The Columbia
SCIENCE AND TECHNOLOGY LAW REVIEW
www.stlr.org

THE REGULATION OF GENETIC ASPECTS OF DONATED REPRODUCTIVE TISSUE—THE NEED FOR FEDERAL REGULATION

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It is estimated that egg and sperm donations account for more than 60,000 births every year in the United States. However, surprisingly, and despite common misconceptions, there are no federal requirements and barely any state requirements to screen and test sperm and egg donors for genetic diseases. The only nationwide standards for genetic screening and testing of donated reproductive tissue are guidelines created by professional organizations, but compliance with those guidelines is voluntary so they cannot be enforced effectively. Furthermore, the few reported cases involving children born from genetically-compromised reproductive tissue illustrate the court system's failure to afford such children and their families the relief they need and deserve. With a continuing rise in the number of babies born each year who are conceived with donated reproductive tissue, it is necessary to create a regulatory framework requiring the screening and testing of reproductive tissue donors for genetic diseases. This article makes the case for federal regulation of the genetic aspects of donated reproductive tissue under the authority granted to the FDA by the Public Health Service Act.

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Available at http://www.stlr.org/cite.cgi?volume=11&article=8

I. INTRODUCTION

Imagine John and Jane, a couple with a common problem experienced by one in every six couples in the United States:[2] infertility.[3] John and Jane seek medical advice and discover that one of them is sterile. They decide to take advantage of one of the numerous assisted reproductive technologies (ART)[4] now available to couples suffering from difficulties such as theirs and start looking for a suitable donor. Browsing through online donor catalogues, they find a donor whose sperm or eggs they would like to use. The sperm/egg bank assures them that their chosen donor—a young, tall, good-looking, gifted, intelligent, and athletic graduate student—has undergone careful screening and was tested[5] for health problems as required by all applicable federal and state laws. Having received such assurances, John and Jane attempt to conceive using the donated reproductive tissue (DRT)[6] they have procured from the bank. They are successful and soon thereafter Jane gives birth to twins, Jean and Juan. Alas, after the birth, Jean is

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[2] *See* S. Rep. No. 102-452, at 1 (1992); ISLAT Working Group, *ART into Science: Regulation of Fertility Techniques*, 281 Science 651, 651 (1998) [hereinafter ISLAT Working Group].

[3] Infertility is commonly defined as the inability to get pregnant after trying for one year. *See* Centers for Disease Control and Prevention (CDC), Assisted Reproductive Technology: Home, http://www.cdc.gov/art (last visited May 9, 2010).

[4] According to the CDC, ART consists of all clinical treatments and laboratory procedures—including the handling of human oocytes and sperm, or embryos—conducted with the intent of conceiving, e.g., in-vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, sperm, oocyte or embryo donation, and gestational surrogacy. *See* Implementation of the Fertility Clinic Success Rate and Certification Act of 1992–A Model Program for the Certification of Embryo Laboratories, 64 Fed. Reg. 39374, 39383 (CDC July 21, 1999) [hereinafter CDC Model Program].

[5] For purposes of this article, "testing" is defined as any procedure involving direct clinical examination of a potential donor or her tissue, whereas "screening" is any inference of clinical information through indirect examination of a donor's background. For example, questioning a potential donor in order to identify possible genetic risk factors in her family's medical history is a screening procedure, while verifying that her genes do not contain certain genetic mutations by attempting to identify certain genetic markers in a cell sample taken from her would be considered testing. Notably, direct testing of the genes of a potential donor is not the only readily available method of testing donor candidates. For example, ECG could assist in identifying heart conditions whose genetic background may be unclear or otherwise difficult to ascertain. *See* Barry J. Maron et al., *Implications of Hypertrophic Cardiomyopathy Transmitted by Sperm Donation*, 302 JAMA 1681, 1684 (2009) (reporting that an electrocardiogram could assist in identifying 80-95% of the cases of hypertrophic cardiomyopathy in adults with left ventricular hypertrophy, a hereditary and potentially lethal cardiac anomaly).

[6] The term "donated reproductive tissue" includes all forms of reproductive cells that can be used in ART, namely sperm and ova (eggs) in different developmental stages and in different media.

diagnosed with cystic fibrosis (CF)[7] and a few years later Juan is diagnosed as suffering from autosomal dominant polycystic kidney disease (ADPKD).[8] John and Jane are devastated. Inquiries conducted by their (very expensive) attorneys reveal that their donor was a carrier of a CF mutation. Moreover, after overcoming numerous legal hurdles, John and Jane find out that their donor's aunt and grandmother died from kidney failure. They sue the DRT bank for regular and punitive damages under numerous causes of action including negligence, products liability, wrongful life, infliction of emotional distress and fraud. Yet, the court rejects the majority of their claims as a matter of law. Furthermore, the court is unsympathetic to the family's situation and holds that children do not have the "right to be born free of diseases" regardless of whether they were conceived naturally or through ART. The tissue bank issues a press release truthfully stating that it is meticulously following and is in full compliance with all federal and state legislation and regulation. It quickly reaches a quiet and relatively cheap settlement with the Does regarding their remaining claims; if it is a member of a professional accreditation organization, such as the American Association of Tissue Banks (AATB), it might lose its membership for a short while.

This hypothetical scenario illustrates actual cases litigated in the United States[9] and foreshadows more that are likely to be brought under the current federal and state

[7] CF is a hereditary disease whose symptoms usually appear shortly after birth and include digestion problems, breathing difficulties and respiratory infections; in the past it was almost always fatal in childhood, but nowadays patients commonly live long past childhood. CF is an autosomal recessive condition, meaning that in order to have an affected child both parents must carry the mutated gene and pass it along to the child, which has a one in four (1:4) likelihood of happening with each pregnancy. *See* National Human Genome Research Institute, Glossary, http://science.education.nih.gov/supplements/nih1/genetic/other/glossary/act1-gloss2.htm (last visited May 9, 2010); National Genome Research Institute, Learning about Cystic Fibrosis, http://www.genome.gov/10001213 (last visited May 9, 2010).

[8] According to the Human Genome Research Institute, ADPKD is one of the most common forms of polycystic kidney disease (PKD), a genetic disorder characterized by the growth of numerous cysts in both kidneys. As the disease progresses, the cysts get filled with fluid and slowly replace much of the normal mass of the kidneys, thus reducing kidney function and leading to kidney failure. PKD can also cause cysts in the liver and problems in other organs such as the pancreas, the heart and the brain, as well as high blood pressure (hypertension), abdominal wall hernias, and more. As indicated by its name, ADPKD is an autosomal dominant disease, which means that if a child inherits one copy the ADPKD gene he or she will likely develop the disease. Each child of a parent having an ADPKD gene has a 50-50 chance of inheriting the ADPKD gene. *See* National Human Genome Research Institute, Learning About Autosomal Dominant Polycystic Kidney Disease, http://www.genome.gov/20019622 (last visited May 9, 2010).

[9] *See Johnson v. Superior Court* (*Johnson II*), 124 Cal. Rptr. 2d 650, 666 (Cal. Ct. App. 2002) (holding that the kidney disease of a child born from DRT (DRT child) was caused by a gene in the sperm rather than by either the sperm bank or the bank's physician's actions in improperly approving the sperm donor, and thus, that the child could not recover general damages or lost earnings); *Becker v. Schwartz*, 386 N.E.2d 807, 811-12 (N.Y. 1978) (rejecting "wrongful life" as a cognizable cause of action and holding that a child does not have a fundamental right to be born

regulation of DRT. Yet, an even greater source of concern is the vast and growing number of children born every year in the United States from DRT[10] who, to their and their families' misfortune, might become a part of such a tragedy.[11] According to the Centers for Disease Control and Prevention (CDC), in 2006 there were 5,393 babies born in the United States from donated eggs and embryos.[12] There is no current data regarding the number of babies born from donated sperm,[13] but a survey conducted by the former Office of Technology Assessment (OTA) estimated the number of births from artificial insemination (AI) by a donor at 30,000 per year in 1986-87.[14] In 1998, the ISLAT

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as a whole, functional human being); *Paretta v. Medical Officers for Human Reproduction*, 760 N.Y.S.2d 639, 644 (N.Y. Sup. Ct. 2003) (re-stating that a child does not have the right to be born free of genetic defects, regardless of how she was conceived, and thus, that a DRT child born with CF did not suffer a legally cognizable injury and her parents did not have a valid claim for damages for the emotional distress they experienced as a result of having a child with a genetic disease).

[10] *See* Elizabeth A. Conrad et al., *Current Practices of Commercial Cryobanks in Screening Prospective Donors for Genetic Disease and Reproductive Risk*, 41 Int. J. Fertil. 298, 303 (1996); *see also* CDC, Assisted Reproductive Technology Success Rates—National Summary and Fertility Clinics Reports 2004, 52 (2006) [hereinafter CDC 2004 Report]; Peggy Orenstein, *Your Gamete, Myself*, N.Y. Times Magazine, July 15, 2007, at 36.

[11] There are no official statistics regarding the transmission of genetic diseases through DRT. *See* Conrad, *supra* note 10, at 299. Thus, it is difficult to accurately evaluate the risks of genetic diseases involved in using DRT.

[12] *See* CDC, 2006 Assisted Reproductive Technology Success Rates: National Summary and Fertility Clinic Reports 59 (2008). Unofficial estimates currently speak of 7,000-10,000 births from egg donation a year.

[13] The author is not aware of any source of statistical data regarding the number of donor sperm specimens sold or of babies born from such DRT yearly in the United States. The legislation authorizing CDC to collect information from "embryo laboratories" regarding egg donations and IVF success rates does not apply to sperm donations and sperm use success rates. *See infra* notes 32-33. Thus, there are no official statistics regarding the number of semen specimens sold and children resulting from artificial insemination (AI) in the United States each year.

[14] *See* Office of Technology Assessment (OTA), Artificial Insemination Practice in the United States: Summary of a 1987 Survey 3 (Aug. 1988) [hereinafter *OTA 1988 Survey*]. According to the survey, in 1986-87, 172,000 women underwent artificial insemination, resulting in about 65,000 births, 35,000 of which were from artificial insemination by the husband. *See id.*

With respect to DRT, one should distinguish between "directed donations," in which the recipient receives DRT from a person whom she knows and is known by prior and unrelated to seeking the donation, and anonymous donations, in which the recipient does not know the identity of the donor (or—in case the donor agrees to expose his/her identity—the recipient knows who the donor is but did not know him or her prior to the acquisition of the DRT). It is important to note that the discussion of DRT in this article focuses almost exclusively on anonymous donations.

Working Group estimated that egg and sperm donations account for more than 60,000 births every year.[15] Yet, despite the significance of these numbers, there is a dearth of state law[16] and a total lack of federal law regulating the genetic aspects of DRT.[17] Court decisions addressing the failure of DRT institutions[18] to screen and test donors for genetic

[15] *See* ISLAT Working Group, *supra* note 2, at 652. Due to a lack of accurate data, it is difficult to determine whether these numbers have grown or dropped as a result of advancements in ART. Regardless, it is clear that the number of DRT children is very significant. *See* Judith F. Daar & Robert G. Brzyski, *Genetic Screening of Sperm and Oocyte Donors: Ethical and Policy Implications*, 301 JAMA 1702, 1702 (2009) (reporting that nearly 3 in every 100 births in the United States is attributable to some form of assisted conception and arguing that the numbers of births using DRT have been steadily increasing since the introduction of IVF in 1978).

[16] Only two states—New York, and Ohio—require genetic screening and testing of DRT donors for some genetic diseases. *See infra* Part II.B.

[17] *See* Maron et al., *supra* note 5, at 1681, 1683 (describing a series of cases in which a genetically inherited disease was transmitted through anonymous sperm donation and characterizing this type of risk as "a problem largely unappreciated by the medical community *and agencies regulating tissue donation*"; "[a]lthough *not required by FDA*, some sperm banks test for cystic fibrosis, thalassemia anemia, sickle cell trait, Tay-Sachs, and other genetic diseases . . . ") (emphases added).

In this article, the term "genetic aspects of DRT" includes (1) screening and testing of DRT donors based on genetic criteria, (2) keeping genetic information on record, (3) informing DRT recipients about relevant donor genetic information and its potential ramifications, and (4) notification of proper authorities and institutions engaging in collection and distribution of DRT and recipients of adverse events having a genetic background or suspected as having a genetic background. For purposes of this article, this term does not apply to genetic aspects of any infectious diseases, e.g., viral infection (such as HIV, herpes, etc.) that influences the nucleic acid makeup of human cells.

The term "genetic aspects of DRT" also does not include the genetic screening and testing of potential DRT recipients. Arguably, genetic screening and testing of DRT recipients would be less cost-effective and more cumbersome than the screening and testing of potential DRT donors. This is because DRT donors (mostly sperm donors) are normally the source of a large number of DRT specimens used to conceive many DRT children while any DRT recipient would normally have a few children at most. Admittedly, only a minority of the candidates eventually become DRT donors, yet DRT programs may test only potential donors that make it through earlier selection stages. Also, a requirement for genetic screening and testing of potential DRT donors rather than DRT recipients is more feasible and more defensible from a privacy perspective because DRT donors normally submit themselves to medical evaluations as part of the selection process and thus, are more readily available and likely to give their consent to have their genetics tested.

[18] For purposes of this article, a DRT institution is any individual or entity engaged in the manufacture of DRT; "manufacture," according to the FDA, includes but is not limited to "any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor." *See* 21 C.F.R. § 1271.3(e) (2005). DRT institutions include, e.g., sperm banks and institutions that harvest donor oocytes as

diseases are sparse and ambivalent. Thus, the only means of protection from genetic disease afforded to DRT children and their families are the standards set by professional organizations.[19] However, membership in such organizations is purely voluntary and non-compliance does not seem to carry any real sanctions.[20] Hence, currently, in the United States, there is no effective protection of DRT recipients from acquiring genetically defective DRT or of DRT children from having such diseases even where there *are* effective means of testing for and preventing the transmission of such diseases.

Despite repeated warnings since the late 1970s regarding the insufficiency of genetic screening and testing of DRT and subsequent calls for regulation,[21] there are no signs that the current framework of regulation of genetic aspects of DRT (or lack thereof) is about to change. Legislators, in general, are averse to legislating about issues pertaining to human reproduction[22] and regulators show a similar disinclination.[23] It thus appears that no one is going to address this void unless forced to do so by the occurrence of a highly publicized tragedy. Furthermore, additional discoveries of genetic bases of diseases and development of means of testing for such diseases in the future would only accentuate the problems existing under the current regulatory scheme. Fortunately, there is a way to correct the situation and fill the regulatory vacuum before more tragedies occur.

On May 25, 2005 the FDA promulgated regulations pertaining to communicable disease aspects of DRT, including requiring the screening and testing of DRT donors for infectious diseases.[24] Yet, the FDA refrained from taking similar steps with respect to the genetic aspects of DRT.[25] I argue that by stepping into the area of regulation of DRT, the

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well as small clinics that serve smaller populations so long as they manufacture donor DRT. This definition of DRT, however, does not include clinics that merely harvest DRT for directed donations.

[19] *See infra* Part IV (discussing professional standards set by the American Society for Reproductive Medicine (ASRM) and the American Association of Tissue Banks (AATB)).

[20] *See infra* notes 181 and 196 and accompanying text.

[21] *See infra* Part II.D.1.

[22] *See* George J. Annas, *The Shadowlands—Secrets, Lies, and Assisted Reproduction*, 339 New Eng. J. Med. 935, 937 (1998); Stacy Huse, *The Need for Regulation in the Fertility Industry*, 35 U. Louisville J. Fam. L. 555, 556 (1996-1997).

[23] *See* Cynthia B. Cohen, *Unmanaged Care: The Need to Regulate New Reproductive Technologies in the United States*, 11 Bioethics 348, 357 (1997); Richard A. Merrill, Human Tissues and Reproductive Cloning: New Technologies Challenge FDA, 3 Hous. J. Health L. & Pol'y 1, 63 n.332 (2002).

[24] FDA, Guidance for Industry, Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 69 F.R. 29786-01 (May 25, 2004) [hereinafter *FDA Final Donor Eligibility Rule*].

[25] The FDA provided no explanation for its avoidance of the area of genetic aspects of DRT. *See infra* Part IV (discussing possible reasons for the FDA's inaction).

FDA has created the necessary infrastructure for expanding its regulatory scheme to include the regulation of the genetic aspects of DRT and has positioned itself as the preferable regulator of this area. The FDA's authority under the Public Health Service Act (PHSA)[26] provides it with ample authority to regulate not only the communicable diseases aspects of DRT but also their genetic aspects, as is done in other countries. This article makes the case for such federal regulation of the genetic aspects of DRT by the FDA.

Part II of this Article will describe the current regulation of DRT in the United States with emphasis on its genetic aspects and the compelling public policy reasons for the regulation of this area. Part III will survey the regulation of genetic screening and testing of DRT in the European Union, the United Kingdom and Ireland and highlight some of the mechanisms they employ to overcome reoccurring problems typical to such regulation. Implementing some of the mechanisms applied abroad to the unique circumstances of the United States, Part IV will offer a framework for the regulation of genetic aspects of DRT by the FDA and will discuss some of the issues involved in and obstacles to such regulation. Part V will conclude this Article with a call for the FDA to rise to the challenge of filling the regulatory vacuum.

II. THE REGULATION OF GENETIC SCREENING AND TESTING OF DONATED REPRODUCTIVE TISSUE IN THE UNITED STATES

The regulation of DRT in the United States has been repeatedly described as lacking in its protection of DRT recipients and DRT children.[27] This Part will explain why this criticism is particularly justified with respect to the regulation of the genetic aspects of DRT.

A. Federal Regulation

Although the federal government has regulated several aspects of ART,[28] there is no federal law addressing the genetic aspects of DRT. The lack of such regulation is peculiar in light of the federal government's actual involvement in the regulation of two aspects of DRT, specifically the creation of a model program for the accreditation of fertility clinics to be carried out by the states[29] and the regulation of DRT as human

[26] Public Health Service Act (PHSA), Ch. 373, 58 Stat. 682 (July 1, 1944), *codified at* 42 U.S.C. §§ 201–300, Ch. 6A.

[27] *See generally* OTA, Infertility: Medical and Social Choices 24-26 (1988) [hereinafter *OTA's Infertility Report*]; Huse, *supra* note 22, at 571-72; Charles Marwick, *Artificial Insemination Faces Regulation, Testing of Donor Semen, Other Measures,* 260 JAMA 1339 (1988); Judith Lynn Bick Rice, *The Need for Statutes Regulating Artificial Insemination by Donors*, 46 Ohio St. L.J. 1055 (1985).

[28] *See infra* Parts II.A.1-II.A.2.

[29] *See* CDC Model Program, *supra* note 4, at 39374.

tissue.[30] Both regulatory schemes stop just short of addressing the genetic aspects of DRT.

1. The Regulation of ART by the CDC

In 1992, concerned with information indicating that some fertility clinics misled patients by making false and exaggerated representations of success rates in achieving pregnancies and provided substandard services,[31] Congress legislated the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA).[32] FCSRCA instructed the CDC to develop a model program for the accreditation of embryo laboratories[33] which would be carried out by the states.[34] The CDC published the Model Program devised under FCSRCA in the Federal Register on July 21, 1999.[35] Although FCSRCA strove to regulate the quality of embryo laboratories, it did not include any requirement for the assurance of the safety of the procedures employed by such laboratories, and so neither did the resulting CDC Model Program.[36] Thus, although Congress may have sought to protect consumers acquiring the services of fertility clinics from false representations and poor quality of services,[37] it neglected to create a more comprehensive regulatory scheme that would protect DRT recipients and DRT children from such hazardous practices as improper testing of DRT for genetic diseases.

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[30] 21 C.F.R. § 1271 (2009) [hereinafter Human Tissue Regulations].

[31] *See* S. Rep. No. 102-452, at 2565-67 (1992); 137 Cong. Rec. E4145-02 (1991) (statement of Rep. Wyden).

[32] 42 U.S.C. § 263a-1 (1992).

[33] FCSRCA § 8 defines an "embryo laboratory" as "a facility in which human oocytes are subject to assisted reproductive technology treatment or procedures based on manipulation of oocytes or embryos which are subject to implantation." 42 U.S.C. § 263a-7 (1992).

[34] 42 U.S.C. § 263a-2 (2008).

[35] *See* CDC Model Program, *supra* note 4, at 39374.

[36] 42 U.S.C. § 263a-2(d) (2008).

[37] *See* note 31 *supra*. Notably, Congress was well aware that FCSRCA was far from providing a sufficiently comprehensive protection for ART consumers in general, and in particular with respect to genetic aspects of DRT. Addressing the House of Representatives in his presentation of FCSRCA, Rep. Wyden said: "I would like to alert my colleagues to another area deserving of vigorous Congressional oversight—the $170 million artificial insemination industry. A study by the Office of Technology Assessment has revealed a startling lack of oversight, particularly in doctor's offices, which could have significant adverse public health effects. . . . [H]alf [of the physicians who provide AI services] don't screen for genetic defects." 137 Cong. Rec. E4145-02 (1991) (statement of Rep. Wyden).

Even further demonstrating its lack of effectiveness, the CDC Model Program is only voluntary for states[38] and embryo laboratories alike.[39] Thus, even had the CDC Model Program been sufficiently comprehensive, it would probably not have contributed to the safety of DRT children.

2. The FDA's Human Tissue Regulations

Repeated calls for a comprehensive scheme of federal regulation of donated tissue, including DRT,[40] prompted the FDA to announce in March 1997 that it intended to create a regulatory scheme for "cellular and tissue based products"[41] (including DRT) which would include donor eligibility standards and donor screening and testing requirements.[42] After a lengthy "notice and comment" process,[43] in January 2001 the FDA published the first of three installments of regulations that would eventually become

[38] 42 U.S.C. § 263a-2(e) (2008). Under the Anti-Commandeering Doctrine, the federal government may not instruct the states to adopt legislation but rather may merely try to convince them to do so through incentives. *See New York v. United States,* 505 U.S. 144, 166-69 (1992); *Printz v. United States,* 521 U.S. 898, 924-25 (1997). Hence FCSRCA could not compel the states to apply for the CDC Model Program. Notably, except for coverage of inspections of fertility institutions by funds collected from participating DRT institutions, the CDC Model Program does not seem to include any real incentive for the states to apply to participate in it. *See* FCSRCA § 7; CDC Model Program, *supra* note 4, at 39382. This lack of incentive may account, at least in part, for the fact that no state has submitted a request with the CDC to join the Model Program. Telephone Interview with CDC Division of Reproductive Health Helpdesk representative, Feb. 23, 2010 (on file with author).

