FERTILE GROUND FOR REGULATION: PRESERVING PRE-IMPLANTATION GENETIC TESTING POST-*DOBBS* WHILE PROTECTING CONSUMERS OF EMBRYONIC TESTING

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INTRODUCTION

Prospective parents concerned about genetic disorders in their offspring have often availed themselves of pre-implantation genetic testing (PGT), a medical technique used in conjunction with in vitro fertilization (IVF)[1] to evaluate the genetic characteristics of their IVF-created embryos before implantation in the uterus.[2] PGT allows prospective parents who are concerned, for example, that some of their embryos carry a familial genetic disorder to choose unaffected embryos to implant.[3] PGT arose as a method for parents to avoid conducting prenatal testing on a fetus developing in the uterus and then opting to terminate the pregnancy in case of disease.[4] Though PGT has become an increasingly common[5] assisted reproductive technology (ART) procedure since the 1990s,[6] the U.S. federal government and state governments have historically declined to regulate it,[7] notwithstanding the need for consumer protection in this area.

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[1] IVF is a series of medical procedures used to help individuals achieve pregnancy if they are infertile or cannot become pregnant through typical means, or, when coupled with other technologies, to allow individuals to seek to avoid genetic problems in their offspring. During IVF, mature eggs are retrieved from ovaries and fertilized by sperm in a lab. The fertilized egg(s), called embryo(s), are transferred to a uterus. *In Vitro Fertilization (IVF)*, MAYO CLINIC (Sept. 1, 2023), https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716.

[2] Firuza Rajesh Parikh et al., *Preimplantation Genetic Testing: Its Evolution, Where Are We Today?*, 11 J. HUM. REPROD. SCI. 306, 306 (2018) (describing PGT as "an early form of prenatal genetic diagnosis where abnormal embryos are identified, thereby allowing transfer of genetically normal embryos").

[3] *Id.* at 310.

[4] Naomi Cahn & Sonia M. Suter, *The Art of Regulating ART*, 96 CHICAGO-KENT L. REV. 29, 30-31 (2022).

[5] Margaret E.C. Ginoza & Rosario Isasi, *Regulating Preimplantation Genetic Testing Across the World: A Comparison of International Policy and Ethical Perspectives*, 10 COLD SPRING HARBOR PERSPECTIVES MED. 1, 5 (2020) (noting "a shift in acceptance of PGT from research to common practice").

[6] *Id.* at 2 (noting the first clinical application of PGT in 1990).

[7] Norbert Gleicher et al., *How Not to Introduce Laboratory Tests to Clinical Practice: Preimplantation Genetic Testing for Aneuploidy*, 68 CLINICAL CHEM. 501, 503 (2022) (stating that "PGT-A can be offered in the U.S. by reference laboratories without regulatory scrutiny from either federal or local state governments" and asserting that the "Food and Drug Administration has no regulatory power over such tests.") *But see infra* notes 164-67 and accompanying text regarding the FDA's assertion of its authority to regulate PGT and similar technologies.

Conversely, states have begun to assert rights to regulate ART pursuant to the U.S. Supreme Court's 2022 decision in *Dobbs v. Jackson Women's Health Organization*,[8] because these technologies involve the creation and possible destruction of embryos.[9] In *Dobbs*, which represents "the first time in its history that the Supreme Court has revoked a previously recognized constitutional right," and "one of only a handful of cases in its history to set aside previously settled precedents,"[10] the Court held that the Constitution does not provide a right to obtain an abortion and that the "authority to regulate abortion must be returned to the people and their elected representatives."[11]

Post-*Dobbs*, states have begun to regulate, limit, and even restrict altogether various assisted reproductive technologies. In particular, some states have declined to specifically exempt IVF embryos from abortion restrictions[12] and others even embrace "personhood" theories that seek to confer legal personhood upon embryos, potentially including preimplantation embryos.[13] In February 2024, the Alabama State Supreme Court ruled that frozen embryos should be considered children,[14] prompting at least three Alabama providers to halt the procedure. While Alabama's Republican-controlled legislature enacted a law protecting IVF providers from both criminal charges and civil lawsuits in response to the state court

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[8] Dobbs v. Jackson Women's Health, 597 U.S. 215 (2022).

