web/20151118212720/http://www.eggdonor.com:80/egg-donation-process/egg-donor-follicle-stimulation] (last visited Oct. 11, 2018) (describing the "simple" process of self-injection using Lupron); *Egg Donor Glossary*, EXTRAORDINARY CONCEPTIONS, https://www.extraconceptions.com/egg-donor-requirements/egg-donor-glossary/ (last visited Oct. 11, 2018) (listing Lupron as the injectable medication "used to prepare [the donor's body] for the retrieval process"); *How Egg Donation Works*, CTR. FOR HUM. REPROD. (Jan. 8, 2015),

menopause.[47] Once artificial menopause begins, donors start daily injections of a second class of drugs known as follicle stimulating hormones (FSHs).[48] FSH injections hyperstimulate donors' ovaries to produce multiple mature eggs, rather than the one egg naturally produced, during a single menstrual cycle.[49] During this time, a period lasting ten to fourteen days, donors must abstain from sexual activity and discontinue contraceptive and prescription drug use.[50] While donors complete the second phase of drug injections, recipients concurrently ingest estrogen supplements to thicken the endometrial lining.[51] Both donors and recipients are closely monitored via blood tests and ultrasounds.[52] When testing indicates sufficient egg development by the donor and sufficient thickening of the recipient's endometrium (at least seven millimeters),[53] the donor self-administers the final drug, Human Chorionic Gonadotropin (HCG).[54] HCG triggers ovulation and phase two—egg retrieval—begins approximately thirty-six hours later.[55] Notably, although drug therapy is a component of the process for both donors and recipients, the risks for the respective parties are not at all equal.[56]

Egg retrieval involves a surgical procedure generally performed under conscious sedation.[57] Using fine needle aspiration guided by

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https://www.centerforhumanreprod.com/egg-donation/how-it-works/ (referencing use of Lupron for suppression of donor's natural cycle).

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

48. *Id.*

49. *Id.*

50. *See Egg Donor Information*, IVF1, https://www.ivf1.com/egg-donor-information/ (last visited Jan. 16, 2019) (noting restrictions on drug use); *The Medical Procedure of Egg Donation*, *supra* note 45 (noting restrictions on sexual activity); *see, e.g.*, *Questions for Egg Donors,* UCSF*,* https://www.ucsfhealth.org/education/common_questions_for_egg_donors/#10 (last visited Dec. 20, 2018) (requiring abstention from sexual activity).

51. *Estrogen—Why Do Fertility Patients Need It?*, YOUR IVF JOURNEY, http://www.yourivfjourney.com/estrogen-why-do-fertility-patients-need-it/ (last visited Oct. 11, 2018).

52. GENESIS FERTILITY & REPROD. MED., HANDBOOK FOR DONOR EGG RECIPIENTS 7–8 (2014) http://www.genesisfertility.com/wp-content/uploads/2014/09/Handbook-for-Recipients.pdf (last visited Oct. 11, 2018).

53. *Estrogen—Why Do Fertility Patients Need It?*, *supra* note 51.

54. *How Egg Donation Works*, *supra* note 46.

55. *In Vitro Fertilization (IVF)*, MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716 (last visited Dec. 20, 2018); *Egg Donation for Beginners*, *supra* note 46.

56. *See infra* discussion in Part IV.

57. *The Medical Procedure of Egg Donation*, *supra* note 45. Many ART service providers emphasize in their online literature that "[m]ost donors feel and remember nothing from their procedure." *Egg Donation for Beginners*, *supra* note 46; *see also The Egg Donation Process*, EXTRAORDINARY CONCEPTIONS,

ultrasound imaging (i.e., insertion of a thin suctioning needle attached to an ultrasound probe), physicians transvaginally remove mature eggs from the donor's ovaries.[58] The procedure itself takes approximately twenty minutes, though it may take several hours for the effects of the anesthesia to wear off.[59] As a matter of protocol, facilities fertilize eggs immediately post-retrieval, and embryos develop in the lab for three to five days before transfer to the recipient's uterus.[60] Egg donors are not involved in phases three, four, or five.

C. ART Donors and Recipients

In 1992, Congress codified reporting requirements for the fertility industry with the Fertility Clinic Success Rate and Certification Act.[61] The Act mandates publication of ART pregnancy success rates, requires the Secretary of Health and Human Services to identify and publish a list of certified ART facilities, and imposes inspection requirements for embryo laboratories on the states and the Secretary.[62]

1. Recipient Demographics and Motivations

The CDC's information collection focuses predominantly on the prospective parents. That is, most of the information we have describes only the recipients of ART services. We know, for example, that a plurality of recipients are younger than thirty-five.[63]

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https://www.extraconceptions.com/egg-donor-requirements/egg-donation-process/ (last visited Apr. 16, 2017) (describing the procedure as "minimally invasive," and stating that "[m]ost donors tell us that they don't remember the procedure afterwards"); *Egg Donation Summary: Stages of Egg Donation*, PAC. FERTILITY CTR., https://www.pfcdonoragency.com/egg-donor/egg-donation-summary (last visited Oct. 11, 2018) ("Because anesthesia is used for the egg retrieval, it is completely painless.").

58. *The Medical Procedure of Egg Donation*, *supra* note 45; *see also Egg Donor Information*, CTR. FOR ASSISTED REPROD., http://www.donoregginfo.com/html/donors/process.html [https://web.archive.org/web/20170512152646/http://www.donoregginfo.com/html/donors/process.html] (last visited Oct. 11, 2018); *How Egg Donation Works*, *supra* note 46.

59. *See In Vitro Fertilization (IVF), supra* note 55 (estimating retrieval time at twenty minutes); *How Egg Donation Works*, *supra* note 46 (noting that clinics often require a day of bed rest).

60. *See Egg Donation Summary: Stages of Egg Donation*, *supra* note 57.

61. Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, § 3, 106 Stat. 3146, 3148 (1992).

62. *Id.* § 6, at 3151.

63. CDC, 2014 NATIONAL SUMMARY, *supra* note 17, at 9.

Predictably, older recipients are less likely to use their own eggs.[64] Only around 4% of women younger than thirty-five elect to use donor eggs.[65] By comparison, about 35% of women forty-three to forty-four years of age use donor eggs, and about 86% of women older than forty-eight use donor eggs.[66] Additionally, we know a great deal about the recipients' medical motivators for ART use. By far, the most common diagnoses associated with infertility among ART recipients are "diminished ovarian reserve" and "male factor[s]."[67] The former refers to a decrease in the recipient's production of eggs; the latter refers to "[a] low sperm count or problems with sperm function that make it difficult for a sperm to fertilize an egg under normal conditions."[68] Diminished ovarian reserve and male factors account for 30.8% and 35.1% of infertility in ART recipients, respectively.[69] Other medical motivators include ovulatory dysfunction (13.7%), endometriosis (9.3%), functional disorders of the uterus (5.5%), fallopian tube abnormalities (14.2%), and non-reproductive factors like immunological problems or chromosomal abnormalities (12.4%).[70] Of course, in some cases (14.1%), there is no clear cause of infertility.[71]

Given the expense associated with assisted reproductive technology,[72] it is unsurprising that ART recipients are overwhelmingly in the upper socioeconomic echelons. Consistent with other reproductive contexts,[73] findings demonstrate that the typical donor egg recipient is in her mid-thirties to early forties, white,

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64. *Id.* at 10.
65. *Id.* at 10.
66. *Id.* at 45.
67. *Id.* at 24.
68. *Id.*
69. *Id.*
70. *Id.*
71. *Id.*
72. *See infra* discussion in Section I.C.
73. Shellee Colen originally coined the term "stratified reproduction" to describe the cultural, social, and economic inequities between West Indian workers and their U.S.-born employers. *See* Shellee Colen, *"Like a Mother to Them": Stratified Reproduction and West Indian Childcare Workers and Employers in New York*, *in* FEMINIST ANTHROPOLOGY: A READER 393, (Ellen Lewin ed., 2006). Colen concluded that employers accomplish reproductive tasks—could, in effect, "buy their way out of a squeeze"—by capitalizing on the commodification of parenthood and reproductive labor. *Id.* Rhacel Salazar Parreñas has applied the term to reproductive labor between middle-class women in receiving nations, migrant domestic workers (specifically, Filipina domestic workers), and Third World women who are too poor to migrate. Rhacel Salazar Parreñas, *Migrant Filipina Domestic Workers and the International Division of Reproductive Labor*, 14 GENDER & SOC'Y 560, 569 (2000). Most recently, Lisa C. Ikemoto has commented on stratified reproduction with respect to corporate egg freezing and banking. Ikemoto, *Logic of Not*, *supra* note 33, at 114–16.

educated (though typically not beyond the bachelor's degree level[74]), and "experiencing above normal levels of marital satisfaction."[75] As in the surrogacy context, recipients tend to have financial stability and disposable income.[76]

2. Donor Demographics and Motivations

The breadth and specificity of available data with respect to ART recipients stands in stark contrast to the available data with respect to egg donors. From 2005 to 2014, ART cycles using donor eggs increased by 27%, representing over twenty thousand cycles[77] and donations by an unknown, but certainly significant, number of women.[78] Though little is known about the *actual* demographics of these donors, the ideal donor profile is clear: she is young, intelligent, highly educated, and has yet to realize her earning potential.[79] Assuming donor solicitation and advertising successfully produces a "desirable" donor pool as defined by recipients and their agents, we know a bit more. Ethnically and racially, Whites and Asian-American egg donors appear overrepresented in relation to their total population proportions in the United States.[80] African-Americans and Latinas appear to be underrepresented.[81] In a data collection "about 359 egg donors from eight [ASRM-approved] fertility clinics," researchers found that age, height, and weight are often fixed as

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74. Cynthia R. Daniels & Erin Heidt-Forsythe, *Gendered Eugenics and the Problematic Free Market Reproductive Technologies: Sperm and Egg Donation in the United States*, 37 SIGNS 719, 731–32 (2012) (stating that there is no empirical data to support the assumption that egg donor consumers are as highly educated as egg donors themselves).

75. Patricia Hershberger, *Recipients of Oocyte Donation: An Integrative Review*, 33 J. OBSTETRIC, GYNECOLOGIC & NEONATAL NURSING 610, 614 (2004).

76. *See* Ikemoto, *Logic of Not*, *supra* note 33, at 115–16.

77. CDC, 2014 NATIONAL SUMMARY, *supra* note 12, at 51.

78. Judy Norsigian & Timothy R.B. Johnson, *A Call to Protect the Health of Women Who Donate Their Eggs*, NAT'L WOMEN'S HEALTH NETWORK (Nov. 12, 2016) https://www.nwhn.org/call-protect-health-women-donate-eggs/ (stating that "although there are no exact figures for how many young women engage in egg-retrieval-for-pay, the numbers are at least in the thousands").

79. *See, e.g.*, Ikemoto, *Logic of Not*, *supra* note 33, at 115–16 ("The ideal egg provider is a college student. She is a bit younger than a surrogate." "Access to education and childlessness may reduce future employment insecurity, but money motivates her now."); Norsigian & Johnson, *supra* note 78 (noting that many donors are in their early twenties "and are often university students who need cash to cover their tuition fees").

80. *See* Daniels & Heidt-Forsythe, *supra* note 74, at 729.

