A Clash at the Petri Dish:

Transferring Embryos with Known Genetic Anomalies

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[Author's Note: I extend my gratitude to Professor Cohen and his students for their willingness to devote attention to this draft-in-progress. Ultimately the paper will contain five segments – an introduction and four distinct parts. What follow are the intro and first two parts which mainly set out the clinical problem and present the patient's perspective on seeking transfer of genetically anomalous embryos. The missing parts offer a combination of counterargument and independent rationale for a provider's position that embryos likely to lead to the birth of an unhealthy child should not be transferred. The final part will describe emerging positions in the U.S. and compare these schemes to a more established protocol in the UK. Final recommendations will urge fertility clinics to adopt and publish guidelines setting out their policies on the transfer of genetically anomalous embryos.]

Introduction

Advancing technologies in genetic testing of preimplantation embryos enable prospective parents to access detailed information about their future child's health status, facilitating and complicating their reproductive decision-making. Rapid developments in preimplantation genetic testing (PGT) offer the opportunity to detect nearly 300 genetic anomalies in an IVF-produced embryo a mere five days after its formation in the laboratory setting.[1] This information is as profound as it is precarious. Armed with a near certainty that a child born of a genetically anomalous embryo will manifest certain health-affecting symptoms, prospective parents must

[1] Preimplantation genetic testing (PGT) of embryos is comprised of two types of testing modalities. Preimplantation genetic screening (PGS) is employed to screen embryos for numeric chromosomal abnormalities, known as aneuploidy. Having too few or too many chromosomes in one (of 23) pairs can be associated with certain disease profiles such as Down Syndrome (Trisomy 21, or 3 chromosomes in the 21st pair) and Turner Syndrome (Monosomy 23, or only 1 X chromosome in the 23rd pair of a female). Preimplantation genetic diagnosis (PGD) is used to detect a specific mutation in a particular gene that is associated with a heritable disorder. Gene-linked disorders include cystic fibrosis, Huntington Disease, and Tay Sachs. *See* Human Fertilisation & Embryology Authority, Pre-implantation Genetic Screening and Pre-implantation Genetic Diagnosis, available at http://www.hfea.gov.uk/preimplantation-genetic-diagnosis.html (last visited Nov. 22, 2016).

wrestle with the choice over transfer, cryopreservation or discard – each of which has impacts on their reproductive future. A decision to seek transfer of a health-affected embryo invites uncertainty as to the child's lifespan, medical needs, and quality of life should the embryo survive the gestational period. Discarding or even freezing an anomalous embryo can mean the end of a long and disappointing infertility journey with scant prospect of producing more embryos in the future. All the while, physicians who are instrumental in the embryos' development are often bystanders to their patients' anguish. In rare, but extant cases, these same providers also experience distress when a patient's request for transfer conflicts with their professional conscience.

Clinical scenarios that evoke this provider dilemma can take shape in at least three ways. For the sake of understanding the range of opportunities for doctor-patient divergence over embryo transfer, imagine that three patients await a much anticipated appointment with their reproductive endocrinologist (RE), a physician trained in reproductive medicine. Patient Room A holds Mr. and Mrs. Johnson, a married couple who have experienced a five-year history of infertility of unknown etiology. Fortunately, their fourth attempt at IVF proved successful at the embryo formation stage, after three prior cycles failed to produce any viable embryos. Mrs. Johnson's egg retrieval yielded eight oocytes, three of which fertilized into viable embryos. The couple discussed PGT before beginning their IVF journey and decided they would proceed to test any resulting embryos. In anticipation of embryo testing, the couple underwent preconception genetic screening to identify any risks of passing a gene-linked disorder to their future child. To both of their surprise, Mr. and Mrs. Johnson were found to be carriers for cystic fibrosis (CF), an autosomal recessive disorder that causes persistent lung infections and digestive

malfunctions.[2] A further and much more devastating finding was that all three of the Johnsons' embryos were found to be positive for CF, meaning that any embryo that is transferred and progresses to delivery will produce a child afflicted with CF, a progressive, lifelong disease with some palliative treatments but no cure. After numerous emotional conversations, the Johnsons ask their RE to transfer two of the CF embryos into Mrs. Johnson's uterus, and cryopreserve the third one for future use. They explain that after four IVF cycles, they lack the financial and emotional wherewithal to undergo further treatment. The only opportunity to achieve their goal of biological parenthood is via the affected embryos.

Carlo and Rosa Gomez wait anxiously in Patient Room B. After two years of "trying" and no pregnancy, the Gomezes sought medical assistance. Mrs. Gomez was diagnosed with polycystic ovary syndrome (PCOS), a hormone imbalance that causes cysts to populate the ovary and often results in anovulation. Women diagnosed with PCOS experience infertility because their ovaries do not release eggs on a monthly basis, inhibiting natural conception.[3] After several courses of ovulation-inducing drug therapy and no pregnancy, the Gomez couple is advised to seek more intensive therapy through IVF. Six days ago Mrs. Gomez underwent egg retrieval and was delighted when three oocytes were recovered. The fertilization process was likewise a success, and now the couple awaits the results of the PGT they requested on the three embryos that made it to the five-day stage. The RE enters the room thinking the news she is about to share will be most welcome by the patient and her spouse. Testing revealed two of the embryos to be

[2] *See* Cystic Fibrosis Foundation, *About Cystic Fibrosis*, available at https://www.cff.org/What-is-CF/About-Cystic-Fibrosis/ (visited Nov. 22, 2016) (noting more than 30,000 individuals are living with CF in the U.S.).

[3] *See* National Institutes of Health, *Polycystic Ovary Syndrome (PCOS): Condition Information*, available at https://www.nichd.nih.gov/health/topics/PCOS/conditioninfo/Pages/default.aspx (visited Dec. 2, 2016).

chromosomally normal, while the third presents with Trisomy 21, or Down syndrome. The physician, certain the Gomezes will instruct her to discard the genetically anomalous embryo and transfer the other two (assuming the standard of care calls for two embryos to be transferred), the RE is surprised when Mrs. Gomez asks that two embryos be randomly selected for transfer. The patient explains that based on her religious beliefs, each embryo represents a full and equal life entitled to equal treatment in the selection process. A quick calculation of the odds reveals to the RE that a random selection of two out of three embryos translates into a 66.66% likelihood the Down syndrome embryo will be transferred.

Kathy Lee waits in Patient Room C, a mixture of nerves and excitement at having finally decided to move ahead with her reproductive plan. Embracing the idea of single motherhood by choice, the prospective patient is seeking medical assistance to assure the well-being of her future child. The mother-to-be hopes to give birth to a baby just like her – deaf. Ms. Lee was born deaf and has since learned that her condition is autosomal dominant, meaning her offspring have a 50% chance of inheriting this "deaf gene" and experiencing life without hearing.[4] Reviewing Kathy Lee's chart and intake questionnaire, the RE assumes that her services are being sought to avoid the birth of a deaf child. Instead, the would-be patient explains her desire to raise a child in her preferred subculture, rejecting the notion that deafness is a disability in her life or the lives of those in her deaf community.[5] Ms. Lee has already selected an anonymous

[4] Genetic deafness can be autosomal dominant, autosomal recessive or X-linked recessive. *See* Richard JH. Smith, et al., *Deafness and Hereditary Hearing Loss Overview*, in GENE REVIEWS (last revised Jan. 2014), available at https://www.ncbi.nlm.nih.gov/books/NBK1434/ (visited Dec. 2, 2016).

[5] The discussion surrounding the nature of deafness – disability or difference – is passionate and evolved. *See, e.g.*, Erica R. Harvey, *Deafness: A Disability or a Difference*, 2 HEALTH LAW & POL'Y BRIEF 42 (2008) (describing that some profoundly hearing impaired persons consider themselves to belong to a social minority group of subculture).

donor from a commercial sperm bank and is ready to begin the IVF and PGT process. As an indication of her preparedness, the signing patient is armed with a waiver drafted by her attorney that purports to release the RE from any and all liability in connection with the provision of reproductive medicine services.

These assisted reproductive technology (ART) inspired scenarios in which a genetically anomalous embryo is either discovered through routine preimplantation testing or intentionally sought through IVF challenge the prevailing norm surrounding PGT – that any and all embryos revealed to bear health-affecting genetic abnormalities will not be selected for transfer.[6] The underlying presumption supporting this norm is that in any given IVF cycle, the provider and the patient share as their common goal the birth of a healthy child, defined in normative terms. Cases in which a prospective parent accesses IVF for purpose of conceiving and birthing a child with an anomalous genome, or those in which new information discovered through PGT provoke a request for transfer of health-affected embryos have the potential to disrupt the doctor-patient relationship. Once aligned, the ART stakeholders now find themselves at odds over a deeply held personal choice that neither can make without the assent of the other.

