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## FDA Approved? A Critique of the Artificial Insemination Industry in the United States

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# FDA APPROVED? A CRITIQUE OF THE ARTIFICIAL INSEMINATION INDUSTRY IN THE UNITED STATES

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Karen M. Ginsberg\*

*Artificial insemination by donor is becoming an increasingly popular means to achieving parenthood. While the majority of couples use artificial insemination to overcome fertility problems, many recipients use artificial insemination to avoid passing a genetic disease to their children. However, case studies reveal the inherent dangers of artificial insemination, namely the lack of proper screening methods to avoid passing genetic diseases to children born by artificial insemination. State-by-state regulation, federal guidelines, and private adjudication have all proven to be inadequate methods of regulating the artificial insemination industry. Ginsberg proposes federal regulation as the only means of achieving a safe artificial insemination industry. The proposed federal regulation would include better genetic screening, a more efficient national sperm donor system, and limited disclosure to recipients of artificial insemination and their children. These measures would help to ensure that couples using artificial insemination get what they expect—healthy sperm, a safe artificial insemination process, and ultimately, a healthy child.*

Mr. "Orange/Red" is . . . a "graduate student involved in genetic research," a fair-skinned, golden-blond, 6-foot-4, 225-pound man with Austrian ancestry. "Very handsome; superb physique; warm; happy; confident . . ." He enjoys martial arts and Ping-Pong, plays the piano proficiently and "comes from a long line of talented professional individuals and has the energy and ambition to match his exceptional gifts."<sup>1</sup>

—Adapted from a California sperm donor catalog.

Described as "a brave and booming new world of baby-making,"<sup>2</sup> artificial reproductive technologies open doors for

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1. Tom Gorman, *Measure of Success Elusive for Sperm Bank*, L.A. TIMES, Apr. 12, 1992, at B1.

2. Liz Willen, *Motherhood Sans Dad—A New Baby Boom: Donor Insemination Gets More Popular—and Personal*, NEWSDAY, Aug. 5, 1993, at 15.

men and women who previously were unable to start families of their own.<sup>3</sup> A 1988 congressional report announced that between two and three million American couples require medical reproductive assistance.<sup>4</sup> More than 45,000 obstetrician-gynecologists (OB-GYNs), general and family practitioners, urologists, and surgeons perform artificial insemination (AI),<sup>5</sup> yet few regulations currently exist to ensure the quality and safety of assisted reproduction. Organizations such as the American Fertility Society and the American Association of Tissue Banks have published professional guidelines for biological and genetic screening of donor semen.<sup>6</sup> However, these organizations lack established mechanisms to police compliance with these guidelines,<sup>7</sup> and therefore, artificial insemination practitioners and sperm banks do not regularly follow them.<sup>8</sup> In response to this problem, then-Senator Al Gore announced in 1988 that if the FDA did not take steps to regulate the screening and testing of donor semen, Congress would take appropriate action.<sup>9</sup> He recommended the establishment of a national data bank on semen donors.<sup>10</sup> Gore stated that the federal government has the authority to develop and enforce a mandatory donor screening system, and he envisioned a collaboration between physicians and government agencies for the development of quality standards.<sup>11</sup> However, no congressional action has yet been taken.<sup>12</sup>

This Note discusses the trends in the regulation of current assisted reproduction technologies, focusing on the artificial insemination by donor (AI) practices of private physicians and sperm banks. Part I describes the practice of AI and

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3. See *id.*

4. See U.S. OFFICE OF TECHNOLOGY ASSESSMENT, INFERTILITY: MEDICAL & SOCIAL CHOICES, OTA-BA-358, at 3 (1988) [hereinafter INFERTILITY CHOICES]. Although artificial insemination by donor (AI) is but one of many forms of assisted reproduction, this Note will deal solely with the players in the AI industry, AI practitioners and sperm banks.

5. See *id.* at 6.

6. See American Fertility Soc'y, *New Guidelines for the Use of Semen Donor Insemination: 1990*, 53 FERTILITY & STERILITY Supp. 1 (Mar. 1990).

7. See Kerry Cork, Comment, *Test-Tube Parents: Collaborative Reproduction in Minnesota*, 22 WM. MITCHELL L. REV. 1535, 1537 & n.13 (1996).

8. See discussion *infra* Part III.A.

9. See Charles Marwick, *Artificial Insemination Faces Regulation, Testing of Donor Semen, Other Measures*, 260 JAMA 1339, 1339 (1988). In addition, Representative Ron Wyden has underscored the need to introduce mandatory genetic testing regulations into the artificial insemination industry. See 137 CONG. REC. E4145-46 (1991) (statement of Rep. Wyden).

10. See Marwick, *supra* note 9, at 1339.

11. See *id.*

12. See discussion *infra* Part III.C.

discusses the factors that lead men and women to seek reproductive assistance. This section focuses primarily on how developments in genetic screening have affected the pool of AI recipients. Part II explains the medical studies, governmental reports, and current litigation that expose the need for increased regulation of artificial insemination in the United States. Part III discusses the current federal, state, and industry regulation of AI practices in both the private physician and sperm bank setting, and this regulation's failure to respond to the problems documented in Part II. Finally, Part IV recommends a plan for reshaping the structure of artificial insemination practices to follow through on Vice President Gore's 1988 recommendation for a cooperative national sperm donor system monitored by the federal government.

This Note proposes that the federal government establish a national system of cooperative sperm donation facilities spread throughout the country. Each donation facility should register with and fall under the control of the FDA in order to provide regulation and enforcement that the current AI industry lacks. The FDA, with the assistance of the American Fertility Society and private physicians, should establish—and continually update—concrete donor screening regulations for sperm banks to follow in every state. Finally, this Note recommends relaxing donor/recipient anonymity standards, thereby encouraging more extensive record keeping of AI procedures and increasing disclosure of non-identifying donor/recipient information. Although this Note refers to current screening practices for both infectious and genetic diseases in donor sperm, it focuses primarily on remedying the inadequacies in genetic screening practices.

## I. A THUMBNAIL SKETCH OF ARTIFICIAL INSEMINATION BY DONOR

### *A. Understanding Artificial Insemination*

The most commonly used artificial reproductive technique is AI,<sup>13</sup> in which sperm from a donor is used to inseminate a

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13. See Judith Lynn Bick Rice, *The Need for Statutes Regulating Artificial Insemination by Donors*, 46 OHIO ST. L.J. 1055, 1055 (1985); Hollace S.W. Swanson, *Donor Anonymity In Artificial Insemination: Is It Still Necessary?*, 27 COLUM. J.L. &

woman on her expected date of ovulation to facilitate conception.<sup>14</sup> The donor generally remains anonymous and receives compensation for his services.<sup>15</sup> The first documented case of human artificial insemination in the United States occurred in 1866.<sup>16</sup> By 1941, approximately 10,000 births resulted from this technique.<sup>17</sup> Between 1941 and 1963, approximately 1,000 to 1,200 children were conceived annually through AI.<sup>18</sup> The first commercial sperm bank opened its doors in 1970.<sup>19</sup> By 1987, at least 11,000 physicians were performing AI,<sup>20</sup> using donors from more than 400 sperm banks.<sup>21</sup> By 1993, more than 80,000 women were undergoing AI each year, resulting in the conception of more than 30,000 babies.<sup>22</sup> In an industry now generating \$164 million a year,<sup>23</sup> AI practitioners and recipients no longer face the stigma that formerly accompanied the procedure.<sup>24</sup>

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SOC. PROBS. 151, 152 (1993). Additional methods of artificial reproduction include surrogate motherhood (in which a woman, after artificial insemination, carries the child to term for the sperm donor and his wife), in vitro fertilization (in which the egg is fertilized in a culture dish and implanted in the woman's uterus), and embryo or ovum transfer (in which the egg is fertilized in the donor and transferred to the prospective mother's uterus). See Rice, *supra*, at 1055.

