



A clash at the petri dish: transferring embryos with known genetic anomalies

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ABSTRACT

Advancing technologies in genetic testing of preimplantation embryos enable IVF patients to access detailed information about their future child's health status, facilitating and complicating their reproductive decision-making. Testing for embryonic genetic anomalies linked to future health has grown increasingly sophisticated. A patient's decision to seek transfer of a health-affected embryo may or may not be compatible with her physician's professional conscience, potentially resulting in a clash at the petri dish. This article sets out arguments in support of physician decisions to assist or decline to assist in the transfer of anomalous embryos upon patient request. Arguments in support of transfer include the preeminence of a patient's reproductive liberty, the value of equal protection as applied to pre- and post-implantation embryos, the allocation of dispositional authority over embryos, and the frailties of predicting a child's future health experience. Arguments that bolster a provider's decision to decline requests for transfer include the role of physician autonomy in the doctor-patient relationship, the theories of reproductive non-maleficence and procreative beneficence, and legitimate concerns over future legal liability. Regardless of a clinic's ultimate position, this article advocates that providers create or adopt detailed policies setting forth their preferences and practices regarding anomalous embryo transfer.

KEYWORDS: embryo transfer, mosaicism, patient autonomy, preimplantation genetic testing, reproductive liberty

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Preface

In Tribute, Memory, and Respect for John Robertson

In December 1981, doctors and nurses at Norfolk General Hospital in Virginia celebrated the delivery of Elizabeth Carr, the first IVF-conceived baby to be born in the USA. Her arrival marked the founding of a new chapter in American reproductive medicine, one that was destined to partner with other professional disciplines—most notably law and ethics. Within a few years, when the world welcomed dozens and then hundreds of IVF-conceived children, the American Society for Reproductive Medicine (then the American Fertility Society) established an ethics committee to provide commentary, policy, and education to guide the emerging field of assisted reproductive technologies (ART). John Robertson was a founding member of the ASRM Ethics Committee, serving as chair for several terms and committing his time and wisdom to the enterprise until 2012. I was appointed to the Committee in 2008, in awe of John's legendary contributions to the field and now incredibly appreciative of the generosity, mentorship, and friendship he graciously dispensed to me for the remainder of his life. Serving as the Ethic Committee chair since 2014, I follow in irreplaceable footsteps that clearly reveal the path taken and illuminate the journey ahead.

John's contributions to the Committee in particular and to the ART field in general cannot be overstated. In the late 1980s, the Committee set out to publish a first-of-its-kind comprehensive review of the new reproductive technologies, tackling subjects ranging from the moral and biologic status of the early embryo to the interworkings of emerging techniques including IVF, insemination by donor, egg donation, and gestational surrogacy. In a 1990 issue of the ASRM peer-review journal, *Fertility & Sterility*, the Committee authored 15 chapters that continue to serve as foundational writings in the field. To me, the most vital and durable was the chapter entitled, 'The Constitutional Aspects of Procreative Liberty'. While individual authorship is not acknowledged, there is no doubt that John wrote these critical pages that linked existing constitutional protections for family formation with emerging and futuristic methods designed to achieve the same result. His ability to see and explain the connection between what was (limited jurisprudence on the affirmative right of married persons to procreate via coitus) and what should be (an expansive right to control all aspects of one's reproductive journey) took shape in that early publication, establishing itself as mainstay on the legal and ethical ART landscape. John's deep respect for people's desire to procreate—and all that it entailed—was driving and thematic from the start, steering the ASRM Ethics Committee and the vast majority of ART scholars to embrace his vision of equal liberty surrounding reproductive choice. His work canvassed the entirety of the field. He was often the first to comment on nascent developments including human cloning, preimplantation genetic testing, egg and embryo banking, and his most recent contributions on uterine transplantation. Each contribution was true to his core beliefs, yet John's work never lacked for reflection, precision, and nuance.

I had the privilege of serving on the ASRM Ethics Committee with John for 4 years and surprisingly (to me) we sometimes disagreed over matters large and small. Of course, I understood my disparate position to mean I was completely wrong in my view, but he never regarded any varying position in this way. He listened, truly listened, to each and every member of the Committee as we waded through the morass that is

assisted reproductive ethics. At times, he guided us to consensus; in other instances, he supported the will of the group under another's turn at the helm. His departure in 2012 after nearly three decades of service was well earned but much lamented. For 3 years beginning in 2014, the Committee researched, debated, and ultimately published an opinion on the topic that occupies my article that follows—patient requests for transfer of genetically anomalous embryos. During that engagement process, I often wondered what John would think about this clinical scenario—but rules of strict confidentiality barred such a conversation. Would he support a patient's right to control her reproductive journey to the point of assuring the birth of a severely health-affected child, or would he see compelling reasons to limit procreative liberty for the sake of reducing a child's potential suffering? Sadly, I never got the chance to delve into the topic as John passed before our opinion was formally published in 2017. While John may not have formally weighed in on the article's specifics, his influence in this piece and all of my work abounds. John helped shape me into the scholar and advocate I am today, a good deed I can only pay forward. A person of vision, compassion, wit, and wisdom, John resides forever in our hearts, minds, and souls.

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 400 genetic anomalies in an IVF-produced embryo a mere 5 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, parents must wrestle with a choice over transfer, cryopreservation, or discard—each of which has impacts on their reproductive future.² 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

¹ 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 (PGS), <https://www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/pre-implantation-genetic-screening-pgs/>; and HFEA, Pre-implantation Genetic Diagnosis (PGD), <https://www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/pre-implantation-genetic-diagnosis-pgd/> (last visited Jan. 4, 2018).

² But see *infra* text accompanying notes 33–38, discussing issues of misdiagnosis and embryo mosaicism that can detract from the certainty that anomalous test results mean the resulting child will be born with a genetic disorder. In addition to transfer into the uterus, donation for research purposes may also be a viable option for parents, particularly as scientists explore methods of germline gene-editing using embryos with known genetic anomalies. See Hong Ma et al., *Correction of a Pathogenic Gene Mutation in Human Embryos*, 548 NATURE 413 (2017) (describing correction through gene editing of an embryo containing a genetic mutation associated with a serious heart condition).

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 the dictates of their professional conscience.³

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 endocrinology and infertility specialist (REI), a physician trained in reproductive medicine. Patient Room A holds Mr. and Mrs. Johnson, a married couple who have experienced a 5-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 yield 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 carrier 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.⁴ 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 REI 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 2 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.⁵ After several courses of ovulation-inducing drug therapy and

³ See eg *Testing Embryos and Ethics: Where Do We Draw the Line?*, AMERICAN MEDICAL NEWS (Feb. 26, 2007), <http://www.amednews.com/article/20070226/profession/302269966/4/> (last visited May 25, 2018). In this article, fertility specialists discuss their personal philosophies and practices regarding patient requests for transfer of embryos detected as carrying genes for what the doctors' label as disabilities—such as deafness and dwarfism. One physician reports he is willing to transfer such embryos, reasoning that the parents, not the doctor, have the authority to make that decision. Another provider takes an opposite view, describing his clinic's practice as follows: 'We are not participating in this kind of request, because our goal is to prevent disease, not to create disease... I can't judge someone who wants to have, for example, a Down syndrome child, but it does not have to be us to participate in it. That is not our goal as scientists and medical professionals.'

⁴ See Cystic Fibrosis Foundation, *About Cystic Fibrosis*, <https://www.cff.org/What-is-CF/About-Cystic-Fibrosis/> (last visited Aug. 29, 2017) (noting more than 30,000 individuals are living with CF in the USA).

⁵ See National Institutes of Health, *Polycystic Ovary Syndrome (PCOS): Condition Information*, <https://www.nichd.nih.gov/health/topics/PCOS/conditioninfo/Pages/default.aspx> (last visited Aug. 29, 2017) (noting that PCOS affects between 8% and 20% of reproductive-age women worldwide).

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 5-day stage. The REI 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 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), 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 infertility doctor 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 prospective mother 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.⁶ Reviewing Kathy Lee’s chart and intake questionnaire, the REI 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 culture, rejecting the notion that deafness is a disability in her life or the lives of those in her deaf community.⁷ Ms. Lee has already selected an anonymous 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 physician and clinic from any and all liability in connection with the provision of reproductive medicine services.

These assisted reproductive technologies (ART) inspired scenarios in which a genetically anomalous embryo is either discovered through routine preimplantation testing or intentionally sought through IVF to challenge the prevailing norm surrounding PGT—that any and all embryos revealed to bear health-affecting genetic abnormalities will not be selected for transfer.⁸ The underlying presumption supporting this norm is that in any given IVF cycle, the provider and the patient share as their common goal

⁶ Genetic deafness can be autosomal dominant, autosomal recessive, or X-linked recessive. See A. Eliot Shearer, Michael S. Hilderbrand & Richard J. H. Smith, *Hereditary Hearing Loss and Deafness Overview*, in GENE REVIEWS (last revised July 2017), <https://www.ncbi.nlm.nih.gov/books/NBK1434/> (last visited Aug. 29, 2017).

⁷ The discussion surrounding the nature of deafness—disability or difference—is passionate and evolved. See eg 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 or subculture).

⁸ 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).

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 dwells 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 burden their infertility journey has wrought.⁹ 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.¹⁰ Provider judgement 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.¹¹ But when the question is not *how many* to transfer but *whether* to transfer at all, 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 likely diverge from those of the medical provider when an embryo with a known genetic anomaly is transferred. From the provider’s perspective, actively participating

⁹ 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, *Guidance on the Limits to the Number of Embryo to Transfer: A Committee Opinion*, 107 FERTIL. & STERIL. 901 (2017), http://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/non-members/guidance_on_the_limits_to_the_number_of_embryos_to_transfer-norprint.pdf (last visited Aug. 28, 2017). 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 HUM. REPROD. 2673 (2007) (data showing patients undergoing IVF prefer twins to one child at a time).

¹⁰ 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?*, <https://www.shadygrovefertility.com/application/files/5014/4968/4250/But-I-Want-Twins.pdf> (last visited Aug. 28, 2017).

¹¹ The morbidity and mortality associated with multiple pregnancy, especially triplet or greater, is well known and oft-described in ART literature. See eg Robert J. Stillman et al., *Elective Single Embryo Transfer: A 6-Year Progressive Implementation of 784 Single Blastocyst Transfers and the Influence of Payment Method of Patient Choice*, 92 FERTIL. & STERIL. 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).

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.¹²

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 about the nature of the child that may ultimately be born.¹³ 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.

This 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 with aneuploidy—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 more than one line of cells, with one line presenting as normal and the other as abnormal.¹⁴ In a handful of studies, researchers report the birth of chromosomally healthy children after transfer of embryos

¹² 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 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.

¹³ See eg JOHN 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).

¹⁴ 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),

determined by PGT to be aneuploid, calling into question the reliability of genetic testing in the presence of mosaicism.¹⁵ 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' 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 non-existence will be offered. Together, these rationales are steeped in the values of patient autonomy, reproductive equality, and the preference for birth over non-existence.

