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### Who's Guarding the Henhouse and What Are They Doing with the Eggs (and Sperm)? A Call for Increased Regulation of Gamete Donation and Long-Term Tracking of Donor Gametes

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WHO'S GUARDING THE HENHOUSE AND WHAT ARE THEY DOING  
WITH THE EGGS (AND SPERM)?  
A CALL FOR INCREASED REGULATION OF GAMETE DONATION AND  
LONG-TERM TRACKING OF DONOR GAMETES

INTRODUCTION

A man is born a red and wrinkled lump of flesh having no will of its own at all, absolutely at the mercy of the parents by whose conspiracy he has been brought into existence. That is what no science of human community . . . must ever forget.<sup>1</sup>

R. G. Collingwood

Carolyn George wanted to expand her family.<sup>2</sup> Being a single mother, she opted to conceive a child through insemination with donor sperm.<sup>3</sup> In selecting a donor, she valued a clean bill of health as well as physical characteristics similar to those of her son from a previous relationship.<sup>4</sup> Ideally, Carolyn aspired to have a healthy child that looked like a member of her family down to the blond hair and green eyes.<sup>5</sup>

Much to Carolyn's surprise and dismay, soon after his birth her donor-conceived son, Ethan, began to exhibit increasingly alarming symptoms including eczema, bloody and oozing skin, asthma, a severe egg allergy, and extensive bruising all over his body.<sup>6</sup> After undergoing a battery of tests, he was diagnosed with a "rare genetic platelet disorder that causes bruises and bleeding from the slightest bump or cut."<sup>7</sup> Although Ethan's diagnosis was not life-threatening and would not shorten his life span, it would last a lifetime.<sup>8</sup> Because of this disorder, Ethan would have to avoid participation in normal childhood activities and interactions, such as sports or rough play that "might cause a blow to the head, leading to a brain bleed" which could result in a potentially life-threatening event.<sup>9</sup>

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1. R. G. COLLINGWOOD, *THE NEW LEVIATHAN OR MAN, SOCIETY, CIVILIZATION & BARBARISM* 176 (Oxford Univ. Press rev. ed. 1999).

2. Jennifer Wolff, *The Truth About Donor 1084*, SELF, Oct. 2006, at 203, 203.

3. *Id.*

4. *Id.*

5. *Id.*

6. *Id.*

7. Wolff, *supra* note 2, at 203.

8. *Id.*

9. *Id.*

Since Carolyn had no history of the disorder in her family, she was alarmed by the discovery.<sup>10</sup> Therefore, she contacted the sperm bank to warn them of the possibility that Ethan's donor, Donor 1084, carried the genetically-linked disorder.<sup>11</sup> Despite her warning, the clinic continued to distribute Donor 1084's sperm for use in insemination and, as a result, at least three other chronically ill children were conceived.<sup>12</sup> In addition, when contacted nearly two years following Carolyn's initial warning, the sperm bank denied any reports of adverse health conditions in Donor 1084's offspring.<sup>13</sup>

Unfortunately, Carolyn's story is not unique. Five out of eleven children conceived with Donor F827's sperm from International Cryogenics contracted severe neutropenia, a hereditary disorder that causes bone marrow failure leading to frequent infections and a high incidence of leukemia.<sup>14</sup> Donor 276 from California Cryobank was a carrier for a kidney disorder that ultimately requires kidney transplantation; 1500 vials of his sperm were sold to an "unknown number of women."<sup>15</sup> Across the country at Fairfax Cryobank in Virginia, Donor 2148's donation resulted in one child afflicted with a latent genetic immune disorder and at least twenty-two other known offspring who may or may not become infected in the future.<sup>16</sup>

Since much of the assisted reproductive technology ("ART") industry is self-regulated, little protection is available to donor offspring.<sup>17</sup> In addition

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10. *Id.* at 203-04.

11. *Id.*

12. Wolff, *supra* note 2, at 204.

13. *Id.*

14. *Id.* See also Laurence A. Boxer & Steven Stein et al., *Strong Evidence for Autosomal Dominant Inheritance of Severe Congenital Neutropenia Associated with ELA2 Mutations*, 148 J. PEDIATRICS 633, 633 (2006). Through DNA testing of the affected children and their mothers, researchers determined that the sperm donor was a carrier of the disorder and did indeed pass it on to the donor-conceived children. *Id.*; Nat'l Cancer Inst., *Inherited Bone Marrow Failure Syndromes*, <http://marrowfailure.cancer.gov/SCN.html> (last visited June 29, 2010).

15. Steven Kotler, *The God of Sperm: How a Powerful L.A. Sperm Peddler Shapes the Nation's Rules on Disease, Genetics—and Accidental Incest*, L.A. WEEKLY, Sept. 28-Oct. 4, 2007, at 40, 42.

16. *Id.*

17. See Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 614-16 (2003) (discussing the minimal amount of federal and state regulation of the ART industry, particularly for reporting adverse events); Judith F. Daar, *Regulating Reproductive Technologies: Panacea or Paper Tiger?*, 34 HOUS. L. REV. 609, 639 (1997) (stating that "practitioners in our country enjoy a nearly regulatory-free environment"). See also generally Lori B. Andrews & Nanette Elster, *Regulating Reproductive Technologies*, 21 J. LEGAL MED. 35, 35-44 (2000) (outlining the history of federal and state regulation of ART).

to unknown health problems that may plague them, there is growing concern that they may inadvertently develop romantic relationships with half-siblings that result in "accidental incest."<sup>18</sup> Without a centralized tracking system, no accurate data is available indicating just how many offspring any particular donor has or where they are located geographically.<sup>19</sup> If a high number of half-siblings were to live in close proximity to one another, there is a possibility that two could meet and become romantically involved. Any children resulting from such a relationship would have a much greater chance of inheriting a genetic disorder than those from unrelated parents.<sup>20</sup>

Therefore, to ensure physical health and healthy relationships for donor offspring this paper calls for increased regulation of the ART industry. Part I provides a history of donor-assisted reproduction and how it developed into the profitable industry it is today. Part II outlines current federal, state, and private regulation of the industry. Part III argues for reform to minimize the health concerns related to the use of donor gametes. Finally, Part IV proposes regulations that support access to genetic and health information with the goal of increasing the safety of donor assisted reproduction while maintaining donor anonymity.

#### I. BACKGROUND

"Donors of the Month Club. It's fun. It's fast. It's free. Meet this month's featured donors and check out their baby photos, snapshot bios, and interesting fun facts."<sup>21</sup>

"Genius Asian Egg Donor Needed—\$35,000 Compensation."<sup>22</sup>

"Seeking Sperm Donor . . . It has always been my dream to have children. Please help me make . . . my dream come true!"<sup>23</sup>

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18. See Kotler, *supra* note 15, at 41 (discussing fears that the lack of industry regulation will inevitably result in half-siblings unknowingly meeting and reproducing); see also Naomi Cahn, *Accidental Incest: Drawing the Line—or the Curtain?—for Reproductive Technology*, 32 HARV. J.L. & GENDER 59, 65 (2009) (arguing for "limits on the number of offspring born from any one individual's gametes" due to the increased concern of incest among donor-conceived children).

19. See Kotler, *supra* note 15, at 41 (discussing the lack of governance in the sperm bank industry and how it has been, and remains, a self-policed industry).

20. FRIEDRICH VOGEL & ARNO G. MOTULSKY, *HUMAN GENETICS: PROBLEMS AND APPROACHES* 566 (3d ed. 1996).

21. Cal. Cryobank, Inc., Reproductive Services, <http://www.cryobank.com/Donor-of-the-Month/2010/February/> (last visited June 30, 2010) (describing a promotion touted in the rolling headlines on the main page of the website. The website also states that February's Donor of the Month features donors who "look like certain 'people' listed in one popular magazine's 2009 Sexiest Men Alive issue. Enjoy!").

22. Genius Asian Egg Donor Needed—\$35,000 Compensation, <http://www.eggdonorneeded.com/> (last visited June 30, 2010) (potential parents seeking egg donor with the goal of having a child capable of attending MIT, Caltech, or other top "world-class university").