81. *Id.*

donation prerequisites.[82] For example, one Massachusetts-based clinic states on its website: "Egg donors should be younger than 31 years old, weigh less than 170 pounds, ovulating, non-smoking, and be maintaining a healthy lifestyle."[83] Another California-based clinic includes "[h]umanitarian motivation," "[a]ge 20–30," and "[w]eight under 160 pounds," in its list of donor qualifications.[84] In general, clinics tend to establish height and weight prerequisites by setting body mass index (BMI) maximums.[85] Although many purportedly prefer proportionality and healthy BMI ranges, "egg donors are strikingly taller and thinner than the average woman."[86] At many clinics, donors who do not meet strict height and weight requirements are considered "poor quality," and are rejected in the early stages of the screening process.[87] With the monetization of everything from skin tone to body weight to hair and eye color, physical attractiveness has risen to a premium in the egg market. Indeed, expansion of choice has resulted in a hierarchy of preferred phenotypical traits such that now "[m]any ads include photos, often professional headshots,"[88] and "agencies spend a great deal of time and energy encouraging applicants . . . to send in attractive pictures."[89] Some clinics have gone so far as to advise donors that they are only accepting women who "range from attractive to strikingly beautiful."[90]

Egg donors are subject to similarly exacting specifications with respect to non-physical traits. Although intelligence and educational achievement are long-standing indicators of donor desirability, the

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82. *Id.* at 729–30.

83. *Frequently Asked Questions*, NAT'L EXCH. FOR EGG DONATION & SURROGACY, https://fertilityneeds.com/faq#5 (last visited Oct. 11, 2018); *see* Daniels & Heidt-Forsythe, *supra* note 74, at 731.

84. *See, e.g.*, *Becoming an Egg Donor*, EGG DONOR PROGRAM, https://www.eggdonation.com/becoming-an-egg-donor/Donor-qualifications.php (last visited Oct. 11, 2018).

85. *See, e.g.*, *Become an Egg Donor*, MAIN LINE FERTILITY & REPROD. MED., https://web.archive.org/web/20170704140233/http://www.mainlinefertility.com/egg-donation-program/become-an-egg-donor/ (last visited Oct. 21, 2018) (setting maximum BMI at 27); *Donor Program*, NASHVILLE FERTILITY CTR., http://www.nashvillefertility.com/nashville-fertility-donor-program/become-a-donor/ (last visited Oct. 11, 2018) (setting maximum BMI at 25); Lauren Muscarella, *FAQ from Egg Donors: Why Does BMI Matter?*, CIRCLE EGG DONATION (Aug. 17, 2015), https://www.circlesurrogacy.com/egg-donors (stating that the required BMI for an egg donor is under 28).

86. Daniels & Heidt-Forsythe, *supra* note 74, at 730.

87. *See, e.g.*, Almeling, *Production of Altruism*, *supra* note 34, at 148.

88. Ikemoto, *Logic of Not*, *supra* note 33, at 116.

89. Almeling, *Production of Altruism*, *supra* note 34, at 149.

90. Helen M. Alvaré, *The Case for Regulating Collaborative Reproduction: A Children's Rights Perspective*, 40 HARV. J. LEGIS. 1, 13–14 (2003).

metaphorical bar for educational excellence has risen substantially in recent years. Studies conducted in the late 1990s indicated that intelligence and education were separate, and less important, considerations in a recipient's selection of an egg donor.[91] But by the late 2000s, agencies and clinics had adopted education as a proxy for genetic-based intelligence.[92] It is now widely recognized that "a donor's selling tool is her brains and her beauty."[93] In 2010, researcher Aaron Levine found that a one hundred point increase in SAT score increases the compensation offered by nearly two thousand dollars.[94] Studies conducted in the last five years—as well as a plethora of anecdotal evidence[95]—only confirm that education level is now "key to many recipients' searches for donors,"[96] such that higher standardized test scores tend to fetch higher fees,[97] as does enrollment at elite

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91. *See, e.g.*, Steven R. Lindheim & Mark V. Sauer, *Expectations of Recipient Couples Awaiting an Anonymous Oocyte Donor Match*, 15 J. ASSISTED REPROD. & GENETICS 444, 445–46 (1998) (finding that 18% of recipients and 3% of recipients listed intelligence and education, respectively, as the most important trait in accepting a donor).

92. *See, e.g.*, Rene Almeling, *Selling Genes, Selling Gender: Egg Agencies, Sperm Banks, and the Medical Market in Genetic Material*, 72 AM. SOC. REV. 319, 326 (2007) [hereinafter Almeling, *Selling Genes, Selling Gender*]; Daniels & Heidt-Forsythe, *supra* note 74, at 732 (stating that consumer demand for academic excellence in donors suggests a popular belief that intelligence is genetically inherited).

93. Almeling, *Selling Genes, Selling Gender*, *supra* note 92, at 326.

94. Aaron D. Levine, *Self-Regulation, Compensation, and the Ethical Recruitment of Oocyte Donors*, 40 HASTINGS CTR. REP. 25, 32–33 (2010).

95. *See, e.g.*, Jessica Cohen, *Grade A: The Market for a Yale Woman's Eggs*, ATLANTIC (Dec. 2002), https://www.theatlantic.com/magazine/archive/2002/12/grade-a-the-market-for-a-yale-woman-s-eggs/302635/ (describing her experience as a Yale undergrad when she responded to a classified offering $25,000 to an Ivy League donor with a minimum SAT score of 1500); Sarah Emily Gilbert, *How Much Are You Worth?*, PRINCETON MAG., http://www.princetonmagazine.com/how-much-are-you-worth/ (last visited Jan. 16, 2019) (reporting that one California-based agency indicated willingness to pay a minimum of $10,000 for eggs from an attractive Princeton undergrad); Joan O'C. Hamilton, *What Are the Costs?*, STAN. MAG., (Nov./Dec. 2000), https://alumni.stanford.edu/get/page/magazine/article/?article_id=39334 (describing targeted egg solicitation campaigns for "blue-ribbon donors" on "candidate-rich campuses" by "picky parents-to-be").

96. Jennifer Haylett, *One Woman Helping Another: Egg Donation as a Case of Relational Work*, 40 POLS. & SOC'Y 223, 229 (2012) (describing a clinic's practice of monitoring solicitation responses to better position advertising to attract "a higher quality pool of donors"—i.e., college-educated donors); *see also* Hershberger, *supra* note 75, at 613 (finding that recipients select donors primarily based on a select few factors, including intelligence).

97. *See* Homero Flores et al., *Beauty, Brains or Health: Trends in Ovum Recipient Preferences*, 23 J. WOMEN'S HEALTH 830, 832 (2014) (finding a highly significant increase in preference for intelligence as a donor quality, from 18% in 2008 to 55% in 2012); Jason Keehn et al., *Recruiting Egg Donors Online: An Analysis of in*

institutions.[98] The current market similarly allows prospective parents to itemize their preferences for athleticism,[99] "evidence of determination and work ethic," chastity, and "good personality."[100]

If available data indicates recipients' motivations are principally medical, egg donors' motivations are far less clear. Reports indicate a variety of psychosocial factors are involved, from confirmation of fertility[101] to making up for a personal loss or past misdeed.[102] The "mixed bag" quality of these reports on motivation is the subject of speculation. On the one hand, altruism is by all accounts significant,

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Vitro Fertilization Clinic and Agency Websites' Adherence to American Society for Reproductive Medicine Guidelines, 98 FERTILITY & STERILITY 995, 997 (2012) (reporting results of systematic review of online donor recruitment by 194 American clinics and agencies and finding that "[o]f the 50 websites mentioning traits . . . 42% mentioned education level, and 18% paid more for it").

98. *See supra* note 79; *see also* Annie M. Lowrey, *Will You Be My Baby's Mama?*, HARV. CRIMSON (Apr. 29, 2004), http://www.thecrimson.com/article/2004/4/29/will-you-be-my-babys-mama/ ("While most egg donors receive a few thousand dollars in compensation . . . Ivy League girls are the crème de la crème of the egg donation pool and routinely earn five-digit compensations.").

99. *See* Justine Durrell, *Women's Eggs: Exceptional Endings*, 22 HASTINGS WOMEN'S L.J. 187, 204 (2011) (stating that higher priced ads target prospective donors with athletic ability); Flores et al., *supra* note 97, at 832 (finding a highly significant increase in recipients' requests for athleticism as a donor quality, from 1% in 2008 to 17% in 2012).

100. *See* Richard Sherbahn, *How to Choose an Egg Donor*, ADVANCED FERTILITY CTR. CHI., http://www.advancedfertility.com/egg-donor-matching.htm (last visited Jan. 16, 2019); *see also* Amanda Hess, *The Golden Egg*, SLATE (Nov. 13, 2014, 10:04 AM), http://www.slate.com/articles/technology/future_tense/2014/11/egg_donation_study_couples_want_donors_to_be_smart_athletic_good_looking.html (reporting that in recent years "the preference for more a [sic] broadly desirable résumé [has] skyrocketed," with prospective parents "increasingly invested in priming their offspring for success").

101. In a 2004 follow-up study assessing the post-donation satisfaction of fifty-four anonymous American donors at a university-based IVF program, researchers found that almost one-third of the donors donated for reassurance about their own fertility. Caren Jordan et al., *Anonymous Oocyte Donation: A Follow-Up Analysis of Donors' Experience*, 25 J. PSYCHOSOMATIC OBSTETRICS & GYNECOLOGY 145, 149 (2004); *see also* Susan Caruso Klock, Jan Elman Stout & Marie Davidson, *Psychological Characteristics and Factors Related to Willingness to Donate Again Among Anonymous Oocyte Donors*, 79 FERTILITY & STERILITY 1312, 1316 (2003) (finding that 17% of donors were motivated by concerns about their own future fertility).

102. In the same 2004 study by Jordan et al., 20% of donors indicated they were motivated by a desire to make up for a personal loss. One donor donated to make up for a past misdeed. Jordan et al., *supra* note 101, at 149. Similarly, in the interviews conducted by Schover et al., two of the twenty-six interviewees described their motivation in terms of expiating guilt over voluntary past abortions. L.R. Schover et al., *The Psychological Evaluation of Oocyte Donors*, 11 J. PSYCHOSOMATIC OBSTETRICS & GYNECOLOGY 299, 306 (1990).

mentioned by donors as a motivating factor in nearly every study on the topic.[103] On the other hand, there is some question about the reliability of self-assessments by donors. That is, reliability may be limited "because donors are more likely in assessment circumstances to report altruistic motives than financial ones."[104] Perhaps more salient in evaluating (perceived or actual) inconsistencies is the fact that the vast majority of these reports come from the United States,[105] where the commercial market is not only robust and unregulated, but where normative practices reinforce altruism as the appropriate narrative.[106] For example, in a series of in-depth interviews with thirty-three former donors, researchers Andrea Kalfoglou and Joel Gittelsohn found that women who initially stated that financial compensation was their motivating factor later reported altruistic motivators.[107] The researchers noted: "It is unclear whether the development of altruistic feelings is a result of the donor adopting the motivation that IVF clinics and recipients find more palatable, or whether there is some internal shift that happens within these women as a result of the donation experience."[108] Whatever the case, it is clear that recruitment and advertising in the U.S. market emphasizes altruistic and financial incentives,[109] and that U.S. egg donors regularly cite both as primary personal motivators for donation.