Prior commentary on clashes over embryo transfer has dwelled in the quantitative arena. Tension at the ART bedside has been described as tug-o-war over the number of embryos to be transferred in a given cycle. Patients, it is reported, sometimes prevail upon their physicians to transfer more embryos than is deemed medically appropriate, often citing a desire for a twin (or higher) pregnancy to offset the financial and/or emotional burdens their infertility journey has

[6] *See* Kristien Hens, *To Transfer or Not to Transfer: The Case of Comprehensive Chromosome Screening of the In Vitro Embryo*, 23 HEALTH CARE ANAL. 197 (2015) (screening of IVF embryos has primary aim to help patients achieve successful pregnancy, defined by birth of healthy offspring).

wrought.[7] Physician acquiescence to patient demands that their embryo transfer exceed recommended levels is difficult to measure, but anecdotal evidence suggests providers do at least attempt to resist violating industry-directed protocols.[8] Provider judgment about the number of embryos to transfer in a single cycle is guided by the prevailing standard of care in reproductive medicine, itself a quasi-regulatory attempt to promote the well-being of IVF pregnancies and offspring.[9] But when the question is not *how many* to transfer but *whether* to transfer at all,

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[7] Professional society recommendations for the number of embryos to transfer in every clinical scenario can be easily accessed by both patients and providers. ASRM publishes and routinely updates its recommendations on embryo transfer on its website. *See* Practice Committee of the American Society for Reproductive Medicine and Practice Committee of the Society for Assisted Reproductive Technology, *Criteria for Number of Embryo to Transfer: A Committee Opinion*, 99 FERTILITY & STERILITY 44 (2013), available at https://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Guidelines_and_Minimum_Standards/Guidelines_on_number_of_embryos(1).pdf (visited Nov. 18, 2016). *See also* Deborah L. Forman, *When "Bad" Mothers Make Worse Law: A Critique of Legislative Limits on Embryo Transfer*, 14 U. PA. J.L. & SOC. CHANGE 273 (2011) (arguing patients actively seek twins as a cost and stress saving measure, while physicians are under pressure to post high success rates, combining to influence decisions about the number of embryos to be transferred); Astrid Hojgaard, et al., *Patient Attitudes Towards Twin Pregnancies and Single Embryo Transfer: A Questionnaire Study*, 22 HUMAN REPROD. 2673 (2007) (data showing patients undergoing IVF prefer twins to one child at a time).

[8] One fertility practice acknowledges that while over 40% of their patients desire twins, their physicians adhere to single embryo transfer, when indicated. A patient pamphlet on the topic discusses the issue using ethical precepts:

> Patient autonomy is important in medicine, especially the final decision regarding the number of embryos to transfer. But fertility specialists are ethically bound to respect not only autonomy, but also the ethical principle of beneficence -"doing good". This "doing good" includes the best interests not only of the patient but also her prospective children. "Doing good" is accomplished by limiting the risks to these children by avoiding multiple pregnancy.

Shady Grove Fertility, *"But I Want Twins"…But What Are the Risks?*, available at https://www.shadygrovefertility.com/application/files/5014/4968/4250/But-I-Want-Twins.pdf (visited Nov. 18, 2016). *But see* [data showing ETs still exceed recommended limits?]

[9] The morbidity and mortality associated with multiple pregnancy, especially triplet or greater, is well-known and oft-described in ART literature. *See, e.g.*, R. Stillman, K. Richter, N. Banks, J. Graham, *Elective Single Embryo Transfer: A 6-Year Progressive Implementation of 784 Single Blastocyst Transfers and the Influence of Payment Method of Patient Choice*, 92(6) FERTILITY &

would the same doctor-patient considerations be at play? The patient's goal for pregnancy and delivery remains, though aspirations for the health of a future child diverge when an embryo with a known genetic anomaly is transferred. From the provider's perspective, actively participating in the birth of a child likely to suffer lifelong health difficulties is markedly different from transferring embryos whose genetic make-up is either unknown or highly likely to produce a genetically normal child based on PGT.[10]

Patient requests for transfer of genetically anomalous embryos invoke at least four considerations spread across a range of ART stakeholders. First, the patient's reproductive autonomy is certainly at stake. Exercising control over whether and how one procreates is at the core of individual reproductive liberty, which arguably also includes the right to make choices

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STERILITY 1895, 1900 (2009) (describing multiple pregnancy-related increases in maternal morbidity and mortality from gestational diabetes, hypertension, cesarean delivery, pulmonary emboli, and postpartum hemorrhage in addition to fetal, neonatal, and childhood complications from neurologic insults, ocular and pulmonary damage, learning disabilities, and retardation, and congenital malformations).

[10] It is important to acknowledge that patient-provider disputes over how many embryos to transfer are not devoid of concerns over offspring health. While the gravamen of the dispute is mostly couched in terms of likelihood of success (measured by the crudely named "take home baby rate") in which the patient wants more embryos transferred to ramp up the odds of delivering a live born child, provider pushback is informed by clinical outcomes in high-order multiple pregnancies. Still, this article persists in the argument there is a meaningful distinction between disputes over how many versus whether to transfer embryos. Because the transfer of multiple embryos is not certain to yield any pregnancy, let alone a high-order multiple pregnancy, and because the salvific technique of selection reduction of multiple pregnancy can help stave off harm to the born offspring, a provider's reluctance to transfer a genetically anomalous health-affected embryo poses a unique cause and effect dilemma. A physician who refuses to acquiesce in a patient's request that two or more embryos be transferred, opting instead to abide the recommended single embryo transfer, does not altogether thwart the possibility of pregnancy. This is exactly what is at stake when a provider refuses to transfer a specific embryo per patient request.

about the nature of the child that may ultimately be born.[11] Second, the physician's professional conscience enters the equation when a doctor is asked to provide treatment that violates deeply held personal and professional values. Doctors have equal humanity to their patients and thus are entitled to feel, express and act upon their sentiments in a reasonable manner that conforms to professional norms, laws, and practices. Balancing the physician's professional conscience against the patient's reproductive autonomy lies at the heart of anomalous embryo transfer requests. Third, the welfare of any child born from the patient's embryo is a factor in this clinical scenario. Challenging aspects of assessing a future child's well-being include the frailties of prediction in determining future health, the spectrum of symptomology associated with many genetically-based diseases, and the perception of harm to the child as measured by the patient and the provider's worldview. Finally, transferring health-affected embryos at patient request has impacts on third parties including non-consenting spouses and partners, the patient's existing children and other relatives, and society at large.

The article tackles four main ideas, each integrating one or more of the four considerations set out above. Part I describes the current technologies used in PGT and the range of information such testing can provide. While the data support a high level of accuracy in preimplantation testing, recent studies suggest a type of false-positive result may be more common than originally contemplated. Embryos that present as aneuploidic – having too many or too few chromosomes in any given pair – may actually develop into genetically normal offspring. This phenomenon is known as mosaicism, a condition in which the embryo contains

[11] *See, e.g.,* John A. Robertson, CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES (1994); A. Kalfoglou, et. al., Ethical Arguments For and Against Sperm Sorting for Non-Medical Sex Selection: A Review, 26 Reprod Biomed Online 231 (2013).

more than one line of cells, with one line presenting as normal and the other as abnormal.[12] In a handful of studies, researchers report the birth of chromosomally healthy children after transfer of embryos determined by PGT to be aneuploidic, calling into question the reliability of genetic testing in the presence of mosaicism. At the very least, these emerging case studies complicate the informed consent process in which ART patients and providers are required to engage. The clinical uncertainty that a genetically anomalous embryo will result in the birth of a health-affected child muddies the already murky waters when physicians bristle against patient requests for embryo transfer.

The chief inquiry of the article will assess the benefits and harms of transferring abnormal embryos upon patient request. Part II sets out the rationales for honoring patient requests for transfer, offering five possible bases on which a provider could acquiesce in good faith. Support for physician acquiescence is largely grounded in the preeminence of reproductive liberty, alongside the worthy goal of equal protection in the quest for biologic parenthood. This latter concern advocates equal treatment of pre- and post-implantation embryos, honoring a woman's choice to give birth, or not, to a particular would-be child. A third argument in favor of honoring patient requests for transfer looks to the growing bank of litigated cases discussing the disposition of disputed embryos in the context of divorce. While not dispositive of a clash between a patient and a provider, the body of law does shed light on the allocation of dispositional authority over preimplantation embryos. Next, Part II highlights the parties'

[12] *See On the Possibility of Selectively Transferring Embryos, by Preimplantation Genetic Diagnosis (PGD/PGS) Determined to be Chromosomally Abnormal*, Center for Human Reproduction Website (Oct. 27, 2014), available at https://www.centerforhumanreprod.com/fertility/possibility-selectively-transferring-embryos-preimplantation-genetic-diagnosis-pgdpgs-determined-chromosomally-abnormal/ (visited Nov. 22, 2016).

inability to accurately predict the future child's well-being. Disability advocates have nicely shaped this prediction problem, which seems quite apropos for the clinical scenario at hand. Finally, an admittedly underdeveloped but earnest argument about the benefits of existence over nonexistence will be offered. Together, these rationales are steeped in the values of patient autonomy, reproductive equality and the preference for birth over nonexistence.

The arguments for declining patient requests for transfer of genetically anomalous embryos are set out in Part III. Again, five possible avenues for argumentation can be rationally configured. Provider autonomy is offered as a prime, yet seriously undervalued basis on which to decline to participate in treatment the physician finds professionally or personally troublesome. Worries about discrimination or capriciousness can be minimized if refusals are applied equally on the basis of the embryo's diagnosis and ensuing prognosis. Next, two theories interchangeably support a physician's refusal to further the patient's reproductive plan. Reproductive non-malfeasance and procreative beneficence invoke notions of "do not harm' and "fulfill a duty to do the most good" in the context of reproductive technologies. Fourth and relatedly, diagnosis-specific predictions about the future child's health profile could support a doctor's desire to prevent the birth of a seriously impaired human being. In a profession dedicated to promoting health and alleviating suffering, a member's reluctance to knowingly facilitate the birth of an unhealthy child is understandable. Finally, as rational actors in a litigious society, physicians may calculate their exposure to legal liability for acts undertaken and refused. Since a patient cannot waive the potential child's future legal claims, concerns about malpractice could motivate an ART provider's actions at the bedside.