"Texas sperm donor and gentleman . . . Two successes in the past and working on a few more this month."<sup>24</sup>

More and more women are waiting until after thirty to start a family.<sup>25</sup> It is estimated that twenty percent of American women now have their first child after the age of thirty-five.<sup>26</sup> This delay may be due to various factors including increased availability of contraception, early focus on career, marrying at an older age, high divorce rate, delaying children until financially secure, or ignorance of decreasing fertility with advancing age.<sup>27</sup>

As the number of "older" women who are trying to conceive grows, so does the incidence of age-related infertility.<sup>28</sup> Approximately ten percent of the general population is affected by infertility.<sup>29</sup> That percentage increases with the age of the potential parents.<sup>30</sup> While a woman in her early twenties has only a six percent chance of remaining childless in her lifetime, a woman in her early forties has a sixty-four percent chance of never having children.<sup>31</sup> In addition, a thirty-year-old woman has a twenty percent chance of getting pregnant each month while a forty-year-old only has about a five percent chance.<sup>32</sup>

Although the use of third party reproduction to facilitate pregnancy has been practiced for over a century,<sup>33</sup> current advances in reproductive

23. Seeking Sperm Donor, <http://www.seekingspermdonor.com/> (last visited June 30, 2010).

24. Yahoo Health Groups, Sperm\_Donors\_for\_Committed\_Couples-Individual\_Coparenting, [http://health.groups.yahoo.com/group/Sperm\\_Donors\\_for\\_Committed\\_Couples-Individual\\_Coparenting/message/356](http://health.groups.yahoo.com/group/Sperm_Donors_for_Committed_Couples-Individual_Coparenting/message/356) (last visited June 30, 2010) (website message board which connects sperm donors with those seeking their services).

25. See OFFICE ON WOMEN'S HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., INFERTILITY: FREQUENTLY ASKED QUESTIONS, at 2 [hereinafter WOMEN'S HEALTH FAQ], available at <http://www.womenshealth.gov/faq/infertility.pdf>.

26. *Id.*

27. AM. SOC'Y FOR REPRODUCTIVE MED., AGE AND FERTILITY: A GUIDE FOR PATIENTS 1, 3 (2003) [hereinafter AGE AND FERTILITY], available at <http://www.asrm.org> (search "age and fertility" in search box).

28. WOMEN'S HEALTH FAQ, *supra* note 25, at 2.

29. RESOLVE: The Nat'l Infertility Ass'n, What Is Infertility?, <http://www.resolve.org/infertility-overview/what-is-infertility/> (last visited June 30, 2010) (RESOLVE is a national organization that provides education, support, and resources for those dealing with infertility.).

30. Nat'l Inst. of Health, Medline Plus, Infertility, <http://www.nlm.nih.gov/medlineplus/infertility.html> (last visited June 30, 2010); AGE AND FERTILITY, *supra* note 27, at 3.

31. AGE AND FERTILITY, *supra* note 27, at 3.

32. *Id.*

33. See AM. SOC'Y FOR REPRODUCTIVE MED., THIRD PARTY REPRODUCTION: A GUIDE FOR PATIENTS 3, 9 (2006) [hereinafter THIRD PARTY REPRODUCTION], available at [http://www.asrm.org/uploadedFiles/ASRM\\_Content/Resources/Patient\\_Resources/Fact\\_Sheets\\_and\\_Info\\_Booklets/thirdparty.pdf](http://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/thirdparty.pdf). "Third party reproduction" refers to the use of *eggs*, *sperm*, or *embryos* that have been donated by a third person (donor) to enable an infertile individual or couple

technology provide individuals and couples more options than ever before for creating a family.<sup>34</sup> Patients undergoing chemotherapy can freeze their eggs or sperm for later use;<sup>35</sup> lesbian couples can experience pregnancy and childbirth through sperm donation;<sup>36</sup> and women with nonfunctioning ovaries can achieve fertility through ovary transplantation.<sup>37</sup>

As the market for ART has increased and more reproductive options have become available, many individuals and couples are taking control of family planning. For single women who hear the ticking of their biological clocks, carriers fearful of passing genetic disease onto their offspring, or couples facing infertility, one viable reproductive option is the use of "third party donors."<sup>38</sup> "Third party donors" provide their own sperm, eggs, or embryos ("gametes") to a clinic or directly to a recipient for reproduction purposes.<sup>39</sup> Depending on the process used to procure the donated gamete, the recipient may or may not know the identity of the donor.<sup>40</sup>

While the word "donor" has traditionally been used to describe those who give freely and altruistically without any expectation of compensation, in the context of ART a "donor" may receive reasonable compensation for the service of providing his or her gametes.<sup>41</sup> As there is no set standard for reasonable compensation in the industry, reimbursement for gamete donation varies between clinics. One sperm bank advertises on its website that sperm donors can earn over \$1000 per month;<sup>42</sup> another reimburses up to \$1200 per month with occasional incentives such as movie tickets or gift certificates rewarded to those who expend "extra time or effort."<sup>43</sup> In

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. . . to become parents. Donors may be known or anonymous to the intended recipient." *Id.* at 3.

34. *See generally id.*

35. *Id.* at 4, 9.

36. *See id.* at 9; BioCentre, Egg & Sperm Donation, <http://www.bioethics.ac.uk/index.php?do=topic&sid=2> (last visited June 30, 2010) (defining egg and sperm donation and explaining their history and current use).

37. Mark Henderson, *British Woman Has World's First Baby by Full Ovary Transplant*, TIMES ONLINE, Nov. 11, 2008, [http://www.timesonline.co.uk/tol/life\\_and\\_style/health/article5133467.ece](http://www.timesonline.co.uk/tol/life_and_style/health/article5133467.ece) (last visited June 30, 2010).

38. *See* THIRD PARTY REPRODUCTION, *supra* note 33, at 3.

39. *Id.*

40. *Id.*

41. Ken Daniels, *Donor Gametes: Anonymous or Identified?*, 21 BEST PRAC. & RES. CLINICAL OBSTETRICS & GYNAECOLOGY 113, 114 (2007) [hereinafter *Donor Gametes*], available at <http://www.donorsiblingregistry.com/kendaniels.pdf>.

42. Northwest Andrology & Cryobank, Be a Sperm Donor, [http://nwcryobank.com/118\\_spermdonorinformation](http://nwcryobank.com/118_spermdonorinformation) (last visited Sept. 23, 2010) (In addition, donors can earn an extra \$250 for referrals, if they become qualified sperm donors.).

43. California Cryobank, Inc., California Cryobank Sperm Donor Compensation, [https://www.spermbank.com/cd\\_secure/newdonors/index.cfm?ID=4](https://www.spermbank.com/cd_secure/newdonors/index.cfm?ID=4) (last visited July 31, 2010). Although the California Cryobank's website emphasizes that donors will help "others

general, men make between fifty and seventy-five dollars per donation.<sup>44</sup> Donations are usually provided on a weekly basis for up to a year.<sup>45</sup> Therefore, in a single year, a sperm donor can make between \$2600 and \$3900. In contrast, egg donors are reimbursed between \$5000 and \$10,000 or more per donor cycle.<sup>46</sup> Generally, egg donors can participate in two to three donor cycles per year.<sup>47</sup>

Since compensation is involved, one may wonder if the motivation of the gamete donor is altruistic or self-serving.<sup>48</sup> For young sperm donors (between the ages of eighteen and twenty-five), financial compensation generally serves as a primary motivator.<sup>49</sup> In one survey of sperm donors, eighty-two percent listed financial reasons as a motivation for donating.<sup>50</sup> In another, sixty-nine percent reported that they would cease donating if they stopped getting paid for it.<sup>51</sup> In addition, many would not donate absent the guarantee of anonymity.<sup>52</sup> In contrast, "older men [who] are more likely to know of people who have experienced infertility" do not consider money an important factor in the decision to donate.<sup>53</sup> Their desire to help others is frequently cited as a motive for donating gametes.<sup>54</sup>

Unlike sperm donation, which poses no physical risk to the donor, egg donation is generally an uncomfortable and time-consuming process requiring three months of hormone injections and ultimately egg retrieval

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in fulfilling their dreams," the front cover of its donor brochure prominently displays a dollar sign outlined in sperm. California Cryobank, Inc., *Why Do I Want to Become a Sperm Donor?*, [https://www.spermbank.com/cd\\_secure/newdonors/index.cfm?ID=2](https://www.spermbank.com/cd_secure/newdonors/index.cfm?ID=2) (last visited July 31, 2010).

44. Letisia Marquez, *UCLA Study Looks at Sperm Donation*, UC NEWSROOM (May 23, 2007), <http://www.universityofcalifornia.edu/news/article/9238>.

45. *Id.*

46. ConceiveAbilities, *Egg Donor Compensation*, [http://www.conceiveabilities.com/donor\\_pg\\_4a.htm](http://www.conceiveabilities.com/donor_pg_4a.htm) (last visited July 31, 2010).

47. *See* ConceiveAbilities, *Frequently Asked Questions*, [http://www.conceiveabilities.com/donor\\_pg\\_6.htm](http://www.conceiveabilities.com/donor_pg_6.htm) (last visited July 31, 2010); Marquez, *supra* note 44.

48. *See Donor Gametes*, *supra* note 41, at 119.

49. BioCentre, *supra* note 36.

50. Ken R. Daniels, Ruth Curson & Gillian M. Lewis, *Semen Donor Recruitment: A Study of Donors in Two Clinics*, 11 HUM. REPROD. 746, 748 (1996) [hereinafter *Semen Donor Recruitment*].

51. Mark V.Sauer et al., *Attitudinal Survey of Sperm Donors to an Artificial Insemination Clinic*, 34 J. REPROD. MED. 362, 362-63 (1989).