14. See Swanson, *supra* note 13, at 151-52.

15. See *id.* at 154 n.2.

16. See Brent J. Jensen, Comment, *Artificial Insemination and the Law*, 1982 BYU L. REV. 935, 938.

17. See *id.*

18. See *id.*

19. See Mark S. Frankel, *Human-Semen Banking: Social and Public Policy Issues*, 1 MAN & MED. 289, 289 (1976).

20. See U.S. OFFICE OF TECHNOLOGY ASSESSMENT, ARTIFICIAL INSEMINATION PRACTICE IN THE U.S., OTA-BP-BA-48, at 8 (1988) [hereinafter ARTIFICIAL INSEMINATION PRACTICE]. This report compiled the results of a 1987 survey of physician and sperm bank practices of artificial insemination. Participating in the study were 1,558 physicians and 15 U.S. commercial sperm banks. See *id.* at 3.

21. See Judith Gaines, *A Scandal of Artificial Insemination*, N.Y. TIMES, Oct. 7, 1990, § 6 (Magazine), at 23.

22. See Swanson, *supra* note 13, at 152.

23. See Gaines, *supra* note 21, at 23.

24. See R. SNOWDEN & G.D. MITCHELL, THE ARTIFICIAL FAMILY: A CONSIDERATION OF ARTIFICIAL INSEMINATION BY DONOR 19 (1981) (discussing the stigma surrounding AI); see also Swanson, *supra* note 13, at 154. Because societal attitudes regarding the "traditional family unit" have undergone remarkable changes within the past 20 years, societal disapproval does not pose a large obstacle to couples seeking AI. See *id.* at 168-71.

### B. Factors Necessitating Medical Reproductive Assistance

AI enables many women to conceive a child where either medical or social obstacles ordinarily would bar this opportunity. A 1988 congressional report documents many of the obstacles to natural conception, citing male partner infertility as the impetus for eight out of ten requests for artificial insemination.<sup>25</sup> Other problems included male impotence (3%), genetic disorders (3%), exposure to mutagens (0.4%), and sexually transmitted diseases (0.2%).<sup>26</sup> Fewer than four percent of the women accepted as patients requested AI to compensate for the absence of a male partner, and none of the responding physicians performed AI in response to patient requests to conceive children with desired characteristics, such as a specific intelligence level or the ability to play basketball.<sup>27</sup>

Although the 1987 study cited a very small percentage of couples seeking AI to combat the risk of genetic disorders,<sup>28</sup> this percentage likely will increase with continued advancements in the field of genetic technology, which will permit more accurate diagnosis of genetic reproductive obstacles.<sup>29</sup> For these couples, one or both partners may carry a genetic

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25. See ARTIFICIAL INSEMINATION PRACTICE, *supra* note 20, at 23.

26. See *id.*

27. See *id.* However, it is possible that more single women seek AI than the 1988 OTA report indicates. The sample of doctors who chose to respond to the survey may have influenced the results of the report. In comparison, Curie-Cohen's well-documented 1979 study found that providing natural children to single mothers was the third most common incentive for AI (cited by 9.5 percent of respondents). See Martin Curie-Cohen et al., *Current Practice of Artificial Insemination by Donor in the United States*, 300 NEW ENG. J. MED. 585, 585 (1979). See *infra* Part II.A for a more detailed discussion of Curie-Cohen's study.

28. See ARTIFICIAL INSEMINATION PRACTICE, *supra* note 20, at 23 (noting that only three percent cited risk of genetic disorders as the reason for seeking AI).

29. See THADDEUS E. KELLY, CLINICAL GENETICS AND GENETIC COUNSELING 1 (2d ed. 1986). Couples facing a strong likelihood of transmitting a genetic disorder to the fetus may choose to accept the risk of natural pregnancy, to adopt children, to seek artificial insemination or ovum donation, to have prenatal testing with the option to abort if the fetus manifests a genetic disorder, or to abstain from parenting altogether. See *id.* at 353-55. However, adoption grows increasingly difficult as fewer children are available for adoption. This decrease in availability may be due to the greater accessibility of abortion and to changes in societal attitudes toward unwed mothers. See Kathryn Venturatos Lorio, *Alternative Means of Reproduction: Virgin Territory for Legislation*, 44 LA. L. REV. 1641, 1641-42 (1984).

disorder, and may choose to undergo AI rather than risk transmitting the disorder to the child.<sup>30</sup> According to a 1979 study, the leading genetic disorders that induce couples to seek AI are, in descending order of prevalence, Rh-factor incompatibility, cystic fibrosis, diabetes, hemophilia, Huntington's disease, muscular dystrophy, and Tay-Sachs disease.<sup>31</sup> As scientists discover additional links between diseases and specific genes (allowing for genetic testing for such diseases), and as genetic science gains more acceptance in the general community, it is probable that more couples will seek AI as an alternative to natural conception in order to preserve a genetic link to the natural mother<sup>32</sup> while decreasing the likelihood that the child will inherit a genetic disorder. Because of this potential trend, the medical profession should provide a safe reproductive alternative for couples with harmful genetic markers by screening potential sperm donors for genetic disorders.

### *C. Abuses in the Current Artificial Insemination Industry*

The rarity of litigation over unsafe artificial insemination techniques<sup>33</sup> should not give potential AI candidates a false sense of security about the quality of the procedure nationwide; rather, the lack of precedent may stem from the fact that most of these cases are resolved in hushed, out-of-court settlements intended to conceal the risks of AI from the public.<sup>34</sup> Three such examples, the Skolnick case, the Jacobson case, and the Cook case, reveal the true victims of the

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30. See Swanson, *supra* note 13, at 153.

31. See Curie-Cohen, *supra* note 27, at 585. In addition, doctors have developed reliable tests to detect sickle-cell anemia, a serious disorder that is linked to persons of African descent. See William G. Johnson et al., *Artificial Insemination by Donors: The Need for Genetic Screening*, 304 NEW ENG. J. MED. 755, 756 (1981).

32. See Swanson, *supra* note 13, at 153 (noting that some couples choose AI over adoption specifically to preserve the biological link to the mother and to allow both parents to participate in pregnancy and the birth of their child).

33. See Rice, *supra* note 13, at 1058-62. In fact, most documented AI cases in the United States concern questions about the legitimacy of AI children. See *id.*

34. See Anita M. Hodgson, *The Warranty of Sperm: A Modest Proposal to Increase the Accountability of Sperm Banks and Physicians in the Performance of Artificial Insemination Procedures*, 26 IND. L. REV. 357, 358 (1993).

government's failure to take action and alert policy makers that the AI industry suffers from a lack of adequate regulation.

1. *The Skolnick Case*—In 1989, Julia Skolnick brought suit against her gynecologist, a Manhattan fertility clinic, and a sperm bank for mistakenly inseminating her with the sperm of an unknown donor, rather than that of her dying husband.<sup>35</sup> Tests revealed that the child was biracial, while both Mrs. Skolnick and her husband were Caucasian.<sup>36</sup> Additional genetic tests comparing the DNA of the child with that found in remaining samples of Mr. Skolnick's sperm proved that Mr. Skolnick's sperm could not have been used to conceive the child.<sup>37</sup> Although the Skolnick record was sealed from the public,<sup>38</sup> Mrs. Skolnick's physician reportedly paid a no-fault settlement of approximately \$300,000, and the sperm bank settled for approximately \$100,000.<sup>39</sup> Had the practices of this gynecologist and sperm bank been regulated, this mix-up might have been prevented.