The arguments for declining patient requests for transfer of genetically anomalous embryos are set out in Part III. Here, four 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 prognosis. Next, two theories interchangeably support a physician's refusal to further the patient's reproductive plan. Reproductive non-maleficence 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 finally, as rational actors in a litigious society, physicians may calculate their exposure to legal liability for assisting in the birth of a seriously impaired human being—assessing a greater risk for acts undertaken versus acts 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

<https://www.centerforhumanreprod.com/fertility/possibility-selectively-transferring-embryos-preimplantation-genetic-diagnosis-pgdpgs-determined-chromosomally-abnormal/> (last visited Aug. 29, 2017).

¹⁵ See *infra* text accompanying notes 33–38.

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 PGT

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 USA, conception by IVF accounts for approximately 1.8% of the total birth rate, leaving 98.2% of newborn Americans to the vicissitudes of nature.¹⁶ Of the roughly 70,000 infants who met their earliest moments in a petri dish, again only a small percentage also endured PGT. According to the Centers for Disease Control and Prevention (CDC), in 2014 approximately 4% of all IVF cycles included PGT.¹⁷ 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 2800 children were born as a result of these combined technologies.¹⁸ While the percentage of PGT cycles has actually declined in

¹⁶ 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 USA 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], <http://www.cdc.gov/art/pdf/2014-report/art-2014-national-summary-report.pdf> (last visited Dec. 7, 2017). The total US birth rate in 2014 was 3985,924 (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, http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_06.pdf (visited Dec. 7, 2017). Thus, IVF accounts for 1.77% of US births.

¹⁷ See 2014 ART REPORT, *supra* note 16, at 5.

¹⁸ 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 2800 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), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3996805/> (last visited Feb. 10, 2017). Thus, if the cohort of PGT embryos is limited to those most at risk for anomaly (and therefore

recent years—falling from 6% in 2013 to 4% in 2014 – experts in the field continue to predict increased usage of genetic technologies to assess embryo health.¹⁹

The opportunity to know one’s future child’s genetic make-up is a relatively recent phenomenon, entering clinical reality in the early 1990s.²⁰ 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 roughly 400 genetic conditions, including Down syndrome, Tay Sachs, CF, 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, today’s parental choices in the face of PGT results are threefold: implant, discard, or freeze.²¹ Selection among this trilogy can be influenced by a number of factors, 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 PGT 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 USA, 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’.²² The impression cast is that

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.

¹⁹ See CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T. OF HEALTH AND HUM. SERVS., 2013 ASSISTED REPRODUCTIVE TECHNOLOGY: NATIONAL SUMMARY REPORT 3 (2015), http://www.cdc.gov/art/pdf/2013-report/art_2013_national_summary_report.pdf (visited Dec. 7, 2017) (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 16, 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 HUM. REPROD. 1418 (2013) (an expert panel agreed that broadened embryo testing is a likely development).

²⁰ 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).

²¹ But see *supra* note 2.

²² See 2014 ART REPORT, *supra* note 16, at 65.

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 aneuploidy.²³ 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.²⁴ PGT to investigate a particular gene (as opposed to the full 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.²⁵

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 CF 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 imbued 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% in PGT cycles performed

²³ See Elizabeth 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).

²⁴ Susannah Baruch, David Kaufman & Kathy L. Hudson, *Genetic Testing of Embryos: Practices and Perspectives of US In Vitro Fertilization Clinics*, 89 FERTIL. & STERIL. 1053 (2008).

²⁵ See Darshak Sanghavi, *Wanting Babies Like Themselves, Some Parents Choose Genetic Defects*, NEW YORK TIMES (Dec. 5, 2006) at FS, <http://www.nytimes.com/2006/12/05/health/05essa.html> (last 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).

over a 10-year period.²⁶ 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.²⁷ 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 technical error can—and have—become the subject of a lawsuit against the IVF provider or facility. In the handful of cases litigated and reported to date based on PGT mishaps, legal claims cluster around causes of action for negligence and/or lack of informed consent.²⁸

Informed consent for PGT—providers 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 analyse genetic material from an IVF embryo has evolved since PGT was first introduced in the 1990s.²⁹ For the first two decades of use, PGT typically involved the extraction and genetic analysis of one of the four to eight totipotent cells of the early embryo, called a blastomere, traditionally performed on the third day of embryonic development.³⁰ The totipotency of these early embryonic cells means that each cell contains the entire genome of the developing human.³¹ 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 one of the 23 pairs) or a single gene disorder (such as Tay-Sachs, sickle cell anemia, Huntington's disease, or CF).³²

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

²⁶ See Leeanda Wilton et al., *The Causes of Misdiagnosis and Adverse Outcomes in PGD*, 24 HUM. 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).

²⁷ *Id.*

²⁸ See Tochi Amagwala et al., *Preimplantation Genetic Diagnosis: A Systematic Review of Litigation in the Face of New Technology*, 98 FERTIL. & STERIL. 1277 (2012) (analysing cases involving adverse outcomes involving PGT, including switched embryos, false-negative results, and the failure to offer the technique during IVF).

²⁹ 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).

³⁰ Totipotency in the early embryo refers to the ability of each cell to develop into all the cell types in the body, plus the placenta, thus potentially giving rise to an entire human being. Embryonic cells remain totipotent only for up to three or so days, when they become pluripotent—capable of developing into any cell type but not the entire human organism. See NYSTEM New York State Stem Cell Science, <https://stemcell.ny.gov/faqs/what-difference-between-totipotent-pluripotent-and-multipotent> (last visited May 25, 2018).

³¹ 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), <https://www.sciencedaily.com/releases/2009/12/091222105103.htm> (last visited Aug. 29, 2017).

³² See News-Medical, *Single Gene Genetic Disorders*, <http://www.news-medical.net/health/Single-Gene-Genetic-Disorder.aspx> (last visited Aug. 28, 2017).

number of chromosomal pairs that could be analysed. 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.³³ 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 analysed. 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 trophoctoderm), rather than extraction of a single cell from the embryo itself at day 3. This move to trophoctoderm biopsy provides more cell material to analyse, thus improving accuracy while reducing embryo loss following the procedure.³⁴ The procedure also avoids invasion of the developing fetus 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.³⁵ 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, 6 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 trophoctoderm and thus did not inhabit the developing infant.³⁶ 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 process. Additional research may shed light on 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

³³ See Laurie Tarkan, *Screening for Abnormal Embryos Offers Couples Hope After Heartbreak*, NEW YORK TIMES, Nov. 22, 2005 (reporting 30% of embryos have mosaicism, leading to a 4% rate of misdiagnosis using PGD).

³⁴ See Ruthi B. Lathi et al., *Outcomes of Trophoctoderm Biopsies on Cryopreserved Blastocysts: A Case Series*, 25 REPROD. BIOMED. ONLINE 504 (2012), [http://www.rbmojournal.com/article/S1472-6483\(12\)00414-2/abstract](http://www.rbmojournal.com/article/S1472-6483(12)00414-2/abstract) (last visited Aug. 29, 2017).

³⁵ E. Fragouli et al., *The Developmental Potential of Mosaic Embryos*, 104 FERTIL. & STERIL. 396 (ASRM Abstracts) (2015).

³⁶ Ermanno Greco & Maria Giulia Minasi, *Healthy Babies After Intrauterine Transfer of Mosaic Aneuploidy Blastocysts* 373 NEW ENG. J. MED 2089 (2015). The errors rates surrounding PGT continue to be studied, with some estimates pegging the proportion of normal embryos discarded following (inaccurate) test results as high as 40%. See Richard Paulson, *Preimplantation Genetic Screening: What is the Clinical Efficiency?*, 108 FERTIL. & STERIL. 228 (2017). Dr Paulson concludes that in light of these unknowns, '[w]e owe it to our patients to understand the clinical efficiency of PGS in order to provide a true picture of the risks and benefits of this procedure and to attain true informed consent'.

be forced 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’.³⁷ 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.³⁸ The admonition by at least one research group that physicians consider transferring abnormal-appearing embryos under certain circumstances raises questions about current clinical practices. What information are clinics sharing with patients about the genetic make-up of their embryos and what recommendations follow as a result? 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 information-sharing approach 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 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’.³⁹ 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 sharing 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’.⁴⁰ 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 positive’ abnormality

³⁷ Fragouli, *supra* note 35.

³⁸ *Id.*

³⁹ *Transferring Supposedly Chromosomally “Abnormal” Embryos in an IVF Cycle*, Center for Human Reproduction (Press Release, Oct. 27, 2014), <https://www.centerforhumanreprod.com/fertility/transferring-supposedly-chromosomally-abnormal-embryos-ivf-cycle/> (last visited Jan. 3, 2018).

⁴⁰ *Id.* See also Kira Peikoff, *In IVF, Questions About ‘Mosaic’ Embryos*, NEW YORK TIMES, Apr. 18, 2016, https://www.nytimes.com/2016/04/19/health/ivf-in-vitro-fertilization-pregnancy-abnormal-embryos-mosaic.html?_r=0 (last 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).

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’.⁴¹

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 CF) 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)? Distinctions among and between medical and social constructions of health, disability, and traits have long engaged academics and advocates alike, creating a rich tapestry of deep thinking that informs the values clash discussed herein. The disability rights critique warns against prospective parents allowing ‘a single trait [to] stand[] in for the whole’, and urges all of us to see that differently abled children ‘are likely to be as enjoyable, pride-giving, positive...as any other child’.⁴² At the same time, voices within the disability rights community report continuing, persistent, pervasive discrimination against people with disabling traits, even when those affected view themselves as ‘normal’ members of society.⁴³ The goal herein is not to parse through the debate over what does it mean to be healthy, unhealthy, or disabled, but rather to acknowledge that in the realm of embryo transfer, patients and providers bring their own answers to the petri dish. For patients like Kathy Lee, selecting for a child with diminished functionality in one sense (hearing) may yield enhanced functionality in other senses.

We know very little about the patient population who request to transfer or seek out embryos with known genetic anomalies other than they do exist in some small measure. As to the quest to give birth to a child with a health-affecting genetic anomaly, 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’.⁴⁴ Likewise, prospective parents of short stature caused by achondroplasia have approached fertility specialists to assure the birth of a little person, expressing a desire for a child who is ‘just like them’.⁴⁵

⁴¹ *Id.*

⁴² See Erik Parens & Adrienne Asch, *The Disability Rights Critique of Prenatal Genetic Testing*, HASTINGS CENTER REPORT (Sept. – Oct. 1999) at S5.

⁴³ *Id.* at S2, S15.

⁴⁴ Richard Gray, *Couples Could Win Right To Select Deaf Baby*, THE TELEGRAPH, Apr. 13, 2008, <http://www.telegraph.co.uk/news/uknews/1584948/Couples-could-win-right-to-select-deaf-baby.html> (last visited Jan. 9, 2018).

⁴⁵ Sanghavi, *supra* note 25.