52. Rachel Cook & Susan Golombok, *A Survey of Semen Donation: Phase II—the View of the Donors*, 10 HUM. REPROD. 951, 954 (1995).

53. K. Daniels et al., *Sperm Donation: Implications of Canada's Assisted Human Reproduction Act 2004 for Recipients, Donors, Health Professionals, and Institutions*, 28 J. OBSTETRICS & GYNAECOLOGY CANADA 608, 610 (2006) [hereinafter *Sperm Donation*].

54. *Id.*

under local anesthesia.<sup>55</sup> In addition to the discomfort of the injections and procedure itself, side effects for the donor may include abdominal swelling, tension and pressure in the ovarian area, mood swings, bruising at injection sites, or hot flashes.<sup>56</sup> A less common risk is ovarian hyperstimulation syndrome ("OHSS"), "a serious complication marked by chest and abdominal fluid buildup and cystic enlargement of the ovaries that can cause permanent injury and even death."<sup>57</sup>

Due to the increased time commitment and complications of egg donation, potential donors whose primary motivation is monetary compensation may be deterred from the process. As such, many egg donors have the more altruistic motive of helping an infertile couple conceive a child.<sup>58</sup> Other potential donors include women who have excess, unused eggs remaining from their own infertility treatments.<sup>59</sup> They may receive compensation in the form of a discount at their infertility clinic or may simply donate the unused eggs for no compensation whatsoever.<sup>60</sup>

To receive donor gametes, recipients have the option of using agencies or clinics, close friends or relatives, or complete strangers located through advertisements in publications or online.<sup>61</sup> Recipients seeking sperm, egg, and embryo donors through clinics often have access to the donor's health history, medical and psychological profile, in addition to non-identifying biographical information.<sup>62</sup> Alternatively, those who use non-traditional means to find a donor are on their own to discover such information.

While minimally regulated, obtaining donor gametes through traditional clinics and banks requires some protocol; on the other hand, "buying sperm over the Internet . . . is not much different from buying shoes."<sup>63</sup>

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55. Michelle Sargent, *Regulating Egg Donation: A Comparative Analysis of Reproductive Technologies in the United States and United Kingdom*, 4 MICH. J. PUB. AFF. 1, 3, 11 (2007), available at <http://www.mjpa.umich.edu/uploads/2/9/3/2/2932559/sargent-eggdonation-final07.pdf>.

56. Stanford University, Egg Donor Information Project: The Medical Procedure of Egg Donation, <http://www.stanford.edu/class/siw198q/websites/eggdonor/procedures.html> (last visited July 31, 2010).

57. *Id.* Center for Genetics & Society, *UK Woman Killed by Rare IVF Risk, Ovarian Hyperstimulation Syndrome*, Apr. 13, 2005, <http://www.geneticsandsociety.org/article.php?id=1625> (reporting that a thirty-three-year-old woman collapsed and later died of a heart attack after contracting OHSS from fertility treatment).

58. BioCentre, *supra* note 36.

59. THIRD PARTY REPRODUCTION, *supra* note 33, at 5, 12.

60. *Id.* at 5.

61. *Id.* at 4-5.

62. *Id.* at 5, 10.

63. *Id.* at 5; Jennifer Egan, *Wanted: A Few Good Sperm*, N.Y. TIMES, Mar. 19, 2006, at 46.



Donor gametes may be obtained from anonymous donors through use of an agency or program or known donors through a personal acquaintance, advertisements, or an intermediary agency.<sup>64</sup> “Today, sperm banking is a business with ‘customers’ instead of ‘patients,’ marketing plans instead of doctor’s orders, professional donors instead of Johnny-on-the-spot medical students.”<sup>65</sup> In fact, donors are often heavily marketed to couples through company websites.<sup>66</sup> In addition to basic characteristics such as eye and hair color, height, and education level, couples may opt to learn of the donor’s hobbies, hear an audio tape of the donor’s voice, or even review the donor’s handwriting analysis (all for an extra fee, of course).<sup>67</sup>

#### A. *A Brief History*

The first reported case of donor insemination occurred in 1884 when a married couple that had been unable to conceive due to sterility of the husband consulted Dr. William Pancoast, a physician and medical school professor.<sup>68</sup> In a procedure that denied the patient couple any ability to consent, Dr. Pancoast anesthetized the wife and inseminated her without either spouse’s knowledge.<sup>69</sup> Since the husband’s semen could not be used, the doctor selected the sperm of the “best looking member of the class.”<sup>70</sup> The procedure resulted in a successful pregnancy and subsequent birth.<sup>71</sup> Although the husband was eventually informed of the procedure,

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64. THIRD PARTY REPRODUCTION, *supra* note 33, at 4.

65. DAVID PLOTZ, *THE GENIUS FACTORY: THE CURIOUS HISTORY OF THE NOBEL PRIZE SPERM BANK* 159 (2005).

66. California Cryobank, Inc., Donor Recruitment: Where Does CCB Find All These Great Donors?, <http://www.cryobank.com/How-It-Works/Donor-Recruitment/> (last visited July 31, 2010) (touting that their donors are “recruited from world-class universities including . . . Stanford University, Harvard University and MIT.”) (internal citations omitted); Conceptual Options, What Conceptual Options Provides in Your Search for an Egg Donor, <http://www.eggdonationcenter.com> (last visited July 31, 2010) (“Our program provides a comprehensive list of . . . egg donors that possess most physical or mental characteristics desired by a recipient family. . . These egg donors possess characteristics of high intelligence that is reflected by outstanding scholastic achievement, and/or high test scores on standardized and/or graduate school entrance exams . . . Our egg donors must be educated, intelligent and between the ages of 20 and 29.”).

67. California Cryobank, Inc., Current Prices as of January 2010, <http://www.cryobank.com/Services/Pricing/> (last visited July 31, 2010) (listing additional services and fees such as a facial features report, donor baby photo, and donor audio interview).

68. *Donor Gametes*, *supra* note 41, at 114.

69. *Id.*

70. *Id.*

71. *Id.*

the wife was never told that her husband was not the biological father of the child.<sup>72</sup>

Although artificial insemination in humans was possible in the early twentieth century, it was not necessarily socially acceptable because women undergoing the procedure were often considered to have committed adultery.<sup>73</sup> In addition, children conceived through donor insemination were considered illegitimate.<sup>74</sup> It wasn't until the 1960s that the procedure became more acceptable, reflected by the states of Georgia and California confirming the legitimacy of donor-conceived children.<sup>75</sup> Finally, in 1973, the passage of the Uniform Parentage Act assured that a husband who consented to his wife's artificial insemination procedure would be considered the natural father of the child.<sup>76</sup> Since the process, no longer considered a social taboo, has been facilitated in recent decades by the cryopreservation of sperm, it has become increasingly popular. Conservative estimates show that "as of 1996, more than 260,000 human births have been achieved through artificial insemination with cryopreserved semen."<sup>77</sup>

While sperm donation and artificial insemination have been practiced for much of the past century, egg donation is a relatively new procedure. The first successful pregnancy resulting from egg donation was reported in 1984.<sup>78</sup> Its use has increased significantly since then. In 2005, donor eggs were used in approximately twelve percent (or 16,161) of all ART cycles, resulting in approximately 5,043 births.<sup>79</sup>

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72. *Id.*

73. G.W. Bartholomew, *Legal Implications of Artificial Insemination*, 21 MOD. L. REV. 236, 238, 239 (1958) (citing a 1921 divorce case in which the judge refused to believe that the wife had undergone artificial insemination as alleged by the husband. However, the judge ruled that artificial insemination, like sexual intercourse with anyone other than one's spouse, "is adulterous because in the case of the woman, it involves the possibility of introducing into the family of the husband a false strain of blood. Any act on the part of the wife which does that would therefore be adulterous.").

74. See *Gursky v. Gursky*, 242 N.Y.S.2d 406, 411 (N.Y. App. Div. 1963) ("[I]t has been held that heterologous artificial insemination by a third party donor [which produces a child] . . . is not a child born in wedlock and is therefore illegitimate."); *Doornbos v. Doornbos*, 139 N.E.2d 844 (Ill. App. Ct. 1956).

75. See GA. CODE ANN. § 19-7-21 (2004); see also *People v. Sorensen*, 437 P.2d 495, 498, 501-02 (Cal. 1968).

76. UNIF. PARENTAGE ACT § 5(a), 9b U.L.A. 407 (2001).

77. Cryogenic Labs., Inc., *The History of Semen Cryopreservation*, <http://www.cryo-lab.com/history.shtml> (last visited Aug. 21, 2010).

78. THIRD PARTY REPRODUCTION, *supra* note 33, at 4.

79. CTRS. FOR DISEASE CONTROL & PREVENTION, 2005 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 56, 56, 59 (2007) [hereinafter ART SUCCESS RATES], available at <http://www.cdc.gov/ART/ART2005/508PDF/2005ART508.pdf>.

