

# Conceiving a National Gamete Donor Registry: Policy Considerations, Privacy Concerns, and Legal Authority

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# CONCEIVING A NATIONAL GAMETE DONOR REGISTRY: POLICY CONSIDERATIONS, PRIVACY CONCERNS, AND LEGAL AUTHORITY

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## I. INTRODUCTION

*“When my wife and I met in college, the attraction was immediate, and we quickly became inseparable. . . . We married soon after graduation . . . and had three children by the time we were 30. We were both born to lesbians, she . . . had sought out her biological father as soon as she turned 18, as the sperm bank her parents used allowed contact once the children were 18 if both parties consented. I decided to . . . see if my biological father was interested in contact as well. He was, and even though our parents had used different sperm banks, it appears so did our father, as he is the same person. . . . I can’t help but think “This is my sister” every time I look at her now. . . . Please help me figure out where to go from here.”<sup>1</sup>*

The scenario described in the advice column above, which Professor Naomi Cahn refers to as “accidental incest,”<sup>2</sup> is one of the three main justifications for establishing a nationwide registry to systematically track sperm, egg, and embryo (hereinafter referred to as “gamete”) donors and the results of those donations.

Advocates argue that a donor gamete registry, in addition to preventing accidental incest, would facilitate increased access to donors’ medical history and outcomes of their previous donations. This information would benefit intended parents and their resulting offspring by informing their reproductive and medical decisions.<sup>3</sup> Consider the case of Anne Morriss and Frances Frei. Their son, who was conceived with donor sperm purchased from a well-known sperm bank, has medium-chain acyl-CoA dehydrogenase deficiency (MCADD), a rare genetic disease that prevents the body from converting fats into sugar.<sup>4</sup> MCADD is a recessive trait, meaning that it develops if “a child inherits two flawed copies of a gene, one from each parent,” which has a 25% chance of occurring if both parents are carriers.<sup>5</sup> Morriss was unaware that she was an MCADD carrier until her son was born, and the sperm donor is probably still unaware that he is an MCADD carrier.<sup>6</sup>

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<sup>1</sup> **Emily Yoffe**, *Dear Prudence: My Wife Is My Sister*, **Slate**, Feb. 19, 2013, 6:15AM, [http://www.slate.com/articles/life/dear\\_prudence/2013/02/dear\\_prudence\\_my\\_wife\\_and\\_i\\_came\\_from\\_the\\_same\\_sperm\\_donor.html](http://www.slate.com/articles/life/dear_prudence/2013/02/dear_prudence_my_wife_and_i_came_from_the_same_sperm_donor.html).

<sup>2</sup> See generally Naomi Cahn, *Accidental Incest: Drawing the Line—Or the Curtain?—For Reproductive Technology*, 32 **HARV. J.L. & GENDER** 59, 59–60 (2009) (quoting Libby Purves, *Whose Body is it Anyway?*, **The Times**, Jan. 15, 2008, available at <http://www.thetimes.co.uk/tto/opinion/columnists/libbypurves/article2043028.ece>) [hereinafter Cahn, *Accidental Incest*].

<sup>3</sup> Michelle Dennison, *Revealing Your Sources: The Case for Non-Anonymous Gamete Donation*, 21 **J.L. & HEALTH** 1, 14–15 (2007).

<sup>4</sup> **Carolyn Y. Johnson**, *Company Seeks to Make Sperm Banks Safer*, **Bos. Globe**, Oct. 14, 2013, <http://www.bostonglobe.com/lifestyle/health-wellness/2013/10/13/company-seeks-make-sperm-banks-safer-but-raises-questions-about-preconception-dna-testing/rIV2rypd3NnRRYQdeszR1M/story.html>; **Paul Rincon**, *Genepeeks Firm to Offer “Digital Baby” Screen for Sperm Donors*, **BBC News: Science & Environment**, Oct. 4, 2013, <http://www.bbc.co.uk/news/science-environment-24398312>.

<sup>5</sup> Johnson, *supra* note 4.

<sup>6</sup> See, e.g., **Jennifer Bleyer**, *A Conception Conundrum*, **Psychol. Today**, Nov. 5, 2013, at 78, 85, available at <http://www.psychologytoday.com/articles/201310/conception-conundrum> (noting “dozens of documented cases” where donated sperm is still on the market even though children

While sperm banks screen donors for the most common genetic diseases, they do not currently screen donors to see if they are recessive carriers for rare genetic conditions. Morriss has now cofounded GenePeeks, a company that simulates the reproductive process to determine the hypothetical offspring's risk for single-gene recessive conditions. This information will inform intended parents' choice of donor by signaling out donors whose genetic material, when combined with the donor's sperm or egg, could result in illness. A gamete donor registry would allow parents to view this information prior to purchasing donor gametes, and allow the donor and any resulting children to share relevant medical history or genetic information with each other and with any other donor offspring.

Finally, children born from gamete donations are increasingly borrowing from the adoption rights movement<sup>7</sup> in claiming a psychological benefit from knowing (perhaps even a right to know) their genetic origins, including the identifying information of their gamete donors,<sup>8</sup> and to establish relationships with their genetic half-siblings. Consider *Generation Cryo*, a new reality show on MTV that “follows Breeanna, daughter of a lesbian couple who was conceived through sperm donation—‘Grandma signed for the sperm,’ her parents tell her—on a search to connect with her genetic half siblings and, ultimately, her sperm donor.”<sup>9</sup> Family law is not necessarily equipped to handle these demands.<sup>10</sup> The legal limitations of guaranteeing a “right to know” one's genetic origins do not diminish the psychological importance of genetic ties for identity formation.<sup>11</sup> A gamete donor registry would facilitate these connections for those who want to make them.

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conceived with that sperm suffer from genetic conditions); **Nathalia Holt**, *Weaving together the DNA of parenthood*, **SciLogs**, Oct. 31 2012, available at <http://www.sciloggs.com/backstory/weaving-together-the-dna-of-parenthood/> (discussing how a parent may unknowingly carry a recessive trait such as MCADD).

<sup>7</sup> Naomi Cahn, *Necessary Subjects: The Need for a Mandatory National Donor Gamete Databank*, 12 DePaul J. Health Care L. 203, 213–214 (2009) [hereinafter Cahn, *Necessary Subjects*].

<sup>8</sup> Dennison, *supra* note 3, at 16–19.

<sup>9</sup> Jon Caramanica, *Half Siblings Linked by a Mystery Father: MTV's "Generation Cryo" Links Families*, **N.Y. Times**, Nov. 24, 2013, [http://www.nytimes.com/2013/11/25/arts/television/mtvs-generation-cryo-links-families.html?\\_r=0](http://www.nytimes.com/2013/11/25/arts/television/mtvs-generation-cryo-links-families.html?_r=0).

<sup>10</sup> For example, the Supreme Court of Appeals of West Virginia recently dismissed a petition asserting a right to sibling visitation with the petitioner's half-sibling who was conceived with the same anonymously-donated sperm because the state's custody and visitation statute only confers parents, not siblings, with visitation rights. *Bobbie Jo R. v. Traci W.*, No. 11-1753, 2013 WL 2462173 at \*2 (W. Va. June 7, 2013)(unpublished opinion)(dismissing a petition asserting a right to sibling visitation with the petitioner's half-sibling who was conceived with the same anonymously-donated sperm because the state's custody and visitation statute only confers parents, not siblings, with visitation rights).

<sup>11</sup> Jean Benward et al., *Maximizing Autonomy and the Changing View of Donor Conception: The Creation of a National Donor Registry*, 12 DePaul J. Health Care L. 225, 232–34 (2009). *But see* H.M.W. Bos & N.K. Gartrell, *Adolescents of the U.S. National Longitudinal Lesbian Family Study: The Impact of Having a Known or an Unknown Donor on the Stability of Psychological Adjustment*, 26 **HUM. REPROD.** 630, 636 (2011) (“Our findings indicate that donor type has no bearing on the development of the psychological well-being of the offspring of lesbian mothers over a 7-year period from childhood through adolescence.”).

In the last few years, dozens of academics, practitioners, and students have written law review articles debating the merits and pitfalls of anonymous gamete donation. Those in favor of non-anonymous gamete donation often advocate two concomitant policy proposals: the creation of a national gamete donor registry,<sup>12</sup> and a requirement that all gamete donations be “open”—that the resulting children have access to their donors’ information at the age of majority.<sup>13</sup> Those against mandatory open gamete donation argue that this policy would compromise the fundamental privacy rights of both the intended parents and the donors.<sup>14</sup> As scholars debate the merits of mandatory open gamete donation, the assisted reproductive technology (ART) industry is trending toward non-anonymous gamete donation. More clinics are providing an open donation option,<sup>15</sup> donor-conceived children and their parents are creating or joining private online donor registries to find their genetic relatives.<sup>16</sup> Donor-conceived children are using the Internet to track down their donors, regardless of whether the clinic guaranteed donor anonymity.<sup>17</sup> Despite the real consumer demand for more information about gamete donors, the current ad-hoc response to this demand is inadequate because participation in existing registries is voluntary and the donor medical history that clinics and banks require is not systematically tracked across different clinics or after donation occurs.<sup>18</sup>

Given these shortcomings, the United States needs a national donor gamete registry to standardize information across states and industry, provide equal access to donor information, and facilitate connections with genetic relatives while respecting the privacy rights of donors and parents. This paper proposes a national donor gamete

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<sup>12</sup> Cahn, *Necessary Subjects*, *supra* note 7, at 223.

<sup>13</sup> *Id.* But see Mary Patricia Byrn & Rebecca Ireland, *Anonymously Provided Sperm and the Constitution*, 23 COLUM. J. GENDER & L. 1 (2012) (arguing that while a donor registry is good policy, offspring do not have a right to know a donor’s identity).

<sup>14</sup> Nicole J. Messing, Note, *Protecting a Man’s Right to Choose: Why Mandatory Identity Release for Sperm Donors Is a Bad Idea*, 16 MICH. ST. U. J. MED. & L. 429 (2012) (arguing against mandatory identity release legislation because it would violate individuals’ constitutionally protected right to privacy with regard to reproduction); Julie L. Sauer, Comment, *Competing Interests and Gamete Donation: The Case for Anonymity*, 39 SETON HALL L. REV. 919 (2009) (arguing that states should balance the privacy interests of parents, children, and donors by permitting, but not requiring, open donation).

<sup>15</sup> Andrea Mechanick Braverman, *How the Internet Is Reshaping Assisted Reproduction: From Donor Offspring Registries to Direct-to-Consumer Genetic Testing*, 11 MINN. J. L. SCI. & TECH. 477, 485 (2010).

<sup>16</sup> DONOR SIBLING REGISTRY, <https://www.donorsiblingregistry.com> (last visited Jan. 3, 2014).

<sup>17</sup> Dawn R. Swink & J. Brad Reich, *Caveat Vendor: Potential Progeny, Paternity, and Product Liability Online*, 2007 BYU L. REV. 857, 857–58 (2007) (“Recently a fifteen-year-old boy decided to track down his genetic father. He sent a swab of his own saliva to an online DNA lab. He waited nine months for initial results to return. He then gathered additional information from his mother about his sperm donor father (year of birth, hometown, and surname) and commissioned an online investigation service to determine the true match. Within ten days, the boy met his biological father. Is this an isolated case? No.”).