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103. *See, e.g.*, Jordan et al., *supra* note 101; Klock et al., *supra* note 101; Schover et al., *supra* note 102.

104. S. Purewal & O.B.A. van den Akker, *Systematic Review of Oocyte Donation: Investigating Attitudes, Motivations and Experiences*, 15 HUM. REPROD. UPDATE 499, 507 (2009).

105. *Id*. (stating that, as of 2009, "[a]ll of the studies with commercial donors have come from the USA").

106. *See infra* discussion at Section IV.A; *see also* Almeling, *Production of Altruism*, *supra* note 34, at 146–47 (examining "how altruistic rhetoric is organizationally produced in egg donation agencies and sperm banks").

107. Andrea L. Kalfoglou & Joel Gittelsohn, *A Qualitative Follow-Up Study of Women's Experiences with Oocyte Donation*, 15 HUM. REPROD. 798, 800 (2000).

108. *Id*.

109. Kenney & McGowan, *supra* note 43, at 456.

II. FREE MARKET COMMERCIALIZATION: THE U.S. APPROACH

The United States has adopted a laissez-faire approach to assisted reproductive technology.[110] The absence of federal regulation[111] has produced "one of the largest and most lucrative" ART industries in the world.[112] It has also produced a muddled legal landscape. In 1999, eminent bioethicist George Annas described the fertility business as the "Wild West" of American medicine.[113] Since then, various scholars have weighed in with their own observations, calling the market an "ethical abyss,"[114] an "incredible legal tangle,"[115] and a "crazy quilt of laws."[116] As the *Kamakahi* litigation was ongoing, a legal expert for CBS News speculated that the strength of the plaintiffs' legal argument was "strong" because "[w]e live in a capitalist society. If we have a product, we should be able to sell it to the highest bidder."[117] And indeed, for well over a decade, the United States has applied its notorious brand of free market capitalism to the fertility industry.

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110. Jason Keehn et al., *supra* note 97, at 996.

111. Existing federal regulations are voluntary and administrative. *See* Michelle Bercovici, *Biotechnology Beyond the Embryo: Science, Ethics, and Responsible Regulation of Egg Donation to Protect Women's Rights*, 29 WOMEN'S RTS. L. REP. 193, 199 (2008) (stating that federal law imposes *voluntary* recordkeeping and reporting requirements on ART facilitators). Federal law does not address egg donation compensation. Durrell, *supra* note 99, at 206.

112. Joseph Gregorio, *Hatching a Plan Towards Comprehensive Regulations in Egg Donation*, 65 DEPAUL L. REV. 1283, 1295 (2016).

113. *Frontline: Making Babies* (PBS television broadcast June 1, 1999), http://www.pbs.org/wgbh/pages/frontline/shows/fertility/interviews/annas.html (interviewing George Annas, who stated "I think it's [the world of assisted reproduction] the Wild West kind of mated with American commerce and modern marketing"); *see also* GEORGE J. ANNAS, AMERICAN BIOETHICS: CROSSING HUMAN RIGHTS AND HEALTH LAW BOUNDARIES 135 (2004) (describing the reproductive research industry as the "Wild West").

114. Oliver Grimm, *America: The Wild West of Family Planning*, DIE PRESSE (Feb. 16, 2013), http://watchingamerica.com/WA/2013/02/21/america-the-wild-west-of-family-planning/.

115. Kitty L. Cone, *Eggs for Sale: The Scrambled State of Legislation in the Human Egg Market*, 35 UALR L. REV. 189, 189 (2012).

116. Mark Hansen, *As Surrogacy Becomes More Popular, Legal Problems Proliferate*, ABA J. (Mar. 1, 2011, 11:40 AM), http://www.abajournal.com/magazine/article/as_surrogacy_becomes_more_popular_legal_problems_proliferate.

117. Jason Kashdan, *Egg Donor Lawsuit Could Rattle Fertility Industry*, CBS NEWS (July 28, 2015, 2:21 PM), http://www.cbsnews.com/news/egg-donor-class-action-lawsuit-could-rattle-fertility-industry/ (quoting a statement of Rikki Klieman, *This Morning* (CBS television broadcast July 28, 2015)).

A. The Ethical Abyss

Despite the punditry, the United States' "lawless free-for-all"[118] is not *entirely* lawless. Rather, there exists an amalgam of disparate legislation at the state level,[119] except in those states that have declined to regulate egg donation altogether.[120] In the states that do regulate egg donation, legislatures have tended to regulate imprudently. For example, Georgia,[121] Louisiana,[122] and Oklahoma[123] have passed blanket prohibitions on compensation for egg donation. Florida[124] and Virginia[125] broadly permit "reasonable" egg donor compensation but have neglected to define "reasonable." Arkansas has sidestepped the issue altogether and adopted a policy of silence.[126] To be fair, states like California (with truth in advertising provisions for egg donor solicitations that include offers of monetary compensation)[127] and Arizona (with provisions classifying egg donors as patients, entitling them to typical duty of care and informed

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118. Alexander N. Hecht, *The Wild Wild West: Inadequate Regulation of Assisted Reproductive Technology*, 1 HOUS. J. HEALTH L. & POL'Y 227, 228 (2001).

119. *See* Cone, *supra* note 115, at 206 (comparing state legislation).

120. As of 2012, Alabama, Alaska, Arizona, Connecticut, Delaware, D.C., Hawaii, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming have not passed oocyte donation-specific legislation. *See id.* at 217–26 (listing details of Fifty State Survey in Appendix A).

121. GA. CODE ANN. § 16-12-160 (2008) ("It shall be unlawful . . . to buy or sell, to offer to buy or sell, or to assist another in buying or selling or offering to buy or sell a human body or any part of a human body or buy or sell a human fetus or any part thereof.").

122. LA. STAT. ANN. § 9:122 (2017) ("The sale of a human ovum, fertilized human ovum, or human embryo is expressly prohibited.").

123. OKLA. STAT. ANN. tit. 10, § 556 (2000) (designating human embryo as trafficking in children if the human embryo is at any time offered for sale or sold).

124. FLA. STAT. ANN. § 742.14 (West 2016) ("Only reasonable compensation directly related to the donation of eggs, sperm, and preembryos shall be permitted.").

125. VA. CODE ANN. § 20-156 (West 2017) (defining "compensation" as "payment of any valuable consideration for services in excess of reasonable medical and ancillary costs").

126. ARK. CODE ANN. § 20-17-1202 (2007) ("By its terms, this [act] is silent on the issue of the use or donation of blastocytes and embryos, neither authorizing nor prohibiting their donation or use.").

127. CAL. HEALTH & SAFETY CODE § 125325 (West 2010) (requiring entities seeking oocyte donations to post a conspicuous notice describing uncertainties inherent in the donation process, informing potential donors that they must receive specific information on certain risks before their agreements can be binding, and advising the potential donors to seek prior advice from a doctor).

consent requirements)[128] have exhibited more regulatory finesse. But on the whole, regulation in the fertility industry is minimal and piecemeal.[129]

In the vacuum of legal guidance, the burden of oversight has fallen to professional organizations. The American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART) are professional organizations collectively responsible for setting reproductive policy in the United States. ASRM is a non-profit and multidisciplinary group that articulates its organizational mission primarily in terms of "education" and "advocacy."[130] SART is similarly advocacy-minded and counts its professional membership as including more than 90% of fertility clinics in the United States.[131] SART works collaboratively with the CDC to publish outcome data and success rates from member clinics,[132] and ASRM's Ethics Committee promulgates opinions on various ART topics. These opinions, however, which represent the only uniform standards for the industry,[133] do not carry the force of law. Rather, they represent professional practice guidelines[134] for ASRM members. ASRM membership is itself entirely voluntary.[135] In

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128. ARIZ. REV. STAT. ANN. § 36-1702 (2010).

129. *See* Cone, *supra* note 115, at 206 (comparing state legislation).

130. *See About Us–Vision of ASRM*, AM. SOC'Y REPROD. MED., http://www.asrm.org/about-us/vision-of-asrm/ (last visited Jan. 16, 2019) ("The Vision of the American Society for Reproductive Medicine (ASRM) is to be the nationally and internationally recognized leader for multidisciplinary information, education, advocacy and standards in the field of reproductive medicine.").

131. *What Is SART?*, SOC'Y FOR ASSISTED REPROD. MED., http://www.sart.org/patients/what-is-sart/ (last visited Jan. 16, 2019).

132. *See* Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. 102-493, 106 Stat. 3146 (1992) ("An Act to provide for reporting of pregnancy success rates of assisted reproductive technology programs and for the certification of embryo laboratories."); *see also* Vera, *supra* note 31, at 412 (stating that "with the cooperation of SART, the CDC published the first annual *Assisted Reproductive Technology Success Rates Report*").

133. Krawiec, *Samaritans and Egomaniacs*, *supra* note 12, 72–74 (discussing the two mechanisms by which the fertility industry self-regulates: informal and unofficial "community standards" based on geographic markets, and national professional standards promulgated by ASRM and SART).

134. *See* Keehn et al., *supra* note 97, at 996 (stating that "the American Medical Association looks to professional societies, such as the American Society for Reproductive Medicine (ASRM), to essentially self-regulate providers of ART"); Levine, *supra* note 94, at 26–27 (stating the fertility industry relies on self-regulation via guidelines issued by ASRM and SART, which "stand in for formal regulation").

135. Keehn et al., *supra* note 97, at 999; Brittany L. Marvin, *Regulating the Procurement of Female Gametes: Donors' Health and Safety*, 16 MICH. ST. U. J. MED. & L. 119, 137 (2011) ("As is true of every professional society, only society members are required to abide by the society's standards."); Vera, *supra* note 31, at 413 ("The

an interview with Fox News, ASRM spokesperson Sean Tipton acknowledged, "Our ability to influence the behavior of non-members is pretty limited."[136] But even the member clinics and physicians that are ostensibly beholden to the organizations' professional codes of conduct exhibit low levels of compliance.[137] "There's no question that there are some agencies that don't seem particularly interested in what our guidelines are, and we don't know how to impact their behavior," Tipton stated in the same interview.[138] Comments like Tipton's implicitly suggest ASRM is at least nominally interested in impacting clinical behavior. And yet, the guidelines themselves appear on ASRM and SART literature with an explicit notice:

> These guidelines have been developed to assist physicians with clinical decisions regarding the care of their patients. They are not intended to be a protocol to be applied in all situations, and cannot substitute for the individual judgment of the treating physicians based on their knowledge of their patients and specific circumstances. The recommendations in these guidelines may not be the most appropriate approach for all patients. Medical science and ethics are constantly changing, and clinicians should not rely solely on these guidelines.[139]

Whether ASRM is actually invested in enforcing its guidelines is an open question. Given its open endorsement of deviation from the guidelines, there is little reason to comply—especially when the

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problem with ASRM guidelines is not necessarily that they embody bad policy, but rather, that compliance is strictly optional and the guidelines are easily ignored.").

136. *Many Egg-Donor Recruiters Ignore Ethical Standards*, FOX NEWS (Aug. 10, 2012), http://www.foxnews.com/health/2012/08/10/many-egg-donor-recruiters-ignore-ethical-standards.html (reporting that "a sizable share" of donor recruiters do not comply with ethical guidelines, including those regarding compensation).

