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The Birth of a Tort Liability Theory? Legal Remedies for Families of Children Who Inherit Genetic Diseases from Gamete Donors

INTRODUCTION

The advancement of assisted reproductive technology (ART) now means that for many would-be parents it takes more than just two to make a baby. But as ART practices such as sperm donation and in vitro fertilization become more available and affordable for individuals seeking to have a child, the risks of such practices are also becoming more evident. One of these risks is the risk of children conceived through gamete donations inheriting a genetic disease from a donor.

Instances of this happening are no longer just anecdotal. In 2009, the *Journal of the American Medical Association* (JAMA) reported on an outwardly healthy sperm donor with no known infectious or genetic diseases who transmitted the genetic heart disease hypertrophic cardiomyopathy to nine of the twenty-two children conceived using his sperm.¹ In the court cases discussed in this paper, children inherited autosomal dominant polycystic kidney disease², cystic fibrosis³, and Fragile X syndrome⁴ from their sperm or egg donors. A recent news article described the legal battle between a gestational surrogate and the recipient couple over the severely disabled child she was

¹ Barry J. Maron, M.D. et al, *Implications of Hypertrophic Cardiomyopathy Transmitted by Sperm Donation*, 302 JAMA No. 15, 1681 (2009).

² Johnson v. Super. Ct. of Los Angeles, 95 Cal. Rptr.2d 864, 868 (Cal. Dist. Ct. App. 2000), *review denied* 124 Cal. Rptr.2d 650 (Cal. Dist. Ct. App. 2002).

³ Paretta v. Med. Offices for Human Reproduction, 760 N.Y.S.2d 639, 641-42 (N.Y. Sup. Ct. 2003).

⁴ Donovan v. Idant Labs., 625 F. Supp.2d 256, 263 (E.D. Pa. 2009), *aff'd in D.D. v. Id..ant Labs.*, 374 Fed.Appx. 319, 2010 WL 1257705 (C.A.3 (Pa.) 2010).

carrying, after the surrogate learned one month before the child's birth that the baby was conceived using an anonymous egg donor, rather than the couple's eggs and semen as she had been led to believe⁵.

Although the legal and medical communities have voiced concerns about the risk of inheriting genetic diseases from gamete donors and the need for state and federal regulation of ART practitioners, few prescriptive measures have been put in place.⁶ As evidenced in the cases below, many parents of children conceived using a gamete donor only learn of their children's inherited genetic illness after the child is born. Those families faced with the challenge of a child with a serious genetic disease or disorder need to be able to pursue post-birth remedies in court.

This paper limits itself to discussing legal claims where a child has inherited a genetic disease or disorder from a sperm or egg donor. Section I provides background information on the current state of ART procedures and the genetic screening and testing options currently available. Section II discusses oversight of gamete testing and screening standards and other preventative measures at the federal and state levels of government and also in the private sector. Section III examines the claims in common that have been brought by parents and children in state and federal courts against ART practitioners, gamete banks, and gamete donors. It discusses the strengths and weaknesses of the common threads of negligence theories in these cases. Since there is very little court precedent on this issue, Section IV of this paper proposes how best to build a legal action

⁵ Elizabeth Cohen, *Surrogate Offered \$10,000 to Abort Baby*, CNN (March 6, 2013, 2:58 PM), http://www.cnn.com/2013/03/04/health/surrogacy-kelley-legal-battle/index.html?hpt=hp_c1.

⁶ Lisa M. Luetkemeyer, *Who's Guarding the Henhouse and What Are They Doing with Eggs (and Sperm)? A Call for Increased Regulation of Gamete Donation and Long-Term Tracking of Donor Gametes*, 3 ST. LOUIS U. J. HEALTH L. & POL'Y 397, 424 (2010), Suriya E.P. Jayanti, Comment, *Guarantors of our Genes: Are Egg Donors Liable for Latent Genetic Disease?* 58 AM. U. L. REV. 405, 411 (2008), Yaniv Heled, Article, *The Regulation of Genetic Aspects of Donated Reproductive Tissue – The Need for Federal Regulation*, 11 COLUM. SCI. & TECH. L. REV. 243, 276 (2010).

that can allow families to recover and help courts understand this unique but growing problem.

I. A Primer on Assisted Reproduction Using Gamete Donors

A. ART Procedures Using Gamete Donors

A couple willing but unable to conceive a child can use either donated semen from a male donor or donated eggs (oocytes) from a female donor, or both, in order to conceive a child.⁷ In some instances, a couple may use both a third-party sperm donor and egg donor in a process called embryo donation.⁸ The donors can be anonymous or directed (known to the recipient couple).⁹

A number of other parties are involved in assisted reproduction besides merely the donors and the recipient couple. A physician who deals specifically with infertility treatments and assisted reproduction is referred to as a reproductive endocrinologist.¹⁰ There is also a team of medical and laboratory technicians, the cryopreservation or storage banks for the donated sperm or eggs, and often separate programs who screen potential gamete donors.¹¹ A couple or individual can go through a fertility clinic or specializing physician for donated gametes, go directly to a tissue bank or donor agency, or deal directly with a donor (particularly in the case of donated eggs); some assisted

⁷ Association for Reproductive Medicine, *Assisted Reproductive Technologies: A Guide for Patients* 14 (2011). Available at http://www.reproductivefacts.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/ART.pdf.

⁸ Association for Reproductive Medicine, *Third Party Reproduction: A Guide for Patients* 12-13 (2012). Available at http://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/thirdparty.pdf.

⁹ *Id.* at 4, 10.

¹⁰ *What is an Infertility Specialist?*, Society for Assisted Reproductive Technology, available at http://www.sart.org/SART_What_Is_An_Infertility_Specialist/ (last visited March 28, 2013).

¹¹ Resolve: The National Infertility Association, *Questions to Ask Series: About Donor Sperm Insemination Programs and Sperm Banks* (#8) 1. Available at http://familybuilding.resolve.org/site/DocServer/Donor_Sperm_Insemination_Programs_And_Sperm_Banks.pdf?docID.=446 (last visited May 9, 2013).

reproduction clinics provide these services in a “all-inclusive” setting.¹² Whether these various players are grouped under one entity or are operating as separate organizations could be very important for legal liability, as will be discussed later.

To donate her eggs, a woman undergoes a medical procedure to stimulate ovulation.¹³ Her eggs are then “harvested” via a process called transvaginal ultrasound aspiration.¹⁴ By contrast, a man simply ejaculates in order to donate a sample of semen.¹⁵ While sperm and resulting embryos can be cryopreserved for storage, the cryopreservation of eggs has not proved as viable.¹⁶ There are a variety of ways that the donated gametes are then used to conceive a child.

In the case of in vitro fertilization, the donor eggs (or the eggs of one of the recipient couple partners) are fertilized with donor sperm (or the sperm of one of the recipient couple partners) in a laboratory.¹⁷ The resulting embryo is then transferred to either the uterus of the female partner of the recipient couple or to a woman serving as the surrogate “mother” (called a gestational surrogate).¹⁸

Alternatively, the female partner of a recipient couple can be directly inseminated with donated semen.¹⁹ In the case of “traditional” surrogacy, a surrogate mother uses her own eggs and is directly inseminated with the sperm of the male partner of the recipient couple.²⁰

¹² Luetkemeyer, *supra* note 6, at 403; *see also* for example, Reproductive Medicine Associates of New Jersey, <http://www.rmanj.com/360-of-fertility-care/3rd-party-reproduction/>, accessed on March 21, 2013.

¹³ *Third Party Reproduction*, *supra* note 6 at 6-7.