<sup>18</sup> See **Rene Almeling**, *The Unregulated Sperm Industry*, N.Y. TIMES, Nov. 30, 2013, <http://www.nytimes.com/2013/12/01/opinion/sunday/the-unregulated-sperm-industry.html> [hereinafter Almeling, *The Unregulated Sperm Industry*] (“In the United States, we do not track how many sperm donors there are, how often they donate, or how many children are born from the donations.”).

registry that mandates a basic level of donor participation, but does not require donors to disclose any identifying information or impose a post-donation obligation to update their medical histories unless they agree to do so. This approach, while modest, would be a huge step forward from the current laissez-faire state of gamete donation. It would respond to the three main consequences of donor anonymity—accidental incest, limited access to medical history, and the psychological desire to know one’s genetic origins—without establishing undue state intrusion into the protected rights associated with individual health information and family privacy.

This paper will fill a gap in the literature by delving into the concrete details of what a national donor gamete registry would actually look like, the legal authority for establishing it, and how it would be implemented. A national gamete donor registry raises several legal and policy questions. Should all clinics and donors be required, or merely encouraged, to participate in the registry? What are the HIPAA implications of creating such a registry? Would only donors and offspring have access to the registry, or would it also be open to clinics, researchers, or commercial entities, or even the public at large? Does the federal government already have the authority to establish a registry pursuant to the U.S. Centers for Disease Control and Prevention’s (CDC’s) authority under the Fertility Clinic Success Rate & Certification Act (FCSRCA), or the Food and Drug Administration’s (FDA’s) regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), or would Congress have to pass a statute? This paper will analyze these questions by considering the U.S. Department of Health and Human Services’ (HHS’s) increased authority over and involvement with post-market patient and product registries and other electronically stored health information, as well as FDA’s assertion of authority over novel ART procedures, to contextualize a national donor gamete registry within the current regulatory atmosphere.

With these legal and policy considerations in mind, this paper proposes that the FDA and the CDC, in collaboration with the American Society for Reproductive Medicine (ASRM), establish a national donor gamete registry that employs a tiered approach to the disclosure of donor information. Tier I would require all fertility clinics and donor gamete banks to disclose donors’ health and screening information (that they already collect pursuant to FDA regulations) at the time of donation. In addition, Tier I would mandate that clinics and banks input how many times a donor’s gametes had been used for conception, and whether that process had resulted in a successful pregnancy and birth. Finally, Tier I would set a national limit on the number of offspring born from any one donor’s contributions.

At the time of donation, the donor would be able to select whether his or her data could be used for research purposes, and would have the option of “upgrading” to a higher tier by agreeing to disclose more information. Tier II would consist of further disclosure of non-medical personal history and physical characteristics, which many donors already disclose to sperm banks (e.g., race, height, weight, education, profession, baby picture, clinic’s impressions of donor, etc.). Tier III would require a more complete medical history beyond what the FDA currently requires and would allow the donor to continually upgrade his or her health information and medical history after donation. Finally, Tier IV would retain the donor’s identifying information and make that information available to any resulting children at the age of eighteen (if so requested). Regardless of tier, all

children born from donor gametes would be able to view their donor's profile, "link" to that profile to identify oneself as the progeny of that donor to connect to other children born from the same donor (and thus prevent accidental incest), and disclose any relevant genetic condition or medical history that they wish to share.

Part II of this paper summarizes the FDA's and the CDC's current authority over ART, provides background on the donor gamete industry, and introduces the privately-run Donor Sibling Registry. Part III discusses in further detail the policy justifications for a gamete donor registry. Part IV provides an overview of HHS's increasing involvement with post-market product and patient registries, as well as the health privacy concerns involved in this increased surveillance. Part V proposes a national gamete donor registry—a public-private partnership between the CDC, the FDA, and the Society for Assisted Reproductive Technology (SART). Part VI explains the legal authority for creating such a registry, as well as its health privacy implications. Ultimately, this paper contends that a national donor gamete registry would represent an incremental change to existing ART regulation that would complement HHS's existing reliance on post-market surveillance.

## II. ASSISTED REPRODUCTIVE TECHNOLOGY: REGULATORY OVERSIGHT & INDUSTRY PRACTICE

### A. Fertility Clinic Success Rate & Certification Act

Approximately 61,610 infants, or 1.56% of the total infants born in the United States in 2011,<sup>19</sup> were born as a result of assisted reproductive technology (ART).<sup>20</sup> Despite the exponential growth of ART, a \$3 billion dollar industry in the United States,<sup>21</sup> Congress has passed only a single law governing the industry: the Fertility Clinic Success Rate Certification Act of 1992 (FCSRCA).<sup>22</sup> The Act's objective is to prevent fertility clinics from inflating their success rates to attract consumers.<sup>23</sup> FCSRCA serves two main purposes: (1) it instructs the CDC to develop a model embryo laboratory certification program for states to adopt on a voluntary basis,<sup>24</sup> and (2) it requires that all ART

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<sup>19</sup> BRADY E. HAMILTON ET AL., CTNS. FOR DISEASE CONTROL AND PREVENTION, DEP'T OF HEALTH & HUMAN SERVS., BIRTHS: PRELIMINARY DATA FOR 2011 (National Vital Statistics Report, Vol. 61, No. 5, Oct. 3, 2012), available at [http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61\\_05.pdf](http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_05.pdf).

<sup>20</sup> *Assisted Reproductive Technology (ART)*, CDC, <http://www.cdc.gov/art/> (last visited Nov. 3, 2013).

<sup>21</sup> *Issues: Assisted Reproductive Technologies, Pro-Choice Alliance for Responsible Research*, <http://prochoicealliance.org.s66061.gridserver.com/Assisted-Reproductive-Technologies> (last visited Nov. 5, 2013).

<sup>22</sup> Fertility Clinic Success Rate Certification Act of 1992 (FCSRCA), Pub. L. No. 102-493, 106 Stat. 3146 (codified at 42 U.S.C. §§ 201, 263a(1-7) (2012)).

<sup>23</sup> See Brenda Reddix-Small, *Assessing the Market for Human Reproductive Tissue Alienability: Why Can We Sell Our Eggs But Not Our Livers?*, 10 VAND. J. ENT. & TECH. L. 643, 659 (2008).

<sup>24</sup> FCSRCA § 3, 42 U.S.C. § 263a-2. No state has adopted the certification program. Yaniv Heled, *The Regulation of Genetic Aspects of Donated Reproductive Tissue: The Need for Federal Regulation*, 11 COLUM. SCI. & TECH. L. REV. 243, 251 n.38 (2010).

programs annually report their pregnancy success rates<sup>25</sup> to the CDC, which must publish this information in a publicly-available annual report.<sup>26</sup> The Act delegates authority to the CDC to establish procedures to approve outside accreditation organizations to inspect and certify embryo laboratories on its behalf.<sup>27</sup> FCSRCA explicitly prohibits the CDC from regulating the practice of ART medicine in developing its embryo laboratory certification program.<sup>28</sup> Although Congress defined ART for purposes of the statute,<sup>29</sup> it unequivocally delegated authority to HHS to amend the definition through notice-and-comment procedures.<sup>30</sup> In its final notice concerning pregnancy success reporting requirements, the CDC clarified that ART does not include artificial insemination;<sup>31</sup> therefore, ART clinics do not have to report pregnancy success rates for patients who only receive donor sperm (e.g., use their own eggs and do not undergo IVF).

To collect ART clinic data on pregnancy success rates, CDC chose to partner with the Society for Assisted Reproductive Technology (SART), a national ART professional organization that had started collecting similar cycle-specific data from its members in 1986.<sup>32</sup> Building on this practice, the CDC's original contract with SART mandated that SART perform random validation site visits to reporting clinics.<sup>33</sup> In response to commenters' concerns about the CDC "ceding its regulatory authority to a private entity," the CDC explained that its partnership with SART, and reliance on its existing data system, would be more efficient than duplicating clinics' reporting burdens by creating another reporting system; the CDC emphasized that it would "maintain[] ultimate control and authority" over the data collection and validation process.<sup>34</sup> In 2006, the CDC launched the National ART Surveillance System (NASS) to collect ART data, though SART member clinics may still report their data to SART, which in turn reports it to NASS.<sup>35</sup> The CDC still refers to SART, as well as the American Society for Reproductive Medicine (ASRM) (SART's parent organization), as partners

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<sup>25</sup> Basically, the number of live births per the number of ovarian stimulation procedures or oocyte retrieval procedures. FCSRCA § 2(b)(2), 42 U.S.C. § 263a-1(b)(2).

<sup>26</sup> FCSRCA § 6, 42 U.S.C. § 263a-5.

<sup>27</sup> FCSRCA § 4, 42 U.S.C. § 263a-3.

<sup>28</sup> *Id.* § 3(i), 42 U.S.C. § 263a-2(i).

<sup>29</sup> "The term 'assisted reproductive technology' means all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer . . ." FCSRCA § 8(1), 42 U.S.C. § 263a-7(1).

<sup>30</sup> FCSRCA § 8(1), 42 U.S.C. § 263a-7(1).

<sup>31</sup> Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs, 65 Fed. Reg. 53,310, 53,313 (Sept. 1, 2000).

<sup>32</sup> *Id.* at 53,311.

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *National ART Surveillance*, CTNS. FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/art/NASS.htm>(last updated July 24, 2012).

who are involved in framing the surveillance and research questions and in collecting and reporting data from member clinics. Other important partners who represent consumers of ART and infertility services include RESOLVE . . . , the American Fertility Association . . . , and most recently, Fertile Hope . . . . These organizations provide ongoing consultations about the ART Report and its use for public health communications and education.<sup>36</sup>

In addition to the pregnancy success rate data, the CDC also requires that ART clinics report data on whether they provide ART services to single women, their patients' ethnicities, and whether they are members of SART, as well as whether the ART clinics use laboratories that are accredited by three industry accreditation programs.<sup>37</sup> The FCSRCA itself does not mandate collection of any data beyond pregnancy success rates. In response to commenters' concerns that ART clinics were being required to report too much information, the CDC explained that its reporting requirements were developed "with consideration for the spirit" of the FCSRCA.<sup>38</sup> The CDC explained that it was mandating provision of the information "as a public service" because stakeholders had indicated that such information is useful and would assist consumers in a "thorough and complete analysis, which will help in their goal of making an informed decision about ART."<sup>39</sup> The CDC thus already has a policy of requiring ART clinics to report more information than the FCSRCA mandates.

## **B. FDA's Human Cells, Tissues, & Cellular & Tissue-Based Products Regulation**

In 1997, the FDA asserted its authority over donor gametes, along with other human cells, tissues, and cellular and tissue-based products (HCT/Ps), when it published a proposed regulatory scheme for cellular and tissue-based products pursuant to its regulatory authority over biologics.<sup>40</sup> The FDA's first regulation established a mandatory registration and listing program for HCT/Ps.<sup>41</sup> The FDA employed a "tiered, risk-based approach . . . to exert only the type of government regulation necessary to protect the public health."<sup>42</sup> Some HCT/Ps—including donor gametes<sup>43</sup>—are regulated only to the extent that they pose a risk of communicable disease transmission under Section 361 of the Public Health Service Act (PHSA). The FDA regulates other HCT/Ps under a broader scope of authority as biological products under Section 351 of the PHSA or as

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<sup>36</sup> *Id.*

<sup>37</sup> Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs, 65 Fed. Reg. at 53,313.

<sup>38</sup> *Id.* at 53,312.

<sup>39</sup> *Id.*

<sup>40</sup> FDA, PROPOSED APPROACH TO REGULATION OF CELLULAR AND TISSUE-BASED PRODUCTS 6 (1997).

<sup>41</sup> *See generally* Human Cells, Tissues and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447 (Jan. 19, 2001) (codified at 21 C.F.R. pt. 1271).

<sup>42</sup> *Id.* at 5448.