[39] *See* CDC Model Program, *supra* note 4, at 39382.

[40] *See* FDA, *Reinventing the Regulation of Human Tissue* (Feb. 1997) [hereinafter *Reinventing the Regulation of Human Tissue*], *available at* http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/RegulationofTissues/ucm136967.htm.

[41] *See generally* Proposed Approach to Regulation of Cellular and Tissue-Based Products: Availability and Public Meeting, 62 Fed. Reg. 9721 (FDA Mar. 4, 1997) [hereinafter *FDA's Proposed Approach*]. Notably, as early as 1993, the FDA published an interim rule that required the screening and testing of some human tissue for HIV and hepatitis. *See* Human Tissue Intended for Transplantation, 58 Fed. Reg. 65514 (FDA Dec. 14, 1993). However, this rule, whose final version was published in 1997, 62 Fed. Reg. 40429 (FDA July 29, 1997), did not apply to DRT. *See* 21 C.F.R. § 1270.3(j)(5) (2005).

[42] *See Reinventing the Regulation of Human Tissue*, *supra* note 40, at 1 ("The agency would require infectious disease screening and testing be done for cells and tissues transplanted from one person to another.").

[43] *See* 66 Fed. Reg. 5448 (FDA Jan. 19, 2001) (describing the process); 69 Fed. Reg. 29786, 29786-87 (FDA May 25, 2004) (same).

the Human Tissue Regulations,[44] which required all DRT institutions to register with the FDA.[45] In May 2004, the FDA published its draft Donor Eligibility Rule,[46] which eventually went into effect on May 25, 2005.[47]

Under the FDA's Final Donor Eligibility Rule, DRT banks must make donor eligibility determinations[48] based on donor screening and testing for an array of infectious diseases that might pass to children born through the use of DRT, including HIV-1 and HIV-2, human cytomegalovirus, hepatitis B and C, syphilis, gonorrhea, chlamydia, West Nile virus and more.[49] Such donor eligibility determinations must be based on an assessment of the donor's risk factors in light of his or her medical records[50] and the results of tests performed on the donated tissue,[51] with additional specific requirements

[44] Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment of Registration and Listing, 66 Fed. Reg. 5447, 5448 (FDA Jan. 19, 2001).

[45] 21 C.F.R. § 1271.1 (2005). For inclusion of DRT institutions in the Human Tissue Regulations, see 21 C.F.R. § 1270.10(a)(4)(i)(c). According to the FDA's Human Cell and Tissue Establishment Registration (HCTERS), as of May 2009 there were 554 establishments involved in the recovery, processing and distribution of semen and 472 establishments involved in recovery, processing and distribution of oocytes registered with the FDA. *See* FDA, Find a Tissue Establishment, http://www.fda.gov/cber/tissue/tissregdata.htm (last visited May 9, 2010).

[46] *See generally FDA Final Donor Eligibility Rule*, *supra* note 24.

[47] *Id*. at 29786. The third "installation" of the Human Tissue Regulations was published in its final form in Nov. 2004 and became effective on May 25, 2005. *See* Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments: Inspection and Enforcement, 69 Fed. Reg. 68612 (FDA Nov. 24, 2004).

[48] 21 C.F.R § 1271.50 (2005).

[49] 21 C.F.R. §§ 1271.3(r), 1271.50, 1271.75, 1271.80, 1271.85 (2005). *See also* FDA, Testing HCT/P Donors: Specific Requirements, http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm151757.htm (last visited June 17, 2010). Tissue manufacturers are also under an obligation to screen and test donors for diseases not enumerated in the *FDA Final Donor Eligibility Rule* that (1) carry a risk of transmission, (2) potentially have sufficiently severe effects and (3) may be screened or tested for. *See* 21 C.F.R. § 1271.3(r)(2) (2005).

[50] 21 C.F.R. § 1271.75 (2005). Although the regulations do not mention specific "risk factors" that would render a person ineligible to donate tissue, such risk factors are enumerated in a "Guidance for Industry" document released by the FDA in February 2007. *See* Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products: Availability, 72 Fed. Reg. 9007 (FDA Feb. 28, 2007) [hereinafter *FDA's Guidance for Industry Announcement*].

[51] 21 C.F.R. § 1271.85 (2005).

set forth for the testing of DRT.[52] "A donor whose specimen tests reactive"[53] or who is "identified as having . . . [a] risk factor for or clinical evidence of any"[54] of the diseases enumerated in the Human Tissue Regulations is deemed ineligible to donate.[55] In addition, tissue manufacturers must investigate and report to the FDA any serious adverse reaction related to donated tissue.[56] Notably, the FDA's Final Donor Eligibility Rule was complemented by a "Guidance for Industry,"[57] which reflected the "FDA's current thinking" on eligibility determination by tissue manufacturers.[58]

Despite its outspoken intention to create a comprehensive regulatory framework for cells and tissue-based products, which "would provide physicians and patients with the assurance of safety that the public has come to expect from . . . products overseen by the FDA,"[59] from the outset, the FDA narrowed the possible scope of its regulatory scheme and limited it to the prevention of infectious diseases.[60] Most importantly, in

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[52] DRT must also be tested for Chlamydia trachomatis and Neisseria gonorrhea. *See* 21 C.F.R. § 1271.85(c) (2005).

[53] 21 C.F.R. § 1271.80(d)(1) (2005).

[54] 21 C.F.R. § 1271.75(d)(1) (2005).

[55] Notably, there are exceptions to this rule. For instance, when DRT is donated by a sexually intimate partner of the recipient for reproductive use the rule does not apply. *See* 21 C.F.R. § 1271.90(a) (2005).

[56] 21 C.F.R. § 1271.350 (2005).

[57] *See FDA's Guidance for Industry Announcement*, *supra* note 50, at 1.

[58] *Id.* It is important to note that according to the FDA, the Guidance for Industry "does not create or confer any rights for or on any person and does not operate to bind FDA or the public" but is rather a detailed explanation of the FDA's expectations from tissue manufacturers with respect to their duties under the *FDA Final Donor Eligibility Rule*. *Id.*

[59] *See* 66 Fed. Reg. 5447, 5448 (FDA Jan. 19, 2001); *FDA's Proposed Approach*, *supra* note 41, at 7. *See also* Tissue Banks: is the Federal Government's Oversight Adequate: Hearing before the Permanent Subcomm. on Investigations of the Comm. on Governmental Affairs, 107th Cong. 106 (2001) (statement by Kathryn C. Zoon, Ph.D., Director, Ctr. for Biologics Evaluation and Research, FDA), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_senate_hearings&docid=f:73395.pdf [hereinafter Zoon Statement] ("FDA can assure the Committee that we are committed to establishing a regulatory framework, which not only helps to ensure the safe use of human tissue for transplantation, but also . . . instills public confidence."); *Reinventing the Regulation of Human Tissue*, *supra* note 40 ("FDA . . . has designed a new regulatory framework for cells and tissues that would protect the public health . . . .").

[60] In its Proposed Approach, the FDA described five public health and regulatory concerns, which do not lend themselves to any reading that would include the prevention of spreading of genetic diseases. *See FDA's Proposed Approach*, *supra* note 41, at 9. Moreover, in addressing safety and efficacy aspects of human tissues having "reproductive function," the *FDA's Proposed*

promulgating the Final Donor Eligibility Rule, the FDA relied only on PHSA § 361,[61] which grants it authority to promulgate regulations "necessary to prevent the introduction, transmission, or spread of communicable diseases"[62] and which has no bearing on the prevention of transmission of genetic diseases.[63] Similarly, the FDA structured its new regulatory scheme in a way that includes DRT under a new FDA-invented category of "minimally manipulated tissue,"[64] which is subject only to regulation under the Human Tissue Regulations.[65]

Interestingly, at least at one time, the FDA considered the possibility of requiring the testing of DRT for genetic diseases.[66] It is unknown why the FDA ultimately did not address this issue at all.[67] As I will show later in this Article, this exclusion of genetic aspects of DRT from the FDA's Human Tissue Regulations was not only undesirable

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Approach plainly stated that "[f]ailure of reproductive tissue generally does not have life-threatening or systemic adverse effects except for fertility per se." *Id.* at 20. This statement does not seem to consider the possible adverse effects that genetically compromised DRT might have on DRT children.

[61] *See* 66 Fed. Reg. 5447, 5449 (FDA Jan. 19, 2001).

[62] *See* PHSA § 361 (codified at 42 U.S.C. § 264 (2008)); *infra* note 278 and accompanying text. The authority under PHSA § 361 was originally granted to the Surgeon General and was later transferred to the Assistant Secretary of Health who delegated it to the FDA. *See* 66 Fed. Reg. 5447, 5449 (FDA Jan. 19, 2001).

[63] *See infra* Part IV.A. Consequently, for example, the requirement in the Human Tissue Regulations to evaluate the donor's medical history only applies to the *donor's own* medical history and not to that of her family. 21 C.F.R. § 1271.3(n) (2005). Similarly, the Human Tissue Regulations do not include any requirement for testing of potential DRT donors for any genetic conditions.

[64] 21 C.F.R. § 1271.3(f) (2005). The term "minimally manipulated tissue" designates tissue that did not undergo substantial processing. Under § 1271.3(f)(2), DRT is considered minimally manipulated tissue.

[65] 21 C.F.R. § 1271.10(a)(4)(ii)(c) (2005). This diminished regulatory burden exempts DRT from additional, possibly more stringent and comprehensive, regulatory requirements under PHSA.

[66] *See* Letter from Diane E. Thompson, Associate Commissioner for Legislative Affairs, DHHS, to Bernice Steinhardt, Director, HEHS, GAO (Oct. 23, 1997), *available at* http://www.gao.gov/archive/1998/he98025.pdf (warning against the insufficiency of the FDA's existing regulation and proposed regulatory approach with respect to the risk of introduction of genetic diseases through DRT).

[67] Notably, a report issued in 2007 by the FDA appointed Human Tissue Task Force did not even mention the issue of genetic screening and testing of DRT. *See* Press Release, FDA, FDA Releases Human Tissue Task Force Report (June 12, 2007) [hereinafter HTTF Report], *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108932.htm.

from a public policy perspective but also could have been avoided had the FDA used a different set of authorities available to it to regulate DRT in general.[68]

B. State Regulation

Although state law has traditionally regulated most aspects of public health and the licensing of medical personnel and facilities,[69] most states do not require any level of screening or testing of DRT for genetic diseases.[70] Roughly half of the states have some kind of regulation pertaining to the screening and testing of DRT donors for infectious diseases,[71] yet only two states—New York and Ohio[72]—impose requirements on DRT institutions to screen and test DRT for genetic risk factors.[73]

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[68] *See infra* Part IV.A.

[69] *See* Kathleen M. Peterson, *Federal Regulation of Artificial Insemination Donor Screening Practices: An Opportunity for Law to Co-Evolve with Medicine*, 96 Dick. L. Rev 59, 84 (1991).

[70] *See* Lori B. Andrews & Nannette Elster, *Adoption, Reproductive Technologies, and Genetic Information*, 8 Health Matrix 125, 135-36 (1998); Alexander Hecht, Note, The Wild Wild West: Inadequate Regulation of Assisted Reproductive Technology, 1 Hous. J. Health L. & Pol'y 227, 252-53 (2001) (noting that most state statutes do not set up requirements regarding donors' medical conditions).

[71] Cal. Health & Safety Code § 1644.5 (1989); Del. C. Ann. tit. 16, § 2801 (1988); Fla. Stat. Ann. § 381.0041 (2002); Ga. Code Ann. § 44-5-151 (1988); Id. Code Ann. §§ 39-3703 (1988), 39-5404 (1982), 39-5408 (1986); Id. Admin. Code §§ 16.02.07.004, 16.02.07.009; 20 Ill. Comp. Stat. Ann. §§ 2310/2310-325 (2000); Ind. Code Ann. § 16-41-14-5 (1993); 410 IAC § 25-2-2 (1992); Ky. Rev. Stat. Ann. § 311.281 (1990); La. Rev. Stat. Ann. §§ 40:1062.1 (1988), 40:1299.143 (1987); Md. Code Ann., Health – General, § 18-334(e) (1988); Mich. Comp. Laws Ann. §§ 333.9123 (1988), 333.16273 (1988), 333.20179 (1988); Mont. Code Ann. § 50-16-1008 (1989); N.H. Rev. Stat. Ann. §§ 168-B:10 (1990), 168-B:14 (1990); N.J. Stat. Ann. § 26:5C-22 (1997); N.Y. Comp. Codes R. & Regs. tit. 10, §§ 52-8.5–52-8.9 (1991); N.C. Gen. Stat. Ann. § 130A-148 (1987); Ohio Rev. Code Ann. § 3111.91 (2000); Ohio Rev. Code. Ann. § 3701.246 (1989); Okla. Stat. Ann. tit. 63, § 2151.1 (1988); Or. Rev. Stat. Ann. § 677.370 (1997); 28 Pa. Code §§ 27.151 (2002), 27.21a (2002); R.I. Gen. Laws 1956, § 23-18.6.1-12 (2006);Va. Code Ann. § 32.1-45.3 (1995); 12 Va. Admin. Code §§ 5-90-240, 5-90-260 (1998); Wis. Stat. Ann. § 252.15(2)(am)(1) (1995). Notably, out of these twenty-one states, twelve (Delaware, Georgia, Illinois, Louisiana, Maryland, Michigan, Montana, New Jersey, Oklahoma, Rhode Island, and Virginia) only require the screening and/or testing of DRT for AIDS. The other twenty nine states do not seem to impose any requirement of their own on DRT institutions to screen and/or test DRT donors for diseases, whether genetic or communicable.

[72] *See supra* note 71.

[73] Two more states, Idaho and Oregon, impose a duty on *semen donors* (only) not to donate if they are aware that they have "any disease or defect known by [them] to be transmissible by genes." *See* I.C. 39-5404 (1982); O.R.S. § 677.370 (1997). However, the subjective element of these statutory duties seems to make them extremely difficult to enforce. Indeed, the author is

Ohio requires that in order to use semen from an anonymous donor, "[a] complete medical history of the donor, including, but not limited to, any available genetic history of the donor, [must be] obtained . . . [and] [t]he donor [must undergo] a physical examination" within one year prior to the donation.[74] In addition, practitioners using anonymously donated frozen semen must test the donor's semen or blood using "appropriate" laboratory studies for the genetic diseases Tay-Sachs[75] and sickle-cell anemia[76] and perform karyotyping[77] of the DRT.[78] Subsequently, the DRT practitioners are explicitly required to determine whether the results of such tests "are acceptable."[79]

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unaware of any case in which a donor was prosecuted or sued based on a cause of action stemming from these provisions.

An interesting question is why only New York and Ohio have relatively comprehensive regulatory schemes with respect to the genetic aspects of DRT while other states, like California—which hosts the nation's largest DRT institution and several others—do not. Different explanations could be offered for the adoption of comprehensive regulation or lack thereof. For example, states with a significant medical industry, such as New York, could be expected to have progressive medically-related regulation. Similarly, states having a significant DRT industry, such as California and New York, could be expected to have a strong anti-regulation lobby. On the other hand, states having a strong DRT industry may strive to have stricter regulation to protect their industry from out-of-state competition. Yet, none of these possible explanations seems to provide a full explanation as to why only New York and Ohio adopted relatively comprehensive regulation of the genetic aspects of DRT while other states, such as California and Massachusetts, did not.

[74] Ohio Rev. Code Ann. § 3111.91(B)(1)(a)-(b) (2000).

[75] Tay-Sachs is a fatal genetic disorder in which harmful quantities of a fatty substance build up in tissues and nerve cells in the brain. Infants with Tay-Sachs disease appear to develop normally for the first few months of life but then suffer an ongoing deterioration of mental and physical abilities until the child's inevitable death before the age of five. The incidence of Tay-Sachs is particularly high among people of Eastern European and Ashkenazi Jewish descent. Patients and carriers of Tay-Sachs disease can be identified by a simple blood test. Tay-Sachs disease is an autosomal recessive condition, meaning that in order to have an affected child both parents must carry the mutated gene and pass it along to the child, which has a one in four (1:4) likelihood of happening with each pregnancy. *See* National Institute of Neurological Disorders and Stroke, NINDS Tay-Sachs Disease Information Page, http://www.ninds.nih.gov/disorders/taysachs/taysachs.htm (last visited May 9, 2010).

[76] Sickle cell anemia is a disease in which the body makes sickle-shaped red blood cells (i.e. red blood cells that are shaped like a "C") rather than normal disc-shaped blood cells. Sickle-shaped cells do not move easily through blood vessels and tend to form clumps and get stuck in the blood vessels thus blocking blood flow in the blood vessels that lead to the limbs and organs. Blocked blood vessels can cause pain, serious infections, and organ damage. Like Tay-Sachs disease, sickle cell anemia is an autosomal recessive condition. *See* Nat'l Heart, Lung and Blood Institute, Diseases and Conditions Index, *What is Sickle Cell Anemia?,* http://www.nhlbi.nih.gov/health/dci/Diseases/Sca/SCA_WhatIs.html (last visited Jun. 17, 2010).

[77] Karyotyping is a test to examine the number and structure of chromosomes used to diagnose numerous types of genetic diseases resulting from irregular chromosome number or structure,

While Ohio's relevant law only applies to the screening and testing of semen,[80] New York's law also applies to donated eggs, thereby making it the only state in which both sperm and oocytes[81] are subject to a requirement of screening and testing for genetic diseases.[82] The New York Regulations require practitioners to "screen and . . . assess donors for conditions that may adversely affect the quality of [DRT] or impair the recipient's and/or the offspring's health."[83] Under the New York Regulations, such screening must include a physical examination of the prospective DRT donor[84] as well as collection of "[a] complete medical history, both individual and family, including first-degree and second-degree relatives."[85] The donor and her family's medical history must be evaluated according to numerous criteria including: (1) the existence of major genetic disorders, autosomal or X-linked, dominant or recessive,[86] (2) a history of an occupation with increased risk of or exposure to radiation or chemicals,[87] and (3) other conditions as determined by the DRT institution.[88] If the donor's ethnic or racial group or family history indicates an increased risk of carrying[89] Tay-Sachs disease, thalassemia,[90] cystic

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e.g., Down's Syndrome. *See* Medline Plus, Karyotyping, http://www.nlm.nih.gov/medlineplus/ency/article/003935.htm (last visited May 9, 2010).

[78] Ohio Rev. Code Ann. § 3111.91(B)(2)(b) (2000).

[79] Ohio Rev. Code Ann. § 3111.91(B)(2)(c) (2000).

[80] Ohio Rev. Code Ann. § 3111.91 (2000).

[81] Unlike sperm banks, for scientific and technical reasons having to do with difficulties in preserving oocytes, "egg banks" essentially only mediate between recipients and potential egg donors who are willing to undergo the medical procedures necessary for harvesting their eggs. Hence, "egg banks" are not "banks" in the same sense as sperm banks, as they do not store eggs for immediate dispensing.

[82] The New York regulations refer to "reproductive tissue" in general. *See* N.Y. Comp. Codes R. & Regs. tit. 10, § 52-8.5 (1991).

[83] N.Y. Comp. Codes R. & Regs. tit. 10, § 52-8.5(a).

[84] Id.

[85] N.Y. Comp. Codes R. & Regs. tit 10, 52-8.5(b).

[86] N.Y. Comp. Codes R. & Regs. tit 10, 52-8.5(b)(2).

[87] N.Y. Comp. Codes R. & Regs. tit 10, 52-8.5(b)(10). Such exposure could, supposedly increase the prevalence of genetic mutations in the donor's gametes.

[88] N.Y. Comp. Codes R. & Regs. tit 10, 52-8.5(b)(13).

[89] For the purposes of the discussion herein, a carrier is an individual who is a heterozygote—i.e., only has one copy of a recessive allele—for a disease that would only manifest itself if the individual has two recessive copies of the gene, e.g., CF, Tay-Sachs, etc.

fibrosis and/or sickle cell disease genes, he or she must be tested for these genetic conditions.[91] All such test results must be made available to the donor, as well as to the practitioner who intends to use the DRT.[92]

In addition, the New York Regulations require notification of the recipient's physician if, at the time of donation, the donor was older than forty-four in the case of a sperm donor or older than thirty-four in the case of an egg donor.[93] Furthermore, to avoid repeated adverse results caused by DRT use, practitioners must report the outcomes of any use, including such adverse results, to the DRT institution which must record them.[94] Finally, the DRT institution must receive informed consent from the recipient "after a physician has explained the risks and benefits of the procedure, [and] made available details of the medical history of the donor or donors."[95] New York is the *only* state with comprehensive regulation pertaining to the genetic aspects of DRT.

C. Genetic Screening and Testing of Donated Reproductive Tissue in the Courts

There are very few reported cases involving claims stemming from deficient genetic screening and testing of DRT.[96] Yet, the little case law that does exist indicates that it is extremely difficult for plaintiffs[97] to recover damages for their injuries.[98]

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[90] Thalassemia is a blood disorder causing the body to make fewer healthy red blood cells and less hemoglobin than normal, which could lead to mild to severe anemia. Beta thalassemia occurs when one or both genes are altered and the severity of the disease depends on how badly the gene or genes are affected. Thalassemia occurs most often among people of Italian, Greek, Middle Eastern, Asian, and African descent. Thalassemia is easily diagnosed in a blood test. *See* Nat'l Heart, Lung and Blood Inst., Diseases and Conditions Index, What Are Thalassemias?, http://www.nhlbi.nih.gov/health/dci/Diseases/Thalassemia/Thalassemia_WhatIs.html (last visited May 9, 2010).

[91] N.Y. Comp. Codes R. & Regs. tit 10, 52-8.6(h).

[92] N.Y. Comp. Codes R. & Regs. tit 10, 52-8.6(k).

[93] N.Y. Comp. Codes R. & Regs. tit 10, 52-8.5(d).

[94] N.Y. Comp. Codes R. & Regs. tit 10, 52-8.9(e).

[95] N.Y. Comp. Codes R. & Regs. tit 10, 52-8.8.