2. *The Jacobson Case*—Dr. Cecil Jacobson assured his patients that he obtained sperm from an anonymous sperm donor bank that solicited donations from medical and seminary school students.<sup>40</sup> He even promised to select a donor who would match the physical characteristics and, at times, the religion of the recipient's mate.<sup>41</sup> In 1992, Dr. Jacobson was convicted on fifty-two counts of fraud and perjury for inseminating up to seventy-five of his patients with his own sperm.<sup>42</sup> Dr. Jacobson admitted that he used his own sperm to artificially inseminate patients at his clinic between 1976 and 1986,<sup>43</sup> unbeknownst to his patients and unregulated by

35. See Ronald Sullivan, *Mother Accuses Sperm Bank of a Mixup*, N.Y. TIMES, Mar. 9, 1990, at B1.

36. See Robin Schatz & Gale Scott, *Sperm Mix-up Raises Doubts*, NEWSDAY, Mar. 10, 1990, at 4.

37. See Sullivan, *supra* note 35, at B1.

38. See Ronald Sullivan, *Sperm Mix-Up Lawsuit is Settled*, N.Y. TIMES, Aug. 1, 1991, at B4.

39. See *id.*

40. See Robert F. Howe, *For Fertility Patient, An Unrelenting Anguish*, WASH. POST, Mar. 6, 1992, at A1.

41. See *Fertility Doctor Found Guilty of Fraud, Perjury*, CHI. TRIB., Mar. 5, 1992, § 1, at 4.

42. See *St. Paul Fire & Marine Ins. Co. v. Jacobson*, 48 F.3d 778, 779 (4th Cir. 1995) (citing *United States v. Jacobson*, No. 92-5406, (4th Cir. Sept. 3, 1993), *cert. denied sub nom. Jacobson v. U.S.*, 511 U.S. 1069 (1994)).

43. See *id.* at 779 n.3.



government authorities. Although no medical society prohibits AI practitioners from using their own sperm in artificial insemination procedures,<sup>44</sup> Dr. Jacobson's repeated fraudulent misrepresentations to his patients about the nature of their procedures demonstrate that regulations over the AI industry must be highly specific to minimize or prevent such abuses.

3. *The Cook Case*—Joedy and Ute Cook filed charges in 1996 against a Columbus, Ohio sperm bank and a Chicago genetic testing facility for failing to screen their donor sperm for the cystic fibrosis gene, despite guarantees of such screening.<sup>45</sup> The Cooks sought AI because they both carry the gene for cystic fibrosis, and their child thus had a one in four chance of developing the disease.<sup>46</sup> However, the sperm bank performed inadequate genetic tests, or none at all, and one of the Cooks' triplets now suffers from cystic fibrosis.<sup>47</sup>

These three case studies emphasize the concerns raised by the Curie-Cohen study and the Office of Technology Assessment report, and demonstrate that sperm banks and private physicians performing AI are not adequately regulated to ensure patient safety. Without regulation of AI procedures, patients like the Skolnicks and the Cooks cannot be certain that the sperm used in their AI procedure meets minimal safety standards, or that it is even the sperm they contracted to use.

## II. SCREENING THE AI INDUSTRY ITSELF: MEDICAL STUDIES AND GOVERNMENT REPORTS

This Part outlines the progression of genetic screening standards in the AI industry over the past twenty years. It discusses in detail a 1979 study by Martin Curie-Cohen, which demonstrated that the majority of physicians performing AI at that time failed to screen donor sperm for genetic disorders, and those who did screen the sperm generally

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44. See Dawn House, *Jurors Say Infertility Doctor Guilty of Defrauding Patients*, SALT LAKE TRIB., Mar. 5, 1992, at A1.

45. See B.G. Gregg, *Sperm Rules are Lax No Standard for Genetic Screening*, CINCINNATI ENQUIRER, Mar. 23, 1996, at B1.

46. See *id.*

47. See *id.*

lacked the knowledge and training to perform the task adequately.<sup>48</sup> In response to this and similar studies, organizations like the American Fertility Society and the American Association of Tissue Banks published professional guidelines to provide physicians and sperm banks with a minimum level of quality for screening techniques.<sup>49</sup> Yet the 1988 report published by the Office of Technology Assessment illustrates that many AI practitioners and sperm banks still failed to comply with even these minimal screening standards.<sup>50</sup> The three cases discussed in Part I.C offer clear proof of how severely the current AI industry suffers from inadequate regulation and illustrate why the industry is ripe for reform.

### A. Curie-Cohen's 1979 Study<sup>51</sup>

According to an influential study conducted by Martin Curie-Cohen in 1979, AI facilities often conduct inadequate genetic screening of donor sperm,<sup>52</sup> indicating that significant revamping may be necessary to best serve the interests of the recipients and the children born from the procedure.<sup>53</sup> Although Curie-Cohen conducted his survey nearly twenty years ago and examined only the practices of private physicians performing AI, his findings and recommendations are still relevant to the current genetic screening practices of physicians and sperm banks.<sup>54</sup>

Curie-Cohen solicited responses from 711 physicians he deemed likely to perform AI.<sup>55</sup> He received 379 viable responses from physicians practicing in forty-six states and the District of Columbia.<sup>56</sup> Curie-Cohen found that although 96%

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48. See *infra* Part II.A.

49. See American Fertility Soc'y, *supra* note 6, at 1S.

50. See *infra* Part II.B.

51. See Curie-Cohen, *supra* note 27.

52. See *id.* at 589.

53. See *id.*

54. Cf. Swanson, *supra* note 13, at 154-55 (citing the relevance of Curie-Cohen's findings to continuing problems of inadequate donor record-keeping).

55. See Curie-Cohen, *supra* note 27, at 585 (explaining that questionnaires were sent to physicians in the American Fertility Society listing of physicians that perform AI, authors of recent articles on AI, and all medical school departments of obstetrics and gynecology).

56. See *id.* (explaining that "viable responses" refers to responses from physicians who actually performed AI).

of the responding physicians took family medical histories, this questioning seldom went beyond "asking a donor if any genetic diseases existed in his family or presenting him with a short checklist of common familial diseases."<sup>57</sup> Because most physicians used a select donor pool consisting predominantly of medical students, hospital residents, or other donors with above-average health and intelligence, the physicians believed that the exceptional donor pool screened out many problematic sources.<sup>58</sup> In addition, some of the doctors expected the medical students and hospital residents to "self-screen" prior to donation.<sup>59</sup> Although many of the physicians could list a number of genetic diseases they felt should disqualify a potential donor, these physicians failed to screen the donors adequately for these diseases.<sup>60</sup> Rather, they conducted only cursory family histories and rarely performed biochemical tests other than blood typing.<sup>61</sup> Furthermore, few physicians who performed screening understood the modes of inheriting genetic diseases.<sup>62</sup>

Curie-Cohen concluded that a need existed for increased regulation of the genetic screening practices in the AI industry.<sup>63</sup> He recommended the compilation of a standard list of genetic traits for which physicians should screen, coupled with a requirement that physicians performing AI receive adequate training to recognize genetic anomalies in donor family histories.<sup>64</sup> In response to this study, members of the AI community made efforts to study and improve AI screening standards,<sup>65</sup> but failed to implement significant improvements to genetic testing in the industry.<sup>66</sup>

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57. See *id.* at 586.

58. See *id.*

59. See *id.*

60. See *id.* at 588. For example, "94.7% [of respondents] would reject a carrier of Tay-Sachs disease, but less than 1% indicated that they tested donors for the carrier state." *Id.*

61. See *id.* Family history inquiries may be insufficient because they rely on both the donor's ability to recognize pertinent genetic traits in his family and his honesty, which may be compromised by his financial incentive to donate. See *id.*

62. See *id.* Doctors did not take into account the severity of the genetic disease or the donor's actual ability to transmit the disease to his offspring. For example, 71.4% of responding doctors reported that they would reject any donor with a family history of hemophilia, even though a donor would be unable to pass on this X-linked disease gene unless he was actually affected. See *id.*

63. See *id.* at 589.

64. See *id.*

65. See Kathleen M. Peterson, *Federal Regulation of Artificial Insemination Donor Screening Practices: An Opportunity for Law to Co-Evolve with Medicine*, 96 DICK. L. REV. 59, 69-70 & n.27 (1991).