<sup>43</sup> FDA, GUIDANCE FOR INDUSTRY: REGULATION OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps), SMALL ENTITY COMPLIANCE GUIDE 4 (2007) (including "reproductive cells and tissues (e.g., semen, oocytes, embryos)" in its list of HCT/Ps regulated solely under Section 361 of the Public Health Service Act (PHSA)).

drugs or devices under Section 510 of the Food, Drug, and Cosmetics Act (FDCA).<sup>44</sup> Various ART providers and clinics objected to the FDA's regulation of donor gametes given the Fertility Clinic Success Rate Certification Act's prohibition on regulating the practice of ART medicine.<sup>45</sup> In response, the FDA claimed that this regulation would not be "duplicative" because the FCSRCA does not focus on the prevention of communicable disease transmission.<sup>46</sup> The second HCT/P regulation established mandatory screening and testing procedures for tissue donors to prevent communicable disease transmission.<sup>47</sup> Donor gametes must be screened for HIV, Hepatitis B, Hepatitis C, syphilis, Chlamydia, and gonorrhea; donated sperm must also be screened for Human T-lymphotropic virus and cytomegalovirus.<sup>48</sup> In addition, HCT/P establishments must conduct a "donor medical history interview" to screen the gamete donor's medical records and relevant social behavior for communicable disease risk factors.<sup>49</sup> These testing and screening requirements do not apply to gametes donated for autologous (one's own) use, for use by a sexually intimate partner, or to embryos donated by individuals who did not undergo a donor-eligibility determination<sup>50</sup> when they donated the original sperm or eggs that resulted in the embryo(s).<sup>51</sup> If a gamete donor is donating to a specific person, the FDA does not prohibit that donor from doing so, even if he or she fails the

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<sup>44</sup> Human Cells, Tissues and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. at 5448–49; *see also* Richard A. Merrill, *Human Tissues and Reproductive Cloning: New Technologies Challenge FDA*, 3 HOUS. J. HEALTH L. & POL'Y 1, 12, 15 (2002) (noting the expansive statutory definitions of biological products and devices).

<sup>45</sup> *E.g.*, Comment on Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products from András Z. Széll, Alta Bates Med. Ctr., to Dockets Mgmt. Branch, FDA (Jan. 26, 1999), *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-1997-N-0011-0041>; Comment on Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products from Wayne S. Maxson, Nw. Ctr. for Infertility and Reprod. Endocrinology, to Dockets Mgmt. Branch, FDA (Jan. 13, 1999), *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-1997-N-0011-0040>. Another fertility doctor's comment asserted that the registration requirements should not apply to in vitro fertilization or egg retrieval or donation because those medical practices involve treating patients, not manufacturing products, and the FDA does not have the mandate to regulate the practice of medicine. Comment on Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products from Sherman J. Silber to Dockets Mgmt. Branch, FDA (Jan. 8, 1999) *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-1997-N-0011-0038>.

<sup>46</sup> Human Cells, Tissues and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. at 5452–53.

<sup>47</sup> Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 69 Fed. Reg. 29,786 (May 25, 2004) (codified at 21 C.F.R. pt. 1271). The FDA's third HCT/P regulation established practices and methods for HCT/P manufacture, recordkeeping, labeling, and reporting. Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement, 69 Fed. Reg. 68,612 (Nov. 24, 2004) (codified at 21 C.F.R. pt. 1271, subpart D–E).

<sup>48</sup> FDA, COMPLIANCE PROGRAM GUIDANCE MANUAL: INSPECTION OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS), ATTACHMENT C—DONOR TESTING (2012).

<sup>49</sup> FDA, GUIDANCE FOR INDUSTRY: ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) 11 (2007).

<sup>50</sup> "A conclusion that a donor is either eligible or ineligible to donate cells or tissues to be used in an HCT/P, based on the results of donor screening . . . and testing . . ." *Id.* at 2.

<sup>51</sup> 21 C.F.R. §§ 1271.90(a)(2)–(3) (2012).

donor-eligibility determination, as long as the clinic ensures the recipient's informed consent.<sup>52</sup> In summary, the FDA established its intent to regulate donor gametes solely for the purpose of preventing communicable disease, not to assert authority over ART procedures themselves.

### C. The Donor Gamete Industry

Donor gametes include sperm, eggs, and embryos. Donor sperm is by far the most common donor gamete because the “low-tech” artificial insemination procedure has been around for decades.<sup>53</sup> However, as medical and storing technology advances, the donor egg market is increasing.<sup>54</sup> Embryo donation for procreation is frequently offered as an option for unused embryos after an IVF cycle. As of 2003, there were approximately 400,000 embryos in storage in IVF clinics in the United States.<sup>55</sup> While that number has likely grown over the past decade, only about two percent, or 8,000 of those 400,000 embryos, were designated for donation for procreation.<sup>56</sup> My proposal for a donor gamete registry includes sperm, egg, and embryo donors because all three types raise the same policy concerns.<sup>57</sup> Before addressing these concerns, it is useful to understand the basics of the egg and sperm donor markets.

The egg and sperm donor markets are very selective. Sperm banks claim that they accept only one to two percent of men who apply,<sup>58</sup> while egg banks reject over eighty percent of applicants.<sup>59</sup> Most sperm banks, in addition to requiring that donors have high sperm counts to survive the cryogenic freezing process, require donors to “be between the ages of eighteen and thirty-eight, be a minimum height (usually around 5’8”), have a college degree or be a currently enrolled college student, not use tobacco or alcohol heavily, and be able to make weekly visits to the sperm bank to donate for some minimum period.”<sup>60</sup> Most sperm and egg donors are young, single, and White.<sup>61</sup> Sperm donors are usually college-educated, while egg donors “have lower levels of education and socioeconomic status than do sperm donors, and are more likely to have children of their own.”<sup>62</sup>

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<sup>52</sup> *Id.* §1271.65(b)(1)(ii).

<sup>53</sup> *Cf.* SUSAN L. CROCKIN & HOWARD W. JONES, LEGAL CONCEPTIONS: THE EVOLVING LAW AND POLICY OF ASSISTED REPRODUCTIVE TECHNOLOGIES 133 (2010) (noting that “both legislatures and courts have had decades of experience” dealing with the legal issues surrounding sperm donation).

<sup>54</sup> Almeling, *The Unregulated Sperm Industry*, *supra* note 18 (“Now that scientists have figured out how to successfully freeze eggs, egg banks are being established, and the scale of production may eventually lead to the same challenges sperm banks face.”).

<sup>55</sup> David I. Hoffman et al. *Cryopreserved Embryos in the United States and Their Availability for Research*, 79 *Fertility & Sterility* 1063, 1066 (2003).

<sup>56</sup> *Id.*

<sup>57</sup> *See infra* Part III.

<sup>58</sup> Bleyer, *supra* note 6, at 82.

<sup>59</sup> Rene Elmeling, *Selling Genes, Selling Gender: Egg Agencies, Sperm Banks, and the Medical Market in Genetic Material*, 72 *AM. SOC. REVIEW* 319, 328 (2007) [hereinafter Almeling, *Selling Genes, Selling Gender*].

<sup>60</sup> Kimberly D. Krawiec, *Sunny Samaritans and Egomaniacs: Price-Fixing in the Gamete Market*, 72 *LAW & CONTEMPORARY PROBLEMS* 59, 69 (2009).

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 64, 69.

Because the pool of eligible sperm donors is so small, sperm banks require men to donate sperm over a period of time, usually nine months to a year, “resulting in large caches of genetic material that can produce tens and perhaps even hundreds of offspring.”<sup>63</sup> Receiving around \$75 per donation, which they make one to two times per week, sperm donors can make over \$7,000 over the course of a year.<sup>64</sup> Men cite financial motivations as their primary incentive to donate.<sup>65</sup> Women, on the other hand, cite altruism as their principal motivation.<sup>66</sup> Women are paid more than men per donation—typically \$5,000 per donation—because the egg extraction process is much more intrusive and carries health risks.<sup>67</sup> Regardless of a donor’s motivation, current FDA regulatory procedures prohibit gamete banks from sharing information about each other’s donors,<sup>68</sup> creating a loophole that allows a man to donate to multiple sperm banks.<sup>69</sup>

#### D. The Donor Sibling Registry

The CDC’s and FDA’s regulatory authority over ART does not currently extend to after the birth of a child<sup>70</sup> or, in the case of gamete donors, to after that donation occurs.<sup>71</sup> Children conceived with donor gametes are limited in their ability to track down gamete donors or connect to other people born with the same donor gamete(s) because ART clinics may close down, lose records, or simply not provide post-birth services.<sup>72</sup> Wendy Kramer, the mother of a child conceived with donor sperm, founded the Donor Sibling Registry (DSR) in 2000 to fill this gap.

The DSR allows individuals conceived with donor gametes to “make mutually desired contact with others with whom they share genetic ties.”<sup>73</sup> Donor-conceived children or gamete donors can, for a small fee, become members of the DSR, then affiliate with a gamete bank or fertility clinic and provide their “donor number” (the ID number

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<sup>63</sup> Almeling, *The Unregulated Sperm Industry*, *supra* note 18. See also Krawiec, *supra* note 59, at 69 (stating that the typical time commitment for sperm donors is nine months).

<sup>64</sup> Rene Almeling, “Why Do You Want to Be a Donor?”: Gender and the Production of Altruism in Egg and Sperm Donation, 25 *NEW GENETICS & SOC’Y* 143, 144 (2006) [hereinafter Almeling, *Why Do You Want to Be a Donor*] (noting that men must sign a contract agreeing to “abstain[] from sexual activity for 48 hours before each visit”). But see Almeling, *Selling Genes, Selling Gender*, *supra* note 58, at 320 (“[M]en are paid only for samples deemed acceptable based on sperm count and quality, things that can be negatively affected by stress, sickness, or having abstained for fewer than 48 hours.”).

<sup>65</sup> Almeling, *Why Do You Want to Be a Donor*, *supra* note 63, at 143.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.* at 144 (“For these fees, women take fertility medications and undergo outpatient surgery, a process that is usually complete in about six weeks.”).

<sup>68</sup> See *infra* note 84 and accompanying text.

<sup>69</sup> See *supra* note 1 and accompanying text.

<sup>70</sup> See Judith Daar, *Federalizing Embryo Transfers: Taming the Wild West of Reproductive Medicine?*, 23 *COLUM. J. GENDER & L.* 257, 262–63 (2012) (noting that CDC measures ART success by rates of pregnancies and live births).

<sup>71</sup> 21 C.F.R. § 1271.55 (2012) (outlining the records that must accompany a gamete donation).

<sup>72</sup> See *infra* notes 90–92 and accompanying text.

<sup>73</sup> *Our History and Mission*, DONOR SIBLING REGISTRY, <https://www.donorsiblingregistry.com/about-dsr/history-and-mission> (last visited Nov. 5, 2013)

associated with the donor that the clinic shares with intended parents). The DSR “matches” children to their donors or their genetic half-siblings through the donor numbers. The DSR has over 41,600 members and has facilitated contact between more than 10,700 genetic relatives.<sup>74</sup> Participation in the DSR, a non-profit organization, is completely voluntary, so membership is not comprehensive, and depends on those who know that the DSR exists and are willing to pay the membership fee.<sup>75</sup> A national, mandatory registry is necessary to centralize donor gamete information to guarantee a unified system of the most essential information that clinics are mandated by law to collect and report to the FDA and CDC.