Setting out the principles and arguments that support honoring or declining patient requests for transfer of genetically anomalous embryos is a necessary first step toward facilitating resolution of this reproductive clash, but does little to assist a provider in the clinical arena. Part IV tackles the more practical side of the dilemma, reviewing a variety of approaches that have or could be employed by fertility clinics and individual practitioners. While publically available information about clinic practices is scant, the limited revelations from the provider side tend to reflect a line-drawing approach. Clinic policies that do address transfer of genetically anomalous embryos typically set out their providers' unwillingness to assist when certain listed diseases are involved. Others refuse transfer when the child is highly likely to be born with untreatable, highly symptomatic syndromes associated with great physical suffering. The merits and drawbacks of such line-drawing are discussed, along with a more broad-based approach that works to recognize the equal dignity in both the patient and provider's position. With so many clinical, ethical, and legal uncertainties bound up in this transfer conundrum, the one bankable feature is that ART patients will continue to seek PGT in growing number. It is to this technology we now turn.

I. Miracles, Milestones, and Misdiagnosis in Preimplantation Genetic Testing

At its core, human reproduction is a game of chance. The vast majority of prospective parents in the world leave to chance the possibility that mating will lead to conception, pregnancy and childbirth. The child's health is likewise a matter of chance in which the gamete providers can only hope the genetic lottery will bless their offspring with good genes. The use of ART and PGT enables its participants to manage their reproductive odds by providing vital

information about the health status of a preimplantation embryo, but this cohort represents a tiny fraction of the overall population. In the U.S., conception by IVF accounts for approximately 1.8% of the total birth rate, leaving 98.2% of newborn Americans to the vicissitudes of nature.[13] Of the roughly 70,000 infants who met their earliest moments in a petri dish, again only a small percentage also endured preimplantation genetic testing. According to the Center for Disease Control and Prevention (CDC), in 2014 approximately 4% of all IVF cycles included PGT.[14] While the exact number of babies born following IVF and PGT is not specifically reported by the CDC, the data allow an inference that around 2,800 children were born as a result of these combined technologies.[15] While the percentage of PGT cycles has actually declined in recent

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[13] According to the annual report published by the Centers for Disease Control and Prevention (CDC), in 2014 (the most recent year for which figures are available) there were 70,354 infants born in the U.S. who were conceived using IVF. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T. OF HEALTH AND HUM. SERVS., 2014 ASSISTED REPRODUCTIVE TECHNOLOGY: NATIONAL SUMMARY REPORT 3 (2016) [hereafter 2014 ART REPORT], *available at* http://www.cdc.gov/art/pdf/2014-report/art-2014-national-summary-report.pdf (visited Dec. 7, 2016). The total U.S. birth rate in 2014 was 3,985,924 (an increase of 1% from 2013). *See* CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T. OF HEALTH AND HUM. SERVS. BIRTHS: PRELIMINARY DATA FOR 2014, 64 NATIONAL VITAL STATISTICS REPORTS, June 17, 2015, at 2, available at http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_06.pdf (visited Dec. 7, 2016). Thus, IVF accounts for 1.77% of U.S. births.

[14] *See* 2014 ART REPORT, *supra* note __, at 5.

[15] Admittedly this number is wildly speculative as the CDC does not specifically report the exact number of IVF cycles in which PGT was used, or the birth rates following IVF/PGT cycles. The 2,800 estimate assumes that since PGT was used in 4% of all ART cycles in 2014, an equivalent percentage of live born infants emerged from those interventions. The potential inaccuracy of this interpolation is grounded in the specific clinical indications for embryo screening. While any embryo *can* be genetically screened, experts typically discuss a handful of indications for use of this advanced technology, including the presence of a single-gene disorder or mitochondrial disease in one of the parents, or to detect aneuploidy in women of advanced maternal age. *See* Amber R. Cooper & Emily S. Jungheim, *Preimplantation Genetic Testing: Indications and Controversies*, 30 CLIN. LAB. MED. 519 (2010), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3996805/ (visited Feb. 10, 2017). Thus, if the cohort of PGT embryos is limited to those most at risk for anomaly (and therefore failure to implant or miscarriage), the number of live-born infants emerging after embryonic genetic testing would be lower than the percentage of all embryos tested.

years – falling from 6% in 2013 to 4% in 2014 – experts in the field continue to predict increase usage of genetic technologies to assess embryo health.[16]

The opportunity to know one's future child's genetic make-up is a relatively recent phenomenon, entering clinical reality in the early 1990s.[17] PGT was originally developed to detect the presence of genetic mutations associated with serious diseases, and its success in so doing is remarkable. Today, the technique can detect over 300 genetic conditions, including Down syndrome, Tay Sachs, cystic fibrosis, thalassemia, sickle cell anemia, Gaucher disease and hemophilia. In addition to these diseases that impact a child's health at birth and throughout his or her life, PGT can detect other genetic disorders that pose minimal risk to a child's health (such as colorblindness) or arise later in a person's life, often in the third or fourth decade (such as Huntington's disease) and thus are called adult-onset diseases. The wide spectrum, penetrance and symptomology of genetic disorders raise questions about the appropriate use of a technology that is so blunt in its application. Since medical science has yet to truly crack the code of repairing genetic anomalies,[18] today's parental choices in the face of PGT results are three fold: implant, discard or freeze. Selection among this trilogy can be influenced by a number of factors,

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[16] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T. OF HEALTH AND HUM. SERVS., 2013 ASSISTED REPRODUCTIVE TECHNOLOGY: NATIONAL SUMMARY REPORT 3 (2015), *available at* http://www.cdc.gov/art/pdf/2013-report/art_2013_national_summary_report.pdf (visited Dec. 7, 2016) (reporting of 163,209 IVF cycles performed in 2013 with the intent to transfer at least one embryo, 6% involved PGD). The figure fell to 4% in 2014. *See* 2014 ART REPORT, *supra* note __, at 5. *See also* Kristien Hens, et al., Comprehensive Embryos Testing. Experts' Opinions Regarding Future Directions: An Expert Panel Study on Comprehensive Embryo Testing, 28 Human Reprod. 1418 (2013) (an expert panel agreed that broadened embryo testing is a likely development).

[17] The first report of a pregnancy following preimplantation genetic diagnosis is attributed to a group of British researchers. *See* Alan Handyside et al., *Pregnancies from Biopsied Human Preimplantation Embryos Sexed by Y-Specific DNA Amplification*, 344 NATURE 768 (1990).

[18] Add literature on recent forays into gene editing.

including developing norms surrounding genetic testing of embryos, the accuracy of such testing, and established policies set out by physicians who are ultimately charged with performing the embryo transfer.

A. Setting and Challenging PGT Norms

The language and norms surrounding PGT are fairly uniform in their characterization of parental motivation for learning the genetic status of their embryos prior to implantation. Patients take up genetic testing to maximize their opportunity to have a healthy child, or at least one whose genes do not reveal a known disease-related anomaly. Interesting, the definition of PGD provided by the CDC, the nation's authority on health in our society, reflects this health-seeking bias. In its 2014 annual report on ART usage in the U.S., the CDC provides a glossary of terms, including the term "PGD/PGS (preimplantation genetic diagnosis or screening)". These technologies are defined as "[t]echniques performed on embryos prior to transfer. PGD is for detecting specific genetic conditions to reduce the risk of passing inherited diseases to children. PGS screens embryos for an abnormal number of chromosomes, which is of special value for women with advanced age, recurrent miscarriages, or failed IVF."[19] The impression cast is that PGT is strictly to avoid transferring embryos that could produce unhealthy children or unsuccessful pregnancies.

Data surveying patients who opt for genetic testing of embryos likewise suggest the goal of avoiding health problems in their future children. In one study looking at indications for PGT usage, researchers found that the primary reason patients opted for testing was to detect

[19] *See* 2014 ART REPORT, *supra* note __, at 65.

aneuploidy.[20] Other studies confirm that detecting aneuploidy is the primary motivation for patients seeking PGT, followed by a search for the presence of gene-specific disorders.[21] PGT to investigate a particular gene (as opposed to verifying the correct complement of chromosomes) is typically the result of a family history in which one or more members have been affected by a heritable illness. To avoid passing on a serious illness such as Huntington's disease or a higher likelihood of adult-onset breast cancer in offspring, prospective parents screen embryos for the presence (and hopeful absence) of these genetic anomalies. Presumably, embryos with too few or too many chromosomes or with the specific disease-causing mutations would be discarded rather than transferred.[22]

This pattern of detect and discard depends upon two key factors – the accuracy of genetic testing results and the patient's goal to avoid the birth of a child with a known genetic disorder. The latter feature is highly individualistic and sensitive to the reliability of diagnostic testing results. As exemplified in the case scenarios presented at the outset of this article, patient reproductive goals can occupy a wide range of desired outcomes and can change as more information is introduced into the clinical setting. Prospective parents like Mr. and Mrs. Johnson whose long struggle with infertility leaves them with three embryos that all test positive for

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[20] *See* E. Ginsburg, et al., *Use of Preimplantation Genetic Diagnosis and Preimplantation Genetic Screening in the United States: A Society for Assisted Reproductive Technology Writing Group Paper*, 96 FERTIL STERIL 865 (2011) (also noting aneuploidy detection is followed by elective sex selection, diagnosis for a specific genetic abnormality, and finally to perform translocation analysis).

[21] Susannah Baruch, David Kaufman, Kathy L. Hudson, *Genetic Testing of Embryos: Practices and Perspectives of US In Vitro Fertilization Clinics*, 89 FERTILITY & STERILITY 1053 (2008).