66. See *id.* at 70.

*B. 1988 Congressional Report on the State of  
U.S. Artificial Insemination Practices*

Nearly ten years after the Curie-Cohen study, the Office of Technology Assessment (OTA) commissioned a follow-up study to assess the state of AI screening practices of physicians and sperm banks.<sup>67</sup> The 1988 OTA report documented that while genetic testing in some areas of the AI industry responded to the concerns published in Curie-Cohen's 1979 study, the AI industry as a whole manifested great inconsistency in its testing procedures.<sup>68</sup> The study revealed that sperm banks generally comply with professional guidelines such as those published by the American Association of Tissue Banks and the American Fertility Society.<sup>69</sup> However, the nature and extent of the tests varied,<sup>70</sup> and few sperm banks performed chromosomal tests for genetic diseases.<sup>71</sup> Most smaller clinics and private physicians also failed to screen donors for genetic defects or diseases prior to accepting them.<sup>72</sup> The report concluded that most physicians and sperm banks favor the establishment of national standards<sup>73</sup> (either voluntary or mandatory) for donor screening.<sup>74</sup> This report underscored the continuing need for increased regulation of AI screening practices. As Part III will demonstrate, the current federal, state, and industry regulation of AI is

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67. See ARTIFICIAL INSEMINATION PRACTICE, *supra* note 20, at 3.

68. See *id.* at 33-40 (discussing donor selection and screening by physicians performing AI); *id.* at 66-70 (discussing donor selection and screening by sperm banks).

69. See *id.* at 71.

70. See *id.* at 67.

71. See *id.* at 67, tbls. 3-5. All of the facilities participating in the study required a donor's personal and family medical history, in addition to his genetic history. Most facilities also required a donor's fertility history, a physical examination, and a personality assessment. See *id.* at 67. Rather than performing chromosomal tests for such autosomal recessive diseases such as Tay-Sachs, sickle cell anemia, and thalassemia, most donor facilities simply reject any donor with a family history of diseases. See *id.* at 68, tbls. 3-6, 69-70.

72. See *id.* at 33. Only 20% of physicians who regularly performed artificial insemination by donor stated "that a family history of genetic disease would lead them to require genetic screening of a potential donor." *Id.* at 35.

73. See *id.* at 10-11 (noting that 80% favor national standards for donor screening by sperm banks, and that 68% favor such standards for screening by private practitioners).

74. See *id.* at 72.

inadequate and in need of reform in order to ensure the safety of future AI recipients and their children.

### III. CURRENT FEDERAL, STATE, AND INDUSTRY REGULATION OF ARTIFICIAL INSEMINATION

Despite the OTA's exposure of the substandard health and safety practices in the AI industry, neither the federal nor the state governments have introduced any significant legislation creating universal genetic screening procedures for donor sperm.<sup>75</sup> Groups such as the American Fertility Society and the American Association of Tissue Banks have published guidelines for testing donor semen.<sup>76</sup> However, these guidelines contain only recommendations for AI practitioners, who remain self-regulating in most states, and who follow a wide variety of screening procedures.<sup>77</sup> This Part discusses the inadequacies of the current industry, state, and federal regulation of AI practices. Only with federal regulation of AI screening procedures can a universal standard of care develop in the AI industry that will best accommodate the interests of AI recipients, donors, and children.

#### *A. The American Fertility Society's 1990 Guidelines For the Use of Semen Donor Insemination*

In 1990, in response to the increase in documented cases of AI and to heightened concern about the transmission of disease through inadequately screened donor samples,<sup>78</sup> the American Fertility Society (AFS) revised its guidelines for the use of donor semen.<sup>79</sup> The 1990 guidelines list two central features in the selection of AI donors: "(1) assurance of good health status and (2) absence of genetic abnormalities."<sup>80</sup>

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75. See Peterson, *supra* note 65, at 61-62.

76. See, e.g., American Fertility Soc'y, *supra* note 6.

77. See Cheryl L. Meyer, *Transmission of HIV Through Donor Semen*, 15 WOMEN'S RTS. L. REP. 115, 118 (1993-94).

78. See American Fertility Soc'y, *supra* note 6, at 1S.

79. *Id.*

80. *Id.* at 2S.

Thus, the AFS has recognized the importance of careful donor selection to curtail the spread of genetic disease.

The guidelines recommend the use of "state-of-the-art tests"<sup>81</sup> to screen for genetic disorders, including nontrivial malformations of complex causes, such as cleft palate, spina bifida, or congenital heart malformation; nontrivial Mendelian disorders, such as albinism or hemophilia; familial diseases with genetic components, such as asthma, juvenile diabetes, epilepsy, or psychosis; autosomal recessive diseases, such as cystic fibrosis or Tay-Sachs disease; and chromosomal rearrangements.<sup>82</sup> The guidelines also recommend that the practitioner should screen for these disorders in the donor,<sup>83</sup> and in his first-degree relatives (parents or offspring) using donor questionnaires.<sup>84</sup> The AFS does not require a complete chromosomal analysis of donors when a thorough genetic history indicates little probability of ethnically linked genetic diseases.<sup>85</sup> The AFS recommends that physicians who purchase samples from commercial sperm banks should take care to obtain sufficient donor and semen quality information consistent with the guidelines before using the samples.<sup>86</sup>

Although the AFS has outlined minimum standards for the genetic screening of sperm donors, compliance by AI practitioners is purely voluntary.<sup>87</sup> Thus, without proper monitoring of AI facilities to enforce compliance, the AFS guidelines are unlikely to significantly increase the safety of the sperm donor pool.

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81. *Id.* at 8S. However, in contrast to a detailed description of laboratory screening methods for sexually transmitted diseases and other infectious diseases, *see id.* at 3S, the guidelines do not elaborate on methods for genetic screening, leaving individual practitioners to implement various screening procedures. For example, the guidelines suggest that AI practitioners obtain a "proper family history" of all donors, but fail to discuss any techniques that will ensure accurate disclosure of information. *See id.* at 3S. Although advanced methods of genetic screening might include expanded use of chromosomal analysis, the guidelines specifically state that this procedure is not necessary under all circumstances. *See id.* at 3S. Thus, the AFS falls short of providing substantive guidance to reduce the disparities in genetic screening and the incidences of genetic disorders in AI.

82. *See id.* at 8S.

83. *See id.* at 3S.

84. *See id.* at 8S-9S.

85. *See id.* at 3S.

86. *See id.*

87. *Cf. Meyer, supra* note 77, at 118 (noting that, despite the AFS guidelines, most sperm banks, hospitals, and practitioners are self-regulating and follow a variety of screening procedures).

### B. State Regulation of Artificial Insemination

Although a number of states have enacted statutes requiring that AI be performed by, or under the supervision of, a licensed physician,<sup>88</sup> few states regulate sperm donation screening.<sup>89</sup> Some states have enacted laws mandating screening for other conditions beyond that usually done for the HIV virus and other infectious diseases, but these laws do not specifically provide for genetic testing.<sup>90</sup> Ohio mandates genetic testing for non-spousal AI, but leaves to the discretion of the physician the choice of screening procedures.<sup>91</sup> Delaware and Illinois require sperm banks to register with the state Department of Public Health.<sup>92</sup> However, in the absence of provisions requiring disclosure about the screening methods actually used, patients remain uninformed about the potential inadequacy of donor screening procedures.<sup>93</sup> Largely self-regulated, doctors and sperm banks in the majority of states view additional biological or genetic screening as purely optional. Furthermore, they are rarely held liable for their failure to perform additional tests "if the donation of contaminated or

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88. See Lorio, *supra* note 29, at 1649 (citing, *inter alia*, CONN. GEN. STAT. ANN. § 45a-772 (West 1993) (requiring AI to be performed only by persons certified to practice medicine in the state); GA. CODE ANN. § 43-34-42 (1994) (stating that only licensed physicians and surgeons may administer or perform AI); OHIO REV. CODE ANN. §§ 3111.30, .32 (Anderson 1996) (allowing AI to be performed only by or under supervision of licensed physicians); OKLA. STAT. ANN. tit. 10, § 553 (West 1987) (stating that only persons licensed to practice medicine in the state may perform AI); OR. REV. STAT. § 677.360 (1995) (allowing only licensed physicians and persons under their supervision to perform AI)).

89. See, e.g., DEL. CODE ANN. tit. 16, § 2801(a) (1995) (mandating testing for HIV); N.H. REV. STAT. ANN. § 168-B:10 (1997) (requiring documented medical evaluation demonstrating "medical acceptability" of donor); OHIO REV. CODE ANN. § 3111.33 (Anderson 1996) (requiring medical history, examination, and laboratory tests of non-spousal donors).