¹⁴ *Id.* at 7.

¹⁵ *Id.* at 10.

¹⁶ *Id.* at 17.

¹⁷ *Id.* at 7, 18.

¹⁸ *Id.* at 14.

¹⁹ *Id.* at 11-12.

²⁰ *Id.* at 13-14.

Assisted reproduction using gamete donors is becoming a common practice in the United States. In 1988, the Congressional Office of Technology Assessment (now defunct) released a study that indicated there were over 30,000 births a year where artificial insemination had been used.²¹ Ten years later, the Institute for Science, Law and Technology (ISLAT) Working Group estimated the number of births resulting from either sperm or egg donation at 60,000.²² The Centers for Disease Control and Prevention (CDC), which annually publishes its ART Success Rates Report, stated that as of 2010, 147,260 treatment cycles were started at 443 reporting ART clinics and 61,546 births resulted from those cycles.²³ These treatment cycles involved only ART procedures which handled both sperm and eggs and did not include ART techniques such as artificial insemination or ovulation inducement.²⁴ Furthermore, the number of treatment cycles performed at fertility clinics or ART facilities had increased from the 107,587 reported in 2001, and the number of children born after successful ART cycles had also increased dramatically from 40,687 in 2001.²⁵ The CDC's preliminary 2011 data showed that 163,038 ART cycles were performed at 451 reporting clinics, resulting in 61,610 infants.²⁶ The 2011 preliminary numbers show that over one percent of infants born in the United States are now conceived using ART.²⁷

²¹ Heled, *supra* note 6 at 246, *citing* Office of Technology Assessment, 1988 Survey 3.

²² *Id.* at 247, *citing* ISLAT Working Group, *ART into Science: Regulation of Fertility Techniques*, 281 *Science* 651, 651-2 (1998).

²³ Centers for Disease Control and Prevention, American Society for Reproductive Medicine, Society for Assisted Reproductive Technology, *2010 Assisted Reproductive Technology Fertility Clinic Success Rates Report* 21 (2012). Available at <http://www.cdc.gov/art/ART2010/index.htm> and http://www.cdc.gov/art/ART2010/PDFs/01_ART_2010_Clinic_Report-FM.pdf.

²⁴ *What is Assisted Reproductive Technology?*, Centers for Disease Control and Prevention (last updated April 4, 2013), <http://www.cdc.gov/art/>.

²⁵ *Section 5: ART Trends 2001-2010*, Centers for Disease Control and Prevention (last updated February 4, 2013), <http://www.cdc.gov/art/ART2010/section5.htm>.

²⁶ Centers for Disease Control and Prevention, *supra* note 24.

²⁷ *Id.*

In short, the practice of ART in the United States seems to be thriving, but as described in the next section, practices of genetic testing and screening of gamete donors do not seem to be developing in proportion to the demand for ART.

B. Current Genetic Screening and Testing Procedures, and Who Is Using Them

In the field of ART, several terms are used to describe the process of analyzing a gamete donor for genetic disease prior to using that donor's tissue in an ART procedure. Practitioners make reference to "genetic counseling," "genetic screening" and "genetic testing." These terms sometimes are used interchangeably but can be roughly categorized as three methods and are all practiced to some degree in the ART industry. However, the data suggests that genetic screening and testing practices are not widely practiced at all among ART practitioners *prior to actually performing an ART cycle*, and current genetic practices focus mainly on screening and testing of fetuses and newborns.

"Genetic counseling" is an umbrella term that generally refers to the communications and advice that a genetic specialist gives to a family.²⁸ In the context of ART, genetic counseling can encompass not only the subjects of a genetic disease but also paternity and maternity issues but also fertility issues and potential issues with carrying a pregnancy to term.²⁹

However, "Genetic counseling does not equal genetic testing."³⁰ According to the National Human Genome Research Institute, "genetic testing" is "the use of a laboratory

²⁸ *Talking Glossary of Genetic Terms: Genetic Counseling*, The National Human Genome Research Institute, available at <http://www.genome.gov/Glossary/index.cfm?Id.=79> (last accessed May 9, 2013).

²⁹ Marie Schuetzle, MS CGC, *Genetic Counseling: An Important Part of Your Care*, RESOLVE, FOR THE JOURNEY AND BEYOND (Resolve: The National Infertility Association, McLean, VA), Winter 2012. Available at <http://www.resolve.org/family-building-options/donor-options/genetic-counseling-an-important-part-of-your-care.html> (last visited May 9, 2013).

³⁰ *Id.*

test to look for genetic variations associated with a disease.”³¹ In other words, an ART couple seeking genetic counseling prior to their procedure could theoretically never be subject to genetic testing if the counselor didn’t deem it necessary.³²

The Food and Drug Administration (FDA), a U.S. government agency which regulates some aspects of human tissue donations and tissue banks,³³ provides a slightly more specific definition of “testing” of human reproductive tissue, although its definition is not limited to testing for genetic diseases. The FDA defines “testing” as using an FDA-approved laboratory test (somewhat misleadingly referred to as a “donor screening test”) to check the tissue for disease.³⁴

As of 2003, it was estimated that there were approximately 900 laboratory genetic tests on the market;³⁵ that number today has surely skyrocketed, and since the FDA is not required to monitor all classes of genetic tests, including those that are processed by labs “in house,”³⁶ the number of tests approved by the FDA is not reflective of the number of genetic tests available to healthcare providers, researchers, and consumers.

“Genetic screening” is a second common technique that falls under the umbrella of genetic counseling, but is arguably also the hardest to define. For instance, just as the FDA refers to a genetic test as a “donor screening test,”³⁷ the National Human Genome Research Institute defines “genetic screening” as “ the process of testing a population for a genetic disease in order to identify a subgroup of people that either have the disease or

³¹ *Talking Glossary of Genetic Terms: Genetic Testing*, The National Human Genome Research Institute. Available at <http://www.genome.gov/Glossary/index.cfm?Id.=88> (last accessed May 9, 2013).

³² Schuetzle, *supra* note 29.

³³ 21 CFR 1271.1

³⁴ 21 CFR 1271.80

³⁵ Francis S. Collins, M.D., Ph.D., *A Brief Primer on Genetic Testing*, presented January 24, 2003. Available at <http://www.genome.gov/10506784> (last reviewed April 30, 2013).

³⁶ *An Overview of Genetic Testing*, The National Human Genome Research Institute. Available at <http://www.genome.gov/10002335> (last updated January 10, 2013).

³⁷ *Supra* note 34.

the potential to pass it on to their offspring.”³⁸ The American Association of Tissue Banks further complicates the meaning by referring to both “donor screening tests” and “diagnostic tests” as methods of “screening” human tissue.³⁹ However, in the instance of analyzing human tissue for disease, the FDA defines “screening” primarily as reviewing a donor’s medical records for a history or indication of disease.⁴⁰ This distinction between “screening” through interviews and medical records and “testing” using a laboratory test is reflected in state statutes such as New York’s, which has requirements of screening for some diseases and testing for others.⁴¹

A specific genetic testing practice performed by ART practitioners is called preimplantation genetic diagnosis, or PGD. PGD is the testing of embryos created through in vitro fertilization for genetic abnormalities; the practitioner then transfers an embryo that tests negative for genetic diseases to the recipient mother.⁴² A related technique is preimplantation screening (PGS); while PGD is used to diagnose a specific patient’s embryos, usually due to other indications of that patient⁴³, PGS is used to look at for a specific set of genetic problems across multiple patients in an effort to reduce fertility and pregnancy issues.⁴⁴ PGD is an increasingly common practice, but it occurs only after an embryo is created and does not test the donor *prior* to any ART procedure.⁴⁵ It is also commonly implemented on the embryos created using the recipient couple’s

³⁸ *Talking Glossary of Genetic Terms: Genetic Screening*, The National Human Genome Research Institute. Available at <http://www.genome.gov/Glossary/index.cfm?Id.=87> (last visited May 9, 2013).