[96] There are, generally, very few reported court cases involving claims of deficient ART practices. Several commentators have argued that this dearth of case law in the area of ART is the result of a strong inclination of DRT institutions and practitioners to settle claims against them. *See* Karen M. Ginsberg, *FDA Approved? A Critique of the Artificial Insemination Industry in the United States*, 30 U. Mich. J.L. Ref. 823, 828 (1997) ("The rarity of litigation over unsafe artificial insemination techniques . . . may stem from the fact that most of these cases are resolved in hushed, out-of-court settlements intended to conceal the risks of [artificial insemination] from the public. . . ."); Hecht, *supra* note 70, at 233-34 (arguing that the likely explanation to the lack of litigation is the reproductive industry's preference for anonymous, out-of-court settlements which serves its attempts to avoid "negative headlines that could deter potential customers from

Plaintiffs seeking to bring a negligence claim relying on a theory of malpractice against DRT institutions or practitioners (defendants) have to show that the defendants (1) owed them a duty of care, (2) which the defendants breached, and (3) that the breach caused (4) the injury they suffered.[99] Yet, it is extremely difficult to prove all of these elements in cases involving genetically compromised DRT.[100] First, many courts are unwilling to recognize the existence of a duty of care to persons who did not yet exist at the time the allegedly tortious actions took place.[101] Similarly, most jurisdictions are unwilling, conceptually, to entertain and flatly reject claims for "wrongful life," i.e. claims that are based on the premise that tortious acts brought about the existence of a

undergoing such procedures"); Anita M. Hodgson, *The Warranty of Sperm: A Modest Proposal to Increase the Accountability of Sperm Banks and Physicians in the Performance of Artificial Insemination Procedures*, 26 Ind. L. Rev. 357, 358, 363-64 (1993) (arguing that the lack of litigation arising from improper artificial insemination is the result of "quiet, out-of-court settlements designed to prevent anxious consumers from discovering the risks involved in the procedure" as well as to protect clinicians' professional reputations and avoid large judgments by sympathetic juries). It is likely that such a strong inclination to settle cases involving DRT institutions and practitioners would also account for the very few cases involving genetic aspects of DRT. Regardless of the reason, the few cases that actually address human reproduction (not just in the context of the genetic aspects of DRT) demonstrate not only a plethora of different approaches but also sharp inconsistencies in analysis and results between different courts (sometimes even in the same jurisdiction). *See* Matthew Browne, *Preconception Tort Law in an Era of Assisted Reproduction: Applying a Nexus Test for Duty*, 69 Fordham L. Rev. 2555, 2588-91, 2596-97 (2001); Hodgson, *supra* at 361-62 (suggesting a UCC-based breach of warranty claim as another possible cause of action for plaintiffs to utilize in litigation since negligence claims are often difficult to prove).

[97] The term "plaintiffs" as it is used herein refers to DRT children suffering from genetic defects resulting from deficient screening and testing of the donors of the DRT used in their conception and their legal parents.

[98] The difficulties faced by plaintiffs may well deter such potential plaintiffs from suing, which may, in turn, explain the dearth of case-law in matters involving claims stemming from deficient genetic screening and testing of DRT.

[99] *See* Black's Law Dictionary 1133 (9th ed. 2009) (defining "negligence" as, *inter alia*, "[a] tort grounded in [the failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation] . . . expressed in terms of the following elements: duty, breach of duty, causation, and damages").

[100] *See* The President's Council on Bioethics, Reproduction and Responsibility, The Regulation of New Biotechnologies 70-71 (2004) [hereinafter Council on Bioethics Report], *available at* http://bioethics.georgetown.edu/pcbe/reports/reproductionandresponsibility/index.html.

[101] *See* Browne, *supra* note 96, at 2555-56, 2558, 2563 (arguing that existing case law illustrates that a doctor-patient relationship between the physician and a potential mother "does not automatically create a duty of care flowing from the doctor to the patient's future child").

severely injured person who would have otherwise (i.e., but for the allegedly wrongful acts) not existed.[102]

Second, the lack of regulatory standards with respect to the duties of DRT institutions and practitioners to screen and test DRT for genetic diseases, report adverse events, etc., both at the federal and state level,[103] makes it difficult to establish the existence of a duty of care owed by such potential defendants to injured DRT children

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[102] Black's Law Dictionary 1752 (9th ed. 2009) (defining "wrongful-life action"). The reason for what appears to be courts' aversion to "wrongful life" claims is the result of what came to be known as the "non-identity problem." *See generally* C. Foster, T. Hope & J. McMillan, *Submissions from Non-Existent Claimants: The Non-Identity Problem and the Law*, 25 Med. & L. 159 (2006) (explaining how courts dismiss wrongful life claims because of the non-identity problem). A good illustration of how most courts approach wrongful life claims is the case of *Becker v. Schwartz*, 386 N.E.2d 807 (N.Y. 1978). *Becker* involved two cases: in one, a couple sued for giving birth to a child suffering from Down's Syndrome after not being informed by their doctors of the increased risk of Down's Syndrome in women over 35 years of age or about the availability of the amniocentesis test. *Id.* at 896. In the second case, a couple who gave birth to a child with polycystic kidney disease, who died five hours after birth, were allegedly told by their obstetricians that the disease was not hereditary, which was not the case. *See supra* note 8. As a result, the couple became pregnant again and gave birth to a child who also suffered from PKD and who died from it at the age of two and a half years. *Becker,* 386 N.E.2d at 896. Both couples sued for "wrongful life," claiming that had it not been for their physicians' actions and omissions they would have chosen not to give birth to or conceive their injured child. The New York Court of Appeals (the highest court of New York State) held that both complaints "failed to state legally cognizable causes of action" because "it [did] not appear that the infants suffered any legally cognizable injury." *Id.* at 811-12. With respect to the parents' causes of action, the Court of Appeals ruled that it is impossible to assess their damages since "notwithstanding the birth of a child afflicted with an abnormality . . . parents may yet experience a love that even an abnormality cannot fully dampen. To assess damages for emotional harm endured by the parents of such a child would, in all fairness, require consideration of this factor in mitigation of the parents' emotional injuries" which remains "too speculative to permit recovery." *Id.* at 814. Judge Wachtler expressed an even stricter opinion that "a doctor who provides prenatal care to an expectant mother should not be held liable if the child is born with a genetic defect" because "the physician cannot be said to have caused the defect." *Id.* at 816 (Wachtler J., dissenting in part). *See also* Browne, *supra* note 96, at 2558 (arguing that some courts find the policy considerations involved in a finding of a pre-conception tort to be "so momentous" that they prefer leaving such a decision to the legislature), 2588-97 (pointing at the inconsistency of analytical approaches and outcomes between different jurisdictions and courts with respect to children who "enter the world 'carrying the seal of another's fault'").

Compare this situation to other types of reproduction related causes of action which do not raise the non-identity problem such as actions for failure to provide appropriate treatment to a fetus in-utero ("regular" negligence) or failure to advise parents about the risks of having a child with birth defects. *See* Black's Law Dictionary 1752 (9th ed. 2009) (defining "wrongful-birth action" as "[a] lawsuit brought by parents against a doctor for failing to advise them prospectively about the risks of their having a child with birth defects.").

[103] *See supra* Parts II.A-B.

and their families.[104] Last, there is inherent difficulty in proving that the acts and omissions of the defendants, rather than the genetic qualities of the DRT used, were the cause of a DRT child's injuries.[105]

Plaintiffs seeking to avoid the hardships involved in bringing a negligence action against a DRT institution might find that they have very few, if any, other possible avenues of recourse. They usually cannot sue a DRT donor who failed to report a genetic disease that eventually passed to the DRT child because the secrecy in which such private medical information is normally kept makes it very difficult to obtain.[106] Furthermore, almost every state excludes breach of warranty causes of action in matters involving human tissues, including cases where deficient DRT screening and testing practices would have otherwise constituted a breach of warranty by defendants.[107] Moreover, those plaintiffs who overcome the above-described legal hurdles, and eventually sue for damages, might encounter an overtly unsympathetic and sometimes even scornful court that might refuse (or fail) to accept the proposition that defendants' mistakes and omissions constituted negligence.[108] Ultimately, the genetically injured DRT children

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[104] *See* Hodgson, *supra* note 96, at 361-62. As discussed *infra*, Part II.D, with the narrow exception of the states of Ohio and New York, the only standards existing in this respect are non-committing self imposed inter-industry guidelines. *See* Andrews & Elster, *supra* note 70, at 136. Courts, however, might not consider such standards authoritative enough to be indicative of the existence of a duty of care in malpractice claims. *See OTA's Infertility Report*, *supra* note 27, at 249. For an explanation of the inherent difficulty in proving the existence of a duty in situations where no established standard of care exists, see The Food and Drug Law Institute, *The Regulation of Human Tissues and Organs*, 46 Food Drug Cosm. L.J. 1, 150 (1990) [hereinafter *Human Tissues and Organs*] (presentation of Geoffrey R.W. Smith). Notably, while it is a "well known tort doctrine that proof of compliance with the applicable 'industry' standard will not insulate a defendant from liability when the standard itself is inadequate," the author is unaware of any case that even mentions the fertility industry's guidelines with respect to genetic screening and testing of DRT as a possible standard of care. *Lambert v. Park*, 597 F.2d 236, 239 (10th Cir. 1979).

[105] *See Becker,* 386 N.E.2d at 816 (Wachtler J., dissenting in part).

[106] *See OTA's Infertility Report*, *supra* note 27, at 249; *see also infra* Part II.C.1(discussing *Johnson v. Superior Court*, 124 Cal. Rptr. 2d 650 (Cal. Ct. App. 2002)).

[107] As far back as 1993, Hodgson pointed out the shortcomings of this policy with respect to the screening and testing practices of DRT and called for its abandonment and for the application of the U.C.C. to sperm transactions. *See* Hodgson, *supra* note 96, at 364-86. Yet, this policy, which essentially views transactions between DRT banks and consumers as performance of "services" rather than as "sales," remains in place. *See Condos v. Musculoskeletal Transplant Found.*, 208 F. Supp. 2d 1226, 1229-30 (D. Utah 2002) ("No court has ever applied strict liability to the distribution of human tissue . . . . This is consistent with a general policy throughout the nation . . . against applying strict liability to the distribution of human tissue."); Restatement (Third) of Torts: Prod. Liab. § 19(c) and cmt. c. (1998); *but see* I.C. § 39-3702 (1987) (excepting paid sale of organs and tissue from the application of this rule).

[108] *See Harnicher v. Univ. of Utah Med. Ctr.*, 962 P.2d 67 (Utah 1998). *Harnicher* involved a "mix-up" of a chosen donor's sperm with that of another donor, leading to the birth of triplets

and their families are left to bear not only the suffering but also, at least to some extent, the costs and damages resulting from the DRT children's injuries. Two relatively recent cases exemplify many of the abovementioned problems and difficulties in litigating claims stemming from deficient genetic screening and testing of DRT donors.

1. *Johnson v. Superior Court of Los Angeles County*

In the first case exemplifying the difficulties experienced by plaintiffs suing for the mishandling of genetic aspects of DRT, Diane and Ronald Johnson bought sperm from the California sperm bank Cryobank.[109] A successful insemination led to the birth of a girl (Brittany) who, six years later, was diagnosed with a severe form of ADPKD.[110] Since ADPKD is an autosomal dominant disease of which the Johnsons had no family history, they suspected that the disease was transferred to their daughter from the sperm donor.[111] After long and burdensome legal proceedings,[112] it was eventually revealed that

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who did not resemble their recipient-father thus thwarting recipients' intention to believe and represent that the "recipient-father" is the biological father of the DRT children. The recipients sued for malpractice, alleging negligent infliction of emotional distress due to the fact that they have "suffered severe anxiety, depression, grief, and other mental and emotional suffering and distress which has adversely affected their relationship with the children and with each other." *Id.* at 68. The Utah Supreme Court chose to accept the trial court's holding that despite an expert opinion stating that plaintiffs have suffered physical symptoms as a result of their distress, they failed to convince the court that they have indeed suffered such injuries and thus cannot recover. *Id.* at 70-71. Notably, in affirming the trial court's findings, the Utah Supreme Court observed that "[plaintiffs] became the parents of three *normal, healthy children* whom the couple suggest do not look as much like [the recipient-father] as different children might have and whose blood type could not be descended from his. This result thwarted the couple's intention to believe and represent that the triplets are [the recipient-father's] biological children. *Exposure to the truth about one's own situation cannot be considered an injury and has never been a tort. Therefore, destruction of a fiction cannot be grounds for either malpractice or negligent infliction of emotional distress.*" *Id.* at 72 (emphasis added). Contrast, however, the insightful dissent of Associate Chief Justice Durham, who argued that "[the majority's conviction that the loss of an unassailable assurance that one's children carry one's genes is of negligible value] is belied by the extraordinary lengths to which thousands of people in this era will go to pursue biological parenthood" and that "[m]ost troubling. . . and unnecessary to the result of the majority opinion is its general tone of disdain for and belittlement of the nature of the suffering claimed by [plaintiffs]. This loss of genetic continuity is an important factor for the husband to discuss and to accept. No matter how well the donor is matched to the husband, this loss is real and has to be grieved over . . . ." *Id.* at 75, 77-78.

[109] *See generally Johnson v. Superior Court* (*Johnson II*), 124 Cal. Rptr. 2d 650 (Cal. Ct. App. 2002).

[110] According to a declaration from Brittany's doctor, she had "cysts [on her kidneys] . . . and clearly has a highly penetrant form of ADPKD. . . . [S]he [will] likely progress much more rapidly than most patients with ADPKD who don't develop cysts until their 4th or 5th decade of life." *Johnson v. Superior Court* (*Johnson I*), 95 Cal. Rptr. 2d 864, 869 (Cal. Ct. App. 2000).

[111] *Johnson II*, 124 Cal. Rptr. 2d at 654.

Cryobank's personnel, who interviewed the donor, knew that he had a family medical history that indicated the existence of ADPKD.[113] Still, Cryobank accepted him as a donor without further investigation to determine whether he might indeed carry the ADPKD gene, and later sold his sperm to the Johnsons without warning them about the possible genetic risks involved.[114] Furthermore, Cryobank represented to the Johnsons that the sperm "had been tested and screened for infectious and 'reasonably detectable genetically transferred' diseases and medical abnormalities and therefore could safely be used."[115]

The Johnsons sued Cryobank and its employees for failing to disclose that the sperm they had used came from a donor with a family history of ADPKD, fraud, breach of contract and, later, also filed a motion to amend their complaint to add a claim for punitive damages.[116] The trial court rejected the Johnsons' fraud claim, held that Brittany was not entitled to recover general damages or damages for lost earnings, and denied the Johnsons' motion to add punitive damages to their claim.[117]

On appeal, while acknowledging that there were substantial policy reasons in favor of allowing for punitive damages, the California Court of Appeals affirmed the trial court's denial of the Johnsons' motion to add punitive damages to their claim.[118] Most importantly, the California Court of Appeals subscribed to the trial court's characterization of Brittany's claim as one for "wrongful life" and thus held that under California Supreme Court case law she was not entitled to recover general damages or damages for lost earnings.[119] In making this decision, the Court of Appeals "recognize[d]

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[112] The Johnsons sought to discover the identity and medical record of their donor. *See Johnson I*, 95 Cal. Rptr. 2d at 868. After a long struggle, the California Court of Appeals eventually was willing to compel the donor to appear at a deposition to answer questions and produce documents regarding his medical condition and his family's medical history, but without having to expose his identity. *See Johnson I*, 95 Cal. Rptr. 2d at 875, 878-79; *Johnson II*, 124 Cal. Rptr. 2d at 654-55.

[113] *Johnson II*, 124 Cal. Rptr. 2d at 655 ("[The donor's] affirmative answers to the questions concerning the presence of kidney disease in his mother and his aunt/uncle were circled, a question mark was written next to each 'X,' and the notation 'at risk for kidney disease' was written directly above the 'X' denoting his mother's kidney disease.").

[114] *Id.* at 654.

[115] *Johnson v. Superior Court* (*Johnson II*), 124 Cal. Rptr. 2d 650, 654 (Cal. Ct. App.2002).

[116] *Id.* at 653-54.

[117] *Id.* at 654-56,

[118] *See id.* at 656-64 .

[119] *Id.* at 664-66. The Court of Appeals explained that since it cannot be said that Defendants *caused* Brittany's inherited abnormalities, wherein these abnormalities were caused by the defective donated gene, under *Turpin v. Sortini*, 643 P.2d 954 (Cal. 1982) and *Andalon v.*

the harshness of the rules set forth [by the California Supreme Court] but was admittedly 'bound' by them."[120] Eventually, the Court of Appeals remanded the case for further proceedings addressing only the Johnsons' negligence and fraud claims.[121] After almost another ten months of procedural back and forth in the trial court and almost seven years after the Johnsons filed their original claim, the parties settled the case for $1,250,000, of which Brittany and her parents eventually received, after deductions of expenses and attorneys' fees, $750,440.56.[122]

Perhaps the most disturbing fact in the *Johnson* case is that according to the Johnsons' complaint, defendants may have sold to other recipients as many as 1,600 sperm specimens originating from the same donor whose sperm was used to conceive Brittany.[123] These specimens may have resulted in an unknown number, possibly hundreds, of DRT children who might carry the ADPKD gene originating from Brittany's donor, develop ADPKD later in their lives, and pass the ADPKD gene along to their own offspring.[124] As mentioned earlier, this case was settled so the trial court did not proceed to address this allegation.

2. *Paretta v. Medical Offices for Human Reproduction*

Josephine and Gerard Paretta underwent IVF using an ovum from an egg donor who was represented to them as "not hav[ing] a history of mental illness or genetic diseases."[125] Although the New York Supreme Court found that "[t]he custom and practice of the [ovum donor] program was to screen [and test] donors for various diseases

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Superior Court, 208 Cal. Rptr. 899 (Cal. Ct. App. 1984), Brittany's damages were the result of her coming into being and thus one cannot calculate them in a reasoned non-arbitrary manner.

[120] *Johnson II*, 124 Cal. Rptr. 2d at 666.

[121] *Johnson v. Superior Court* (*Johnson II*), 124 Cal. Rptr. 2d 650, 666 (Cal. Ct. App.2002).

[122] Plaintiffs' Brief in Support of Petition Approve Compromise of Claim at 1-2, *Johnson v. Cal. Cryobank, Inc.*, No. SC043434 (Cal. Super. Ct. June 13, 2003). Of this sum, each parent received $250,000 minus a quarter of the expenses and $100,000 attorneys' fees. Brittany received the remainder, $750,000 minus $241,862.22 for additional fees and expenses, leaving her with $508,137.78.

[123] *See* Fourth Amended Complaint for Fraud, Negligent Misrepresentation/Suppression, Professional Negligence, Unfair Business Practices, at ¶¶ 63-64, 69, *Johnson v. Cal. Cryobank, Inc.*, No. SC043434 (Cal. Super. Ct. Apr. 2, 2003).

[124] *Id.*

[125] *Paretta v. Med. Offices for Human Reprod.*, 760 N.Y.S.2d 639, 641 (N.Y. Sup. Ct. 2003). Other details given to the Parettas about the donor included "that she was white, a second-time donor, a heterosexual, an only child of an Irish father and English mother, a Protestant, that she was five feet six inches tall, that she had dark brown hair and brown eyes, was long necked with small eyes and ears, that she had a short thin nose, dimples and high cheekbones, and that she did not have freckles." *Id.*

and cystic fibrosis" and to "inform the patient that there was a donor or that a potential donor was a carrier,"[126] the program did not inform the Parettas that their egg donor was a carrier of cystic fibrosis. Subsequently, Mr. Paretta, who provided the sperm for the fertilization, did not undergo genetic testing to make sure that he was not a carrier of the CF gene—which he was—and the baby born from the fertilized egg (Theresa) was afflicted with CF.[127]

In October 2000, the Parettas, including Theresa, sued the medical centers and units involved in their fertilization treatments for medical malpractice for failing to (1) properly screen and test the egg, (2) inform the Parettas that it tested positive for the CF gene and (3) test Mr. Paretta for the CF gene.[128] The parents also sued for emotional pain and suffering as parents of a child affected with CF and asked that punitive damages be awarded for defendants' "egregious, grossly negligent and reckless conduct."[129] Interestingly, the Parettas avoided the difficulties in establishing the causation element of their negligence claim by explicitly claiming that it was the defendants who "introduced the agent, which caused [cystic fibrosis] and manipulated the embryonic material [that] was implanted into Mrs. Paretta."[130]

Relying on the New York Court of Appeals decision in *Becker v. Schwartz,*[131] the New York Supreme Court held that Theresa's claims were for "wrongful birth" and denied them in their entirety.[132] The Supreme Court further ruled:

> Theresa . . . , like any other baby, does not have a protected right to be born free of genetic defects. A conclusion to the contrary permitting infants to recover against doctors for wrongs allegedly committed during in vitro fertilization would give children conceived with the help of modern medical technology more rights and expectations than children conceived without medical assistance. The law does not recognize such a distinction and neither will this court.[133]

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[126] *Id.* at 641.

[127] *Id.* at 641-42. According to the New York Supreme Court, "[f]or the first two months, Theresa was in intensive care. She underwent several surgeries and wore a colostomy bag for a month. According to plaintiffs she 'will have to take medication for the rest of her life . . . [and] will remain under a doctor's and/or hospital's care for the rest of her life.'" *Id.* at 642.

[128] *Id.* at 642.

[129] Id.

[130] *Id.* at 643.

[131] *See supra* note 102.

[132] *Paretta v. Med. Offices for Human Reprod.*, 760 N.Y.S.2d 639, 643-46 (N.Y. Sup. Ct. 2003).

[133] *Id.* at 646.

The New York Supreme Court also denied the Parettas' claims for emotional distress as a result of their daughter's birth with a congenital disease.[134] Relying once again on *Becker*, the court explained:

> [T]here can be no recovery for the emotional distress a parent may experience as a result of having a child with a genetic disease. There is no compelling legal authority permitting a distinction where a child has been conceived with the help of a medical technology and is born with a genetic disease. This court cannot treat the emotional distress and psychic pain suffered by parents who give birth to a sick child after in vitro fertilization any differently from that sustained by other parents. The emotional distress experienced as a result of watching a genetically diseased child suffer, horrible as it may be, is the same regardless of how the child was conceived.[135] It unfortunately is not compensable.[136]

The New York Supreme Court then went on to dismiss Mr. Paretta's claim for loss of consortium as "predicated on and inextricably interwoven with the emotional injuries suffered by Mrs. Paretta."[137] The court did hold, however, that the action did not have to be dismissed in its entirety: that "the Parettas can pursue recovery for the pecuniary expense they have borne and continue to bear for the care and treatment of their sick infant" and for punitive damages.[138] Having limited the Parettas' claims in this manner, the Supreme Court encouraged the Parettas "to vigorously pursue recovery."[139] The parties proceeded to trial and, similar to the Johnsons, after about ten more months, eventually settled their claims for $1,300,000.[140]

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[134] *Id.* at 645.

