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## Two & A Half Parents: Three-Parent IVF and Medical Malpractice in the United States

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# STUDENT COMMENT

## TWO & A HALF PARENTS: THREE-PARENT IVF AND MEDICAL MALPRACTICE IN THE UNITED STATES

*Jay M. Fulk\**

*Fertility medicine is seeing a rapid advancement with the emergence of a new procedure called three-parent in vitro fertilization (IVF). This novel procedure provides an opportunity for women who have defective mitochondria to bear their own healthy genetic children. As women encounter fertility issues, they will often turn to regular IVF by receiving an egg from a donor—ultimately resulting in a child with no genetic relation to the mother.*

*Women with defective mitochondria will likely pass down a mitochondrial disease to their children, therefore, bearing a child without the assistance from a donor does not present a viable option. Mitochondrial disease can be quite severe and traumatic, usually affecting the central nervous system. It can contribute to many serious illnesses such as Parkinson's, Alzheimer's, and cancer. Currently, there are no treatment options available for people with mitochondrial disease. Regular IVF requires an egg from a donor to replace the mother's egg, therefore, the mother is not genetically related to the child she bears, as the egg donor is the genetic mother. Three-parent IVF is a breakthrough fertility treatment procedure that allows women with defective mitochondria to bear a healthy child by receiving healthy mitochondria from a donor. This procedure enables women to retain a genetic bond to their child. Since a donor's healthy mitochondria is transferred to the mother's egg, the child will technically have three genetic parents (two mothers and a father).*

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*Three-parent IVF is currently not allowed in the United States, but with responsible legislation, it could be legal in the near future. This Comment proposes that three-parent IVF is implemented as a clinical trial for the purposes of conducting research to assess for safety and effectiveness. Current safety regulations and guidelines, primarily those regarding human tissue donation and transplantation, are quite instructive when put in the three-parent IVF context. These regulations and guidelines are discussed in some detail. There are a couple of steps that need to be taken in order to successfully implement three-parent IVF in the United States. First, great strides need to be made to reform the broken medical malpractice system in the United States. Current medical malpractice standards, and the available remedies to fertility plaintiffs, are not adequate to accommodate such a procedure. This Comment proposes that we move away from the customary care standard, and towards an evidence-based standard of care, while adopting the reasonable patient standard of informed consent. These standards will help address the inefficiency problems that exist within the medical profession. Second, since medical malpractice lawsuits are too costly for most fertility plaintiffs to pursue, there needs to be a fertility court established within the United States Court of Federal Claims—following in the successful footsteps of vaccine court. A fertility court will give fertility plaintiffs a remedy when they are injured by a doctor’s negligence, when no such remedy would have otherwise been available. Also, the establishment of a fertility court will lower fertility doctor’s medical malpractice premiums by reducing their overall litigation liability—as fertility plaintiffs will primarily turn to fertility court to redress their injuries.*

*The United Kingdom is leading the world into the future by being the first country to approve the three-parent IVF procedure. The time has come for the United States to take a serious look at three-parent IVF to help advance fertility medicine into a promising and hopeful future.*

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## INTRODUCTION

A revolution is currently underway. Three-parent in vitro fertilization<sup>1</sup> (IVF) has burst onto the scene within reproductive health over

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<sup>1</sup> *In Vitro Fertilization (IVF)*, MAYO CLINIC, <https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/home/ovc-20206838> (last visited Feb. 24, 2018). Here is a brief and concise overview of IVF:

In vitro fertilization (IVF) is a complex series of procedures used to treat fertility or genetic problems and assist with the conception of a child. During IVF, mature eggs are collected (retrieved) from [the] ovaries and fertilized by sperm in a lab. Then the fertilized egg (embryo) or eggs are implanted in [the] uterus. One cycle of IVF takes about two weeks. IVF is the most effective form of assisted reproductive technology. The procedure can be done using [the females] own eggs and [her] partner's sperm. Or IVF may involve eggs, sperm or embryos from a known or anonymous donor. In some cases, a gestational carrier—a woman who has

the last few years, which has sparked rigorous discussion and debate. In April 2016, the world said hello to the first child conceived using three-parent IVF.<sup>2</sup> A couple from Jordan contacted Dr. John Zhang<sup>3</sup> from New Hope Fertility Center in New York to assist them in conceiving a healthy child.<sup>4</sup> The woman had “a condition called Leigh syndrome, a neurological condition that killed her two prior children.”<sup>5</sup> Since the genes that carried this disease were transported within her mitochondrial DNA (mtDNA)—and since mothers pass down their mitochondria to their children—the only way for her to have a healthy child was a mitochondrial transplant.<sup>6</sup> The baby boy was delivered in Mexico, since the mitochondrial transplant procedure is currently not allowed in the United States, and there are currently no regulations in place for Mexico.<sup>7</sup> While the procedure is still new, Dr. Zhang continues to discuss his three-parent IVF activities—specifically about advertising the procedure—in the United States with the Food and Drug Administration

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an embryo implanted in her uterus—might be used. [The] chances of having a healthy baby using IVF depend on many factors, such as [the females] age and the cause of infertility. In addition, IVF can be time-consuming, expensive and invasive. If more than one embryo is implanted in [the] uterus, IVF can result in a pregnancy with more than one fetus (multiple pregnancy).

*Id.*

<sup>2</sup> Andrew Joseph, *World's First Baby Born with Novel Three-Parent Embryo Technique*, STAT (Sept. 27, 2016), <https://www.statnews.com/2016/09/27/three-parent-baby-embryo/>.

<sup>3</sup> John Zhang, *John Zhang, MD, MsC, PhD*, NEW HOPE FERTILITY CTR., <https://www.newhopefertility.com/about-us/fertility-doctors/john-zhang/> (last visited Feb. 24, 2018). Dr. John Zhang is a fertility specialist and the “Founder/CEO of New Hope Fertility Center in New York City.” *Id.* He is considered to be a pioneer in the area of assisted reproductive technology (ART). *Id.* He earned his medical degree from Zhejiang University School of Medicine and his Ph.D. in In-Vitro-Fertilization (IVF). *Id.*

Today, Dr. Zhang continues his research in non-embryonic stem cell research, long-term cryopreservation of oocytes, and oocyte (human egg cell) reconstruction by nuclear transfer. He is currently one of a handful of Reproductive endocrinologists in the United States to hold a Ph.D. in embryology while also being certified as a High Complexity Lab Director.

*Id.*

<sup>4</sup> Joseph, *supra* note 2.

<sup>5</sup> *Id.*

<sup>6</sup> James D. McCully et al., *Mitochondrial Transplantation: From Animal Models to Clinical Use in Humans*, 34 MITOCHONDRION 127, 127 (2017) (“Mitochondrial transplantation is a novel therapeutic intervention to treat . . . disorders. The method for mitochondrial transplantation is simple and rapid and can be delivered to the end organ either by direct injection or vascular infusion.”).

<sup>7</sup> Joseph, *supra* note 2.

FDA).<sup>8</sup> In January 2017, the first girl<sup>9</sup> conceived using the three-parent IVF procedure was born in Kiev, Ukraine.<sup>10</sup>

When confronted with fertility issues, women often turn to Assisted Reproductive Technology (ART).<sup>11</sup> Fertility treatments can take many forms:

ART is used to treat infertility. It includes fertility treatments that handle both a woman's egg and a man's sperm. It works by removing eggs from a woman's body. The eggs are then mixed with sperm to make embryos. The embryos are then put back in the woman's body. In vitro fertilization (IVF) is the most common and effective type of ART.<sup>12</sup>

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<sup>8</sup> Susan Scutti et al., *FDA Warns '3-Parent' Baby Fertility Doctor Over Marketing*, CNN (Aug. 7, 2017, 10:49 AM), <http://www.cnn.com/2017/08/07/health/fda-3-parent-fertility-zhang/index.html>. Since Dr. Zhang performed the three-parent IVF procedure in Mexico, he has been advertising three-parent IVF as a service offered by New Hope Fertility Center. *Id.* The FDA sent Dr. Zhang a letter, warning him that marketing the technique is not authorized by the FDA because three-parent IVF has not been authorized to be used on human beings in the United States. *Id.*

Mary A. Malarkey, the director of the FDA's Office of Compliance and Biologics Quality at the agency's Center for Biologics Evaluation and Research, said Zhang had submitted a written request dated April 22, 2016, "asking for a pre-investigational new drug (IND) meeting for a clinical investigation of a 'spindle transfer for assisted pregnancy in patients with mitochondrial disease.'"

*Id.* The FDA rejected the request citing "Congress' prohibition on the use of funds to accept IND submissions for clinical investigations that involve a human embryo being 'intentionally created or modified to include a heritable genetic modification.'" *Id.*

<sup>9</sup> Susan Scutti, *First Three-Parent Baby Girl Born Using Controversial IVF Technique*, CNN (Jan. 18, 2017, 4:08 PM), <https://www.cnn.com/2017/01/18/health/ivf-three-parent-baby-girl-ukraine-bn/index.html>. The sex of the embryo could have significant ramifications, which has sparked an ethical debate. *Id.* Doctors in Kiev, Ukraine, helped a previously infertile couple conceive and deliver a baby girl using three-parent IVF. *Id.* According to Lori P. Knowles, adjunct professor at the University of Alberta School of Public Health, skeptics are arguing that if three-parent IVF is going to be utilized, it should be limited to a male embryo. *Id.* A male baby "carrying donor mitochondria cannot pass their modified genetics onto any future children they may have because once a sperm fuses with an egg to form an embryo, the masculine mitochondrion withers and dies leaving the resulting embryo with only mitochondrion from the mother's egg." *Id.* Speaking about the baby girl born in Ukraine, Ms. Knowles states: "I do think it's highly significant that this is a girl because we know for sure that she will be passing on her mitochondrial DNA through her maternal line[.]" *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Assisted Reproductive Technology*, MEDLINE PLUS, <https://medlineplus.gov/assistedreproductivetechnology.html> (last visited Feb. 24, 2018).

<sup>12</sup> *Id.*

Most people have heard about regular IVF, which is a procedure designed to assist women who have fertility issues to become pregnant through egg donation.<sup>13</sup> Although the mother bears the child,<sup>14</sup> she is not genetically related to the child, as the egg comes from a third-party donor. Three-parent IVF provides a remedy for women with fertility issues who long to be genetically related to their child.