³⁹ American Association of Tissue Banks, *Guld..ance Document: Current Good Tissue Practice*, 16 (No. 3, June 27, 2006).

⁴⁰ 21 CFR 1271.75

⁴¹ N.Y. Comp. Codes R. & Regs. Tit. 10, § 52-8.5(b)(2) and N.Y. Comp. Codes R. & Regs. Tit. 10, § 52-8.6

⁴² ElpId..a Fragouli, *Preimplantation genetic diagnosis: present and future*, 24 *Assist. Reprod. Genet.* 201 (2007).

⁴³ *Id.* at 203.

⁴⁴ *Id.* at 204.

⁴⁵ *Id.* at 201.

own sperm and eggs as opposed to an embryo created using a donor's sperm and eggs.⁴⁶ Therefore it is not a genetic testing method targeted at gamete donors. However, it is helpful to understand that multiple genetic testing techniques are employed by ART practitioners prior to pregnancy.

So, given the variety of testing methods available to ART practitioners, how often are they actually performed? ART practitioners seem to have broad discretion as to whether, when and how to test egg or sperm donors for genetic diseases. The current practice is “best described as inconsistent” due to the lack of external oversight.⁴⁷ In 2010, ARSM published a survey of 26 sperm banks to evaluate their genetic testing practices. The results showed that while the banks did screen for cystic fibrosis and perform chromosome and hemoglobin evaluations and screened for a history of Tay-Sachs disease in donors of Ashkenazi Jewish descent, “The genetic testing performed on sperm donors varies significantly at sperm banks across the United States.”⁴⁸ The study also found that different facilities used different types of tests.⁴⁹ In 2013, an ASRM study concluded based on a mere thirteen responses that there were comparable inconsistencies in how semen donors were screened for genetic disorders, how they were informed and whether they were given informed consent for such screening.⁵⁰ By contrast, an ASRM study published in 2008 concluded based on 186 responses from reporting clinics that a

⁴⁶ Resolve: The National Infertility Association, Questions to Ask Series: *Questions to Ask If You Are Considering Preimplantation Genetic Diagnosis (#19B) 1*. Available at http://familybuilding.resolve.org/site/DocServer/If_You_Are_Considering_Preimplantation_Genetic_Diagnosis.pdf?docID.=453 (last visited May 9, 2013).

⁴⁷ Judith F. Daar, JD, Robert G. Brzyski, MD, PhD, *Genetic Screening of Sperm and Oocyte Donors: Ethical and Policy Implications*, 302 JAMA No. 15, 1702, 1703 (2009).

⁴⁸ Charles A. Sims, M.D., et al., *Genetic testing of sperm donors: survey of current practices*, 94 Fertil. Steril. 126 (2010). Abstract only available at [http://www.fertstert.org/article/S0015-0282\(09\)00263-5/abstract](http://www.fertstert.org/article/S0015-0282(09)00263-5/abstract) (published online April 1, 2009).

⁴⁹ Id.

⁵⁰ Lauren Isley, M.S., C.G.C., et al., *Genetic evaluation procedures at sperm banks in the United States*, 99 Fertil. Steril. 1587 (2013). Abstract only available at [http://www.fertstert.org/article/S0015-0282\(13\)00136-2/abstract](http://www.fertstert.org/article/S0015-0282(13)00136-2/abstract) (published online February 6, 2013).

“majority of US IVF clinics” offered preimplantation genetic diagnosis as a service to recipient couples.⁵¹ A comprehensive survey of the general public, published in 2004 by the Genetics and Public Policy Center, asked survey participants about various aspects of genetic testing in reproductive medicine but limited the focus to prenatal genetic testing, PGD, and carrier testing of parents without differentiating gamete donors.⁵² Regardless, many of the survey’s focus group participants believed that carrier testing for genetic diseases should be made widely available prior to pregnancy.⁵³

As seen above, there are various combinations of technique and donated gamete that can be used to assist a couple in having a child, and more and more recipient couples or individuals are utilizing them. However, the practice of preventative genetic testing or screening of gamete donors doesn’t seem to be keeping pace. Furthermore, considering the scope of the techniques and the number of parties involved, there is surprisingly limited state and federal oversight of these various procedures.

II. Current Regulation of Assisted Reproductive Technologies Using Gamete Donors

Assisted reproductive technologies are regulated at the state and federal levels; various professional associations and accreditation institutions also privately regulate tissue banks, infertility clinics and physicians who specialize in assisted reproduction. However, the vast majority of these government and private regulations deal with issues other than genetic testing. There are very few government requirements for genetic

⁵¹ Susannah Baruch, J.D., et al, *Genetic testing of embryos: practices and perspectives of US in vitro fertilization clinics*, 89 *Fertil. Steril.* 1053 (2008). Abstract only available online at [http://www.fertstert.org/article/S0015-0282\(07\)01216-2/abstract](http://www.fertstert.org/article/S0015-0282(07)01216-2/abstract) (published online July 12, 2007).

⁵² Genetics & Public Policy Center, *Reproductive Genetic Testing: What America Thinks* 4 (2004).

⁵³ *Id.* at 24, 37.

screening or testing of donated eggs and sperm, and private guidelines are voluntary.⁵⁴ With such a noticeable lack of preemptive or proactive regulations for donors, court remedies after conception or birth become much more important.

A. Existing Regulation at the Federal Level

The federal government does regulate ART practitioners through legislation and administrative agencies.⁵⁵ The United States Department of Health and Human has the authority under the Public Health Service Act (42 U.S.C. 201 et seq.) to directly regulate ART procedures primarily via the FDA and the CDC.⁵⁶ These two administrative entities regulate the storing and procuring of human tissue and the reporting of ART success rates, respectively, but neither emphasize genetic testing as a part of good tissue practice.

The CDC's primary function is to monitor how successful ART procedures are and that they are being reported accurately. Under the 1992 Fertility Clinic Success Rate and Certification Act, any fertility clinic or ART practitioner has to report to the CDC its yearly success rate and how many treatment cycles it performs (regardless of the number of patients it treats).⁵⁷ The CDC also established a model program to regulate embryo laboratories for states.⁵⁸ However, this model program is voluntary and has not been considered effective.⁵⁹

The CDC has also attempted to encourage state oversight of ART procedures through the States Monitoring Assisted Reproductive Technology Collaborative, a project

⁵⁴ Luekemeyer, *supra* note 6 at 414.

⁵⁵ Heled, *supra* note 6 at 249-50.

⁵⁶ J. Brad Reich and Dawn Swink, Article, *You Can't Put The Genie Back in the Bottle: Potential Rights and Obligations of Egg Donors in the Cyberprocreation Era*, 20 Alb. L.J. Sci. & Tech. 1, 24 (2010). See also 42 U.S.A. 216.

⁵⁷ *Assisted Reproductive Technology*, Centers for Disease Control and Prevention, <http://www.cdc.gov/art/>, last updated February 12, 2013. Also 42 U.S.C.A. Section 263a-1.

⁵⁸ Heled, *supra* note 6 at 250, citing the Fertility Clinic Success Rate and Certification Act (42 U.S.C. §263a-1. .