### III. POLICY CONSIDERATIONS FOR A NATIONAL GAMETE DONOR REGISTRY

Academics and policymakers point to three justifications for a national, mandatory gamete donor registry: (1) to standardize information and requirements across states and the private industry, particularly regarding a nationwide limit on the number of gamete donations or resulting pregnancies per donor; (2) to increase access to donors’ medical information beyond the snapshot provided at the time of donation; and (3) to recognize the benefits of knowing one’s genetic origins, which include connecting with genetic half-siblings and preventing accidental incest. While scholars generally frame these three points around the child’s perspective, they also acknowledge the privacy interests of the donors and parents. I will explore these points in greater detail below.

#### A. Standardizing Donor Information & Requirements Across States & Industry

The FDA’s regulations on donor gametes and the CDC’s requirements pursuant to the Fertility Clinic Success Rate & Certification Act (FCSRCA) are supplemented by state and industry regulation.<sup>76</sup> The Society for Assisted Reproductive Technologies (SART) requires that member clinics, which represent over 90% of U.S. fertility clinics,<sup>77</sup> adhere not only to state medical licensing requirements, but also to SART’s ethics and practice

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<sup>74</sup> DONOR SIBLING REGISTRY, *supra* note 16.

<sup>75</sup> The California Cryobank, one of the country’s largest gamete banks, runs a similar registry for its clients. Participation is optional; those who enroll have access to half-siblings’ profiles and contact information. *Sibling Registry*, CAL. CRYOBANK, <http://www.cryobank.com/Services/Sibling-Registry/> (last visited Nov. 3, 2013). Genetisafe is another company that provides “donor profile storage, updated donor genetic and health information, and facilitated anonymous communication with the donor” if amenable. GENETISAFE, LLC, <http://genetisafe.com/frmAceptAgreement.aspx> (last visited Nov. 3, 2013).

<sup>76</sup> PRAC. COMM., AM. SOC’Y REPROD. MED. & PRAC. COMM., SOC’Y ASSISTED REPROD. TECH., RECOMMENDATIONS FOR GAMETE AND EMBRYO DONATION: A COMMITTEE OPINION 2 (2012) (“In some instances, the federal [HCT/P] requirements may be less rigorous than those in the state in which an individual practice is located or than those recommended by ASRM and . . . SART.”) [hereinafter RECOMMENDATIONS FOR GAMETE AND EMBRYO DONATION]. *See also* Messing, *supra* note 14, at 440 (“Some of the major criticisms of the FDA regulations are: (1) the lack of a requirement for genetic testing; (2) the lack of limitations on the number of times one person can donate and a limitation on the number of live births per donor; and (3) the lack of a network for tracking the children actually conceived as a result of these donations.”).

<sup>77</sup> AM. SOC’Y REPROD. MED., OVERSIGHT OF ASSISTED REPRODUCTIVE TECHNOLOGY 9 (2010).

committee guidelines.<sup>78</sup> These guidelines encourage clinics to limit the number of pregnancies resulting from each donor; however, SART refrains from setting a firm limit given the regional variation in population and geography:

It is difficult to provide a precise number of times that a given donor can be used because one must take into consideration the population base from which the donor is selected and the geographic area that may be served by a given donor. It has been suggested that in a population of 800,000, limiting a single donor to no more than 25 births would avoid any significant increased risk of inadvertent consanguineous conception. This suggestion may require modification if the population using donor insemination represents an isolated subgroup or if the specimens are distributed over a wide geographic area.<sup>79</sup>

Comparing the practices of the Fairfax Cryobank and the California Cryobank, two of the largest sperm banks in the United States,<sup>80</sup> demonstrates how sperm banks vary in their approach to limits on the number of pregnancies from a single donor. The Fairfax Cryobank limits sales of a donor's sperm when twenty-five children are born from that donor in the United States (though it will distribute further donations for "sibling pregnancies").<sup>81</sup> The California Cryobank, on the other hand, is more cryptic about its limitations, stating on its website that it "has taken steps to resolve concerns regarding the number of live births per sperm donor. Each donor is limited by the length of time he remains active in the program. Most donors remain in the program anywhere between 12 and 18 months."<sup>82</sup> Thus it is unclear exactly how California Cryobank limits a donor's sales, or whether there is even a limit of sales per live births at all.

A determined gamete donor could circumvent SART's non-binding guidelines<sup>83</sup> by donating to multiple clinics (as the sperm donor in the Slate column did).<sup>84</sup> The current regulatory scheme does not allow ART clinics to share information with each other about individual gamete donors.<sup>85</sup> A national, mandatory gamete donor registry would prevent this practice because each clinic would have access to that individual's donor history

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<sup>78</sup> *Id.*

<sup>79</sup> RECOMMENDATIONS FOR GAMETE AND EMBRYO DONATION, *supra* note 75, at 53. Cahn warns that these advisory limits may not be sufficient given American mobility. Cahn, *Accidental Incest*, *supra* note 2, at 83.

<sup>80</sup> Gina Kolata, *Psst! Ask for Donor 1913*, N.Y. TIMES, Feb. 17, 2007, [http://www.nytimes.com/2007/02/18/weekinreview/18kolata.ART.html?\\_r=0](http://www.nytimes.com/2007/02/18/weekinreview/18kolata.ART.html?_r=0).

<sup>81</sup> *Limitations on Donor Births*, FAIRFAX CRYOBANK, <http://www.fairfaxcryobank.com/ReadFirst.shtml> (last visited Nov. 3, 2013).

<sup>82</sup> *California Cryobank Policy of Openness*, CAL. CRYOBANK, <http://www.spermbank.com/newdonors/index.cfm?ID=6> (last visited Nov. 3, 2013).

<sup>83</sup> Cahn, *Necessary Subjects*, *supra* note 7, at 213.

<sup>84</sup> Dennison, *supra* note 3, at 16.

<sup>85</sup> See *infra* Part III.B about federal regulation of protected health information. Cf. Nanette R. Elster & Andrea Braverman, *The Future Is Now: A Voluntary Gamete Donor Registry is Feasible*, 12 DEPAUL J. HEALTH CARE L. 195, 197 (2009) (noting that a centralized donor gamete registry "would enable ART programs to share information with one another about donors").

across all ART clinics.<sup>86</sup> Great Britain’s Human Fertilisation and Embryology Authority requires that all ART clinics report information on all donor cycles, including a donor’s identifying information and the outcome of any treatment.<sup>87</sup> A firmer, nationwide limit on gamete donations would lower the risk of accidental incest<sup>88</sup> and minimize disease transmission associated with a particular donor.<sup>89</sup>

## **B. Broader Access to Medical History**

Intended parents have access to the medical history that the donor provides to the clinic. However, this information is not comprehensive because clinics cannot screen donors for “every known genetic condition,”<sup>90</sup> nor are they required to do so because FDA’s authority over donor gametes is limited to preventing communicable disease transmission. Furthermore, donors’ medical history is not necessarily updated after donation,<sup>91</sup> and clinics’ recordkeeping practices vary widely.<sup>92</sup> ART clinics do not communicate with a donor’s primary care doctor, and there is no mechanism in place that requires donors or resulting offspring to update the clinic when they discover new medical conditions that could impact their genetic relative(s).<sup>93</sup> Genetic history is becoming increasingly important in disease diagnosis and treatment.<sup>94</sup> A gamete donor registry could preserve donor medical information, allow donors to update their medical

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<sup>86</sup> Clinics could be required to collect social security numbers or other individually identifying information. Cf. Cahn, *Necessary Subjects*, *supra* note 7, at 218 (“A federal-level structure could more efficiently and effectively implement any large-scale collection of information and oversight of the process.”).

<sup>87</sup> *Directions Given Under the Human Fertilisation & Embryology Act 1990 as Amended*, HUM. FERTILISATION & EMBRYOLOGY AUTH., [http://www.hfea.gov.uk/docs/2009-06-03\\_GENERAL\\_DIRECTIONS\\_0005\\_Collecting\\_and\\_recording\\_information\\_for\\_the\\_HFEA\\_-\\_approved.pdf](http://www.hfea.gov.uk/docs/2009-06-03_GENERAL_DIRECTIONS_0005_Collecting_and_recording_information_for_the_HFEA_-_approved.pdf) (last visited Nov. 3, 2013).

<sup>88</sup> Dennison, *supra* note 3, at 16.

<sup>89</sup> See Cahn, Cahn, *Accidental Incest*, *supra* note 2, at 102–03 (noting that five children in Michigan conceived by the same sperm donor share the “extremely rare disease of congenital neutropenia”). This limit would also mitigate the health risks associated with repeated egg donation. *Id.* at 99–100.

<sup>90</sup> Vardit Ravitsky, “*Knowing Where You Come From*”: *The Rights of Donor-Conceived Individuals and the Meaning of Genetic Relatedness*, 11 MINN. J.L. SCI. & TECH 655, 672 (2010). But see Mary Crane, *Sperm for Sale*, FORBES, Feb. 9, 2007, [http://www.forbes.com/2007/02/09/spermbank-fertility-fda-ent-manage-cx\\_mc\\_0209bizoflovesperm.html](http://www.forbes.com/2007/02/09/spermbank-fertility-fda-ent-manage-cx_mc_0209bizoflovesperm.html) (“‘I’ve been married to my wife for 38 years and she doesn’t even know as much about me as parents know about their donors with our long-form medical history,’ says Dr. Cappy Rothman, who founded the California Cryobank in 1976.”).

<sup>91</sup> See RECOMMENDATIONS FOR GAMETE AND EMBRYO DONATION, *supra* note 75, at 7 (noting that clinics “should” keep records on subsequent follow-up evaluations, and that clinics should “ideally” record the outcome of each clinical cycle to report any adverse outcomes or genetic diseases identified later on).

<sup>92</sup> Ravitsky, *supra* note 89, at 672.

<sup>93</sup> See *id.* at 673 (noting that most donors are young and healthy at the time of donation, but many donors fail to update the clinic with their medical history as they age and new conditions emerge); see also Benward et al., *supra* note 11, at 230 (reporting that there is no evidence that programs have a way to indefinitely main records, and concluding that the current system of tracking outcomes and maintaining information is deficient).

<sup>94</sup> Dennison, *supra* note 3, at 14.

history themselves after donation, allow children conceived with donor gametes to update relevant genetic information or medical history for the benefit of their donor or their genetic half-siblings, and ensure the availability of this information, even if individual clinics or providers terminate their practice or lose touch with the donors or clients.<sup>95</sup> In the case of egg donation, a registry could track the procedure's long-term health effects on the donor, which are still unknown.<sup>96</sup>

### C. Psychological Benefits of Knowing Genetic Origins & Half-Siblings

Professor Vardit Ravitsky notes that the “first generation of donor-conceived offspring is now becoming young adults who are beginning to share their unique perspectives. Many are telling a story of psychological distress. They describe a strong need to know ‘where they came from;’ to know their genetic origins as an essential part of constructing their identities.”<sup>97</sup> This emerging need to know one's genetic origins shares similarities with adopted children's advocacy around liberalizing adoption records.<sup>98</sup>

In the gamete donor context, Professor Naomi Cahn has noted that the “need to know” has two parts: the need to know that one was conceived through donor gametes, and the need to know the donor's identity,<sup>99</sup> which is broader than a need to know for medical decisionmaking purposes.<sup>100</sup> Professor Ravitsky explains this need as follows:

The biological aspect of our connection to our past provides a sense of continuity. As we develop a sense of personal identity we constantly refer to ‘where we come from’ as a way of grounding ourselves, establishing a sense of belonging, or our place in the world. Lack of knowledge about the donor as a person could thus create a gap or a void in the formation of personal identity, undermine a sense of continuity and grounding, and lead to troubling and disruptive feelings of completeness.<sup>101</sup>

However, even this “need to know” does not necessarily have to include a donor's identifying information. It could be at least partially satisfied by knowing a donor's physical and genetic traits, ethnic ancestry, and other facts, such as education, profession, and interests. In fact, most donor gamete banks already collect this information from donors, which intended parents use to decide which donor's gametes to purchase.<sup>102</sup>

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<sup>95</sup> Benward et al., *supra* note 11, at 230. See also Messing, *supra* note 14, at 455 (“A voluntary medical-update system would provide a happy medium for donor-conceived children with a need for the information and donors who still wish to remain anonymous.”).