137. Molly Maguire, *ASRM Report Denies Regulatory Reality*, CTR. FOR GENETICS & SOC'Y (July 14, 2010), http://www.biopoliticaltimes.org/article.php?id=5296 (stating that "U.S. fertility clinics routinely flout the ASRM's own guidelines"); Pete Shanks, *The Limits of Voluntary Guidelines*, CTR. FOR GENETICS & SOC'Y (Aug. 21, 2012), http://www.biopoliticaltimes.org/article.php?id=6356, ("ASRM's own members fail to follow best practices and ethical guidelines.").

138. *Many Egg-Donor Recruiters Ignore Ethical Standards*, *supra* note 136.

139. *Practice Committee Documents*, AM. SOC'Y FOR REPROD. MED., http://www.asrm.org/news-and-publications/practice-committee-documents/ (last visited May 2, 2017) (listing document information on right-side panel).

penalties for noncompliance are fairly benign.[140] Noncompliance risks loss of ASRM and SART membership, although this consequence is rarely imposed.[141] Failure to adhere to ASRM standards does not affect professional certification,[142] and, moreover, professional certification is not required to provide ART services.[143]

Coupled with the lack of enforcement mechanisms are strong incentives for clinics to eschew professional guidelines. ASRM recommends, for instance, limiting the number of embryo transfers in women forty-two years or younger to one.[144] The Committee Opinion states:

> Justification for transferring additional embryos beyond recommended limits should be clearly documented in the patient's medical record. . . . [U]se of a clinic's own data cannot be used to routinely exceed the recommended limits. Programs that have a multiple pregnancy rate that is well above average for all SART-reporting clinics may be audited by SART, and persistent non-compliance may result in expulsion.[145]

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140. *See* Cone, *supra* note 115, at 192 (stating that there are no penalties for non-compliance with ASRM guidelines); Keehn et al., *supra* note 97, at 999 (acknowledging "that ASRM and SART do exert *a measure* of influence over its members by issuing guidelines and suggestions," but questioning their effectiveness and suggesting "there may be a need for stronger regulatory mechanisms") (emphasis added); Levine, *supra* note 94, at 33 ("SART has *some* leverage to encourage compliance by fertility clinics, most of which are SART members and presumably value this membership. Indeed, compliance with practice and ethical guidelines is a requirement of membership.") (emphasis added).

141. To this author's knowledge, only one member, Dr. Michael Kamrava of "Octomom" fame, has ever been expelled from the ASRM. *See* Rita Rubin, *"Octomom" Doctor Expelled from Fertility Group*, USA TODAY (Oct. 19, 2009, 11:01 AM), http://usatoday30.usatoday.com/news/health/2009-10-18-octomom-doctor-fertility_N.htm; *see also* Jim Hawkins, *Selling ART: An Empirical Assessment of Advertising on Fertility Clinics' Websites*, 88 IND. L.J. 1147, 1172 (2013) (calling expulsion for noncompliance "extremely rare").

142. Rubin, *supra* note 141 (quoting ASRM spokesman Scott Tipton as stating that "only state medical boards, not his group, have the power to revoke doctors' medical licenses").

143. Gregorio, *supra* note 112, at 1301.

144. Ethics Comm. of Am. Soc'y for Reprod. Med., *Guidance on the Limits to the Number of Embryos to Transfer: A Committee Opinion*, 107 FERTILITY & STERILITY 901, 902 (2017), http://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/guidance_on_the_limits_to_the_number_of_embryos_to_transfer-norpirnt.pdf [hereinafter, ASRM, *Embryo Transfer Limits*].

145. *Id.*

But as in any market, clinics are highly responsive to clients' desires. In a competitive industry, it is in a clinic's commercial interest to maintain the highest possible rates of fertility success.[146] And with the current cost of conception using donor eggs averaging at least $17,000—$12,000 for a single round of standard IVF[147] and upwards of $5,000 in egg donor compensation[148]—prospective parents often request to transfer a higher number of embryos to avoid the cost of multiple rounds.[149] More than half of U.S. ART member-clinics admit they would readily transfer more than the recommended number of embryos upon a patient's request.[150] Even absent a patient request, inflated success rates better position a clinic to attract new clients in the first place. Unsurprisingly, clinics frequently transfer many more than the recommended number of embryos.[151] And notwithstanding the ASRM's strongly worded Committee Opinion, only one physician has ever been disciplined for noncompliance.[152]

Similarly ASRM guidelines also state that "[a]ll oocyte donors should be advised explicitly of the risks and adverse effects of ovarian stimulation and retrieval, with such counseling documented by informed consent in the [donor's] permanent medical record."[153] The FDA requires clinics to maintain donor records for at least ten years, but ASRM recommends that clinics retain records permanently.[154] And yet, clinics often neglect to retain donors' medical records, effectively precluding long-term monitoring of adverse side effects and making it near impossible for donors to seek legal recourse after the

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146. Gregorio, *supra* note 112, at 1306 ("Good fertility rates are extremely valuable to fertility clinics . . . clinics must strive harder to keep their rates competitively high."); Vera, *supra* note 31, at 403 ("The fertility clinic has much to gain financially by completing any given ART cycle, which creates an interest in harvesting as many third-party-supplier eggs as possible.").

147. DAAR, *supra* note 18, at 55 (stating that the average cost per cycle of "no frills" IVF is "around $12,000").

148. *Id.* at 60 (stating that "the average egg donor in the United States earns around $5,000 for her trouble").

149. Durrell, *supra* note 99, at 216.

150. Radhika Rao, *How (Not) to Regulate Assisted Reproductive Technology: Lessons from "Octomom"*, 49 FAM. L.Q. 135, 144 (2015); *see also* Cone, *supra* note 115, at 202 (stating that "there is substantial pressure on physicians and clinics to maximize a recipient's chance of getting pregnant on the first attempt").

151. Rao, *supra* note 150, at 144.

152. *Id.*

153. Ethics Comm. of Am. Soc'y for Reprod. Med., *Recommendations for Gamete and Embryo Donation: A Committee Opinion*, 99 FERTILITY & STERILITY 47, 58 (2013), http://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/recommendations_for_gamete_and_embryo_donation-noprint.pdf.

154. *Id.* at 60.

fact.[155] Available research also indicates that many donors (an estimated 20%) are unaware of the health risks attached to the egg donation process,[156] suggesting clinics do not consistently obtain truly informed consent.[157]

With respect to egg donor compensation, compliance is even more sporadic. There is evidence in nearly every survey to date demonstrating that clinics advertise and compensate egg donors at levels exceeding ASRM's 2007 recommended cap.[158] Indeed, "[t]he reality is that professionals do not adhere to these guidelines, as evidenced by many of the advertisements that offer exorbitant compensation" to prospective donors.[159] In the context of the greater U.S. fertility market, Lindsay Kamakahi's experience with an ASRM-compliant fertility clinic appears, if not the exception, then certainly not the rule.

B. Kamakahi v. American Society for Reproductive Medicine

In its early iterations, the *Kamakahi* litigation seemed like an exercise in irony. For decades, policy-makers had been wringing their hands, asking: Is the baby market's profit-driven machinery targeting vulnerable populations? Is the fertility industry exploiting supply-and-demand at the expense of "good medicine"?[160] Is free market capitalism commodifying young women, the womb, womanhood, motherhood, personhood? The list goes on.[161] For decades, ethicists

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155. Cone, *supra* note 115, at 215.

156. Durrell, *supra* note 99, at 212 (discussing a retrospective evaluation of egg donors wherein "a disturbing 20% [of donors] reported being unaware of any possible physical risks"); Vera, *supra* note 31, at 420–21.

157. Though it is beyond the scope of this Article, research suggests that deficiencies in the informed consent process are not limited to the issue of adverse health risks. *See, e.g.*, Gerald Owen Schaefer, Ninet Sinaii & Christine Grady, *Informing Egg Donors of the Potential for Embryonic Research: A Survey of Consent Forms from U.S. In Vitro Fertilization Clinics*, 97 FERTILITY & STERILITY 427 (2012) (finding that only 30% of U.S. IVF clinics inform donors that embryos initially intended for reproductive purposes may be used for research (e.g., stem cell research) instead).

158. Levine, *supra* note 94, at 33 (finding that advertisements "often violate [ASRM] recommendations . . . highlight[ing] the challenge of using self-regulation to ensure that oocyte donation proceeds in an ethical manner"); Marvin, *supra* note 135, at 129 (placing most fertility clinic solicitation offers in the $3,000 to $8,000 range, but noting that some ads promise up to $100,000).

159. Cone, *supra* note 115, at 211.

160. *Frontline: Making Babies*, *supra* note 113 (asking George Annas whether the fertility industry is engaging in "bad medicine").

161. Kimberly D. Krawiec, *Altruism and Intermediation in the Market for Babies*, 66 WASH. & LEE L. REV. 203, 204 (2008) [hereinafter Krawiec, *Altruism and*

highlighted potential conflicts of interest between ART participants, especially as between clinics and donors, and between economic philosophies (i.e., commercialism versus altruism). Critics trumpeted the failings of self-regulation as study after study demonstrated low guideline-compliance rates by clinics, dubious donor recruitment strategies, lavish donor compensation offers, and negligible industry interest in bioethical cornerstones like informed consent, full disclosure, and donor follow-up. International observers decried[162] America's penchant for "extreme baby-making"[163] as foreign nations—e.g., Canada,[164] Japan, and the United Kingdom—outlawed egg donation compensation altogether.[165] The question on the table was whether America's Wild West *should* be tamed, not whether the West was wild *enough*. And then Lindsay Kamakahi filed her complaint. It alleged not that she had been harmed by the absence of regulatory protections, but that she had been harmed by *too* much regulation.

Irony aside, more nuanced considerations of *Kamakahi* immediately recognized the litigation for what it was: a manifestation of the uneasy coexistence of market and nonmarket forces in the U.S. fertility industry.[166] The most surprising thing about *Kamakahi*, of course, is not that American women subscribe to the free market capitalism that is a hallmark of the American ethos—it is that it took so long for American donors to demand full exercise of their free market rights. By all estimates, *Kamakahi* was the plaintiffs' case to

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Intermediation] (commenting that "[f]ew proposals generate the moral outrage engendered by a suggestion that babies—or, more accurately but less vividly, parental rights—should be traded on the open market"); *see also Frontline: Making Babies*, *supra* note 113 (interviewing Nigel Cameron, a minister and bioethics professor, and reporting his concern that we are using technology to undermine human dignity).

162. *See, e.g.*, Grimm, *supra* note 114 (commenting on reproductive medicine in America as compared to Austria).

163. Debora Spar, *Taming the Wild West of Assisted Reproduction*, COLUM. SPECTATOR (Mar. 27, 2013, 10:16 PM), http://columbiaspectator.com/2009/02/26/taming-wild-west-assisted-reproduction/.

164. *See infra* Part III.

165. Gina Kolata, *Price of Donor Eggs Soars, Setting Off A Debate on Ethics*, N.Y. TIMES (Feb. 25, 1998), http://www.nytimes.com/1998/02/25/us/price-of-donor-eggs-soars-setting-off-a-debate-on-ethics.html (stating that "[i]n other countries, like England and Japan, governments forbid payments to egg donors and there are essentially no such donors available").