[22] *See* Darshak Sanghavi, *Wanting Babies Like Themselves, Some Parents Choose Genetic Defects*, NY TIMES (Dec. 5, 2006) at F5, available at http://www.nytimes.com/2006/12/05/health/05essa.html (visited Mar. 1, 2017) (reporting most patients whose embryos contain a serious health-affecting genetic anomaly choose not to transfer those embryos, electing wither discard or cryopreservation)..

cystic fibrosis may adjust their parental aspirations to embrace the birth of a child with health challenges. The well-worn parental adage, "you know what you want but you love what you get" has especially deep meaning in a world where (mostly) infertile individuals are foisted with control over a process that nature directs for the vast majority of the population. Providers are well-advised to adopt an empathic approach to patients who are confronted with the choices that genetically anomalous embryos often present. Key to provider empathy is the accuracy of testing that informs the physician-patient dialogue surrounding embryo transfer.

B. Inaccuracies in Embryonic Genetic Testing

In the matter of embryonic genetic testing, the uncertainties of life find no refuge at its beginnings. In the main, results obtained in genetic testing of preimplantation embryos are accurate and reliably predict the genetic health status of the offspring. But very occasionally testing can produce results that are inaccurate, indeterminate, or both. In one study, researchers reported an error rate of less than 1 percent in PGT cycles performed over a ten-year period.[23] The reasons for inaccurate results or adverse outcomes vary, but include mix-up of embryos or the material extracted from the embryos for testing, transfer of the wrong embryo back into the patient's uterus, and use of incorrect or inappropriate probes linked to detection of specific genes or chromosomes.[24] These laboratory-based errors can produce a false-negative result in which the patient is told the embryo is normal when it is not, or a false-positive result in which the patient is told the embryo is abnormal when it is not. Inaccuracies attributable to human or

[23] *See* Leeanda Wilton, et al., *The Causes of Misdiagnosis and Adverse Outcomes in PGD*, 24 HUMAN REPROD. 1221 (2009) (reporting 24 misdiagnosis and adverse outcomes from 15,158 PGD cycles (0.16%) collected by the European Society of Human Reproduction and Embryology PGD Consortium).
[24] *Id.*

technical error can – and have – become the subject of lawsuits against the IVF provider or facility. In the handful of cases litigated and reported to date based on PGT mishaps, legal claims cluster around both negligence and lack of informed consent theories.[25]

Informed consent for PGT – discussing with patients the risks and benefits of opting for or declining genetic testing of their IVF embryos – is challenging for a number of reasons including the technical complexity of the procedure and the sweeping nature of the information it yields. The technique used to extract and analyze genetic material from an IVF embryo has evolved since PGT was first introduced in the 1990s.[26] For the first two decades of use, PGT typically involved the extraction and genetic analysis of one of the 4-8 totipotent cells of the early embryo, called a blastomere, traditionally performed on the third day of embryonic development. The totipotentcy of these early embryonic cells means that each cell contains the entire genome of the developing human.[27] Seeing the genetic make-up of one cell is, in most cases, equivalent to seeing the entire embryonic genome. PGT analysis from a single blastomere can detect vital genetic information, including the presence of aneuploidy (too many or too few chromosomes in

[25] *See* Tochi Amagwula et al., *Preimplantation Genetic Diagnosis: A Systematic Review of Litigation in the Face of new Technology,* 98 FERTILITY & STERILITY 1277 (2012) (analyzing cases involving adverse outcomes involving PGT, including switched embryos, false-negative results, and the failure to offer the technique during IVF).

[26] For a general discussion of the PGT technique involving biopsy of a single blastomere, *see* Judith Daar, REPRODUCTIVE TECHNOLOGIES AND THE LAW 290-91 (2d. ed. 2013).

[27] Importantly, research on the use of PGD indicates that removing a single totipotent cell does not interfere with the remaining seven cells' ability to develop into a fully-formed human being. The procedure merely delays continued cell division for a few hours, after which the embryo reaches the same number of cells as before and continues its normal development. *See Embryo Biopsy Safe for Singleton Pregnancies, Largest Study of PGD Children Suggests,* Science Daily (Dec. 23, 2009), available at http://www.sciencedaily.com/releases/2009/12/091222105103.htm.

one of the 23 pairs) or a single gene disorder (such as Tay-Sachs, sickle cell anemia, Huntington's disease or cystic fibrosis).[28]

Over time, embryologists noted several clinical drawbacks in this traditional Day 3 PGT technique. First, results were incomplete because the testing was limited in the number of chromosomal pairs that could be analyzed. Since not all 23 pairs could be probed for the presence of aneuploidy, false negatives were a clinical reality. Second, the results sometimes yielded a misdiagnosis because the DNA contained in the single cell did not match the genetic make-up of the remaining cells of the embryo - a condition known as mosaicism.[29] To improve PGT reliability, embryologists began to wait until the embryo developed into a more evolved entity, when the blastocyst stage is reached at Day 5 post-fertilization. At the blastocyst stage, the organism contains roughly 100-200 cells and thus multiple cells can be extracted and analyzed. At this point in embryonic development, the PGT technique changes considerably. Instead of taking a single blastomere from the embryo itself, the standard of care is moving to removing multiple cells from the outer or placental portion of the embryo (the trophectoderm), rather than extraction of a single cell from the embryo itself at Day 3. This move to trophectoderm biopsy provides more cell material to analyze, thus improving accuracy while

[28] *See* News-Medical, *Single Gene Genetic Disorders*, available at http://www.news-medical.net/health/Single-Gene-Genetic-Disorder.aspx.
[29] *See* Laurie Tarkan, *Screening for Abnormal Embryos Offers Couples Hope After Heartbreak*, NY Times, Nov. 22, 2005 (reporting 30% of embryos have mosaicism, leading to a 4% rate of misdiagnosis using PGD).

reducing embryo loss following the procedure.[30] The procedure also avoids invasion of the embryo by taking cells from the area destined to become the placenta.

While Day 5 PGT has improved clinical outcomes as measured by pregnancy and live birth rates, the potential for mosaicism in the embryo remains. Researchers estimate that 30% of all blastocysts (Day 5 embryos) are affected by mosaicism.[31] Moreover, the clinical impact of this condition remains largely unknown. A small number of studies conducted in the past few years reveal that embryos deemed to be abnormal via PGT can yield a normal (genetically-speaking) baby. In one published study, 18 women who produced only mosaic embryos were offered transfer of those embryos; of those transfers, six resulted in the birth of singleton, chromosomally healthy infants. The other 12 transfers did not result in pregnancy or live birth, thus all of the offspring in the study were chromosomally normal. The study authors hypothesized that the mosaic embryos either self-corrected or the aneuploid cell line had migrated to the trophectoderm and thus did not inhabit the developing infant.[32] Whatever the mechanism, the ability of embryos initially classified as genetically abnormal after genetic testing to then produce genetically normal offspring is both fascinating and confounding.

The mysteries surrounding mosaicism and the extent of its link to the birth of children with genetically anomalies add uncertainty to the already challenging patient decision-making

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[30] *See* Ruthi B. Lathi et al.,,*Outcomes of Trophectoderm Biopsies on Cryopreserved Blastocysts: A Case Series*, 25 REPROD. BIOMED. ONLINE 504 (2012), http://www.rbmojournal.com/article/S1472-6483(12)00414-2/abstract.

[31] E. Fragouli et al., *The Developmental Potential of Mosaic Embryos*, 104 FERTILITY & STERILITY 396 (ASRM Abstracts) (2015).

[32] Ermanno Greco & Maria Giulia Minasi, *Healthy Babies After Intrauterine Transfer of Mosaic Aneuploidy Blastocysts* 373 NEW ENG. J. MED 2089 (2015).

process. Additional research may illuminate the extent to which mosaic embryos should no longer be considered highly likely to result in the birth of a chromosomally abnormal infant, but until there is greater scientific certainty providers and patients will be force to balance the known risks, limited as this fund of information is. One group of researchers recommends that "mosaic embryos should not necessarily be excluded but should be given a lower priority for transfer than those that appear to be fully euploid, as the likelihood of producing a child is reduced."[33] This latter phrase referencing the likelihood of a live birth is based on studies showing that only 13% of mosaic embryos produced an ongoing pregnancy, suggesting the genetic infirmity interacts with successful implantation and gestation.[34] The admonition by at least one research group that physicians consider transferring abnormal-appearing embryos under certain circumstances raises questions about current clinical practices. As the next section shows, data points are scant but illuminating.

C. Discerning Current Clinic Practices

Reproductive endocrinologists who operate in the highly technical, highly fraught PGT space position themselves best when they are well-informed about the availability and meaning of genetic testing technologies and then share this information with patients in an accessible manner. One New York City fertility clinic attempted this balancing act in 2014 with a press release explaining the phenomenon of mosaicism. In an article posted on its website, the Center for Human Reproduction describes in plain terms how early embryos can contain "a mix of

[33] Fragouli, *supra* note __.
[34] *Id.*

normal and abnormal cell lines" in which the "normal cell lines often become dominant, while abnormal cell lines segregate away from the developing fetus into what later becomes the placenta."[35] These embryos, the clinic explains, can self-correct, leading to a false-positive diagnosis if the abnormal cells are biopsied, which later may no longer be part of the developing embryo. The clinic's purpose in posting this explainer was both to inform and to set out its policy on the transfer of embryos that present as genetically abnormal. The Center further urges other providers to adopt the same position.