90. See CAL. HEALTH & SAFETY CODE § 1644.5 (West Supp. 1997); DEL. CODE ANN. tit. 16, § 2801(b) (1995); FLA. STAT. ch. 381.0041 (1993); 20 ILL. COMP. STAT. 2310/55.46 (West 1993); IND. CODE ANN. § 16-41-14-5 (West 1996).

91. See OHIO REV. CODE ANN. § 3111.33(B)(2)(b) (Anderson 1996) (requiring that physicians conduct "appropriate" laboratory studies, including but not limited to, karyotyping, Tay-Sachs, and sickle cell anemia).

92. See DEL. CODE ANN. tit. 16, § 2801(a) (mandating registration and establishing a fine for noncompliance); 20 ILL. COMP. STAT. ANN. 2310/55.46(a) (West 1993) (same).

93. See Lori B. Andrews & Lisa Douglass, *Alternative Reproduction*, 65 S. CAL. L. REV. 623, 634 (1991).

defective sperm results in the birth or abortion of genetically defective or diseased offspring."<sup>94</sup>

The variations in regulation of sperm banks and donor screening from state to state prevent AI recipients from being assured of the safety of the AI procedure. For the protection of AI recipients, the federal government should establish uniform regulation and should monitor the AI industry.

### *C. Federal Regulation of Artificial Insemination*

Despite then-Senator Al Gore's promise in 1988 to "take appropriate action" if the FDA failed to strengthen regulation of the screening and testing practices in the AI industry,<sup>95</sup> the federal government has not enacted any legislation that addresses genetic testing of donor semen.

The federal government appeared to be making some progress toward fulfilling Gore's vision with the following entry in the 1993 Code of Federal Regulations (C.F.R.):

FDA is proposing regulations intended to prevent the transmission of *communicable* disease through the use of human semen for artificial insemination. The proposed regulations would provide for the registration with FDA of establishments collecting, manufacturing, and distributing semen intended for artificial insemination. Registered facilities would be required to meet standards intended to ensure that semen donors are appropriately screened and tested, that the collected semen is not contaminated with an agent of *communicable* disease through errors of poor practices, and that records are kept documenting that the appropriate procedures have been followed. Registered facilities meeting these standards would receive a certification from FDA that would permit the continued distribution of semen intended for artificial insemination. Human semen collected from a donor who is the spouse or other sexually intimate partner of the intended recipient would not fall under the scope of the proposed regulation.<sup>96</sup>

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94. Hodgson, *supra* note 34, at 363.

95. Marwick, *supra* note 9, at 1339.

96. Human Semen for Artificial Insemination, 21 C.F.R. § 1260 (1993) (emphasis added).



Unfortunately, this C.F.R. entry included neither a legal deadline nor timetable for action, nor did it address the need to screen for genetic diseases.<sup>97</sup> The corresponding C.F.R. entry in 1994 disclosed no plans to implement this regulation within the following twelve months.<sup>98</sup> The federal government has taken no further steps toward the national regulation of the AI industry, leaving regulation to either the individual states or the AI practitioners themselves.<sup>99</sup>

#### IV. SOLVING THE PROBLEM

The artificial insemination industry affects enough people to merit closer control.<sup>100</sup> Because of the private nature of the industry, however, AI practitioners do not effectively police themselves.<sup>101</sup> Physicians with various specialities perform AI as a subset of their practice,<sup>102</sup> making it difficult to monitor involvement in the industry. Further, the sparse regulation of sperm banks precludes a nationwide count of the number of banks in operation,<sup>103</sup> and allows "sperm banks and laboratories [to] operate free of any official oversight."<sup>104</sup>

This Part proposes that the federal government should establish a national system of cooperative sperm donation facilities spread throughout the country.<sup>105</sup> Each donation facility should register with, and be monitored by, the Food and Drug Administration (FDA) in order to provide the regulation and enforcement that the current AI industry

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97. *See id.*

98. *See* Human Semen for Artificial Insemination, 21 C.F.R. § 1260 (1994).

99. *See* Cork, *supra* note 7, at 1550-51 (noting that Congress has been slow in its response to problems in the AI industry); Peterson, *supra* note 65, at 61-62 (noting the lack of response by the federal government to requests for regulation of the AI industry).

100. *Cf.* Cork, *supra* note 7, at 1536 (reporting that 40,000 patients receive "assisted reproductive treatment" annually).

101. *See* Cork, *supra* note 7, at 1537.

102. *Cf.* INFERTILITY CHOICES, *supra* note 4, at 6 (reporting that infertility treatment may be obtained from obstetrician-gynecologists, general or family practitioners, urologists, and surgeons).

103. *See* Cork, *supra* note 7, at 1540-41 & n.31 (noting that estimates of the number of sperm banks in the U.S. vary from 400 to 1,100).

104. *Id.* at 1541.

105. *See infra* Part IV.B.

lacks.<sup>106</sup> The FDA, with the assistance of the AFS and private physicians, should establish and continually update concrete nationwide donor screening regulations for sperm banks.<sup>107</sup> Finally, the sperm donor system should require that AI practitioners keep better records of AI procedures and disclose non-identifying donor information to AI recipients and their children.<sup>108</sup>

### A. Federal Regulation of a National Sperm Donor System

Although matters of medical practice and family law fall within the traditional bounds of state responsibility,<sup>109</sup> establishing a national sperm donor system under the control of the FDA would universalize the testing procedures of donor sperm and potentially reduce the number of genetic diseases perpetuated by the transmission of unscreened sperm.<sup>110</sup> The Constitution does not speak directly to issues of medical care or human reproduction, but the federal government derives the power to regulate interstate public health through the authority granted by the Commerce Clause.<sup>111</sup>

The FDA could derive its authority to regulate the testing procedures of sperm banks from several sources.<sup>112</sup> First, within its Center for Devices and Radiological Health, the FDA has the power "to regulate tissues, including semen."<sup>113</sup> Furthermore, under the Food, Drug, and Cosmetic Act, the FDA has the authority to establish standards for biological products.<sup>114</sup> The definition of "biological product"—any "virus, therapeutic serum, toxin, antitoxin or *analogous product* applicable to the prevention, *treatment* or cure of diseases or

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106. See Meyer, *supra* note 77, at 121 (discussing problems resulting from lack of federal regulation).

107. See *infra* Part IV.C.

108. See *infra* Part IV.D.

109. See INFERTILITY CHOICES, *supra* note 4, at 10.

110. See *id.* at 176.

111. U.S. CONST. art. I, § 8, cl. 3; see Peterson, *supra* note 65, at 86–87 (arguing that the taxing, spending and commerce powers supply the federal government with regulatory authority over health care).

112. See generally INFERTILITY CHOICES, *supra* note 4, at 176–83 (discussing grounds for federal authority to regulate infertility treatment and research).

113. *Id.* at 24.

114. See Peterson, *supra* note 65, at 88 (citing 21 C.F.R. § 610 (1989) as the basis of FDA authority over biological products).

injuries of man"<sup>115</sup>—could easily include donor semen, particularly in light of the elaborate process of collection, preservation and storage.<sup>116</sup> Because many couples seek AI as a result of infertility or medical problems that impede natural reproduction,<sup>117</sup> they arguably are seeking treatment to cure infertility disease. In addition, the straws of donor semen purchased by these couples serve as an integral part of the AI procedure, and thus are an essential part of the "treatment" of infertility disease.<sup>118</sup> Thus, the Food, Drug, and Cosmetic Act provides the FDA with the requisite authority to regulate the standards of the donor semen used in a national sperm donor system.

Even though the Tenth Amendment to the U.S. Constitution reserves to the state governments the power to protect the health and safety of the public,<sup>119</sup> the states are not well suited to provide the universal regulation necessary to guarantee the safety of the AI industry.<sup>120</sup> Each state government retains the power to legislate, or not to legislate, testing requirements for donor sperm.<sup>121</sup> Because AI practitioners often import donor sperm from sperm banks in other states which may not regulate adequately the screening of donor sperm, an AI recipient cannot be certain, absent national regulatory standards, that the sperm she uses meets the screening requirements of the state in which she purchased it.<sup>122</sup> Even if a state guaranteed higher standards of sperm donor genetic testing, an AI clinic in that state might purchase samples from a sperm bank in a non-regulated state because such samples can be purchased at a reduced cost.<sup>123</sup> Furthermore, without federal regulation of the AI

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115. 21 C.F.R. § 600.3(h) (1989) (emphasis added).