[9] *See supra* notes 1-4 and accompanying text.

[10] American Society for Reproductive Medicine, *The Supreme Court Overturns Right to Abortion, Raising Questions and Uncertainties for Art Patients and Providers*, https://preprod.asrm.org/news-and-events/asrm-news/legally-speaking2/the-supreme-court-overturns-right-to-abortion-raising-questions-and-uncertainties-for-art-patients-and-providers/ (last visited Dec. 15, 2024) [hereinafter ASRM, The Supreme Court Overturns Right to Abortion].

[11] *Dobbs*, 597 U.S. at 215.

[12] ASRM, The Supreme Court Overturns Right to Abortion, *supra* note 10 (stating that state laws that do not explicitly exempt IVF or IVF embryos, and/or that include language to the effect that "life begins at fertilization," will have a "problematic or concerning" potential impact on IVF and ART).

[13] I. Glenn Cohen, *The Right(s) to Procreate and Assisted Reproductive Technologies in the United States*, 1022 THE OXFORD HANDBOOK OF COMPARATIVE HEALTH LAW (Tamara K. Hervey & David Orentlicher eds., 2020), https://academic.oup.com/edited-volume/42622/chapter/357709799 (noting the rise of the "personhood" movement that advances state legislative bills or ballot initiatives voted on directly by the public with the aim of securing legal rights for embryos starting from the moment of fertilization or conception) (citation omitted); Oriana González, *Democrats Look to Protect Fertility Treatments in Post-Roe Era*, AXIOS, https://www.axios.com/2022/12/15/fertility-ivf-abortion-post-roe-duckworth-murray (describing state legislative proposals purporting to confer personhood on fetuses and embryos, which might impact individuals' use of ART) (Dec. 15, 2022). *See infra* Part III for a discussion of how theories of legal personhood may impact PGT and other reproductive technologies.

[14] LePage v. Center for Reproductive Medicine, P.C., 2024 WL 656591, *1 (Ala. 2024).

ruling,[15] in the weeks after the Alabama Supreme Court's ruling, four states enacted laws granting personhood rights to fertilized embryos and one dozen more introduced similar legislation.[16]

This Article contends that because PGT offers significant health benefits to some families it must be preserved, and further advocates that the U.S. Food and Drug Administration (FDA) and Federal Trade Commission (FTC) regulate PGT with the goal of protecting consumers from the overstated claims of some providers of this technology. Experts warn that certain types of PGT[17] are fraught with limitations that lead to many false-positive results, causing families to discard healthy embryos,[18] an outcome that both opponents and proponents of reproductive choice seek to avoid. Patients paying for these costly procedures often are not properly informed about these limitations. While progressives have shied away from ART regulation in the past, due to its connection to the regulation of abortion,[19] several medical researchers have called for regulation of PGT in particular.[20] The current focus on ART regulation presents an opportunity for those seeking to maintain the availability of ART and PGT to propose a regulatory scheme that protects families using PGT by expanding the remit of the U.S. Food and Drug Administration (FDA) and Federal Trade Commission (FTC).

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[15] Reuters, *Republican Alabama Governor Signs IVF Protections into Law* (Mar. 7, 2024), https://www.reuters.com/world/us/republican-alabama-governor-signs-ivf-protections-into-law-2024-03-07/.

[16] Adam Edelman, *An Uptick in State Personhood Bills Fuels Growing Fears Over IVF Restrictions*, NBC NEWS (Feb. 23, 2024), https://www.nbcnews.com/politics/personhood-bills-ivf-restrictions-alabama-rcna140228 .

[17] *See infra* notes 35-44 and accompanying text regarding the different types of PGT.

[18] D. H. Barad et al., *IVF Outcomes of Embryos with Abnormal PGT-A Biopsy Previously Refused Transfer: A Prospective Cohort Study*, 37 HUMAN REPROD. 1194, 1195 (2022) (citations omitted); Norbert Gleicher et al., *Preimplantation Genetic Testing for Aneuploidy – a Castle Built on Sand*, 27 TRENDS IN MOLECULAR MED. 731, 732 (2021) (citation omitted); Hui Yang et al., *Preimplantation Genetic Testing for Aneuploidy: Challenges in Clinical Practice*, 16 HUM. GENOMICS 69, 70 (2022) (citation omitted).