The Center asserts the position that "under carefully controlled circumstances, and with detailed informed consent, IVF centers should offer to poor prognosis patients without "normal" embryos in a given cycle, the option of transferring selected embryos deemed "abnormal by PGD/PGS."[36] Interestingly, the Center refines its advocacy according to the severity of the disease associated with the detected anomaly, adding "[s]uch transfers should only utilize embryos with so-called presumed "lethal" chromosomal abnormalities since "lethal" abnormalities either do not implant or lead to early miscarriages." Presumably, the rationale for this position is that aneuploidies detected as causing severe diseases will either fail to survive upon transfer (a true positive) or will self-correct as the embryo develops (a false positive due to mosaicism) – a win-win if the goal is to avoid the birth of an unhealthy child. But if a "true

[35] *Transferring Supposedly Chromosomally "Abnormal" Embryos in an IVF Cycle*, Center for Human Reproduction (Press Release, Oct. 27, 2014), available at https://www.centerforhumanreprod.com/fertility/transferring-supposedly-chromosomally-abnormal-embryos-ivf-cycle/ (visited Mar. 3, 2017).

[36] *Id. See also* Kira Peikoff, *In IVF, Questions About 'Mosaic' Embryos*, NY TIMES, Apr. 18, 2016, available at https://www.nytimes.com/2016/04/19/health/ivf-in-vitro-fertilization-pregnancy-abnormal-embryos-mosaic.html?_r=0 (visited Mar. 6, 2017) (reporting other fertility practices willing to transfer mosaic embryos if a patient has no normal embryos and has genetic counseling first).

positive" abnormality poses a risk of implantation and eventual birth, the Center argues against transfer. "Non-lethal" abnormalities (for example Down or Turner Syndromes) often lead to births and, therefore, should not be transferred."[37]

Taken at face value, the Center's position regarding the transfer of genetically anomalous embryos that could lead to live birth would rule out assisting patients such as the Johnsons (certain to have a child with cystic fibrosis) and the Gomezes (very likely to have a child with Down syndrome). Should the Center have this veto authority? What role should providers play in a patient's quest to make a genetic choice in favor of disability? Should it matter to the physician if the requesting patient is infertile and thus making a selection as a by-product of necessary IVF treatment (the Johnsons and the Gomezes), compared to a fertile individual who seeks out PGT for the sole purpose of selecting for a child with a disability (Kathy Lee, the deaf woman)? We know very little about the patient populations who request to transfer or seek out embryos with known genetic anomalies other than they do exist in some small measure. As to the active quest to birth a child with a health-affecting abnormality, we know the two most common traits that patients seek are inherited forms of deafness and achondroplasia (dwarfism). Anecdotes relaying these requests occasionally appear in the popular press. A British couple who visited their local fertility clinic to assure the birth of a deaf child defended their actions in the press by explaining, "Being deaf is not about being disabled. It's about being part of a linguistic minority."[38] Likewise, prospective parents of short stature caused by achondroplasia have approached fertility

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[37] *Id.*

[38] Richard Gray, *Couples Could Win Right To Select Deaf Baby*, The Telegraph, Apr. 13, 2008, *available at* http:// www.telegraph.co.uk/news/uknews/1584948/Couples-could-win-right-to-select-deaf-baby.html (Dec. 11, 2014).

specialists to assure the birth of a little person, expressing a desire for a child who is "just like them."[39]

As reported in these same news items, some physicians express an unwillingness to treat patients in pursuit of so-called "intentional diminishment".[40] One Washington, D.C. area physician who has denied requests to use PGD for selecting deafness and dwarfism said in an interview, "In general, one of the prime dictates of parenting is to make a better world for our children. Dwarfism and deafness are not the norm."[41] Another Chicago ART provider agreed, commenting on the appropriate use of genetic screening technologies, "If we make a diagnostic tool, the purpose is to avoid disease."[42] At the same time, survey research indicates that a few IVF practices are willing to assist patients to select in favor of a disabling condition. In 2008, researchers at the Genetics and Public Policy Center asked ART clinics about their practices and perspectives on genetic testing of embryos. When asked if the responding clinic performed PGD to "select for a disability," three percent of clinics answered in the affirmative.[43] The authors did not define the term "disability" but in their report associated this response with using PGD "simply to satisfy the preferences of the future parents."[44]

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[39] Sanghavi, *supra* note __.
[40] *See* I. Glenn Cohen, *Intentional Diminishment, The Non-Identity Problem, and Legal Liability*, 60 Hastings L. J. 347 (2008).
[41] Sanghavi, *supra* note __.
[42] *Id.*
[43] Baruch, *supra* note __.
[44] *Id.* at 1056.

Line-drawing in the face of facilitating or avoiding the birth of a less-than-healthy child is understandable and observable in both the patient and provider populations. Patients whose entire batch of embryos is deemed genetically anomalous often must choose between raising a health-impaired child or accepting a childless existence. Those whose religious or other values-based sentiments guide them toward offering each embryo an equal opportunity to be born accept known odds of forgoing the birth of a healthy child. Provider anguish is no less relevant in the clinical setting. Placing an embryo into a woman's uterus knowing the resulting child will likely suffer a life of pain and constant medical needs can be life-affecting for a physician long after the transfer is made. While some fertility clinics have considered and set out policies explaining their approach to the transfer of embryos with known genetic anomalies, most have not and confront each request in an ad hoc fashion.[45] This individualized approach, while clearly not ideal, can be helped along by a compendium of factors that can be considered in each case. Providers who apprise themselves of the arguments attendant to honoring and declining patient request for transfer of genetically anomalous embryos stand to improve their decision-making capacity immensely. With the goal of informed provision or withholding of medical services in mind, Parts II and III offer rubrics for assessing patient requests and provider responses.

II. **Honoring Patient Request for Transfer**

Intrinsic in ART family formation is the relationship, ideally the partnership, between the patient and the provider. Key to any successful relationship are common values and goals that reduce conflict and support shared decision-making. Research surrounding the doctor-patient

[45] Get cite?

relationship in ART focuses primarily on the frailties of informed consent, supplying no indicia that these stakeholders are routinely at odds over the desire for treatment to yield a live born infant.[46] Setting aside for another time and place a discussion about physician refusals to provide treatment to certain prospective patients on non-medical grounds, this paper's focus moves up the timeline to a point where the patient-physician relationship has been established and treatment commenced.[47] Once embryos are in the mix, the physician's refusal to transfer a genetically anomalous embryo is typically couched in terms of trilogy of harm avoidance rationales: 1) avoiding harm to the patient through a miscarriage should the embryo implant, 2) avoiding harm to a potential child whose predicted quality of life is severely health-compromised, and 3) avoiding harm to the provider's professional conscience by assisting in the birth of a suffering child.

The physician's desire for harm-avoidance, discussed more fully in Part III, must be balanced against other values including the patient's assertion of her reproductive autonomy embedded in a request for embryo transfer. While procreative liberty may be a dominant feature in shaping the ART patient-physician relationship, it is not the only driving force. The depth of patient desire for embryo transfer regardless of the predicted health status of any resulting child is informed by assertions of autonomy as well as skepticism surrounding others abilities to envision her future.

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[46] *See, e.g.*, Jody Madeira and Barbara Andraka-Christou, *Paper Trails, Training Behind: Improving Informed Consent to IVF Through Multimedia Applications*, 3 J. LAW & BIOSCIENCES 2 (2016), available at https://academic.oup.com/jlb/article/3/1/2/1751255/Paper-trails-trailing-behind-improving-informed?searchresult=1.

[47] For a discussion of ART treatment denials for reasons unrelated to a patient's medical suitability for IVF, *see generally* Judith Daar, THE NEW EUGENICS: SELECTIVE BREEDING IN AN ERA OF REPRODUCTIVE TECHNOLOGIES (2017); Judith Daar, *The Role of Providers in Assisted Reproduction: Potential Conflicts, Professional Conscience, and Personal Choice*, in THE OXFORD HANDBOOK OF REPRODUCTIVE ETHICS (Leslie Francis, ed. 2017).

Providers have shared their introspective views on the merits of non-directed counseling in reproductive medicine, acknowledging their inability to perceive the future from the patient's perspective.[48] Stepping into the shoes of one's patient may give some insight into the risk of harm that person willingly undertakes, but such transformations are hardly possible. Instead, physicians can be guided by a more knowable catalog of supporting rationales for honoring patient requests for the transfer of genetically health-affected embryos.