<sup>96</sup> Justine Durrell, *Women's Eggs: Exceptional Endings*, 22 HASTINGS WOMEN'S L.J. 187, 229 (2011).

<sup>97</sup> Ravitsky, *supra* note 89, at 665. See also Benward et al., *supra* note 11, at 232–34 (explaining the cultural importance of genetic ties for identity formation).

<sup>98</sup> Cahn, *Necessary Subjects*, *supra* note 7, at 206–10 (exploring the similarities and differences in secrecy in the adoption and ART contexts). Of course, no court has recognized a constitutional right to know one's genetic origins. Sauer, *supra* note 14, at 938.

<sup>99</sup> Cahn, *Necessary Subjects*, *supra* note 7, at 218–19.

<sup>100</sup> Ravitsky, *supra* note 89, at 674.

<sup>101</sup> *Id.* at 675.

<sup>102</sup> *Id.* at 676. See also *Donor Search*, CAL. CRYOBANK, <http://www.cryobank.com/Search.aspx?listview=0#> (last visited Nov. 3, 2013) (where one can search by height, eye color, hair color,

Given that intended parents value this information, it is unsurprising that resulting offspring do as well.<sup>103</sup>

This “need to know” is not limited to a child’s genetic parent; the original purpose of the DSR was to connect genetic half-siblings that shared the same donor.<sup>104</sup> A donor gamete registry can allow half-siblings to connect without revealing a donor’s identifying information. While mandating donor identity disclosure is controversial, the SART notes “it is widely agreed that such release is acceptable if all parties agree.”<sup>105</sup>

#### **D. Protecting Donors’ and Parents’ Privacy Rights & Choices**

Various academics have noted that requiring parents to tell their children that they were conceived as a result of gamete donation would not only be difficult to enforce, but could also raise constitutional concerns regarding reproductive choice, family privacy, and child-rearing.<sup>106</sup> No jurisdiction in the world currently mandates that parents tell their children that they were conceived by donor gametes, so one’s “need to know” only arises if parents disclose their use of donor gametes.<sup>107</sup> While SART recommends that parents of children born from donor gametes share the circumstances of their children’s conception with them, SART recognizes that this is ultimately the parents’ choice.<sup>108</sup> Prohibiting anonymous donation could overstate the role of genetics and discount the existing bonds between a child and his actual parents.<sup>109</sup> This emphasis would be particularly problematic for LGBT advocates working to minimize the legal importance of genetic connections to secure equal parenting rights and responsibilities for parents with no genetic or gestational connection to their children.<sup>110</sup> While a national donor gamete registry would clearly be beneficial for increasing access to medical history and

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hair texture, blood type, educational level, areas of study, ethnic origin, ancestry, religion, and celebrity “look-a-likes”). Fairfax Cryobank allows consumers to search by, among other factors, astrological sign, favorite subject, favorite pet, personal goals, talent, and “FaceMatch,” which matches an intended parent’s and a donor’s facial features. *Donor Search*, FAIRFAX CRYOBANK, <http://donorsearch.fairfaxcryobank.com/> (last visited Nov. 3, 2013).

<sup>103</sup> Ravitsky, *supra* note 68, at 676. *See also* Dennison, *supra* note 3, at 17 (“It’s hypocritical of parents and medical professionals to assume that biological roots won’t matter to the ‘products’ of cryobanks’ service, when the longing for a biological relationship is what brings customers to the banks in the first place.” (quoting a teenager born from an anonymous sperm donor)).

<sup>104</sup> *Our History and Mission*, DONOR SIBLING REGISTRY, <https://www.donorsiblingregistry.com/about-dsr/history-and-mission> (last visited Nov. 3, 2013) (“The Donor Sibling Registry was founded in 2000 to assist individuals conceived as a result of sperm, egg or embryo donation that are seeking to make mutually desired contact with others with whom they share genetic ties.”).

<sup>105</sup> ETHICS COMM., AM. SOC’Y REPROD. MED., INFORMING OFFSPRING OF THEIR CONCEPTION BY GAMETE OR EMBRYO DONATION: A COMMITTEE OPINION 1, 2 (2013) [hereinafter INFORMING OFFSPRING OF THEIR CONCEPTION].

<sup>106</sup> Cahn, *Necessary Subjects*, *supra* note 7, at 219; Ravitsky, *supra* note 89, at 683; Dennison, *supra* note 3, at 19.

<sup>107</sup> Ravitsky, *supra* note 89, at 681.

<sup>108</sup> INFORMING OFFSPRING OF THEIR CONCEPTION, *supra* note 83, at 45.

<sup>109</sup> Sauer, *supra* note 14, at 940.

<sup>110</sup> *See* Jennifer S. Hendricks, *Essentially a Mother*, 13 WM. & MARY J. WOMEN & L. 429, 477 (2007) (noting the “harm that exaltation of genetics works for families with adoptive, same-sex, or other non-traditional sets of parents”). *See also* *Legal Recognition of LGBT Families*, NAT’L CTR.

knowing one's genetic origins, it should not cross the line of unnecessary state intrusion into health and family privacy.

#### **IV. HHS RELIANCE ON ELECTRONIC HEALTH DATA & HEALTH PRIVACY OVERSIGHT**

Just as the ART industry and its users are trending toward increasing openness, access to clinical trial and patient or product registry data has also become more publicly available.<sup>111</sup> Consequently, creating a national donor gamete registry would be a modest reform that fits into the current atmosphere of creating electronic systems that increase access to important health data. The rise of electronic health records and human subject research data means that the federal government already has the technical skills and systems necessary to safeguard the privacy of participants' protected health information.<sup>112</sup> Outside the ART context, federal involvement and regulation have joined this trend toward transparency. For example, the White House's Office of Science and Technology Policy issued a memorandum in February 2013 instructing agency heads to expand public access to data in federally funded projects.<sup>113</sup> In June of this year, the FDA published a notice and request for comment on a proposal to make available de-identified and masked clinical data from medical product applications.<sup>114</sup>

A national donor gamete registry brings many of the same benefits as those associated with increased access to clinical research data and product registries in general. Researchers and policymakers argue that public access to such data increases public confidence in clinical research, improves drug and product safety and effectiveness, advances scientific development and innovation, and mitigates individual participant risk.<sup>115</sup> However, increasing access to human subject research data also has its downsides: the difficulty of guaranteeing participants' privacy; the potential of poorly conducted, but widely publicized, data analyses that could mislead the public; the possible reduction of incentives for competition and innovation; and the potential to overwhelm regulators and increase costs associated with monitoring data systems.<sup>116</sup> HHS's participation in patient or product registries takes many forms, though it usually does not hold registry or study data exclusively, preferring to work with private or academic partners and

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LESBIAN RTS., [http://www.nclrights.org/wp-content/uploads/2013/07/Legal\\_Recognition\\_of\\_LGBT\\_Families.pdf](http://www.nclrights.org/wp-content/uploads/2013/07/Legal_Recognition_of_LGBT_Families.pdf) (last visited Nov. 3, 2013).

<sup>111</sup> Michelle M. Mello et al., *Preparing for Responsible Sharing of Clinical Trial Data*, 369 *NEW ENGLAND J. MED.* 1651, 1651 (2013) ("Data from clinical trials, including participant-level data, are being shared by sponsors and investigators more widely than ever before.").

<sup>112</sup> *Id.* at 1653 (noting that "a leading concern in expanding access to participant-level data is whether the privacy of research participants can be guaranteed").

<sup>113</sup> Memorandum from John P. Holdren, Dir., Office Sci. & Tech. Policy, Exec. Office President, to Heads of Exec. Dep'ts & Agencies 1 (Feb. 22, 2013), available at [http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp\\_public\\_access\\_memo\\_2013.pdf](http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf).

<sup>114</sup> Availability of Masked & De-Identified Non-Summary Safety & Efficacy Data, 78 *Fed. Reg.* 33,421 (June 4, 2013).

<sup>115</sup> Mello et al., *supra* note 110, Table 2.

<sup>116</sup> *Id.* at 1653–54.

limiting its role to providing guidance or best practices.<sup>117</sup> I recommend a similar public-private collaboration for the national donor gamete registry, which can build on the best practices of patient and product registries.

### **A. Examples of HHS Involvement in Clinical Trials & Patient & Product Registries**

The 1997 Food and Drug Modernization Act (FDAMA) was the first federal law mandating that the NIH “operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions.”<sup>118</sup> The NIH must collect information about federally and privately funded clinical trials for experimental treatments (drug and biological products) for patients with serious or life-threatening diseases or conditions, including the purpose of each experimental drug, patient eligibility criteria, the location of clinical trial sites, and a point of contact for patients wanting to enroll in the trial.<sup>119</sup> The NIH and the FDA implemented this mandate by developing Clinicaltrials.gov, which debuted on February 29, 2000.<sup>120</sup> Clinicaltrials.gov represents a centralized approach to data management, where private researchers and companies are required to submit information to the federal government. I suggest a similar centralized system for a national donor gamete registry, where ART clinics would submit data to a unified government system.

The FDA’s approach to pregnancy exposure registries has been more permissive. The agency defines a pregnancy exposure registry as “a **study that collects health information from women who take medicines or vaccines when they are pregnant.**”<sup>121</sup> Its website contains a page titled “List of Pregnancy Exposure Registries,” where users can search for registries by medical condition or by drug or vaccine. The FDA notes that the agency does not run any of these registries but invites companies that want their registry listed on the site to contact the FDA Office of Women’s Health. In 2002, the FDA released guidance on how to establish pregnancy exposure registries. This guidance notes that a sponsor is free to establish a pregnancy exposure registry on its own at any time; the FDA may also require that the sponsor establish such a registry “under an IND [investigational new drug procedure] before approval or, more typically, as part of a phase 4 commitment [a post-market study required by FDA as a condition of

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<sup>117</sup> M. Nielsen Hobbs, *Registries Rising: FDA Looking at TNF Inhibitors; AHRQ Updates Standards*, PINK SHEET, Aug. 24, 2009, at 8 (noting that disease-based registries are “usually public-private partnerships”). See also AGENCY FOR HEALTHCARE RESEARCH & QUALITY, REGISTRIES FOR EVALUATING PATIENT OUTCOMES: A USER’S GUIDE 1 (2d ed. 2010) (describing the purpose of the publication as “intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes”).

<sup>118</sup> Food and Drug Modernization Act, P.L. 105-115, § 113, 111 Stat. 2296, 2311 (1997).

<sup>119</sup> *Id.*; see also Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions 2 (2002).

<sup>120</sup> *About This Site*, CLINICALTRIALS.GOV, <http://clinicaltrials.gov/ct2/about-site/background>; <http://clinicaltrials.gov/ct2/about-site/history> (last visited Nov. 3, 2013).