[135] *See infra* Part II.E.

[136] *Paretta,* 760 N.Y.S.2d at 646.

[137] *Id.* at 647.

[138] *Paretta v. Med. Offices for Human Reprod.*, 760 N.Y.S.2d 639, 647 (N.Y. Sup. Ct. 2003). The New York Supreme Court also did not dismiss Mrs. Paretta's claims for compensation related to her decision to leave her job so that she could care for Theresa on a full-time basis and for the reasonable value of her services even though the court stated that it was "far from convinced of the viability of recovery of lost earnings." *Id.*

[139] *Id.* at 648.

[140] The case was settled before trial on Feb. 2, 2004. *See* http://iapps.courts.state.ny.us/webcivil/FCASSearch (index no. 122555-2000). The court records do not provide any further information about the terms of the settlement.

Leaving any critique of the *Johnson* and *Paretta* decisions aside,[141] these cases exemplify not only how restricted the avenues of legal recourse available to injured DRT children and their families are, but also how burdensome, time consuming, expensive and legally difficult it is to recover for genetic injuries associated with DRT. Furthermore, even if we assume that the settlement amounts in the above cases were sufficient to compensate the DRT children and their families for their damages—which is highly doubtful[142]—it is not clear that they are sufficiently high to create a deterrent effect that would improve the genetic screening and testing practices of DRT institutions and practitioners.

D. Self Regulation by Professional Organizations

1. The Need for Genetic Screening and Testing of Donated Reproductive Tissue Recognized

The lack of effective DRT screening and testing practices in the United States and the need for further regulation was described as early as 1979 by Martin Curie-Cohen.[143] Curie-Cohen surveyed 711 physicians who indicated that they were "likely to perform artificial insemination by [a] donor." Of the 471 who responded to the survey, 379 reported that they actually performed artificial insemination. According to Curie-Cohen, although the risk of genetic diseases was a concern of many recipients, the survey revealed very little, if any, screening and testing of donors.[144] While many DRT practitioners could indicate whether the donor was part of a "select donor pool" (medical students automatically qualifying as select), screening was largely superficial. Though 96% of the physicians participating in the survey asked questions regarding donors' family medical history, the questioning often did not entail more than asking the donor if

[141] Some of the courts' rationales in denying some of the plaintiffs' causes of action are controversial while others simply are not convincing. For instance, the *Johnson* court's decision not to allow the Johnsons to add punitive damages to their claim despite the existence of policy reasons to the contrary arguably did not allocate enough weight to what appeared to be egregious and fraudulent behavior of Cryobank's personnel in that case. As for the *Paretta* court, in holding that "[t]he emotional distress experienced as a result of watching a genetically diseased child suffer . . . is the same regardless of how the child was conceived" the court seems to have simply ignored the fact that it was Defendants' acts and omissions that led to the birth of Theresa with the debilitating genetic disease that brought about the Parettas' suffering. *See supra* notes 129 and 136 and accompanying text.

[142] For example, the settlement amounts do not reflect the loss of potential earnings of the respective DRT children had they not been afflicted with their debilitating genetic disorders.

[143] *See* Martin Curie-Cohen et al., *Current Practice of Artificial Insemination by Donor in the United States*, 300 N. Eng. J. Med. 585, 589 (1979).

[144] *Id.* at 585-86 ("[d]onors of semen were . . . only superficially screened for genetic diseases").

there were any genetic diseases in the family. Also, many of the DRT practitioners expressed an underlying expectation that medical student and hospital resident would "screen themselves before donating semen."[145] The survey revealed that while 94.7% of the physicians said they would reject a carrier of Tay-Sachs disease, only 1% of them said that they actually tested donors for it and only 28.8% of the physicians performed *any* biomedical test on donors in addition to blood typing.[146] Furthermore, the data collected by the survey revealed that many of the physicians had little understanding of genetic diseases. For example, 71.4% of the surveyed physicians said they would exclude a healthy donor who had a family history of hemophilia.[147] According to Curie-Cohen, only 37% of physicians surveyed actually kept records about the children born from DRT that they provided and only 30% kept any records on donors.[148] Curie-Cohen concluded that the screening and testing of donors for genetic diseases was inadequate and called for the establishment of a list of genetic traits that would be routinely screened and tested for, evaluation by "people trained in recognizing and evaluating genetic traits," and a recordkeeping minimum that would include the outcome of pregnancies achieved through DRT and paternity.[149]

Two case studies published in 1981 further illustrated the dangers of which Curie-Cohen warned. In one case, a girl was born with Tay-Sachs disease to a mother of an ethnic group in which this disease is not prevalent and the sperm of an anonymous donor, who, as it turned out, was a carrier of the disease's gene.[150] In the second case, two consecutive artificial inseminations resulted in the transmission of a rare and lethal

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[145] *Id.* at 586.

[146] *Id.* at 588.

[147] *Id.* Hemophilia is a rare bleeding disorder in which a person's blood does not clot normally. Hemophilia is caused by a defect in one of the genes located on the X chromosome that determine how the body makes blood clotting factors VIII and IX. Females have two X chromosomes, while males have one X and one Y chromosome. Since only the X chromosome carries the genes related to clotting factors a male who has the abnormal gene on his X chromosome will have hemophilia while a female must have the abnormal gene on both of her X chromosomes to have hemophilia, which is very rare. This also means that while healthy females might be carriers of a hemophilia allele, males cannot possibly be carriers of this allele without actually having the disease. *See generally* National Heart, Lung and Blood Institute Diseases and Conditions Index, What is Hemophilia?, http://www.nhlbi.nih.gov/health/dci/Diseases/hemophilia/hemophilia_what.html (last visited May 9, 2010).

[148] Curie-Cohen, *supra* note 143, at 588.

[149] *Id.* at 589.

[150] William Johnson et al., *Artificial Insemination by Donors: the Need for Genetic Screening*. Late-Infantile GM2-Gangliosidosis Resulting From This Technique, 36 N. Eng. J. Med. 572, 755 (1981).

genetic disease to two siblings conceived from the sperm of a single donor.[151] Tragically, the second insemination, leading to the birth of the second afflicted child, had already taken place by the time the doctors diagnosed the lethal disease in the older sibling. Both siblings died very young—at sixteen and three months, respectively—as a result of the genetic disease they inherited from the sperm donor.[152]

During the 1980s, these data prompted more calls for regulation of DRT in general and their genetic aspects in particular. A 1988 survey of the former Office of Technology Assessment (OTA) revealed that donor screening and testing practices were "quite varied." For example, while many physicians routinely rejected potential donors for such traits as "psychological immaturity," "less than a high school education" and "less than average height," only about half of the physicians tested any of their potential donors for any genetic diseases.[153] The OTA 1988 Survey further revealed that only 44% of the physicians performing AI required screening and testing for genetic diseases for which the potential donors were at high risk.[154] The Survey found that while all of the fifteen DRT institutions that responded to the survey did *some* testing of varying nature and extent, two of the fifteen DRT banks reviewed did not test for ethnically prevalent genetic diseases such as Tay-Sachs, sickle-cell anemia and thalassemia.[155] In addition, the Survey disclosed that only two-thirds of the DRT banks *ever* rejected a donor for having a family history of a serious genetic disease or for being over forty years of age.[156]

Another OTA report published in 1988 further revealed that only 20% of the physicians who regularly performed AI indicated that a family history of genetic disease would prompt them to require further genetic testing of a potential donor and only 18% indicated they would do so with a potential donor from a high risk ethnic group.[157] The OTA 1988 Infertility Report concluded that "genetic testing is not routine for donors, including those in higher than average risk groups."[158]

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[151] David Shapiro & Raymond J. Hutchinson, *Familial Histiocytosis in Offspring of Two Pregnancies after Artificial Insemination*, 36 N. Eng. J. Med. 573, 757 (1981). Shapiro and Hutchinson called for extreme caution in using sperm from the same donor for artificial insemination when a child conceived from the sperm is afflicted with an unknown disorder. *Id.* at 759.

[152] *Id.* at 757-58.

[153] *See OTA 1988 Survey*, *supra* note 14, at 9, 33-35, 66-70.

[154] *Id.* at 9.

[155] *Id.* at 11, 68.

[156] *Id.* at 67. Like Curie-Cohen, the 1988 OTA Survey also found that 49-63% of the physicians performing AI would reject a healthy potential donor for having a family history of X-linked genetic diseases although it would be impossible for such a donor to transmit those defects to their offspring. *Id.* at 10; *see also supra* note 147.

[157] *See OTA's Infertility Report*, *supra* note 27, at 35.

[158] *Id.*

The OTA's 1988 reports proved to be a benchmark in the calls for the regulation of DRT in general, and their screening and testing in particular.[159] Later commentators have also recognized the importance of genetic screening and testing of DRT donors and their evaluation by genetics specialists.[160] Ultimately, it was not government authorities who rose to the challenge but rather professional organizations, such as the American Society for Reproductive Medicine (ASRM) and the American Association of Tissue Banks (AATB).

2. The ASRM Guidelines for Gamete and Embryo Donation

The ASRM Guidelines[161] set out to "provide the latest recommendations for evaluation of potential sperm, oocyte, and embryo donors, incorporating recent information about optimal screening and testing for . . . genetic diseases."[162] With respect to semen donation, the ASRM Guidelines determine that the "main qualities to seek in selecting a donor . . . are an assurance of good health status and the absence of genetic abnormalities . . . [and] [t]he donor should be . . . ideally, less than 40 years of age;"[163] oocyte donors should preferably be between the ages of 21-34.[164] The ASRM Guidelines specify that potential sperm and egg donors should undergo genetic screening

[159] *See* Marwick, *supra* note 27, at 1339 (describing [then] Senator Albert Gore's criticism of the FDA's non-regulation of AI in light of the *OTA 1988 Survey*).

[160] *See, e.g.,* Lisa Kump et al, *The Importance of Genetic Screening for Oocyte Donors*, 78 Fertility & Sterility S43, S43 (2002) (describing the genetic screening and testing of 607 prospective egg donors, which resulted in the exclusion of 71 of them, i.e., more than 12%, and concluding that genetic screening of prospective egg donors that included detailed family history and testing for a number of diseases should be encouraged "to assure optimal short-term and long-term outcomes for pregnancies achieved through . . . donation"); Rubens L.C. Tavares et al., *The Value of Genetic Screening of Oocyte Donors Couples,* 80 Fertility & Sterility S138, S138 (2003) (reporting that genetic screening of prospective egg donors resulted in the exclusion of more than 20% of the prospective donors for such reasons as having sickle cell anemia and having prior children with mental retardation); Robert Wallerstein et al., *Genetic Screening of Prospective Oocyte Donors*, 70 Fertility & Sterility 52, 52 (1998) (reporting the exclusion of eight out of 73 egg donor candidates (11%) due to "serious genetic findings" and concluding that "[a] thorough genetic evaluation, including a history and laboratory [test]ing, is essential to any oocyte donation program to maximize positive outcomes").

[161] *See generally* The Practice Comm. of the Am. Soc'y for Reproductive Med. and the Practice Comm. of the Soc'y for Assisted Reprod. Tech., *2006 Guidelines for Gamete and Embryo Donation*, 86 Fertility & Sterility S38 (2006) [hereinafter *ASRM Guidelines*].

[162] *Id.* at S38.

[163] *Id.* at S40 § VI.A.1-2.

[164] If a prospective donor is older than 34, the Guidelines require that the donor's age be revealed to the recipient as part of the informed consent discussion concerning the possible effect of donor age on genetic risks. *Id.* at S44 § VI.B.3, 5.

and testing for heritable diseases, including carrier status for CF in all donors and other genetic testing as indicated by the donor's ethnic background and in light of the family history.[165] The ASRM Guidelines also set an explicit "minimum" standard for genetic screening and testing of DRT donors, according to which donors and their first degree relatives (parents, siblings and children) must not have (1) any major Mendelian disorder, such as Huntington's disease;[166] (2) any major functional or cosmetic malformation of complex cause, such as spina bifida[167] or heart malformation;[168] or (3) any significant familial disease with a major genetic component.[169] The ASRM Guidelines further require that donors must not carry any known karyotypic abnormality that might result in chromosomally unbalanced gametes and that donors should be tested for carrier status of CF and genetic disorders for which they are in a high-risk group.[170]

3. The American Association of Tissue Banks (AATB) Standards for Tissue Banking

Like the ASRM Guidelines, the AATB Guidelines[171] are meant to "prevent disease transmission"[172] and preliminarily require compliance with any and all applicable

[165] *See id.* at S40 § VI.B.2 (sperm donors); *see also id.* at S44 §§ VI.B.7, VI.C.1 (egg donors). Notably, the ASRM Guidelines clarify that as new tests for genetic risk factors become available, "every effort should be made" to have samples of sperm that are cryopreserved tested in accordance with the new standards. *Id.* at S42 § IV.B.6.d.

[166] Huntington's disease (HD) results from a genetically programmed degeneration of brain cells in certain areas of the brain which causes uncontrolled movements, loss of intellectual faculties, and emotional disturbance. HD is an autosomal dominant disease, which means that if a child inherits the HD gene he or she will develop the disease. Each child of an HD parent has a 50-50 chance of inheriting the HD gene. A person who inherits the HD gene will sooner or later develop the disease. *See* Nat'l Inst. of Neurological Disorders and Stroke, Huntington's Disease Information Page, http://www.ninds.nih.gov/disorders/huntington/huntington.htm (last visited May 9, 2010).

[167] Spina bifida (SB) is a disorder involving incomplete development of the brain, spinal cord, and/or their protective coverings caused by the failure of the fetus's spine to close properly during the first month of pregnancy. Infants born with SB sometimes have an open lesion on their spine where significant damage to the nerves and spinal cord has occurred. *See* Nat'l Inst. of Neurological Disorders and Stroke, Spina Bifida Information Page, http://www.ninds.nih.gov/disorders/spina_bifida/spina_bifida.htm (last visited May 9, 2010).

[168] Notably, the ASRM Guidelines acknowledge that "'major' is a matter of judgment." *ASRM Guidelines*, *supra* note 161, at Appendix A S50.

[169] *Id.*

[170] *Id.*

[171] *See generally* Am. Ass'n of Tissue Banks, Standards for Tissue Banking (10th ed. 2002) [hereinafter *AATB Guidelines*].

statutory and regulatory standards.[173] The AATB Guidelines state that donor suitability should be evaluated based upon medical, social and sexual history,[174] physical examination and laboratory tests.[175] The evaluation should include "any history of chemical and/or radiation exposure as well as family medical history and genetic background;"[176] specifically, it should entail an evaluation by a person knowledgeable in clinical genetics of at least three generations of the donor's family history.[177] The AATB Guidelines set an age limit of forty years for semen donors and thirty-five years for egg donors[178] and require that "[a]ny condition in a prospective donor or donor's family history that would pose a risk of producing an offspring with a genetic disease or defect greater than the risk in the general population shall disqualify him/her as a donor."[179] The Guidelines further explicitly require that if there is an indication of a risk of Tay-Sachs disease, thalassemia, sickle cell anemia or CF in the donor's medical history, family history or ethnic background, the donor should be tested for such conditions.[180]

Interestingly, although the AATB Guidelines use compulsory language, their sole sanction for non-compliance is withdrawal of accreditation "upon a determination . . . that significant non-compliance, such as repeated violations, one or more egregious violations, uncorrected violations or deliberate falsehoods, have occurred."[181]

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[172] *Id.* at iv.

[173] *Id.* at 1 § A1.000.

[174] According to the AATB Guidelines, the medical history should be reviewed by a "trained individual" and include previous medical records, test results, and conversation with attendant medical staff. *Id.* § D4.230.

[175] *Id.* at 31 § D4.100.

[176] *Id.* at 34 § D4.220.

[177] *AATB Guidelines*, *supra* note 171, at 35 § D4.221.

[178] *Id.* at 45-46 § D4.400.

[179] *Id.*

[180] *Id.*

[181] *Id.* at iv-v, 1 § A1.000.

4. Contemporary Genetic Screening and Testing Practices of DRT Institutions and Adherence to the Professional Guidelines

Relatively recent studies indicate that not much has changed since the 1980s with respect to the genetic screening and testing practices of DRT.[182] According to a study published in 2007, the four participating DRT institutions tested potential donors for blood type, Rh factor, drugs and sexually transmitted infections, gave them psychological evaluations and required them to prepare a detailed family health history for three generations.[183] Yet, none of the DRT institutions had a requirement for any mandatory genetic testing and not even all of them had the donors' medical history evaluated by a genetics specialist who, presumably, could have indicated whether further testing was necessary.[184]

Another survey attempted to determine how the practices of DRT institutions which are members of the AATB vary from the AATB Guidelines.[185] According to this survey, while all sixteen sperm banks that responded[186] required prospective donors to provide their medical and family history and undergo a physical examination, only thirteen (81% of the DRT institutions) tested men of ethnic risk groups for Tay-Sachs disease, sickle cell anemia and thalassemia; only four (25%) tested all donors for CF; only eight (50%) reported they would test for CF even if there was a positive family history of the disease;[187] and only six had a genetic professional on staff.[188] Amazingly, three DRT institutions (19%) rejected prospective sperm donors based on a positive family history of color blindness and seven banks (44%) did so with a family history of

[182] *See, e.g.,* U.S. General Accounting Office (GAO), Human Tissue Banks: FDA Taking Steps to Improve Safety, but some Concerns Remain 14-15 (1997) [hereinafter *GAO 1997 Report*] (discussing non-compliance of AATB members with the AATB Guidelines).

[183] Rene Almeling, *Selling Genes, Selling Gender: Egg Agencies, Sperm Banks, and the Medical Market in Genetic Material*, 72 Am. Soc. Rev. 319, 324, 327-28 (2007) (discussing how the social process of bodily commoditization varies based on sex and gender in the context of egg and sperm donations).

[184] *Id.* at 328.

[185] *See* Conrad, *supra* note 10, at 298.

[186] Notably, another twenty-one DRT institutions chose not to participate in the survey. According to Conrad, those DRT institutions that participated in the survey "were primarily large-volume, private, nationally based commercial cryobanks, in contrast to regional cryobanks serving a limited population." *See id.* at 299. Presumably, the non-participating DRT institutions were in even poorer compliance with the AATB Guidelines than the participating DRT institutions.

[187] *See id.* at 298.

[188] *Id.*

hemophilia.[189] The survey's conclusion was that "[c]onsiderable differences exist among semen bank practices in accordance with guidelines published by national agencies."[190]

A similar survey focusing on the compliance of 159 oocyte donation programs with the ASRM Guidelines revealed "considerable variability" in the practices of screening and testing for genetic disorders.[191] According to this survey, only 72% of the oocyte donation programs tested donor candidates from ethnic groups at higher risk for sickle cell anemia and only 77% did so with respect to Tay-Sachs disease.[192] The survey had several even more alarming findings, e.g., that only 62% of the participating programs said they would exclude applicants with first-degree relatives who had ADPKD.[193] In other words, more than a third of the programs that took the survey confirmed that they would knowingly expose babies born from eggs originating from donors who had a first degree relative with ADPKD to a risk of 25% of developing ADPKD.[194] The survey's conclusion was that while most programs followed ASRM Guidelines, "a significant minority . . . do[] not use well-established [genetic] . . . tests."[195] The findings of the abovementioned surveys are underscored by the fact that not all DRT institutions participate in professional accreditation programs, such as those of the AATB and ASRM.[196]

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[189] *Id.* at 300. Like hemophilia, color blindness is an X-linked recessive disorder. As explained above, such rejection could have no medical/genetic basis. *See supra* note 147.

[190] Conrad, *supra* note 10, at 300.

[191] Vivian Lewis et al*., Survey of Genetic Screening for Oocyte Donors*, 71 Fertility & Sterility 278, 278 (1999).

[192] *Id.* at 279.

[193] *Id.* at 280 (Table 1). Similarly, only 76% of the programs reported they would do so in the case of Huntington's disease. *Id.* For a discussion of Huntington's disease, see *supra* note 166.

[194] *See supra* note 8 (discussing ADPKD). With only 62% of the programs taking the survey confirming that they would exclude applicants with first-degree relatives who had ADPKD, the implication is that 38% of the programs *would not exclude applicants with first-degree relatives who had ADPKD*. This means that these programs would actually include in their DRT donation programs individuals with first-degree relatives having ADPKD. Statistically speaking, this would mean that these egg donation programs would knowingly sell eggs from donors having a 50% chance of having ADPKD themselves. Since a child has a 50% chance of getting the ADPKD gene from a parent having this gene, children born from eggs originating from such donors have a 25% chance (50% of 50%) of having the ADPKD gene themselves. *See supra* note 8.

[195] Lewis et al., *supra* note 191, at 280-81.