### B. *A Culture of Secrecy*

Since Dr. Pancoast first inseminated his patient without her knowledge, secrecy and anonymity have been an industry norm.<sup>80</sup> The gamete donor is regarded more as a producer of goods than a person; the offspring, a product.<sup>81</sup> One physician wrote "donor semen should then be regarded as 'material' from an anonymous testis, the donor being actually a 'nonperson.'"<sup>82</sup> Since donors have traditionally favored anonymity, as have recipient individuals or couples, many clinics encourage and some require that donors remain anonymous.<sup>83</sup> As a result of a policy of secrecy, few banks maintain any donor records<sup>84</sup> and many even destroy donor records once the supply has been exhausted.<sup>85</sup>

In recent years, more and more donor-conceived children are expressing a vocal opposition to donor anonymity.<sup>86</sup> Since ART clinics either refuse to divulge any donor information or have no records at all, voluntary registries, such as the Donor-Sibling Registry, have formed to link offspring to their donors and/or half-siblings.<sup>87</sup> The registry is purely voluntary and matches individuals via use of the donor number assigned by each sperm bank or clinic.<sup>88</sup>

The first legislative push to allow children access to their donors' identities occurred in 1984 in Sweden.<sup>89</sup> Since then, anonymity for gamete donors has been abolished in Austria, Switzerland, the United Kingdom, Norway, the Netherlands, New Zealand, and parts of Australia.<sup>90</sup> The loss of anonymity has resulted in a dramatic drop in the number of gamete donors.<sup>91</sup> In Britain, clinics that previously had an excess of donated specimens must now make concerted efforts to recruit enough donors to

80. See generally *Donor Gametes*, supra note 41, at 114, 116-17.

81. See generally BRENDA ALMOND, *MATTERS OF LIFE AND DEATH* 142 (1998).

82. Marek Glezerman, *Two Hundred and Seventy Cases of Artificial Donor Insemination: Management and Results*, 35 *FERTILITY & STERILITY* 180, 185 (1981).

83. See, e.g., California Cryobank, Inc., *About Your Confidentiality and Anonymity*, <https://www.spermbank.com/newdonors/index.cfm?ID=5> (last visited Aug. 21, 2010).

84. D. Meiorow & J.G. Schenker, *The Current Status of Sperm Donation in Assisted Reproduction Technology: Ethical and Legal Considerations*, 14 *J. ASSISTED REPROD. & GENETICS* 133, 137 (1997).

85. Kotler, supra note 15, at 42.

86. See Amy Harmon, *Hello, I'm Your Sister. Our Father Is Donor* 150. *N.Y. TIMES*, Nov. 20, 2005, at 1, 34.

87. *Id.*; The Donor Sibling Registry, Home Page, <http://www.donorsiblingregistry.com> (last visited Aug. 21, 2010).

88. *Id.*

89. See *Donor Gametes*, supra note 41, at 115.

90. *Id.*

91. BioCentre, supra note 36.

meet patient demand.<sup>92</sup> Some clinics are resorting to imported sperm, mostly from Scandinavia where anonymity is still guaranteed.<sup>93</sup>

"On the other hand, in countries such as Sweden, New Zealand, and Australia, different types of donors are coming forward [who] tend to be older, in ongoing partnerships and have children."<sup>94</sup> Ken Daniels, an adjunct professor at the University of Canterbury in New Zealand and a scholar on the creation of families through artificial insemination, argues that a culture of openness and information sharing should bring new donors to the fore; donors whose primary motivation is altruistic rather than self-serving.<sup>95</sup> They would be "donors" in the true sense of the word.<sup>96</sup>

## II. CURRENT FEDERAL, STATE, AND PRIVATE REGULATION OF GAMETE DONATION FOR ASSISTED REPRODUCTION

In *Reproduction and Responsibility*, a 2004 report about the regulation of ART, the President's Council on Bioethics concluded that "there is no uniform, comprehensive, and enforceable system of . . . monitoring, or oversight for the biotechnologies affecting human reproduction. . . [or] how they affect the well-being of the children conceived with their aid."<sup>97</sup> Although some federal and state regulations exist, they are piecemeal regulations that do not provide comprehensive rules.<sup>98</sup> Despite attempts at self-regulation, compliance with the standards set forth by industry leaders is "purely voluntary."<sup>99</sup>

### A. Federal Regulation

The federal government did not take action to regulate ART until 1992 in the form of The Fertility Clinic Success Rate and Certification Act ("the Act").<sup>100</sup> Passage of the Act was in response to grossly exaggerated and misleading success rates advertised by various fertility clinics to lure

92. Denise Grady, *Shortage of Sperm Donors in Britain Prompts Calls for Change*, N.Y. TIMES INT'L, Nov. 12, 2008, at A10.

93. *Id.*

94. *Donor Gametes*, *supra* note 41, at 119.

95. *Id.* at 118, 119.

96. *Id.* at 119.

97. THE PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES xvi, xliii (2004) [hereinafter REPRODUCTION AND RESPONSIBILITY].

98. See Pino D'Orazio, *Half of the Family Tree: A Call for Access to a Full Genetic History for Children Born by Artificial Insemination*, 2 J. HEALTH & BIOMEDICAL L. 249, 256 (2006) (arguing that current regulation of the artificial insemination procedure is inadequate); see also *Guiding Regulatory Reform in Reproduction and Genetics*, 120 HARV. L. REV. 574, 578 (2006) (stating that the current regulation of the ART industry may not be sufficient to "resolve the dilemmas" of the future).

99. See REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at xliii.

100. See JUDITH DAAR, REPRODUCTIVE TECHNOLOGIES AND THE LAW 687 (2006).

customers.<sup>101</sup> To date, the Act continues to be the only federal law that directly regulates ART.<sup>102</sup>

The Act serves two purposes: "(1) to provide consumers with reliable and useful information about the efficacy of ART services offered by fertility clinics, and (2) to provide states with a model certification process for embryo laboratories."<sup>103</sup> First, to ensure that consumers have access to accurate data, all ART programs and clinics must provide success rates annually to the Society for Assisted Reproductive Technology ("SART").<sup>104</sup> These rates include information such as the number of pregnancies and live births achieved, the types of ART used, and any diagnosed birth defects in live-born or still-born infants.<sup>105</sup>

To meet the requirements of the Act, a clinic or program must merely report its data to SART.<sup>106</sup> There are no minimum standards.<sup>107</sup> In the year 2000, 384 of the nation's 421 ART clinics complied with the reporting requirements of the Act.<sup>108</sup> For those clinics that fail to report data results, the only consequence is being labeled as "nonreporting" in the annual CDC report.<sup>109</sup> No other penalty is imposed.<sup>110</sup>

The second half of the Act provides a model certification process for states to increase and maintain quality in embryo labs.<sup>111</sup> The Act recommends monitoring factors such as record keeping, performance of procedures, and quality of personnel, as well as overall quality control.<sup>112</sup> To maintain certification, labs are required to comply with standards established by the College of American Pathologists in conjunction with the American Society of Reproductive Medicine.<sup>113</sup> If the labs fail to comply with the standards, states have the authority to remove certification.<sup>114</sup>

State participation in the model certification program is purely voluntary.<sup>115</sup> However, no state has adopted the program.<sup>116</sup> One reason

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101. *Id.* at 687-68.

102. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at 47.

103. *Id.*

104. *Id.* at 48. SART is under contract with the U.S. Centers for Disease Control (CDC) to implement the Act. *Id.*

105. *Id.*

106. *Id.*

107. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at 48.

108. *Id.* at 49.

109. *Id.* at 48.

110. *Id.*

111. *Id.* at 50.

112. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at 50.

113. *Id.* at 73.

114. *Id.* at 51.

115. *Id.*

116. *Id.* at 50.

the program has not been adopted could be that it does not allow the states to establish "any regulation, standard or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technologies."<sup>117</sup> In addition, clinic participation is purely voluntary.<sup>118</sup> Therefore, "even if a state were to adopt the program, there is no requirement that laboratories apply for certification."<sup>119</sup>

Although the Act provides a variety of information to prospective ART patients, it only defines ART services as those that "include the handling of . . . oocytes or embryos."<sup>120</sup> Therefore, sperm donation and artificial insemination programs are exempt from the requirement.<sup>121</sup> As such, they essentially operate all aspects of their programs independent of any direct federal oversight whatsoever.