⁵⁹ Heled, *supra* note 6 at 250.

intended to promote increased surveillance of infants born as a result from ART after they are born and develop.⁶⁰ While the CDC and, currently, three states (Massachusetts, Florida and Michigan) track birth defect and cancer registries of the infants,⁶¹ there are no widely disseminated state reports yet that exclusively analyze the relationship of infants with genetic defects and the genetic conditions of sperm or egg donors.

While the CDC focuses on the results of ART practice, the Food and Drug Administration regulates the procedural aspects of ART. The FDA is authorized under the Public Health Service Act to monitor the registration, inspection and donor selection practices of any facility that deals with human tissue.⁶² As of 2005 the FDA had three codified rules that specified that any facility that dealt with human tissue, including sperm and eggs, had to register with the FDA, be open to inspections, and screen all human tissue and test all human tissue for specific communicable diseases.⁶³ Specifically, facilities manufacturing, screening, storing or processing human cells and tissue had to register with the FDA,⁶⁴ list the tissues, cells, or tissue products it handled,⁶⁵ screen all donors for certain infectious diseases⁶⁶, and maintain FDA approved tissue handling practices.⁶⁷ These rules were finalized in 2005.⁶⁸ The donor eligibility provisions specify only that the tissue is to be screened and tested only for communicable diseases such as

⁶⁰ *States Monitoring Assisted Reproductive Technology Collaborative*, Centers for Disease Control and Prevention, <http://www.cdc.gov/art/SMART.htm#> (last updated July 24, 2012).

⁶¹ *Id.*

⁶² Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 69 Fed. Reg. 29,786, 29,787 (May 25, 2004)(to be codified at 21 CFR 210, 211, 820, and 1271).

⁶³ 21 CFR 1271.1 and *Donor Eligibility Final Rule and Guid..ance Questions and Answers*, Food and Drug Administration, available at <http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/QuestionsaboutTissues/ucm102842.htm> (last visited May 10, 2013).

⁶⁴ 21 CFR 1271.21

⁶⁵ 21 CFR 1271.25

⁶⁶ 21 CFR 1271.75; 21 CFR 1271.80

⁶⁷ 21 CFR 1271.150

⁶⁸ Note 63 *supra*.

HIV.⁶⁹ Reproductive tissue is also screened for chlamydia and gonorrhea, two sexually transmitted diseases.⁷⁰ There is no current FDA rule that requires any fertility clinic, tissue bank or other facility that handles human reproductive tissue to screen it or test it for genetic diseases.⁷¹

B. Existing Regulation at the State Level

While some states have put in place laws requiring donor semen and oocytes to be screened for HIV,⁷² only two states, New York and Ohio, explicitly require ART practitioners to screen or test gamete donors for genetic diseases.⁷³ New York regulations require facilities dealing with reproductive tissue donors to screen through a detailed medical history for “major genetic disorders,”⁷⁴ and also requires donors who have indicated there is a family or personal history of Tay-Sachs disease, thalassemia, cystic fibrosis and/or sickle cell disease to be genetically tested.⁷⁵ Ohio law requires that a physician, physician’s assistant, nurse, or nurse practitioner has to take a “complete medical history of the donor, including, but not limited to, any available genetic history of the donor,” in order to use donor sperm in artificial insemination.⁷⁶

By contrast, several states have statutory provisions that actually shield ART practitioners from liability. For instance, many states have “blood shield laws” which prevent plaintiffs from bringing product liability or negligence claims for injuries

⁶⁹ 21 CFR 1271.3(r)

⁷⁰ 21 CFR 1271.75(c)

⁷¹ Heled, *supra* note 6, at 253-54.

⁷² *E.g.*, VA Code Ann. § 32.1-45.3.

⁷³ Heled, *supra* note 6 at 255.

⁷⁴ N.Y. Comp. Codes R. & Regs. tit. 10, § 52-8.5(b)(2)

⁷⁵ N.Y. Comp. Codes R. & Regs. tit. 10, § 52-8.6(h)

⁷⁶ Ohio Rev. Code Ann. § 3111.91(B)(1)(a)(West 2013)

resulting from infected or botched blood transfusions.⁷⁷ While some of these state statutes apply specifically to blood and blood products, others encompass other types of human tissue.⁷⁸ Moreover, Georgia also has a broad statute that exempts a physician from civil actions, other than those for negligence, for performing artificial insemination.⁷⁹ In short, the overwhelming majority of states have either not considered the genetic risks of ART or have chosen to exempt ART practitioners from certain types of liability.

C. Existing Regulation by Private Institutions

The most rigorous regulations for genetic testing of donors are set out by private associations and accreditation institutions. The two principle associations dealing with ART practice are the American Society for Reproductive Medicine (ASRM) and the affiliated Society for Assisted Reproductive Technology (SART).⁸⁰ These guidelines call for genetic testing and screening of donor sperm and donor eggs for major diseases such as cystic fibrosis.⁸¹ ASRM is merely a professional accreditation association, however, so while it promulgates guidelines to its members, they are voluntary and not required to be followed.⁸²

III. The Case Precedent and What It Means for ART Families

There are only a small number of cases that have been brought by recipient couples after their child has inherited a disease from a sperm or egg donor. In general, these cases reflect a growing concern of courts as to how to treat such claims, which do

⁷⁷ Jennifer M. Vagle, Comment, *Putting the Product in Reproduction: The Viability of a Products Liability Action for Genetically Defective Sperm*, 38 Pepp. L. Rev. 1175, 1219-20 (2011).

⁷⁸ *Id.* at 1220, citing, e.g., Ind. Code. Ann. §16-41-12-11(a).

⁷⁹ *Id.* at 1205, citing Ga. Code. Ann. §43-34-37(b).

⁸⁰ The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology, *Recommendations for Gamete and Embryo Donation: A Committee Opinion*. 99 FERTIL. STERIL. 47 (2013).

⁸¹ Note 80 *supra* at 49, 55.

⁸² Luetkemeyer, *supra* note 6 at 414.

not fall neatly under a particular theory of tort or contract law. The plaintiffs below brought many different causes of action against ART practitioners, and the courts have had opportunities to examine several recurring theories of liability, the most common of which is “straight” and professional negligence, products liability, and wrongful life or wrongful birth.

A. *Stiver v. Parker*

This case from the early 1990s involves a contagious rather than genetic disease and actually does not involve a child born from a gamete donor – although the parties certainly intended him to be so. However, it’s a helpful early case to look at negligence claims for children born with donor-related diseases. In this case of first impression, the Court of Appeals for the Sixth Circuit examined the liability of a surrogacy broker and ART practitioners for negligence. The plaintiff, a Michigan woman named Judith Stiver, was a surrogate who agreed to bear a child for a man named Alexander Malahoff.⁸³ Stiver contracted with Malahoff to bear his child through a “surrogacy broker” who worked in conjunction with several medical and legal professionals.⁸⁴ The surrogacy agreement required “both parties to undergo a complete physical and genetic evaluation, under the direction and supervision of a licensed physician, to determine whether the physical health and well being of each is satisfactory.”⁸⁵ Beyond the contract, however, there were no follow-up procedures that tracked whether or not Malahoff or Stiver ever actually received counseling or testing of any kind.⁸⁶ Although Stiver was encouraged to see her independent obstetrician, she was also obligated to sign the surrogacy agreement on the

⁸³ *Stiver v. Parker*, 975 F.2d 261, 263 (6th Cir. 1992).

⁸⁴ *Id.* at 264.

⁸⁵ *Id.* at 265.