[196] For example, out of an estimated 400 or more tissue banks existing in the United States in the early 1990s, only forty were inspected and accredited by the AATB. *See* Barbara Indech, *The International Harmonization of Human Tissue Regulation: Regulatory Control Over Human Tissue Use and Tissue Banking in Select Countries and the Current State of International Harmonization Efforts,* 55 Food & Drug L.J. 343, 348 (2000). In 2003, out of 115 sperm banks

Importantly, by 2005 the FDA was aware of the non-uniform compliance of DRT institutions with self-imposed professional standards. According to the FDA Final Donor Eligibility Rule, only 80% of the examined institutions providing ART services adhered to professional standards and guidelines.[197] Moreover, while the FDA estimated that compliance of tissue banks with professional standards of donor screening and testing neared 100% for several types of tissues, it recognized that "facilities handling reproductive tissue [were] the primary exception to this finding" and that most sperm banks did not follow voluntary industry standards.[198] The FDA also acknowledged that only a small percentage of the sperm banks surveyed were members of the AATB and followed its Guidelines on screening and testing.[199]

In conclusion, despite the existence of professional guidelines setting clear requirements for genetic screening and testing of DRT, effective enforcement mechanisms and deterring sanctions are lacking. As such, compliance by DRT institutions with such guidelines is varied and depends on the level of commitment of each individual DRT institution. Persistent findings of non-compliance with self-imposed professional guidelines since the 1990s indicate that this picture of non-uniform

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nationwide, only 11 were accredited by the AATB. *See* Gail Schmoller Philbin, *Web of Conception; Couples Turning to Internet Sites to Secure Donated Sperm*, Chicago Tribune, Aug. 20, 2003, at C1. Similarly, the GAO 1997 Report disclosed that only approximately one-third of the reproductive laboratories in the United States existing at that time were accredited by the ASRM. *See GAO 1997 Report*, *supra* note 182, at 10. The reality of non-participation in professional regulation of DRT is easily noticeable upon browsing through internet websites of DRT banks: out of about a dozen internet websites of sperm banks visited by the author, while all of the sperm banks boasted the "quality" of their DRT, only one sperm bank clearly indicated that the bank is a member of the AATB. Notably, this fact is a further indication of the low enforceability of professional guidelines on DRT institutions. The fact that many DRT institutions are not members of the ASRM and AATB is also an indication that DRT institutions might not be concerned that such non-membership would have a detrimental effect on their ability to do business, which, in turn, reflects on the ability of the ASRM and AATB to enforce their guidelines on those DRT institutions that *are* members. In other words, the fact that there are, apparently, many DRT institutions that are not even members of or accredited by the AATB and ASRM is an indication that non-compliance with the guidelines of such professional organizations is of little or no concern to DRT institutions and that the potential implications of such non-compliance (if any) carry little (if any) deterrent effect.

[197] The FDA's survey covered 110 sperm banks and 400 establishments providing ART services. *See FDA Final Donor Eligibility Rule, supra* note 24, at 68654. This data was part of the FDA's reasoning for the need for federal regulation of DRT institutions with respect to communicable diseases.

[198] *Id.* at 29817-18.

[199] *Id.*

compliance is not transitory and is unlikely to change without government intervention.[200]

E. Why the Current Regulation of Genetic Aspects of Donated Reproductive Tissue is Insufficient and the Need for Additional Protection of DRT Recipients and DRT Children

1. The Insufficiency of Self-Regulation

Evidently, and as recognized by fertility professionals and the FDA, self-regulation is insufficient for ensuring the health and welfare of DRT children and their families.[201] There is persistent data showing that a significant portion of DRT institutions are not even members of the ASRM or AATB.[202] Even those establishments that are members of ASRM and AATB often do not adhere to the professional guidelines set by these organizations,[203] and there is significant variance in genetic screening and testing

[200] *See also* Conrad, *supra* note 10, at 301 (pointing out that despite more than a decade (at that time) of proposals for genetic screening and testing of DRT, no changes have taken place in the practices of DRT institutions).

[201] *See also* 66 Fed. Reg. 5452 (FDA Jan. 19, 2001) (expressing the FDA's view that, in the context of communicable diseases, "extending regulation to reproductive cells and tissues will remedy a significant gap in oversight. Although we recognize the value of professional efforts to self-regulate, and of regulatory efforts of other agencies and the States, we disagree that these piecemeal, often voluntary, efforts are adequate"); Cohen, *supra* note 23, at 352 (expressing doubts regarding the ability of the medical profession to effectively self-regulate the field of ART); Ginsberg, *supra* note 96, at 829 (arguing that the lack of established mechanisms to police compliance with professional guidelines causes irregular compliance); Jennifer L. Rosato, *The Children of ART: Should the Law Protect them from Harm?*, 57 Utah L. Rev. 57, 62-63 (2004) ("Although there is some self-regulation of fertility practices through professional medical organizations, the system is not well-equipped to curb harmful or unethical practices.").

Notably, some commentators have expressed concerns that the current regulation of genetic aspects of DRT also fails to recognize and promote the interests and well-being (not only the safety) of DRT children and their families as well as those of society as a whole. *See* Council on Bioethics Report, *supra* note 100, at 195; Erik Parens & Lori Knowles, *Reprogenetics and Public Policy—Reflections and Recommendations*, Hast. Ctr. Rep., July-August 2003, at S3, S7-S9 (2003).

[202] *See supra* note 196 and accompanying text. This non-compliance with self regulation requirements was apparently one of the rationales for the FDA's creation of the Human Tissue Regulations. *See also* 66 Fed. Reg. 5450 (FDA Jan. 19, 2001) ("[FDA has] considered the efforts of professional organizations and we will continue to do so as we implement the new regulations. However, not all [tissue] establishments belong to or are accredited by such groups and voluntary programs are not enforceable.").

[203] *See GAO 1997 Report, supra* note 182, at 14-15; ISLAT Working Group, *supra* note 2, at 651 ("Despite the existence of voluntary guidelines . . . abuses continue to occur"); *Human*

standards between DRT institutions.[204] The resultant risks of this reality are further exacerbated by the general vulnerability of DRT recipients. In particular, many DRT recipients do not possess the medical or scientific background necessary to enable them to "ask the right questions" or properly evaluate some of the risks involved.[205]

Moreover, the current scheme of self-regulation relies primarily on the diligence and integrity of practitioners as well as on donors volunteering pertinent information about their medical history and that of their families. However, practitioners operate in a highly competitive market that creates strong financial incentives that do not necessarily coincide with the best interest of DRT recipients and DRT children.[206] Potential donors' answers regarding their medical history and that of their families are also often insufficient to properly evaluate the genetic risks they might pose.[207] Furthermore, the financial benefit to donors accompanied by the absence of a clear legal duty to accurately

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Tissues and Organs, *supra* note 104, at 56 (presentation of Armand M. Karow) ("Perhaps the most important problem here is the inability of private groups to compel compliance . . . voluntary standards are just that—voluntary."). In addition, the enforcement mechanisms of professional societies are ineffective and the only penalty for non-compliance is revocation of membership. See Daar & Brzyski, *supra* note 15, at 1704 ("[D]ata suggest the majority of sperm banks and egg donor agencies do not follow the established screening protocols . . . Even in centers that did report testing, most did not fully follow the guidelines set forth by the American Society for Reproductive Medicine."); Alicia Ouellette et al., *Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, 31 Am. J.L. & Med. 419, 430 (2005) ("[T]here are no legal consequences for non-accredited U.S. programs . . . there is also 'no consumer-recognized seal of approval or standard symbol that conveys that any minimum standards of quality have been met.'"); Rosato, *supra* note 201, at 66-67.

[204] *See, e.g.*, The N.Y. State Task Force on Life and the Law, Assisted Reproductive Technologies, Analysis and Recommendations for Public Policy 251 (1998) ("The type of family history information that would disqualify a prospective egg donor varies considerably at programs in New York State."); Daar & Brzyski, *supra* note 15, at 1704 ("Current use of genetic screening by sperm and egg donor enterprises is best described as inconsistent.").

[205] *See* Julie Marquis, *Gift of Life, Questions of Liability*, Los Angeles Times, Aug. 9, 1997, at A1 (describing the *Johnson* Case and referring to Diane Johnson's admission that she "didn't even know what to ask"); *see also* Rosato, *supra* note 201, at 71 (arguing that future parents tend to want to achieve pregnancy as quickly as possible thereby making them more prone to take unnecessary risks), Meena Lal, Comment, *The Role of the Federal Government in Assisted Reproductive Technologies*, 13 Santa Clara Computer & High Tech. L.J. 517, 535 (1997) (arguing that "consumers" of IVF treatments, are often too emotionally involved to "maintain an objective and cautious stance toward the practices of institutions and individuals providing the service").

[206] *See, e.g.,* Rosato, *supra* note 201, at 71-72 (describing the strong incentives fertility practitioners have to provide couples with a pregnancy as quickly as possible).

[207] *See GAO 1997 Report*, *supra* note 182, at 37 (disclosing a study conducted by one tissue bank which found that 9.8% of 1,000 donors whose families provided a medical history that did *not* indicate genetic risk factors were rejected upon testing or autopsy).

disclose such information[208] might render the current screening practices—which rely mostly on questioning of potential donors—unreliable because they create an incentive for potential donors to hide negative medical facts about themselves and their families.[209] As a result, a significant number of the many thousands of children born every year from DRT are exposed to a heightened risk of having severe genetic diseases which could have been avoided through proper genetic screening.

2. The Inadequacy of the Relief Afforded by Courts

One would have expected that once the risks embedded in the current system came to bear on a particular child, such individual born from genetically defective DRT would be able to obtain appropriate relief in court. Yet, the few published cases pertaining to genetic injuries of children born from DRT raise significant doubts as to the adequacy of the court system for providing sufficient and timely remedies to such children and their families or to create the deterrent effect needed in order to avoid similar future injuries.[210]

First, in order to make a viable claim, injured DRT children and their families have to trace their maladies back to the acts and omissions of a DRT institution—a legal and scientific feat in and of itself.[211] Second, as demonstrated by the *Johnson* and *Paretta* cases, the causes of action available to plaintiffs in such matters are limited[212] and difficult to establish.[213] Finally, to the extent that *Johnson* and *Paretta* are representative of cases involving injuries caused by genetically defective DRT, the

[208] Only two states explicitly require potential donors to disclose relevant medical information fully and accurately. *See supra* note 73.

[209] *See* Curie-Cohen, *supra* note 143, at 588.

[210] Annas, *supra* note 22, at 936 (arguing that the courts' deference to the contractual relationship between DRT manufacturers and parent-consumers is inadequate due to its failure to acknowledge and protect underlying interests of children, parents and society); Amy Shelf, *A Need to Know Basis: Record Keeping, Information Access and the Uniform Status of Children of Assisted Conception Act*, 51 Hastings L.J. 1047, 1067 (2000) (raising doubts as to the sufficiency of tort claims to create an incentive for DRT manufacturers to perform genetic testing and compile medical records).

[211] *See supra* Part II.B (discussing this issue); *see also supra* note 112 and accompanying text.

[212] The current law, at least in California and New York, does not provide injured DRT children with effective means of suing for their injuries. *See supra* Part II.C; *see also* Annas, *supra* note 22, at 938 (arguing that the current regulatory framework is a "bad way to protect children" because it focuses on "provid[ing] the adults involved with what they want" rather than making the children born the first priority).

[213] *But see* Browne, *supra* note 96, at 2608-09 (suggesting a different approach to establishing liability of DRT manufacturers that would circumvent some of the problems and hardships inherent to the current legal framework).

settlement amounts in such cases are arguably too low to create a real incentive for DRT institutions to improve their genetic screening and testing practices.[214]

Even if we ignore the fact that lawsuits impose significant financial burdens that not everyone is capable of bearing, judicial remedies are, by definition, case-specific and retrospective and, therefore, too late for the genetically injured child and her family; by the time of the trial, the child and her family have already experienced pain and suffering and will live with the consequences of the genetic injury for the rest of their lives.[215] Additionally, because the genetic risks to DRT children might manifest many years after the treatment took place, medical malpractice litigation may not be an effective venue for obtaining "real time" quality control.[216]

3. DRT Recipients and DRT Children are Entitled to and It Is Desirable that They Have Additional Legal Protection

The *Paretta* court's proposition that DRT children's injuries are not compensable where similar injuries of non-DRT children would not be compensable[217] is unjustifiable and ignores significant differences between the circumstances of conception and gestation of DRT and non-DRT children. First, the conception of DRT children always involves a third party—a "middleman"—that normally makes certain representations, both direct and implied, to the recipients regarding the DRT, which often create certain expectations—reasonable or not—regarding the characteristics of the DRT and future

[214] Since *Johnson* and *Paretta* are the only two reported cases available, it is difficult to make an inference from them as to all matters involving injuries resulting from genetically defective DRT. Still, *Johnson* and *Paretta* may be indicative of how plaintiffs in such cases perceive their chances in court and therefore their leverage in settlement negotiations. *See also* Hecht, *supra* note 70, at 258 ("[The] unfavorable trial conditions force plaintiffs to settle for less, while clinics are not required to improve the safety of their facilities."); Hodgson, *supra* note 96, at 364 (observing that while settlement amounts in cases involving defective sperm ensure minimal compensation, they do little to compel sperm banks and physicians to take action that would circumvent similar defects in the future).

[215] *See* Cohen, *supra* note 23, at 353 (arguing that the court system does not provide an adequate method of regulation in the area of ART, where it is necessary to avert permanent harm in advance); Ginsberg, *supra* note 96, at 841 (arguing that litigation is an inadequate enforcement mechanism because it is retrospective, deals with injuries of individual parties, results in ad-hoc policy limited to case-specific circumstances and generally fails to deter abuses in the AI industry); Hodgson, *supra* note 96, at 364 (observing that once a genetic disease has manifested in a child, it is difficult to compensate for the pain and suffering resulting from the injury); Shelf, *supra* note 210, at 1067 (arguing that tort remedies, by nature, are insufficient to recover lost genetic and medical information).

[216] *See* ISLAT Working Group, *supra* note 2, at 651.

[217] *See supra* note 136 and accompanying text.

DRT child.[218] Second, in assisted reproduction, gametes go through an "in-vitro stage," a period of time in which they are external to the donor and recipient's body alike. This period of time, even if short, creates a unique opportunity to manipulate the DRT or subject it to selection that is meant to achieve favorable results in the future DRT child[219] and which, as before, often creates expectations regarding the future DRT child and her genetic makeup. Thus, the *Paretta* court was mistaken in its refusal to distinguish between assisted and non-assisted reproduction, especially in the context of DRT.[220]

Furthermore, the proposition that parents cannot have reasonable expectations that their DRT children will not suffer from genetic diseases[221] flies in the face of reality as DRT recipients often have an underlying—many would say justified—expectation that their DRT children would have significantly lower chances of having genetic diseases than non-DRT children.[222] In fact, many DRT recipients seek to use DRT precisely *because* they wish to avoid the risk of their child having a genetic disease and ensure "high quality" genetic traits.[223] Thus, denying DRT recipients the assurance of genetic

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[218] The third party is also usually well informed and aware of the medical risks typical to the use of DRT. This makes the representations of the third party—normally a medical practitioner—credible and therefore more likely to be relied upon. Unsurprisingly, it is that "third party" that is usually being sued. Arguably, parties choosing to procreate in a non-assisted manner have, at least hypothetically, sufficient opportunity to inform each other and become informed with respect to their respective medical condition and genetic makeup.

[219] E.g., manipulation of sperm to select the sex of the future child, picking sperm from a donor who resembles the future father to maintain semblance between him and the future DRT child and more.

[220] Rather than refuse to distinguish between assisted and non-assisted reproduction, the *Paretta* Court should have determined whether the DRT institution had a duty toward the recipients and DRT child based on the particular circumstances of the case and regardless of the question of comparability to non-assisted reproduction. The court should have left the comparability question to later cases addressing the issue from the non-assisted reproduction perspective, i.e., whether children conceived *via unassisted reproduction* could receive the same type of relief as children conceived *via* assisted reproduction.

[221] *See supra* notes 134-136 and accompanying text.

[222] *See, e.g.*, Orenstein, *supra* note 10, at 39 ("[Future parents seeking to use DRT to achieve a pregnancy instead of adopting a child] wanted the opportunity to hand-pick a donor's genes rather than gamble on a birth mother's and father's."); John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 Am. J.L. & Med. 439, 460 (2003) ("[U]sing gamete and embryo selection technologies to ensure healthy offspring [is] of great importance to individuals."); Amy Harmon, *First Comes the Baby Carriage*, N.Y. Times Oct. 13, 2005, at G.1 ("You're paying for it, so you kind of want the best of the best.").

[223] This incentive was acknowledged by the *Johnson* Court. *See Johnson v. Superior Court* (*Johnson II*), 124 Cal. Rptr. 2d 650, 660 (Cal. Ct. App. 2002) ("A wide variety of factors leads individuals to their decision to use [AI] including genetic disorders."); Helen M. Alvare, *The Case for Regulating Collaborative Reproduction: A Children's Rights Perspective*, 40 Harv. J. on Legis. 1, 25 (2003) (arguing that "[t]he industry is in the business of selling superior genetic

quality that many of them seek by not affording them appropriate legal remedies when they and their DRT children are injured defeats one of the main reasons for using DRT.

From a torts policy point of view, the current regulatory scheme is contrary to notions of justice and economic efficiency.[224] As explained above, DRT recipients are the least informed and least equipped party to assess the genetic risks involved in the use of DRT. Moreover, under the current regulatory scheme, DRT recipients run the most significant risk involved in the use of DRT—giving birth to very sick individuals. Meanwhile, DRT institutions that could have prevented the injury most efficiently and effectively, and which are also the "deep pocket," are left practically unscathed.[225] This situation is not only inefficient from an economic standpoint but also offensive from distributive and corrective justice points of view.

It is prudent to assume that with the persistently high number of individuals using DRT, constant improvement in preconception diagnosis technology and the maturation of DRT children (and manifestation of dormant genetic diseases), claims of DRT children and recipients, which are still relatively rare, will increase in number.[226] In other words, unless the regulatory framework is changed, the problems stemming from the current regulatory scheme are only going to be aggravated.

In sum, the DRT market, given its particular characteristics, is currently under-regulated to an extent that poses a significant risk to the lives, health and welfare of a large and ever growing population of DRT recipients and DRT children.[227] In the several decades since ART became available to the public, the federal government, states, courts and professional organization have all failed to create a coherent regulatory scheme that would protect DRT recipients, DRT children and the public from avoidable genetic hazards involved in DRT.[228] This type of systemic failure calls for the involvement of

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inheritances for high fees"); Ginsberg, *supra* note 96, at 823, 827-28 ("[M]any recipients use artificial insemination to avoid passing a genetic disease to their children."); Peterson, *supra* note 69, at 62-63 (asserting that the second most common reason for the use of AI is that the intended father carries a genetic mutation which the intended parents fear transmitting to their child).

[224] *See* Hodgson, *supra* note 96, at 359 (calling for increased moral accountability and legal liability where economizing the results of the creation of "low-cost, low-quality human offspring").

[225] Indeed, the settlement amounts of over $1M in the *Johnson* and *Paretta* cases are significant. Yet, they did not include any punitive component and, arguably, were not substantial enough to create a deterrent effect.

[226] *See* Browne, *supra* note 96, at 2591. *See also* Denise Grady, *As the Use of Donor Sperm Increases, Secrecy Can Be a Health Hazard*, N.Y. Times, June 6, 2006, at F5, *available at* http://www.nytimes.com/2006/06/06/health/06opin.html.

[227] *See* Parens & Knowles, *supra* note 201, at S12, S14 (arguing that although many groups and federal agencies have commented on or asserted authority over DRT, "there is, at best, a patchwork system of oversight" which calls for improved government oversight)

[228] Notably, numerous commentators have highlighted the lack of protection of DRT children as especially problematic. *See generally* Alvare, *supra* note 223, at 25-26 (arguing that the DRT industry accommodates and prefers the interests of adults over the needs and well-being of

the federal government.[229] As discussed *infra* in Part IV, the FDA is the federal government branch best positioned for and capable of regulating the genetic aspects of DRT and has the authority to do so. By way of comparison, the next section describes the federal-like regulation of genetic aspects of DRT in the European Union and exemplifies some of its features that may be "imported" to a similar future scheme in the United States.

III. THE REGULATION OF GENETIC ASPECTS OF DONATED REPRODUCTIVE TISSUE IN EUROPE

Given its unique history and circumstances, regulation in the United States generally, and that of reproductive technologies in particular, is not comparable to the regulation in other countries. However, there is merit in observing how some of the problems that plague the regulation of this area in the United States are addressed in Europe so that similar solutions may be crafted for the regulation of DRT in the United States.

A. The European Union

Article 152(4)(a) of the Treaty Establishing the European Community gives the European Union ("E.U.") the mandate to pass laws on the quality and safety of human tissues and cells.[230] In light of the fact that many DRT recipients acquire their DRT through cross-border exchange, the E.U. sought to create uniformity of standards among member states so that E.U. citizens would benefit from the same protection as they would under the laws of their own country.[231] Accordingly, in 2004, the E.U. issued the Tissues and Cells Directive, which established rules and principles meant to ensure the safety and quality of DRT in E.U. countries.[232] The 2004 Directive recognized that

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children); Rosato, *supra* note 201, at 62, 69 (noting that "[t]he market rules and no one in the entire contracting process speaks for the future child" and "it does not appear that self-regulation sufficiently protects children and is unlikely to do so in the near future"). Some commentators reached the same conclusion over a decade ago. *See* Ginsberg, *supra* note 96, at 823-41 (arguing that state-by-state regulation, self-imposed guidelines and private adjudication have all proven inadequate for regulating the artificial insemination industry and calling for federal regulation of the screening and testing of donated sperm).

[229] *See* Annas, *supra* note 22, at 938 (concluding that "it will probably take federal action to move children to the center of consideration in the fertility business").

[230] Consolidated Versions of the Treaty on European Union and of the Treaty Establishing the European Community art. 152, Dec. 29, 2006, 2006 O.J. (C321) 115, *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:321E:0001:0331:EN:pdf.

[231] *See* Press Release, Europa, Questions and Answers on Human Tissues and Cells (Feb. 8, 2006), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/06/66.

[232] *See* Council Directive 2004/23, 2004 O.J. (L102) 48-58 (EC) [hereinafter 2004 Directive].

> [t]he use of tissues and cells for application in the human body can cause diseases and unwanted effects . . . [most of which] can be prevented by careful donor evaluation and the testing of each donation in accordance with rules established and updated according to the best available scientific advice.[233]

Accordingly, the 2004 Directive required each member state to establish a system for the accreditation of tissue establishments and for notification regarding adverse events linked to the testing and distribution of tissue.[234] The 2004 Directive further required setting donor selection criteria and donor testing requirements and stipulated that member states were required to pass appropriate laws and regulations to implement the 2004 Directive no later than April 7, 2006.[235]

Subsequently, in 2006, the European Commission issued two additional directives expanding on the 2004 Directive. The first directive, 2006/17, covered the collection and processing of reproductive tissue.[236] Recognizing that "[r]eproductive cells have, due to the specific nature of their application, specific quality and safety characteristics,"[237] 2006/17 requires that the use of reproductive cells other than for directed donation must meet several criteria, including:[238] (1) donors must be selected on the basis of their age, health and medical history, as determined based on a questionnaire and a personal interview performed by healthcare professionals;[239] (2) a decision to use any particular DRT must be based on an assessment of the risk of transmission of inherited conditions known to be present in the donor's family and genetic testing for autosomal recessive genes known to be prevalent in the donor's ethnic background; and (3) the recipient must receive a clear explanation of all of the information about the risks associated with using the DRT and the measures undertaken to mitigate them.