166. *See, e.g.*, Kimberly D. Krawiec, *Markets, Morals, and Limits in the Exchange of Human Eggs*, 13 GEO. J.L. & PUB. POL'Y 349, 358–60 (2015) [hereinafter Krawiec, *Markets, Morals, and Limits*] (arguing that egg donation represents an instance of "incomplete commodification—a transaction that is neither fully market nor fully gift, but somewhere in between the two").

win, not the least because "the negative economic impacts of the ASRM-SART guidelines [were] readily apparent, and the claimed procompetitive benefits [were] highly contestable."[167] That said, ASRM had little to gain from a protracted legal battle,[168] and little to lose by agreeing to rescind its pricing guidelines. According to Kimberly Krawiec, ASRM's compensation guidelines were motivated by the desire to dissipate negative publicity and forestall legislative solutions.[169] A judicially-dictated removal of compensation caps would ostensibly provide valuable political cover. Four years after Kamakahi filed her initial complaint, ASRM and the class of human-egg donors reached a settlement.[170] By its terms, ASRM agreed to retract its guidelines concerning suggested compensation levels.[171] The four named plaintiffs (Lindsay Kamakahi, Justine Levy, Chelsea Kimmel and Kristin Wells) each received $5,000 in compensation, in addition to payment of the $1.5 million incurred in legal fees and expenses.[172]

In many ways, *Kamakahi* and its resolution represents a reaffirmation of the U.S. approach to egg donation. Although much of the world continues to exhibit discomfort with attaching a price tag to the priceless "gift of life," *Kamakahi* is an expression of free market ideals. In the words of lawyer and three-time egg donor Sierra Poulson, "the industry [is] making more money and business. . . .

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167. Kimberly D. Krawiec, *Egg-Donor Price Fixing and* Kamakahi v. American Society for Reproductive Medicine, 16 VIRTUAL MENTOR 57, 58–59 (2014) [herinafter Krawiec, *Egg-Donor Price Fixing*].

168. Kimberly Krawiec succinctly summarized ASRM's catch-22 by noting that "acknowledge[ing] that the guidelines are ineffective is to concede that . . . industry self-regulation has failed. To defend the effectiveness of the guidelines is to concede that they reduce egg-donor compensation below [free market] levels . . . thus assisting the plaintiffs' case. *Id.* at 60.

169. Kim Krawiec, *Politics and Profits in the Egg Business (When Sunny Samaritans Sue, IV)*, FAC. LOUNGE (April 21, 2011, 7:12 PM), http://www.thefacultylounge.org/2011/04/politics-and-profits-in-the-egg-business-when-sunny-samaritans-sue-iv.html [hereinafter Krawiec, *When Sunny Samaritans Sue*].

170. *See generally* [Proposed] Order Granting Preliminary Approval of Proposed Settlement; Preliminarily Certifying the Settlement Class; & Authorizing Dissemination of Notice, Kamakahi v. Am. Soc'y for Reprod. Med., No. 3:11-CV-1781 JCS (N.D. Cal. 2016).

171. Specifically, ASRM agreed to remove language suggesting that "[t]otal payments to donors in excess of $5,000 require justification and sums above $10,000 are not appropriate." Kelly Knaub, *Egg Donors Get Pay Limits Axed with Antitrust Settlement*, LAW360 (Feb. 1, 2016, 7:01 PM), https://www.law360.com/articles/753389/egg-donors-get-pay-limits-axed-with-antitrust-settlement.

172. *Id*.

We're in America—the market would take care of itself without guidelines."[173]

III. ANTI-COMMODIFICATION: THE CANADIAN APPROACH

In 2006, Françoise Baylis, a respected philosopher and bioethicist at Dalhousie University, penned an expert opinion at the federal government's request on the constitutionality of Canada's Assisted Human Reproduction Act (AHRA).[174] Baylis' opinion was in response to the filing of a constitutional challenge to the AHRA by the Québecian government, which was itself supported by the expert opinion of Canadian lawyer and bioethicist Bartha Maria Knoppers.[175] Interestingly, the basis of Québec's challenge was wholly federalism. At issue was not *whether* free market commercialism was appropriate for buying and selling human materials, but rather *who* should be responsible for setting and policing restrictions on that market.[176] It was by that point well-established that Canada's legal environment was in direct contravention with a commercial fertility industry.[177] Indeed, if the United States has positioned itself as a prototype for a free market approach to ART, then Canada has positioned itself as the antithesis. Accordingly, Canada's most recent refutation of free market commercialism is a prime exemplar of a counter-approach.

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173. Tamar Lewin, *Egg Donors Challenge Pay Rates, Saying They Shortchange Women*, N.Y. TIMES, Oct. 16, 2015, at A1, https://www.nytimes.com/2015/10/17/us/egg-donors-challenge-pay-rates-saying-they-shortchange-women.html.

174. Françoise Baylis, *The Regulation of Assisted Human Reproductive Technologies and Related Research: A Public Health, Safety and Morality Argument [Expert Opinion for the Federal Government]*, *in* REGULATING CREATION: THE LAW, ETHICS, AND POLICY OF ASSISTED HUMAN REPRODUCTION 490 (Trudo Lemmens, Andrew Flavelle Martin, Cheryl Milne & Ian B. Lee eds., 2017).

175. *Id.*; *see* Bartha Maria Knoppers & Élodie Petit, *Quebec: A Pioneer in the Regulation of AHR and Research in Canada [Expert Opinion for the Government of Quebec]*, *in* REGULATING CREATION: THE LAW, ETHICS, AND POLICY OF ASSISTED HUMAN REPRODUCTION 463 (Trudo Lemmens, Andrew Flavelle Martin, Cheryl Milne & Ian B. Lee eds., 2017) (describing involvement with the government's legislation of AHR procedures).

176. The Canadian Supreme Court ultimately ruled in favor of Québec in 2010 and invalidated as *ultra vires* key provisions of the AHRA. As a result, the regulatory agency created by the Act is now defunct and the ART landscape across the provinces exists much as it did before the AHRA. George J. Annas, *Assisted Reproduction—Canada's Supreme Court and the "Global Baby,"* 365 NEW ENG. J. MED. 459, 459 (2011).

177. *See* Assisted Human Reproduction Act, S.C. 2004, c 2 (Can.) (severely limiting industry activities).

The Assisted Human Reproduction Act was more than a decade in the making.[178] Following the first successful human pregnancy via in vitro fertilization in 1978,[179] provincial governments in Canada quickly recognized that whatever Canada's moral qualms, "the genie of the new reproductive technologies (NRTs) was now out of the bottle, for good and/or ill."[180] The existence of a geographically close and unregulated market in the United States raised also the specter of reproductive tourism[181] and its attendant social (i.e., coercion, exploitation, and commodification)[182] and economic[183] hazards. Even without easy accessibility to the U.S. market, the fact of an increasingly mobile population made absolute elimination of commercial ART an impossibility. That is, with an international

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178. Trudo Lemmens & Andrew Flavelle Martin, *Introduction* to REGULATING CREATION: THE LAW, ETHICS, AND POLICY OF ASSISTED HUMAN REPRODUCTION 1, 1 (Trudo Lemmens, Andrew Flavelle Martin, Cheryl Milne & Ian B. Lee eds., 2017).

179. Knoppers & Petit, *supra* note 175, at 463.

180. Bernard M. Dickens, *A Historical Introduction to the Supreme Court's Decision on the* Assisted Human Reproduction Act, *in* REGULATING CREATION: THE LAW, ETHICS, AND POLICY OF ASSISTED HUMAN REPRODUCTION 23, 27 (Trudo Lemmens, Andrew Flavelle Martin, Cheryl Milne & Ian B. Lee eds., 2017)

181. Reproductive tourism most often refers to the practice of travelling across jurisdictional lines to obtain ART services. *See* Lisa C. Ikemoto, *Reproductive Tourism: Equality Concerns in the Global Market for Fertility Services*, 27 LAW & INEQ. 277, 281 (2009) [hereinafter Ikemoto, *Reproductive Tourism*] (using the term "narrowly to refer to those seeking ART access for the purpose of becoming parents"). But reproductive tourism may also refer to the practice of travelling to provide ART services. *See* Richard F. Storrow, *Quests for Conception: Fertility Tourists, Globalization and Feminist Legal Theory*, 57 HASTINGS L.J. 295, 300 (2005) (defining reproductive tourism to include travel for the purposes of both obtaining and providing ART services). Some commentators also use the term "procreative tourism." *See* Abigail Farrand, *Reproductive Tourism—A Price Worth Paying for Reproductive Autonomy*, 25 CRITICAL SOC. POL'Y 91, 92 (2005) (discussing procreative tourism as a means "to exercise . . . personal reproductive choices in other less restrictive states").

182. *See* Lisa C. Ikemoto, *Assisted Reproductive Technology Use Among Neighbours: Commercialization Concerns in Canada and the United States, in the Global Context*, *in* REGULATING CREATION: THE LAW, ETHICS, AND POLICY OF ASSISTED HUMAN REPRODUCTION 255–56 (Trudo Lemmens, Andrew Flavelle Martin, Cheryl Milne & Ian B. Lee eds., 2017) [hereinafter Ikemoto, *ART Among Neighbours*] (noting that "[c]ommercialization's problematic effects include the risks of coercion, exploitation, and commodification" and discussing the differences between the three concepts); *see also* Trudo Lemmens, *The Commodification of Gametes: Why Prohibiting Untrammelled Commercialization Matters*, *in* REGULATING CREATION: THE LAW, ETHICS, AND POLICY OF ASSISTED HUMAN REPRODUCTION 424 (Trudo Lemmens, Andrew Flavelle Martin, Cheryl Milne & Ian B. Lee eds., 2017) (stating that three different concepts arise in the context of commercial reproduction: coercion, undue influence, and exploitation).

183. *See, e.g.*, Storrow, *supra* note 181, at 324–25 (noting that restrictive ART laws may have negative impacts on national economies).

network of ART facilitators available, it was not only possible, but easy, for Canadians to sidestep Canadian laws. Thus, if Canada could not wholly escape the fertility market, it could, at least, exercise some measure of control over its place in the global industry.

In 2009, Lisa Ikemoto described reproductive tourism as an "interactive reality" with shifting "destination spots" and "points of departure."[184] Destination spots and points of departure are not mutually exclusive classifications, but restrictive regulation tends to incentivize travel to foreign locales.[185] Conversely, nations with regulatory schemes that encourage commercialization and cultivate high-demand services (i.e., "permissive" jurisdictions) tend to attract foreign consumers.[186] In the early part of the twenty-first century, prospective parents considered Canada an attractive option for entering the ART market.[187] The country's discomfort with its status as a destination spot is apparent in its stated motivations for passing the AHRA. In drafting the legislation, the Royal Commission stated: "[P]ermisiveness in one jurisdiction—quite apart from the 'reproductive tourism' it would encourage—would convey tacit acceptance, or even affirmative state sanction, of a practice that is likely to undermine the value, dignity, reproductive capacity, and bodily integrity of Canadian women."[188] Françoise Baylis cited reproductive tourism as the "most significant problem" justifying the necessity of the AHRA in her Expert Opinion.[189] But even after the AHRA's passage, Canada has remained a hub for ART tourism[190]—in part, ironically, because of the AHRA itself. By prohibiting the

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184. Ikemoto, *Reproductive Tourism*, *supra* note 181, at 280.