A. The Preeminence of Reproductive Liberty

The concept of procreative liberty has long guided discussion, law, and policy surrounding the regulation of reproductive medicine. Nearly a quarter century ago, Professor John Robertson described procreative liberty as "a negative right against state interference with choices to procreate or to avoid procreation."[49] He expounded on the import of this right by asserting, "reproductive experiences . . . are central to personal conceptions of meaning and identity. To deny procreative choice is to deny or impose a crucial self-defining experience, thus denying persons respect and dignity at the most basic level."[50] The source of denial of reproductive liberty to which Professor Robertson refers is the government whose various enactments in the procreative realm have given rise to a robust jurisprudence. While grounded almost entirely in the right to avoid procreation through contraception and abortion, the

[48] Get cite?
[49] John A. Robertson, CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES 23 (1994).
[50] *Id.* at 4.

reproductive rights legal landscape arguably holds sway over the right to access the means to reproduction through ART.[51]

The judicial volley over validation and rejection of state and federal regulation of abortion continues, still anchored to principles set out in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, the U.S. Supreme Court's 1992 abortion decision.[52] The Court recognized procreative liberty as being at stake in the abortion context, but warned this liberty is not absolute but must be balanced against the State's legitimate interest in the life of the unborn. Thus, the Court formulated a legal standard for evaluating state regulation of abortion, weighing the woman's liberty interest against the government's interest in potential life. State abortion regulation, the Court declared, will be invalid if it poses an "undue burden" on the right of a woman to decide whether to terminate a pregnancy. An undue burden exists, "if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability."[53] In 2016, the Court reaffirmed the basic parameters of *Casey,* applying the undue burden test to a Texas law requiring abortion providers obtain admitting privileges at

[51] The debate over whether the constitutional treatment of abortion extends to ART has been robust and long-standing. *See, e.g.,* John A. Robertson, Children of Choice: Freedom and the New Reproductive Technologies (1994) (arguing the right to procreate via ART is constitutionally equal to right attached to natural conception and childbirth); Radhika Rao, *Constitutional Misconceptions*, 93 Mich. L. Rev. 1473 (1995) (rejecting the presumptive primacy of procreative liberty as applied to ART, noting that other constitutional rights may be at issue when donors or surrogates are used and their rights need to be taken into relative account); Ann MacLean Massie, *Regulating Choice: A Constitutional Law Response to Professor John A. Robertson's Children of Choice*, 52 Wash. & Lee L. Rev. 135 (1995) (expressing concern that constitutionally equalizing coital and noncoital means of reproduction might suppress the interests of resulting offspring); Sonia M. Suter, *The "Repugnance" Lens of Gonzales v. Carhart and Other Theories of Reproductive Rights: Evaluating Advanced Reproductive Technologies*, 76 Geo. Wash. L. Rev. 1514 (2008) (finding a right to ART potentially supported by theories based on procreative liberty and autonomy, equality and family privacy).

[52] 505 U.S. 833 (1992).

[53] *Id.* at 878.

nearby hospitals and facilities meet more onerous ambulatory surgical center standards. Finding these requirements posed an undue burden on women seeking abortion, the Court struck down the Texas law as unconstitutional.[54]

The import of this jurisprudence to decision-making over embryo transfer is derivative but nonetheless vital. Decisions at the bedside are not akin to legislative enactment and thus not an equal foe to reproductive rights. But imbuing physicians with preemptive power over patient decision-making could approximate the force of government mandate and thus should be subject to equal scrutiny. From the patient's perspective, a physician's refusal to transfer existing embryos is as much an obstacle to her reproductive liberty as a law that deprives her the right to end an unwanted pregnancy. The quest for reproductive control can take shape as a desire to avoid or engage in procreation. Placing an undue burden on negative or positive reproduction, whether by state action or provider assertion, is equally impactful as measured from the person whose reproductive choices are wrested out of her hands.

In its broadest context, the centrality of reproductive autonomy to personal identity and meaning extends not just to decisions about whether to become a parent, but also to decisions about which child to bring into the world. For better or worse, the deliberate decision-making inherent in ART enables the distinct investigation of such personal choice along the procreative process. Women who conceive naturally cannot decide whether the embryo that forms in their fallopian tube and implants in their uterus will give rise to a genetically healthy child, but ART-conceiving patients often have this power. The rise of PGT does separate naturally-conceiving women from their infertile counterparts in the ability to decide which embryo (whether on its

[54] Whole Woman's Health v. Hellerstedt, 579 U.S. __ (2016).

own or as part of a batch) will have the chance to become a live born child. To exclude this choice from the reach of reproductive liberty is to suppress the usefulness of this vital protected right.

Acknowledgement of reproductive liberty as a protected right arises not just in law but in the policies that surround clinical practice. The American Society for Reproductive Medicine, the largest U.S.-based organization of reproductive medicine professionals, publishes guidelines and opinions to inform and assist ART stakeholders in the myriad scenarios that present in the field. In various published statements, the ASRM Ethics Committee has discussed the essential role that patient autonomy and reproductive liberty play in the practice of reproductive medicine, stating these principles "have long guided patient/physician relationships in the field."[55] In an opinion discussing the ethics and law surrounding sex selection of embryos for nonmedical reasons, the Ethics Committee averred that it would be permissive to give patients this choice based on notions of reproductive liberty. Specifically, the ASRM affiliate wrote,"[t]he preeminent ethical considerations that support patient choice of sex selection for nonmedical reasons are patient autonomy and reproductive liberty."[56] The Committee opinion then discusses the various reasons patients might have to preferring one sex over another – i.e., family balancing, an anticipated rearing experience – and concludes, "[i]n such cases, sex selection is a material aspect of that person's reproductive decision making…Having access to technologies that enable individuals to shape the course of their pregnancy and child-rearing experience may

[55] Ethics Committee of the American Society for Reproductive Medicine, *Transferring Embryos with Genetic Anomalies Detected in Preimplantation Testing*, __ FERTILITY & STERILITY __ (in press, 2017).
[56] Ethics Committee of the American Society for Reproductive Medicine, *Use of Reproductive Technology for Sex Selection for Nonmedical Reasons*, 103 FERTILITY & STERILITY 1418 (2015).

be embedded in the concept of constitutionally protected reproductive liberty and thus not amenable to infringement by the government or those who operate as state actors."[57]

The power of these words and their transferability to embryo selection based on genetic health cannot be denied. This is not to claim legal equivalency between state action by force of law and individual action by discretion of a physician, but rather to harmonize their impacts on a patient's freedom to choose her own reproductive path. As exemplified by the case scenarios at the outset, patients who request transfer of genetically anomalous embryos may do so because it is their only opportunity for biologic parenthood, or they are willing to raise a child with impaired health status, or they desire a child who reflects their life experience, or they are unwilling to freeze, discard or donate embryos they worked to create.[58] Policing the reasons why patients make certain reproduction-related choices, whether by the government or by providers, should be shunned under the protective cover of reproductive liberty.[59] So long as the patient is provided appropriate counseling and information in line with principles of informed consent, the provider's obligation – indeed authority -- to intervene in her decision-making should be curtailed.

B. The Role of Equal Protection: Harmonizing Pre- and Post-Implantation Choices

"You can't just be a little bit pregnant." This popular refrain suggests there is a certain biological marker that distinguishes the pregnant from the non-pregnant state, dismissing any

[57] *Id. at 1419.*
[58] *Genetic Anomalies, supra* note __, at __.
[59] It should be noted that a handful of states have enacted laws that police a woman's reason(s) for seeking an abortion. Laws in at least eight states prohibit women from procuring an abortion for reasons related to the sex of the fetus. *See* International Human Rights Clinic, University of Chicago Law School, REPLACING MYTHS WITH FACTS: SEX-SELECTIVE ABORTION LAWS IN THE UNITED STATES (2014).

suggestion that pregnancy is a process rather than an existential condition.[60] In clinical reality, the formation and development of early human life involves a series of precisely orchestrated steps that begins with the release of male and female gametes from their glandular homes and ends with the removal of the product of conception from the uterine cavity. By linguistic account these steps comprise a process, despite designation by medical and legal authorities as a singular occurrence capable of distinction from the immediately preceding events. Accordingly, the concept of pregnancy stands as a distinct biological marker with enormous significance for the regulation of activities that occur on either side of this bright line. Perhaps the most striking example of the pregnancy divide can be seen in the treatment of pre- and post-implantation embryo destruction. Generally speaking, discard of IVF embryos prior to transfer into the uterus is not the subject of much legislative activity, while destruction of post-implantation embryos (i.e., abortion) is highly regulated and subject to an ever-increasing network of restrictions.[61]

Let us assume for the sake of analysis that equality is an important value in the treatment of reproductive decision-making. The equality lens in ART can be applied at least two situations, 1) equal treatment of embryos no matter their situs (in the laboratory or in the body), and 2) equal treatment of fertile and infertile prospective parents. Advocacy for equal treatment of pre- and post-implantation embryos does have a voice, most actively asserted in the so-called personhood movement, a grassroots effort to amend state laws to recognize personhood from the

[60] For a fuller discussion of pregnancy as distinct biological marker with legal, ethical and practical significance, *see* Judith Daar, *The Outdated Pregnancy: Rethinking Traditional Markers in Reproduction*, 35 J. LEGAL MED. 505 (2014).

[61] For a listing of the current state and federal laws regulating abortion, *see* Guttmacher Insitute, An Overview of Abortion Laws, available at https://www.guttmacher.org/state-policy/explore/overview-abortion-laws (visited Mar. 9, 2017).

moment of conception – thus making abortion illegal in most circumstances.[62] To date, this movement has not realized abundant success, in part because of its potential negative impact on IVF. In a 2011 effort to win personhood status for embryos at the ballot box, voters in Mississippi defeated a measure by a 58-42% margin. This surprised some election experts who noted that fewer than 10% of the state's voters considered themselves pro-choice.[63] Post-election surveys revealed that 31% of voters stated they voted against the measure for fear that it would reduce the availability of IVF.[64] In addition to verifying that voting on social matters is a complex phenomenon, these results speak to the disparate treatment of embryos according to their location in the reproductive process.[65] The popularity of IVF and its embedded role in

[62] For competing advocacies on legislating personhood of embryos *compare* Personhood.com, available at http://www.personhood.com/petitions (visited Mar. 9, 2017) *with* ASRM Position Statement on Personhood Measures, available at https://www.asrm.org/ASRM_Position_Statement_on_Personhood_Measures/ (visited Mar. 9, 2017).

[63] *See* Jonathan F. Will, *Beyond Abortion: Why the Personhood Movement Implicates Reproductive Choice*, 39 AM. J. L & MED. 573, 584 (2013).

[64] *Id.* at 585.