⁸⁶ *Id.* at 265-66.

same day that she first read it, and only saw the participating doctors and counselors days before she was inseminated with the untested semen of Malahoff.⁸⁷

Stiver was also married, and the child she gave birth to turned out to be the biological child of her husband, not Malahoff's.⁸⁸ However, the child had severe and permanent birth defects as a result of Stiver's exposure to cytomegalovirus, a communicable disease that is carried through semen.⁸⁹ The Stivers, believing that Malahoff's untested semen was the source of Judith's exposure, sued the surrogacy broker as well as four doctors and an additional involved lawyer for negligence.⁹⁰ The District Court for the Eastern District of Michigan granted summary judgment in favor of the defendants, and the Stivers appealed.⁹¹

The Sixth Circuit admitted it was in "uncharted waters" but decided the surrogacy broker and the participating physicians were not merely exercising the standard of care typical to regular obstetric practice, but had all voluntarily entered the highly specific business of locating and inseminating surrogates, and would all see a profit from a successful surrogacy.⁹² Therefore, under Michigan law, the defendants met the standard of having a "special relationship" with the plaintiff, and owed her an affirmative duty of care to protect her from foreseeable harm.⁹³ Their current surrogacy practices and the generality of the surrogacy agreement, as well as the defendants' failure to test Malahoff's semen, raised a material issue of fact as to a breach of that affirmative duty

⁸⁷ *Id.* at 266, 268.

⁸⁸ *Id.* at 263.

⁸⁹ *Id.* at 263 and n5.

⁹⁰ *Id.* at 264.

⁹¹ *Id.* at 264.

⁹² *Id.* at 268.

⁹³ *Id.*

and causation, and the Stivers could continue to pursue their claim.⁹⁴

B. Johnson v. The Superior Court of Los Angeles County (I) and (II)

The California state courts were some of the first to consider an action against a sperm bank after a child was born with a disease inherited from the sperm donor. Diane and Ronald Johnson conceived their daughter Brittany using frozen donor semen provided to them by California Cryobank, Inc.⁹⁵ California Cryobank assured the Johnsons that the semen had been “fully tested and genetically screened.”⁹⁶ It also required the Johnsons to sign an agreement that stated that since the donor was to remain anonymous, Cryobank would destroy the donor’s records.⁹⁷

Brittany was diagnosed with Autosomal Dominant Polycystic Kidney Disease (ADPKD) roughly six years after she was born.⁹⁸ It was determined that the sperm donor used to conceive her had transmitted the disease to her.⁹⁹ The Johnsons allegedly learned that their sperm donor had in fact informed California Cryobank physicians at the time of his donation that his mother and a maternal aunt both suffered from kidney disease as well as other symptoms that were indicative of ADKPD.¹⁰⁰ Despite this, the Johnsons claimed that Cryobank and its affiliated physicians never followed up with testing of the semen, that they were never informed prior to artificial insemination of any issues with their donor and that California Cryobank assured them the semen had been tested and screened for genetic disorders.¹⁰¹ They then sued California Cryobank for professional negligence,

⁹⁴ *Id.* at 269.

⁹⁵ *Johnson v. Super. Ct. of Los Angeles*, 95 Cal. Rptr.2d 864, 867 (Cal. Dist. Ct. App. 2000), *review denied* 124 Cal. Rptr.2d 650 (Cal. Dist. Ct. App. 2002).

⁹⁶ *Id.* at 867.

⁹⁷ *Id.*

⁹⁸ *Id.* at 867-68.

⁹⁹ *Id.* at 868.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

fraud, and breach of contract.¹⁰²

In the Johnson's first reported court proceeding, the California Court of Appeals granted a writ of mandate to decide whether the Johnsons had a right to get the name, contact information and medical history from California Cryobank for their sperm donor.¹⁰³ The Court of Appeals decided that the California Code of Civil Procedure permitted the Johnsons to pursue all "relevant" discovery that revealed the donor's information.¹⁰⁴ They also determined that the anonymous sperm donor was not shielded by any privileged doctor-patient relationship with California Cryobank, and that public policy concerns outweighed his contractual right to anonymity and his constitutional right to privacy.¹⁰⁵ The court tried to strike a balance between the rights of the Johnsons and the rights of the donor by allowing the petitioners to take the donor's deposition and examine his personal and family medical history and relationship with California Cryobank, but "only as to those issues which are relevant to the pending litigation."¹⁰⁶

In the second *Johnson* case in 2002, the Court of Appeals examined a second writ of mandate brought by the Johnsons, and dealt with substantive issues of the case.¹⁰⁷ One of the key issues the court examined on its second pass was whether or not California Cryobank as an entity was considered a "health care provider" for the purposes of a medical malpractice suit.¹⁰⁸ Interestingly, the Johnsons took the position that California Cryobank was *not* a health care provider, since if it fell under California's statutory

¹⁰² *Id.* at 867.

¹⁰³ *Id.* at 870.

¹⁰⁴ *Id.* at 871.

¹⁰⁵ *Id.* at 873, 877.

¹⁰⁶ *Id.* at 879.

¹⁰⁷ *Johnson v. Super. Ct. of Los Angeles*, 124 Cal. Rptr.2d 650 (Cal. Dist. App. 2002)

¹⁰⁸ *Id.* at 653

definition then they would be procedurally barred from claiming punitive damages.¹⁰⁹ The court, however, disagreed and decided that California Cryobank was a health care provider under the California Code of Civil Procedure, because it dispensed a product linked to human healthcare.¹¹⁰

Furthermore, the Court held Brittany Johnson's claim for general damages and loss of earnings to be the same as a claim for "wrongful life," a tort not generally recognized in California.¹¹¹ The court characterized the claim for wrongful life as stating that if not for the negligent (or fraudulent, etc.) actions of the defendant, the child never would have been born.¹¹² The Court also very briefly addressed the issue of causation in Brittany's claim against California Cryobank and the physicians, stating only that "...it cannot be said that Cryobank, Sims and Rothman caused Brittany's inherited abnormalities by improperly approving Donor No. 276 as a sperm donor. Brittany's kidney condition was caused by the gene contained within the sperm provided by Donor No. 276."¹¹³

However, as described below, not all jurisdictions have followed Johnson's outright denial of damages.

C. Paretta v. Medical Offices for Human Reproduction

The plaintiffs, Josephine and Gerard Paretta, brought an action on behalf of themselves and their daughter Theresa against Columbia Presbyterian Medical Center and affiliated fertility clinics as well as two individual physicians after Theresa was born

¹⁰⁹ *Id.* at 660, 664.

¹¹⁰ *Id.* at 660-61.

¹¹¹ *Id.* at 666.

¹¹² *Id.*

¹¹³ *Id.*

with cystic fibrosis inherited from the egg donor used to conceive her.¹¹⁴ The principal fertility clinic's practice was to prescreen egg donors for some genetic diseases, including cystic fibrosis.¹¹⁵ The Paretas selected an egg donor through the defendants' Ovum Donor Program and conceived Theresa using the donor's egg and Gerard Paretta's semen.¹¹⁶

Cystic fibrosis is a condition that must be inherited from both parents in order to manifest itself in a child.¹¹⁷ Therefore, both the egg donor and Mr. Paretta were carriers of the disease.¹¹⁸ Although the clinic had tested the donated egg for cystic fibrosis, the Paretas alleged the clinic never informed them that the egg donor was a carrier.¹¹⁹ Moreover, at no time did the clinic test Mr. Paretta to see if he was a carrier as well.¹²⁰ The Paretas brought a claim of medical malpractice against the clinic and its participating doctors, as well as claims for negligent infliction of emotional distress and loss of consortium.¹²¹ The clinic then moved to dismiss the Paretas' Complaint.¹²²

Looking at case precedent, the New York Supreme Court decided that Theresa Paretta did not have legal standing as a plaintiff, as allowing her claim was comparable to a claim for "wrongful life," which is not recognized in New York.¹²³ The Court stated that to allow Theresa to recover based on acts that occurred before she was conceived "would give children conceived with the help of modern medical technology more rights

¹¹⁴ *Paretta v. Med. Offices for Human Reproduction*, 760 N.Y.S.2d 639, 641 (N.Y. Sup. Ct. 2003).