Later in 2006, the European Commission issued another directive, 2006/86, that imposed several additional requirements related to the processing of DRT and to the traceability and reporting of serious adverse events.[240] 2006/86 requires tissue manufacturers to have procedures in place to retain records of tissues and cells they

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[233] *Id.* at Whereas 17.

[234] *Id.* at Whereas 25; arts. 11, 15.

[235] *Id.* at arts. 28, 31.

[236] *See* Council Directive 2006/17 2006 O.J. (L38) 40-52 (EC) [hereinafter 2006/17].

[237] *Id.* at Whereas 4.

[238] *Id.* at Annex III § 3.

[239] Specifically, the 2006 Directive requires that different sources of information be used to obtain the relevant information, including an interview with the donor (mandatory), review of the donor's medical records and their evaluation by a qualified health professional, interview with the donor's treating physician and physical examination of the donor. *Id.* at Annex IV § 1.2.

[240] *See* Council Directive 2006/86 2006 O.J. (L204) 23-36 (EC) [hereinafter 2006/86].

procured and to immediately report to the appropriate authorities and other tissue establishments serious adverse conditions in a donor that may reflect on the quality and safety of a donated tissue.[241] The Directive further stipulates that the records must be kept for a period of at least thirty years and that all data be coded in a unified single European identification code system.[242]

In conclusion, the E.U. adopted a mandatory framework requiring, among other things, the genetic screening and testing of DRT donors and reporting adverse events, including those suspected as having a genetic background. I will now discuss implementation of the 2004 and 2006 Directives (E.U. Directives) in the United Kingdom and Ireland.

B. The United Kingdom

Even before the European Commission issued the E.U. Directives, matters involving DRT were regulated in the United Kingdom under the Human Fertilisation and Embryology Act (HFE Act).[243] On May 25, 2007, a new set of regulations went into effect that extensively amended and supplemented the HFE Act to comply with the E.U. Directives.[244] The HFE Regulations included a list of requirements pertaining to the procurement and distribution of DRT, operation of a DRT institution and engaging in various related activities. In particular, the HFE Regulations required DRT institutions to keep records containing information regarding the quality and safety of gametes and embryos and any information necessary to trace gametes and embryos back to their donors.[245] The HFE Regulations further required that the British Human Fertilisation and Embryology Authority (HFEA) investigate serious adverse events related to DRT and fertilization and communicate to the European Commission and parallel authorities in other member states relevant information which may assist in withdrawal of compromised DRT.[246]

Most importantly, with respect to donations of gametes or embryos other than between partners, the HFE Regulations stipulate that DRT institutions must comply with the selection criteria for donors and the requirements for laboratory tests set forth in Section 3 of Annex III of 2006/17.[247] Specifically, the HFE Regulations require the

[241] *Id.* at art. 5, Annex VI.

[242] *Id.* at arts. 9-10.

[243] Human Fertilisation and Embryology Act, 1990, c. 37 (Eng.).

[244] Human Fertilisation and Embryology (Quality and Safety) Regulations, 2007, S.I. 2007/1522 (U.K.) [hereinafter HFE Regulations].

[245] *Id.* at § 13.

[246] *Id.* at §§ 10, 18.

[247] *Id.* at § 30, Annex 3A § 7.

selection of donors on the basis of their age, health and medical history and an assessment of the risk of transmission of inherited conditions known to be present in the donor's family as well as genetic testing for autosomal recessive genes known to be prevalent in the donor's ethnic background.[248] In other words, in order to receive a license under the HFE Act, a DRT institution must have in place an appropriate framework for the minimization of the genetic risks to DRT children.

In addition, the HFEA has published a Code of Practice that expands upon and clarifies the requirements set forth in the amendments to the HFE Act.[249] According to the HFEA Code, DRT institutions must not collect sperm from donors older than forty-six or harvest ova from donors older than thirty-six[250] and should not use DRT from any specific donor in more than ten families.[251] The HFEA Code requires DRT institutions to take donors' family medical histories and test donors as necessary based on the risk factors identified.[252] The HFEA Code further directs DRT institutions to follow contemporary professional guidance of relevant professional bodies on the genetic tests and screening techniques they should implement.[253] In particular, the HFEA Code mentions the guidelines of the British Andrology Society and the British Fertility Society.[254]

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[248] *See supra* note 238 and accompanying text. Notably, an additional requirement is that the recipient must receive a clear explanation of complete information on the genetic risks associated with the gametes received and on the measures undertaken for their mitigation.

[249] The Human Fertilisation and Embryology Authority, Code of Practice (7th ed. 2008) [hereinafter *HFEA Code*], *available at* http://www.hfea.gov.uk/docs/Seventh_Edition__R3.pdf.

[250] *Id.* at §§ G.4.2.1-G.4.2.2.

[251] *Id.* at § G.4.6.1.

[252] *Id.* at §§ G.4.7.1-G.4.7.2.

[253] *Id.* at § G.4.9.1.

[254] Id. See also Ass'n of Biomedical Andrologists et al., UK Guidelines for the Medical and Laboratory Screening of Sperm, Egg and Embryo Donors, 11 Human Fertility 201, 201 (2008) [hereinafter British Professional Guidelines]. The British Professional Guidelines set forth an extensive list of tests that DRT institutions and practitioners should perform and instructions to be followed as part of the donor screening and selection procedures. Importantly, the British Professional Guidelines stipulate that when taking medical histories of potential donors, inquiries should be made to ensure that the donor does not have "familial disease with a major genetic component . . . any significant Mendelian disorders, such as (but not exclusively) albinism, hemophilia, hemoglobin disorders," "familial disease with a known or reliably indicated major genetic component, such as debilitating asthma, juvenile diabetes mellitus, epileptic disorder," "a chromosomal rearrangement that may result in unbalanced gametes," and more. Id. at 203. The British Professional Guidelines further instruct that "the potential donor should ordinarily not be heterozygous for an autosomal recessive gene for a disease known to be prevalent in the donor's ethnic background, e.g., CF in Caucasian populations, α^0 or β-Thalassemia in Mediterranean populations, sickle cell disease in African & Afro-Caribbean populations and Tay-Sachs disease

Finally, the HFEA Code imposes duties on DRT institutions to notify the appropriate authorities, other institutions *and recipients* once they discover "that a gamete donor has a previously unsuspected genetic disease or is the carrier of a deleterious recessively inherited condition."[255]

C. Ireland

As a member state in the European Union, Ireland was also required to incorporate the E.U. Directives into its legislation and did so with two sets of regulations promulgated by the Irish Minister for Health and Children and administered by the Irish Medicine's Board (IMB).[256] Under S.I. No. 158, in order to be licensed to engage in the collection and distribution of DRT, institutions must comply with numerous donor selection and testing requirements.[257] S.I. No. 158 stipulates that donors must be selected on the basis of their age, health and medical history, which the donor should provide on a questionnaire and in a personal interview by a healthcare professional.[258] S.I. No. 158 further requires the "[g]enetic [test]ing for autosomal recessive genes known to be prevalent . . . in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family" and stipulates that "[c]omplete information on the associated risk and on the measure undertaken for its

in Jews of Eastern European descent. The British Professional Guidelines also dictate that inquiries should be made to verify that the potential donor's genetic parents, siblings and offspring are free of (1) major malformations listed in the British Professional Guidelines, (2) non-trivial disorders showing Mendelian inheritance e.g., autosomal dominant disorders, such as Huntington's disease and autosomal recessive diseases, particularly if such diseases have a high frequency in the population such as CF, (3) a chromosomal abnormality (unless the donor has a normal karyotype) and (4) in egg and embryo donors, a history of any mitochondrial disorders. If there is any evidence of any of the above, the British Professional Guidelines instruct that a qualified clinical geneticist should evaluate the risk. Id. The British Professional Guidelines also require that "[a]ll donors should undergo appropriate genetic/cytogenetic testing" which includes karyotyping of all donors, and testing according to ethnic background for α^0 or β-Thalassemia, sickle-cell disease, Tay-Sachs disease and common mutations of CF. Id. at 204.

[255] *HFEA Code*, *supra* note 249, at § G.4.10.5.

[256] *See* European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 (S.I. No. 158 of 2006) (Ir.) [hereinafter S.I. No. 158], *available at* http://www.irishstatutebook.ie/2006/en/si/0158.html (implementing 2004/23 and 2006/17); European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) Regulations 2007 (S.I. No. 598 of 2007) (Ir.) [hereinafter S.I. No. 598] *available at* http://www.irishstatutebook.ie/2007/en/si/0598.html (implementing 2006/86).

[257] S.I. No. 158 at §§ 5-6, 11(2), 11(6).

[258] *Id.* at Schedule 3, § 3.1.

mitigation must be communicated and clearly explained to the recipient."[259] S.I. No. 598 supplements the regulatory framework created in S.I. No. 158 by imposing traceability and adverse events reporting requirements as directed by 2006/86.[260]

The European model of regulation of the genetic aspects of DRT could be characterized as relying on three premises. First and foremost, the recognition that "while those seeking assisted reproductive treatment deserve and can expect proper consideration of their medical and social needs, licensed treatments may result in children who would not otherwise have been born and whose interest must be taken into account."[261] Second, the structure of the European regulations reflects the recognition that the protection of DRT children (and their families) requires the uniformity and authoritativeness that can only be afforded by legislation and regulation. And third, the European regulatory framework, while setting general principles and requirements, leaves the actual "nuts and bolts" to be decided by professionals who have the necessary technical knowledge and expertise; in this respect, state authorities serve as a facilitator and enforcer of professional standards.

An additional advantage of the European model of regulation is that it enables state authorities to defer possible bioethical issues to professionals who, by virtue of their expertise and involvement in the regulated area, are best equipped to tackle such issues.[262] The "importation" of professional standards into the regulatory framework enables state authorities to avoid having to spend the time and money necessary for tackling bioethical issues as well as possible political strife (which administrative entities are loathe to provoke) involved with delving into bioethical debates.[263]

Despite the particularities of the United States legal system, the three abovementioned premises of the European regulation of genetic aspects of DRT can be adapted into a feasible model for federal regulation in the United States' in a fashion that would resolve many of the problems that characterize the current regulation of genetic aspects of DRT.

IV. TOWARDS FEDERAL REGULATION OF THE GENETIC ASPECTS OF DONATED REPRODUCTIVE TISSUE—THE CASE FOR FDA REGULATION

The first and most important advantage of federal regulation of genetic aspects of DRT would be the institution of a uniform and feasibly enforceable standard of conduct that would increase adherence of DRT institutions to testing standards thereby promoting safety for DRT children regardless of the origin of the DRT from which they were

[259] *Id.* at Schedule 3, § 3.6.

[260] *See* S.I. No. 598 at §§ 5-22.

[261] *HFEA Code*, *supra* note 249, at § 1.2.

[262] For further discussion, see *infra* Part IV.B.4.

[263] Notably, this approach may be especially fitting to the United States, where disagreements on bioethical issues often run deep.

conceived.[264] In other words, the main function of federal regulation of the genetic aspects of DRT would lie in its general applicability. Assuming that most DRT institutions and practitioners would do their best to conform to such standards, the safety of using DRT from a genetic standpoint could increase dramatically.[265]

Second, the high enforceability of federal regulations[266] and adherence to them would serve to preempt many occurrences of transmission of genetic diseases to DRT children in the first place, thereby providing an *ex ante* solution to avoid cases like *Johnson* and *Paretta*.

Third, the imposition of a federal standard of conduct would diminish the need for injured DRT children and their families to resort to *ex post* solutions. Third, the imposition of a federal standard of conduct would, at the very least, strengthen the legal stances of DRT children and their families. A standard set by federal regulations may be accepted by courts as the standard of conduct by which the actions of DRT professionals should be evaluated when a negligence claim is brought, thereby enabling a quick and efficient resolution of such matters.[267] Federal standards of conduct set by federal

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[264] *See* Annas, *supra* note 22, at 938 ("it will probably take federal action to move children to the center of consideration in the infertility business"); *Human Tissues and Organs*, *supra* note 104, at 46-47, 56 ("Unfortunately for those of us in the semen banking business we don't necessarily know which states have [put regulations in place]. . . I would highly support the FDA in regulating semen banking;" "FDA standard seems far more likely to prevent state variances than voluntary standards.").

[265] *Human Tissues and Organs*, *supra* note 104, at 56 ("[A]nother advantage of government standards is their ability to reassure the public . . . FDA's involvement would moot [the] concern [that voluntary standards and adherence to them are lacking.]"). Federal regulation of genetic aspects of DRT would also serve to assure consumers in every state and U.S. territory that the DRT they acquire is indeed safe without them having to become experts in clinical genetics.

The need for a generally applicable regulation of the genetic aspects of DRT is further highlighted by the lack of such applicability of state regulation. Since many DRT recipients order their DRT from states other than those in which they live, even the few states that do seek to regulate the genetic aspects of DRT are likely to find the enforcement of such regulation difficult, if not impossible. It would be impractical and unrealistic to expect that New York State, for example, would verify that every semen specimen sent *via* overnight delivery to consumers within its borders was processed, screened and tested in accordance with the New York Regulations.

[266] It is preferable that—like the Human Tissue Regulations—federal regulations pertaining to the genetic aspects of DRT be enforced by the FDA.

[267] Since the Human Tissue Regulations only address the communicable diseases aspects of DRT, DRT institutions sued for negligence in their genetic screening and testing of DRT donors could raise a regulatory compliance defense arguing that they are in full compliance with the federal standard of practice with respect to the genetic screening and testing of DRT and therefore cannot be held liable for incompliance with higher standards set by the states. Similarly, DRT institutions could raise federal preemption arguments seeking to preempt such heightened state standards in view of the non-existent federal standard of practice with respect to the genetic aspects of DRT. For a discussion of regulatory compliance and federal preemption defenses, see

regulations could also serve to preempt outright refusal by courts to recognize the existence of additional causes of action available to DRT recipients, as was done by the *Paretta* court.[268] Finally, the imposition of duties as part of federal regulation may potentially provide plaintiffs with additional causes of action for breach of statutory duty, which may further assist in securing appropriate relief for genetically injured DRT children and their families.[269]

The FDA is the natural and most promising candidate for carrying out and enforcing federal regulation of the genetic aspects of DRT. As discussed above, the FDA has been involved in regulation of donated tissues since the late 1990s and DRT since 2001. It is prudent to assume that the FDA has acquired much of the technical expertise and understanding of the DRT market necessary to also regulate the genetic aspects of DRT in an effective and efficient manner. Thus, it would be desirable to utilize the FDA's acquired expertise as well as its proven abilities in enforcing the Human Tissue Regulations[270] in the regulation of the genetic aspects of DRT.[271]

The idea of having the federal government, and specifically the FDA, regulate the genetic aspects of DRT is not a new one and has been raised time and again, at least since 1988.[272] And yet, in promulgating its relatively recent Human Tissue Regulations, the

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Wyeth v. Levine, 129 S.Ct. 1187, 1194-95 (2009); Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 Cornell L. Rev. 1003, 1004 (2008). A discussion of federal preemption is beyond the scope of this Article. A comprehensive federal regulatory standard of practice could prevent DRT institutions from avoiding liability by raising these defenses. *See also supra* note 101 and accompanying text.

[268] *See supra* notes 134 and 136 and accompanying text.

[269] For additional possible advantages of setting uniform regulatory standards for DRT see *Human Tissue and Organs*, *supra* note 104, at 53-54.

[270] *See, e.g.*, HTTF Report, *supra* note 67 (discussing the FDA's enforcement of the Human Tissue Regulations).

[271] In this respect, due to the rapidly changing and technically complicated nature of the area of genetic medicine and ART, the FDA would also be better suited than Congress to address issues as they arise. *See* Alvare, *supra* note 223, at 32 ("The size and scope of the legislative project—even the definition of individual and the social dilemmas to be approached—may appear too large and too rapidly changing a target for legislatures."). The regulation of genetic aspects of DRT may coincide with the FDA's own perception of its mission with relation to the regulation of human tissue. *See* Zoon Statement, *supra* note 59, at 88-89, 101 ("FDA has prioritized the regulation of human cellular and tissue-based products, and the public should be confident that the FDA is committed to regulating these products in a manner where benefits to patients are maximized and risks to patients are minimized;" "FDA's goals are to protect the public from unsafe tissue products.").

[272] *See GAO 1997 Report*, *supra* note 182, at 3-4, 31 ("FDA should also add to its oversight plans provisions that would require . . . disclosure of genetic tests that have been performed on donated reproductive tissues."); Annas, *supra* note 22, at 935; Marwick, *supra* note 27, at 1340 (describing [then] Senator Gore's call for FDA regulation of DRT, including its genetic aspects, to ensure the safety and welfare of DRT children).

FDA sought only to regulate the communicable diseases aspects of DRT.[273] Notably, the FDA did not address the genetic aspects of DRT at any point in the process of promulgating the Human Tissue Regulations and the issue never arose in any of the abundant public commentary on the proposed FDA regulations.[274]

It is highly unlikely that the FDA was unaware of the genetic aspects of DRT in 2005 when it issued the Final Donor Eligibility Rule.[275] In fact, at the time it promulgated the Final Donor Eligibility Rule, the FDA was aware of professional guidelines that specifically addressed the genetic aspects of DRT[276] and probably had knowledge of good reasons for regulating the genetic aspects of DRT.[277] It therefore appears that the absence of genetic aspects of DRT from the Human Tissue Regulations was not the result of an oversight but rather intentional avoidance of this area by the FDA.

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[273] *See supra* note 60 and accompanying text.

[274] It is likely that since, from the outset, the FDA defined the Human Tissue Regulations as directed exclusively to the communicable diseases aspects of DRT, it chose not to make public any comments it may have received that were related to the genetic aspects of DRT as, purportedly, irrelevant to the Human Tissue Regulations. It is also possible that the FDA has made it so abundantly clear that the Human Tissue Regulations, by definition, were only meant to address communicable diseases aspects of human tissue, that commentators refrained from addressing the genetic aspects of DRT. *See infra* Part IV.A.

[275] *See supra* notes 47-60 and accompanying text.

[276] For example, in 2004, the ASRM issued an updated version of its Guidelines, which the FDA referred to during the process of making the FDA Final Donor Eligibility Rule. *See* 69 Fed. Reg. 29819 (FDA May 25, 2004) ("Although ASRM has published guidelines for donor screening and testing and other aspects of oocyte donation . . . .").

[277] Among the rationales for regulation mentioned in the FDA Final Donor Eligibility Rule was concern for public health that is equally applicable to genetic and communicable diseases aspects of DRT:

> Certain diseases are transmissible through the implantation, transplantation, infusion or transfer of [donated tissue] . . . To prevent the introduction, transmission, or spread of such diseases, we consider it necessary to take appropriate measures to prevent the use of cells or tissue from infected donors. Thus, these regulations require that, before the use of most [donated tissues], the cell or tissue donor must be determined to be eligible to donate, based on the results of screening and testing for relevant . . . diseases. In most cases, a donor who . . . possesses clinical evidence of or risk factors for such a disease, would be considered ineligible, and cells and tissues from that donor would not ordinarily be used.

See FDA Final Donor Eligibility Rule, supra note 24, at 29787.

A. The FDA's Statutory Authority to Regulate the Genetic Aspects of Donated Reproductive Tissue

There are several possible explanations for the FDA's failure to regulate the genetic aspects of DRT, the first of which is possible doubts regarding its legal authority to do so. As mentioned earlier, in promulgating the Human Tissue Regulations, the FDA relied on PHSA § 361, which reads, in relevant part, as follows:[278]

> Regulations to control communicable diseases
>
> (a) Promulgation and enforcement by Surgeon General[279]
>
> The Surgeon General . . . is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection . . . destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

Arguably, PHSA § 361 grants only the authority to promulgate regulations pertaining to the prevention of the transmission and spread of infectious diseases rather than genetic diseases.[280] Under this construction of "communicable diseases," PHSA §

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[278] PHSA § 361 (codified at 42 U.S.C. § 264).

[279] As mentioned earlier, the authority under PHSA § 361 was delegated to the FDA. *See supra* note 62.

[280] This reading of PHSA § 361 relies on a construction of the definition of "communicable diseases" as only reasonably including diseases caused by infectious agents rather than by chromosomes and genes. The term "communicable diseases" is not defined in the PHSA. However, 21 C.F.R. § 1240.3(b) defines "communicable diseases" as "[i]llnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment." Notably, this restrictive definition was created pursuant to the legislation of PHSA § 361 and is in accord with its legislative history, which only sought to address infectious diseases as these are defined by the FDA. Yet, under a liberal view on the duties and authorities of executive agencies, should the FDA ever choose to change its definition of "communicable diseases" to include genetic diseases, it may, arguably, be able to do so, subject the requirements of the Administrative Procedure Act. *See* 5 U.S.C. §§ 551(5), 553. Moreover, it is not clear how scientifically sound the 42 U.S.C. § 361 dichotomy between communicable and genetic diseases is and whether it is justifiable from a public health policy perspective. For example, many diseases could be branded as both infectious and genetic (e.g., HIV, cervical cancer caused by a viral infection). Nonetheless, for purposes of the discussion herein, the term "communicable diseases" is

361 could not serve as a source of authority to regulate genetic aspects of DRT. Such authority, however, exists elsewhere.

Among the several other possible routes for regulation of genetic aspects of DRT suggested in the past,[281] the most promising source of authority is PHSA § 351,[282] which reads, in relevant part, as follows:[283]

> Regulation of biological products
> (a) Biologics license
> (1) **No person shall introduce or deliver for introduction into interstate commerce any biological product unless—**
> (A) **a biologics license is in effect for the biological product**
> . . .
> (2) (A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.
> . . .
> (C) The Secretary shall approve a biologics license application—
> (i) on the basis of a demonstration that—
> (I) **the biological product that is** the subject of the application is **safe, pure, and potent**; and
> . . .
> (3) The Secretary shall prescribe **requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1)**.
> . . .
>
> (i) Definition; application
> In this section, the term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or **analogous product** . . . applicable to the **prevention, treatment**, or cure **of a** disease or **condition of human beings**.
> (emphasis added)

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construed as exclusive of diseases having genetic background (but not diseases resulting from viral infections).