[65] The analysis of the legal status of pre- and post-implantation embryo is clearly far more nuanced and complicated than this simple example admits. But to further the "situs" analysis to its logical extreme, imagine we could detect pregnancy – typically measured according to the embryo's implantation in the uterus – as soon as five days post-fertilization. We currently cannot know if an embryo will yield a clinical pregnancy, as the markers for implantation do not begin producing in detectable levels until 8 to 18 days post-fertilization. *See* Allen J. Wilcox, et al., *Time of Implantation of the Conceptus and Loss of Pregnancy*, 340 NEW ENG. J. MED. 1796 (1999). If we could detect whether a viable embryo was on its way to implantation at 5 days post-fertilization, the woman housing the embryo would be pregnant and subject to any abortion restriction in force in her jurisdiction, including any outright bans on the procedure. If this same woman underwent IVF and decided to discard preimplantation embryos at 5 days post-fertilization, she would be completely free to do so for any reason. The same 5-day old embryo would be subject to opposite legal regimes, depending on whether it was the result of a natural or assisted conception cycle.

American family formation seems to transcend long-held views about the sanctity of human life in all its forms.[66]

Forty years of debate over abortion and IVF reveals we appear to accept unequal treatment of embryos based on instrumental goals (most would allow discard of IVF embryos because it is a necessary part of the technique, some don't want to allow abortion at any point in a woman's pregnancy because it amounts to baby-killing). Sadly, this same inequality drives disparate treatment of fertile and infertile women in their quest for biologic parenthood. For example, in the privacy realm women who engage ART are the subject of mandated reporting to the federal government via a law enacted in 1992. The Fertility Clinic Success Rate and Certification Act requires standardized reporting of pregnancy success rates to the Secretary of Health and Human Services through the Centers for Disease Control (CDC), which data is in turn made available to the public.[67] As a result of the law, the vast majority of ART clinics in the U.S. annually report their success rates and a host of other data (including their patients' ages, diagnosis, number of IVF cycles and more) to the CDC which publishes a comprehensive report detailing national statistics, as well as specific information about each reporting clinic. The CDC has published an annual ART Success Rate Report since 1997, and each report is now available online at the CDC website.[68]

By comparison, a woman who conceives "the old-fashioned" way is not subjected to having the timing or circumstances of her baby's earliest moments documented by the federal government on a public website. Other inequalities arise in the health insurance arena,

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[66] *See supra* note [13], noting IVF accounts for nearly 2 of every 100 births in the U.S. today.
[67] 42 U.S.C. §263a-1 et seq. (1992).
[68] A compendium of all the CDC ART reports is available on the agency website at http://www.cdc.gov/art/ (last visited Mar. 15, 2017).

evidenced by the typically generous reimbursement for diagnostic tests, surgeries and medication that facilitate conception through intercourse compared with almost no coverage for conception via IVF.[69] Applying this (in)equality lens to the topic at hand, an argument can be made that physicians who honor patient requests to transfer genetically anomalous embryos do so in support of equal treatment of women in their reproductive decision-making. The basic structure of the argument goes as follows. A pregnant woman who learns that her fetus is afflicted with a devastating disease is free to decide whether to continue or terminate her pregnancy, the latter decision subject to state and federal laws governing access to abortion. Even if the government has a say in the patient's course of action, her physician does not. At no point in a woman's pregnancy can a provider mandate that her patient maintain or extract the fetus within her body, no matter how strongly held the doctor's views about the child's likely quality of life.

Converting back to a post-PGT scenario when the affected embryos lay in the darkness of the laboratory petri dish, the provider should likewise have no say in the fate of those would-be children. Refusing to honor a patient's request for transfer infringes upon the woman's right to be left alone by her physician once the reproductive process has commenced. In ART, the procreative journey begins (sometimes) long before a woman's interest in bodily integrity is at stake, a point that should not diminish the import of reproductive autonomy. Admittedly, this equality argument requires the conceptual disaggregation of a physician's technical skills from the angst and culpability she might experience in assisting in the birth of a severely disabled child. A possible salve is the reminder that the physician did not cause the embryo's malformation. Nature is responsible for that mishap and at the heart of most patient requests for

[69] Get cite.

transfer is an abiding respect for that natural process.

C. **A Theory of Dispositional Preemption**

The legal question of who owns – and thus has the right to exercise dominion and control over – preimplantation embryos has occupied courts and commentators for over 25 years. Overwhelmingly, disputes over the disposition of preimplantation embryos dwell in the shadow of divorce. The typical scenario involves a married couple who experience infertility during the marriage and seek assistance via IVF. As is common in most IVF cycles, excess embryos are created and cryopreserved for later use. The intervening dissolution of the relationship reconfigures the couple's original reproductive plan, pitting the progenitors against each other as they vie to pursue or avoid parenthood through the now disputed frozen embryos. Some dozen appellate courts across the U.S. have weighed in on the disposition of disputed frozen embryos, advancing a variety of rationales for resolving the cases – most frequently in favor of the party wishing to avoid procreation.[70]

What can disputes between one-time aspirational parents teach us about conflicts between physicians and patients over the transfer of genetically anomalous embryos? On the surface, probably very little because conflicts between divorcing couples are resolved under family law principles, while clashes in the medical setting are typically analyzed as a matter of contract or tort law.[71] But there is at least one relevant finding that emerges from the dissolution

[70] For an excellent review of U.S. case law surrounding disposition of disputed frozen embryos, *see* I. Glenn Cohen & Eli Y. Adashi, *Embryo Disposition Disputes: Controversies and Case Law*, 46 HASTINGS CEN. RPT. 13 (2016) (reporting on 12 cases decided since 1992, only 2 of which permit embryos to be used for reproduction).

[71] And occasionally under criminal law, as in the handful of cases in which physicians have committed crimes in connection with their dealing with patients. In the ART world, these

case law that could inform disputes over embryo transfer – the allocation of dispositional authority exclusively to the prospective parents (one or both) to the exclusion of the physician who aided in the embryos' development. While courts have differed on their final orders – awarding embryos to the person who does not want to become a parent, awarding them to the person who does want to procreate using the embryos, requiring joint agreement on disposition, and even awarding them for research in accord with the intended parents' preconception agreement – the assumption underlying each of these dispositions is that control over embryos rests with those who orchestrated their existence and not those who accomplished their development. If the notion that a physician could even claim dispositional authority over a patient's embryos seems absurd, case and statutory law prove otherwise.

In one of the earliest legal disputes involving IVF, in 1987 a New Jersey couple underwent treatment at the Jones Institute for Reproductive Medicine located in Norfolk, Virginia. The IVF cycle yielded six embryos; five were transferred into the wife's uterus and one was frozen for later use. A year later, the couple moved to California and sought to have their frozen embryo transferred to a fertility clinic in nearby Los Angeles. The physicians at the Jones Institute refused to approve transfer of the embryo, prompting the progenitors to sue for injunctive and declaratory relief. In *York v. Jones*, the court deemed the legal status of the arrangement a bailment, "impos[ing] on the bailee [the Jones Institute], when the purpose of the bailment has terminated, an absolute obligation to return the subject matter of the bailment to the

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instances are rare but notorious. *See, e.g., Fertility Doctor Fathers 75*, DOMINION POST, Jul. 18, 2006, at 3 (reporting on Cecil Jacobson, fertility doctor who used his own sperm to unwittingly impregnate over 70 patients. Following a 1992 trial, Dr. Jacobson was convicted of 53 counts of fraud and perjury and served five years in federal prison); Mary Dodge & Gilbert Geis, STEALING DREAMS: A FERTILITY CLINIC SCANDAL (Northeastern University Press 2004) (describing theft and unconsented transfer of patient eggs and embryos at the UCI Center for Reproductive Health in the early 1990s).

bailor [the Yorks]."[72] The court further explained that a bailment involves one party's possession of personal property of another in which an obligation to return the property is implied. Looking to the terms of the agreement signed by Mr. and Mrs. York in preparation for treatment, the court upheld the couple's breach of contract claim.[73]

Applied broadly to all IVF treatment scenarios, the bailment theory could certainly limit the ability of physicians to direct the disposition of embryos over the objection of any patient. The physician could not – for a host of reasons – transfer an embryo into a woman's uterus without her express consent because a bailee's dominion and control over the personal property item is limited by the bailor's grant of authority. But what about a bailee who refuses to comply with the demands of a bailor, such as in the case when a patient demands transfer of a genetically anomalous embryo likely to result in the birth of an unhealthy child? Other than moral objection, does the bailee have any legal authority under which to refuse to act?

Reference to the law of personal property yields concern about the tort of conversion should the bailee fail to deliver possession of the property upon demand of the bailor.[74] Conversion is broadly defined as "the appropriation of a chattel by a party to his own use and beneficial enjoyment, or its destruction, or the exercise of dominion over it to the exclusion or in defiance of the rights of the owner."[75] In the context of IVF and embryo storage prior to transfer, one can imagine a claim of conversion being successfully launched by a patient against a physician who refuses to place "the chattel" in "defiance of the rights of the owner." Leaving for

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[72] York v. Jones, 717 F. Supp. 421, __ (E.D. Va. 1989).
[73] *Id.* at __.
[74] *See Conversion of Bailed Property: Particular Conduct as Constituting Conversion*, 75 A.L.R.2d 1044, Sec. 7(b) (West 2017).
[75] *Id.*

another time, the judicial and jurisprudential debate over the status of embryos as persons, property or some other categorization, a simple analysis under bailment and conversion principles does provide a thumb on the patient's side of the ledger.