This Comment will discuss the two different infertility-causing conditions that can be remedied by mitochondrial transplants: “aged eggs”<sup>15</sup> and mitochondrial disease.<sup>16</sup> Three-parent IVF remedies both issues for women by allowing the mother to receive assistance from a donor while maintaining a genetic bond with her child. The three-parent IVF procedure essentially results in a child with three genetic parents, hence its name.<sup>17</sup> Exciting as it may sound, three-parent IVF is currently not allowed in the

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<sup>13</sup> *In Vitro Fertilization (IVF)*, JOHNS HOPKINS MED., <http://www.hopkinsmedicine.org/fertility/services/ivf/index.html> (last visited Feb. 24, 2018).

<sup>14</sup> *Bearing*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/bearing> (last visited Feb. 24, 2018) (meaning “the act, power, or time of bringing forth offspring”).

<sup>15</sup> *Aging Eggs: Exciting Research is on the Horizon*, FERTILITY AUTHORITY, <https://www.fertilityauthority.com/articles/aging-eggs-exciting-research-horizon> (last visited Feb. 24, 2018). Aging takes a toll on the human body and a female’s eggs are no exception:

We get tired as we age, and so do our eggs—the oocytes don’t have enough energy to go through the rapid cell division for fertilization. It becomes harder to get pregnant naturally and through fertility treatments such as in vitro fertilization (IVF). These aging eggs are more likely to have chromosomal abnormalities known as aneuploidy, less likely to develop into embryos once fertilized, and if they do develop, they are more likely to not implant or be lost through miscarriage.

*Id.*

<sup>16</sup> *Mitochondrial Disease*, MEDICINET.COM, [https://www.medicinenet.com/mitochondrial\\_disease/article.htm](https://www.medicinenet.com/mitochondrial_disease/article.htm) (last visited Nov. 26, 2017). Mitochondrial disease greatly affects the human body’s ability to function properly:

Mitochondrial disease includes a group of neuromuscular diseases caused by damage to intracellular structures that produce energy, the mitochondria. . . . Mitochondrial myopathies are a group of neuromuscular diseases caused by damage to the mitochondria—small, energy-producing structures that serve as the cells’ “power plants.” Nerve cells in the brain and muscles require a great deal of energy, and thus appear to be particularly damaged when mitochondrial dysfunction occurs.

*Id.*

<sup>17</sup> Bob Zhao, *Mitochondrial Replacement Therapy and the Regulation of Reproductive Genetic Technologies in the United States*, 15 DUKE L. & TECH. REV. 121, 123 (2017). Three-parent IVF results in DNA from the mother and father, along with the mitochondrial DNA from the donor. *Id.*

United States. The global discussion about three-parent IVF is on the rise, as the United Kingdom has recently passed legislation to allow the procedure.<sup>18</sup> This rise in global awareness gives the United States a prime opportunity to take a hard look at the procedure. The question then becomes: What is the liability associated with three-parent IVF procedures when the inevitable first injury occurs within the United States?

Consider the following hypothetical: John and Mary have been married for 18 years and are interested in starting a family together. They are both in their late 40s, and Mary has enjoyed a career as an attorney for the last 15 years. Mary made the conscious choice to pursue a career before establishing a family, but that choice has put her in a difficult position. Her mtDNA is defective due to her age (“aged eggs”<sup>19</sup>), and as a result, she will likely be unable to become pregnant. Mary yearns to be genetically attached to her child, so she rules out regular IVF and adoption. John, a physician, hears about three-parent IVF through a colleague and decides to look into it. He contacts a fertility specialist who performs three-parent IVF procedures, and the specialist informs them of a new clinical trial that was just approved. John and Mary meet with the fertility specialist, who is willing to perform the procedure. Mary signs an informed consent form to go ahead with the procedure; during the procedure, the fertility specialist makes crucial mistakes, causing serious complications with the embryo. The child is born with multiple issues—all attributable to the fertility specialist’s failure to use reasonable care in the process. John and Mary are now wondering what the fertility specialist’s liability for the procedure will be if they file a medical-malpractice lawsuit against him.

The purpose of this Comment is to explore the relationship between three-parent IVF and medical malpractice in the United States. The first section begins with a basic scientific overview of three-parent IVF. It then transitions into the current professional standards pertaining to care and informed consent—primarily as they apply to the doctor-patient relationship. A discussion follows in the third section regarding the current regulatory climate for safety within the human-based product industry and within the medical profession itself. This Comment concludes by proposing the

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<sup>18</sup> Kate Kelland, *For the First Time, U.K. Allows Clinic to Proceed with “3-Parent” Baby Procedure*, SCI. AM. (Mar. 16, 2017), <https://www.scientificamerican.com/article/for-the-first-time-u-k-allows-clinic-to-proceed-with-3-parent-baby-procedure/>.

<sup>19</sup> See *supra* note 15 and accompanying text.

implementation of three-parent IVF as a clinical trial so that physicians, scientists, and researchers can monitor risks and outcomes. If the resulting empirical evidence is satisfactory to legislators, the eventual goal is to fully legalize the procedure in the United States—offering three-parent IVF to patients who cannot utilize regular IVF or other means to satisfy their fertility needs. This Comment recommends that the evidence-based standard of care should be adopted, along with the reasonable patient standard of informed consent, when it comes to dealing with three-parent IVF procedures in the United States. Lastly, this Comment addresses the need to establish a fertility court to assist injured plaintiffs in medical-malpractice lawsuits involving three-parent IVF procedures.

## I. THE SCIENCE

### A. *An Overview of Three-Parent IVF*

“The field of reproductive technology is renowned for pushing boundaries and contributing innovative approaches to the pursuit of fertility enhancement.”<sup>20</sup> Robert Edwards<sup>21</sup> was the recipient of a Nobel Prize in physiology and medicine for pioneering IVF—a procedure that ultimately helped alleviate the mental and emotional pain associated with infertility.<sup>22</sup> Unprecedented scientific breakthroughs are transforming reproductive medicine as we know it.<sup>23</sup> Human germline genetic modification (HGGM)

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<sup>20</sup> Zhao, *supra* note 16, at 121.

<sup>21</sup> Robert Edwards was a fertility medicine pioneer, making many significant contributions throughout his career—culminating in a Nobel Prize:

Sir Robert Geoffrey Edwards [was a] British medical researcher who developed the technique of in vitro fertilization (IVF). Edwards, together with British gynecologist Patrick Steptoe, refined IVF for the human egg. Their work made possible the birth of Louise Brown, the world’s first “test-tube baby,” on July 25, 1978. Edwards was awarded the 2010 Nobel Prize for physiology or Medicine for his discoveries.

*Robert Edwards: British Medical Researcher*, ENCYCLOPEDIA BRITANNICA, <https://www.britannica.com/biography/Robert-Edwards> (last visited Feb. 24, 2018).

<sup>22</sup> Eli Y. Adashi, *Fifty Years After Huxley: The Roadmap of Reproductive Medicine Revisited and Updated: The 2015 SRI-Pardi Distinguished Scientist Plenary Lecture of the Society of Reproductive Investigation*, 22 REPROD. SCI. 1330, 1330 (2015).

<sup>23</sup> *Id.*

has the potential to play an instrumental role in these breakthroughs by altering genes in sperm and embryos<sup>24</sup> in fertility treatment.<sup>25</sup>

[HGGM] means deliberately changing the genes passed on to children and future generations – in other words, creating genetically modified people. [HGGM] has for many years been widely considered off-limits, for both safety and social reasons. It is formally prohibited in more than 40 countries.<sup>26</sup>

The human body is comprised of cells, each containing 46 chromosomes of DNA that provide the blueprint for the cell's development and function.<sup>27</sup> Each cell contains a nucleus that houses human genetic material, including mitochondria, which act as the cell's "battery pack," using oxygen to create energy that powers the cell.<sup>28</sup> Each cell contains mtDNA.<sup>29</sup>

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<sup>24</sup> *Embryo*, FREE DICTIONARY, <https://medical-dictionary.thefreedictionary.com/embryo> (last visited Feb. 24, 2018). The definition of an embryo is as follows:

[A] new organism in the earliest stage of development. In humans this is defined as the developing organism from the fourth day after fertilization to the end of the eighth week. After that the unborn baby is usually referred to as the fetus. . . . Immediately after fertilization takes place, cell division begins and progresses at a rapid rate. At approximately 4 weeks the cell mass becomes a recognizable embryo from 7 to 10 mm long with rudimentary organs. The beginnings of the eyes, ears, and extremities can be seen. By the end of the second month the embryo has grown to a length of 2 to 2.5 cm, and the head is the most prominent part because of the rapid development of the brain; the sex can be distinguished at this stage. At the time of fertilization the ovum contains the potential beginnings of a human being. As cell division takes place the cells of the blastoderm (embryonic disk) gradually form three layers from which all the body structures develop. The ectoderm (outer layer) gives rise to the epidermis of the skin and its appendages, and to the nervous system. The mesoderm (middle layer) develops into muscle, connective tissue, the circulatory organs, circulating lymph and blood cells, endothelial tissues within the closed vessels and cavities, and the epithelium portion of the urogenital system. From the endoderm (internal layer) are derived those portions not arising from the ectoderm, the liver, the pancreas, and the lungs.

*Id.*

<sup>25</sup> Zhao, *supra* note 16, at 121–22.

<sup>26</sup> *About Human Germline Gene Editing*, CTR. FOR GENETICS & SOC'Y (July 9, 2015), <https://www.geneticsandsociety.org/internal-content/about-human-germline-gene-editing>.

<sup>27</sup> J. Ravindra Fernando, Note, *Three's Company: A Constitutional Analysis of Prohibiting Access to Three-Parent In Vitro Fertilization*, 29 NOTRE DAME J.L. ETHICS & PUB. POL'Y 523, 528 (2015).