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.* at 641-42.

¹¹⁸ *Id.* at 642.

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.* at 643.

¹²³ *Id.* at 645-47.

and expectations than children conceived without medical assistance.”¹²⁴ Furthermore, the court said that the Paretta parents could not recover from the defendants for their emotional distress.¹²⁵

However, the Court emphasized that the Paretts had stated a relationship between the acts of the defendant fertility clinic and doctors and Theresa’s resulting disease, and that if supported by the evidence, the actions of the doctors could be negligent or even fraudulent, and that the Paretts were entitled to pursue both compensatory damages for Theresa’s treatment expenses and punitive damages in court.¹²⁶ The case ultimately settled for \$1.3 million.¹²⁷

D. Donovan v. Idant Laboratories

Donna Donovan entered a contract with the sperm bank Idant Laboratories to be artificially inseminated with semen that Idant stored and sold.¹²⁸ As part of the agreement, Idant provided Donovan with a consent form that stated “(1) semen stored at Idant is exceptionally safe; (2) Idant has a screening program that far exceeds mandated standards; and (3) Idant’s donors go through a rigorous screening process to ensure that they have a good genetic background and history.”¹²⁹ Donovan signed the consent form, selected a sperm donor whom she believed had been adequately tested, and was artificially inseminated.¹³⁰ Her daughter (like the Johnson’s daughter, also named Brittany) was born with Fragile X syndrome, an inherited developmental disorder.¹³¹

¹²⁴ *Id.* at 646.

¹²⁵ *Id.* at 645.

¹²⁶ *Id.* at 647-48.

¹²⁷ Heled, *supra* note 6 at 8.

¹²⁸ *Donovan v. Idant Labs.*, 625 F.Supp. 2d 256, 262 (E.D. Pa. 2009), *review denied* 374 Fed.Appx. 319, 2010 WL 1257705(3d. Cir. 2010).

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.* at 263.

Donna Donovan was not a carrier of Fragile X, and the sperm donor was determined to be the carrier.¹³²

On behalf of herself and Brittany, she brought nine claims encompassing negligence and product liability theory as well as contract doctrine: “negligence, breach of contract, third-party beneficiary breach of contract, breach of the express warranty of merchantability, breach of implied warranty of merchantability, third-party beneficiary breach of express and implied warranties of merchantability, negligent misrepresentation, strict products liability and negligent infliction of emotional distress for selling defective sperm to Donna Donovan.”¹³³ The case was complicated by questions of appropriate venue and the applicable statute of limitations; ultimately, Donna Donovan was barred from bringing her claims due to the statute of limitations expiring.¹³⁴

However, the District Court for the Eastern District of Pennsylvania did discuss the merits of Brittany Donovan’s actions as well, and left open the possibility of future products liability actions for sales of sperm that carried genetic disease.¹³⁵ Under the theory that “wrongful life” was not a recognizable claim under New York law (the choice of law applied), Brittany Donovan’s claims for negligence and negligent misrepresentation were dismissed.¹³⁶ However, finding that New York law did not specifically exempt reproductive human tissue from being categorized as a product for strict liability purposes, the court decided the Donovans’ strict products liability claim could withstand a motion to dismiss.¹³⁷ The Court did not elaborate on the merits of the

¹³² *Id.*

¹³³ *Id.* at 262.

¹³⁴ *Id.* at 264-65, 268.

¹³⁵ Vagle, *supra* note 77, at 1212.

¹³⁶ *Id.* at 271.

¹³⁷ *Id.* at 273.

strict liability claim, but it did “touch on [the] important distinction” that the strict liability claims were against Idant as a vendor and not as a healthcare provider.¹³⁸

These four cases demonstrate all plaintiffs are willing to bring an extensive variety of claims in order to try and recover for the birth of a child with a genetic disorder. However, a common claim brought by all of the plaintiffs was negligence, whether it was against a ART practitioner or a sperm bank. The merits and problems of negligence claims regarding gamete donors with genetic diseases is discussed in the next section.

IV. Crafting a Claim the Courts Will Accept

As discussed above, a common claim among all of the cases above is that of negligence, whether it stands on its own, as in *Stiver*, falls under the tort theories of medical malpractice or products liability as in *Paretta, Johnson* and *Donovan*, or ends up paralleling the tort of wrongful life or birth, it is appears in all of the cases. The elements of negligence seem to apply to the fact patterns presented in the cases described in the above section. However, there are various hurdles for plaintiffs to consider before bringing a similar negligence claim to court, and it is especially helpful for families bringing these actions to understand the basic tenets of these claims (and why some courts are unwilling to accept them). First, an overview of the relevant law is in order. Recommendations then follow for how families can proceed in civil court.

A. What is the current law?

Negligence

¹³⁸ Daniel Park, *Select Recent Court Decisions*, 36 Am. J.L. & Med. 682, 684 (2010).

Of the above cases, the negligence claim brought by the Stivers in *Stiver v. Parker* most parallels the tort of “classic” negligence.¹³⁹ A plaintiff can claim that the defendant’s negligence caused the plaintiff’s physical or emotional harm.¹⁴⁰ Negligence that causes physical harm has five elements: a duty owed by the party allegedly at fault to the person injured, a breach of that duty (“failure to exercise reasonable care”), cause, an actual resulting injury, and “proximate cause.”¹⁴¹ Proximate cause means that the resulting harm must fall within “the scope of the risk” of the unreasonable conduct.¹⁴² In other words, the resulting harm or injury has to be a reasonable or sensible effect of the tortious conduct¹⁴³; it cannot be an attenuated or freak consequence of someone’s actions.

Negligence that causes emotional harm includes the same elements as above, but has some limitations, since emotional harm is more difficult to show.¹⁴⁴ Emotional harm is considered “impairment or injury to a person’s emotional tranquility.”¹⁴⁵ In order for the injured party to show that someone’s negligent conduct resulted in their emotional harm, he generally must show either that he was also in immediate physical danger and that in turn caused his emotional harm, or that the liable party was negligent in a situation where it was extremely likely that negligence would cause emotional harm (for instance, in a hospital morgue, where the attendant negligently misidentifies the body and then notifies the wrong victim’s family).¹⁴⁶

¹³⁹ *Stiver*, 975 F.2d at 264.

¹⁴⁰ Restatement (Third) of Torts § 45(2012).

¹⁴¹ Restatement (Third) of Torts § 6 (2012).

¹⁴² Restatement (Third) of Torts § 29 (2012); see also Restatement (Second) of Torts § 281(1965).

¹⁴³ See *Palsgraf v. Long Island RR. Co.*, 248 N.Y. 339, 162 N.E. 99, 353-54, 104-04 (N.Y. 1928) is considered one of the landmark cases describing the concept of proximate cause.

¹⁴⁴ Restatement (Third) of Torts § 45 cmt. a, b (2012).

¹⁴⁵ Restatement (Third) of Torts § 45(2012).

¹⁴⁶ Restatement (Third) of Torts § 47 cmt. f (2012); see also *Consol. Rail Corp. v. Gottshall*, 512 U.S. 532, 547-48 (1994).