Since ART clinics deal with biological products, they are also subject to the oversight of the U.S. Food and Drug Administration ("FDA") under Section 351 of the Public Health Services Act ("PHSA"), outlined in section 1271 of chapter twenty-one of the Code of Federal Regulations.<sup>122</sup> Pursuant to the PHSA, since 2005 the FDA has required that businesses dealing with human cells, tissues, and cellular and tissue-based products ("HCT/P's"), including semen and ova: (1) register with the FDA and list all HCT/P's under the establishment's control and (2) screen and test donors for communicable diseases such as HIV, Hepatitis B and C, and (in the case of reproductive tissue) sexually transmitted diseases.<sup>123</sup> However, the FDA requires that only anonymous sperm donors be screened for communicable diseases; no such screening is required for known donors.<sup>124</sup> In that case, it is up to the patient's discretion or the individual clinic's policy to determine if testing is warranted.<sup>125</sup>

Although Section 1271 of the Code establishes some requirements for sperm and egg banks, they are exempt from many of the requirements with

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117. See REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at 51; 42 U.S.C. § 263a-2(i)(1) (2006).

118. See REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at 51.

119. *Id.*

120. *Id.* at 47.

121. See generally *id.*

122. 21 C.F.R. § 1271 (2007); see also REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at 55.

123. 21 C.F.R. § 1271.1 (2007); 21 C.F.R. § 1271.75 (2007); see also U.S. FOOD & DRUG ADMIN., DIVISION OF INSPECTIONS & SURVEILLANCE, COMPLIANCE PROGRAM GUIDANCE MANUAL: INSPECTION OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) 7341.002 3 (2005) [hereinafter FDA GUIDANCE MANUAL].

124. THIRD PARTY REPRODUCTION, *supra* note 33, at 9.

125. See *id.* at 10.

which other tissue banks must comply.<sup>126</sup> Most establishments dealing with HCT/P's must implement a tracking system to "facilitate the investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action."<sup>127</sup> The system must allow tracking of donor to recipient and recipient to donor.<sup>128</sup> In addition, the tracking system must ensure that each HCT/P has an anonymous tracking code, excluding any information that may reveal the donor's identity.<sup>129</sup> This system ensures that, in the event of a contaminated HCT/P, all relevant parties may be notified to discontinue use of the tissue, recall the contaminated tissue, and initiate appropriate treatment for recipients while maintaining donor anonymity.<sup>130</sup>

In addition to the tracking system, establishments dealing with HCT/P's (with the exception of those dealing with reproductive tissue) "must investigate any adverse reaction involving a communicable disease related to an HCT/P" and then report such adverse reaction to the FDA "if it: (1) [i]s fatal; (2) [i]s life-threatening; (3) [r]esults in permanent impairment of a body function or permanent damage to a body structure; or (iv) [n]ecessitates medical or surgical intervention, including hospitalization."<sup>131</sup> To facilitate reporting of adverse events, the FDA runs Medwatch, an electronic reporting program.<sup>132</sup> Its interactive website allows access not only to mandatory reporters, such as those dealing with HCT/Ps, but also to health professionals and consumers.<sup>133</sup> Therefore, those who may be most severely impacted by adverse events (i.e., tissue recipients) have the opportunity to report adverse experiences directly to the FDA.

Unlike the Act, which has minimal enforcement powers, the FDA has authority to conduct inspections to determine compliance.<sup>134</sup> In the event of noncompliance, the offending organization is subject to licensure revocation, recall or seizure of previously approved products (e.g., a defective batch), or criminal prosecution.<sup>135</sup> However, according to the

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126. FDA GUIDANCE MANUAL, *supra* note 123, at 41 (listing exemptions for reproductive tissue).

127. 21 C.F.R. § 1271.290(a) (2007).

128. 21 C.F.R. § 1271.290(b) (2007).

129. 21 C.F.R. § 1271.290(c) (2007).

130. 21 C.F.R. § 1271.290(e) (2007).

131. 21 C.F.R. § 1271.350(a) (2007).

132. U.S. Food & Drug Admin., MedWatch: The FDA Safety Information and Adverse Event Reporting Program, <http://www.fda.gov/medwatch/default.htm> (last visited Aug. 21, 2010).

133. *See* U.S. Food & Drug Admin., MedWatch: Reporting Serious Problems to FDA, <http://www.fda.gov/safety/medwatch/howtoreport/default.htm> (last visited Aug. 21, 2010).

134. REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at 59.

135. *Id.*

Office of the Inspector General of the Department of Health and Human Services, inspection of tissue banks is inconsistent and, in some cases, nonexistent.<sup>136</sup> In addition, the inspections focus solely on preventing the transmission of communicable disease and the reinforcement mechanisms are weak: the FDA may serve a written order that the HCT/P be recalled or destroyed, order that the establishment cease manufacture until compliance is achieved, or itself seize and destroy the HCT/P.<sup>137</sup> Once again, the regulation exempts reproductive tissue: the FDA will neither destroy such tissue, nor will it issue an order to destroy it.<sup>138</sup>

In general, federal oversight is minimal with weak enforcement mechanisms.<sup>139</sup> In addition, the protections provided to patients and potential offspring are weak: they focus on data collection and prevention of communicable disease.<sup>140</sup> However, no genetic testing of gamete donors or recipients is required and no long-term tracking system is in place to monitor and report adverse events, such as genetic disorders.<sup>141</sup> Therefore, if a latent health issue becomes evident in the donor or offspring, there is no system in place to inform the parties involved or prevent the continued use of the affected gametes.

#### B. State Regulation

Since the federal government provides little oversight of ART, some states provide additional regulation through direct legislation.<sup>142</sup> However, most of the legislation targets single issues related to ART rather than overall

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136. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., OVERSIGHT OF TISSUE BANKING 7 (2001). The report stated that only thirty-six out of a 154 tissue bank sample pool had never been inspected by FDA. *Id.* Of course, this data is from 2001, prior to the implementation of the Public Health Services Act. In that year, 132 inspections were conducted, according to the FDA website. U.S. Food and Drug Administration, Inspections Performed in Fiscal Years 1998 - 2009, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm136342.htm> (last visited Aug. 21, 2010). In 2006, the number of inspections increased to 354. *Id.* In light of the increase in ART in the past 10 years, it is unlikely that the increase in FDA inspections has kept pace with the number of clinics operating across the country.

137. 21 C.F.R. § 1271.440(a) (2007).

138. 21 C.F.R. § 1271.440(f) (2007).

139. *See generally* 21 C.F.R. § 1271 (2007); REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at xliii.

140. *See* 21 C.F.R. § 1271.1(a) (2007).

141. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at xlv; Judith F. Daar & Robert G. Brzyski, *Genetic Screening of Sperm and Oocyte Donors: Ethical and Policy Implications*, 302 JAMA 1702, 1703 (2009).

142. Lynn D. Wardle, *Global Perspective on Procreation and Parentage by Assisted Reproduction*, CAP. U. L. REV. 413, 464 app. II (2006) (provides a table for an overview of all state codes regulating ART or artificial insemination including relevant cases).



industry standards: mandated insurance benefits, parental rights and obligations, regulation of research, and surrogacy to name a few.<sup>143</sup>

Of all the states that have created such legislation, New Hampshire most widely regulates ART's effect on the health and safety of patients and their offspring.<sup>144</sup> Under its legislation, all patients, gamete donors, and gestational carriers must "undergo a medical evaluation and be deemed 'medically acceptable' before treatment can be administered." In addition, "parents enlisting a gestational carrier" are required to "undergo genetic counseling, if the surrogate is [thirty-five] or older."<sup>145</sup> However, other than those requirements, clinics have free rein regarding all aspects of their practice. In addition, even if one state elects to regulate the ART industry, clinics are free to move to other states to avoid such requirements.

In addition to direct legislation, states may regulate through licensing of health care providers and facilities<sup>146</sup> and through civil claims.<sup>147</sup> Through licensure requirements, physicians who deviate from a quality standard of care may be subject to discipline as determined by their state licensure boards.<sup>148</sup> Of course, proving the standard of care in such a laissez-faire industry may be difficult.<sup>149</sup> Through licensure of facilities, states can ensure minimal compliance with safety regulations.<sup>150</sup> However, currently New York and California are the only states to inspect sperm and egg banks prior to issuing a license.<sup>151</sup> Therefore, state oversight may be questionable.

Like the federal regulation, state regulation does not create or reinforce a system to ensure the future health of donor offspring. For example, under New Hampshire regulations, all parties involved in ART must be deemed medically acceptable to participate; once they pass the initial medical evaluation, no additional medical testing or reporting is required.<sup>152</sup> The statute does not define "medical acceptability."<sup>153</sup> Therefore, it is unclear what present health concerns are addressed under the law and apparent that future health concerns are not addressed at all.

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143. See DAAR, *supra* note 100, at 691.

144. *Id.*

145. *Id.*

146. *Id.*; REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at 68.

147. DAAR, *supra* note 100, at 692.

148. *Id.*

149. See REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at 70-71.

150. See *id.* at 67-68.

151. ChoiceMoms.org, How to Carefully Choose a U.S. Sperm Bank, [http://www.choice-moms.org/choosing\\_a\\_sperm\\_bank/42](http://www.choice-moms.org/choosing_a_sperm_bank/42) (last visited Aug. 21, 2010).