<sup>121</sup> *List of Pregnancy Exposure Registries*, FDA, <http://www.fda.gov/scienceresearch/specialtopics/womenshealthresearch/ucm134848.htm> (last visited Nov. 3, 2013).

drug approval].”<sup>122</sup> If the registry records a serious or unexpected adverse event where it is reasonably probable that the drug or product caused that event, the company must report that event to the FDA within fifteen calendar days.<sup>123</sup>

In other words, even if the FDA requires that a company establish a pregnancy exposure registry, the company still has discretion as to how the registry should be run. This approach is arguably already in place in the donor gamete registry realm, given that the Sibling Donor Gamete Registry, as well as other private registries run by individuals or sperm clinics, each runs separate systems that do not communicate with each other. This lack of communication is one of the obstacles that a single donor gamete registry would overcome, making it easier to enforce a nationwide limit on pregnancies per donor.

In addition to tracking particular drugs, other registries track medical devices. In 2011, the FDA shared the results of its internal review of breast implants and a possible association with anaplastic large cell lymphoma (ALCL). In its news release, the FDA announced that it is working with the American Society of Plastic Surgeons and others to create a breast implant registry to improve understanding of this association. In the meantime, the FDA encourages health care providers to report any confirmed ALCL cases. Even though two of the largest breast implant manufacturing companies support the idea of a registry, the FDA and the industry have not been able to agree on who will cover the costs of the registry, whether participation will be mandatory, and related privacy issues.<sup>124</sup> The delay in creating a breast implant registry demonstrates the need to carefully think through the cost, participation, and privacy implications of a donor gamete registry.

The NIH has had more success establishing DS-Connect, the Down Syndrome Registry that launched in September 2013. DS-Connect allows “people with Down syndrome and their family members, researchers, and parent and support groups to share information and health history in a safe, confidential, online database.”<sup>125</sup> Users may choose to make their contact information available to researchers for participation in research studies but are not required to do so to create a DS-Connect profile.<sup>126</sup> The NIH de-identifies the data stored in the registry and only shares the data, with users’ permission, with approved scientists, clinicians, and drug companies.<sup>127</sup> The NIH Down Syndrome Consortium, a coalition of government officials, researchers, and Down Syndrome advocates, recommended a national registry in 2007 as a vehicle to help achieve general

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<sup>122</sup> FDA CTR. FOR DRUG EVALUATION AND RESEARCH & CTR. FOR BIOLOGICS EVALUATION AND RESEARCH, GUIDANCE FOR INDUSTRY: ESTABLISHING PREGNANCY EXPOSURE REGISTRIES 4 (2002).

<sup>123</sup> *Id.* at 15 (citing 21 C.F.R. §§ 310.305(c)(1), 314.80(c)(2)(iii) and (e), 600.80(c)(1), (c)(2)(iii) and (e)).

<sup>124</sup> Anna Yukhananov, *Keeping Patients Safe: The Case for a Breast Implant Registry*, ATLANTIC, Jan. 5, 2012, <http://www.theatlantic.com/health/archive/2012/01/keeping-patients-safe-the-case-for-a-breast-implant-registry/250709/>.

<sup>125</sup> *DS-Connect Registry*, NIH DOWN SYNDROME CONSORTIUM, <http://downsyndrome.nih.gov/registry/Pages/default.aspx>.

<sup>126</sup> *Id.*

<sup>127</sup> *Understanding Your Participation in DS-Connect*, NIH, <https://dsconnect.nih.gov/en/about-ds-connect/faq.html#12> (last visited Nov. 6, 2013).

Down Syndrome research goals.<sup>128</sup> The NIH justified its authority to create DS-Connect by pointing to congressional directives in the FY2007 House and Senate Appropriations Committee Reports for Labor–HHS–Education.<sup>129</sup> While Down Syndrome advocacy organizations are generally supportive of DS-Connect, individuals have expressed skepticism about the potential for abuse and stigmatization of an already vulnerable population.<sup>130</sup> DS-Connect’s experiences could be relevant for a national donor gamete registry, particularly regarding whether donors and offspring would want to make their data accessible to researchers. The social stigma surrounding infertility, single parenthood, and LGBT families is also something to keep in mind when considering opening this data to the public.<sup>131</sup>

Different agencies, along with states and non-profit organizations, can also jointly manage a registry. The NIH and CDC are working together to launch a Sudden Death in the Young Registry. This registry will not be limited to a particular condition; rather, its scope is broad to try to fill the knowledge gap around why sudden death occurs among infants and children.<sup>132</sup> State public health agencies will apply to participate, and the Michigan Public Health Institute will manage the data. Blood samples from a subset of cases will also be collected; the data will not contain personally identifiable information.<sup>133</sup> The collaboration between the CDC, the NIH, and a non-governmental third party provides a model for how the FDA and the CDC could partner with the ASRM to establish a donor gamete registry.

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<sup>128</sup> NIH, RESEARCH PLAN ON DOWN SYNDROME 42 (2007).

<sup>129</sup> *Id.* at 24 (summarizing language encouraging the NIH to establish a strategic plan for Down Syndrome Research).

<sup>130</sup> See MsAmericanPatriot, Comment to Shaun Heasley, *National Down Syndrome Registry Goes Live*, DISABILITYSCOOP, <http://www.disabilityscoop.com/2013/09/09/national-ds-registry-live/18676/> (last visited Nov. 3, 2013) (“Boards like this should NOT be in existence. With Down Syndrome and Autism both demonized by the liberals, this would be used by them to hunt these individuals down. I see NO good come from boards like the one above. It would be abused and the cost could be people with Down or Autism lives. These boards just demonize and chastise us to no end. We should be allowed to live out our lives in PRIVATE and boards like that would NOT allow for it AT ALL.”); see also Sharona Hoffman & Andy Podgurski, *Balancing Privacy, Autonomy, and Scientific Needs in Electronic Health Records Research*, 65 SMU L. REV. 85, 107–08 (2012) (explaining the potential for group stigmatization if research identifies a group of individuals pre-disposed to a particular illness or condition).

<sup>131</sup> See Carrie Friese et al., *Older Motherhood and the Changing Life Course in the Era of Assisted Reproductive Technologies*, 22 J. AGING STUD. 65 (2008) (discussing how couples that use donor gametes negotiate identity and stigma associated with infertility); MOVEMENT ADVANCEMENT PROJECT ET AL., ALL CHILDREN MATTER HOW LEGAL AND SOCIAL INEQUALITIES HURT LGBT FAMILIES 2–3 (2011) (summarizing how stigma against LGBT families creates socioeconomic and health obstacles for children). *But see* Julia Medew, *Donor Sperm Families Just As Happy*, AGE NAT’L, Dec. 4, 2012, <http://www.theage.com.au/national/donor-sperm-families-just-as-happy-20121203-2arab.html> (describing results of a study of “donor insemination families” that found that children born through sperm donation are just as psychologically healthy as those born as a result of typical conception).

<sup>132</sup> Sudden death is not systematically reported, nor does it have established definitions or standards. Press Release, NIH, *NIH and CDC Launch Registry for Sudden Death in the Young* (Oct. 24, 2013, 9:00 a.m.), available at <http://www.nih.gov/news/health/oct2013/nhlbi-24.htm>.

<sup>133</sup> *Id.*

Following FDAMA, Congress has continued to play a role in expanding access to clinical trial and health registry data. The Food and Drug Administration Amendments Act of 2007 (FDAAA) created a nationwide health care data network, the Sentinel Initiative, “to track the safety of drugs, biologics, and medical devices once they reach the market.”<sup>134</sup> The Sentinel Initiative will allow FDA “to query multiple data environments” concerning potential product safety problems while effectively managing privacy and security to augment the agency’s current surveillance capabilities.<sup>135</sup> However, the original owners will still hold and manage the data, and the FDA, through its contractors, will only be able to access de-identified information.<sup>136</sup> Potential sources of this health data include the Centers for Medicaid and Medicare Services, the U.S. Department of Veterans Affairs, the healthcare exchanges created pursuant to the Affordable Care Act (ACA), private insurance companies, and state agencies, among others.<sup>137</sup> The sheer volume of available data that could be included in the Sentinel Initiative, along with the fact that the FDA will “engage private-sector companies to develop and operate the system infrastructure,” has raised health privacy and security concerns that are also relevant to any decisions regarding the establishment of a national donor gamete registry.<sup>138</sup>

## **B. HIPAA Implications of Increased Patient & Product Surveillance**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established federal privacy protections for individually identifiable health information.<sup>139</sup> HHS implemented HIPAA by promulgating the Privacy Rule, which sets national protection standards for the “confidentiality, integrity, and availability of electronic protected health information” that bind health plans, health care clearinghouses, and health care providers.<sup>140</sup> Thus, the Privacy Rule covers health care research concerning human subjects and their medical records, and would apply to the medical information included in a national donor gamete registry.

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<sup>134</sup> FDA’s Sentinel Initiative, FDA, <http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm2007250.htm> (last visited Sept. 30, 2014); see also Barbara J. Evans, *The Ethics of Postmarketing Observational Studies of Drug Safety Under Section 505(o)(3) of the Food, Drug, and Cosmetic Act*, 38 AM. J.L. & MED. 577, 582 (2012) (describing FDA’s increased authority under Section 505(o)(3)) [hereinafter Evans, *Ethics of Postmarketing Observational Studies*]

<sup>135</sup> JANET M. MARCHIBRODA, *eHEALTH INITIATIVE FOUNDATION, DEVELOPING A GOVERNANCE & OPERATIONS STRUCTURE FOR THE SENTINEL INITIATIVE: A REPORT TO THE U.S. FOOD & DRUG ADMINISTRATION 4* (2009).

<sup>136</sup> *Id.*

<sup>137</sup> *Id.* at 21.

<sup>138</sup> Barbara J. Evans, *Congress’ New Infrastructural Model of Medical Privacy*, 84 NOTRE DAME L. REV. 585, 589 (2009) [hereinafter *Evans*, *Congress’ New Infrastructural Model*]; cf. Hoffman & Podgurski, *supra* note 129, at 85 (acknowledging the “tension between realizing societal benefits from medical research and granting individual preferences for privacy”).

<sup>139</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified at scattered sections of the U.S.C.).

<sup>140</sup> *Health Information Privacy*, HHS OFFICE FOR CIVIL RIGHTS, <http://www.hhs.gov/ocr/privacy/hipaa/administrative/index.html> (last visited Nov. 3, 2013). These three types are known as “covered entities.” *Id.*

The Privacy Rule covers any patient information that is identifiable. That information is considered “protected health information,”<sup>141</sup> and patients must authorize its release for use in a research study.<sup>142</sup> The Privacy Rule does not cover de-identified health records.<sup>143</sup> Covered entities are in the “safe harbor” and patient records are considered “de-identified” if they remove eighteen specific items from patient records.<sup>144</sup> However, many experts acknowledge that de-identification procedures are not foolproof.<sup>145</sup> The national donor gamete registry would include protected health information, and thus would be subject to the Privacy Rule.

In addition to the Privacy Rule, HHS administers the HIPAA Security Rule for electronically stored health information.<sup>146</sup> The Security Rule requires a variety of safeguards, but only applies to health plans, clearinghouses, and providers, not to researchers.<sup>147</sup> The Security Rule does not cover de-identified records databases that meet the Privacy Rule’s safe harbor standards.<sup>148</sup> Because the national donor gamete registry would be an online registry, it would be subject to the Security Rule in addition to the Privacy Rule.

Researchers can get around the general requirement for patient authorization of protected health information by requesting a waiver from an Institutional Review Board or privacy board (collectively referred to as “IRB”).<sup>149</sup> Under the “research purposes” exception, an IRB may grant a waiver if protected health information is necessary for research purposes.<sup>150</sup> In addition, the use of protected health information cannot involve more than a “minimal risk to the privacy of individuals.”<sup>151</sup> The “research purposes” exception would be relevant if a national donor gamete registry allowed users to make their identifying information available to approved researchers, similar to DS-Connect.