[281] *See, e.g.*, Hodgson, *supra* note 96, at 360-85 (advocating treating the sale of sperm as a "sale" rather than as a "service" under the U.C.C.); Parens & Knowles, *supra* note 201, at S19 (calling for the creation of an HFEA-like body in the United States which would license institutions participating in ART related activities).

[282] *See Human Tissue and Organs*, *supra* note 104, at 14, 19, 21-22; Peterson, *supra* note 69, at 88.

[283] PHSA § 351 (codified at 42 U.S.C. § 262 (2007)).

The FDA construes the PHSA § 351(i) definition of "biological product" as follows:[284]

> Biological products include a wide range of products such as . . . somatic cells . . . [and] tissues. . . . Biologics . . . may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism . . . .

Thus, according to the FDA, "biological products" include human cells and tissues.[285] PHSA § 351(i) also clarifies that biological products do not necessarily have to be used as cures for diseases but could serve *for the treatment of a condition of a human being*. Arguably, even if infertility cannot be categorized as a disease in the conventional sense,[286] it could still fall within the boundaries of a "condition of a human being" which could be "prevented" or "treated" *via* the use of DRT.[287] Thus, the PHSA § 351(i) definition of "biological product" could conceivably encompass DRT such that PHSA § 351 would give the FDA authority to regulate DRT as a biological product.[288]

Admittedly, it is possible to imagine several scenarios where the use of DRT does not fall within the PHSA § 351(i) definition of biologics. For example, it is difficult to classify as "treatment" the use of donated sperm to impregnate a perfectly fertile woman whose husband suffers from infertility.[289] Similarly, it is difficult to classify as

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[284] *See* FDA, What Are "Biologics" Questions and Answers, http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucm133077.htm (last visited May 10, 2010).

[285] Although the FDA's definition only specifically mentions somatic cells, it does not exclude reproductive cells and the denominator "such as" indicates that somatic cells are only mentioned as an example. Thus, it appears that reproductive cells could also be biological products under the FDA definition.

[286] *See* Andrews & Elster, *supra* note 70, at 37.

[287] *See* Peterson, *supra* note 69, at 88 ("[T]he phrase 'analogous product' easily could be interpreted to include semen samples . . . . The straws containing the frozen semen derivative could easily be categorized as a 'biological product' which is applicable to the 'treatment or cure' of human infertility diseases.").

[288] Interestingly, this also appears to have been the opinion of the FDA's General Counsel in 1973. *See Human Tissues and Organs*, *supra* note 104, at 5 (presentation of Stuart Nightingale, Associate Comm'r for Health Affairs, FDA); Merrill, *supra* note 23, at 9 (presenting the response of the Chief Counsel: "Human tissues . . . could be considered 'analogous' to materials such as blood, over which FDA had authority under section 351"). Similar positions were presented by Paul Parkman, the Director of CBER in 2001. *See Human Tissues and Organs*, *supra* note 104, at 22.

[289] The reason for this is that the person who is actually being "treated" (i.e., the female) is not the one actually suffering from infertility.

"treatment" the use of DRT due to a couple's wish to avoid passing along a genetic condition existing in one of them.[290] Even more significantly, it would be difficult and even disturbing to classify the use of sperm by single women or of DRT by single-sex couples as a "cure" or "treatment." Yet, there are obviously many situations in which the use of DRT would fall neatly within the boundaries of PHSA § 351(i) and which ought to be "sufficient," from a regulatory perspective, to deem DRT suitable for regulation under PHSA § 351.[291]

Furthermore, broad construction of the term "condition of human beings" could conceivably encompass almost any scenario involving the use of DRT and it does not have to be construed as relating to a medical condition but rather as relating to a social or familial situation or even status, e.g., infertility (as a couple or family), childlessness or the inability to have children on one's own or with one's chosen partner. In view of the above, it is highly unlikely that courts would reject a construction of PHSA § 351(i) that would encompass reproductive tissue within the definition of biological products thereby facilitating the application of this section to DRT.[292]

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[290] The reason is that it is not the genetic condition that is being treated. Rather, the underlying reason for using DRT is the couple's reproductive preferences.

[291] Examples of scenarios that fit into the PHSA § 351(i) framework would include the use of donated eggs to enable women who no longer ovulate to conceive, in which case the donated eggs could be perceived as "treatment" for such women's "condition" of infertility; using donated sperm in tandem with IVF treatments, in which case the donated sperm is the "treatment" for the husband's inability to provide sperm to fertilize the eggs in order to create embryos that would be implanted into his female partner or into a surrogate.

[292] It is well accepted that agencies have discretion to interpret their statutory authorities to enable their application in new ways to meet new challenges unforeseen by Congress and that they are *expected to* do so. *See infra* note 297 and accompanying text. Accordingly, although Congress might not have envisioned the use of PHSA § 351 for regulating DRT when it enacted the section, it is well within the power of the FDA to apply this section to such an end so long as its construction of the statutory language meets the *Chevron* standard. *See Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-44 (1984) ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme . . . ."). Under what came to be called the "*Chevron* Doctrine," courts generally grant agencies' discretionary decisions and actions a great measure of deference and are not easily persuaded to set them aside so long as (1) "Congress has [not] directly spoken to the precise question at issue," and (2) "the agency's answer is based on a permissible construction of the statute." *See id.* at 842-44. According to the Supreme Court, if both conditions are met, then the agency's construction of the statute it is entrusted to administer should receive "considerable weight" and "the principle of deference to administrative interpretations [should be] followed." *Id.* Given the plausibility of viewing DRT as biological products under at least some circumstances that fall neatly within the boundaries of PHSA § 351(i) and the fact that PHSA § 351 does not address reproductive tissue in general or DRT in particular, it is likely that courts would accept an agency's construction of PHSA § 351(i) as inclusive of DRT. Notably, this entire regulatory conundrum could be resolved if Congress were to amend PHSA § 351(i) so it explicitly included reproductive tissue, thereby also indicating that DRT should be comprehensively regulated by the FDA.

Despite possible concerns that if DRT were to be regulated as a biological product every sperm sample would require its own separate approval and licensure, PHSA § 351(a)(3) provides the FDA with the authority to exempt a biological product from the licensure requirements of PHSA § 351(a)(1). Thus, when promulgating a regulatory framework that would address genetic aspects of DRT, the FDA could conceivably stipulate, for example, that DRT coming from a donor who was properly screened and tested in accordance with regulations promulgated under PHSA § 351(a)(2) would be exempt (under PHSA § 351(a)(3)) from the burdensome licensure requirements of PHSA § 351(a)(1).

PHSA § 351 also provides the FDA with effective enforcement tools that include (1) the authority to inspect DRT institutions engaging in collection, processing or distribution of DRT[293] and (2) the authority to determine whether DRT originating from a specific donor would present an imminent or substantial hazard to public health and to issue orders for the recall of such DRT.[294] Furthermore, in addition to any deterrents and incentives the FDA may include in regulations promulgated under PHSA § 351 to ensure effective enforcement of the regulation of biologics, violation of PHSA § 351 is a criminal offense, punishable by fines and up to one year in prison; it also sets a civil penalty of up to $100,000 per day for non-compliance with an order recalling a biological product.[295] Thus, PHSA endows the FDA with ample authority and sufficient enforcement tools to effectively regulate the genetic aspects of DRT.

B. Other Possible Reasons for the FDA's Non-Regulation of Genetic Aspects of Donated Reproductive Tissue

1. Lack of Authority to Tend to the Safety of Future People

Under a narrow construction of the FDA's authority under PHSA § 351, the FDA's power is arguably limited only to the assurance of the safety of DRT recipients rather than that of DRT children.[296] Such a reading of FDA authority appears to be unnecessarily and unjustifiably narrow, especially in light of the conventional understanding that agencies have discretion and are expected to interpret their statutory authority so it applies in new ways to meet new challenges that Congress did not

[293] 42 U.S.C. § 262(c) (2007) (granting the FDA authority to inspect any establishments engaging in the propagation or manufacture and preparation of any biological product).

[294] *Id.* at § (d)(1).

[295] *Id.* at §§ (d)(2), (f).

[296] *See, e.g.*, Council on Bioethics Report, *supra* note 100, at 177 (arguing that the FDA has no explicit legal authority to regulate on grounds of protection of a child resulting from ART as such).

foresee.[297] Looking specifically at PHSA § 351, nothing in its language suggests that the FDA's mandate to ensure the safety and efficacy of biologics is limited only to DRT recipients or even just to "currently existing people." Moreover, there are examples of cases where the FDA asserted its regulatory authority over matters involving "future individuals," i.e. individuals not yet in existence when the treatment is carried out or the drug is administered. One prominent example is the FDA's prohibition on tests involving human cloning out of concern for the health of the future children that might be created by such a procedure.[298] Furthermore, arguably at least in relation to the regulation of small molecule drugs (rather than biologics), in authorizing the FDA to require safety data analysis in relation to pregnant women, Congress granted the FDA the authority to tend to the safety of unborn children.[299] At the very least, the abovementioned precedents indicate that it is not unreasonable for the FDA to construe its authority under PHSA § 351 broadly enough to encompass a role for itself in ensuring the safety of future individuals, including DRT children. Therefore, if the FDA were to construe its authority under PHSA § 351 as including the safety of DRT children, a court would most likely uphold that statutory construction under the *Chevron* doctrine.[300]

2. Lack of Authority to Regulate in the Area of Genetic Aspects of DRT

The issue of the FDA's authority to regulate the genetic aspects of DRT comes up also in a federal context as part of the question of the Federal Government's authority to

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[297] *See* Merrill, *supra* note 23, at 1 ("It is conventional wisdom that regulatory agencies possess discretion to interpret their program statutes in new ways in order to meet challenges that the congressional authors did not, and in many cases could not, anticipate . . . we have come to expect that agencies will often confront new challenges by adapting traditional tools, rather than reflexively returning to the legislature for new authority or instructions.").

[298] For the FDA's controversial assertion of authority over human cloning due to concerns for the health and safety of individuals resulting from cloning procedures, see Letter from Stuart L. Nightingale, M.D., Associate Comm'r, FDA, to Inst. Review Boards 1 (Oct. 26, 1998), *available at* http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm150508.htm. Another controversial example is the FDA's exceptional regulation of the drug thalidomide, known for its potential to cause severe birth defects out of concern for the unborn children. *See generally* Allen E. White, *Thalidomide and the FDA: Authority Overstepped or Legitimate Safety Measures?* (December 2001), *available at* http://ssrn.com/abstract=294563.

[299] *See* 21 U.S.C. § 355(k)(3)(C)(iv)(I) (2009).

[300] *See supra* note 292 (discussing the *Chevron* doctrine). Congress has clearly not addressed the matter of genetic aspects of DRT in PHSA and thus the question becomes whether a construction of PHSA that would require screening and testing of DRT donors for genetic diseases to ensure the safety of DRT children is a permissible construction of PHSA § 351. As argued above, such a construction is not only reasonable but also desirable. Assuming that courts would not find this view fundamentally inconsistent with the statutory language, they should uphold a construction of PHSA § 351 that would grant the FDA authority to regulate the genetic aspects of DRT.

regulate in the field of healthcare. DRT transactions routinely occur across state borders as well as over the Internet.[301] Accordingly, the Commerce Clause of the Constitution provides the FDA, via congressional delegation, the authority to regulate DRT.[302] Furthermore, it is quite possible that the federal power to regulate DRT also extends to intrastate commerce in DRT.[303] Thus, the FDA has the authority under PHSA § 351 to regulate genetic aspects of DRT so long as traditional state regulatory prerogatives are not impermissibly impinged upon.

While the practice of medicine has traditionally been regulated by the states,[304] the Supreme Court has recognized the ability of the federal government to set uniform national standards for health and safety.[305] Thus, to the extent that FDA regulation of the

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[301] *See* Gail Schmoller Philbin, *Web of Conception; Couples Turning to Internet Sites to Secure Donated Sperm*, Chicago Trib., Aug 20, 2003 at 1 ("While the Web has transformed the way couples . . . find donor sperm, it has also changed the way sperm banks do business."); Don Oldenburg, *Sperm Banks Online: Going Too Far?* Wash. Post, Nov. 18, 1999, at C4. *See also OTA's Infertility Report*, *supra* note 27, at 24 ("Sperm [is] sold by commercial sperm banks throughout the United States and [has] been for many years."). In the absence of exact DRT sales' statistics it is difficult to estimate the volume of interstate transactions in DRT and their percentage out of the total number of DRT transactions. However, it appears prudent to assume that a large portion of the DRT transactions occurring over the internet are not confined to within a single state's borders. The prevalence of the use of the internet as well as several advantages the internet offers to DRT purchasers (e.g., privacy, a large selection of potential donors, ease of access), all increase the prevalence of the internet in DRT transactions, thereby presumably increasing the quantity of interstate DRT transactions both in general and as compared to intrastate DRT transactions.

[302] *See* U.S. Const. art. I, § 8, cl. 3; *see also OTA's Infertility Report*, *supra* note 27, at 181-82 (discussing the use of the Commerce Clause to regulate in other fields of health care and medical laboratories).

[303] At least on one occasion, a federal court upheld an FDA ban on intrastate commerce based on authority granted by PHSA § 361, recognizing that such a ban was reasonable to prevent the interstate spread of disease. *See Louisiana v. Mathews*, 427 F.Supp. 174, 176 (E.D. La. 1977). Notably, in so doing, the District Court for the Eastern District of Louisiana explicitly stated that "[i]t has long been established that businesses which affect interstate commerce may have their intrastate activities regulated." *Id.* Thus, to the extent the regulation of intrastate commerce in DRT is necessary to prevent negative outcomes in interstate commerce, it is likely that the FDA could establish authority to regulate such intrastate commerce. *Cf. Wickard v. Filburn*, 317 U.S. 111 (1942) (holding that Congress's power to regulate the production of wheat going into interstate commerce extends to wheat intended for personal use and not placed in interstate commerce.).

[304] *See* Annas, *supra* note 22, at 938 ("[T]he regulation of medicine . . . [has] historically been dealt with under state law, not federal law."); *Human Tissues and Organs*, *supra* note 104, at 15 (mentioning FDA's policy of not regulating the practice of medicine).

[305] *Gonzales v. Oregon*, 546 U.S. 243, 271 (2006) (internal citations omitted) ("Even though regulation of health and safety is primarily, and historically, a matter of local concern . . . there is no question that the Federal Government can set uniform national standards in these areas.").

genetic aspects of DRT would touch upon the practice of medicine as some have argued,[306] such regulation would be permissible[307] and, at any rate, would not constitute a regulation of the practice of medicine any more than the well-accepted safety requirements of the Food, Drug and Cosmetic Act.[308]

Moreover, FDA regulation of the genetic aspects of DRT requiring the screening and testing of potential donors for genetic diseases would not directly impact the practice of medicine but would merely set the minimum safety standards for DRT intended for a *later* use by physicians. For example, it would not influence the interaction between physicians and their patients. Rather, the regulation would influence directly only the interaction between DRT institutions and practitioners with potential donors, and, *only later on*, affect DRT recipients. Admittedly, it is likely that some of the employees of DRT institutions are physicians and that in small institutions it might be the same physician who would harvest the DRT and then dispense it to patients. Yet, this fact does not automatically make the relationship between such physicians and donors a physician-patient relationship.[309] Finally, to the extent that FDA regulation of the genetic aspects of DRT may impinge upon state regulation of the practice of medicine, it would do so no more than the FDA's existing regulation of the communicable diseases aspects of DRT.[310]

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[306] When the FDA was just making its first steps into the regulation of DRT, professional organizations argued that it was "wading into the practice of medicine." *See FDA Tissue Practices Rule is Criticized by Industry, Physicians*, FDA Week, June 1, 2001, at 14. Yet, even those who criticized the FDA's intentions to regulate some of the transactions taking place between physicians and their patients agreed that regulation "at the sperm bank level" is justified and even desirable. *Id*.

[307] Notably, an issue remains with respect to potential preemption of state laws by FDA regulation of the genetic aspects of DRT. However, this issue exceeds the scope of this Article.

[308] *Cf.* Merrill, *supra* note 23, at 79 ("FDA has assumed oversight of other novel medical technologies and the common feature—use in the delivery of medical care—may lead to an assumption [that] Congress expects the agency to assume responsibility.").

[309] *See* Annas, *supra* note 22, at 938 ("[T]o the extent that [ART] has become big business and to the extent that it is more accurately characterized as a commercial enterprise than as a medical or family-related enterprise, federal regulation of at least its interstate commercial aspects deserves consideration.").

[310] A requirement in federal regulation to screen and test donors for genetic diseases would not represent more interference in the practice of medicine or in the standards of practice upheld by the states than the similar federal requirements that are already in place with respect to communicable diseases. Furthermore, as stated by a former FDA official in the context of communicable diseases: "when one considers the obvious need to screen and test donors for communicable disease, [it makes] the practice of medicine issue less prominent." *Human Tissues and Organs*, *supra* note 104, at 11 (presentation of Stuart Nightingale, Associate Comm'r for Health Affairs, FDA). A similar argument could be made with respect to the screening and testing for genetic diseases.

3. The Difficulty in Defining "Genetic Diseases"

A conceptual difficulty that seems to haunt the discussion of genetic diseases is how to define the term "genetic disease." This difficulty is twofold: in order to define "genetic disease" one must first define "disease"—an elusive concept which baffles healthcare professionals and policymakers. Second, one must generally characterize the phenotypes that fall within the boundaries of the concept of "disease." The genetic context only complicates things further since many genetic traits cannot be characterized merely as either present or not-present but rather manifest themselves in many variations. For example, at what point (if at all) does one's stature become debilitating enough to be considered a "disease?" And are conditions such as dwarfism and genetic deafness "genetic diseases" that justify exclusion of those having them from the DRT donor pool?[311]

These conceptual difficulties could pose a real obstacle to a regulation of the genetic aspects of DRT.[312] Yet, regardless of whether the difficulties in defining "genetic diseases" played a role in the FDA's decision not to regulate the genetic aspects of DRT, such difficulties should not serve as a justification for not pursuing regulation of this area. One does not have to be in possession of a clear and coherent definition of genetic diseases to determine that conditions such as Huntington's disease and ADPKD are genetic diseases that should be screened out of any donor pool. As for those genetic conditions in which a decision is not as easy, the FDA could elect to rely on the judgment of professional organizations, expert bodies and the like to determine whether they warrant exclusion from the donor pool in promulgating its regulations.[313]

4. Bioethical Issues

Another possible reason for the FDA's avoidance of the genetic aspects of DRT is that regulation of this area would inevitably raise a variety of ethical issues.[314] As

[311] *See* Robertson, *supra* note 222, at 441 ("Persons with disabilities are concerned about biases in genetic screening [and testing] programs that disfavor persons with disabilities."); *see also* Martha A. Field, *Killing "the Handicapped"—Before and After Birth*, 16 Harv. Women's L.J. 79 (1993); Erik Parens and Adrienne Asch, *The Disability Rights Critique of Prenatal Testing: Reflections and Recommendations*, 29(5) Hastings Center Report at S1 (1999) (laying out the disabled-rights criticism of genetic screening and testing).

[312] *See, e.g.,* Conrad, *supra* note 10, at 301-02.

[313] *See infra* note 336 (discussing the privatization of regulation). Notably, reliance on bodies of experts has been a widely used method for tackling complicated public policy issues. *See, e.g.*, The Presidential Comm'n for the Study of Bioethical Issues, http://www.bioethics.gov (last visited Jun. 17, 2010). A possible advantage of such expert bodies is that they serve as a "black box"—a socially acceptable decision-making method which is especially suited for issues that spur social controversy.

[314] Such issues may include the following: which genetic diseases (if any) should render a candidate ineligible to become a donor? How much choice should potential parents have in

recognized by several scholars, executive agencies are known to be averse to regulating matters that raise bioethical issues, especially in the context of ART, and therefore tend to refrain from regulating such matters to the extent possible.[315] Others have suggested that the FDA might be trying to avoid the regulation of DRT because it wishes to prevent a hijacking of the regulatory process by interest groups wishing to promote their ethical preferences.[316] Thus, it is conceivable that in avoiding the regulation of genetic aspects of DRT the FDA might have actually been trying to avoid the bioethical issues involved, thereby passing this hot potato along to others, e.g., professional organizations, state courts and expert commissions.

If this is indeed the case, the FDA might be throwing the baby out with the bath water because in so doing it foregoes an opportunity to regulate aspects of this area that do not raise difficult ethical issues.[317] Moreover, as discussed earlier with relation to the European model of regulation of DRT, it is possible to maintain the safety of DRT children without compromising ethics by deferring to and adopting into its regulation "ready-made" practical and ethical solutions devised by other authoritative institutions

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choosing the traits of their offspring? Who should have access to a candidate's genetic data or to that of her family members which she has unavoidably disclosed as part of the screening and testing process? *See* Robertson, *supra* note 222, at 457-459 (addressing the impact of screening and testing on offspring and arguing that screening and testing are a "private" form of eugenics that is permissible); Terra Ziporyn, *'Artificial' Human Reproduction Poses Medical, Social Concerns*, 255 JAMA 13, 14 (1986) (describing issues related to donors' privacy).

[315] According to the President's Council on Bioethics, "[t]he appeal of doing nothing in [the area of ART] is, frankly, rather great, not only because the costs of regulation may be high . . . but also because the areas of assisted reproduction, new genomic knowledge, and embryo research are socially and politically quite sensitive." Council on Bioethics Report, *supra* note 100, at 185; *see also* Eugene Bardach & Robert A. Kagan, Going by the Book: The Problem of Regulatory Unreasonableness 48-49 (1982) (arguing that "[r]egulatory officials . . . often are grateful for the opportunity to escape responsibility for the intellectually difficult and politically touchy task of making [risk vs. social benefit] trade-off decisions" and quoting former FDA commissioner, Donald Kennedy statement that "[f]ortunately, our statute does not allow us to weigh adverse health conditions against dollars"); Annas, *supra* note 22, at 937 (arguing that the United States has been slow to regulate the ART industry because of bioethical controversies); Judith Daar, *Regulating Reproductive Technologies: Panacea or Paper Tiger?*, 34 Hous. L. Rev. 609, 639 (1997) (suggesting that the lack of regulation of ART is a result, at least in part, of the fact that this area is politically charged).