As reported in these same news items, some physicians express an unwillingness to treat patients in pursuit of so called ‘intentional diminishment’.⁴⁶ One Washington, DC, 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.’⁴⁷ 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.’⁴⁸ 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’, 3% of clinics answered in the affirmative.⁴⁹ 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’.⁵⁰

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 must often choose between raising a health-impaired child and accepting a childless existence.⁵¹ 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.⁵² 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 role in the informed consent process immensely. With the goal of facilitating provider decision-making, Parts II and III offer rubrics for assessing patient requests for the transfer of genetically anomalous embryos and possible provider responses.

⁴⁶ See I. Glenn Cohen, *Intentional Diminishment, The Non-Identity Problem, and Legal Liability*, 60 HASTINGS L. J. 347 (2008).

⁴⁷ Sanghavi, *supra* note 25.

⁴⁸ *Id.*

⁴⁹ Baruch, *supra* note 24.

⁵⁰ *Id.* at 1056.

⁵¹ This assertion is made in the context of patients who desire a full biologic offspring and eschew other family formation techniques such as gamete or embryo donation and adoption.

⁵² In 2016, genetic counselor researchers conducted a survey of their peers at the annual ASRM meeting to understand how clinics approach patient requests for transfer of abnormal embryos. When asked about clinic policies on these scenarios, 44% responded that their clinics handle requests on a case-by-case basis. One third responded their clinics have a policy and it is discussed with patients prior to testing (31%). Nine per cent of respondents said their clinics have no policy in place. Lauri Black, Emily Mounts & Alyssa C. Snider, 2016 ASRM Annual Meeting, Interactive Session, *Managing the Gray Results with Preimplantation Genetic Testing: What Do We Tell Patients When the Results Are Not Black or White?* [hereafter Black] (on file with author).

II. Honoring Patient Requests for Transfer

Intrinsic in ART family formation is the relationship, ideally the partnership, between the patient and the provider. Key to any successful relationship is common values and goals that reduce conflict and support shared decision-making. Research surrounding the doctor–patient relationship in ART focuses primarily on the challenges of informed consent, supplying no indicia that these stakeholders are routinely at odds over the desire for treatment to yield a live born infant.⁵³ 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.⁵⁴ 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 and suffer demise, (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 an 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. 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.⁵⁵ Stepping into the patient’s shoes may give the physician 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,

⁵³ See eg Jody Madeira & Barbara Andracka-Christou, *Paper Trails, Training Behind: Improving Informed Consent to IVF Through Multimedia Applications*, 3 J. L. & BIOSCI. 2 (2016), <https://academic.oup.com/jlb/article/3/1/2/1751255/Paper-trails-trailing-behind-improving-informed?searchresult=1> (last visited Jan. 9, 2018).

⁵⁴ 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).

⁵⁵ For a discussion of physicians’ negative attitudes toward disability in general, and toward reproduction by women with disabilities in particular, see Ora Prilietensky, *A Ramp to Motherhood: The Experiences of Mothers with Physical Disabilities*, 21 SEXUAL & DISABILITY 22–23 (2003). As explained by Ora Prilietensky, professor, author, and mother with a disability, ‘In addition to the myth of asexuality and skepticism regarding their ability to attract partners, women with disabilities have been discouraged from having children for a variety of other reasons. Concerns that they will give birth to ‘defective’ babies and prejudicial assumptions about their capacity to care for children often underpin the resistance that they may encounter.’

Professor John Robertson described procreative liberty as ‘a negative right against state interference with choices to procreate or to avoid procreation’.⁵⁶ 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’.⁵⁷ 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 reproductive rights legal landscape arguably holds sway over the right to access the means to reproduction through ART.⁵⁸

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 US Supreme Court’s 1992 abortion decision.⁵⁹ 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’.⁶⁰ In 2016, the Court reaffirmed the basic parameters of *Casey*,^x applying the undue burden test to a Texas law requiring abortion providers obtain admitting privileges at 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.⁶¹

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 enactments 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,

⁵⁶ JOHN ANDREA ROBERTSON, *CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES* 23 (1994).

⁵⁷ *Id.* at 4.

⁵⁸ The debate over whether the constitutional treatment of abortion extends to ART has been robust and longstanding. See eg ROBERTSON, *supra* note 56 (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 non-coital 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).

⁵⁹ 505 U.S. 833 (1992).

⁶⁰ *Id.* at 878.

⁶¹ *Whole Woman’s Health v. Hellerstedt*, 579 U.S. (2016).

a physician's refusal to transfer existing embryos is as much a structural obstacle to her right to exercise reproductive liberty as a law that prohibits her from ending an unwanted pregnancy. This argument is made with conscious exclusion of the disparate impact these reproduction-related acts would likely have on the affected woman, but is offered to inject a patient-centered framework on the external forces that interact with reproductive decision-making. A woman's 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 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 US-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'.⁶² In an opinion discussing the ethics and law surrounding sex selection of embryos for non-medical 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.'⁶³ The Committee opinion then discusses the various reasons patients might have to preferring one sex over another—ie 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 be embedded in the concept of

⁶² Ethics Committee of the American Society for Reproductive Medicine, *Transferring Embryos with Genetic Anomalies Detected in Preimplantation Testing*, 107 FERTIL. & STERIL. 1130 (2017) (hereafter *ASRM Genetic Anomalies Opinion*).

⁶³ Ethics Committee of the American Society for Reproductive Medicine, *Use of Reproductive Technology for Sex Selection for Nonmedical Reasons*, 103 FERTIL. & STERIL. 1418 (2015).

constitutionally protected reproductive liberty and thus not amenable to infringement by the government or those who operate as state actors.⁶⁴

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.⁶⁵ 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.⁶⁶ So long as the patient is provided appropriate counseling and information in line with principles of informed consent, the provider's obligation—in deed 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 well-worn refrain suggests there is a certain biological marker that distinguishes the pregnant from the non-pregnant state, dismissing any suggestion that pregnancy is a process rather than an existential condition.⁶⁷ 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

⁶⁴ *Id.* at 1419. The preeminence of reproductive liberty in the USA comes into even sharper focus when ART policies from other developed nations are compared to the relatively regulatory-free environment under which American patients and physicians operate. Most countries with a developed IVF infrastructure prohibit the use of PGT for non-medical sex selection. In the UK, for example, where non-medical sex selection is prohibited under the country's Human Fertilisation & Embryology Act, the perceived harms of selecting a child's sex are seen by the public as more important than a woman's reproductive autonomy. See *Id.* at 1420, citing P. Herrison-Kelly, *The Prohibition of Sex Selection for Social Reasons in the United Kingdom: Public Opinion Trumps Reproductive Liberty?*, 15 CAMBRIDGE Q. HEALTHCARE ETHICS 261 (2006).

⁶⁵ ASRM *Genetic Anomalies Opinion*, *supra* note 62, at 1131.

⁶⁶ 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).

⁶⁷ 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).

of post-implantation embryos (i.e., abortion) is highly regulated and subject to an ever-increasing network of restrictions.⁶⁸

Let us assume for the sake of analysis that equality is an important value in the regulation 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 in their choices regarding embryo disposition. 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 moment of conception—thus making abortion illegal in most circumstances.⁶⁹ To date, this movement has not realized abundant success, in part because of its agenda's 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.⁷⁰ Post-election surveys revealed that 31% of voters stated they voted against the measure for fear that it would reduce the availability of IVF.⁷¹ 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.⁷² The popularity of IVF and its embedded role in American family formation seems to transcend long-held views about the sanctity of human life in all its forms.⁷³

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

⁶⁸ For a listing of the current state and federal laws regulating abortion, see Guttmacher Institute, *An Overview of Abortion Laws*, <https://www.guttmacher.org/state-policy/explore/overview-abortion-laws> (last visited Mar. 9, 2017).

⁶⁹ For competing advocacies on legislating personhood of embryos compare The Personhood Movement, <https://www.propublica.org/article/the-personhood-movement-timeline> (accessed Jul. 16, 2018) with ASRM Position Statement on Personhood Measures, https://www.asrm.org/ASRM_Position_Statement_on_Personhood_Measures/ (last visited Mar. 9, 2017).

⁷⁰ See Jonathan F. Will, *Beyond Abortion: Why the Personhood Movement Implicates Reproductive Choice*, 39 AM. J. L. & MED. 573, 584 (2013).

⁷¹ *Id.* at 585.

⁷² 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 5 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.

⁷³ See *supra* note 16, noting IVF accounts for nearly 2 of every 100 births in the USA today.

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), whose data are in turn made available to the public.⁷⁴ As a result of the law, the vast majority of ART clinics in the USA 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.⁷⁵

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, 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.⁷⁶ 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.⁷⁷

⁷⁴ 42 U.S.C. §263a-1 et seq. (1992).

⁷⁵ 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).

⁷⁶ See eg Marissa A. Mastroianni, *Bridging the Gap Between the 'Have' and the 'have-Nots': The ACA Prohibits Insurance Coverage Discrimination Based Upon Infertility Status*, 79 ALB. L. REV. 151 (2015–2016); Camille M. Davidson, *Octomom and Multi-fetal Pregnancies: Why Federal Legislation Should Require Insurers to Cover In Vitro Fertilization*, 17 WM. & MARY J. WOMEN & L. 135, 167 (2010); Deborah Spar & Anna M. Harrington, *Building a Better Baby Business*, 10 MINN. J.L. SCI. & TECH 41 (2009); Elizabeth Pendo, *The Politics of Infertility: Recognizing Coverage Exclusions as Discrimination*, 11 CONN. INS. L. J. 293 (2004–2005).

⁷⁷ An interesting side story to the impact that physician values and preferences may have on patient reproductive decision-making is being played out in the form of state laws that protect doctors from legal liability for failing to inform a pregnant patient that her prenatal test results indicate some abnormality with her fetus. Physicians in these states who personally oppose abortion can intentionally (and legally) withhold prenatal test results for the express purpose of preventing their patient from terminating her pregnancy. These so called 'wrongful birth' statutes, now enacted in nine states, prohibit a cause of action under the medical malpractice rubric against physicians who withhold information from patients about a child's potential health issues that could influence their decision to have an abortion. For example, the law in Arizona provides, 'A person is not liable for damages in any civil action from wrongful birth based on a claim that, but for an act or omission of the defendant, a child or children would not or should not have been born.' ARIZ. REV. STAT. §12-718 (2017). Presumably the broad language in the Arizona bill could also be used to shield ART providers from liability who fail to disclose PGT results indicating a genetic anomaly in one or more embryos. Likewise, the statute might protect a physician who agrees to honor a patient request for transfer—eliminating one of the rationales discussed in Part III supporting refusals to transfer.

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 any 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 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 USA 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.⁷⁸

What can disputes between one-time aspirational parents teach us about conflicts between physicians and patients over the transfer of genetically anomalous embryos? Jurisprudentially, probably very little. Conflicts between divorcing couples are resolved through family law, while clashes in the medical setting are typically analysed as a matter of contract or tort law.⁷⁹ But there is at least one relevant finding that emerges from the dissolution case law that could inform disputes over embryo transfer—the allocation of dispositional authority exclusively to the prospective parents to the exclusion of the physician who aided in the embryos' development. While courts have differed on their

⁷⁸ For an excellent review of US 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). See also Tim Schlesinger, *Embryo Disposition Upon Separation or Divorce*, 12 No. 4 ABA SCITECH LAW 22 (2016); Michael T. Flannery, 'Rethinking' *Embryo Disposition Upon Divorce*, 29 J. CONTEMP. HEALTH L. & POL'Y 233 (2013); Deborah L. Forman, *Embryo disposition and Divorce: Why Clinic Consent Forms Are Not the Answer*, 24 J. AM. ACAD. MATRIM. LAW. 57 (2011).