185. Ikemoto, *ART Among Neighbours*, *supra* note 182, at 260.

186. Categorizing countries in terms of "permissive" or "restrictive" ART regulation is Lisa Ikemoto's brainchild. *See id.* (noting that the International Federation of Fertility Societies (IFFS) employs a different method of categorization).

187. Brian Alexander, *How Far Would You Go to Have a Baby?*, GLAMOUR, May 2005, at 116–22 (listing Canada as a country that "make[s] babies for infertile American couples for prices that are low compared with those in the U.S."); Felicia R. Lee, *Driven by Costs, Fertility Clients Head Overseas*, N.Y. TIMES, Jan. 25, 2005, at A1 (listing Canada as a donation for American fertility tourists in 2005).

188. Baylis, *supra* note 174, at 503.

189. *Id.* at 500.

190. Heather Rivers, *Woodstock Mom Subject of CBC Surrogacy Documentary*, WOODSTOCK SENTINEL–REV. (Feb. 27, 2017, 3:54 PM), http://www.woodstocksentinelreview.com/2017/02/27/having-our-baby-the-surrogacy-boom-featuring-woodstock-mom-has-its-world-premiere-on-tuesday-february-28-at-10-pm-and-1-am (referring to the fertility industry with the phrase, "[i]t's booming, but it's not a business" and reporting that "hundreds of Canadian women have signed on to carry babies for couples they barely know," even in the absence of compensation).

purchase of donor eggs[191] and setting limits on reimbursement for expenditures incurred in relation to egg donation,[192] but not prohibiting egg donation altogether, the Act allowed prospective parents to access ART and donor services in Canada at roughly a third of the price offered in the United States.[193] Bizarrely, Canada's anti-commodification culture is also a lure for some ART consumers. Sara Cohen is a Toronto-based fertility lawyer.[194] Many of her clients explore the American market first before opting for the Canadian experience.[195] According to Cohen, "They said it was almost like looking to buy a family car [in America] and that's not the feeling they want[] to have."[196] Some prospective parents, it seems, would prefer their commercial exchange to feel a bit less . . . commercial.

Notwithstanding its lack of success in achieving its objectives—that is, in compelling a shift in Canada's status from destination spot to point of departure—the AHRA is still seminal as a conversational exercise. If rhetorical expression is a first step toward practical implementation, then the AHRA did much to facilitate honest dialogue about a topic regularly marred by misleading and contradictory jargon. Canada's "failure" is nonetheless far closer a legislative inroad than any of the United States' regulatory attempts.

IV. ASSUMPTION OF WHAT?: RISK MANAGEMENT IN ART

The American and Canadian models represent diametrically different approaches to the same problem. Both are policy manifestations of widespread cultural mores in their respective countries. Both prioritize different ideals. The American model elevates entrepreneurial spirit and neoliberal autonomy. "[The] supremacy of liberal philosophy" in the United States "translates into the idea that only the individual is capable of assessing the risks and benefits that an action (a donation in this instance) poses for him or her."[197] Unsurprisingly, the United States assumes in its market sophisticated consumers. Supply-and-demand is the watchword.[198] By

191. Assisted Human Reproduction Act, S.C. 2004, c 2, s 7 (Can.).

192. Assisted Human Reproduction Act, S.C. 2004, c 2, s 12 (Can.).

193. Tom Blackwell, *Foreign Buyers Flocking to Canada to Find Surrogate Mothers After Asian Countries Crack Down*, NAT'L POST (Sept. 7, 2015, 6:59 PM), http://news.nationalpost.com/health/canada-a-major-destination-for-surrogate-shoppers.

194. *Id.*

195. *Id.*

196. *Id.*

197. Knoppers & Petit, *supra* note 175, at 481.

198. *See id.* (noting the United States' regulation of supply and demand).

contrast, Canada is far less confident in the infallibility of market controls.[199] The Canadian approach assumes that some consumers will be more vulnerable than others.[200] The prioritization of personhood translates into the idea that some goods—no matter how purposefully tendered—are inseparable from their context and thus cannot not be sold without moral ramifications. Supply-and-demand theory, then, as applied to human materials, is not only wholly inappropriate, but dangerous.

A. Evaluating Comparative Approaches

The most striking difference in comparative assessments of commercialism and anti-commodification is that of focus. Egg donors are central figures in anti-commodification models. The belief that women are not, to borrow a phrase from Canadian science fiction writer Margaret Atwood, "two-legged wombs"[201] undergirds the approach. But anti-commodification advocates are not unaware of the obvious counterargument—namely, that denying donors the choice to leverage their wombs for commercial purposes is paternalism in its most virulent form. A female politician in the United States recently articulated a version of this objection with her 2016 statement before the California State Assembly: "[Banning payment is] insulting to women . . . because it assumes women shouldn't be allowed to make their own decisions."[202] Scholars have similarly pointed out that baseless stereotypes may drive anti-commodification approaches. According to Mathilde Formet, "these kinds of policies are framed by sexist stereotypes about women who cannot be trusted to make sound moral judgments about their bodies."[203] And yet, Formet points out, "women are just as able as men to make a choice when money is involved."[204] Of course, free market skeptics might argue that, given an imbalance of power, distinguishing between autonomous choice and coercion is difficult. The reality is that, in an unregulated system,

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199. *See* Baylis, *supra* note 174, at 503 (noting Canada's failure to impose adequate market controls).

200. *Id.*

201. *See* Annas, *supra* note 176, at 463 (citing MARGARET ATWOOD, THE HANDMAID'S TALE 176 (1986)).

202. Michael Hiltzik, *Should We Pay Women to Donate Their Eggs for Research? No, and Here's Why*, L.A. TIMES (July 22, 2016), http://www.latimes.com/business/hiltzik/la-fi-hiltzik-egg-donors-20160722-snap-story.html (quoting California Assemblywoman Autumn Burke).

203. Mathilde Formet, *Should Women Be Paid to Provide Eggs for Research or Reproduction?*, 4 LEGAL ISSUES J. 25, 35 (2016).

204. *Id.*

few safeguards exist to ensure donors enter these agreements with a sophisticated understanding of the transaction. And, of course, there is little incentive for clinics to encourage donors to secure legal counsel.[205] Further, egg donor demographics may exacerbate the risk differential. That is, "[w]e may indeed question whether eighteen-year-old students in need of some money fully grasp what it may mean for them to have a biological connection to future children."[206] In the egg market, the possibility of asymmetric knowledge and agency on the part of market participants justifies legal restrictions, and even bans, on commercialization.

If anti-commodification positions donors as the theoretical focal point, commercialism is the converse. At its heart, commercialism is directed at consumers—buyers, egg donor recipients, and prospective parents.[207] The principal relationships are between clinics and recipients. There is a doctor-patient relationship, with the clinic occupying the role of "physician" and the recipient occupying the role of "patient." Similarly, there is a fiduciary relationship, with the clinic as service-provider and the recipient as customer. In the free market, egg donors are neither patients nor doctors; they are neither customers nor providers. In fact, all the popular terms ascribed to egg donors in the U.S. are misleading. The most common term, "donor," is clearly false, given that eggs from unrelated donors are nearly always transferred via a monetary exchange.[208] Quite simply, recipients pay egg providers for their eggs. The term "donor" cloaks these commercial exchanges in a persistent and, to this author's mind, pernicious "dialogue of gift-giving."[209] Other erroneous terms less frequently used include: "egg sellers" (but donors do not transfer property); "reproductive workers" (but donors are not employed[210] and are strongly discouraged from viewing donation as a job);[211] "vendors"[212]

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205. *See infra* notes 218–20 and accompanying text.

206. Lemmens, *supra* note 182, at 424–25.

207. ANNAS, *supra* note 113, at 135 (noting that practitioners in the field "are exclusively focused on the potential parent-clients").

208. Krawiec, *Samaritans and Egomaniacs*, *supra* note 12, at 63 (stating that in America, "nearly all oocytes from unrelated donors are procured through payment").

209. Krawiec, *Samaritans and Egomaniacs*, *supra* note 12, at 63.

210. *See* Ikemoto, *Logic of Not*, *supra* note 33, at 117 (discussing why characterizations of donors as sellers, family, or workers is unsatisfying).

211. Almeling, *Selling Genes, Selling Gender*, *supra* note 92, at 326 (noting that while sperm banks explicitly acknowledge that sperm donors are interested in employment, egg agencies are far less comfortable conceptualizing egg donation as a "job").

212. Norsigian & Johnson, *supra* note 78, at 5 (objecting to the industry's treatment of donors as vendors).

(but the term suggests an affirmative element—"offering something for sale"[213]—that belies the reality of targeted and aggressive advertising by fertility clinics); "relational helpers" (but donors do not have any relationship to speak of with their recipients);[214] and "angels"[215] (but c'mon!). The most accurate term offered thus far to describe an egg donor is "third-party."[216] The term does little descriptive work, but perhaps that is most appropriate, given that third parties occupy a grey area in the egg market.

Terminology aside, there is widespread agreement that the aforementioned grey area risks negative outcomes for egg donors. On the demand side, clinics do not consider egg donors patients. Because the exchange is overwhelmingly commercial,[217] the safeguards that typically operate in professional medical contexts are largely absent.[218] In ordinary doctor-patient relationships, for example, the best interests of the patient reign supreme.[219] For medical doctors employed by clinics, however, there is a potential conflict of interest between the egg donor's best interests and the clinic's bottom-line.[220] Even absent such a conflict, because donors are not "patients," clinics

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213. The Oxford English Dictionary defines "vendor" as "a person or company offering something for sale, especially a trader in the street." *Vendor*, OXFORD ENGLISH DICTIONARY, https://en.oxforddictionaries.com/definition/vendor (last visited Oct. 23, 2018).

214. Jennifer Haylett frames egg donation "as a case of relational work," wherein fertility clinics encourage donors to construct fictional identities for their recipients to make the donation process more emotionally palatable. Haylett, *supra* note 96, at 225.

215. Daniels & Heidt-Forsythe, *supra* note 74, at 733 (observing that marketing materials portray donors as angels, "with one website displaying photos of young, attractive women with angel wings").

216. Ikemoto, *Logic of Not*, *supra* note 33, at 116.

217. *Frontline: Making Babies*, *supra* note 113 (quoting George Annas as saying that in the egg market, "the medicine is secondary" and "commerce has overwhelmed this whole industry"); Vera, *supra* note 31, at 400 (calling the environment for egg donors at fertility clinics "unusual and highly manipulative").

218. *See* Vera, *supra* note 31, at 421 (describing medical safeguards are needed to protect the donor); *see also* NAOMI R. CAHN, TEST TUBE FAMILIES: WHY THE FERTILITY MARKET NEEDS LEGAL REGULATION 191 (2009) ("There is currently some regulation in place, but additional safeguards that cover all aspects of the market are necessary.").

219. *See Frontline: Making Babies*, *supra* note 113 (listing examples of patient safeguards in other medical fields).