<sup>28</sup> *Id.*

<sup>29</sup> Ruth L. Fischbach et al., *Creating a Three-Parent Child: An Educational Paradigm for the Responsible Conduct of Research*, 15 J. MICROBIOLOGY & BIOLOGY EDUC. 186, 186

“Mitochondria are ‘responsible for providing more than 90% of the energy needed by the body to sustain life and support growth.’”<sup>30</sup>

In reproduction, the egg and the sperm each carry half of the required number of chromosomes and combine their nuclear DNA (nDNA)<sup>31</sup> to create a zygote,<sup>32</sup> which divides to form an embryo.<sup>33</sup> MtDNA, however, is unique in that it is not created by a combination of the parents’ DNA.<sup>34</sup> Instead, individuals inherit mtDNA exclusively from their mothers.<sup>35</sup> Although mtDNA accounts for a very small percentage of the human genome, mitochondrial gene mutations can cause severe neurological consequences.<sup>36</sup> “Mitochondrial dysfunction has been recognized as a significant cause of a number of serious multi-organ diseases. Tissues with a high metabolic demand such as brain, heart, muscles, [and central nervous system] CNS are often affected.”<sup>37</sup> Health conditions that arise out of mitochondrial disease can be due to mutations in mtDNA or in nuclear genes involved in mitochondrial function.<sup>38</sup> Mitochondrial disease may contribute to many common and serious illnesses such as Alzheimer’s, Parkinson’s, diabetes, arthritis, cancer, and premature aging.<sup>39</sup> “There is no curative treatment for patients with mitochondrial disease, [and] given the lack of treatments and the limitations of prenatal and preimplantation diagnosis, attention has focused on prevention of transmission of mitochondrial disease through

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(2014).

<sup>30</sup> Nicole Baffi, *The Good, The Bad, and the Healthy: How Spindle-Chromosomal Complex Transfer Can Improve the Future*, 74 ALB. L. REV. 361, 363 (2010).

<sup>31</sup> *Difference Between Mitochondrial DNA and Nuclear DNA*, MAJOR DIFFERENCES, <http://www.majordifferences.com/2015/05/difference-between-mitochondrial-dna.html#.WhhZ-kyZPgo> (last visited Feb. 24, 2018). Nuclear DNA (nDNA) makes up approximately 93% of the total DNA in a human being. *Id.* It is made up of 3.3 billion DNA base pairs and codes for all proteins required for its function. *Id.* nDNA is inherited equally between the parents, unlike mtDNA, which is only inherited from the maternal line. *Id.*

<sup>32</sup> *Zygote*, COLLINS, <https://www.collinsdictionary.com/us/dictionary/english/zygote> (last visited Feb. 24, 2018) (“A zygote is an egg that has been fertilized by sperm, and which could develop into an embryo.”).

<sup>33</sup> ASSOC. OF REPROD. HEALTH PROF’LS, HUMAN CLONING AND GENETIC MODIFICATION: THE BASIC SCIENCE YOU NEED TO KNOW 5, <http://www.arhp.org/uploadDocs/cloning.pdf>.

<sup>34</sup> Fischbach et al., *supra* note 29, at 187.

<sup>35</sup> Fernando, *supra* note 27, at 529.

<sup>36</sup> Fischbach et al., *supra* note 29, at 187.

<sup>37</sup> Paula Amato et al., *Three-Parent IVF: Gene Replacement for the Prevention of Inherited Mitochondrial Diseases*, NAT’L CTR. FOR BIOTECHNOLOGY INFO. (Jan. 1, 2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4005382/>.

<sup>38</sup> *Id.*

<sup>39</sup> Baffi, *supra* note 30, at 361.

[HGGM] therapy.”<sup>40</sup> MtDNA mutations are difficult to identify within the mother’s eggs because of the mutation’s inconsistent and erratic nature.<sup>41</sup> This has created a considerable challenge to find ways to prevent mutated mtDNA from genetically transferring to the child.<sup>42</sup> Approximately 1 in 4,000 children are born in the U.S. with an inherited mitochondrial disease.<sup>43</sup>

#### B. *Mitochondrial Replacement Therapy*

Mitochondrial Replacement Therapy (MRT) is an experimental ART for women with “aged eggs”<sup>44</sup> or mitochondrial disease who want to avoid passing the disease to their children.<sup>45</sup> Essentially, MRT involves transferring DNA between two fertilized eggs, creating a new embryo containing the core nDNA from the mother and father and the healthy mtDNA from a female egg donor.<sup>46</sup> This therapy results in a child with DNA from three different people.<sup>47</sup> There are two methods by which MRT can be performed: the pronuclear transfer method and the maternal spindle transfer method.<sup>48</sup>

**1. *Pronuclear transfer method.*** The pronuclear transfer method involves removal of genetic material from an embryo created from the donor sperm and egg, which is then replaced with genetic material from a second embryo created from the paternal sperm and egg.<sup>49</sup> First, the mother’s egg (with mitochondrial disease) is fertilized with the father’s sperm, creating an embryo.<sup>50</sup> Second, the donor egg is fertilized with donor sperm and the nDNA is removed—leaving behind the donor’s healthy mitochondria and also creating an embryo.<sup>51</sup> The final step is to transfer the nDNA from the mother’s embryo to the donor embryo where the healthy mitochondria

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<sup>40</sup> Amato et al., *supra* note 37.

<sup>41</sup> Baffi, *supra* note 30, at 362.

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

<sup>43</sup> Amato et al., *supra* note 37.

<sup>44</sup> *See supra* note 15 and accompanying text.

<sup>45</sup> *See supra* note 15 and accompanying text.

<sup>46</sup> Padmini Cheruvu, *Three-Parent IVF and Its Effect on Parental Rights*, 6 HASTINGS SCI. & TECH. L.J. 73, 76 (2014).

<sup>47</sup> Amy B. Leiser, Note, *Parentage Disputes in the Age of Mitochondrial Replacement Therapy*, 104 GEO. L.J. 413, 414 (2016).

<sup>48</sup> *Id.* at 420.

<sup>49</sup> Cheruvu, *supra* note 46.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

remains.<sup>52</sup> This provides a viable, healthy embryo with the nDNA of the mother and father and the mtDNA of the donor.<sup>53</sup>

2. ***Maternal spindle transfer method.*** Dr. Zhang, from New Hope Fertility Center in New York, utilized the maternal spindle transfer method (MST) for the Jordanian couple.<sup>54</sup>

[MST] involves placing nuclear material from the mother's egg into a donor egg "shell," which contains healthy mitochondria but no nDNA. In this method the egg is fertilized with the father's sperm in vitro, but not until after the transfer occurs. Since an unfertilized egg is more susceptible to damage, researchers believe that the more complex pronuclear transfer method, which involves two in vitro fertilizations, will be the preferred, future technique.<sup>55</sup>

The medical profession is highly regarded because of the significant role it plays in the well-being of society. This high regard comes with high standards: the imposition of heightened standards of care and informed consent on the medical industry. Pronuclear transfer and maternal spindle transfer are both methods used in three-parent IVF procedures that require great care and diligence from the medical professionals administering the procedures to patients. This next section will discuss those standards and how they pertain to three-parent IVF.

## II. PROPER STANDARDS OF CARE AND INFORMED CONSENT FOR MEDICAL PROCEDURES

Medical professionals are held to high standards, but those standards are not always adequate for every medical procedure. There is a standard of care that is practically universal to all physicians in the United States: the customary care model.<sup>56</sup> But, is this model sufficient for three-parent IVF procedures? And, what role the patient should play when deciding for or against a certain medical procedure? These are questions that must be answered, especially within the context of three-parent IVF.

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<sup>52</sup> Tina Hesman Saey, *How to Make a 'Three-Parent' Baby: Scientists Combined an Egg, Sperm and Some Donor DNA to Create a Baby*, SCI. NEWS FOR STUDENTS (Feb. 21, 2017 7:10 AM), <https://www.sciencenewsforstudents.org/article/how-make-three-parent-baby>.

<sup>53</sup> *Id.*

<sup>54</sup> Liat Clark, *Three-Parent Babies: How are They Made and is the IVF Legal?*, WIRED (Jan. 18, 2017), <http://www.wired.co.uk/article/what-is-three-person-ivf>.

<sup>55</sup> Cheruvu, *supra* note 46, at 76 (footnotes omitted).

<sup>56</sup> BARRY R. FURROW ET AL., HEALTH LAW 265 (2nd ed. 2000).

A. *The Standards of Care in the United States*

Judges and juries do not establish the standards by which medical services are to be delivered to the public.<sup>57</sup> In fact, these standards are created solely by the medical professionals themselves, and courts simply enforce these standards in lawsuits.<sup>58</sup> A plaintiff has the burden to prove that the doctor breached the standard of care, and most courts give conclusive weight to that standard.<sup>59</sup>

Tom Baker, author of *The Medical Malpractice Myth*, states his opinion relating to the seriousness of having correct standards of care in place:

One very clear conclusion emerges from the research on medical malpractice and medical malpractice lawsuits: The real medical malpractice problem is medical malpractice. It is not pretty to say, but doctors and nurses make *preventable* mistakes that kill more people in the United States every year than workplace and automobile accidents combined. Any research-driven approach to medical liability reform must start with this fact firmly in mind.<sup>60</sup>

This section will discuss the two standard of care models: the customary care standard and the evidence-based standard.

Doctors are liable when they make certain mistakes. Society generally demands that a doctor not be immune from liability to ensure quality healthcare delivery. The customary care standard is used throughout the country to determine a doctor's liability.<sup>61</sup> This custom-based standard of care is the requisite degree of both care and skill, based on the medical knowledge available, that a PR actioner in a provider's specialty must demonstrate.<sup>62</sup> "Custom-based medical practice can have a profoundly negative impact on the quality and cost of healthcare. . . . The customary care (or eminence-based) model of medical practice is based on physician

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<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> TOM BAKER, *THE MEDICAL MALPRACTICE MYTH* 157 (reprt. 2007).

<sup>61</sup> Katharine Van Tassel, *Harmonizing the Affordable Care Act with the Three Main National Systems for Healthcare Quality Improvement: The Tort, Licensure, and Hospital Peer Review Hearing Systems*, 78 BROOK. L. REV. 883, 884 (2013).

<sup>62</sup> David Goguen, *What is the Medical Standard of Care?*, ALLLAW, <http://www.alllaw.com/articles/nolo/medical-malpractice/standard-of-care.html> (last visited Feb. 24, 2018).

preference grounded in tradition, opinion, or clinical experience and not on objective, scientific evidence.”<sup>63</sup> Conversely, the evidence-based standard of care can have a positive impact on the quality and cost of healthcare because it includes research, clinical expertise, and patient preferences and values.<sup>64</sup>

There are five ways that the evidence-based standard benefits the healthcare system as a whole: (1) it helps physicians stay up-to-date on standardized protocols that are evidence-based; (2) the standard requires near real-time data for physicians to make health care decisions; (3) it promotes transparency and accountability; (4) it improves the overall quality of care administered; and (5) it has better clinical outcomes.<sup>65</sup> Dr. John Haughom, senior advisor of Health Catalyst University, described the necessary and proper steps to be taken in evidence-based medicine.<sup>66</sup> First, teams of physicians must identify problems that need to be addressed, such as reducing

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<sup>63</sup> Van Tassel, *supra* note 61.