⁷⁹ 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 instances are rare but notorious. See eg *Fertility Doctor Fathers* 75, DOMINION POST, July 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 5 years in federal prison); MARY DODGE & GILBERT GEIS, *STEALING DREAMS: A FERTILITY CLINIC SCANDAL* (2004) (describing theft and unconsented transfer of patient eggs and embryos at the UCI Center for Reproductive Health in the early 1990s).

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, 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 development and not those who actually 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 bailor [the Yorks]'.⁸⁰ 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 against the clinic.⁸¹

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? Setting aside 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.⁸² 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'.⁸³ 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 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.

⁸⁰ *York v. Jones*, 717 F. Supp. 421, 425 (E.D. Va. 1989).

⁸¹ *Id.* at 427.

⁸² See *Conversion of Bailed Property: Particular Conduct as Constituting Conversion*, 75 A.L.R.2d 1044, Sec. 7(b) (West 2017).

⁸³ *Id.*

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 US 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.⁸⁴

The Louisiana law is consistent with a bailment theory in that the physician is expressly deemed to hold no ownership interest but rather is regarded as an agent entitling the provider to deal with the property in good faith. Deeming a physician as temporary guardian of an embryo 'until adoptive 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 standing 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 patient and provider. The problem of prediction has already been discussed, as it relates to the phenomenon of embryonic mosaicism.⁸⁵ While providers can (and should) explain the possibility of a false-positive PGT test result due to the presence of both normal and abnormal cell lines, the discussion should further include a description of the potential disorder affecting the embryo. While the symptoms and treatment, if any, for the detected disease can be conveyed to the patient, the likelihood of accurately predicting the course or extent of the offspring's disease course remains low. 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.

⁸⁴ La. Rev. Stat. §9:126 (2017).

⁸⁵ See *supra* text accompanying notes 33–38.

Recall Mr. and Mrs. Johnson whose entire batch of embryos tested positive for CF, a progressive autosomal recessive disease that causes persistent lung infections and limits the ability to breathe over time.⁸⁶ 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’.⁸⁷ Symptoms such as lung infections and coughing can be mild or severe. In a hopeful note, researchers predict a child born with CF in the 2000s will survive into their 50s, compared with average life expectancy of 10 years old for a child with CF in the 1960s.⁸⁸ The Johnsons might heavily favor transferring one or more of their CF embryos over any of the other options open to them, including childlessness, 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.⁸⁹

Hypothetical patients Rosa and Carlos Gomez expressed a desire that their providers select two embryos for transfer from the batch of three that remain viable. One of those embryos has been deemed aneuploid—with an extra chromosome in the 21st pair, consonant with Down syndrome. In addition to discussing the possibility of mosaicism, in this clinical scenario the provider 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 CF, 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, ‘Down syndrome symptoms vary from person to person and can range from mild to severe.’⁹⁰ The National Down Syndrome Congress concurs, adding, [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.⁹¹

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 non-existence (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

⁸⁶ See The Cystic Fibrosis Foundation Website, *About Cystic Fibrosis*, <https://www.cff.org/What-is-CF/About-Cystic-Fibrosis/> (last visited Mar. 31, 2017).

⁸⁷ *Id.*

⁸⁸ Wendy Henderson, *Life Expectancy When You’re Living with Cystic Fibrosis*, CYSTIC FIBROSIS NEW TODAY (May 24, 2017), <https://cysticfibrosisnewstoday.com/2017/05/24/living-cf-life-expectancy/> (last visited Jan. 10, 2018).

⁸⁹ 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 Cystic Fibrosis Foundation Website, *supra* note 86.

⁹⁰ *Down Syndrome*, MEDLINEPLUS, <https://medlineplus.gov/ency/article/000997.htm> (last visited Apr. 4, 2017).

⁹¹ *Facts About Down Syndrome & Language Guidelines*, National Down Syndrome Congress, <http://www.ndscenter.org/wp-content/uploads/VO-Down-Syndrome-Facts-and-Language-Guidelines.pdf> (last visited April 3, 2017).

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 non-birth 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 (hypothetical persons) 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 every case to the never born.⁹² 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.'⁹³ 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.⁹⁴

The prediction problem coupled with corollary principle of favoring life over nonexistence 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 mental health professionals 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 treats 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.

⁹² See DAAR, *supra* note 54, at 176 (2017), citing Seana Valentine Shiffrin, *Wrongful Life, Procreative Responsibility, and the Significance of Harm*, 5 LEGAL THEORY 117 (1999).

⁹³ ASRM *Genetic Anomalies Opinion*, *supra* note 62.

⁹⁴ *Id.*

III. Declining Patient Requests for Transfer

The absence of published studies or other formal reporting on the frequency and motivation for physician refusals to transfer embryos on the basis of anticipated offspring health poses challenges to an empirical analysis of this clinical scenario, but sufficient anecdotal and ancillary data exist to permit a reasonable discussion. Part I(C) reports on two physicians who refused to aid patients with sensory and mobility deficits use PGT to create similarly-(dis)abled embryos. Asserting that parents have a duty to ‘make a better world for our children’ such that diagnostic tools should be used ‘to avoid disease’, these providers refused requests for fertility care in which a child was highly certain to be born with gene-based health difficulties.⁹⁵ These cases, like the hypothetical case of Kathy Lee (the deaf woman in pursuit of a non-hearing child), speak to provider refusals when patients seek to orchestrate the formation of a genetically anomalous embryo. A deviation on this scenario—and one more likely to occur in the clinical setting—involves clashes over transfer when embryos are tested to assure offspring health but are determined to be anomalous by PGT. Anomalies that are the result of one or both parents being carriers of a genetic mutation (the hypothetical Johnsons) or are spontaneous in the embryo (the hypothetical Gomezes) can be unexpectedly requested for transfer. The ‘unexpected’ element of this scenario arises from the logic that if would-be parents utilize PGT to screen for embryo health, they presumably are only interested in transferring healthy embryos. But this logic is disrupted when the realities of one or possibly all embryos present as anomalous. At least one fertility clinic has published a thoughtful review of this scenario where transfer of an embryo with a BRCA-1 mutation was contemplated; in that case the consulting ethics committee concluded that transfer of a known affected embryo should be prohibited ‘based on the principle that if a patient is willing to accept an affected embryo, then PGD is unnecessary.’⁹⁶ In its careful analysis, the Boston-area hospital ethics committee considered a range of values and ethical precepts to guide its decision toward refusing to transfer the affected embryo. What follows is a survey of the primary rationales that support provider refusals to transfer embryos with known genetic anomalies.

A. The Preeminence of Provider Autonomy

The sway and import of patient autonomy in the realm of bioethics in general and reproductive decision-making in particular is long standing and well accepted. Tracing its policy origins at least back to the 1979 Belmont Report setting out ethical principles and guidelines for research involving human subjects, the concept of autonomy recognizes that a ‘person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.’⁹⁷ The Belmont Report further clarified that in the research setting, ‘to respect autonomy is to give weight to autonomous persons’ considered opinion and choices while refraining from obstructing their actions

⁹⁵ See *supra* note 48.

⁹⁶ Iris G. Insogna & Elizabeth Ginsburg, *Transferring Embryos With Indeterminate PGD Results: The Ethical Implications*, FERTIL. RES. & PRACT. (Feb. 2016), <https://fertilityresearchandpractice.biomedcentral.com/articles/10.1186/s40738-016-0014-9> (last visited Sept. 12, 2017).

⁹⁷ The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Department of Health, Education and Welfare, ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (Apr. 18, 1979), <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html> (last visited Sept. 12, 2017).

unless they are clearly detrimental to others'.⁹⁸ Respect for patient autonomy in the medical treatment setting is equally vaunted, often discussed as a core value in medical ethics.⁹⁹ The notion that patients are entitled to self-determination and freedom from physician paternalism has translated into a complex network of policies and jurisprudence grounded in the protection of a person's bodily integrity. In the specific realm of reproductive decision-making, bodily integrity plays an essential role in upholding patient autonomy and rights to self-determination. As briefly set out in Part II(A), procreative autonomy is regarded as a preeminent value in reproductive medicine, often serving as the basis for physician deference to patient choice. With such robust and established adherence to patient autonomy in reproductive medicine, the question for this Part is what role, if any, does physician autonomy play in the delivery of infertility care?

Though not nearly as well developed in the literature as patient autonomy, the notion of physician autonomy does occasionally make its way into discussions surrounding medical ethics. Once a doctor–physician relationship is established—an entry point itself subject to assertions of physician autonomy—providers are not obligated to meet every patient demand for treatment.¹⁰⁰ Even in the face of an established relationship, the right of doctors to assert their own self-determination interest by refusing to provide requested care is a recognized value in medical ethics. The American Medical Association includes broad language about a physician's right to decline to provide specific care in its published principles of medical ethics. According to the AMA Code of Medical Ethics, a physician may refuse to provide care when '[t]he patient requests care that is beyond the physician's competence or scope of practice; is known to be scientifically invalid; has no medical indication, or cannot reasonably be expected to achieve the intended clinical benefit; or is incompatible with the physician's deeply held personal, religious, or moral beliefs in keeping with the ethics guidance on exercise of conscience'.¹⁰¹ At its most basic level, the AMA's support for physician refusals of care can be justified by reasons of medical non-benefit and personal conscience. On the limits of

⁹⁸ *Id.*

⁹⁹ See TOM BEAUCHAMP & JAMES CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* (7th ed. 2013) (first published in 1979, setting out four principles at the core of moral reasoning in health care—respect for autonomy, non-maleficence, beneficence, and justice).

¹⁰⁰ The concept that a physician is free to determine whether or not to enter into a doctor–patient relationship with a prospective patient is embedded in medical ethics and health law. The American Medical Association recognizes physician autonomy in the selection of patients as a basic principle of medical ethics, stating 'a physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve'. See American Medical Association, *PRINCIPLES OF MEDICAL ETHICS VI* (adopted June 1957, revised 1980, 2001), <https://www.ama-assn.org/sites/default/files/media-browser/principles-of-medical-ethics.pdf> (last visited Sept. 25, 2017). Legal recognition of physician autonomy is also a key component of American health law. Professor Barry Furrow and his colleagues, who authored a major textbook in health law, describe the principle of physician autonomy in the context of the doctor–patient relationship as follows: 'The traditional legal principle governing the physician-patient relationship is that it is a voluntary and personal relationship which the physician may choose to enter or not for a variety of reasons. Legal obligations on the part of providers to furnish care operate as exceptions to this general rule.' BARRY R. FURROW ET AL., *HEALTH LAW* 529 (5th ed. 2004).