152. N.H. REV. STAT. ANN. § 168-B:14 (LexisNexis 2001).

153. N.H. REV. STAT. ANN. § 168-B:1 (LexisNexis 2001).

Finally, the ART industry may be regulated through civil action.<sup>154</sup> Dissatisfied patients may seek monetary damages through claims of negligence, misrepresentation, fraud, or lack of informed consent.<sup>155</sup> Although issues regarding ART practices are litigated, the effect of such litigation on overall quality of care is debatable.<sup>156</sup>

In *Johnson v. California Cryobank*,<sup>157</sup> a couple sued a sperm bank for failure to disclose that the donor had a family history of kidney disease.<sup>158</sup> The family alleged that the sperm bank knew of the donor's history, which the sperm bank vehemently denied.<sup>159</sup> Due to the seriousness of the disease, the court determined that the state interest outweighed the donor's right to privacy and ordered the sperm bank to turn over the donor's medical records and present the donor for depositions, while protecting his identity as much as possible.<sup>160</sup> However, the court ultimately determined no liability on the part of the sperm bank or its physicians because, although they were improper in approving a donor at risk for kidney disease, they did not cause the inherited disorder.<sup>161</sup>

### C. Private Regulation

Many tissue banks seek accreditation through a variety of non-profit agencies such as the American Association of Tissue Banks ("AATB"), the College of American Pathologists ("CAP"), American Society for Reproductive Medicine ("ASRM"), Reproductive Laboratory Accreditation Program, the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), or the New York State Tissue Bank Program ("NYSTB").<sup>162</sup> While they may impose stricter standards than the FDA, accreditation is, once again, generally voluntary.<sup>163</sup> In addition to accreditation, the ART industry in the U.S. is regulated primarily by voluntary guidelines issued by SART.<sup>164</sup> To promote consistency of practice, the guidelines incorporate information and recommendations from

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154. DAAR, *supra* note 100, at 692.

155. *Id.*

156. *Id.* at 692-93.

157. *Johnson v. California Cryobank, Inc.*, 95 Cal. Rptr. 2d 864, 864 (Cal. Ct. App. 2000).

158. *Id.* at 867.

159. *Id.* at 868.

160. *Id.* at 878.

161. *Johnson v. Superior Court*, 124 Cal. Rptr. 2d 650, 666 (Cal. Ct. App. 2002).

162. ART SUCCESS RATES, *supra* note 79, at 83; Am. Ass'n of Tissue Banks, Accreditation, <http://www.aatb.org/Accreditation> (last visited Aug. 21, 2010).

163. See ART SUCCESS RATES, *supra* note 79, at 83.

164. REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at 71.

organizations including the CDC, FDA, and AATB.<sup>165</sup> In addition to the standard testing for communicable disease required by the FDA, the ASRM recommends a psychological consultation, physical examination, and a minimum genetic screening of donors.<sup>166</sup> Once screening and test results are complete, the ASRM recommends that a permanent record be kept.<sup>167</sup>

Although the guidelines may exceed requirements of federal and state regulations, they are mere recommendations without any enforcement mechanism to induce compliance.<sup>168</sup> Therefore,

the current system of self-regulation does not effectively curtail harmful and unethical ART practices . . . . [E]xisting enforcement mechanisms are ineffective. On-site validations of laboratories only occur every three years, which is too infrequent to assess practices in such a quickly evolving field. Further, compliance with the standards is voluntary and not every program is a member of ASRM. The penalty for noncompliance is removal from group membership, but violators are still free to offer services to willing parents. As a result, non-reporters can still build a lucrative fertility practice without any effective oversight.<sup>169</sup>

In light of the dearth of accountability in the field, there is increased demand for more stringent oversight of the industry because having the fox guard the henhouse may not be the wisest decision.<sup>170</sup>

### III. HEALTH CONCERNS RELATED TO UNREGULATED DONOR ASSISTED REPRODUCTION

According to the Code of Medical Ethics of the American Medical Association, "a physician shall . . . regard responsibility to the patient as paramount."<sup>171</sup> By playing a major role in the creation of offspring through ART, surely the physician has a duty to take reasonable precautions to ensure the health of those donor-conceived offspring.

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165. Practice Comm. of the Am. Soc'y for Reprod. Med., & Practice Comm. of the Soc'y for Assisted Reprod. Tech., *2008 Guidelines for Gamete and Embryo Donation: A Practice Committee Report*, 90 FERTILITY & STERILITY S30, S30 (2008) [hereinafter ASRM Guidelines].

166. *Id.* at S32, S34.

167. *Id.* at S42.

168. *Id.* at S30.

169. Jennifer L. Rosato, *The Children of ART (Assisted Reproductive Technology) Should the Law Protect Them from Harm?*, 2004 UTAH L. REV. 57, 67-68 (2004).

170. LORI B. ANDREWS, *THE CLONE AGE: ADVENTURES IN THE NEW WORLD OF REPRODUCTIVE TECHNOLOGY* 218-21 (1999).

171. COUNCIL ON ETHICAL & JUDICIAL AFF., AM. MED. ASS'N, *CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION XV* (2008).

### A. Health History

In 2003, the federal government believed so strongly in the health benefits of knowing family history that it supported the collaboration of the Surgeon General and Department of Health and Human Services in establishing the Family History Initiative “to encourage all American families to learn more about their family health history.”<sup>172</sup> The Family History Initiative states on its website that:

Knowing your family history can help your doctor predict your risk of developing diseases like heart disease, stroke, diabetes, and cancer . . . . Using family history helps identify if you or others in your family . . . may be at increased risk for disease. A family health portrait given to your primary care provider helps your provider consider both your genes and these other shared risk factors influencing your health.<sup>173</sup>

Even with a predisposition to a certain disease or disorder, individuals can change behaviors that affect their health, such as smoking, inactivity, and poor eating habits.<sup>174</sup> By making lifestyle changes, the risk of disease can be reduced even if it is genetic.<sup>175</sup> In addition to making changes in diet and exercise, at-risk individuals can

participate in screening tests, such as mammogram and colorectal cancer screening, for early detection of disease. People who have a family health history of a chronic disease may benefit the most from screening tests that look for risk factors or early signs of disease. Finding a disease early, before symptoms appear, lends to a better prognosis and better health in the long run.<sup>176</sup>

Of course, individuals who don't know their health history, such as adoptees or donor-conceived children, are at a disadvantage when it comes to predicting their risk of developing a particular disease. To address this issue, the Initiative's website provides helpful tips for adoptees to discover their health history including using the Child Welfare Information Gateway to gain access to birth parents.<sup>177</sup> Unfortunately, such resources are unavailable to donor-conceived children.

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172. U.S. Dep't of Health & Human Servs., *Surgeon General's Family Health History Initiative*, <http://www.hhs.gov/familyhistory/> (last visited Aug. 21, 2010).

173. U.S. Dep't of Health & Human Servs., *Why Is Family History Important to Health?*, <http://answers.hhs.gov/questions/5380> (last visited Aug. 21, 2010).

174. U.S. Dep't of Health & Human Servs., *How Can Knowing My Family Health History Help Lower My Risk of Disease?*, <http://answers.hhs.gov/questions/3012> (last visited Aug. 21, 2010).

175. *Id.*

176. *Id.*

177. See Child Welfare Information Gateway, *Adoption*, <http://www.childwelfare.gov/adoption/> (last visited Aug. 21, 2010) (provides information and resources on searching for

Although they may have a copy of their health history provided by the ART clinic, there is no guarantee that the data is correct. First, gamete donors may be hesitant to reveal any negative health history for fear of being excluded from the program (and, therefore, excluded from the income).<sup>178</sup> Second, most gamete donors are young—in their early to mid-twenties—and either do not know their family history or may be susceptible to disorders that surface only later in life.<sup>179</sup> Since clinics generally do not conduct long-term follow-up on donor health, latent disorders aren't included in the history.<sup>180</sup>

### B. Consanguinity

Another major health concern surrounding the donor-gamete industry is consanguinity, or “accidental incest.” Due to the potentially large numbers of progeny resulting from unregulated donation as well as the anonymity of the donors, there is legitimate concern over whether half-siblings could unknowingly meet and develop a romantic relationship. The number of children born through ART has increased annually.<sup>181</sup> According to the CDC, 20,840 infants were born through ART in 1996; that number increased to 52,041 in 2005.<sup>182</sup> Since the reporting of births using donor conception is voluntary, estimates vary widely. A survey of Artificial Insemination Practice conducted by the U.S. Office of Technology Assessment estimated that 30,000 births resulted from donor insemination in 1986-1987.<sup>183</sup> Numbers may be as low as 4,000-5,000 children born each year through donor insemination or as high as 40,000.<sup>184</sup> Unfortunately, since no tracking system of donor gametes exists, it is unclear how many offspring each individual donor has produced.<sup>185</sup> However, the creator of the Donor Sibling Registry, Wendy Kramer, confirmed that one

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birth relatives, reunion, obtaining birth and adoption records, support groups, and relevant laws and policies).