<sup>64</sup> John Haughom, *5 Reasons the Practice of Evidence-Based Medicine is a Hot Topic*, HEALTHCATALYST, <https://www.healthcatalyst.com/5-reasons-practice-evidence-based-medicine-is-hot-topic> (last visited Feb. 24, 2018). The evidence-based standard of care brings more efficiency to the healthcare system by incorporating meaningful patient involvement:

Practicing evidence-based medicine is important in today’s healthcare environment because this model of care offers clinicians a way to achieve the Triple Aim’s objectives of improved quality, improved patient satisfaction, and reduced costs. To understand how, consider the prostate cancer example. With evidence-based medicine, a provider can assess the strength of the evidence as well as the risks and benefits of ordering diagnostic tests and treatments for each cancer patient. Such an approach, couples with the provider’s clinical experience, enables the provider to better predict if a treatment will do more harm than good. It also helps the organization establish a systematic approach to caring for patients with specific conditions . . . . As reported in the article “The Importance and Impact of Evidence-Based Medicine,” using evidence-based medicine “help[s] physicians provide more rational care with better outcomes.” Evidence-based medicine is not just about using evidence to design treatment plans; It also encourages a dialogue between patients and providers, so patients can share in the decision-making and make their values and preferences known. Together, patient and provider can determine an appropriate course of action—or no course of action if that’s on the joint decision. The benefit of this approach is that providers listen to patient concerns and take them into consideration to determine the appropriate treatment plan.

*Id.*

<sup>65</sup> *Id.*

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

readmissions or some other high-priority problem.<sup>67</sup> Some questions that physicians can ask themselves are: Why are we practicing in this manner? Are we adhering to best practices, and can we produce better outcomes with more consistency? Second, the physicians must acquire the best possible evidence that is available to them.

There are many different sources of evidence—from the knowledge clinicians gain from treating their patient populations to new research being discovered from highly organized randomized controlled trials (RCTs). . . . To help clinicians compare the quality between the various sources of evidence, Dr. David Sackett, MD, popularized the evidence-based medicine pyramid.<sup>68</sup>

The evidence-based medicine pyramid recognizes four types of evidence that physicians must wade through to find the best information out there.<sup>69</sup> Third, Dr. Haughom notes that the physician must appraise the evidence to make sure it is applicable to the patient(s) being considered.<sup>70</sup> Fourth, the physician applies the evidence to her practice of medicine on a regular basis.<sup>71</sup> “If the evidence passes the appraisal step and adds value to the practice of medicine, then clinicians can incorporate the new knowledge into their daily clinical practice.”<sup>72</sup> Finally, the physician must assess her performance to ensure that best outcomes are being consistently achieved.<sup>73</sup> An evidence-based standard of care that follows these steps can lower medical costs and help achieve more efficient patient care in the United States.<sup>74</sup> Three-parent IVF, along with

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<sup>67</sup> *Id.*

<sup>68</sup> *Id.* (“[In the evidence-based pyramid,] the top level is the strongest because it underwent a systematic review process and meta-analysis. Evidence in the lowest is the weakest because it is primarily based on opinions and small sample sizes, which increases room for error.”).

<sup>69</sup> *Id.* The levels of evidence in the evidence-based pyramid are as follows: The first level is considered to be “the gold standard,” RCTs. *Id.* These RCTs are “free from any bias that might otherwise be introduced by the people involved.” *Id.* Level two consists of evidence from controlled trials without randomization and other relevant studies. *Id.* This level is not as reliable as the first level, but is still quite reliable. *Id.* The third level of evidence is based largely on expert opinions and has a large margin for errors. *Id.* The fourth and final level of evidence on the pyramid is evidence that is based on personal experiences. *Id.* Level three and four seem to makeup the custom-based standard of care when put together. *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> Van Tassel, *supra* note 61, at 889. Professor Van Tassel argues for a shift to an evidence-based standard of care:

regular IVF, requires such a standard due to the sensitive and technical nature of the procedure. Patients are required to sign an informed consent form for each and every medical procedure to be performed. That begs the question: What does being informed actually mean in the context of the medical profession? The next section deals with two different standards that exist and how they could affect three-parent IVF procedures in the future.

B. *Informed Consent: Paternalistic or Reasonable Patient?*

A person's body is her temple.<sup>75</sup> It is a general norm in American society that people must consent to activities—especially those that deal with the body<sup>76</sup>—and visiting the doctor is no exception to that rule.

The doctrine of informed consent developed out of strong judicial deference to individual autonomy, reflecting a prevalent belief in American jurisprudence that an individual has a right to be free from nonconsensual interference with his or her person, and a basic moral principle that it is wrong to force another to act against his or her will.<sup>77</sup>

At this point, some historical perspective on how informed consent has evolved over the years seems proper. Jay Katz,<sup>78</sup> physician and law

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The last several decades of public health research have revealed that customary care can actually be “bad” patient care. Customary care can lead to misuse and underuse of the delivery of healthcare. . . . The quality and cost problems with the customary care model have led to new national initiatives to move the United States toward a modern, evidence-based model of medical practice . . . .

*Id.* at 889, 899.

<sup>75</sup> *I Corinthians* 6:19 (“Do you not know that your body is a temple of the Holy Spirit who is in you, whom you have received from God? You are not your own.”).

<sup>76</sup> *Schloendorff v. Soc’y of New York Hosp.*, 211 N.Y. 125, 129 (1914) (“Every human being of adult years and sound mind has a right to determine what shall be done with his own body.”).

<sup>77</sup> FURROW ET AL., *supra* note 56, at 310.

<sup>78</sup> *Yale Law School Mourns Professor Jay Katz; Read Dean Koh Memorial Remarks*, YALE L. SCH. (Nov. 17, 2008), <https://law.yale.edu/yls-today/news/yale-law-school-mourns-prof-essor-jay-katz-read-dean-koh-memorial-remarks>. Yale Law School held a memorial service in Jay Katz’ memory and an article was written detailing his remarkable life:

[Jay Katz] graduated from the University of Vermont in 1944, and earned an M.D. from Harvard Medical School in 1949. After completing his internship and residency in New York, Katz served as 1st Lieutenant and Captain at the USAF Hospital at Maxwell Air Force Base in Alabama. He came to Yale in 1953 and was soon named Chief Resident of the outpatient

professor, authored *The Silent World of Doctor and Patient*. He stated: “[D]isclosure and consent, except in the most rudimentary fashion, are obligations alien to medical thinking and practice.”<sup>79</sup> Historically, the standards of consent primarily served as the basis for physicians to impose their will, essentially forcing the patients to agree with their physicians’ treatment plans.<sup>80</sup> The judiciary created the doctrine of informed consent, which moved, according to Katz, through three distinct eras of evolution before reaching its modern iteration.<sup>81</sup> The first era simply required the physician to tell the patient which course of treatment would be taken and nothing more.<sup>82</sup> This era can be roughly traced to the mid-twentieth century.<sup>83</sup> The second era of informed consent saw the arrival of patient inclusion, requiring physicians to give patients alternative treatment options along with any risks associated with those options.<sup>84</sup> This era lasted until the early 1970s.<sup>85</sup> The third era—the current state of informed consent—has changed very little from the previous one, in that physicians are required to give patients all available treatment options and all accompanying risks.<sup>86</sup>

The first case to mention informed consent was *Salgo v. Leland Stanford Jr. University Board of Trustees* in 1957.<sup>87</sup> Justice Bray stated in the majority opinion:

A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. A physician may not

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clinic at the School of Medicine. Katz began teaching psychiatry at Yale in 1955 and psychiatry and law in 1958 when he was named Assistant Professor of Psychiatry and Law at Yale University. . . . He was a leader in the area of reproductive technology law and ethics and was an outspoken opponent of the criminal prosecution of pregnant women, citing privacy and equal protection concerns.

*Id.*

<sup>79</sup> FURROW ET AL., *supra* note 56, at 311 (quoting JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 1 (1984)).

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *See generally* *Salgo v. Leland Stanford Jr. Univ. Bd. of Tr.*, 154 Cal.App.2d 560 (1957).

minimize the known dangers of a procedure or operation in order to induce his patient's consent.<sup>88</sup>

Generally speaking, the disclosure requirement means physicians must inform the patient of all available treatment options and any risks and benefits associated with them.<sup>89</sup> Further, it must include any alternative treatment options that are available, as well as the potential risks and benefits that flow from those alternatives.<sup>90</sup> Lastly, it is essential to include the option of no treatment at all, followed by a similar risk-benefit analysis.<sup>91</sup>

There are two models of informed consent, and they conflict with one another. The first standard is known as the "paternalistic" or physician-based standard, which is closely related to the customary care model.<sup>92</sup> It is grounded in profession uniformity and physician preference.<sup>93</sup> The second standard is known as the "reasonable patient" standard, where the patient's values and preferences are integrated into the decision-making process.<sup>94</sup>

***1. Physician-based standard, a.k.a. the paternalistic standard.***

A majority of states have adopted the physician-based standard as the standard for the disclosure requirement of informed consent.<sup>95</sup> It is rooted in the notion that the medical practice field needs to be uniform and consistent so that doctors are able to advance their patients' best interests in the most efficient and safe manner possible.<sup>96</sup> It requires expert testimony so doctors do not need to concern "themselves with the risk that an uninformed lay jury will later decide they acted improperly."<sup>97</sup> The majority of jurisdictions that have adopted this as the standard to disclosure require a plaintiff to show two things: that a reasonable doctor similarly situated would make the disclosure, and that the doctor did not comply with this standard.<sup>98</sup>

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<sup>88</sup> *Id.* at 578.

<sup>89</sup> Suzanne K. Ketler, Note, *The Rebirth of Informed Consent: A Cultural Analysis of the Informed Consent Doctrine After Schreiber v. Physicians Insurance Co. of Wisconsin*, 95 NW. U. L. REV. 1029, 1037 (2001).

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> FURROW ET AL., *supra* note 56, at 313.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.* at 314.