¹⁰¹ American Medical Association, *CODE OF MEDICAL ETHICS*, Sec. 1.1.2(a) (2001), <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-1.pdf> (last visited Sept. 12, 2017).

exercise of personal conscience, the AMA acknowledges that ‘physicians should have considerable latitude to practice in accord with well-considered, deeply held beliefs that are central to their self-identities’.¹⁰²

Treatment refusal as an exercise of physician autonomy has also been considered by the subset of clinicians who provide infertility care—specialists in obstetrics and gynecology. The American College of Obstetrics & Gynecology Committee on Ethics has written extensively on the topic of conscientious refusal in reproductive medicine, presenting a thorough analysis of the nuances involved in this delicate decision-making process. While ACOG does support—in most but not all instances—a physician’s right to decline to provide treatment based on assertions of conscience, the limits of these refusals occupy the realm of patient requests for ‘medically indicated’ or ‘standard care’.¹⁰³ In the main, the ACOG discussion centers on physician objection to abortion, but other clinical scenarios are provided. The ART example used in the ACOG ethics committee opinion is a physician who refuses to perform intrauterine insemination for a lesbian couple, prompted by the provider’s religious beliefs and disapproval of lesbians having children.¹⁰⁴ In that case, the standard of care for the patient’s medical presentation would have been IUI (or perhaps IVF), so the assertion of conscientious refusal was a deprivation of medically indicated care. Whether refusal to transfer a genetically anomalous embryo can be similarly described as a deprivation of medically indicated care is far less certain, potentially casting such a decision outside ACOG’s well-reasoned parameters about assertions of a provider’s moral or religious integrity. An argument that transfer of genetically anomalous embryos is not medically indicated might find support in the presumption that patients who seek and consent to PGT do so for the purpose of avoiding the birth of an unhealthy child. Thus, the only medically indicated course following testing would be transfer of embryos deemed genetically normal.

Physician refusals to render treatment they consider outside the realm of medically indicated care often invoke the concept of futility or non-beneficial care. While hardly a settled matter at the bedside, medical ethics supports the principle that doctors are

¹⁰² *Id.* at Sec. 1.1.7. The AMA guidance on physician exercise of conscience further admonishes physicians who follow their conscience to give notice to prospective patients of the physician’s unwillingness to provide certain services, take care to not discriminate against or unduly burden individual patients, and uphold standards of informed consent by informing the patient about all relevant options for treatment including options to which the physician morally objects.

¹⁰³ American College of Obstetrics & Gynecology Committee on Ethics, *The Limits of Conscientious Refusal in Reproductive Medicine* (Committee Opinion 385) (Nov. 2007, reaffirmed 2016), <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Ethics/co385.pdf?dmc=1&ts=20170906T1956212396> (last visited Sept. 20, 2017). The ACOG opinion acknowledges that ‘[a]lthough respect for conscience is important, conscientious refusals should be limited if they constitute an imposition of religious or moral beliefs on patients, negatively affect a patient’s health, are based on scientific misinformation, or create or reinforce racial or socioeconomic inequalities’.

¹⁰⁴ *Id.*, referring to the then-pending California Supreme Court decision in *North Coast Women’s Care Medical Group, Inc. v. San Diego County Superior Court*, 44 Cal. 4th 1145, 189 P.3d 959, 81 Cal. Rptr.3d 708 (2008). In a unanimous decision, the court ruled that the rights of religious freedom and free speech, as guaranteed in both the federal and state Constitutions, do not exempt physicians from complying with the state’s civil rights laws’ prohibition against discrimination based on a person’s sexual orientation. Citing US Supreme Court precedent, the California high court explained that the First Amendment right to the free exercise of religion does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability on the ground the law is contrary to the objector’s religious beliefs. The California civil rights law—the Unruh Act—was deemed such a law of valid and neutral character.

not obligated to provide a clinical intervention that is reliably predicted to produce no medical benefit.¹⁰⁵ The notion of medical futility has been embedded in law as well as academic literature as a limitation on the patient's right to receive any and all treatment requested. The Uniform Health-Care Decisions Act, first promulgated in 1993, provides that a 'health-care provider or institution may decline to comply with an individual instruction or health-care decision that requires medically ineffective health care or health care contrary to generally accepted health-care standards applicable to the health-care provider or institution'.¹⁰⁶ The comment accompanying this particular language clarifies that 'medically ineffective health care' means treatment which would not offer the patient any significant benefit. The further inquiry, of course, is how is 'benefit' to be measured and by whom? Patients requesting embryo transfer, it seems logical to assume, see enormous benefit in experiencing a live birth no matter the health status of the resulting offspring. But the UHCDA language suggests a physician-oriented definition of benefit insofar as it references 'generally accepted health-care standards'. As such, a physician's assertion that transfer of an embryo with a health-affecting anomaly is inconsistent with generally accepted healthcare standards would likely be within the protective spirit set out in the uniform law.

Support for assertions of physician autonomy in the delivery of ART services may also arise independently of the medical appropriateness of the requested care, from a place deep within the doctor's personal identity. A physician's professional conscience, developed from the person's background, values, and experiences, can be an essential guide to clinical practice. When a physician's professional conscience conflicts with a patient's values and preferences as applied to a transfer decision, the limited data available suggest provider autonomy is rarely, if ever, suppressed under the weight of patient requests for treatment. The scant mentions of provider refusals to transfer anomalous embryos have not produced a single published case in which a court awarded specific performance or damages as a result of the doctor's refusal.¹⁰⁷ Anecdotal reports suggest assertion of physician values drive clinical outcomes. One REI, who offers PGT and alerts his patients to the possibility of a 'false positive' due to mosaicism, is clear about his position on assisting in the birth of an unhealthy child. Writing on his practice blog, Dr. Geoffrey Sher states that he is willing to transfer certain aneuploidy embryos so long as the patient completes 'a detailed informed consent agreement which would include a commitment by the patient(s) to undergo prenatal testing (amniocentesis/CVS) aimed at excluding a chromosomal defect in the developing baby and/or a willingness to terminate the pregnancy should a serious birth defect be diagnosed'.¹⁰⁸ Asking patients to agree in advance to terminate a pregnancy based on certain

¹⁰⁵ See BEAUCHAMP & CHILDRESS, *supra* note 99, at 112–15 (5th ed.).

¹⁰⁶ Uniform Health Care Decision Act, Sec. 7(f).

¹⁰⁷ In contrast, in end-of-life scenarios, physician refusals to provide care they deem medically futile have met with (mostly) rebuke by courts asked to referee these beside disputes. See eg *In re Wanglie*, No. PX-91-283 (Hennepin County Prob. Ct. Minn. July 1, 1991) (court refused to authorize physicians to discontinue ventilator support from an elderly patient in a persistent vegetative state); *In re Jane Doe*, 418 S.E.2d 3 (Ga. 1991) (holding physicians could not issue a Do Not Resuscitate order for a comatose adolescent without consent of both parents); *In re Ryan N. Nguyen*, #94206074-5 (Wash. Super. Ct., Spokane County, Nov. 22, 1994) (court ordered hospital to treat severely brain damaged infant over objection of overseeing physicians).

¹⁰⁸ Geoffrey Sher, *PGS in IVF: Some Embryos that Test PGS-Chromosomally Abnormal Can Self-Correct in the Uterus: Are We Wrongly Discarding Embryos that are Capable of Developing into Healthy Babies?*, Official

prenatal test results—while utterly unenforceable at law—is strong evidence that physician values play a leading role in ART clinical practice.

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

Principlism in medical ethics is an enduring and dominant approach to assessing and resolving ethical dilemmas in clinical medicine. Embedded into the bioethics psyche by renowned philosophers Tom Beauchamp and James Childress in their seminal book first published in 1979, *Principles of Biomedical Ethics*, four principles have served as the basis for decades of discourse on ethical best practices at the bedside and in the global health care arena. The four principles—respect for autonomy, non-maleficence, beneficence, and justice—are offered to guide moral reasoning for stakeholders in the medical realm. As previously discussed, the principle of respect for autonomy figures prominently in the armamentarium supporting a physician's decision to assist a patient seeking transfer of a genetically anomalous embryo.¹⁰⁹ Two other of these core principles seem most apt to support a physician's refusal to transfer embryos likely to lead to the birth of a health-affected child. Non-maleficence, the edict that physicians should 'above all, do no harm', and beneficence, the command to act in the best interest of the other in mind, arguably justify an REI's refusal to act in a way that brings harm to an individual (the future child) and serves the best interest of others (potentially another child who could be born from a different, genetically normal embryos, as well as society).¹¹⁰ That fact that, as applied, the Beauchamp and Childress principles do not resolve the dilemma—and in fact support completely opposite outcomes—has come to be discussed as both a flaw and an appeal of principlism.¹¹¹

A further refinement of applying ethical principles to resolve moral dilemmas in the clinical setting narrows the field to matters involving reproduction. Reproductive ethics, particularly as they apply to reproductive technologies, can be especially challenging in their application to the complexities surrounding conception and birth. One reproductive ethics framework—the principle of procreative beneficence—advocates the selection of the best child of the possible children that one could have. At its core, the principle argues that 'couples (or single reproducers) should select the child, of the possible children they could have, who is expected to have the best life, or at least as good a life as the others, based on the relevant, available information'.¹¹² Promulgated by Australian philosopher and bioethicist Julian Savulescu, procreative beneficence has attracted praise for its duty-based admonition that parents maximize the health and well-being of their future children, as well as criticism for its revitalization of long-repudiated eugenic practices aimed at suppressing the birth of 'lesser' human

Blog of Dr. Geoffrey Sher (Jan. 11, 2016), <http://drgeoffreysherivf.com/pgs-in-ivf-are-some-chromosomally-abnormal-embryos-capable-of-resulting-in-normal-babies-and-being-wrongly-discarded/> (last visited Sept. 25, 2017).

¹⁰⁹ See *supra* text accompanying notes 56–66.

¹¹⁰ See Thomas R. McCormick, *Principles of Bioethics*, in *ETHICS IN MEDICINE* (Univ. Washington School of Medicine), <https://depts.washington.edu/bioethx/tools/princpl.html> (last visited Sept. 26, 2017).

¹¹¹ Ruth Macklin, *Applying the Four Principles*, 29 *J. MED. ETHICS* 275 (2003).

¹¹² Julian Savulescu, *Procreative Beneficence: Why We Should Select the Best Children*, 16 *BIOETHICS* 413 (2001).

beings in the interest of societal betterment.¹¹³ It is noteworthy that the clinical context in which the principle of procreative beneficence arose and largely remains is the parental selection of IVF embryos based on the results of PGT. Adherents to the wisdom of procreative beneficence would be hard-pressed to support transfer of a genetically anomalous embryo under almost any circumstances. If the prospective parents have other normal embryos—either fresh or frozen—they would clearly be favored for transfer. If no other normal embryos were produced, procreative beneficence might require another IVF cycle, or even resort to adoption.