220. Vera, *supra* note 31, at 403 (discussing potential conflicts of interest stemming from the fact that "[a]s employees of fertility clinics, the physicians' compensation depends on the continued success of the clinic"); *see also* Gregorio, *supra* note 112, at 1295 ("Financial incentives can undermine informed consent because physicians could purposely or unintentionally omit or downplay descriptions of donation risks, ignore a donor's predisposing factors to OHSS, or make them reluctant to cancel or modify hyperstimulation cycles.").

do not adequately maintain donors' medical records, comply with informed consent requirements, or follow-up with donors post-donation.[221] On the supply side, "because egg donors are dealing with medical personnel in a clinical setting, they frequently fail to understand upfront that they are not patients, and thus enter into egg donation agreements on terms that are less than fully understood."[222]

On this last point, a recent *New York Times* article criticized compensation caps for egg donors. "However well-intentioned," the reporter argued, "[a payment cap] shortchanges the egg donors . . . . And if there are indeed risks, they can be addressed and mitigated by the clinics and the doctors, who can strengthen their screening and counseling procedures and provide more information."[223] In addition to the conflict of interest concerns already discussed, the *New York Times* reporter failed to consider the possibility that, in addition to disincentives for clinics to strengthen screening and counseling procedures, clinics simply do not have "more information" to provide. There have been no long-term studies of donors' physical[224] or mental health[225] post-donation. Consequently, the risks associated with fertility drugs[226] and egg retrieval[227] are unknown, even to medical professionals. If information is necessary equipment to build a defensible informed consent process, egg donors are plainly ill-equipped.

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221. *See supra* text accompanying notes 131–34; *see also* Durrell, *supra* note 99, at 229 (discussing the need for a "true patient-physician relationship" between donors and doctors to protect donors' best interests and ensure informed consent).

222. *Three Things You Should Know About Egg Donation*, CTR. FOR BIOETHICS & CULTURE NETWORK, http://www.cbc-network.org/pdfs/3_Things_You_Should_Know_About_Egg_Donation-Center_for_Bioethics_and_Culture.pdf (last visited Jan. 16, 2019).

223. *Paying for Egg Donations*, N.Y. TIMES, Oct. 21, 2015, at A26.

224. *See* Durrell, *supra* note 99, at 201 ("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.").

225. *See id.* at 203 (noting that "only a few small studies" on donors' mental health have been conducted).

226. For example, the FDA has only approved Lupron for prostate cancer treatments. *See* discussion *supra* Section I.B. Its use for ovarian hyperstimulation is off-label. Although technically legal, off-label use suggests a lack of information about potential adverse side-effects. The FDA had received upwards of 4,000 adverse drug reports relating to Lupron from egg donors since 1999. Marvin, *supra* note 135, at 124.

227. With respect to egg retrieval, ovarian hyperstimulation syndrome is likely the most serious risk. *Id.* at 125. While the syndrome is regularly listed on informed consent forms, clinics also "consistently [tell] women that it [is] a safe procedure, likening it at one point to having wisdom teeth removed. In general, staff's discussions of health risks were vague and brief." Haylett, *supra* note 96, at 228.

B. Policy Considerations

The purest forms of the two approaches—as in the United States after *Kamakahi*[228] and as in Canada before the Supreme Court's 2010 decision[229]—operate on extreme ends of the spectrum. In the United States, carefully cultivated market architecture ensures both that traditionally precious goods (here, human reproductive materials) enter the literal market and that the rhetorical language of that market minimizes commodification concerns.[230] Thus, egg providers are "donors" and the motivational narrative is altruism.[231] According to Kimberly Krawiec, "gift discourse provides sufficient cultural acceptance of a contested commodity—in this case human eggs—to facilitate operation of the literal marketplace."[232] In Canada, there is explicit rejection of the type of "universal commodification" a pure free market supports. Indeed, contrary to the assumption of free market enthusiasts that all goods and good-dependent services have a monetary value and are salable,[233] anti-commodification adopts the view that "not everything in life is for sale, nor should it be."[234] Of course, neither universal commodification nor anti-commodification theory is wholly accurate. The reality is that, without affirmative regulation operating as a thumb on one side of the scale or the other, human eggs are neither wholly commodifiable nor wholly invaluable.[235] The reality is that a market for human eggs exists—internationally and indefinitely. The reality is that egg donors are neither vessels of altruism nor fully informed market participants. If "[a]ccess to the collaborative reproduction marketplace requires

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228. *See generally* Kamakahi v. Am. Soc'y for Reprod. Med., 305 F.R.D. 164 (N.D. Cal. 2015).

229. *See generally* Attorney Gen. of Can. v. Attorney Gen. of Que., [2010] S.C.R. 457 (Can.).

230. *See* Krawiec, *Markets, Morals, and Limits*, *supra* note 166, at 352 (describing a middle ground of "incomplete[] commodification").

231. *Kamakahi*, 305 F.R.D. at 177.

232. Krawiec, *Markets, Morals, and Limits*, *supra* note 166, at 353.

233. Judge Posner is considered one of the foremost free market enthusiasts. *See generally* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW (2d ed. 1977). Although he does not explicitly embrace universal commodification, Margaret Radin argues that he comes "as close to the universal commodification pole of the hypothetical continuum as any theorist." Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849, 1858 n.38 (1987).

234. Hiltzik, *supra* note 202 (quoting California Governor Jerry Brown as he vetoed a bill that would have allowed payments for egg donation).

235. Krawiec, *Markets, Morals, and Limits*, *supra* note 166, at 352 ("In other words, a thing can be both priceless and bought and sold for a price, at the same time.").

finding women willing to assume the risks associated with supplying their eggs in exchange for payment,"[236] then the ethical obligation on the part of governments is to coordinate an infrastructure that compels discovery of those risks. In the ART context, the best approach will recognize that risk cannot be ignored or avoided. The best approach will not authorize ignorance of risk (as in U.S. commercialism) nor seek to eliminate risk entirely (as in Canadian anti-commodification). The best approach will be directed at risk management.

V. A BETTER APPROACH FOR RISK MANAGEMENT IN ART

Assisted reproduction is a field that "evolved as a business, not as a research enterprise."[237] As such, market forces have set the pace for ART development and uptake. In the United States, under-regulation has produced incredible profits[238] in the absence of a legal infrastructure. State-based legislation, where it exists, is fragmentary. Professional practice guidelines are puppet rules—gentle suggestions that offer no real guiding lines. Clearly, legal infrastructure is a necessary first step in appropriately managing risk in ART.

Risk management is a problem with many possible solutions, but "comprehensive regulation"[239] is frequently presented as a cure-all for regulatory ills. Under-regulation is not *per s*e detrimental—there are certainly industries that flourish absent comprehensive regulation.[240]

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236. Vera, *supra* note 31, at 401.

237. Michael Ollove, *States Not Eager to Regulate Fertility Industry*, PEW CHARITABLE TR. (Mar. 18, 2015), http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/3/18/states-not-eager-to-regulate-fertility-industry (quoting Arthur Caplan, director of New York University School of Medicine's Medical Ethics division).

238. *See generally* Gregorio, *supra* note 112; Vera, *supra* note 31.

239. Note that demands for comprehensive regulation are generally demands for greater government oversight, be it at the federal or state level. The following discussion adopts this assumption as true.

240. There are few true regulatory voids. Cryptocurrency networks are a rare, and contentious, example of a wholly unregulated industry. Indeed, with respect to blockchain technologies, the marked absence of regulation is the very feature fueling the demand and development of virtual currencies like Bitcoin. *See* Ronald J. Colombo, *Bitcoin: Hype or Harbinger*, 16 J. INT'L BUS. & L. 1, 3 (2016) (noting that "the lack of a centralized authority supervising the system" is directly related to the technology's appeal). But in most cases, "unregulated" denotes under-, minimal, or fragmentary regulation. The U.S. pharmaceutical industry is an easy example of an industry regularly denounced as "unregulated." *See* Joseph Golec & John A. Vernon, *Financial Effects of Pharmaceutical Regulation on R&D Spending by EU Versus US Firms*, 28

The legal profession in the United States is perhaps an apt example. Federal laws and regulations governing businesses, banks, and other financial service providers do not apply to the practice of law. Lawyers are exempt, for instance, from key provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act, which otherwise applies to providers of consumer financial products and services.[241] Lawyers are similarly exempt from Federal Trade Commission regulations that generally apply to market participants who extend credit to consumers.[242] In Canada, government regulation of the legal profession cannot even be characterized as "piecemeal" because regulatory authority by the provincial governments is wholly absent.[243] To say that under-regulation is not *always* problematic,

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PHARMACOECONOMICS 615, 616 (2010) ("US pharmaceutical prices are relatively unregulated."). In fact, there are regulations governing pharmaceutical prices—they are just, depending on your perspective, dangerously deficient or minimal-by-design. *See id.* at 626 (estimating that implementing EU-style price controls would cost the United States $12.67 billion in R&D, 117 fewer new medicines, and 438 fewer research jobs over an eighteen-year period); Ronald J. Vogel, *Pharmaceutical Pricing, Price Controls, and Their Effects on Pharmaceutical Sales and Research and Development Expenditures in the European Union*, 26 CLINICAL THERAPEUTICS 1327, 1327 (2004) (finding that commenting that "the pharmaceutical industry was, by far, the most profitable industry in the United States in 2001"). *But see* Sudip Bose, *The High Cost of Prescription Drugs in the United States*, HUFFINGTON POST (Aug. 29, 2017, 8:39 PM), https://www.huffingtonpost.com/entry/the-high-cost-of-prescription-drugs-in-the-united-states_us_59a606aae4b0d81379a81c1f (noting that there are "no specific regulations to keep a ceiling on [drug] costs" in the US); Sheila Kaplan & Katie Thomas, *Drug Price Proposal Seeks to Ease Rules on Industry*, N.Y. TIMES, June 21, 2017, at A14 (quoting Pew health programs director Allan Coukell, who commented that "other countries [i.e., but not the US] pay lower prices for drugs in part because their governments control prices"). Fantasy sports is another controversial industry inaccurately described as unregulated. *See America's Days of Unregulated Fantasy Sports May Soon Be Over*, ECONOMIST (Nov. 11, 2015), https://www.economist.com/news/united-states/21678186-crackdown-begins-new-york-and-nevada-americau2019s-days-unregulated-fantasy (commenting that "for years the 'daily fantasy sports' industry has escaped the scrutiny of regulators"); Joe Drape & Jacqueline Williams, *Scandal Erupts in Unregulated World of Fantasy Sports*, N.Y. TIMES (Oct. 6, 2015), at A1, B18.

241. Rhonda McMillion, *ABA and Other Bar Groups Work to Limit Federal Regulation of Lawyers*, ABA J. (Dec. 2010), http://www.abajournal.com/magazine/article/let_the_states_do_it_aba_working_to_limit_federal_regulation_of_lawyers (discussing the ABA's "major victory" in securing an exclusion for practicing lawyers).

242. Martha Neil, *Congress Votes to Exempt Lawyers From 'Red Flags Rule'*, ABA J. (Dec. 7, 2010, 9:53 PM), http://www.abajournal.com/news/article/congress_votes_to_exempt_lawyers_from_red_flags_rule/ (discussing attorneys' exemption from the Red Flags Rule provision of the Fair and Accurate Credit Transactions Act).

243. Elizabeth H. Gorman, *Professional Self-Regulation in North America: The Cases of Law and Accounting*, 8 SOC. COMPASS 491, 496 (2014) ("All provincial

however, is not to say that under-regulation is appropriate in every industry. Under-regulation of the legal professions in the United States and Canada is possible only because professional organizations act as proxies. The American Bar Association ("ABA") is actively engaged in the project of self-regulation. ABA rules heavily influence codes of professional conduct,[244] and compliance with those codes is compulsory versus recommended.[245] In Canada, too, professional organizations have and exercise the authority to investigate and discipline misconduct.[246] The U.S. fertility industry, then, differs from American and Canadian legal industries in at least one important respect. In the vacuum of legal guidance, egg donation is largely left to professional self-regulation—but the relevant organizations are neither actively involved in the project of self-regulation nor apparently interested in enforcing compliance.[247]

Professional self-regulation has proven an ineffective solution to the problem of risk management for ART. If, however, legal professional organizations are an inapposite analog for constructing

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governments have delegated regulatory responsibility over both the legal profession and the accounting profession.").