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* at 313.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* at 314.

2. **Reasonable patient standard.** The reasonable patient standard rebuts the majority view. The landmark case, *Canterbury v. Spence*, held that the reasonable patient standard was the most effective standard, with the court stating that “[w]e do not agree that the patient’s cause of action is dependent upon the existence and nonperformance of a relevant professional tradition.”<sup>99</sup> The *Canterbury* court emphasized that each patient has specific needs that are distinct and separate from other patients—thus the need for a reasonable patient disclosure standard.<sup>100</sup> In *Wheeldon v. Madison*, the court concluded that the physician-based standard may conflict with the patient’s specific needs.<sup>101</sup> The *Wheeldon* court stated: “[W]e adopt the *Canterbury v. Spence* rule that the standard measuring the performance of the physician’s duty to disclose is conduct which is reasonable under the circumstances.”<sup>102</sup> Even though the physician-based standard is currently followed by a majority of states, the reasonable patient standard is quickly approaching a majority position.<sup>103</sup>

### III. CURRENT CLIMATE FOR SAFETY REGULATION IN THE UNITED STATES

Three-parent IVF requires the use and manipulation of human-based products; therefore, great care and diligence are required to ensure patient safety. There are many federal agencies that oversee the human-based product industry to make sure that safety is the number one priority of medical providers.

The process of administering three-parent IVF, or regular IVF for that matter, requires multiple steps and has many different layers of safety regulation. First, there are technologies (such as devices and software) used in fertility treatment that are governed by the FDA.<sup>104</sup> It also regulates the safety of tissue-based products, including donated eggs and semen.<sup>105</sup> Second, there are laboratory tests performed on human tissues (such as eggs and semen), which are governed under the Clinical Laboratory Improvement Amendments (CLIA).<sup>106</sup> Third, there are safety regulations in place for techniques in the practice of medicine that are regulated by the individual states under their police powers.<sup>107</sup> Since safety is always a top priority when

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<sup>99</sup> *Canterbury v. Spence*, 464 F.2d 772, 783 (D.C. Cir. 1972).

<sup>100</sup> *Id.*

<sup>101</sup> *Wheeldon v. Madison*, 374 N.W.2d 367, 374 (S.D. 1985).

<sup>102</sup> *Id.*

<sup>103</sup> FURROW ET AL., *supra* note 56, at 314.

<sup>104</sup> *See infra* Part III.A.

<sup>105</sup> *See infra* Part III.A.

<sup>106</sup> *See infra* Part III.B.

<sup>107</sup> *See infra* Part III.C.

it comes to performing medical procedures, current safety regulations must be applied to three-parent IVF.

A. *FDA Safety Regulations for Human-Based Products*

The regulation of reproductive technologies seems to be an area from which the law tends to shy away: history has revealed that regulating reproductive health is a particularly sensitive topic.<sup>108</sup> At first glance, reproductive technologies regulation seems to be something that should fall to the individual states so they can protect their citizens' health and welfare.<sup>109</sup> However, states rarely oversee reproductive technologies. The FDA is responsible for safety regulation under the Public Health Service Act (PHSA), which means the FDA regulates reproductive technologies, not the individual states themselves.<sup>110</sup>

Three-parent IVF would fall directly under the FDA's safety regulations because the procedure deals with human-based products—semen and eggs—that are manipulated in laboratories.<sup>111</sup> Proper screening protocols for eligible patients and donors is of paramount importance to avoid the spread of communicable diseases. The FDA regulates safety in all of these areas.

The FDA currently regulates human tissue-based products,<sup>112</sup> which consist of the following: “human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient.”<sup>113</sup> Examples of human tissue that fit within the FDA's regulatory responsibility are “bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells, . . . oocytes, and semen.”<sup>114</sup>

The purpose of FDA tissue regulation is “to create an electronic registration and listing system for establishments that manufacture human cells, tissues, and cellular and tissue-based products . . . and to establish

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<sup>108</sup> See *Lawrence v. Texas*, 539 U.S. 558 (2003); *Bellotti v. Baird*, 443 U.S. 622 (1979); *Roe v. Wade*, 410 U.S. 113 (1973); *Griswold v. Connecticut*, 381 U.S. 479 (1965).

<sup>109</sup> Tandice Ossareh, *Would You Like Blue Eyes with That? A Fundamental Right to Genetic Modification of Embryos*, 117 COLUM. L. REV. 729, 734–35 (2017).

<sup>110</sup> *Id.* at 735.

<sup>111</sup> *Id.*

<sup>112</sup> *Tissue and Tissue Product Questions and Answers*, U.S. FOOD & DRUG ADMIN. (Feb. 2, 2018), <https://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/QuestionsaboutTissues/ucm101559.htm>.

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

donor-eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by [tissue-based products].”<sup>115</sup> It will be imperative that three-parent IVF donors and patients alike are adequately screened for eligibility. This safety regulation will help form the basis for the screening protocol for three-parent IVF procedures. The FDA should look to current screening protocols in place for regular IVF when deciding proper protocols to implement for three-parent IVF.

The FDA takes a risk-based approach to its regulation of tissue-based products with three goals in mind.<sup>116</sup> First, the regulation seeks to “limit[] the risk of transmission of communicable disease from donors to recipients.”<sup>117</sup> Second, it “establish[es] manufacturing practices that minimize the risk of contamination.”<sup>118</sup> Finally, it “requir[es] an appropriate demonstration of safety and effectiveness for cells and tissues that present greater risks due to their processing or their use.”<sup>119</sup> Limiting the transmission of communicable diseases and lowering the risk of contamination will be important goals when dealing with three-parent IVF. The procedure is quite invasive and technical—even more technical than regular IVF. Therefore, these three goals should be of the utmost importance for the FDA when determining a risk level to associate with three-parent IVF.

The main objective and focus for the FDA is to limit the transmission of communicable diseases. It is with this objective in mind that it applies safety regulations to the human tissue-based product industry. Three-parent IVF should and will be required to meet all FDA regulations and guidelines in order to ensure patient safety.

B. *Procedures Performed in Laboratories are Governed by CLIA*

Human-based products are regulated and screened for safety by the FDA, but the regulation does not stop there. These human-based products are manufactured and manipulated inside medical laboratories, and there are separate regulations applied to these individual laboratories under CLIA. This section will discuss these laboratory safety regulations and their importance to three-parent IVF.

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<sup>115</sup> 21 C.F.R. § 1271.1 (West 2016).

<sup>116</sup> *Tissue and Tissue Product Questions and Answers*, *supra* note 112.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

The world is seeing a rapid advancement in technology, and its reach has broad implications. Health care delivery is turning to a model of “personalized medicine,” which fosters more predictability and efficiency.<sup>120</sup> “U.S. laboratories that process human samples for health care treatment or prevention are subject to federal, state, and professional organization standards and regulations.”<sup>121</sup> Although CLIA is the federal regulatory standard, it does not preempt heightened state standards.<sup>122</sup> If a state chooses to implement standards that exceed CLIA, it is free to do so without objection from the federal regulatory bodies.<sup>123</sup>

Diagnostic testing helps health care providers screen for or monitor specific diseases or conditions. It also helps assess patient health to make clinical decisions for patient care. . . . [CLIA] regulate[s] laboratory testing and require[s] clinical laboratories to be certificated by their state as well as the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing. Laboratories can obtain multiple types of CLIA certificates, based on the kinds of diagnostic tests they conduct.<sup>124</sup>

The CLIA program’s main objective is to ensure both universal quality control over laboratory operations and the accuracy, proficiency, timeliness, and reliability of patient test results.<sup>125</sup> Laboratories that are regulated by CLIA are defined as “clinical laborator[ies].”<sup>126</sup> The broad definition of

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<sup>120</sup> MICHAEL J. MALINOWSKI & ANDREA NEAL, *Regulation of Commercial Laboratories*, in BIOTECHNOLOGY: LAW, BUS., & REG. 171 (2016).

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> *Clinical Laboratory Improvement Amendments (CLIA)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm> (last visited Feb. 24, 2018).

<sup>125</sup> MALINOWSKI & NEAL, *supra* note 120, at 172.

<sup>126</sup> The CLIA definition of what constitutes a “clinical laboratory” is as follows:

A facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings.

*Id.* at 171.

clinical laboratory includes hospitals, private physician offices, and all other clinical laboratories that are not engaged solely in research.<sup>127</sup>

Every laboratory that falls within the definition of a “clinical laboratory” must be CLIA certified.<sup>128</sup> CMS is primarily responsible for implementing the CLIA program, but the administration of CLIA is not the sole responsibility of one single department.<sup>129</sup> Instead, it is a combination of multiple federal agencies that are needed to administer CLIA in an efficient manner.<sup>130</sup>

The three federal agencies that help administer CLIA are CMS, FDA, and the Centers for Disease Control (CDC).<sup>131</sup> CMS is responsible for issuing laboratory certificates, collecting user fees, conducting site inspections, approving private accreditation organizations for performing site inspections, approving state exemption applications, monitoring laboratory performance, and publishing CLIA rules and regulations.<sup>132</sup> FDA is responsible for categorizing laboratory tests based on complexity and reviewing requests for waivers.<sup>133</sup> CDC is responsible for providing analysis, research, and technical assistance to laboratories; developing technical standards and laboratory practice guidelines; conducting laboratory quality improvement studies; and developing and distributing professional information and educational resources.<sup>134</sup> CMS lacks the resources to oversee all laboratories in the United States, so it approves private organizations to act as CLIA accreditation entities.<sup>135</sup> By statute, CMS must follow certain criteria when selecting a private accreditation organization.<sup>136</sup> To date, CMS has approved only seven CLIA accreditation organizations.<sup>137</sup>

CLIA regulation is not geographical in scope; in fact, geography does not even play any role in CLIA regulation.<sup>138</sup> Instead, CLIA regulates on the

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<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

<sup>129</sup> *Id.* at 173.

<sup>130</sup> *Id.*

<sup>131</sup> *Clinical Laboratory Improvement Amendments (CLIA)*, *supra* note 124.

<sup>132</sup> *Id.*

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

<sup>134</sup> *Id.*

<sup>135</sup> MALINOWSKI & NEAL, *supra* note 120, at 173.

<sup>136</sup> See 42 U.S.C.A. § 263a (e)(2)(A) i–vi (West 2012) (stating the criteria for selecting accreditation organizations).