A key thread of procreative beneficence is the availability of information upon which parents can make an informed choice. The principle dictates that when genetic testing reveals that one embryo is genetically normal and another has a genetic anomaly that will or may subject the future child to a lesser quality of life, the parents have a moral obligation to select the healthy embryo over the potentially unhealthy one.¹¹⁴ While critics raise numerous objections to this admonition, including the unsettled, subjective, and speculative nature of a future child's well-being, the critique most applicable to the selection of PGT embryos is the possibility of mosaicism.¹¹⁵ Selecting the child who is expected to have the best life—measured by health and other well-being criteria—becomes a matter of assessing the odds when the information available is known to have possible flaws. When the limited data to emerge suggest that certain aneuploid embryos either will result in miscarriage or emerge as genetically normal babies, can a physician say with authority that selecting a euploid embryo will produce a child with the better life? If the aneuploid embryo self-corrects and the euploid embryo develops a somatic deficit (for example, microcephaly as a result of the mother being infected with the Zika virus), the 'better' decision would have been to transfer the anomalous (appearing) embryo.

A companion precept to procreative beneficence is the concept of reproductive non-maleficence, imposing an obligation on the physician to not inflict harm in the course of delivering reproductive health care.¹¹⁶ Viewed from the perspective of the physician, and perhaps from society's viewpoint, transferring an embryo that is highly likely to result in the birth of a child with a serious disease or disability could be interpreted as the doctor causing harm by facilitating the birth of an unhealthy person.¹¹⁷ Importantly, however, it should be noted that the physician is not responsible for causing the

¹¹³ See eg Ben Saunders, *Procreative Beneficence, Intelligence, and the Optimization Problem*, 40 J. MED. PHIL. 653 (2015); Rebecca Bennett, *The Fallacy of the Principle of Procreative Beneficence*, 23 BIOETHICS 265 (2009).

¹¹⁴ Savulescu, *supra* note 112, at 414.

¹¹⁵ The principle of justice is also at issue in these settings, in large measure because of the sheer unaffordability of both IVF and PGT for most infertile individuals and couples. Professor Savulescu acknowledges the unequal access to preimplantation genetic testing but urges that the benefit of the information supports it being freely available to all. Barring this social change, he likens this inequality to the purchase of many biological, psychological and social advantages. Julian Savulescu, *In Defence of Procreative Beneficence*, 33 J. MED. ETHICS 284 (2007).

¹¹⁶ See Marta Kolthoff, *Assisted Reproduction and Primum Non Nocere*, 9 VIRTUAL MENTOR 605 (2007).

¹¹⁷ Here the notion of harm is presented as a monolithic concept, based on an assumption that physicians would universally agree that serious disease or disability is harmful to the person so affected. This oversimplified notion warrants further exploration in a future project, where individualized and nuanced notions of harm could be explored. It is noteworthy that each of the hypothetical prospective parents introduced at the outset reflect divergent views of harm: the Johnsons accept that a child with CF would require intensive, lifelong medical care but accept this prospect compared to the harm (to them) of childlessness; the Gomezes perceive

genetic anomaly—and it is the anomaly that directly causes harm to the resulting child. Nevertheless, application of the principle of reproductive non-maleficence might encompass a duty to prevent or avoid harm. If so, a strong argument can be made that affecting the transfer of a health-affected embryo is a violation of the affirmative duty to avoid harm in the reproductive setting. Only by declining to make the transfer (and perhaps declining to refer the patient to another willing provider) can the physician avoid harm to a resulting offspring, and thus fulfill the duty set out under reproductive non-maleficence.

The above analysis positions the benefit-producing and harm-avoiding principles from the perspective of the provider. This contrivance seems sound when the principles are being invoked to support a provider's decision to decline to assist in the requested embryo transfer. Procreative beneficence counsels the provider to navigate the future child's best possible outcome by declining to facilitate the birth of a baby likely to suffer greater health challenges than another offspring who could be born instead. Reproductive non-maleficence further supports a physician's decision to decline to transfer an anomalous embryo, given the high likelihood the resulting child will suffer harm as compared to a child with no health maladies. Arguments that birth of an unhealthy child produces greater benefit than no birth at all—so long as the child does not suffer from a life not worth living—are unavailing in the context of reproductive non-maleficence. Harm avoidance, no matter the degree of harm in question, guides clinical decision-making to the exclusion of others values including patient autonomy.

The verdure of procreative beneficence and reproductive non-maleficence to support physician refusals in the context of embryo transfer is of questionable strength given two obvious challenges to the theories' admonitions. First, there is the question of by whom and what methodology are benefit and harm measured? The clinician's uptake of these theories in defense of treatment refusals could be matched by patient assertions that she is in the best position to adjudicate which child will have the best possible life, and that failure to transfer any and all embryos produced causes her tremendous harm. Second, we could—and have—challenge the certainty that transferring an anomalous embryo will produce harm (by the consequence of producing a child with health care needs). The problems of mosaicism and inaccuracies in test results are aspects of this prediction problem, but even when the genetic disorder is correctly diagnosed at the embryo stage, physicians are not always in the best position to predict or judge the quality of life the resulting child will experience. The possibility that the child will endure a difficult life is real, and raises the possibility that the parents may seek legal redress against the physician, despite earlier pleas for assistance and assurances of non-retribution. Concerns about potential legal liability may provide the strongest tug toward transfer refusal.

C. Avoiding Legal Liability

Physician concern over potential legal liability for actions taken and decisions made in the course of patient relations is a reality that significantly impacts the practice of

the discard of an embryo as harmful; Kathy Lee views life as a deaf person as entirely fulfilling and harm-free (and she may perceive her child's life as a hearing person harmful to the child or herself).

medicine.¹¹⁸ Classically, physicians respond to perceived threat of malpractice lawsuit by engaging in defensive medicine—defined by one research group as ‘medical practices that may exonerate physicians from liability without significant benefit to patients’.¹¹⁹ These practices are sometimes referred to as assurance behaviors, and include ordering imaging, laboratory tests, specialist referrals, and hospitals admission done to avoid a possible lawsuit.¹²⁰ Concerns about legal liability are no less robust in the field of infertility care, and may be even greater compared to other specialties because of the unique potential harms at stake.¹²¹ Damage calculations, generally limited to harm suffered by the patient, can escalate substantially when an award provides for the lifetime medical and custodial care of a child born with health deficits linked to ART.¹²²

Medical liability claims in the ART sphere can allege a failure to meet the standard of care in both the commission and omission of treatment provided. Narrowing our focus to liability in the context of PGT, claims for the commission of sub-par performance typically allege a provider or laboratory botched the detection of carrier status in one of the intended parents, misread or misreported the results of PGT analysis, or selected the wrong embryo for transfer after testing.¹²³ These claims generally sound in medical malpractice or negligence. Plaintiff harm attributed to omission can raise a physician’s failure to recommend or offer genetic testing (either of the intended parents or the embryo), failure to inform patients of the inherent risks and errors associated with PGT, or failure to disclose the physician or lab’s minimal experience in performing genetic testing.¹²⁴ These claims often fall under the lack of informed consent rubric, and require

¹¹⁸ See eg L. Reisch et al., *Medical Malpractice Concerns and Defensive Medicine: A Nationwide Survey of Breast Pathologists*, 133 AM. J. CLIN. PATHOL 916 (2015) (reporting US breast pathologists exercise defensive medicine by using assurance behaviors due to malpractice concerns); Y. Cheng et al., *Litigation in Obstetrics: Does Defensive Medicine Contribute to Increases in Cesarean Delivery?*, 27 J. MATERN. FETAL NEONATAL MED. 1668 (2014) (concluding obstetric malpractice lawsuits and worry about lawsuits associated with higher propensity of recommending caesarean delivery); M. Sethi et al., *Incidence and Costs of Defensive Medicine Among Orthopedic Surgeons in the United States: A National Survey Study*, 41 AM. J. ORTHOP 69 (2012) (finding 96% of respondents reported having practiced defensive medicine by ordering imaging, lab tests, referrals, or hospitals admission to avoid possible lawsuit; 24% of all ordered tests were for defensive reasons).

¹¹⁹ Sethi, *supra* note 118.

¹²⁰ *Id.* See also Reisch, *supra* note 118.

¹²¹ Professor Dov Fox provides a more optimistic perspective as viewed from the provider side, averring in an excellent, comprehensive article that ‘[c]ourts routinely decline to grant remedies when reproductive professionals negligently deprive, impose, or confound procreation’. Dov Fox, *Reproductive Negligence*, 117 COL. L. REV. 149, 154 (2017) (calling for a unitary tort of reproductive negligence to redress harms caused by substandard conduct associated with reproduction, including ART). Even if Professor Fox’s calculation is correct—that current legal regimes ultimately favor physicians and ancillary personnel over patients when ART is alleged to have gone awry—the prospect of being named in and defending a legal claim is sufficiently concerning for physicians to adjust their conduct to avoid such an outcome. Fearing a legal claim over the transfer of an anomalous embryo can arguably be at the heart of a provider’s response, even if a claim is never brought or brought unsuccessfully.

¹²² Note that medical malpractice awards can also include payments for harm to third parties such as spouses in the form of loss of consortium.

¹²³ See eg *Grossbaum v. Genesis Genetics Inst.*, 07-1359 (GEB), D. NJ (2011) (parents with known carrier status for CF underwent PGD but embryologist at clinic substituted wrong embryo for unaffected one, resulting in birth of child with disease); *Bergero v. University of Southern California Keck School of Medicine*, Cal. Ct. of App. Case No. B200595 (2009) (mother with carrier status for X-linked Fabry’s disease sought PGD to rule out affected males embryos but male embryo mistakenly transferred son born with disease).

¹²⁴ See eg *Coggeshall v. Reproductive Endocrine Associates of Charlotte*, 376 S.C. 12, 656 S.E.2d 476 (So. Car. 2007) (parents of child with Down syndrome sue clinic for failing to inform them of option for PGD); *Paretta*

discernment of both the standard by which disclosure is measured in a particular jurisdiction and whether the particular patient-physician exchange met that standard. In the majority of US states, the standard for informed consent is measured according to a prudent physician standard.¹²⁵ A court would be asked to discern what a reasonably prudent physician would have disclosed to a patient under similar circumstances. The less-adopted reasonable patient standard requires the physician to disclose those risks and benefits a reasonable patient would deem material to her medical decision-making.

With this rough framework in mind, what liability concerns might an infertility specialist dwell upon in either agreeing or refusing to transfer embryos with known genetic anomalies? A crude assessment suggests the potential liability for refusing to make the transfer subjects the provider to a far lower damage calculus than transferring an embryo that results in the birth of a health-affected child. Damage awards for the birth of unhealthy or unwanted children can include the steep costs associated with lifetime medical and custodial costs, as well as damages for loss of consortium or even punitive damages.¹²⁶ These claims include wrongful life (a claim brought on behalf of the child for damages resulting from being born with a defect due to defendant's negligence), wrongful birth (a claim brought on behalf of parents for damages they face as a result of giving birth to and raising a child with health issues), and wrongful conception (a claim for birth of a healthy child whose conception was the result of the defendant's negligence).¹²⁷ On the other hand, claims for refusing to make a requested transfer would likely not include costs associated with child-rearing. Instead, at most, a provider might be assessed the value of a dignitary harm or even the cost associated with procuring the embryo in the first place (essentially reimbursement for the IVF and PGD costs). Perhaps a claim for intentional infliction of emotional distress or conversion could be mounted, but again the value of these claims are likely small in comparison to those that could arise once an unhealthy child is born. While not trivial, a rational assessment of the potential damages associated with complying with a patient's request for transfer favors refusal over compliance. This is true even if a patient agrees to waive any future claims against the provider. Such a waiver might be effective to bar the patient's future claim after change of heart, but it would be ineffective against a claim by the child—such as a claim for wrongful life—as a parent cannot waive a future child's legal claims against the provider.¹²⁸ Further, some scholars have suggested the

v. Medical Offices for Human Reproduction, 195 Misc. 2d 568, 760 N.Y.S.2d 639 (NY Sup. Ct. 2003) (couple using egg donor gave birth to child with CF after clinic failed to offer to screen husband for carrier status and failed to offer PGD to test embryos).