244. *Id*. (stating that the drafting of professional codes in the U.S. has outsourced to bar associations); Stephen Gillers, *How to Make Rules for Lawyers: The Professional Responsibility of the Legal Profession*, 40 PEPP. L. REV. 365, 366 (2012) (calling the ABA "unique" among private organizations in its dedication and involvement in developing professional rules of conduct); Ted Schneyer, *The Case for Proactive Management-Based Regulation to Improve Professional Self-Regulation for U.S. Lawyers*, 42 HOFSTRA L. REV. 233, 234 (2013).

245. McMillion, *supra* note 241 (arguing that "federal regulations are unnecessary and counterproductive" because "the current structure [of ABA-influenced and state bar-enforced oversight] has been effective in dealing with lawyer misconduct"); *cf*. Schneyer, *supra* note 244, at 234–35 (conceding that professional self-regulation has been effective in protecting clients from serious professional misconduct but has done little to deter lesser harms by "unsatisfactory professional conduct").

246. Gorman, *supra* note 243, at 499 (explaining the mechanisms for the profession's "almost complete control over the disciplinary process").

247. Interestingly, critics also describe the fantasy sports industry as a regulatory "Wild West," and concerns are routinely raised about the extent to which "the industry can—or wants—to police itself." Drape & Williams, *supra* note 240, at B18; *see also* John T. Holden & Sam C. Ehrlich, *Esports, Skins Betting, and Wire Fraud Vulnerability*, 21 GAMING L. REV. 566, 574 (2017) (calling the law governing fantasy sports a "Wild West"); Sean Gregory, *How the Sports Industry Is Fueling the Daily Fantasy Scandal*, TIME (Oct. 7, 2015, 12:18 AM), http://time.com/4063474/draftkings-fanduel-daily-fantasy-scandal/ ("Daily fantasy sports is functioning in a Wild West void within the legal structure."); Chris Isidore, *Fantasy Sports May Face Big Crackdown*, CNN MONEY (Oct. 25, 2015, 6:39 PM), http://money.cnn.com/2015/10/25/news/companies/casinos-fantasy-sports/index.html (quoting Pennsylvania Representative George Dunbar as saying about fantasy sports: "It's the wild wild west.").

oversight regimes, that is not to say the United States is not without better reference points. Organ donation in the United States is an instructive historical analog. In the early 1980s, organ transplantation was still a relatively new science. The first successful organ transplants were not performed until the late 1960s.[248] Cyclosporine, the first drug to prevent organ rejection without life-threatening side effects,[249] was not discovered until 1976.[250] But as medical advances moved organ transplants from the realm of "experimental procedures" to "clinical services,"[251] the dearth of comprehensive regulation led to public outcry for a federal response. Political pressure and media attention motivated the 98th Congress to replace "ad hoc efforts" with "a more comprehensive solution to the problems associated with organ transplantation and transplant reimbursement."[252] The federal effort was meant to remedy an organ allocation system that was, among other deficiencies, "decentralized, purely voluntary, [and] lack[ing in] criteria for sharing organs."[253] The

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248. *Timeline of Historical Events and Significant Milestones*, US DEP'T HEALTH & HUM. SERVS., https://organdonor.gov/about/facts-terms/history.html (last visited Jan. 16, 2019).

249. J.F. Borel, Z.L. Kis & T. Beveridge, *The History of the Discovery and Development of Cyclosporine (Sandimmune®)*, *in* THE SEARCH FOR ANTI-INFLAMMATORY DRUGS 28 (Vincent J. Merluzzi & Julian Adams eds., 1995) (describing cyclosporine's discovery as "momentous" because the drug "selectively inhibits . . . the ability of the immune system to reject foreign tissues, as in transplantation . . . [without] the life-threatening side effects that had previously been a major problem with other immunosuppressants").

250. In 1969, a Swiss biologist collected a soil sample while on vacation in Norway containing the fungus *Tolypocladium inflatum*. Hanne Svarstad et al., *From Norway to Novartis: Cyclosporin From* Tolypocladium Inflatum *in an Open Access Bioprospecting Regime*, 9 BIODIVERSITY & CONSERVATION 1521, 1523 (2000). Cyclosporine was extracted from the fungus in 1970. Delia Colombo & Enrico Ammirati, *Cyclosporine in Transplantation—A History of Converging Timelines*, 25 J. BIOLOGICAL REGULATORS & HOMEOSTATIC AGENTS 493, 493 (2011). Its clinical applications were not apparent until six years thereafter. *See* J. F. Borel, *Comparative Study of In Vitro and In Vivo Drug Effects on Cell-Mediated Cytotoxicity*, 31 IMMUNOLOGY 631, 631 (1976) (describing the application of immunosuppressive drugs).

251. Tom Meek, *This Month in 1980: 33 Years Since Cyclosporine Demonstrated Its Potential as An Immunosuppressant*, PMLIVE (Mar. 25, 2013), http://www.pmlive.com/pharma_news/33_years_since_cyclosporine_demonstrated_its_potential_as_an_immunosuppressant_468977.

252. BERNARD D. JR. REAMS, NATIONAL ORGAN TRANSPLANT ACT OF 1984: A LEGISLATIVE HISTORY OF PUB. L. NO. 98-509, at 3 (1990).

253. Frank A. Sloan, May W. Shayne & Marilyn D. Doyle, *Is There a Rationale for Regionalizing Organ Transplantation Services?*, *in* ORGAN TRANSPLANTATION POLICY: ISSUES AND PROSPECTS 115, 128 (James F. Blumstein & Frank A. Sloan eds., 1989).

National Organ Transplant Act of 1984 (NOTA) was also meant to "prevent[] the for-profit marketing of kidneys and other organs."[254] The Committee tasked with evaluating the organ donation market remarked:

> It is the sense of the Committee that individuals or organizations should not profit by the sale of human organs for transplantation. This is not meant to include blood and blood derivatives, which can be replenished and whose donation does not compromise the health of the donor. The current state of the law is uncertain with regard to the sale of organs, and the Committee believes that legislation is necessary to clarify this issue. The Committee believes that human body parts should not be viewed as commodities.[255]

At the time, ethicists objected to compensation for organ donation as "the expansion of unfettered commercialism."[256] Much of the public debate was undoubtedly fueled by the suspicion that "lack of a national policy . . . encouraged the practices of the sale of human organs for profit."[257] And although they recognized "that *some* Americans clearly were donating organs altruistically," critics nonetheless highlighted that there was "scant evidence of an adequate informed consent process" and raised "doubts that the living donors would receive needed follow-up care."[258]

In this context, NOTA was signed in 1984.[259] It is important to note that NOTA did not end the ethical debates attendant to organ donation. Many of the salient pre-NOTA concerns remain under

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254. REAMS, *supra* note 252, at 4; *see also* National Organ Transplant Act, Pub.L. 98-507, 98 Stat. 2339 (1984).

255. REAMS, *supra* note 252, at 16–17.

256. Jed Adam Gross, Note, *E Pluribus UNOS: The National Organ Transplant Act and Its Postoperative Complications*, 8 YALE J. HEALTH, L. & ETHICS 145, 178–79 (2008) (quoting *Procurement and Allocation of Human Organs for Transplantation: Hearings Before the Subcomm. on Investigations & Oversight of the H. Comm. on Science & Tech.*, 98th Cong. 377 (1983) (statement of Samuel Gorovitz, Department of Philosophy, University of Maryland, College Park)).

257. Sally Satel et al., *State Organ-Donation Incentives under the National Organ Transplant Act*, 77 L. & CONTEMP. PROBS. 217, 227 (2014); National Organ Transplant Act of 1984, Pub. L. No. 98–507, 98 Stat. 2339 (1984).

258. Gross, *supra* note 256, at 179, 183–84.

259. National Organ Transplant Act, Pub.L. 98-507, 98 Stat. 2339 (1984).

discussion[260]—as does the question of NOTA's overall success.[261] But whatever NOTA's failings, the Act did succeed with respect to one of its primary purposes: It established a centralized system with clear and enforceable rules.

There are obvious parallels with respect to the "markets" for human organs and human eggs. As the preceding discussion demonstrates, many of the perceived deficiencies with the organ donation system prior to 1984 mirror existing concerns regarding egg donation. Then, as now, comprehensive—i.e., more—regulation is regularly bandied as a solution.[262] Then, as now, it is unlikely that comprehensive regulation will be a panacea—but it is certainly a first step.

CONCLUSION

Comparative evaluations of egg donor compensation models in the United States and Canada demonstrate that our existing approaches are fragmented. Free market commercialism models allow egg donors to assume unknown, and potentially serious, risks without fully informed consent. Anti-commodification models ignore the reality of the global market and adopt a "head in the sand" approach that undervalues donor autonomy. Governments should replace current

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260. *See* Flynn v. Holder, 684 F.3d 852, 858–59 (9th Cir. 2012) (raising the argument that "there is no rational basis for allowing compensation for blood, sperm, and egg donations, while disallowing compensation for bone marrow donations," notwithstanding the fact that NOTA explicitly includes "bone marrow" in its definition of "human organ"); Ana S. Iltis, *Organ Donation, Brain Death and the Family: Valid Informed Consent*, 43 AM. SOC. L., MED. & ETHICS 369, 369 (2015) (arguing for revision of organ donation policies for informed consent); Didier A. Mandelbrot et al., *Practices and Barriers in Long-Term Living Kidney Donor Follow-Up: A Survey of U.S. Transplant Centers*, 88 TRANSPLANTATION 855, 858–60 (2009) (stating that there is little data on living organ donors' long-term outcomes and concluding that follow-up procedures at post-operative discharge are insufficient); *see also* Gross, *supra* note 256, at 148 (providing LexisNexis search data to show that the ethical issues attendant to organ donation continue to be controversial even after NOTA).

261. *See* Satel et al., *supra* note 257, at 217 ("Our current transplant regime is a qualified failure."). *See generally* David L. Kaserman, *Fifty Years of Organ Transplants: The Successes and the Failures*, 23 ISSUES L. & MED. 45 (comparing the successes and failures of NOTA).

262. *See* CAHN, *supra* note 218, at 191–92 (arguing for "a coherent set of laws" for the fertility market and suggesting that federal oversight is preferable over state oversight because "[s]tate regulation . . . is too inconsistent at the moment to offer the kind of assurance [that the industry needs]"); Press Statement, Center for Genetics and Society, A Call for Congressional Hearings on Fertility Industry (Mar. 3, 2009), https://www.geneticsandsociety.org/press-statement/call-congressional-hearings-fertility-industry ("Federal regulation and oversight are needed, and Congress should take the first step by holding hearings.").

approaches with policies built on accurate understandings of donors' role in the marketplace. Long-term research on the risks attendant to egg donation is necessary, as is development of compliance and enforcement mechanisms. To that end, governments would do well to invest in building better market architecture for the fertility industry.