[316] *See* Merrill, *supra* note 23, at 63 n.332 ("It is possible, perhaps even likely, that FDA was reluctant to acknowledge its authority to regulate a set of procedures that have excited intense interest, considerable controversy, and wide publicity . . . if the Agency were to enter the [area of assisted reproductive services], it would surely face pressure from opponents of many of these services to go much further than 'mere' public health concerns might lead it to go.").

[317] For example, the merits of requiring the screening and testing of potential donors for ADPKD, Tay-Sachs and other lethal genetic conditions is not controversial.

such as professional organizations.[318] Thus, hypothetically, if the FDA were to regulate the genetic aspects of DRT it could use practice guidelines and professional standards for determining which conditions should be screened and tested for. In this way, the FDA could remain within its element—the safety of DRT recipients and DRT children—and avoid the need to address specific bioethical issues while deferring to and benefiting from thoughtful solutions devised by professionals, which usually reflect careful balances struck through a significant investment of resources and expertise.

5. Cost Considerations

Arguably, regulation of the genetic aspects of DRT would impose such costly requirements that it might make DRT more, and possibly even prohibitively, expensive for some potential DRT recipients.[319] This might not only cause many DRT institutions to go out of business[320] but also may encourage many potential consumers who would no longer be able to afford to pay for DRT to seek other, less strictly regulated sources of DRT (e.g., abroad) or even forego the option of using DRT altogether.

Although there is no current estimate of the costs of applying the genetic screening and testing schemes recommended by the ASRM and AATB, it is possible to estimate the cost of such screening and testing. First, all of the states fund programs for the genetic testing of newborns for various genetic conditions that, with proper care, could be treated if diagnosed at an early stage.[321] New York State, for example, runs a Newborn Screening Program that performs over eleven million tests annually and tests

[318] Choosing this course of action may give rise to constitutional issues having to do with the delegation of FDA power to private entities. *See infra* note 336.

[319] Requiring the routine testing of every potential DRT donor for various conditions could result in a considerable increase in the costs involved in the processing of DRT.

[320] The most costly elements of regulation of the genetic aspects of DRT would probably be the heightened screening and testing requirements. There are a few other possible costs involved in such regulation, e.g., costs involved in inspection and complying with inspection requirements, costs involved in appropriate recordkeeping, costs of communicating adverse events, etc. Yet, it appears that such costs would be very low, if not nominal. For example, the FDA estimated the costs related to being subject to periodic inspections at approximately $768 per establishment per inspection. *See* 69 Fed. Reg. 68663 (FDA Nov. 24, 2004).

[321] *See* Nat'l Newborn Screening & Genetic Resource Ctr., State Map Page, http://genes-r-us.uthscsa.edu/resources/consumer/statemap.htm (last visited May 9, 2010). For a list of genetic conditions for which newborns are tested, see the National Newborn Screening Status Report (July 7, 2009), *available at* http://genes-r-us.uthscsa.edu/nbsdisorders.pdf. The existence of such genetic testing programs funded by all of the states also seems to reinforce the arguments in favor of genetic testing of DRT donors. Specifically, if it is justifiable to conduct genetic testing *after* a child is born, then it is even *more justified* to screen beforehand, i.e. prior to the actual manifestation of the genetic risk which arguably occurs at the moment of conception. In other words, genetic testing of DRT donors is a true preventative measure while newborn screening could at best guarantee appropriate treatment of an existing and irreversible genetic condition.

over a quarter of a million newborns a year for more than forty genetic conditions as well as HIV and congenital hypothyroidism.[322] The annual cost of all of the testing done by the New York Program is $11.9 million.[323] Second, numerous private laboratories offer various genetic testing products and services: for as little as $25, parents and physicians may acquire kits or sets of genetic tests.[324] For instance, the University of Colorado offers a kit that tests for twenty disorders recommended by the American College of Medical Genetics (ACMG) for $25;[325] another private laboratory offers testing for about fifty genetic conditions for $199.[326] Third, some laboratories also offer *prenatal* genetic screening. For example, for a price of $1,850, one private laboratory offers genetic testing of fetuses based on DNA chip technology that evaluates over 2,100 DNA sequences associated with over 100 genetic syndromes.[327] These figures suggest that the average cost of genetic testing for a given genetic mutation could be estimated at about $1-3, depending on the technology used. Thus, under a rough estimate, it is not unreasonable to expect that the genetic testing of potential DRT donors in accordance with professional guidelines would cost several hundreds of dollars per donor.[328]

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[322] *See* Wadsworth Center Newborn Screening Program, http://www.wadsworth.org/newborn/index.htm (last visited May 9, 2010).

[323] Electronic mail letter from Deborah Rodriguez, Newborn Information Coordinator, Wadsworth Center, to author (July 21, 2009) (on file with author). Based on these figures it is possible to roughly calculate the cost of testing at about $47.6 per newborn and $1.08 per test.

[324] *See, e.g.*, Save Babies Through Screening Foundation, A Parent's Guide to Newborn Screening 2 (May 2005), *available at* http://www.savebabies.org/library/HandoutAParentsGuidetoNBS.pdf.

[325] *See* Univ. of Colorado Health Sciences Ctr., Expanded Newborn Screening Program, http://www.uchsc.edu/newbornscreening/index.htm (last visited May 9, 2010).

[326] *See* PerkinElmer Genetics, Order StepOne®, http://www.perkinelmergenetics.com/OrderScreeningPacket.htm (last visited May 9, 2010). For a list of the genetic conditions tested for, see http://www.perkinelmergenetics.com/DisordersScreened.htm (last visited Jun. 17, 2010).

[327] *See* The President's Council on Bioethics, The Changing Moral Focus of Newborn Screening 80 (2008) [hereinafter *Changing Moral Focus*] *available at* http://bioethics.georgetown.edu/pcbe/reports/newborn_screening/index.html. *See also* Signature Genomic Laboratories, Signature PrenatalChip®, http://www.signaturegenomics.com/prenatalchip.html (last visited May 9, 2010).

[328] This estimate is based on the assumption that professional guidelines would require testing for a few hundred known genetic mutations and that the cost of testing for each individual mutation is, as mentioned above $1-3. It is probably also safe to assume that, in the future, as testing technologies advance and become more commonplace, genetic testing of DRT donors would become cheaper. It is anticipated that by 2014, the sequencing of an entire human genome would cost only about $1,000. *See Changing Moral Focus*, *supra* note 327, at 52. Analysis of an entire individual's genome would make it possible to analyze the genome of such individual for

It is important to note that not all potential DRT donors should be subject to such extensive testing; only the most promising candidates who make it through vigorous initial screening based on a physical examination and thorough questioning would merit such expenditure. Thus, even if we assume that such extensive genetic testing of potential DRT donors would impose additional costs on DRT institutions and—by way of roll over—recipients, it is expected that such additional costs and expenditure would not make DRT significantly more costly or less accessible than it already is.[329]

Moreover, if one is to accept the picture of institutional compliance with professional guidelines among DRT institutions portrayed by the FDA, it may well be that regulating the genetic aspects of DRT would not substantially affect the DRT industry. According to the FDA, the twenty largest DRT institutions that account for 95% of the DRT industry already screen and test potential DRT donors in accordance with professional guidelines.[330] Thus, presumably, regulations requiring compliance with professional standards as they pertain to genetic aspects of DRT would not impose additional costs on most DRT transactions. Rather, such regulations would only affect DRT institutions that do not already follow professional guidelines and recipients purchasing DRT from such institutions.[331]

Another aspect of the costs involved in regulating the genetic aspects of DRT is the costs that such regulation would impose on the FDA itself. Agencies' ability and willingness to regulate are closely linked to the financial burden that the regulation would impose on their limited resources. Yet, the cost of regulation to agencies often tends to be

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all the genetic mutations known without having to resort to costly and cumbersome specific testing for specific genetic conditions, as is done now.

[329] With each sperm sample sold at a few hundreds of dollars and under the assumption that each sperm donor would be the source of at least dozens of samples, it may be assumed that the additional cost of extensive genetic testing would not significantly contribute to the cost of sperm. The cost of egg donations, on the other hand, is already so high, that arguably, the additional cost of proper genetic testing of potential donors is not expected to change it significantly.

Notably, the area of DRT raises numerous issues related to the accessibility of DRT and related services to different income groups. DRT in general and egg donations in particular are expensive propositions and, as such, are more available to individuals and families with higher income and/or better medical insurance coverage that includes DRT and related services. Yet, given the above conclusion that proper genetic screening and testing of DRT is not expected to make DRT and related services significantly more expensive, it is also not expected that it would push DRT and related services further beyond the reach of lower income groups.

[330] According to the FDA, those institutions that were in compliance with AATB standards would have felt minimal impact as a result of the FDA Final Donor Eligibility Rule, while the remaining 90 smaller institutions examined, which accounted for 5% of the industry, "[would] be more significantly affected." *See FDA Final Donor Eligibility Rule*, *supra* note 24, at 29819.

[331] Regulatory requirement of genetic screening and testing that conforms to professional guidelines would therefore prevent a possible market failure where such non-compliant DRT institutions externalize the costs involved in appropriate screening and testing to DRT recipients and DRT children in the form of heightened risk.

overlooked.[332] However, given that the FDA is already involved in the regulation of DRT and inspection of DRT institutions, applying the FDA's Human Tissue Regulations' framework to genetic aspects of DRT should not create a substantial additional financial burden for the FDA.[333]

Finally, in performing the cost-benefit analysis in the context of genetic screening and testing of DRT, it is imperative to consider the possible long-term benefits that mandatory testing requirements may have on future healthcare expenditure on a societal scale.

In conclusion, the regulation of the genetic aspects of DRT is likely to raise conceptual and bioethical issues and impose at least some additional costs on DRT institutions and recipients. Yet, these obstacles are not unique to this area of regulation and should not deter the FDA. Furthermore, as demonstrated above, FDA regulation of the area of genetic aspects of DRT could rely on solid legislative and constitutional grounds. Accordingly, such regulation is not only desirable but also feasible.

C. Some Recommendations for FDA Regulation of the Genetic Aspects of Donated Reproductive Tissue

As mentioned earlier, this article does not purport to suggest exactly what FDA regulation of the genetic aspects of DRT should look like and what it should include; these issues are best left to the expertise of the FDA and DRT professionals. However, it is possible to enumerate key elements that such regulation should include.

Perhaps the most important purpose of regulation of the genetic aspects of DRT should be ensuring the health and safety of DRT children rather than just those of DRT recipients and donors.[334] Just as in the context of communicable diseases, the regulation should be based on an understanding that the mere fact that a disease might occur in the general population—which does not have its reproductive cells and tissues screened and

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[332] It is not unfathomable that one of the reasons that the FDA has not regulated the genetic aspects of DRT is simply a lack of resources. For example, according to an FDA official, lack of manpower and resources to regulate sperm banks was the underlying reason for allowing self-regulation in the area of DRT. *See Human Tissues and Organs*, *supra* note 104, at 23-24 ("[S]ince basically the entire scientific staff and other personnel devoted to sperm banking was myself about half-time, and because the American Association of Tissue Banks had been formed at the same time, we decided that we would maintain a liaison with AATB and allow voluntary standards to be used in the area of semen banking."). According to Merrill, the FDA appears to "confront more than its share of novel challenges" and thus may have to decide how to distribute its limited resources more frequently than other agencies. *See* Merrill, *supra* note 23, at 2.

[333] *See* Merrill, *supra* note 23, at 80 (characterizing the FDA's Human Tissue Regulations as striking "a reasonable balance between public health protection, on the one hand, and the constraints of its own budget and tissue bank resources on the other").

[334] *See* Council on Bioethics Report, *supra* note 100, at 217.

tested—does not justify not taking measures to avoid it in DRT children.[335] Thus, in regulating the genetic aspects of DRT, the FDA should strive to ensure that DRT institutions take all reasonable measures to prevent and avoid the occurrence of genetic diseases in DRT children.

In promulgating regulations addressing the genetic aspects of DRT, especially in the context of screening and testing requirements, the FDA should consider the recommendations and guidelines of professional organizations.[336] As explained above, the FDA could greatly benefit from the accumulated knowledge, experience and thinking in professional organizations and from solutions they have come up with through years of dealing with the issues that are going to become the focus of regulation. By relying on professional standards, the FDA would not only ensure that its regulatory scheme is always reasonably up-to-date and relevant but also preserve the financial and political

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[335] *See* Ziporyn, *supra* note 314, at 14 (quoting Lori Andrews' argument that the position that there is no need to test DRT donors for medical and genetic defects because "normal" couples do not always undergo genetic testing before conception is "unscientific and unethical"); *see also supra* Part II.E.

[336] *See* Council on Bioethics Report, *supra* note 100, at 217 (recognizing that professional oversight has traditionally been the principal mechanism of regulation for the practice of medicine). Notably, coordination with the recommendations and guidelines of professional organizations coincides with the FDA's own preferences with relation to the regulation of human tissue. *See* Zoon Statement, *supra* note 59, at 105 ("In the future . . . FDA intends to use various venues to continue our dialogue with industry organizations such as the AATB . . . [and] the American Society for Reproductive Medicine (ASRM)/Society or [*sic*] Assisted Reproductive Technology (SART).").

Importantly, deferment to and reliance on standards set by professional organizations raises the issue of "privatization as delegation." *See generally* Gillian Metzger, *Privatization as Delegation*, 103 Col. L. Rev. 1367 (2003). According to Metzger, when private entities "wield substantial power over government programs and their participants," the government effectively delegates power to such private entities in a manner that might undermine "constitutional accountability." *Id.* at 1376-77. Metzger argues that for such delegation of government power to private entities to be constitutional it must be sufficiently constrained, e.g., by ensuring government supervision over the private entities' decision-making by creating a complaint or appeal system through which affected third-parties could challenge specific decisions, policies and procedures of the private entities that affect them. *Id.* at 1471-72. Arguably, per Metzger, FDA reliance on and deferment to professional guidelines (such as those of the AATB and ASRM) in the context of regulation of genetic aspects of DRT could constitute a delegation of government power to private entities because it may effectively enable such entities to act on behalf of the government in formulating professional standards of practice for third parties, i.e. DRT institutions. *Id.* at 1462. Accordingly, in order to ensure that such reliance on professional guidelines is endowed with sufficient constitutional accountability, the FDA could include in the regulations addressing the genetic aspects of DRT a mechanism that would enable DRT institutions affected by professional guidelines to challenge the inclusion of a particular guideline or standard in the regulations. Notably, such a mechanism, the Tissue Reference Group (TRG) has already been established in the Human Tissue Regulations to resolve disputes arising from implementation of these regulations. *See* 66 Fed. Reg. 5451 (FDA Jan. 19, 2001) (comment 7).

resources that it would otherwise need to expend on tackling complicated bioethical issues.[337]

As for the screening and testing of potential donors, the FDA could rely on a protocol similar to the one it already employs in its Human Tissue Regulations, which requires, among other things, the collection of relevant medical records, including a donor's medical history and physical examination report.[338] The FDA should also require the collection of as detailed a family medical history as possible and its use to identify risk factors that may prompt further specific testing beyond that which would be required from every donor or from donors belonging to particular ethnic groups.[339]

The FDA regulations should set up a national record-keeping system that includes information on all donors nationwide. The database should assist in keeping track of the number of DRT children born from each donor's gametes and include the medical history of donors, their contact information and adverse events in DRT children as they pertain to genetic conditions. Such a database could assist in avoiding procreation between blood-related DRT children.[340] Even more importantly, it would ensure that DRT suspected of causing adverse effects is not used again and that the donor is not permitted to donate any more DRT anywhere in the country before the source of the genetic problem is verified.[341]

Finally, as recommended by the GAO, the FDA regulations should require that prospective DRT recipients be made aware and receive an explanation of relevant genetic

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[337] *See supra* Part IV.B.4.

[338] *See FDA's Guidance for Industry Announcement*, *supra* note 50, at 12-14.

[339] Identifying risk factors and assessing them are also required by the FDA with respect to communicable diseases. *See id.* at 15.

[340] *See* Cohen, *supra* note 23, at 363.

[341] Such a database would have helped in preventing cases such as that of the Michigan donor whose sperm was used for conceiving 11 children, five of whom were later found to have an extremely rare type of leukemia. *See* Denise Grady, *Sperm Donor Seen as Source of Disease in 5 Children*, N.Y. Times May 19, 2006, at A16. According to experts, this particular genetic defect, which is passed along by an autosomal dominant gene, would probably not have been picked up as part of a regular screening and testing protocol. *Id*. However, a database would have enabled reporting of the discovery of the first case of leukemia in the donor's progeny, thereby not only alerting other recipients (through their DRT institutions) regarding possible risks to their DRT children, but also ensuring that DRT institutions did not further use the compromised donor's DRT. *Cf.* Daar & Brzyski, *supra* note 15, at 1703 (calling for the institution of a national gamete donor registry to avoid such cases as the recently reported transmission of potentially lethal heart defect by a sperm donor to 9 out of 24 children conceived using his sperm, including the donor's own child); Maron et al., *supra* note 5, at 1681-83 (reporting a case where a donor transmitted a unique genetic condition causing a lethal heart defect to at least 9 out of 24 children conceived from his sperm, including one of his own two sons, recommending assembling and sharing clinical data for all individuals born from the same donor's DRT and emphasizing the importance of notifying gamete donors, recipients, and other affected parties about the occurrence of genetic diseases).

data of potential donors in accordance with existing informed consent standards. DRT recipients should also be advised about the types of genetic testing, if any, performed on any particular DRT and the potential risks of genetic diseases embodied in that particular DRT as compared to the level of risk in the general population.[342] In this manner, the FDA regulations would not only ensure that DRT recipients only use genetically compromised DRT *after* making an informed choice but also that they are made aware of the possible monetary and legal ramifications of such a choice.[343]

V. CONCLUSION

Three decades have passed since Curie-Cohen published the results of a survey revealing significant deficiencies in the practices of genetic screening and testing of sperm and yet, children born from donated reproductive tissue, whether sperm or ova, are still exposed to unnecessarily high levels of genetic risk. Despite ongoing efforts by professional organizations, the extent of self-regulation of the donated reproductive tissue industry is unclear and its effectiveness is questionable. Accompanied by inconsistent state regulation of the reproductive tissue industry and non-deterring relief afforded by

[342] Enforcing such a requirement would put DRT recipients in the place of other couples who undergo prenatal medical screening and testing for genetic diseases prevalent in their ethnic group and would enable them to make their own decision whether they wish to use the DRT at the risk of passing an identified genetic condition to their DRT child, forego the use of the particular DRT or utilize pre-implantation genetic diagnosis (PGD) to test their embryo. *See* Robertson, *supra* note 222, at 456-57 (describing the different possible choices prospective parents have); *see also GAO 1997 Report*, *supra* note 182, at 31 ("We recommend that the Secretary . . . direct FDA to take action in several areas to improve the safety of [DRT] and to increase FDA's ability to regulate tissue facility activities . . . FDA should also add to its oversight plans provisions that would require . . . disclosure of genetic tests that have been performed on donated reproductive tissue."). Interestingly, in its response to the *GAO 1997 Report*, the FDA agreed with these requirements. *See* Letter from Diane E. Thompson, Associate Commissioner for Legislative Affairs, DHHS, to Bernice Steinhardt, Director, HEHS, GAO (Oct. 23, 1997) ("In general, FDA agrees that recipients of tissue should know, through appropriate labeling of the tissue, the results of testing performed. Ethical, scientific and regulatory issues regarding genetic tests are currently under discussion within the Department of Health and Human Services in connection with the final report of the Task Force on Genetic Testing."). Notably, the report of the Task Force on Genetic Testing mentioned in the FDA's response does not mention the genetic screening or testing of DRT. *See* Final Report of the Task Force on Genetic Testing (Neil A. Holtzman and Michael S. Watson eds. 1997), available at http://www.genome.gov/10001733.

[343] Some of the ramifications of choosing to use genetically-compromised DRT could include, for example, an implied waiver of possible claims against professionals involved in the preparation, distribution and use of the DRT. Requiring disclosure and informed consent with respect to genetic conditions that might be passed along by particular DRT would also provide adequate response to any concerns regarding the reproductive freedom of recipients. *See* Robertson, *supra* note 222, at 457 ("[W]anting information about the genetic makeup of prospective offspring and then acting on it fits squarely within conventional understandings of procreative liberty.").

the courts in matters involving children born from genetically defective donated reproductive tissue, the genetic safety of individuals born from such tissue is a cause for concern.

This Article described only a handful of publicized tragedies that befell children born from genetically defective reproductive tissue and their families. There is no way of knowing how many more such cases actually occurred, and yet, without a fundamental change in the regulation of donated reproductive tissue to address genetic risks involved in the use of such tissue, more tragedies are very likely to occur. As we accumulate knowledge about human genetics and develop more diagnostic means to test for and possibly prevent the transmission of genetic diseases through donated reproductive tissue, the need for regulation will only become more accentuated. Furthermore, without appropriate regulation, the growing demand for donated reproductive tissue will further increase the genetic risks involved in the use of donated reproductive tissue.

As recognized by the FDA, non-involvement of the federal government in the area of donated reproductive tissue jeopardizes the safety of the public. Thus, at least as a matter of public health policy, the FDA's distinction between communicable diseases and genetic diseases in the context of donated reproductive tissue cannot be justified. The Public Health Service Act endows the FDA with ample authority to regulate all aspects of donated reproductive tissue and provides it with all the tools necessary to ensure the safety of recipients of such tissue and their children. Indeed, the regulation of genetic aspects of donated reproductive tissue would undoubtedly raise difficulties resulting, for example, from bioethical issues involved in this area and the need to carefully balance costs against potential benefits. However, overcoming such difficulties is well within the capabilities of the FDA.

Furthermore, regulations addressing the genetic risks involved in the use of donated reproductive tissue could offer "a unique opportunity to reduce or even eliminate genetic risks,"[344] which would benefit generations to come. Unfortunately, it appears that the regulation of genetic aspects of donated reproductive tissue is not on the FDA's "to do list."[345] Hopefully, renewed interest in the regulation of sectors that are not sufficiently self-regulated will prompt the FDA to supplement its current regulation so as to also address the genetic aspects of donated reproductive tissue.

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[344] *See* Conrad, *supra* note 10, at 298.

[345] In its June 2007 report, the FDA's Human Tissue Task Force listed numerous "recommendations that may be implemented with additional planning and/or resources," which would improve the breadth and depth of the FDA's Human Tissue Regulations. However, these recommendations did not include addressing genetic aspects of DRT. *See* HTTF Report, *supra* note 67, at 7.