Another exception to the Privacy Rule that is relevant to donor gamete registries is the public health exception, which allows covered entities to disclose protected health information without a patient’s authorization for “public health activities and purposes.”

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<sup>141</sup> 45 C.F.R. § 160.103 (2012).

<sup>142</sup> *Id.* § 164.508(b)(3)(i).

<sup>143</sup> *Id.* § 160.103 (2012); *see also* Hoffman & Podgurski, *supra* note 129, at 94 (“Consequently, health care providers, including clinicians and medical facilities, can disclose de-identified data to researchers without obtaining patient consent or applying HIPAA’s privacy safeguards to the de-identified data.”).

<sup>144</sup> 45 C.F.R. § 164.514(b)(2)(i) (including names, geographic subdivisions smaller than a state, zip code information, relevant dates, telephone and fax numbers, e-mail addresses, social security numbers, medical and health plan numbers, account numbers, vehicle information, URLs, IP addresses, biometric identifiers, “full face” photographic images, and any other “unique identifying” information).

<sup>145</sup> *See* Hoffman & Podgurski, *supra* note 129, at 104–107 (explaining the shortcomings of de-identification).

<sup>146</sup> 45 C.F.R. § 164.302-.318 (2010).

<sup>147</sup> Hoffman & Podgurski, *supra* note 129, at 137–138.

<sup>148</sup> *Id.* at 138.

<sup>149</sup> 45 C.F.R. § 164.512(i).

<sup>150</sup> *Id.* § 164.512(i)(1)(ii)

<sup>151</sup> *Id.* § 164.512(i)(2)(ii)(A).

Cite? The public health exception includes reports for public health surveillance, investigations, interventions authorized by law, or at the direction of a public health authority.<sup>152</sup> This exception would potentially be relevant for any person on the registry who discovered a medical condition that could impact his genetic relatives. For example, if Ann Morriss's son was a user on a national donor gamete registry, he could report that his donor was a genetic carrier of MCADD, alerting the donor and any genetic half-siblings.<sup>153</sup> Covered entities rely on this exception to provide data to an FDA-regulated manufacturer.<sup>154</sup> Any national gamete donor registry will have to comply with the Privacy Rule and the Security Rule and not exceed the scope of the federal government's regulatory authority.

## V. PROPOSAL: A TIERED GAMETE DONOR REGISTRY

To comply with the Privacy Rule and remain within the bounds of the federal government's existing regulatory authority, I propose a tiered gamete donor registry under the joint authority of the FDA and the CDC. Tier I will provide a mandatory floor for disclosure, but gamete donors may choose to share more information by participating in Tiers II through IV. This tiered approach complements the Society for Assisted Reproductive Technology (SART) Ethics Committee's categorization of gamete donor information sharing into four levels: (1) non-identifying information, (2) non-identifying contact for medical updates, (3) non-identifying personal information, and (4) identifying personal information.<sup>155</sup> Participation in the donor gamete registry would be limited to those who make donations through a gamete bank; the proposed registry would not require participation of those who donate gametes to a specific person because such donors already have relationships with their donees.

### A. Tier I

Tier I would mandate that all ART clinics upload to the registry all donors' health and screening information that clinics already collect pursuant to FDA regulations. In addition, clinics would be obligated to disclose the number of times a donor's gametes are used for conception, as well as the conception and pregnancy outcomes. Tier I would prohibit any ART clinic from selling a donor's gametes after that donation resulted in a certain number of successful pregnancies.<sup>156</sup>

Each donor would have an individual code that clinics would share with intended parents. Children would be able to view the donor's registry profile and "link" to it to identify themselves as offspring to connect to their genetic half-siblings. Children could also update the profile by listing their own relevant medical information.<sup>157</sup> In addition, donors could decide whether their data could be used for research purposes, or

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<sup>152</sup> *Id.* § 164.512(b)(1)(i).

<sup>153</sup> *See supra* notes 4–6 and accompanying text.

<sup>154</sup> Evans, *Ethics of Postmarketing Observational Studies*, *supra* note 133, at 589.

<sup>155</sup> ETHICS COMM., AM. SOC'Y REPROD. MED., INTERESTS, OBLIGATIONS, AND RIGHTS OF THE DONOR IN GAMETE DONATION Table 1 (2008) hereinafter DONOR INTERESTS, OBLIGATIONS, AND RIGHTS].

<sup>156</sup> I refrain from suggesting a specific numerical limit, preferring to defer to scientific authorities for the proper number.

<sup>157</sup> Parents would be authorized to create profiles on behalf of their children.

be only accessible to parents who purchased donor gametes and thus have their donor code. Data available for research purposes would not include individually identifiable information, and thus would not raise HIPAA compliance concerns.

Tier I's requirements would not extend much further than what is already required. The Fertility Clinic Success Rate & Certification Act (FCSCRA) mandates that ART clinics report conception and pregnancy outcomes for ART procedures using donated eggs and embryos. As mentioned earlier, the CDC already requires clinics to report more data than the specific categories mentioned in the statute. Furthermore, HHS already has the authority to amend the "pregnancy success rate" definition to include ART procedures using donated sperm.<sup>158</sup> The FDA's human cells, tissues, and cellular and tissue-based products (HCT/P) regulations already require gamete donors to undergo specific testing and screening procedures;<sup>159</sup> the only additional step would be that clinics would have to enter this data into a database that tracked donors across the country.

Professor Ravitsky notes that "drawing the policy line at the level of medical history and genetic information emphasizes the biomedical meaning of inheritability."<sup>160</sup> In other words, greater access to a donor's medical history is justifiable without the danger of essentializing the importance of genetic ties for other aspects of identity formation.<sup>161</sup> Furthermore, because donors are already required to disclose medical information to their individual clinic, pooling it with other clinics' records does not further intrude on donor privacy, but does limit the possibility of donors circumventing individual clinic donation limits and producing a large number of pregnancies.

## **B. Tier II**

Tier II would allow donors the option of disclosing additional, non-medical history and physical characteristics. The largest sperm clinics already collect much of this information and disclose it to intended parents at various fee levels. This information includes a donor's race, education, and profession, as well as baby pictures, a recording of a donor's voice, and the clinic's impressions of a donor. If donors consented to sharing some or all of this information, the clinic would share this information with the registry along with the information mandated by Tier I. Again, sharing this information could satisfy some donor-conceived children's need for further information without compromising donor anonymity,<sup>162</sup> and it would relieve the individual clinic of being the steward of this information in perpetuity. Neither the FDA nor the CDC's current regulatory authority over ART extends to these characteristics, so this tier must remain

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<sup>158</sup> FCSRC § 8, Pub. L. No. 102-493, 106 Stat. 3146, 3151 (codified at 42 U.S.C. § 263a –7(2006) (defining ART to include "all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency)" (emphasis added)).

<sup>159</sup> 21 C.F.R. § 1271.80.

<sup>160</sup> Ravitsky, *supra* note 89, at 673.

<sup>161</sup> *Id.* at 673-74.

<sup>162</sup> *Id.* at 677.

voluntary. Because this information is not protected health information that raises the risk of individual identification, it does not raise any HIPAA concerns.

### C. Tier III

If donors chose to opt for Tier III, they would provide a more complete medical history beyond what the FDA currently collects to assess risk of communicable disease transmission. In addition, donors could update the registry with their health information and medical history post-donation. This would allow intended parents to make more informed choices when considering which donor gametes to purchase, and would let children conceived with donor gametes to stay continuously apprised of their donors' post-donation medical information even after donation occurred.

SART already recommends that donors provide medical updates when appropriate,<sup>163</sup> however, the FDA does not currently have the legal authority to mandate this information because its scope is limited to risk of communicable disease exposure and transmission prior to donation, and does not include authority over genetic disease prevention.<sup>164</sup> While the CDC already exercises considerable discretion under the FCSRCA by requesting more information that the statute requires, it is unlikely that this discretion could be reasonably interpreted to require individual donors to update their medical history post-donation because this information is not rationally related to the narrow definition of “pregnancy success rates.” The purpose of mandating increased disclosure of medical information is not limited to the success of the pregnancies themselves, but rather focuses on the quality of life for the child that results from the pregnancy.

Because neither the CDC nor the FDA currently has the authority to mandate donors to update their information post-donation, this option must remain voluntary. Nonetheless, market forces could play a role in encouraging post-donation medical updates. Clinics could incentivize Tier III by providing higher compensation to or only accepting Tier III donors. The sperm bank industry is already engaged in a donor profile “arms race,” where banks feel pressure to add more demographic information about the donor to keep up with the competition.<sup>165</sup> Again, providing medical history, without revealing individual identifying information, would not intrude on donor privacy or raise HIPAA concerns.

### D. Tier IV

Tier IV, the highest level of disclosure, would allow the registry to make donors' identifying information available to any resulting offspring that requested it upon reaching eighteen. While neither the FDA nor the CDC has the current authority to require “open donation,” this option is already becoming increasingly popular at sperm

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<sup>163</sup> DONOR INTERESTS, OBLIGATIONS, AND RIGHTS, *supra* note 154, at 4.

<sup>164</sup> 21 C.F.R. § 1271.1(a). See Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399, 1455–56 (2013) (arguing that the PHSA should be amended to give FDA authority to regulate genetic material for disease diagnosis and treatment purposes).

<sup>165</sup> Kolata, *supra* note 79 (“‘One year someone adds a personality profile, the next year someone adds something else,’ [Director of Fairfax Cryobank] says. ‘If one of your competitors adds a service, you add a service.’”).

and egg banks.<sup>166</sup> Given the regulatory limitations as well as the privacy policy concerns, this tier would need to be voluntary.

## VI. LEGAL AUTHORITY FOR REGISTRY

As stated previously, my tiered proposal would be a modest step forward because only the first tier would be mandatory, and the federal government already imposes these requirements or has the authority to do so. While many advocate for more binding disclosure requirements, Tiers II through IV would be voluntary so that the FDA and CDC would not have to assert additional authority or wait for Congress to pass legislation to establish a donor gamete registry. Once the donor gamete registry was in use, if Tiers II through IV became popular and stakeholders advocated for these tiers to become binding, the executive or legislative branches could respond appropriately with incremental disclosure requirements.

### A. Current FDA Jurisdiction

As previously described in Part II.B, the FDA currently has authority over donor gametes pursuant to its authority under Section 361 of the Public Health Service Act. Scholars note that while the FDA has broad discretion over how to pursue communicable disease prevention, the goal itself is narrow, and in the ART context, does not provide authority to regulate cloning or genetic diseases.<sup>167</sup> As such, FDA has looked beyond its powers to prevent communicable disease transmission to assert its authority over specific, cutting-edge ART procedures by classifying them as clinical drug investigations.

In 2001, the FDA asserted authority over “human cells used in therapy involving the transfer of genetic material by means other than the union of gamete nuclei” by deeming any such transfer a “clinical investigation” that required submission of an Investigational New Drug (IND) application.<sup>168</sup> This description included ooplasm transfer, where donor ooplasm (cytoplasm of an egg)<sup>169</sup> is injected into infertile eggs along with sperm to aid fertilization and embryonic development,<sup>170</sup> nuclear transfer, where doctors take nuclei from infertile eggs and transfer them to enucleated donor eggs and then fertilized

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<sup>166</sup> Braverman, *supra* note 15, at 485.

<sup>167</sup> PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW: CASES AND MATERIALS* 949 (3d ed. 2007) (noting that while Section 361 “allows FDA to use virtually any means” to accomplish disease prevention, this authority “arguably limits the measures that FDA might adopt”); Merrill, *supra* note 44, at 61. *But see* Cahn, *Accidental Incest*, *supra* note 2, at 105 (“The existing federal regulation infrastructure thus provides an appropriate starting place. A new section could be added to the existing regulations which mandate safety tests for gametic material.”).