116. See Peterson, *supra* note 65, at 88 & n.50 (describing the process utilized by larger semen donation facilities).

117. See ARTIFICIAL INSEMINATION PRACTICE, *supra* note 20, at 23 (reporting that 8 out of 10 requests for AI are the result of male infertility); Curie-Cohen, *supra* note 27, at 585 (reporting that male infertility accounts for over 95% of requests for AI); Peterson, *supra* note 65, at 59 (reporting the popularity of AI as a treatment for male infertility).

118. See Peterson, *supra* note 65, at 88.

119. See INFERTILITY CHOICES, *supra* note 4, at 172 (interpreting "police power" to include governmental power to protect health, safety, and morals of citizens).

120. See discussion *supra* Part III.B.

121. See INFERTILITY CHOICES, *supra* note 4, at 172-76 (discussing methods by which states may regulate infertility treatment).

122. See Peterson, *supra* note 65, at 82-83.

123. See *id.*

industry, this Note's proposal for a cooperative network of sperm donor centers<sup>124</sup> would not be feasible. Thus, federal regulation of the AI industry is preferable to state-by-state regulation to achieve the uniformity of health and safety standards needed in the AI industry.

Common law litigation is also an inadequate enforcement mechanism, as it deals retrospectively with the injuries of individual parties. The result is ad-hoc policy created by state courts in response to case-specific disputes.<sup>125</sup> Such piecemeal litigation, like state-by-state regulation, fails to adequately deter abuses in the AI industry.

In contrast, government regulation acts prospectively to anticipate potential problems and create a coherent public policy that prevents people from suffering unnecessary injury as a result of AI.<sup>126</sup> The federal government is in a better position than state governments to promulgate the uniform regulation necessary to ensure safe and effective practice of AI.<sup>127</sup>

### *B. National System of Sperm Donor Centers*

In general, larger commercial sperm banks have adopted the AFS donor screening guidelines,<sup>128</sup> while an unknown number of small, private sperm banks operate without license from any state, registration with an organization, or governmental oversight.<sup>129</sup> The proposed national donor system would restrict donations to an established network of donor centers spread throughout the country.<sup>130</sup> Potential AI recipients still would be able to seek reproductive treatment from private physicians; however, these physicians would be required to obtain donor samples from one

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124. See *infra* Part IV.B.

125. See Cork, *supra* note 7, at 1537.

126. Cf. Anne Reichman Schiff, *Solomonic Decisions in Egg Donation: Unscrambling the Conundrum of Legal Maturity*, 80 IOWA L. REV. 265, 267 (1995) (asserting this position with regard to the egg donation industry).

127. See Peterson, *supra* note 65, at 92.

128. See ARTIFICIAL INSEMINATION PRACTICE, *supra* note 20, at 71.

129. See Cork, *supra* note 7, at 1541.

130. *But cf.* Peterson, *supra* note 65, at 91 (recommending a broadly inclusive definition of semen donation facility).

of the FDA-monitored donor centers.<sup>131</sup> By limiting the sources for donor sperm to official sperm banks registered with the FDA, donor sperm would more likely receive the screening necessary to ensure its safety. This system would establish a universal standard of care for AI practitioners that is lacking in the current system of donor screening.

Critics of a national sperm donor bank system have argued that "the legislative process is too slow and enforcement too rare to provide the needed swift, effective solution" to the problems of the current AI industry.<sup>132</sup> They have also argued that the Center for Disease Control should issue recommendations that emphasize the need to take comprehensive genetic histories of sperm donors and their families.<sup>133</sup> However, this does not explain how these CDC recommendations will promote greater compliance than the recommendations released by the AFS. As in the case of the AFS, the CDC would issue only *recommendations* and would have no enforcement mechanism or authority to police compliance with these recommendations. The problems stemming from the current practice of self-regulation in the AI industry are not likely to disappear as long as practitioners are permitted.<sup>134</sup>

Critics have also argued that Congress will have a difficult time passing any legislation because of the stigma associated with donor insemination.<sup>135</sup> However, with over 11,000 private physicians performing AI nationwide,<sup>136</sup> and with more permissive social attitudes toward alternative forms of the American family unit,<sup>137</sup> this multimillion dollar industry no longer faces an overwhelming social stigma.<sup>138</sup>

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131. This restriction would not apply to recipients who have selected their own donor. This system only applies to artificial insemination by *anonymous* donors.

132. Hodgson, *supra* note 34, at 360.

133. See Peterson, *supra* note 65, at 90.

134. See *supra* Part II.

135. See Hodgson, *supra* note 34, at n.13 (citing Rice, *supra* note 13, at 1073 & n.197). In the past, some lower courts have held that AI constituted adultery. See, e.g., *Doornbos v. Doornbos*, 23 U.S.L.W. 2308 (Ill. Super. Ct. 1954) (holding that AI was "contrary to public policy and good morals" and constitutes adultery on the part of the mother). In addition, some courts discussed the illegitimacy of children born by AI. See, e.g., *id.* (holding that a husband's consent to the procedure would not legitimize a child born by AI); *Gursky v. Gursky*, 242 N.Y.S.2d 406, 410 (Sup. Ct. 1963) (holding that the legislature's failure to pass a statute legitimizing children born by AI demonstrated an intent to exclude these children from legitimacy).

136. See ARTIFICIAL INSEMINATION PRACTICE, *supra* note 20, at 8.

137. See Swanson, *supra* note 13, at 170.

138. See SNOWDEN & MITCHELL, *supra* note 24, at 15 ("The climate of public opinion on questions of sexual behaviour has undergone a considerable change and AID, though still a controversial subject, is now looked upon with less reluctance by

In creating a national sperm donor system, the FDA might seek guidance from other countries, including the French CECOS Federation, which regulates twenty AI treatment centers across France.<sup>139</sup> The French system boasts extensive collaboration between the centers on both practical and ethical issues, providing a forum for collective discussion and preparation of long-term strategies in the field of AI.<sup>140</sup> Not only does this collaboration facilitate comparisons of different artificial reproductive procedures and their results, but it also allows for the establishment of permanent advisory groups and the adoption of universal practices that provide security to AI recipients.<sup>141</sup> Although the United States system should not duplicate the French system—the FDA must take into account the differences between the French and U.S. social and economic environments<sup>142</sup>—the CECOS Federation demonstrates that a national sperm donor bank system is a potential solution to the problems currently plaguing the American AI industry.

### *C. Heightened Standards of Genetic Screening*

The proposed national donor system would require that all sperm samples undergo strict viral, bacterial, and genetic screening before they are released for AI treatments. The 1990 AFS guidelines would provide the *absolute minimum* threshold for donor screening. However, physicians involved with artificial insemination, genetics, and epidemiology should collaborate with the FDA and the AFS to determine whether the 1990 guidelines require supplementation,<sup>143</sup> and should reexamine annually the adopted FDA guidelines to incorporate medical advancements affecting AI screening.

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both the medical profession and the general public.”). Note, however, that many major religions continue to oppose AI. See discussion *infra* note 180.

139. See Pierre Jalbert et al., *Genetic Aspects of Artificial Insemination With Donor Semen: The French CECOS Federation Guidelines*, 33 AM. J. MED. GENETICS 269, 269 (1989). In addition, Australia contains 12 regional sperm donor centers. See Terra Ziporyn, “Artificial” Human Reproduction Poses Medical, Social Concerns, 255 JAMA 13, 13 (1986).