178. Kathryn Venturatos Lorio, *Alternative Means of Reproduction: Virgin Territory for Legislation*, 44 LA. L. REV. 1641, 1651 (1984).

179. ANDREWS, *supra* note 170, at 80, 82.

180. *See id.* at 82.

181. ART SUCCESS RATES, *supra* note 79, at 61.

182. *Id.*

183. U.S. CONG., OFFICE OF TECH. ASSESSMENT, ARTIFICIAL INSEMINATION: PRACTICE IN THE UNITED STATES: SUMMARY OF A 1987 SURVEY—BACKGROUND PAPER 3 (1988), available at <http://www.princeton.edu/~ota/disk2/1988/8804/8804.PDF>.

184. Cryogenic Labs., Inc., Just for Donor Offspring, <http://www.cryolab.com/donorOffspring.shtml> (last visited Aug. 21, 2010); The Donor Sibling Registry, Archive for July, 2008, <http://www.donorsiblingregistry.com/DSRblog/?m=200807> (last visited Aug. 21, 2010).

185. E-mail from Wendy Kramer, Executive Director and Founder, Donor Sibling Registry, to Lisa M. Luetkemeyer, Staff Editor, Saint Louis University Journal of Health Law and Policy (Jan. 5, 2009, 03:10 CST) (on file with author).

group of donor-conceived children from a single donor numbers 110, not counting the current pregnancies.<sup>186</sup>

Accidental incest was a concern even in the early days of donor insemination.<sup>187</sup> A 1957 medical text states

it is by no means an imaginary danger, especially if such a thing takes place in a small town, that 25 years later a young man and girl with a common father may marry . . . . This danger has been envisaged by a clinic in England and an attempt has been made to ward it off by forbidding a donor to offer his services more than 100 times. But what is to prevent this donor from going to some other clinic or doctor and starting all over again?<sup>188</sup>

The text goes on to predict

in the foreseeable future, [donor insemination] will be legally sanctioned in many of the States in the U.S.A., for which reason there should be no further delay in: (a) Setting up semen banks for the supply of carefully checked semen. (b) Keeping records, both at the bank and at the Registry of Births, of the name of the biological father and the name of the couple having the custody of the donor-child; (c) Taking the necessary steps to prevent the couple and the donor from knowing each other's identity despite these inroads made upon anonymity.<sup>189</sup>

Unfortunately, other than the creation of banks for donated gametes, none of the other recommended precautions have been implemented. However, in response to such concerns, the ASRM recommends that use of a specific donor's sperm be limited to twenty-five live births per population area of 800,000.<sup>190</sup> Once again, these guidelines are strictly voluntary and, even if followed, do not prevent a donor from spreading his donations among several clinics, thereby skirting the limitation.<sup>191</sup>

Although concerns regarding accidental incest may seem far-fetched, they were realized for a newlywed couple in Britain who discovered that they were twins separated at birth.<sup>192</sup> "It was appalling for this couple to discover they were married to a close relative."<sup>193</sup> Upon discovering their familial

186. E-mail from Wendy Kramer, Executive Director and Founder, Donor Sibling Registry, to Lisa M. Luetkemeyer, Staff Editor, Saint Louis University Journal of Health Law and Policy (Jan. 5, 2009, 07:28 CST) (on file with author).

187. A.M.C.M. SCHELLEN, *ARTIFICIAL INSEMINATION IN THE HUMAN* 259 (1957).

188. *Id.*

189. *Id.* at 260.

190. ASRM Guidelines, *supra* note 165, at S36.

191. *Id.* at S30.

192. Fiona Barton, *Shock for the Married Couple Who Discovered They Are Twins Separated at Birth*, DAILY MAIL ONLINE, Jan. 11, 2008, <http://www.dailymail.co.uk/news/article-507588/Shock-married-couple-discovered-twins-separated-birth.html> (last visited Aug. 21, 2010).

193. *Id.*

relationship, the couple immediately requested an annulment.<sup>194</sup> Since no children were produced, the only harm suffered was the emotional pain of losing a loved one.<sup>195</sup> Similarly, Lori Andrews recounts in her book, *The Clone Age*, two accounts of infertility doctors halting marriages between “individuals they knew to have been fathered by the same donor.”<sup>196</sup>

If half-siblings are raised in close proximity to one another, it is not outside the realm of possibility that they may meet and interact. And, according to Pam Hodgkins, chief executive officer of Adults Affected by Adoption, such siblings may be attracted to one another because people are “naturally drawn to [those] who are quite similar to [them]selves.”<sup>197</sup>

Since adopted children are generally more knowledgeable about their birth history and there has been a greater legislative push to open adoption records, consanguineous relationships may be less likely for them in the future.<sup>198</sup> In contrast, children conceived via donor gametes may not be told of the circumstances surrounding their conception due to secrecy and, even with that knowledge, may find it impossible to discover their genetic history due to a lack records.<sup>199</sup> Therefore, concerns about consanguinity remain a distinct possibility.

### C. *Adoption Model: Current Rights of Adoptees Regarding Health History and Genetic Information*

Like donor-conceived offspring, adopted children have traditionally been excluded from knowing the identity of their biological parents.<sup>200</sup> Like donor-conceived offspring, many seek their biological parents without success due to long-standing protocols that aim to preserve anonymity.<sup>201</sup> In recent years, there has been a push to allow adoptees’ access to their original birth records, including the birth parents’ identifying information.<sup>202</sup> A report published by the Evan B. Donaldson Adoption Institute in 2007

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194. *Id.*

195. *Id.*

196. ANDREWS, *supra* note 170, at 81.

197. Barton, *supra* note 192.

198. *Id.*

199. *Id.*; see also Meirou & Schenker, *supra* note 84, at 138 (stating that, as opposed to adoption, sperm donation is protected by maximum secrecy and the children are not informed as to how they were conceived or who their natural fathers are).

200. MADELYN FREUNDLICH, EVAN B. DONALDSON ADOPTION INST., FOR THE RECORDS: RESTORING A LEGAL RIGHT FOR ADULT ADOPTees 9 (2007), available at [http://www.adoptioninstitute.org/publications/2007\\_11\\_For\\_Records.pdf](http://www.adoptioninstitute.org/publications/2007_11_For_Records.pdf).

201. *Id.* at 9-10.

202. *Id.* at 10-11 (six states—Alabama, Delaware, Maine, New Hampshire, Oregon, and Tennessee—have opened birth records to adoptees).

analyzed the outcomes of such laws.<sup>203</sup> Despite fears that some adopted children might stalk their birth parents or exhibit intrusive behavior, no such evidence emerged.<sup>204</sup> In fact,

[f]or many adopted persons, the desire to obtain their records is entirely separate from any desire to search for their birthmothers or other relatives; they simply believe—as a human and civil right—that they are entitled to the same basic information about themselves that people raised in their birth families receive as a matter of course. Indeed, many who do get their birth certificates or other documents never search, while others successfully search (a growing phenomenon because of the internet) without any of their documents.<sup>205</sup>

#### V. RECOMMENDED POLICIES TO IMPROVE ACCESS TO GENETIC HISTORY OF DONOR OFFSPRING AND THEIR POTENTIAL CHILDREN

Since states and the ART industry itself have provided little oversight of donor-assisted reproduction,<sup>206</sup> the process has become a lucrative business that prioritizes profits over the well-being of its participants.<sup>207</sup> The federal government must intervene and set some minimal national standards to assure the health and well-being of donor-conceived children. To prevent clinics, donors, or recipients from hopping state-to-state in search of the most favorable regulations, a national standard is preferable to piecemeal state legislation.

Although many donor-conceived offspring support non-anonymous gamete donation,<sup>208</sup> it is not addressed in the following recommendations. As a practical matter, change is more likely to be implemented in a timely fashion if controversial issues are excluded. Since non-anonymous donation continues to be a topic of contentious debate,<sup>209</sup> it is beyond the scope of this paper.

##### A. *Required Accreditation of All ART Facilities*

Legislation should be enacted to require that all facilities implementing ART be accredited by a national organization, such as the ASRM. Absent such accreditation, those facilities should receive no federal funding tied to

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203. *Id.* at 3-5.

204. *Id.* at 4.

205. EVAN B. DONALDSON ADOPTION INSTITUTE, *supra* note 200, at 4.

206. *Daar, supra* note 17, at 639.

207. *Id.* at 661-63.

208. Pamela Foohey, *Potential National Voluntary Gamete Donor Registry Discussed at Recent Health Law Symposium*, 36 J.L. MED. & ETHICS 597, 597 (2008).