A party can also claim emotional harm caused by witnessing physical harm (according to the Restatement (Third) of Torts, “serious bodily injury”) happen to another person.¹⁴⁷ In order to uphold this claim, the injured party has to either have witnessed the physical harm while it was happening or be a close family member to the victim.¹⁴⁸ Although it is not described in the cases, this may have been the theory the plaintiff parents were proceeding under in *Donovan* and *Paretta* when they made claims of emotional distress.¹⁴⁹

Negligence is considered an action governed by state law¹⁵⁰, and so one can see variations on negligence depending on the jurisdiction in these cases. For instance, in *Stiver*, the Sixth Circuit found that the surrogacy broker owed Judy Stiver an “affirmative duty” of protection.¹⁵¹ An affirmative duty under Michigan law is considered a heightened duty under a negligence theory that arises from a “special relationship” between two parties, and requires one party to not merely “exercise reasonable care” but actually protect the other party from harm.¹⁵² Although the court in *Stiver* acknowledged that the heightened responsibilities of an “affirmative duty” didn’t generally fall under negligence claims, here the circumstances justified finding that responsibility.¹⁵³

A more specific theory of negligence applies when making claims against physicians or other healthcare practitioners. These claims of medical malpractice incorporate the elements of traditional negligence but require the injured party to show

¹⁴⁷ Restatement (Third) of Torts § 48(2012).

¹⁴⁸ *Id.*

¹⁴⁹ *Paretta*, 760 N.Y.S.2d at 642; *Donovan*, 625 F. Supp.2d at 264.

¹⁵⁰ The landmark case *Erie R. Co. v. Tompkins*, 304 U.S. 64, 75-76 (1938) arose from a personal injury action and establishes that federal courts must defer to the common law of the states, including negligence and contract law.

¹⁵¹ *Stiver*, 975 F.2d at 268.

¹⁵² *Id.* at 270, see also *Williams v. Cunningham Drug Stores, Inc.*, 418 N.W.2d 381, 382, 384 (Mich. 1988)

¹⁵³ *Stiver*, 975 F.2d at 270.

that the healthcare provider breached their duty to provide reasonable medical care, with “reasonableness” defined by the standard of care in the medical profession.¹⁵⁴ The plaintiff parents specifically targeted their healthcare practitioners with medical malpractice claims in *Paretta* and *Johnson*.¹⁵⁵

Finally, there is a theory of negligence that the courts in all of the above-described cases considered – the theory of “wrongful life.”¹⁵⁶ Wrongful life is a controversial tort in the United States and its meaning appears to be elusive, but it is integral for potential plaintiffs to understand what its overall elements are, and what it means to courts in particular jurisdictions.

When does a claim for negligence become a claim for wrongful life?

The concept of wrongful life in the ART context has been described as a “paradox. If offspring are ‘harmed’ by being born in those [risky or poor] conditions, then the only way to prevent the harm is not to use those [ART] techniques. But this means that the children sought to be protected will never be born.”¹⁵⁷

Wrongful life is generally defined as the claim that a child would never have been born but for the acts or omissions of the tortfeasor.¹⁵⁸ However, there are many variations on this theme, depending on the jurisdiction. For some, the claim alleges “that the

¹⁵⁴ Jay M. Zitter, Annotation, *Standard of Care Owed to Patient by Medical Specialist as Determined by Local, “Like Community,” State, National, or Other Standards*, 18 A.L.R. 4th 603 (2011). See also *Molloy v. Meier*, 679 N.W.2d 711, 717 (Minn., 2004) (A medical malpractice action is based on principles of tort liability for negligence...); *Borillo v. Beekman Downtown Hospital*, 537 N.Y.S.2d 219, 220 (N.Y.A.D. 2 Dept. 1989) (“When the duty owing to a patient by a practitioner or medical facility arises from the physician-patient relationship or is substantially related to medical treatment, the breach thereof gives rise to an action sounding in medical malpractice as opposed to simple negligence [citation omitted]”).

¹⁵⁵ *Johnson*, 95 Cal.Rptr. 2d at 867; *Paretta*, 760 N.Y.S.2d at 642.

¹⁵⁶ Reich and Swink, *supra* note 56 at 63.

¹⁵⁷ John A. Robertson, *Procreative Liberty and Harm to Offspring in Assisted Reproduction*, 30 AM. J.L. & MED. 7, 14 (2004).

¹⁵⁸ Gregory G. Sarno, *Tort Liability for Wrongfully Causing One to Be Born*, 83 A.L.R. 3d 15 (2011).

physician's negligence precluded any parental decision to abort the fetus."¹⁵⁹ In other states like New York, the tort of wrongful life is also described as the claim that, but for the defendant's tortious acts, a child would never have been *conceived*.¹⁶⁰ The tort has also been classified in the genetic counseling context as "an informational one; [footnote omitted] the physician must provide accurate genetic counseling in keeping with professional standards of care, [footnote omitted] or face liability for the consequences proximately caused by such failure."¹⁶¹

To confuse matters more, the tort of "wrongful life" is considered the same as the tort of "wrongful birth" in some jurisdictions, while other jurisdictions recognize "wrongful birth" as a tort distinguishable from wrongful life.¹⁶² Many states reject the torts of wrongful life and wrongful birth as legal claims either through judicial decisions or by state statute.¹⁶³

Why? Courts seem to recognize shades of difference between a negligence claim, a wrongful life and/or a wrongful birth claim based on the damages sought and who is seeking them. Some courts "have refused to award damages in such instances on the ground, generally speaking, that it is extremely difficult, if not absolutely impossible, for the judiciary to evaluate in pecuniary terms the philosophical problem of being versus nothingness."¹⁶⁴ However, this is not always the case. Because there is so little uniformity as to how these cases are considered across jurisdictions, it's helpful to examine individual judicial opinions.

¹⁵⁹ Francis Sohn, *Products Liability and the Fertility Industry: Overcoming Some Problems in Wrongful Life*, 44 CORNELL INT'L L.J. 145, 159 (2011).

¹⁶⁰ *Paretta*, 760 N.Y.S.2d at 644.

¹⁶¹ Sohn, *supra* note 157 at 159.

¹⁶² Sarno, *supra* note 156.

¹⁶³ Reich and Swink, *supra* note 56 at 63. *See also, e.g.*, the Minnesota statute M.S.C. §145.424, which prohibits actions of both wrongful life and wrongful birth from being brought in Minnesota courts.

¹⁶⁴ Sarno, *supra* note 156.

In the cases described in Section III, each opinion voiced a concern over whether claims brought on behalf of the afflicted child were considered logically or unethically untenable. In *Johnson v. Superior Court of Los Angeles County* (I), the court stated that claims brought on behalf of Brittany Johnson were properly barred as a claim for “wrongful life” because in essence, she was seeking recovery for negligent actions that caused her to born.¹⁶⁵ The California court interpreted this to mean that there was a causal relationship between the negligence of the defendant ART physicians in failing to test the donor’s sperm and Brittany’s illness, which it considered illogical.¹⁶⁶ The court also did not recognize a difference between a claim for a wrongful birth and, as the Johnsons argued, a claim for wrongful conception.¹⁶⁷ As a result, the California Court of Appeals held the child Brittany had no standing to sue.¹⁶⁸

However, the court was careful in *Johnson* to distinguish the Johnson’s result from that of *Turpin v. Sortini*, an earlier California case.¹⁶⁹ Although *Turpin* did not involve a gamete donor, it did set a standard for recovery for children born with genetic diseases. In *Turpin*, the parents of a deaf child claimed that their physicians misinformed them that their child’s deafness was hereditary, and as a result conceived a second child who was also born deaf.¹⁷⁰ While the court in *Turpin* was unwilling to award the child general damages on a claim for “wrongful life,” it did allow both the parents and child to recover calculable damages for the cost of the child’s care.¹⁷¹

This standard was narrowed in *Paretta*, where the New York Supreme Court did

¹⁶⁵ *Johnson*, 124 Cal.Rptr. 2d at 666.