140. See Jalbert, *supra* note 139, at 273.

141. See *id.*

142. See *id.* at 269.

143. See Marwick, *supra* note 9, at 1339.

Fertility experts are divided on whether to require chromosomal testing of donor sperm to screen for genetic disease.<sup>144</sup> The 1990 AFS guidelines note that “[i]t would be impractical to screen donors for all deleterious recessive diseases detectable in a heterozygote state, but it would be desirable to screen them for mutant genes at high frequency in their own ethnic population.”<sup>145</sup> Participants in the FDA donor system should not be required to perform chromosomal tests for all known genetic disease genes, due to the high cost of such testing.<sup>146</sup> Rather, the sperm banks should examine carefully the donor’s medical and family histories to determine the genetic diseases for which he is most at risk.<sup>147</sup> Then, rather than screening out all *at-risk* donors, as is the current practice at many sperm banks,<sup>148</sup> the sperm banks should perform chromosomal tests to determine whether the individual donor carries the disease gene.<sup>149</sup> By carefully conducting medical history inquiries and selectively using genetic screening tests, the national donor system could prevent the unnecessary rejection of acceptable potential donors while still excluding sperm carrying genetic disorders.

Critics of widespread genetic testing of sperm donors state that because “‘normal’ couples don’t generally undergo genetic testing before conception,”<sup>150</sup> and genetic tests cannot screen for 100% of all genetic mutations for a single disease,<sup>151</sup> sperm banks should not be required to guarantee safety and perfect conception results.<sup>152</sup> Many couples, however, do undergo genetic testing prior to natural conception.<sup>153</sup> Furthermore, those couples who seek AI for genetic reasons

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144. See Peterson, *supra* note 65, at 78 & n.200 (comparing and contrasting authorities on issue of mandatory genetic testing of donors).

145. American Fertility Soc’y, *supra* note 6, at 8S.

146. See Ziporyn, *supra* note 139, at 14.

147. See *id.* at 85–95.

148. See ARTIFICIAL INSEMINATION PRACTICE, *supra* note 20, at 69–70.

149. See American Fertility Soc’y, *supra* note 6, at 8S.

150. Ziporyn, *supra* note 139, at 14.

151. See Gregg, *supra* note 45, at B1.

152. See Ziporyn, *supra* note 136, at 13–14 (discussing criticism of mandatory donor screening).

153. See *Genetic Testing and Assessment*, in ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY 59, 75 (Lori B. Andrews et al. eds., 1994) (discussing frequency of genetic testing for older couples and those who have a family history of genetic disease) [hereinafter *Genetic Testing*]. In fact, the American College of Obstetrics and Gynecology believes that offering prenatal genetic testing is part of the medical “standard of care” for pregnant women over the age of 35. *Id.*

expect the highest quality spermatozoa from sperm banks.<sup>154</sup> Since the malpractice liability of AI practitioners remains unclear,<sup>155</sup> "more stringent and uniform medical and genetic testing is especially important."<sup>156</sup>

A further argument against more exhaustive genetic testing requirements for sperm donor banks is that furnishing in-depth genetic tests will be too costly, adding \$500 to \$1000 to the cost of artificial insemination.<sup>157</sup> Yet couples such as the Cooks,<sup>158</sup> who have already invested a large sum of money in prior reproductive tests or treatments,<sup>159</sup> may be willing to pay an additional amount to reduce the risk that their child will be born with a serious genetic disease.<sup>160</sup>

Members of the AI community fear that heightened standards for the genetic testing of sperm donors will severely deplete the donor pool.<sup>161</sup> Each person carries between three and five lethal recessive genes, and, therefore, may carry some deleterious genetic disease gene.<sup>162</sup> In light of the fact that more than 2,000 genetic diseases exist,<sup>163</sup> such "highly detailed screening would ultimately result in the exclusion of such a high proportion of donors as to preclude any recruitment."<sup>164</sup> On the other hand, the failure to implement proper genetic testing also may needlessly eliminate many potential donors. Sperm banks often automatically reject several categories of donors, such as members of certain ethnic groups, homosexuals, and drug users.<sup>165</sup> Therefore, to reduce the risk of discrimination in donor selection,<sup>166</sup> donor banks should determine whether the donor *himself* poses a risk of HIV or

154. See Ziporyn, *supra* note 139, at 14.

155. See Frankel, *supra* note 19, at 305; Ziporyn, *supra* note 136, at 14.

156. Frankel, *supra* note 19, at 298.

157. See Lorio, *supra* note 29, at n.51 (discussing estimated costs in 1984).

158. See discussion *supra* Part II.C.3.

159. See ARTIFICIAL INSEMINATION PRACTICE, *supra* note 20, at 48. The cost of artificial insemination varies with each recipient, depending on her medical condition and the number of inseminations required for conception. At the time of the 1987 OTA Report, most women spent an average of \$309 for pre-insemination treatments, and an additional \$93 for each of seven insemination treatments. See *id.*

160. See Ziporyn, *supra* note 139, at 14.

161. See Jalbert, *supra* note 139, at 271.

162. See Peterson, *supra* note 65, at 89-90; Jalbert, *supra* note 139, at 271; see also *Genetic Testing*, *supra* note 153, at 70-71 (discussing the likelihood that an individual carries a gene for a genetic disorder).

163. See Peterson, *supra* note 65, at 90.

164. Jalbert, *supra* note 139, at 271.

165. See ARTIFICIAL INSEMINATION, *supra* note 20, at 35-37.

166. See Peterson, *supra* note 65, at 90.



genetic disease, using only those genetic tests deemed to be necessary after an evaluation of the donor's medical, family and genetic history.<sup>167</sup>

Furthermore, even if a donor tests positive for certain genetic disease genes, he should not be rejected automatically. The French CECOS Federation genetic screening procedures are designed to eliminate "only the most frequent and most severe genetic defects."<sup>168</sup> When certain donors test positive for genetic disease genes that do not constitute a substantial risk unless they are present in both the donor and the recipient (recessive disease genes), the French CECOS centers place these donors in a separate pool and pair them only with women who lack the corresponding recessive gene.<sup>169</sup> Thus, genetic screening actually opens up the donor pool by breaking the general pool into smaller, gene-based pools, thereby avoiding automatic rejection of many donors, including those with recessive disease genes.

The proposed national donor system will take this idea one step further, eventually segregating donor centers by genetic disease, with each center testing solely for one specific disease.<sup>170</sup> This restructuring would cut the cost of genetic testing significantly, because the donor centers would not be expected to test for every genetic disease.<sup>171</sup> Thus, a recipient who seeks AI because she has a gene for cystic fibrosis will purchase sperm from a cystic fibrosis testing center. She does not need to incur extra costs for additional genetic tests unless she chooses to solicit these tests on a fee-for-service basis. The FDA system could retain several centers that do

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167. Cf. Jalbert, *supra* note 139, at 273 (recommending that donor evaluations be conducted by physicians trained in genetic counseling to avoid unnecessary rejection of donors); Peterson, *supra* note 65, at 90 (same).

168. Jalbert, *supra* note 139, at 271. Such defects include severe dominant conditions, chromosomal abnormalities, confirmed heterozygosity for an autosomal recessive disease, and perhaps even probable heterozygosity for common and serious conditions, such as cystic fibrosis. *See id.*

169. *See id.*

170. The FDA would only establish testing centers for the most commonly tested diseases, such as cystic fibrosis, diabetes, hemophilia, Huntington's disease, muscular dystrophy, and Tay-Sachs disease, identified by Curie-Cohen, *supra* note 27, at 585, as the diseases most frequently cited by couples seeking AI for genetic reasons. However, the FDA advisory group should examine medical trends to determine whether this list accurately reflects the needs of the AI community and innovations in genetic technology.

171. *See generally* Ziporyn, *supra* note 139, at 14 (discussing costs, in 1986, of genetic testing of donors).

not perform specialized genetic chromosome testing for those recipients who are not concerned with genetic screening. These centers nonetheless would be required to take rigorous genetic histories of all donors.