¹²⁵ Laurent B. Frantz, *Modern Status of Views as to General Measure of Physician's Duty to Inform Patient of Risks of Proposed Treatment*, 88 A.L.R.3d 1008, § 2a (2012) (explaining that '[t]he traditional view or views, apparently still in effect in most jurisdictions, are that the duty is measured by a professional medical standard: either the customary disclosure practices of physicians or what a reasonable physician would disclose under the same or similar circumstances... A number of jurisdictions, however, have recently embraced the view that a physician's duty to inform his patient of the risks of a proposed treatment is measured, not by the professional medical standard, but by the patient's need for information material to his decision whether to accept or reject the proposed treatment').

¹²⁶ See Amagwula, *supra* note 28.

¹²⁷ *Id.*

¹²⁸ See *eg* Apicella v. Valley Forge Military Academy, 630 F. Supp. 20 (E.D. Pa. 1985); *Fedor v. Mauwehu Council, Boy Scouts of America*, 143 A.2d 466 (Conn. Super. 1958); *Doyle v. Bowdoin College*, 403 A.2d 1206 (Me. 1979); *Fitzgerald v. Newark Morning Ledger Co.*, 267 A.2d 557 (NJ Super 1970); *Childress v. Madi-*

physicians who agree to transfer embryos with known, disabling anomalies should be subject to civil or even criminal liability for child abuse.¹²⁹

Whether legal claims have the potential to be filed by the child, the parents, or the state, physician reluctance to facilitate the birth of an unhealthy child for fear of future liability is a strong disincentive to agreeing to such transfers. Enduring, defending, and possibly reporting such legal claims—even if they fail or prove frivolous—can have lasting impacts on physicians, including their willingness to continue to provide specialty care. Even physicians with deep respect for patient autonomy and the value of reproductive liberty may pause when confronted with the reality that a patient's pledge to hold the provider harmless for the consequences of the transfer may later prove to be worthless. Predicting a patient's future sentiments about rearing a health-impaired child is as illusive for the provider as it is for the would-be parent. Accurately assessing the exact course of a genetic disease known for deep variation in health impact, as is true in numerous instances, is simply not clinically possible and thus invites uncertainty as to the legal recourse a patient might seek. For this reason, concerns about potential legal liability for embryo transfer stand as a rationale for physician refusal to assist with such patient requests.

IV. Improving the Clinical Landscape

The clinical landscape surrounding patient requests for transfer of anomalous embryos has only recently come into focus. In all likelihood, patients and physicians will face this dilemma with increasing frequency as testing technologies grow more sensitive and greater knowledge surrounding mosaicism emerges. Best practices dictate that clinics debate and develop written guidelines detailing their approach toward patient requests for transfer of embryos determined to be abnormal through preimplantation testing. In so doing, providers can consider the range of arguments in support of assisting and declining to assist in such transfers, as detailed in Parts II and III. In addition, policy makers could consider at least two approaches suggested by professional ART societies and government oversight entities. Both the American and British infertility organizations—the former a voluntary trade group and the latter a national government oversight and licensing authority—have published guidance on the question of abnormal embryo transfer. Given the generally laissez-faire environment in the US surrounding ART regulation, clinics can feel fairly unburdened to draft and implement policies along a broad spectrum of permissiveness and restriction. Deciding where to set the mark may be of matter of physician values and preferences, along with possible market impacts arising from patient behavior in response to announced clinic policies.

son County, 777 S.W.2d 1 (Tenn. App. 1989), cert. denied; *Scott v. Pacific West Mountain Resort*, 834 P.2d 6 (Wash. 1992) (holding a parent cannot anticipatorily release their children's potential claims against third parties).

¹²⁹ See Jacob M. Appel, *Genetic Screening and Child Abuse: Can PGS Rise to the Level of Criminality?*, 80 U.M.K.C. L. REV. 373 (2011) (analysing child abuse charges against either parents or fertility clinics who use IVF intentionally to produce severely impaired infants). See also Kristen Rabe Smolensky, *Creating Children with Disabilities: Parental Tort Liability for Preimplantation Genetic Interventions*, 60 HASTINGS L. J. 336 (2008) (arguing children should be able to successfully sue their parents who engage in certain direct genetic interventions). But see Brigham A. Fordham, *Disability and Designer Babies*, 45 VALPARAISO U. L. REV. 1473 (2011) (arguing parents who make genetic choices in favor of disability should not face liability).

A. *The ASRM View*

In May 2017, the American Society for Reproductive Medicine published the opinion of its Ethics Committee on the question of genetically anomalous embryo transfer.¹³⁰ After setting out the clinical circumstances in which patients request such transfers, followed by the interests and arguments invoked when patients and physicians clash over these transfer decisions, the Ethics Committee sets out its recommendations. Adopting a non-directive approach, the Committee found ‘[v]alid and reasoned argument exist to support provider decision to assist in transferring genetically anomalous embryos, and in declining to assist in such transfers’.¹³¹ The only exception to this stance of neutrality involves offspring who are born into extreme illness with no hope for recovery. ‘[I]n circumstances in which a child is highly likely to be born with a life-threatening condition that causes severe and early debility with no possibility of reasonable function, it is ethically acceptable to refuse to transfer such embryos upon patient request.’¹³² To distinguish these dire circumstances from its previous nod to provider refusal, the Committee further clarifies that patient requests to move the embryos to another provider (who will presumably do the transfer into the uterus) should not be honored. As set out in the opinion, ‘[p]hysician assistance in the transfer of embryos in this category is ethically problematic and therefore highly discouraged’.¹³³ The opinion does not enumerate the conditions that would satisfy such a high bar, relying instead on infertility specialists who are steeped in embryonic genetics to appropriately flag the contenders for presumptive non-transfer.

The low frequency of requests for embryo transfer in which a resulting child is ‘highly likely to be born with a life-threatening condition’ or even a life-altering condition suggests most potential disputes will arise over embryos with milder conditions or those with indeterminate or ambiguous PGT results. Currently, the phenomenon of mosaicism occupies this latter realm, with many IVF clinics working to balance their patients’ desire for a healthy offspring against the many unknowns surrounding ambiguous test results. In some cases, physicians are looking deeper into lab findings that an embryo is abnormal—investigating the degree of abnormality determined to present in each embryo. An emerging technology enhances PGT using a powerful DNA technology known as next-generation sequencing.¹³⁴ Preliminary studies are promising, showing that embryos deemed abnormal under standard PGT methods can be further classified into embryos that are likely to yield a healthy child and those that are not once next-generation sequencing is applied.¹³⁵ One report describing the new technology explains that PGT results can now deem a mosaic embryo to be ‘a little abnormal

¹³⁰ ASRM *Genetic Anomalies Opinion*, *supra* note 62.

¹³¹ *Id.* at 1134.

¹³² *Id.* at 1135. The opinion also addresses less severe health circumstances, deeming it ethically acceptable for providers to transfer embryos in circumstances ‘in which a child is highly likely to be born with a condition that is treatable or effectively manageable through medical interventions’. *Id.*

¹³³ *Id.*

¹³⁴ See Stephen S. Hall, *A New Last chance: There Could Soon Be a Baby-Boom Among Women Who Thought They’d Hit an IVF Dean End*, *NEW YORK MAGAZINE* (Sept. 18, 2017), <https://www.thecut.com/2017/09/ivf-abnormal-embryos-new-last-chance.html> (last visited Dec. 14, 2017).

¹³⁵ See A. Capalbo et al., *Abnormally Fertilized Oocytes Can Result in Healthy Live Births: Improved Genetic Technologies for Preimplantation Genetic Testing Can Be Used to Rescue Viable Embryos in In Vitro Fertilization Cycles*, *108 FERTIL. & STERIL.* 1007 (2017).

(20 percent) to a lot abnormal (up to 79 percent) and that clinical decisions can be based on this new scale'.¹³⁶

Layering a more precise technology to separate healthy from unhealthy embryos may advance the field of reproductive medicine by reducing the number of embryos discarded or unused and increasing the live birth rate for patients who produce only abnormal embryos, but the issue of problematic patient requests for transfer will continue. Even if a definitive line is drawn on the new scale of low to high abnormality—separating those embryos deemed safe for transfer from those more likely to result in an unhealthy offspring—patients will continue to request transfer of embryos their providers advise should be discarded. The clash at the petri dish will endure, making more urgent the need for IVF clinics to develop and draft policies setting out their approach to anomalous embryo transfer. Armed with this information in a pre-test setting, patients can make more informed decisions about opting for or against preimplantation testing.

B. The HFEA Approach

In well-known contrast to the USA, the UK long ago adopted a comprehensive regulatory scheme governing ART at the federal level. IVF clinics are regulated and licensed under the Human Fertilisation and Embryology Act of 1990, which established the Human Fertilisation and Embryology Authority ('HFEA') to draft and publish standards of practice in reproductive medicine. The HFEA publishes clinical standard in its Code of Practice, now in its eighth edition.¹³⁷ On the matter of selection of embryos for transfer into the uterus, the Code sets out the following admonition:

The law prohibits the selection of an embryo for treatment if it is known to:

- a) Have a gene, chromosome or mitochondrial abnormality involving a significant risk that the person with the abnormality will develop a serious physical or mental disability, a serious illness, or a serious medical condition, or
- b) Be of a sex that carries a particular risk that any resulting child will have or develop a gender-related serious physical or mental disability, serious illness, or serious medical condition.¹³⁸

The guideline then sets out an important qualification: 'This applies only where there is at least one other embryo suitable for transfer that is not known to have the characteristics. Where there is no other embryo suitable for transfer, an embryo with these characteristics may be transferred.'¹³⁹ The term 'suitable for transfer' is defined in the negative in a note following the guideline, explaining that, '[a]n example of an embryo

¹³⁶ Hall, *supra* note 134.

¹³⁷ The Human Fertilisation and Embryology Act grew out of a government-commissioned study chaired by Mary Warnock in the 1980s. Today, the HFEA 'covers the use and storage of sperm, eggs and embryos for human application, as well as all research involving the use of live human and admixed embryos'. See <https://ifqlive.blob.core.windows.net/umbraco-website/2062/2017-10-02-code-of-practice-8th-edition-full-version-11th-revision-final-clean.pdf> (last visited Dec. 14, 2017).