209. *E.g.*, F. Shenfield, *Privacy Versus Disclosure in Gamete Donation: A Clash of Interest, of Duties, or an Exercise in Responsibility?* 14 J. ASSISTED REPROD. & GENETICS 371, 371 (1997).



research or reimbursement. To earn such accreditation, facilities should be required to comply with all current ASRM guidelines, including:

(i) the Minimum Genetic Screening for Gamete Donors which would exclude potential donors with major mendelian disorders, major malformations of complex cause, familial disease with any genetic component, or any abnormality that “may result in chromosomally unbalanced gametes.”<sup>210</sup> In addition, the Minimum Genetic Screening recommends genetic testing for any member of a high-risk group “to determine carrier status.”<sup>211</sup>

(ii) the Limitation on donor use restricting a single donor to no more than 25 births in a population of 800,000.<sup>212</sup>

Implementation of these precautions would reduce the chance of donor offspring inheriting genetic disorders or being exposed to inadvertent consanguinity and its negative health consequences.<sup>213</sup>

Since implementation of this recommendation may be costly, expenses could be offset by accreditation fees and fines imposed for violations of these guidelines.<sup>214</sup> In addition to the fines, continued noncompliance with the guidelines should result in revocation of accreditation and withdrawal of federal funding.<sup>215</sup>

#### *B. Expand FDA Oversight*

As previously discussed, the FDA already has the authority to oversee ART clinics under Section 351 of the Public Health Services Act.<sup>216</sup> However, its authority is limited and requires neither tracking of reproductive material nor reports of adverse reactions.<sup>217</sup> In addition, there are minimal consequences for noncompliance with the regulations.<sup>218</sup> The following are recommended to strengthen the FDA’s oversight of ART clinics:

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210. ASRM Guidelines, *supra* note 165, at S44.

211. *Id.*

212. *Id.* at S36.

213. *Id.*

214. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 97, at 190-91 (emphasizing that the federal government can use financial means to regulate certain practices).

215. *See id.* at 50-51. Under the model certification program, embryo laboratories may apply to their respective states for certification. *Id.* Then, the Secretary of state, through the CDC maintains authority to inspect any certified laboratory to ensure compliance with the standards. *Id.* The penalty for noncompliance is revocation of certification. *Id.* at 51.

216. *See* discussion *supra* Part II.A.

217. *Id.*

218. *Id.*

(i) Require Tracking of Donor Gametes under 21 C.F.R. § 1271.290.<sup>219</sup>

The system should allow, as outlined in the regulation, tracking of gametes from the donor to the recipient and the recipient to the donor through implementation of a code system to allow continued donor anonymity.<sup>220</sup> Such a tracking system would facilitate notification of recipient families of potential genetic disorders reported by other families who received gametes from the same donor. Timely notification would provide the families with the power to initiate genetic testing for detection of the disease, intervene as early as possible with lifestyle modifications to prevent or delay onset of the affliction, participate in regular screenings for early detection, or begin treatment. In addition, a tracking system would facilitate recall of unused gametes that may carry a genetic disorder.

(ii) Require Clinics Dealing with Reproductive Tissue to Comply with Reporting Guidelines and Expand Reporting of Adverse Reactions to Include Genetic Disorders under 21 C.F.R. § 1271.350.<sup>221</sup>

Requiring them to comply with reporting guidelines that already exist under section 1271.350 could enforce the accountability of sperm and egg banks to recipient families.<sup>222</sup> In addition, the regulations should be expanded to require that clinics report not only adverse reactions involving communicable diseases, but also those involving genetic disorders. The current wording of the regulation as it applies to communicable disease could also apply to genetic disorders.<sup>223</sup> Therefore, clinics would be required to report to the FDA an adverse reaction involving a genetic disease if it: (1) is fatal, (2) is life-threatening, (3) results in permanent impairment of a body function or permanent damage to a body structure; or (4) necessitates medical or surgical intervention, including hospitalization.<sup>224</sup>

Since a mandatory reporting system of adverse reactions is currently in effect through MedWatch, implementation of the additional reporting requirements would place a minimal burden on the system.<sup>225</sup> In addition, compliance with reporting requirements would be reinforced through MedWatch's system of allowing not only clinics to report but also health care workers and families.<sup>226</sup> Having those with the most at stake take part in the reporting process would likely increase the incidence of reporting and would also provide the FDA with information regarding adverse reactions

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219. *Id.*

220. 21 C.F.R. § 1271.290.

221. *See* discussion *supra* Part II.A.

222. 21 C.F.R. § 1271.350.

223. *See id.* §1271.350(a).

224. *Id.*

225. *See* discussion *supra* Part II.A.

226. *Id.*

that may not have been independently reported by the clinics, thereby increasing clinic accountability.

(iii) Implement Fines as an Enforcement Mechanism.

In the past, the FDA has not enforced regulation of the tissue industry with fines, primarily because most of the organizations involved are traditionally not-for-profit.<sup>227</sup> However, the FDA has the authority to impose fines for noncompliance.<sup>228</sup> If clinics are faced with fines that may eat into their profit margins, they may be more likely to comply with the regulations than if faced with inconsistent inspections.

*C. Creation of Mandatory National Database of Gamete Donors*

The three largest sperm banks in the U.S. advocate for the creation of a voluntary registry of gamete donors.<sup>229</sup> Unfortunately, no industry-wide voluntary registry has been formed. Therefore, establishment of a mandatory national database of gamete donors is essential to allow donor-conceived offspring anonymous access to their medical and/or genetic histories. Such a registry would address two of the controversial issues surrounding donor-assisted conception and could be implemented through the authority of the ASRM. First, if each donor were assigned a unique number, clinics could track the number of gamete donations per donor and the number of offspring produced, even if the donor elected to use different clinics.

Second, with such a system, donations could be effectively limited by the ASRM recommendations. Without a tracking system, clinics must rely solely on their own data. If a donor elects to donate at more than one clinic, each clinic's data is irrelevant as the total number of offspring would go unmonitored. Pooled into a national database, the data would provide a clearer picture of whose gametes were going where.

*D. Mandatory Documentation of Donor-Conception in Birth Record*

Even if a national donor registry is created documenting the health history of donors, it is useless unless the donor-conceived child has knowledge of the circumstances surrounding his or her conception. Although the ASRM encourages parents to disclose genetic heritage to their children, some opt to keep the facts surrounding their child's conception a secret, even to the child. If a child believes he is the biological offspring of both his parents, he has no incentive to investigate his true genetic history.

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227. Mary H. Wang, *FDA Oversight of the Tissue Bank Industry* 21 (Winter 2002) (unpublished thesis, Harvard University Law School), available at [http://leda.law.harvard.edu/leda/data/306/tissue\\_donation\\_paper\\_final\\_with\\_abstract.pdf](http://leda.law.harvard.edu/leda/data/306/tissue_donation_paper_final_with_abstract.pdf).

228. *Id.*

229. Foohey, *supra* note 208, at 599.

Therefore, without a mechanism to inform children of their biological parentage, the database would be pointless.

To ensure that all donor-offspring are informed of their true genetic heritage, there should be mandated documentation of donor conception on each child's birth record. This documentation would not affect the true parent from being listed on the birth record; it would merely clarify that the child was conceived through the use of donor gametes.

By providing this information, each donor-conceived child would have the opportunity to access the database for an accurate health history and any other pertinent information available on the record.

#### *E. Possible Barriers*

Because a national tracking system would require collaboration of hundreds of clinics and individuals, it would likely cost a significant amount of money to implement. The extra time and manpower required to maintain records and provide reports would likely increase the cost of already expensive ART. Such cost increases might affect patients' access to this type of care, as insurance typically does not cover most ART procedures and any increase could price many patients out of the market.

In addition, fears regarding loss of anonymity through the tracking system may result in a reduction of gamete donations. If potential donors believe their identity could be compromised through the database, they may be more reluctant to donate.

As a result of increased regulation, higher costs, or a reduction in gamete donors, recipient couples may opt to travel internationally for their reproductive procedures. Such medical tourism has become popular in recent years for those interested in cosmetic surgery, orthopedics, or weight loss surgery.<sup>230</sup> It is conceivable that couples desperate for a child would elect to travel for treatment rather than spend a life's savings for a procedure that would be half the cost abroad or wait months or years on a waiting list for donor sperm.

### CONCLUSION

As the use of ART becomes more common and its technology allows more options for creating a family, society must consider the effect on all participants involved in the process—and in particular the resultant children. Success should not be measured by whether a child was conceived or whether the child exhibits the genetic traits selected by the parents. Rather, success should be measured by whether that child has the ability to know his

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230. WorldMedAssist, Medical Tourism Procedures, <http://www.worldmedassist.com/procedures> (last visited Aug. 21, 2010).

or her genetic heritage and whether that child can develop serious relationships without fear of consanguinity.

Since the ART industry has failed thus far to self-impose regulations to ensure the health and well-being of its most innocent patients, it is time for the legislature to step forward. To prevent the spread of hereditary disorders and the risk of inadvertent consanguinity, increased regulation of the industry must be implemented including required accreditation of ART facilities, expanded FDA oversight of ART, creation of a mandatory national gamete donor database, and mandatory documentation of donor conception in birth records.

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