Case law on the allocation of dispositional authority over embryos as between the patient and the provider is scarce, and enacted law is even rarer. Only one U.S. state addresses the rights and obligations of IVF doctors toward the embryos they help create. In Louisiana, an IVF physician is accorded standing to protect the embryo's rights. The statute provides:

> An in vitro fertilized human ovum is a biological human being which is not the property of the physician which acts as an agent of fertilization, or the facility which employs him or the donors of the sperm and ovum. If the in vitro fertilization patients express their identity, then their rights as parents as provided under the Louisiana Civil Code will be preserved. If the in vitro fertilization patients fail to express their identity, then the physician shall be deemed to be temporary guardian of the in vitro fertilized human ovum until adoptive implantation can occur. A court in the parish where the in vitro fertilized ovum is located may appoint a curator, upon motion of the in vitro fertilization patients, their heirs, or physicians who caused in vitro fertilization to be performed, to protect the in vitro fertilized human ovum's rights.[76]

The Louisiana law is consistent with a bailment theory in that the physician is expressly deemed to hold no ownership interest but rather that of an agent entitling the provider to deal with the property in good faith. Deeming a physician as temporary guardian of an embryo "until adoptive

[76] La. Rev. Stat. §9:126 (2017).

implantation can occur" suggests this outcome is the preferred, perhaps the only fate that can befall a preimplantation embryo in the state. The provision granting a physician authority to move a court to appoint a curator "to protect the in vitro fertilized ovum's rights" furthers the state's public policy that embryos not be discarded. A patient in Louisiana seems well-supported in her demand that a provider transfer any and all embryos formed in an IVF cycle. Like-minded patients in other states may invoke a bailment rubric to achieve their desire for transfer. At least to date, no legal authority countenances against such an asserted right.

D. The Problem of Prediction

The final argument discussed herein highlights the inherent inaccuracies that accompany forecasting future health, including predicting with any precision the spectrum of symptomology associated with many genetically-based diseases. Even if such predictability were possible both as to the expression of disease and its severity, it is unlikely the worldview toward sickness and disability would align as between the patient and provider. The problem of prediction has already been discussed, as it relates to the phenomenon of embryonic mosaicism.[77] While the possibility of a false-positive is far less likely when the anomaly detected is a single-gene disorder as opposed to aneuploidy (mosaicism generally only applies the latter category), the likelihood of accurately predicting the nature or extent of the offspring's disease course remains low.[78] We need look no further than the hypothetical patients who introduced the problem of disputed embryo transfer to us to understand how variable genetic disease processes can be.

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[77] *See supra* text accompanying notes __.

[78] *See* Email to author from Dr. Paula Amato, Reproductive Endocrinologist and Associate Professor of OB/GYN at Oregon Health & Science University, dated March 15, 2017 explaining that the term mosaicism usually applies to aneuploidy and not single gen disorders (on file with author).

Recall Mr. and Mrs. Johnson whose entire batch of embryos tested positive for cystic fibrosis, a progressive autosomal recessive disease that causes persistent lung infections and limits the ability to breathe over time.[79] According to the Cystic Fibrosis Foundation website, CF "is a complex disease and the types and severity of symptoms can differ widely from person to person."[80] Symptoms such as lung infections and coughing can be mild or severe. In a hopeful note, the CF Foundation reports the predicted median age of survival of a CF patient rose to nearly 40 years in 2016, up from 32 years in 2000.[81] The Johnsons might heavily favor transferring one or more of their CF embryos over any of the other options open to them, including childlessness, adoption, gamete donation, or further IVF treatment. Raising and caring for a child diagnosed with CF does pose known challenges, but the disease variability and promise of therapies on the horizon, coupled with the good possibility of the child surviving well into adulthood add verdure to the couple's rational request for transfer.[82]

Hypothetical patients Rosa and Carlos Gomez expressed a desire that their provider select two embryos for transfer from the batch of three that remain viable. One of those embryos has been deemed aneuploidic – with an extra chromosome in the twenty-first pair, consonant with Down syndrome. Setting aside the possibility of mosaicism, in this clinical scenario the provider

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[79] *See* About Cystic Fibrosis, The Cystic Fibrosis Foundation Website, available at https://www.cff.org/What-is-CF/About-Cystic-Fibrosis/ (visited Mar. 31, 2017).

[80] *Id.*

[81] *Id. See also, Frequently Asked Questions About Cystic Fibrosis*, available at http://www.cff.org/aboutcf/faqs/#What_is_the_life_expectancy_for_people_who_have_CF_(in_the_United_States) (last visited April 28, 2008).

[82] According to the CF Foundation, "In 2015, the FDA approved the second drug to treat the root cause of cystic fibrosis, a defective protein known as CFTR. The first drug targeting the basic genetic defect in CF was approved in 2012. The arrival of this group of drugs, called CFTR modulators, signals a historic breakthrough in how CF is treated. It's expected that CFTR modulators could add decades of life for some people with CF." *See* CF Foundation Website, *supra* note __.

can discuss the nature of the genetic anomaly detected in the Gomez embryo, but the physician cannot predict how the disease will be expressed during the child=s life. As with cystic fibrosis, to date there is no clinical measure for accurately predicting the severity of symptoms associated with Trisomy 21. According to the National Institutes of Health, ADown syndrome symptoms vary from person to person and can range from mild to severe.@[83] The National Down Syndrome Congress concurs, adding, A[t]here is wide variation in mental abilities, behavior and physical development in individuals with Down syndrome. Each individual has his/her own unique personality, capabilities and talents.@[84]

In addition to the inability of providers to accurately predict the variability or severity of many genetic disorders, there is a potential clash of values between the patient whose goal is parenthood and the provider whose goal is to avoid the birth of a particular child. In its most basic form, this clash weighs the value of existence (of a particular child) over nonexistence (of that same child). In the main, this debate is far better tackled by those steeped in philosophy but even legal types can weigh in, and have. As an initial inquiry we might wonder, Can a person who is never born be harmed from lack of existence? Resolution of whether a person can be harmed by nonbirth depends upon the value placed on human existence. If one views human life, no matter its quality or quantity, as an absolute good then its deprivation could be said to work a harm to those denied the opportunity to come into existence. But if one views human life as a balance of benefits and burdens, then skirting existence would not necessarily work a harm in

[83] Down Syndrome, Medline Plus, available at https://medlineplus.gov/ency/article/000997.htm (last visited April 4, 2017).

[84] *Facts About Down Syndrome & Language Guidelines*, National Down Syndrome Congress available at http://www.ndsccenter.org/wp-content/uploads/VO-Down-Syndrome-Facts-and-Language-Guidelines.pdf (last visited April 3, 2017).

every case to the never born.[85] In considering just this existential conundrum, the ASRM Ethics Committee noted that "[a] slight variation of this view would be to deem certain lives not worth living, due to extreme pain and suffering or lack of any interactive cognitive abilities, and thus not bringing such a person into existence would not be deemed an overall harm."[86] The Committee further opined:

> In the context of embryo transfer, there may be a clash of values between the provider and the intended parents as to whether that prospective child would have a life not worth living. Complicating this analysis are the unknowns about the life the child will actually lead and the weight, if any, to be accorded the parents' preference for existence over nonexistence. This argument attaches to each embryo regardless of the availability of one or more embryos for transfer. It is the value of the embryo and its potential to evolve into a resulting child that is at stake, not the relative health or well-being of that offspring compared to other possible lives. The presentation of these philosophical quandaries in clinical practice by no means guarantees their resolution; rather, highlighting the declared interests and potential benefits and harms to the patient and the child to be born may facilitate a provider's understanding of the complexities inherent in the transfer of genetically anomalous embryos.[87]

The prediction problem, coupled with corollary principle of favoring life over nonexistence

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[85] *See* Judith Daar, THE NEW EUGENICS: SELECTIVE BREEDING IN AN ERA OF REPRODUCTIVE TECHNOLOGIES 176 (2017), citing Seana Valentine Shiffrin, *Wrongful Life, Procreative Responsibility, and the Significance of Harm*, 5 Legal Theory 117 (1999).
[86] ASRM Ethics Committee, *Genetics Anomalies Opinion*, *supra* note __.
[87] *Id.*

except in rare circumstances rounds out the arguments in favor of honoring patient requests for transfer of genetically anomalous embryos. Acceding to a patient's request does not at the same time discharge the physician from providing adequate informed consent to meet the decision-making challenges of this clinical scenario. Ideally, patients should be offered the opportunity to seek consultation with a mental health professional who can assist the prospective parents in sorting through the range of emotions they are likely experiencing. In addition, referral to a medical specialist who teats the disease process at issue seems essential. It is one thing to research a disease online or speak with friends and colleagues who have experienced raising an affected child, it is quite another to hear about the disease process from someone dedicated to its care on a daily basis. If forewarned is forearmed, patients who avail themselves of the relevant information surrounding PGT results are better positioned to withstand the skepticism and hostility to transfer a physician can display. Recognizing that providers' reactions to requests for anomalous embryo transfer are often heartfelt, rational, and morally defensible, let us turn to a review of the arguments for declining such patient requests.

III. Declining Patient Requests for Transfer

A. The Preeminence of Provider autonomy

B. Twin Theories: Reproductive Non-Malfeasance and Procreative Beneficence

C. The Reliability of Prediction and Child Welfare Concerns

D. The Legitimacy of Avoiding Legal Liability

IV. Improving the Clinical Landscape

A. The Established HFEA Approach

B. Selected U.S. Fertility Clinics Take a Stand

C. The Emerging ASRM View

D. Suggested Configurations and Compromises

V. Conclusion