<sup>137</sup> MALINOWSKI & NEAL, *supra* note 120, at 174.

<sup>138</sup> *Id.* at 175.

basis of its complexity model—the higher the risk, the more stringent the regulation.<sup>139</sup> A laboratory seeking CLIA certification is evaluated using a risk scorecard that lists seven criteria.<sup>140</sup> Based on the results from the complexity scorecard's criteria, CMS will apply the requisite regulatory standards to that particular laboratory. Three-parent IVF will likely receive a high complexity score due to its invasive and technical nature, leading to tougher regulations. CLIA will ensure that three-parent IVF is administered in a safe and healthy environment each and every time.

C. *Medical Malpractice is Governed by the Individual States*

Practicing physicians are primarily regulated by their respective states.<sup>141</sup> States govern and regulate the practice of medicine because it directly relates to the health and general welfare of their citizens.<sup>142</sup> Fertility physicians who perform three-parent IVF procedures will be required to adhere to their states' procedures and policies concerning the practice of fertility medicine.<sup>143</sup> As mentioned before, three-parent IVF is a procedure

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<sup>139</sup> *Id.*

<sup>140</sup> The CLIA complexity scorecard criteria are as follows:

- (1) Knowledge: the degree of scientific and technical knowledge that is required to perform the test;
- (2) Training and experience: the degree of experience required for the pre-analytical, analytical, and post-analytical phases of the testing process;
- (3) Reagents and materials: the extent to which reagents and materials used in the test process or system are generally stable and reliable or require special handling, precautions, and storage conditions;
- (4) Characteristics of operational steps: the extent to which steps in the testing process are automatically executed and otherwise easily controlled or require close monitoring, special specimen preparation, temperature control, timing, extensive calculations, and other precautions;
- (5) Calibration, quality, and control, and proficiency testing materials: the stability and availability of these materials;
- (6) Test system troubleshooting and equipment maintenance: the extent to which test system troubleshooting is automatic or self-correcting and requires minimal judgment, or requires decision making and direct intervention;
- (7) Interpretation and judgment: the level or interpretation and judgment required to perform pre-analytic, analytic, and post-analytic processes to resolve problems.

*Id.* at 177–79.

<sup>141</sup> *Medical Liability and Malpractice*, NAT'L CONF. ST. LEGISLATURES, <http://www.ncsl.org/research/financial-services-and-commerce/medical-liability-and-malpractice.aspx> (last visited Feb. 24, 2018).

<sup>142</sup> *Id.*

<sup>143</sup> *Id.*

with multiple steps—each step with its own set of safety regulations.<sup>144</sup> This section will discuss the steps that are necessary to provide adequate health care to patients and how negligence principles dominate the practice of medicine.

The relationship between a doctor and patient is an intimate one. Patients oftentimes trust their doctor completely and, without reservation, agree to her recommendations regarding treatment. This surely seems logical because the doctor has been through medical school and is well-versed in the human body and its ailments. The average person is not comfortable with self-diagnosis, so visiting the doctor's office is essential for health and well-being. What happens when that trusted doctor makes a critical mistake while treating her patient? Is she liable for her actions? The short answer: it depends.

In order to find liability, a number of factors must be present. There must be an adequate doctor–patient relationship.<sup>145</sup> This relationship is developed by implied and express contracts between doctor and patient.<sup>146</sup> Doctors expressly contract with patients in many different situations, such as when an orthopedic surgeon expressly contracts to perform orthoscopic knee surgery or when an ophthalmologist expressly contracts to perform a surgery for cataracts. Both of these situations require the doctor and patient to enter into an express contract with one another, thus creating the adequate doctor–patient relationship. Express contracts are not the only means to develop this doctor–patient relationship; in fact, they are not even the dominant method.<sup>147</sup> “The vast majority of contracts in the field between healthcare professionals and their patients are implied contracts.”<sup>148</sup> For example, when a patient visits a doctor's office, the patient is essentially offering to enter into a contract with the doctor.<sup>149</sup> An implied contract is created once the doctor agrees to evaluate the patient.<sup>150</sup>

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<sup>144</sup> See *supra* Parts III.A–B.

<sup>145</sup> FURROW ET AL., *supra* note 56, at 260.

<sup>146</sup> *Id.*

<sup>147</sup> *Express & Implied Contracts from a Physician*, MALPRACTICE LAWS, <https://malpractice.laws.com/professional-patient-relationship/express-implied-contracts-from-a-physician> (last visited Feb. 24, 2018).

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

<sup>149</sup> FURROW ET AL., *supra* note 56, at 260–61.

<sup>150</sup> *Id.* at 264.

“The liability of health care providers is governed by general negligence principles. Malpractice is usually defined as unskillful practice resulting in injury to the patient, a failure to exercise the ‘required degree of care, skill and diligence’ under the circumstances.”<sup>151</sup> Each individual state, not the federal government, regulates medical-malpractice claims among its physicians.<sup>152</sup>

Under state law, a patient may pursue a civil claim against physicians or other health care providers, called medical liability or medical malpractice, if the health care provider causes injury or death to the patient through a negligent act or omission. To recover damages, the patient must establish: (1) The physician owed a duty to the patient; (2) The standard of care and that the physician violated that standard; (3) A compensable injury; and (4) The violation of the standard of care caused the harm suffered by the patient.<sup>153</sup>

Three-parent IVF claims will likely be primarily rooted in negligence principles, although contract claims will always persist among fertility plaintiffs with the lack of defined remedies available to them.

The real problem with medical malpractice is that it is unavailable to a vast majority of fertility plaintiffs due to its high costs. A physician’s medical-malpractice insurance company will likely have a team of lawyers that can defend any lawsuit that comes its way. Unfortunately, the same cannot be said for most fertility plaintiffs. Money seems to put up an insurmountable barrier, due to most fertility plaintiffs’ inability to pay for the high cost of medical-malpractice litigation.

Medical malpractice has far-reaching effects. Patients, and the healthcare industry as a whole, are greatly affected by the inefficient medical-malpractice system in the United States.<sup>154</sup> Patients are affected in many different ways, which can include reluctance to seek out medical help due to negligence claims towards a physician or hospital.<sup>155</sup> Such malpractice suits could impede the trust and openness in the doctor-patient relationship, which

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<sup>151</sup> *Id.*

<sup>152</sup> *Medical Liability and Malpractice*, *supra* note 141.

<sup>153</sup> *Id.*

<sup>154</sup> *Malpractice and Its Effects on the Healthcare Industry*, TEX. A&M U. CORPUS CHRISTI (Sept. 27, 2016), <https://online.tamucc.edu/articles/malpractice-and-its-effects-on-the-healthcare-industry.aspx>.

<sup>155</sup> *Id.*

is foundational to the efficient delivery of healthcare in the United States.<sup>156</sup> Generally, physicians purchase medical-malpractice insurance, as most physicians do not possess the necessary resources to adequately defend a medical-malpractice lawsuit on their own.<sup>157</sup>

Any and every system in the modern world seems to have a common overarching concern—efficiency. Dr. Ezekiel Emanuel<sup>158</sup> believes there is an efficiency problem with the medical-malpractice system in the United States that is largely due to defensive medicine practices,<sup>159</sup> stating that “[o]ne of the biggest concerns for physicians is medical malpractice. It agitates them so much that it is often hard for them to focus on anything else, and it is not hard to be sympathetic to their concerns.”<sup>160</sup> Dr. Emanuel goes on to say, “[m]any physicians are convinced that the high rate of medical-malpractice suits encourage high levels of defensive medicine and excessive costs, such as MRIs of the head after mild trauma that are unnecessary according to professional guidelines but are done just in case of a lawsuit.”<sup>161</sup>

This connection between exorbitant health care costs and the fear of being sued is easily understood. Aside from being expensive for physicians, the medical-malpractice system cripples the patient. There are three general goals, or purposes, that the medical-malpractice system aims to accomplish: first, to make sure that patients who are injured by a physician’s negligence are adequately compensated in a reasonable time frame; second, to ensure

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<sup>156</sup> *Id.*

<sup>157</sup> Dixon Davis, *Malpractice Insurance: What Physicians Need to Know*, PHYSICIANS PRAC. (Jan. 9, 2013), <http://www.physicianspractice.com/blog/malpractice-insurance-what-physicians-need-know>.

<sup>158</sup> Dr. Ezekiel Emanuel is an American bioethicist and oncologist. Juliet Eilperin & Amy Goldstein, *Ezekiel Emanuel, An ACA Architect, is Now Advising Trump as GOP Works to Level the Law*, CHICAGO TRIB. (March 21, 2017, 7:20 AM), <http://www.chicagotribune.com/news/nationworld/politics/ct-ezekiel-emanuel-trump-gop-obamacare-20170320-story.html>. His brother is Rahm Emanuel, current Mayor of Chicago. *Id.* Dr. Emanuel served as a special advisor on health policy for the Obama administration—playing a critical role in the creation of the Affordable Care Act (ACA). *Id.* Dr. Emanuel was hired as a Fox News contributor and he is currently serving the Trump administration as a health care policy advisor. Peter Sterne, *Fox News Hires Dr. Ezekiel Emanuel*, POLITICO (Feb. 21, 2017, 12:05 PM), <https://www.politico.com/blogs/on-media/2017/02/fox-news-hires-ezekiel-emanuel-as-contributor-235227>. He also is a regular columnist for the New York Times. *Id.* Dr. Emanuel is famous for being known as the “death doctor” due to his views of old age in relation to quality of life. Ezekiel J. Emanuel, *Why I Hope to Die at 75*, ATLANTIC (2014), <https://www.theatlantic.com/magazine/archive/2014/10/why-i-hope-to-die-at-75/379329/>.

<sup>159</sup> EZEKIEL J. EMANUEL, *REINVENTING AMERICAN HEALTH CARE* 120 (2014).