<sup>168</sup> Letter from Kathryn C. Zoon, Dir. of the Ctr. for Biologics Evaluation and Research, FDA, to Sponsors/Researchers, Human Cells Used in Therapy Involving the Transfer of Genetic Material by Means Other Than the Union of Gamete Nuclei (July 6, 2001), available at <http://www.fda.gov/biologicsbloodvaccines/safetyavailability/ucm105852.htm>. Investigational biologics are subject to IND requirements of Section 505(i) of the FD&C Act prior to their licensure for marketing. 21 C.F.R. § 312.2(a).

<sup>169</sup> *Ooplasm Definition*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/medical/ooplasm> (last visited Nov. 3, 2013).

<sup>170</sup> Kerry Lynn Macintosh, *Brave New Eugenics: Regulating Assisted Reproductive Technologies in the Name of Better Babies*, 2010 U. ILL. J. L. TECH & POL’Y 257, 271 (2010).

with sperm,<sup>171</sup> and reproductive cloning.<sup>172</sup> The FDA referred to earlier notice of its authority over somatic cells and gene therapy products to support its regulatory power over these transfers.<sup>173</sup> In that 1993 notice,<sup>174</sup> the FDA explained that somatic cellular therapies were biologics, subject to the product license application process, and drugs, subject to the new drug application process and current good manufacturing practices.<sup>175</sup> As for gene therapy, the FDA stated that products containing modified genetic material for therapeutic purposes are also biologics or drugs requiring product license or new drug applications.<sup>176</sup>

Scholars' reactions are mixed over the FDA's increasing involvement in the ART field. For example, Professor Macintosh argues that the FDA's analogy to its power over drugs, even biological drugs, is "extremely weak" because these transfers, unlike gene therapy, are not transferred "directly into patients," but rather into "unfertilized eggs that are not human beings."<sup>177</sup> Others advocate that the FDA should go even further and screen donor gametes for genetic disease as part of its mandate "to ensure the safety and efficacy of biologics" under Section 351 of PHSa.<sup>178</sup> While the debate over the FDA's legal authority to regulate cutting-edge ART procedures is beyond the scope of this article, the FDA's recent actions demonstrate that the agency is increasingly involving itself in ART procedures, and thus its collaboration in setting up a national donor gamete registry with the CDC and the American Society for Reproductive Medicine would not represent a novel incursion into the ART industry.<sup>179</sup> Furthermore, establishing a donor gamete registry is arguably less intrusive into the realm of the practice of medicine because a registry merely records data. Besides setting a limit on the number of pregnancies associated with each donor, the registry would not impose any other new requirements on ART clinical practices.

Of course, the most common donor gamete is sperm, and artificial insemination with donated sperm is actually the one of the most low-tech ART procedures<sup>180</sup> and does

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<sup>171</sup> *Id.* at 269–70.

<sup>172</sup> *Id.* at 271.

<sup>173</sup> Letter from Kathryn C. Zoon, *supra* note 167. See also Macintosh, *supra* note 145, at 273 ("Such gene transfers have the same purpose and effect as drugs, making it plausible that the FDA has authority and can require an IND application.").

<sup>174</sup> Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53,248 (Oct. 14, 1993).

<sup>175</sup> *Id.* at 53,250.

<sup>176</sup> *Id.* at 53,251.

<sup>177</sup> Macintosh, *supra* note 145, at 169.

<sup>178</sup> Held, *supra* note 23, at 291–95. See also Dolin, *supra* note 163, at 1455–56 (arguing that the PHSa should be amended to give FDA authority to regulate genetic material for disease diagnosis and treatment purposes).

<sup>179</sup> Cf. FDA, GUIDANCE FOR INDUSTRY: REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS 3 (2011) ("FDA defines 'genetically engineered (GE) animals' as those animals modified by rDNA techniques, including the entire lineage of animals that contain the modification." (emphasis added)).

<sup>180</sup> See Daniel Wikler & Norma J. Wikler, *Turkey-Baster Babies: The Demedicalization of Artificial Insemination*, 69 *Milbank Q.* 5, 8 (1991) ("Turkey basters, a common kitchen utensil, are adequate instruments, and, in any case, the physician's syringe is readily available.").

not require medical intervention.<sup>181</sup> Because the FDA cannot claim that artificial insemination is a clinical investigation or a new drug, the FDA does not have sufficient regulatory power to create a donor gamete registry on its own. For this reason, partnership with the CDC, which has broader authority over ART procedures, is necessary to establish the registry.

## **B. CDC Authority**

Unlike the FDA, the CDC already has the necessary authority to establish a donor gamete registry and mandate the Tier I requirements. The Fertility Clinic Success Rate & Certification Act (FCSRCA) delegated to HHS the authority to amend the definition of ART through notice-and-comment procedures,<sup>182</sup> so the CDC could broaden this definition to include artificial insemination with anonymous donor sperm. Doing so would require that clinics performing these procedures would also have to report their pregnancy success rates.

As for the definition of “pregnancy success rates,” the FCSRCA also allows HHS to amend this definition in consultation with ART consumer and professional organizations. Congress directed the Secretary to consider “the effect of success rates of age, diagnosis, and other significant factors.”<sup>183</sup> Thus the CDC, in consultation with these stakeholders, could revise its regulations to include the Tier I requirements.<sup>184</sup> Scholars have already criticized the CDC’s narrow definition of pregnancy success rates. For example, Professor Judith Daar notes the incongruity of the ART system: “while [ART procedures] are directed at patients, outcomes are measured by the well-being of any resulting children . . . the birth of a healthy ART child is not necessarily a sign of health in the ART system.”<sup>185</sup> Thus, it is likely that stakeholders would support amending the definition of pregnancy success rates to enable the CDC to work with the FDA to gather more the Tier I data—donors’ health and screening information, including the number of times a donor’s gametes are used for conception and the donor’s conception and pregnancy outcomes—and make this available to donors and families through a registry.

As stated earlier, the CDC’s regulatory discretion does have its limits, especially concerning medical events following pregnancy, which is why only the first tier of the registry would be mandatory. These limits, especially when coupled with the FDA’s regulatory authority over donor gametes that is limited to prevention of communicable

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<sup>181</sup> See DEBORA L. SPAR, *THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION* 18 (2006) (noting that artificial insemination has been practiced for more than a century).

<sup>182</sup> FCSRCA § 8, Pub. L. No. 102-493, 106 Stat. 3146, 3151 (codified at 42 U.S.C. § 263a-7 (2006)).

<sup>183</sup> *Id.* § 2(b)(2).

<sup>184</sup> Accord Naomi Cahn, *The New Kinship*, 100 Geo. L.J. 367, 412 (2012) (“The centers for Disease Control and Prevention already collect information on the success of ART procedures involving eggs and embryos; this collection could be expanded to include information about sperm as well as the number of children born.”); see also Daar, *supra* note 69, at 290 (recommending that any mandatory reporting requirements for embryo transfer should “parallel or piggyback on the existing system used to collect data on ART outcomes under FCSRCA”).

<sup>185</sup> Daar, *supra* note 69, at 262–63. See also Cahn, *Necessary Subjects*, *supra* note 7, at 223.

disease transmission, demonstrate the need for the FDA and the CDC to form a public-private partnership with an entity like SART to establish a donor gamete registry.

### ***C. National Donor Gamete Registry: A Public-Private Partnership***

While the FDA and CDC would only have to undertake modest regulatory revisions to create a donor gamete registry with Tier I requirements, their authority, even when considered jointly, does not extend past Tier I. If HHS stopped there and only created a donor gamete registry with these requirements, many of the policies justifying the registry would not be realized. For example, because neither FDA nor the CDC has authority once the donation or pregnancy occurs, parents and donor-conceived children would not be able to benefit from broader access to medical history. Tier IV would certainly not be an option because facilitating connections between donor-conceived children and their genetic relatives is outside the scope of the FDA's and the CDC's limited authority. Thus, creating a donor gamete registry solely within the bounds of current HHS regulatory authority would not be worth the effort.

However, if the FDA and CDC partnered with a private party like American Society for Reproductive Medicine (ASRM), and allowed donors and families to volunteer to higher tiers of disclosure, then the registry would be more comprehensive and have a better chance of achieving its policy goals. Partnering with ASRM would allow the joint-entity to use its power as a professional organization to encourage more disclosure than HHS is currently allowed to mandate, and would justify the creation of a registry that collects more information than the HHS can legally require.

Both the CDC and the FDA have a current practice of partnering with private professional organizations. The CDC already has an extensive partnership with ASRM and its partner organization, the Society for Assisted Reproductive Technology (SART) under the FCSRCA, where it allows clinics to report their data to SART directly. As for the FDA, it already has a practice of encouraging individuals to participate in pregnancy registries run by private parties by linking to them on the FDA website. Thus, establishing the donor gamete registry as a joint project between the FDA, the CDC, and ASRM would allow the entities to pool their authority to create the most comprehensive registry by encouraging participants to volunteer more information than the government is currently allowed to collect.

### **D. HIPAA Implications of a National Donor Gamete Registry**

One of the biggest challenges to creating a successful donor gamete registry is ensuring the privacy of the participants. The donor gamete registry would contain protected health information because donors would be tracked across clinics through a social security number, insurance number, or some other individual identifiable information. As a result, the registry and its owner would be subject to the Privacy and Security Rules.<sup>186</sup> Donors, as well as children linked to donors, would have to authorize the release of their data for research purposes.<sup>187</sup> The donor gamete registry could follow the NIH's model in DS-Connect, where NIH stores all the data, but only releases de-

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<sup>186</sup> 45 C.F.R. § 160.103 (2012).

<sup>187</sup> *Id.* § 164.508(b)(3)(i).

identified data to approved researchers.<sup>188</sup> This “sponsor review model” would, on the one hand, prevent inappropriate uses of sensitive information, but could also raise public distrust because then the registry would be owned by the government and the ASRM, not by the donors and children.<sup>189</sup>

The relatively small donor gamete community heightens existing concerns with privacy breaches.<sup>190</sup> Furthermore, even de-identifying this data does not necessarily mean that people’s protected health information will be secure. Professor Barbara Evans, in her discussion of the Sentinel Initiative, recommends “segregating key functions that use identifiable health information as inputs, and sharply restricting the number of [entities] handling patients’ sensitive health data” to prevent harmful disclosure.<sup>191</sup> These recommendations would apply to a gamete donor registry as well.

## **VII. CONCLUSION: HHS IS TRENDING TOWARD A DONOR GAMETE REGISTRY**

Despite the very real privacy concerns that a donor gamete registry raises, it is undeniable that HHS has experience partnering with non-governmental entities to facilitate public access to data from post-market clinical trials and patient and product registries. The increasing post-market surveillance suggests that not only does the public support this trend, but also that the health and technology sectors have the necessary expertise to create secure systems. The rising use of donor gametes to create families, coupled with the success of the Donor Sibling Registry, suggests that it is an optimal time to create a national donor gamete registry.

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<sup>188</sup> See *Understanding Your Participation in DS-Connect* *supra* note 127.

<sup>189</sup> Mello et al., *supra* note 110, at 1656.

<sup>190</sup> See Swink & Reich, *supra* note 17, for an example of how a child tracked down his sperm donor online even though the donation was supposed to be anonymous.

<sup>191</sup> Evans, Congress’ New Infrastructural Model, *supra* note 137, at 640–41.