Because the sperm donor centers would function as a cooperative unit under this proposed system, the FDA could transport sperm samples from state to state as needed. The AFS guidelines limit donor use to ten pregnancies to reduce the chance that two half-siblings will unwittingly marry.<sup>172</sup> Under this cooperative structure, the FDA may be able to increase the number of pregnancies permitted per donor, because the FDA could dilute the donor pool by dispersing samples from each individual to donor centers in different parts of the country. Permitting greater use of each donor not only increases the number of available sperm samples, but also makes heightened donor screening more economically feasible.

#### *D. More Relaxed Standards for the Disclosure of Non-identifying Donor Information*

Even with more rigorous genetic testing standards, the proposed sperm donor system will not guarantee that every child born from AI would be free from disease, genetic or otherwise.<sup>173</sup> Therefore, it is important to the well-being of both AI recipients and their offspring that donor facilities and practitioners allow them to trace their respective genetic and medical histories.<sup>174</sup> The proposed FDA-regulated system must establish a better flow of information between AI donors, couples, and children by requiring AI practitioners to maintain better records of the procedure, and by requiring the release of any non-identifying information that the FDA deems appropriate. Historically, complete confidentiality has

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172. See American Fertility Soc'y, *supra* note 6, at 4S.

173. Cf. Peterson, *supra* note 65, at 92 (concluding that federal regulation is likely to reduce significantly the spread of disease). Scientists have not found genetic links for most disorders, and cannot prevent most congenital abnormalities. See *Genetic Testing*, *supra* note 153, at 80.

174. See generally Swanson, *supra* note 13, at 184-90 (recommending legislation for record-keeping in the AI industry).

been considered an "important requisite" to the donor insemination procedure.<sup>175</sup> As one clinician has explained:

It is our practice to destroy all records after 1 year to ensure confidentiality and to prevent either the donor seeking out any resultant offspring or the reverse. Because only donors with a negative medical and genetic history are used, we feel that providing medical data about them is unnecessary. Furthermore, we believe that anonymity is one of the most important requisites of this procedure.<sup>176</sup>

According to Curie-Cohen's study on AI practices,<sup>177</sup> only 36.9% of responding doctors maintained any records on children born by AI, and even a smaller percentage of doctors (30.4%) kept records on the donors.<sup>178</sup> This resistance to disclosure may have stemmed either from the fear that donors would be held financially responsible for the children born by AI,<sup>179</sup> or from the opposition to AI expressed by many major religions.<sup>180</sup> Yet many state statutes have eliminated the threat of the donor's financial responsibility by mandating that a child born by AI should be deemed the natural child of the AI recipient and her husband and not of the donor.<sup>181</sup>

1. *Concerns about donor-recipient anonymity*—A survey by the AI Research Project determined that doctors, rather than AI couples, show the most concern about maintaining anonymity in the AI process.<sup>182</sup> The donors themselves are more willing to provide personal information to doctors, AI

175. Andrews & Douglass, *supra* note 93, at 659; see Swanson, *supra* note 13, at 154–55 (discussing historical practice of donor anonymity).

176. Randall A. Loy & Mabelle M. Seibel, *Therapeutic Insemination, in INFERTILITY: A COMPREHENSIVE TEXT* 199, 208 (Mabelle M. Seibel ed., 1990).

177. See *supra* Part II.A.

178. See Curie-Cohen, *supra* note 27, at 588.

179. See Andrews & Douglass, *supra* note 93, at 660.

180. See Swanson, *supra* note 13, at 164–68. The Catholic Church, the Eastern Orthodox Church, many denominations of Protestantism, the Episcopal Church, many branches of the Evangelical and Baptist Churches, Judaism, and Islam have expressed opposition to AI. See *id.*

181. See *id.* at 162 (discussing the Uniform Parentage Act, which, as of 1993, had been adopted by 18 states).

182. See GENA COREA, *THE MOTHER MACHINE* 53–54 (1985); see also Swanson, *supra* note 13, at 171–73 (discussing physicians' concern about maintaining donor anonymity); Ziporyn, *supra* note 139, at 14 (same).

couples, and AI children than previously believed.<sup>183</sup> Under the proposed FDA regulated system, physician-patient confidentiality would require the AI practitioner to restrict access so that only the parties involved in the procedure could obtain the medical records.<sup>184</sup> In addition, donors and recipient couples who wish to protect their privacy could instruct the AI practitioner to restrict access to any identifying information absent any medical emergency that would necessitate limited disclosure.<sup>185</sup> Therefore, the interchange of non-identifying information about donors, recipient couples, and AI offspring would create few conflicts of interest among AI participants.

*2. Interests served by the release of non-identifying AI records*—The release of non-identifying information serves several important interests of the AI donor and child, and of the medical community itself. First of all, children born by AI have an interest in learning about their family medical histories.<sup>186</sup> Doctors use this information to advise their patients on their risks of developing certain diseases, and whether patients should alter their behavior to prevent certain health problems.<sup>187</sup> In addition, disclosing this information may reveal the identity of a relative who can provide a suitable match for lifesaving transplant procedures.<sup>188</sup>

Both AI donors and children also have a parallel interest in the release of any genetic information that would enable them to prevent future children from developing genetic disease. If the donor unknowingly passes a disease gene to his AI offspring, he should be notified so he can make

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183. See Swanson, *supra* note 13, at 171. Ninety percent of donors surveyed allowed physicians to record extensive information about their medical, social, educational, and personal histories. Further, 96% of this sample agreed to release this non-identifying information to the recipient couple and resultant child, and 60% allowed disclosure of their identity to the child when he or she reaches the age of majority. Only 29% of the donors required anonymity, while 36% agreed to donate sperm, regardless of any guarantee of anonymity. See *id.* at 171 & nn.135-41.

184. See *id.* at 186-90. Access to the records should be determined on the basis of "the person requesting it, the substance of the information sought, and the reasons for which the requesting person asks for it." *Id.* at 187.

185. See *id.* at 187, 189. A medical emergency, such as the need for a bone marrow or organ transplant, may necessitate limited disclosure of identifying information. See *id.* at 174.

186. See Swanson, *supra* note 13, at 174.

187. See *id.*

188. See *id.* at 175.

educated genetic choices about his future procreation.<sup>189</sup> The AI child also needs to know his or her complete genetic history in order to make informed reproductive choices.<sup>190</sup> He or she may marry accidentally a half-sibling, or, if the AI child is female, she may marry her own biological father.<sup>191</sup> Finally, without proper record keeping and follow-up of AI procedures, the FDA and AI practitioners cannot track the success of the current donor system, or propose changes to provide better protection for future treatments.<sup>192</sup> It is important to ensure the privacy of AI donors, recipients, and children; yet these privacy interests must be weighed against the numerous interests served by heightened documentation and disclosure.

One of the most important aspects of a regulated sperm donor system is the full disclosure of all medical information, whether from AI recipient to physician or from potential donor to sperm bank. Increasing the flow of medical information from biological child to biological parent, and vice versa, is consistent with this spirit of disclosure and will help to ensure that the AI system is as safe as possible for all involved parties.

## CONCLUSION

The current system of artificial insemination by donor is plagued with problems caused by the lack of universal regulation, insufficient donor screening techniques for both contagious and genetic disease, inadequate record-keeping procedures, and disclosure requirements that fail to reflect the interests of the parties involved. Continued self-regulation of procedures by AI practitioners will jeopardize the integrity of this multi-million dollar industry by failing to provide sufficient medical protection for AI donors, recipients, or the children born from the procedure.

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189. *See id.*

190. *See id.* at 177.

191. *Id.* at 177. To decrease the likelihood of incest, the AFS has recommended limiting each donor to 10 successful inseminations, and less than 10 if donation use is concentrated in an isolated subgroup. *See American Fertility Soc'y, supra* note 6, at 4S.

192. *See Swanson, supra* note 13, at 182.

By implementing a national sperm donor system regulated by the FDA, Congress could ensure that all individuals who seek AI would know that the donor sperm samples they receive have met rigorous biological and genetic screening standards, regardless of the state or setting in which they undergo the procedure. The United States Supreme Court has ruled that the right to procreate is "fundamental to the very existence and survival of the race."<sup>193</sup> Congress should take steps to ensure that individuals are also guaranteed the right to procreate safely, no matter which method of reproduction they choose.

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193. *Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942).