¹³⁸ Code of Practice, Interpretation of Mandatory Requirements 10C, <https://ifqlive.blob.core.windows.net/umbraco-website/2062/2017-10-02-code-of-practice-8th-edition-full-version-11th-revision-final-clean.pdf> (last visited Dec. 14, 2017).

¹³⁹ *Id.*

not suitable for transfer in this context is one that has no reasonable prospect of resulting in a live birth.¹⁴⁰ No further explanation or specific examples are provided, leaving such clinical determinations up to IVF and genetic specialists. Working backwards, the HFEA policy seems to permit transfer of abnormal embryos only when the patient lacks any other fresh or frozen viable and normal-appearing embryos.

The HFEA's 'last chance' approach is more restrictive (and prescriptive) than the ASRM Ethics Committee opinion which discusses the existence of other embryos as a consideration rather than a driving factor in determining transfer policy. The ASRM opinion provides, '[t]he presence or absence of one or more unaffected or healthy embryos can be taken into account in generating clinic policies.'¹⁴¹ Clearly the individual rights streak that runs through US law and policy governing ART shows its influence in the American approach. The ASRM approach exudes deference to the values and preferences of providers—rather than honing in on community values or shared preferences across a relevant populous. The American opinion offers guidance and support for nearly any position a clinic might adopt in response to patient requests for transfer of abnormal embryos. Arguably in contrast, the UK position permitting transfer only when no other normal embryos exist reflects different values and preferences, possibly influenced by the government's financial commitment to its citizen's health via the National Health System.¹⁴² The NHS funds neonatal care as well as some IVF treatment and thus the government may deem it appropriate to limit the costs associated with avoidable births of severely health-impacted offspring.¹⁴³ In the USA where ART is largely self-funded by patients, decisions about the acceptability of expenditures surrounding the birth of IVF-conceived children is left up to those who agree to bear this responsibility.¹⁴⁴ Inevitably, health care financing controls health policy in the USA and across the pond.

C. Shaping ART Clinic Policy

The growing use and emerging improvements to preimplantation embryo testing soar in comparison to settled policies and approaches formally adopted by fertility practices. As suggested herein, few ART providers have issued formal written policies on the question of anomalous embryo transfer, leaving most patients and providers to navigate

¹⁴⁰ *Id.*

¹⁴¹ ASRM Genetic Anomalies Opinion, *supra* note 62, at 1135.

¹⁴² Launched in 1948, the UK National Health Service 'was born out of a long-held ideal that good healthcare should be available to all regardless of wealth'. The NHS provides healthcare services, with some exceptions such as prescriptions, optical services, and dental services, to all UK residents. Website for the NHS in England, <https://www.nhs.uk/NHSEngland/thenhs/about/Pages/overview.aspx> (last visited Dec. 15, 2017).

¹⁴³ While economics may play a role in British policy, it shares its precautionary approach with the largest professional ART organization in Europe. The European Society of Human Reproduction and Embryology (ESHRE) comments that physicians, as 'collaborators in the parental project' ought to refuse transfer of an embryo that may be affected by a condition that poses a 'high risk of serious harm to the future child'. ESHRE, however, offers no concrete definition of the term 'serious harm' in its discussion of transfer policy. See Guido Pennings et al., *ESHRE Task Force on Ethics and Law 13: The Welfare of the Child in Medically Assisted Reproduction*, 22 HUMAN REPRODUCTION 2585 (2007).

¹⁴⁴ The high cost of IVF skews the demographic of patients toward upper income levels, suggesting these parents would have the means to support the medical needs of any health-affected children born after directed embryo transfer.

these rough waters in ad hoc and inefficient fashion.¹⁴⁵ Though hardly a trend or developing norm, providers who have spoken in the public domain about patient requests for such transfers have expressed reluctance to assist in the birth of a child likely to suffer from significant health impacts. Recall the New York City clinic whose website discusses the scenario of mosaicism concludes, ‘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’.¹⁴⁶ But these providers limit the scope of such abnormal embryo transfers to lethal chromosomal abnormalities—those unlikely to survive the implantation and gestation period—while declaring, ‘[n]on-lethal abnormalities (for example Down or Turner Syndromes) often lead to births and, therefore, should not be transferred’.¹⁴⁷ Simply put, this clinic takes the position it will not assist in the transfer of any embryos likely to result in the birth of an unhealthy child. The Boston-area IVF practice mentioned earlier—whose ethics committee wrestled with the question of transferring an embryo with a BRCA mutation—took the position that ‘[t]he transfer of known-carrier embryos was felt to be unethical for certain disease-states, depending on the severity of illness and timing of disease onset’.¹⁴⁸ The ethics committee acknowledged the import of patient reproductive autonomy, but prioritized the physician’s duty toward the future child as well as toward society in general in its balancing calculus. Urging the need for thorough counseling in these situations, the authors acknowledged the need to move away from a case-by-case approach to a system in which overarching guidelines facilitate clinical decision-making and outcomes.

In addition to the few reports detailing actual clinic responses to patient requests, researchers have conducted surveys to gauge providers’ views on hypothetical cases involving anomalous embryos. In 2016, a team of genetic counselors surveyed their peers attending an interactive session at the annual ASRM meeting. A series of scenarios were posed, querying whether the respondent’s clinic would agree to transfer the embryo in each case. Eight scenarios were present, including embryos that tested BRCA positive, displayed a mosaic trisomy, produced inconclusive results, and were confirmed as Trisomy 21 (Down syndrome). Of the 137 respondents, over 90% answered they would transfer a male embryo that tested BRCA positive; nearly two thirds said they would not transfer an embryo with Down syndrome.¹⁴⁹ In a follow-up discussion of the issues, the genetic counselor researchers emphasized the need to counsel patients about the possibility of a false-positive result, the potentially wide variability of many genetic disorders, and the need to seek information from a disease specialist to understand the child’s possible life course. While those surveyed did not agree on the specifics of a transfer policy, they did agree that such a policy should be in place and ‘should be the product of an informed, deliberative, and collaborative process that includes all relevant clinic personnel’.¹⁵⁰ This is a sound approach and should be embraced.

¹⁴⁵ See *supra* note 52, reporting the results of an informal survey taken of genetic counselors attending the 2016 annual ASRM meeting about whether their clinics had a written policy on embryo transfer. Forty-four per cent of respondents said clinic decisions are made on a case-by-case basis.

¹⁴⁶ See *supra* note 39.

¹⁴⁷ *Id.*

¹⁴⁸ See *supra* note 96.

¹⁴⁹ Black, *supra* note 52.

¹⁵⁰ *Id.*

Once a clinic decides to create or adopt a policy on anomalous embryo transfer, what are the optimal next steps? With noted challenges, the best approach for patients and providers alike is for IVF clinics to make readily available—at the pre-treatment stage—specific policies developed as suggested above, via a collaborative process with input from all relevant clinic stakeholders. The challenges include the need to reach consensus among all members of the treatment team (or in the event of disagreement determine how each provider’s values and preferences will be honored); the possibility that changes in personnel will necessitate changes in clinic policy; and the initial and possible ongoing investment of time, resources, and research required to produce and maintain a workable policy. But once in place, a written policy that patients can surveil as early as possible—preferably prior to beginning treatment—will be well worth the providers’ investment.

In its highest and best form, a transfer policy should specify which disease profiles the clinic will and will not assist in transfer. The list can be gleaned from a compilation of prior cases the clinic has amassed over a certain number of years (that is, the anomalies detected in their specific patient population through PGT) or drafters can turn to existing lists of anomalies that can be detected through PGT, assigning a transfer status to each. For the latter approach, the HFEA publishes on its website an ongoing list of conditions for which PGD is approved in the UK.¹⁵¹ A clinic could incorporate this list by reference along with its own policy choices, or select out those diseases for which transfers will not be made. Such specificity avoids having to make post hoc decisions about whether an embryo’s disease is ‘serious’ or ‘debilitating’ or allows for ‘reasonable function’ when these more vague standards are adopted. Admittedly, broad-based qualitative standards—such as those suggested by the ASRM Ethics Committee—do permit a greater degree of flexibility for providers to include or exclude particular embryos once results are known, but fare less well than disease-specific guidelines in their capacity to provide notice to patients.

In addition to the substantive aspects of a transfer policy, clinics should consider the processes that will accompany the policy’s implementation. Matters such as the appeal process, the opportunity for storing affected embryos, and the clinic’s willingness to transfer embryos to another willing provider should be made clear. Should a clinic opt to institute a policy similar to the HFEA approach in which anomalous embryos will be transferred only if no other normal-appearing embryos are available, the exact parameters of this policy should be clear: Does availability include all previously frozen embryos? Is an embryo with indeterminate PGT results considered available under the policy? If frozen embryos have not undergone testing, are these considered available under the policy? A secondary process matter that deserves consideration is the clinic’s policy on conducting PGT if the patient expresses a desire to transfer all the viable embryos, regardless of disease status. For some, the need to know the embryo’s genetic make-up is premised on the desire to prepare for the birth of a certain child, not the desire to birth a child of a certain health status. If a clinic policy prohibits transfer of certain embryos, then it may also stake out a position on its willingness to test embryos whose parents would not agree to discard or forgo transfer under certain circumstances. Each

¹⁵¹ See HFEA PGD Conditions, <https://www.hfea.gov.uk/pgd-conditions/> (last visited Jan. 3, 2018).

of these factors, substantive and procedural alike, must be included in a robust pre-test counseling dialogue as well as made an integral part of the informed consent process.

CONCLUSION

Pursuing family formation through IVF is a characteristically difficult journey, fraught with financial challenges, emotional burdens, and medical uncertainties that can tax patients and providers alike. In an ideal world, those seeking and those providing fertility treatment should be aligned in their goals to produce a healthy infant at the end of the process, creating an effective and supportive doctor–patient relationship. Advancing and increasingly sensitive embryo testing techniques impact of the ART process, occasionally imbuing patients and providers with disparate aims than those agreed upon at the outset of the treatment process. This clash at the petri dish deserves careful consideration. Patient autonomy and its companion assertion of reproductive liberty is a powerful force in the practice of reproductive medicine in the USA, grounding the deference that physicians typically display toward patient choice. But physicians—as personal and professional actors—are entitled to equal dignity and respect in their commitment to advance human health to the best of their abilities. Patient requests for transfer of genetically anomalous embryos can disrupt the patient–physician relationship, with each party supported by a number of legal, ethical, policy, and practical rationales for their perspective. While the clash may prove difficult to overcome or even intractable, all the relevant stakeholders are better off from if clear, detailed, and readily available policies are integrated into the conversation from the outset. Knowing an IVF clinic’s limits on embryo transfer alerts patients to the values, preferences, and practices of the medical staff, enabling those seeking treatment to reflect upon their compatibility with health care team. Inevitably, patients may shift to alternative providers who support their worldview on embryo transfer. It is better for all involved that such shifting take place before embryos are formed and the urgencies surrounding selection and transfer take hold. News that an embryo is genetically abnormal is devastating enough. Clashing over the embryo’s destiny adds a strain that infertility specialists should strive to avoid.

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