¹⁶⁶ *Id.* at 665-66.

¹⁶⁷ *Id.* at 665-66.

¹⁶⁸ *Id.* at 666.

¹⁶⁹ *Id.* at 664-65.

¹⁷⁰ *Turpin v. Sortini*, 643 P.2d 954, 956 (Cal. 1982).

¹⁷¹ *Id.* at 966.

not even directly address the issue of whether the child Theresa Paretta's claims were for "wrongful life" or "wrongful" birth, but relied on case precedent that allowed for actual damages to the parents of a child claiming wrongful life or wrongful birth, but no damages for the child herself.¹⁷² Thus *Paretta* stated that *only* parents can recover where a physician's negligence has resulted in the birth of a sick child.¹⁷³ However, by awarding the same type of damages to parents regardless of whether the child was already conceived, as in *Paretta*, the courts may have defeated their own reasoning in denying what they consider "wrongful life" claims.¹⁷⁴

New York law was then applied to the child Brittany Donovan's negligence claims in *Donovan v. Idant Laboratories*, and Brittany was barred from bringing a claim for negligence because her claim was essentially one for "wrongful life."¹⁷⁵ The United States District Court for the District of Pennsylvania reasoned that while the sperm bank's negligence might have led to Donna Donovan simply choosing another donor and having a healthy child as opposed to no child at all, Brittany would not have been born with her specific "genetic identity" and therefore was attempting to claim damages for being born with a genetic illness.¹⁷⁶

Other state courts, however, have drawn different distinctions between various claims on behalf of a child born with a genetic disease. In New Jersey, the state Superior Court relied on New Jersey Supreme Court precedent and drew a clear line between claims that alleged negligence causing prenatal injury and claims for *negligent genetic*

¹⁷² *Paretta*, 760 N.Y.S.2d at 645.

¹⁷³ *Id.* at 647.

¹⁷⁴ Daniel Park, *supra* note 136 at 685.

¹⁷⁵ *Donovan*, 625 F.Supp. 2d at 271.

¹⁷⁶ *Id.*

counseling that caused parents to make a misinformed decision not to abort a child.¹⁷⁷ It considered the latter a “wrongful birth” claim.¹⁷⁸ It also allowed parents and children to recover “the normal measure of damages” for such a claim, including damages for emotional harm.¹⁷⁹

Minnesota law recognizes an even more specific distinction between negligence claims involving children born with genetic disease due to negligence and children conceived with genetic disease due to negligence. In *Molloy v. Meier*, the Minnesota Supreme Court answered the certified question of whether an action by parents alleging that negligence led to them conceiving a second child was considered a claim for “wrongful life” or “wrongful birth” and thus barred by Minnesota statute.¹⁸⁰ The Supreme Court determined that while a claim alleging that negligence prevented parents from aborting a child was barred as a claim for wrongful life or wrongful birth, a claim alleging that negligence *caused parents to conceive a sick child* fell under neither tort and was allowed.¹⁸¹

In short, the tort of “wrongful life” means different things to different courts. For some it seems to encompass a number of claims relating to the birth of an ill child; for others it requires a narrow and specific fact pattern. Any parent who wishes to bring a claim for negligence that resulted in their child’s genetic disease needs to understand the law of their state very well and tread carefully.

B. Recommendations

¹⁷⁷ *Geler v. Akawie*, 818 A.2d 402, 413 (N.J.Super. Ct. App. Div. 2003), *citing Berman v. Allan*, 80 N.J. 421, 432-33 (1979).

¹⁷⁸ *Id.* at 411.

¹⁷⁹ *Id.* at 412.

¹⁸⁰ *Molloy v. Meier*, 679 N.W.2d 711, 722 (Minn., 2004)

¹⁸¹ *Id.* at 723.

As evidenced above, courts have yet to come up with clear guidelines as to how these cases will be handled, and these claims raise complicated questions about the cause-and-effect relationships between gamete donor selection, ART procedures, parental decisions and the child's birth. Parents seeking to bring a negligence claim in court against an ART practitioner for children with inherited diseases from a gamete donor have to be willing to take the time to carefully construct their legal theories.

First, parents should consider whether their state recognizes a heightened duty between an ART facility or fertility clinic and the recipient couple, as Michigan did in *Stiver*.¹⁸² If so, then the parents may be able to claim that the fertility clinic owes them a duty to protect from foreseeable harm, which in turn could translate into a duty to carefully screen gamete donors from genetic disease.

Parents need to make a related inquiry as to whether or not their ART physician or practitioner was following the acceptable standard of care under a medical malpractice theory. This could be tricky, since the surveys referenced in Section I suggest that genetic testing of donors is not standard practice in the ART industry.¹⁸³ Furthermore, even if genetic testing or screening is the practice for a particular clinic or donor bank, the parents need to check for which diseases the clinic or bank screens. "Even in retrospect, it is difficult to envision a practical screening protocol that could reliably target the entire multitude of genetically transmitted diseases that could arise in such clinical circumstances."¹⁸⁴

Parents also need to know whether or not state case law has allowed parents to recover for emotional harm. For instance, while the parents of Theresa Paretta were

¹⁸² *Stiver*, 975 F.2d at 268.

¹⁸³ Notes 50 and 51 *supra*.

¹⁸⁴ Marron, *supra* note 1 at 1684.

barred from seeking damages for emotional distress,¹⁸⁵ the parents in *Geler v. Akawie* were allowed to seek those damages,¹⁸⁶ and the court in *Geler* even stated that damages for emotional harm were an integral part of the remedy for legal claims involving children born with genetic disease due to faulty genetic counseling.¹⁸⁷

Finally, parents need to understand what the court considers to be a “wrongful life” claim in their jurisdiction, and whether those claims are barred. This is undoubtedly the largest hurdle to overcome in bringing an effective claim against an ART practitioner, as it incorporates the tricky elements of causation. However, if the cases described above are indicative of what courts will decide in future cases, then parents should consider what claims they can bring on their own behalf rather than what claims they can bring on behalf of their child, who may not have standing to sue. They should take care to show a causal relationship not between the ART facility’s negligence in securing the donor gamete and the child’s birth, but between the ART facility’s negligence in securing the donor gamete and their (the parent’s) decision to continue with that particular donor’s gametes. Furthermore, parents should be prepared to present a calculable claim for damages for the care of the child, rather than general damages for pain and suffering under a wrongful life theory. While it is possible that a jurisdiction might consider a general award of damages that would be greater than actual damages, the likelihood of such a decision seems small in light of the case law that has emerged so far, and the goal of bringing this type of negligence claim in court is to maximize recovery for the burden families will have to bear.

¹⁸⁵ *Paretta*, 760 N.Y.S.2d at 647-48.

¹⁸⁶ *Geler*, 818 A.2d at 414.

¹⁸⁷ *Id.* at 413.

CONCLUSION

The medical and legal ramifications from the growing ART industry have yet to be fully felt, and it's clear from the limited case precedent presented in this paper that state and federal courts have yet to determine whether or not ART practitioners and sperm banks should be held accountable for a child who inherits a genetic disease from a donor. If they are to be liable, courts have yet to present a unified theory on how or why. However, they have left open some possibilities for affected families. If enough families start to bring these types of actions in courts at the state and federal levels, ART practitioners may take notice and move for more proactive measures to insure healthy ART births.