<sup>160</sup> *Id.*

<sup>161</sup> *Id.* at 122–23.

accountability among physicians, hospitals, and other health care providers; and third, to improve the quality of health care by deterring negligent behavior from physicians and other health care providers.<sup>162</sup>

The inefficiency problem of the medical-malpractice system is harmful to fertility plaintiffs around the country. Harvard researchers conducted a study that looked into just how inefficient medical malpractice truly is. The study involved more than 30,000 medical records in the state of New York and came to the conclusion that “97% of the time when a physician or hospital commits a mistake that harms a patient, there is no lawsuit.”<sup>163</sup> Dr. Emanuel explained:

The malpractice system is . . . not efficient. . . . [T]he average time to settle a malpractice lawsuit is 20.3 months. Further, only about 40 cents of every dollar in malpractice premiums paid by physicians goes to injured patients; the rest is absorbed in administrative and litigation costs and insurance company profits.<sup>164</sup>

The inefficiency of the medical-malpractice system in the United States is harmful to both physicians and patients alike. The three general goals of the medical-malpractice system (timely compensation, accountability, and deterrence) are not being met; therefore, there is a need for medical-malpractice reform in the United States. Until this reform can take place, three-parent IVF will need something to ensure remedies for injured fertility patients.

#### IV. TOWARD A SOLUTION: THREE-PARENT IVF AND MEDICAL MALPRACTICE IN THE UNITED STATES

The law is usually slow when dealing with new developments in technology.<sup>165</sup> There are currently no legal theories or claims that are available specifically for IVF plaintiffs: therefore, no claims will exist for three-parent IVF plaintiffs, either.<sup>166</sup> Legal practitioners often use existing legal theories, such as tort law and contract law theory, to deal with new

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<sup>162</sup> *Id.* at 121.

<sup>163</sup> *Id.* at 122.

<sup>164</sup> *Id.*

<sup>165</sup> Vivek Wadhwa, *Laws and Ethics Can't Keep Pace with Technology*, MIT TECH. REV. (April 15, 2014), <https://www.technologyreview.com/s/526401/laws-and-ethics-cant-keep-pace-with-technology/>.

<sup>166</sup> *Basic Law of In Vitro Fertilization*, STIMMEL L., <https://www.stimmel-law.com/en/arti-cles/basic-law-vitro-fertilization> (last visited Feb. 24, 2018).

technological developments.<sup>167</sup> For example, an IVF plaintiff will oftentimes claim breach of contract when seeking damages.<sup>168</sup> Legislation is currently silent on the specific legal remedies that are available to IVF plaintiffs, hence the need for the application of other legal theories. The immediate need is for specific legislation addressing IVF liability in the United States; in the future, three-parent IVF liability must also be addressed. Regular IVF and three-parent IVF liability should be treated differently, as three-parent IVF procedures are riskier and more complex. The science behind three-parent IVF is also in its infancy, unlike regular IVF, so considerable precautions should be taken as the law moves forward to deal with what liability to assess. This section will recommend legislation addressing three-parent IVF liability in regards to the following: (1) the standard of care given by physicians; (2) the informed consent standard imposed on physicians; and (3) the medical-malpractice arena concerning three-parent IVF procedures—specifically the implementation of a fertility court.

A. *Recommendations for Three-Parent IVF in the United States*

**1. Implement three-parent IVF as a clinical trial to conduct research.** Three-parent IVF is in its infancy, and much research is needed to ensure that it is reasonably safe. The lack of empirical evidence to show that three-parent IVF is safe is a primary reason for countries holding back from legalizing the procedure.<sup>169</sup> Another reason is the argument that three-parent IVF could lead to “designer babies.”<sup>170</sup> To date, the United Kingdom is the only country that has legalized the procedure.<sup>171</sup> Other countries, such as Mexico and Ukraine, are silent on the procedure, which is likely part of the

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<sup>167</sup> *Id.*

<sup>168</sup> *Id.*

<sup>169</sup> Nicholas Misketi, *Why Canada Isn't Ready to Talk About '3-Parent' Babies: Stiff Penalties, 'Designer Baby' Fears May be Silencing Debate About Mitochondrial Replacement Therapy*, CBCNEWS (Mar. 1, 2015, 9:47 AM), <http://www.cbc.ca/news/health/why-canada-isn-t-ready-to-talk-about-3-parent-babies-1.2956257>.

<sup>170</sup> *Designer Babies*, FUTUREFORALL.ORG, <http://www.futureforall.org/bioengineering/designer-babies.html> (last visited Feb. 24, 2018) (“The colloquial term ‘designer baby’ refers to a baby whose genetic makeup has been artificially selected by genetic engineering combined with in vitro fertilization to ensure the presence or absence of particular genes or characteristics. In simpler terms, using biotechnology to choose what type of baby you want.”).

<sup>171</sup> Gretchen Vogel & Erik Stokstad, *U.K. Parliament Approves Controversial Three-Parent Mitochondrial Gene Therapy*, SCIENCE (Feb. 3, 2015), <http://www.sciencemag.org/news/2015/02/uk-parliament-approves-controversial-three-parent-mitochondrial-gene-therapy>.

reason that fertility physicians have performed procedures in those countries. Legislation in the United States is unlikely to occur in the near future, at least until more rigorous testing and research can be conducted on three-parent IVF's safety and effectiveness.

However, this should not prevent women who suffer from mitochondrial disease from having healthy children in the United States. If they so choose, the option should be available to them within the borders of the United States before legislation fully legalizes the procedure. This Comment recommends that three-parent IVF be implemented in the United States as a clinical trial<sup>172</sup> to procure the necessary data required to make an educated decision on proper legislation going forward. Those who choose to have a child using the three-parent IVF procedure in the United States shall participate (as a patient in the clinical trial) in a follow-up program, primarily for purposes of monitoring the child into adulthood. This will allow scientists and researchers to assess and monitor risks and outcomes, with the long-term goal of gathering enough empirical evidence to write legislation to formally legalize three-parent IVF in the United States as a fertility treatment.

**2. *The need for an evidence-based standard of care for three-parent IVF procedures in the United States.*** Three-parent IVF is new, innovative, and groundbreaking in fertility medicine. A medical standard of care needs to be able to keep up with the implementation of such a procedure, and the customary care standard is not sufficient to adequately serve the purposes of three-parent IVF. The customary care model of medical practice is based on physician preferences that are grounded in tradition, opinion, or clinical experience and not on objective, scientific evidence.<sup>173</sup> It is quite evident that this standard will fall short, because there will be no clinical

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<sup>172</sup> Nat'l Heart, Lung, & Blood Inst., *What Are Clinical Trials*, U.S. DEP'T HEALTH & HUM. SERV., <https://www.nhlbi.nih.gov/studies/clinicaltrials> (last visited Feb. 24, 2018) (follow "What Are Clinical Trials?" hyperlink). Clinical trials are essential for gathering important empirical data for research purposes to ensure the safety of three-parent IVF procedures:

Clinical trials are research studies that explore whether a medical strategy, treatment, or device is safe and effective for humans. These studies also may show which medical approaches work best for certain illnesses or groups of people. Clinical trials produce the best data available for health care decision-making. The purpose of clinical trials is research, so the studies follow strict scientific standards. These standards protect patients and help produce reliable study results.

*Id.*

<sup>173</sup> Van Tassel, *supra* note 61, at 884.

experience or tradition of three-parent IVF from which physicians can glean a standard. Three-parent IVF desperately needs an evidence-based standard to be implemented because it will ensure that objective, scientific evidence will be properly considered in the decision-making process by physicians when treating patients. Evidence-based medicine relies heavily on scientific data to allow physicians to make informed decisions regarding patient care. Skeptics will argue that this will create a problem in courts dealing with three-parent IVF cases, since scientific data will be sparse in the beginning stages of clinical trials.<sup>174</sup> Although it is true that three-parent IVF has limited scientific evidence of its effectiveness and safety to date, this hurdle will be overcome by looking to other countries around the world, including the United Kingdom, to see clinical outcomes and safety.

**3. *Informed consent standards for three-parent IVF: the reasonable patient standard over paternalism.*** Patients are increasingly becoming more involved with their own care.<sup>175</sup> “[H]ealth care leaders are

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<sup>174</sup> Skeptics of the evidence-based standard will argue that the court system will not be able to effectively accommodate such a new medical procedure:

Because much medical research consists of case reports or small case studies with a limited number of patients, quality data outcomes are sparse. Treatments for some conditions or diseases have no empirical proof of efficacy or safety. Regardless, these treatments may be recognized by a particular medical specialty as the standard of care.

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Courts typically do not have the luxury of holding their decisions in abeyance until a body of research develops. Although there may be expert opinions and animal studies, will the absence of human population epidemiological studies prevent claimants from proving their cases? Indeed, would a proliferation of evidence-based medicine prevent courts from resolving a significant number of disputes? Would this shift favor criminal and civil wrongdoers?

In a civil case, verdicts are determined to be the “great weight of the evidence.” This is often defined as 51 percent. Yet in science, a finding is not deemed reliable unless it is proven to have at least 95 percent reliability. Does this mean that the civil proof requirement will de facto shift from 51 percent to 95 percent? And would such a standard, if adopted, deny access to the courts and prevent courts from performing their duties to resolve disputes and maintain order?

J. Douglas Peters, *Evidence-Based Medicine in Court*, 38 TRIAL 74, 77–78 (2002).

<sup>175</sup> Len Schlesinger & John Fox, *Giving Patients an Active Role in Their Health Care*, HARV. BUS. REV. (Nov. 21, 2016), <https://hbr.org/2016/11/giving-patients-an-active-role-in-their-health-care>.

focused more than ever on patient engagement as a key to driving down costs and improving outcomes.”<sup>176</sup> Fertility treatment, in particular, is a sensitive topic to discuss, and a woman who consents to a procedure as intimate as three-parent IVF must be afforded the right to be involved in her care every step of the way. The only standard that can adequately meet this burden is the reasonable patient standard. In order for this standard to be fully effective, the healthcare system must define a specific role for the patient within the delivery of care.<sup>177</sup> In essence, we need to define the role of the patient as a person with a job:<sup>178</sup>

If the patient is to have a job in the care-delivery process, we must apply the same principles of intentional work design to their jobs as we do to those of physicians and clinical staff. . .

We know from classic management theory . . . applied and tested in other service-industry contexts what good job design looks like. Well-designed jobs, for example, give individuals a clearly defined role to play with sufficient autonomy and regular performance feedback built in. This not only allows people to execute tasks effectively but also gives them a sense of meaning and satisfaction in their work by seeing the connection between their efforts and outcomes.<sup>179</sup>

It is important that patients are given the opportunity to play a meaningful role in the administration of three-parent IVF because, like most ART procedures, it will likely include very personal and patient-specific needs.

Medical professionals are some of the most skilled and valuable people in society. But just as with any other profession, they are not without fault. As discussed earlier, physicians make mistakes and these mistakes can oftentimes lead to injuries—both physical and psychological—to their patients. The manner in which these injuries are remedied must be equitable for each and every patient, because injured patients should not be required to live with an injury without just compensation. Since filing a medical-malpractice lawsuit can be costly, to the point of being out of reach for some patients due to cost, there needs to be an alternative way to reach equitable solutions for all fertility plaintiffs. This Comment proposes the establishment

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<sup>176</sup> *Id.*

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> *Id.*

of a fertility court within the United States Court of Federal Claims to provide a no-fault system for injured fertility plaintiffs who are seeking compensation for their injuries.

B. *A Lesson Learned from Vaccines: A Need for Fertility Court*

It is no secret that filing a medical-malpractice lawsuit can be expensive. So many would-be plaintiffs choose not to file suit due to the inherent risks that run with filing such a lawsuit. These are people who have suffered real and cognizable injuries—yet they choose to forgo compensation due to the costly nature and uncertainty of a medical-malpractice lawsuit. This generally limits injury awards in medical-malpractice cases to the upper-class plaintiffs who have the money to file these suits. In the 1980s, pharmaceutical companies were being hit hard with lawsuits over select childhood vaccines.<sup>180</sup> These lawsuits created uncertainty regarding vaccine shortages, with the fear that preventable diseases would make a resurgence if vaccine companies stopped manufacturing vaccines.<sup>181</sup> In 1986, the implementation of the National Vaccine Injury Compensation Program (NVICP)<sup>182</sup> attempted to remedy this dilemma by providing financial compensation to plaintiffs who filed a petition with the United States Court

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<sup>180</sup> Anders Kelto, *Vaccine Court Aims to Protect Patients and Vaccines*, NPR (June 2, 2015, 3:21 PM), <https://www.npr.org/sections/health-shots/2015/06/02/411243242/vaccine-court-aims-to-protect-patients-and-vaccines>. Vaccine court ensured the continued production of life-saving vaccines by limiting litigation liability for vaccine companies:

The [National Vaccine Injury Compensation Program] was established in 1986 after a series of high-profile lawsuits against drug companies. A number of children had serious adverse reactions—including seizures and brain damage—that appeared to be linked to the diphtheria, pertussis, tetanus vaccine or DPT vaccine. . . . The parents filed lawsuits against the makers of the DPT vaccine and, in at least two cases, won awards worth millions of dollars.

Several drug companies then threatened to cease vaccine production, claiming the risk of litigation was too high.

*Id.*

<sup>181</sup> *About the National Vaccine Injury Compensation Program*, HEALTH RESOURCES & SERV. ADMIN., <https://www.hrsa.gov/vaccine-compensation/about/index.html> (last visited Feb. 24, 2018).

<sup>182</sup> “The program’s objectives are to: (1) ensure an adequate supply of vaccines, (2) stabilize vaccine costs, and (3) to establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines.” *Id.*

of Federal Claims,<sup>183</sup> and were found to have been injured by a NVICP-covered vaccine.<sup>184</sup> The NVICP provides a no-fault resolution for vaccine injury petitions.<sup>185</sup> “Congress intended that the Vaccine Program provide individuals a swift, flexible, and less adversarial alternative to the often costly and lengthy civil arena of traditional tort litigation.”<sup>186</sup> The vaccine court fund was created by the administration of a 75-cent tax for every dose of a vaccine sold by the pharmaceutical companies.<sup>187</sup> Vaccine courts have encouraged pharmaceutical companies to continue developing much needed vaccines by largely decreasing their litigation liability. It also provides a remedy for injured plaintiffs, who may not have the necessary funds to file a lawsuit, to seek compensation for their injuries caused by vaccines.

This Comment proposes the implementation of a fertility court within the United States Federal Court of Claims to combat the same inequities that the vaccine court dealt and still deals with on a regular basis. Like vaccine court, it will operate as a no-fault court. Three-parent IVF requires such a court, along with other ART procedures, to ensure that fertility plaintiffs are justly compensated for their injuries and to reduce the occurrence of fertility

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<sup>183</sup> *About the Court*, UNITED STATES CT. FEDERAL CLAIMS, <http://www.uscfc.uscourts.gov/about-court#> (last visited Feb. 24, 2018). Specialty courts play an instrumental role in the functioning of our judicial system, and the United States Court of Federal Claims provides equitable remedies for injured plaintiffs:

The United States Court of Federal Claims is a court of record with national jurisdiction. The United States Court of Federal Claims was recreated in October 1982 by the Federal Courts Improvement Act pursuant to Article 1 of the United States Constitution. The court consists of sixteen judges nominated by the President and confirmed by the Senate for a term of fifteen years. After 1982, the court retained all the original jurisdiction of the Court of Claims and continues, uninterrupted, a judicial tradition more than 140 years old. The court has since been given new equitable jurisdiction in the area of bid protests, as well as jurisdiction in vaccine compensation. The Court of Federal Claims is authorized to hear primarily money claims founded upon the Constitution, federal statutes, executive regulations, or contracts, express or implied in fact, with the United States. . . . Its expertise, in recent years, has been seen as its ability to efficiently handle large, complex, and often technical litigation.

*Id.*

<sup>184</sup> *National Vaccine Injury Compensation Program*, HEALTH RESOURCES & SERV. ADMIN., <https://www.hrsa.gov/vaccine-compensation/index.html> (last visited March 11, 2018).

<sup>185</sup> *Id.*

<sup>186</sup> *Vaccine Claims/Office of Special Masters*, UNITED STATES CT. FEDERAL CLAIMS, <http://www.uscfc.uscourts.gov/vaccine-program-readmore> (last visited March 11, 2018).

<sup>187</sup> Kelto, *supra* note 180.

malpractice litigation. An injured three-parent IVF patient should not be left out in the cold due to her inability to finance a costly medical-malpractice lawsuit. A fertility court will ensure that injured three-parent IVF patients will always have an available remedy, regardless of financial or socioeconomic status.

**1. Funding fertility court: a licensing fee to a federal fertility fund.** Vaccine court is funded by a taxing system where the pharmaceutical companies pay a 75-cent tax for every dose of vaccine they sell. This incentivizes the pharmaceutical companies to pass the cost to the consumers through an increased vaccination price. It is proposed that Congress enact legislation to require a “licensing fee” to be administered to patients by every fertility physician who performs fertility treatment.

Fertility physicians who administer the three-parent IVF procedure in the United States would charge their fertility patients a fee that would be directly routed to a fertility court fund. The incentive for such a system will be a two-way street. First, it incentivizes the physician to charge the fee because she will be able to provide three-parent IVF procedures to patients without adding cost to her own practice of medicine. Second, it incentivizes the patient to pay the fee because she will have the opportunity to have the procedure done at home in the United States, and she will have the peace of mind that a fertility court will be there to support her if she is injured from the procedure.

Funding fertility court this way will benefit both the physician and the patient. As discussed earlier, defensive medicine practices are a prevalent problem in the United States. The inefficient practice of defensive medicine can largely be attributed to fear that a physician feels about looming medical-malpractice lawsuits. A fertility court will help remedy defensive medicine practices among fertility physicians by lowering their medical-malpractice insurance premiums, as medical-malpractice litigation liability for ART procedures will likely plummet due to the availability of a fertility court.

**2. A fertility court will lower medical malpractice insurance premiums for fertility physicians by reducing their litigation liability.** Physicians who practice fertility medicine experience some of the most outrageously high medical-malpractice premiums in the United States—some paying as much as \$195,000 annually in premium payments alone.<sup>188</sup>

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<sup>188</sup> Henry Mann, *2013-2014 Malpractice Premiums: Doctors Paying \$195,891 a Year for Coverage*, DOCTORCPR.COM (June 22, 2014), <http://www.doctorcpr.com/blog/2013-2014-malpractice-premiums-doctors-paying-195891-a-year-for-coverage/>.

Routing a majority of fertility plaintiffs to a fertility court should drastically lower the medical-malpractice premiums for fertility physicians, as the litigation liability should lower significantly. Fertility physicians may be hesitant to perform a three-parent IVF procedure because it could mean even higher medical-malpractice insurance premiums due to the procedure's technical nature and infancy status. This concern is valid and would be addressed by the implementation of a fertility court. Fertility physicians will likely see their medical-malpractice insurance premiums lower because they will have less exposure with the existence of a fertility court. Fertility plaintiffs will have the option to file a claim with fertility court instead of being required to hire an attorney to sue a medical-malpractice insurance carrier, which is costly, time-consuming, and stressful.

In the 1980s, pharmaceutical companies that manufactured select vaccines nearly stopped making them due to overexposure to litigation liability. The implementation of a vaccine court significantly dropped that liability and allowed pharmaceutical companies to continue manufacturing important and life-saving vaccines—all of which would not have been possible without a vaccine court.

The implementation of three-parent IVF in the United States needs to be followed by the establishment of a fertility court, following in the successful footsteps of the vaccine industry. Implementing three-parent IVF without a fertility court would likely have negative consequences. It would discourage fertility physicians from performing the procedure altogether, out of fear of the possibility of increased medical-malpractice litigation. It would also discourage patients from seeking out the procedure due to the inability to remedy an injury, if one were to occur. Fertility court provides a solution for both of these concerns.

#### CONCLUSION

Three-parent IVF is here and most likely to stay. The United Kingdom has rung in a new era in fertility medicine by legalizing three-parent IVF—giving women with mitochondrial disease new hope. Legislation in the United States to regulate three-parent IVF as a clinical trial is necessary to help rid the world of mitochondrial disease. The legislation must stress the importance of safety regulations that are already in place for tissue donation and transplantation.

Three-parent IVF legislation is also needed to address the cost and efficiency problems of the medical-malpractice system in the United States. The benefits of implementing a fertility court would be two-fold. First, it should drive down medical-malpractice premium payments for fertility physicians, as their litigation liability will likely fall. Second, it should give all fertility plaintiffs a viable option to be compensated for their injuries. The importance and value of having a no-fault court system for three-parent IVF and other fertility injuries should increase the efficiency and reduce the cost of the medical-malpractice system in the United States.

This legislation will ensure that women, from all walks of life, who suffer from mitochondrial disease can have the opportunity to rear and raise their own genetic children. United States citizens should not be hindered when it comes to the right to create a family. Legislation needs to reflect this precious and sacred societal value.