[19] Cohen, *supra* note 13, at 1021-22 (noting that "any serious attempt at regulation of reproductive technologies, which may be laudable on its own terms (depending on the proposed regulation), threatens to become a tool for restricting abortion as well" and that therefore progressives may be leery of opening up this "can of worms").

[20] Gleicher et al., *supra* note 18, at 731 (stating that "[b]ecause of a high false-positive rate, PGT-A,[sic] actually reduces live IVF birth chances for many patients: and "therefore, should clinically only be offered within experimental study frameworks"); Yang et al., *supra* note 18 at 72 (noting that the "current professional self-regulation system for PGT-A may not be sufficient" and that a "designated agency may be needed to monitor PGT-A use and address relevant concerns").

Part I of this Article explains the science and use of PGT, including its benefits and risks. Part II examines how the lack of federal regulation of PGT contributes to these risks. Part III explores theories that purport to confer legal personhood on preimplantation embryos, which may lead many states to ban PGT, and the potential negative impact of such bans on families reliant on this technology for the health of their children. Part IV proposes a regulatory scheme that expands the powers of the FDA and FTC for the purposes of maintaining the availability of PGT and protecting consumers from inflated claims about the effectiveness of the technology.

I. THE BENEFITS AND RISKS OF PGT TECHNOLOGY

Once embryos are created through IVF, no state or federal law directly regulates what kinds of tests may be conducted on the embryos or which embryos to implant.[21] While in theory PGT can be used to select for any genetically determined characteristic desired by prospective parents, including sex and certain physical characteristics,[22] prospective parents often use PGT to avoid the transmission of genetic disorders, as well as to increase the likelihood of a healthy birth after in vitro fertilization (IVF) and decrease the time required to achieve it.[23] It should be noted that PGT

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[21] Michelle Bayefsky, *Who Should Regulate Preimplantation Genetic Diagnosis in the United States?*, 20 AMA J. ETHICS 1160, 1163 (2018).

[22] Ginoza & Isasi, *supra* note 5, at 1. A 2017 study showed that 72.7 per cent of U.S. fertility clinics offer sex selection, and 83.5 per cent of those clinics offer sex selection for couples without infertility, meaning couples elected IVF solely for the purpose of selecting their child's sex. Bayefsky, *supra* note 21, at 1160. As one scholar explained, while some worry that PGT could be used to select for traits such as hair color, height, and athletic ability, "these are unlikely to be single-gene traits for which we can easily select in the near term." *Id.*

[23] The American College of Obstetricians and Gynecologists, Committee on Genetics, Committee Opinion No. 799, Preimplantation Genetic Testing, 135 Obstetrics & Gynecology e133, e133-34 (Mar. 2020) (citations omitted) (describing PGT as a means to "increase live birth rates and decrease early pregnancy failure rates") [hereinafter ACOG PGT Opinion]. While some scholarly articles refer to preimplantation genetic diagnosis (PGD), and the term preimplantation genetic screening (PGS) has also been used, the international medical community now calls it preimplantation genetic testing (PGT) to better convey that the procedure involves testing but does not necessarily convey a definitive diagnosis. Cooper Surgical, Misconceptions About PGT, https://fertility.coopersurgical.com/webinars/misconceptions-about-pgt/ (last visited Dec. 15, 2024); *see also* Wilcox Fertility, PGS/PGD – PGT Testing, https://www.wilcoxfertility.com/services/pgs_pgd_pgt_testing/ (last visited Dec. 15, 2024) ("In 2018, the American Society of Reproductive Medicine, The European Society of Human Reproduction and Embryology and The International Committee Monitoring Assisted Reproductive Technologies changed the name of PGS and PGD Testing."). As described below, clinicians and researchers distinguish between different types of

is sought not only by those who require IVF to achieve a pregnancy. Some prospective parents who could achieve a pregnancy without IVF use it because they wish to couple it with PGT, due to their suspicion that they are at risk of passing on a genetic disorder and their wish to have the ability to screen their embryo for a genetic abnormality before implanting it.[24]

The technological underpinnings of PGT lie in scientists' use in 1967 of fluorescence microscopy to identify the sex of rabbit embryos in early stages of development. In 1990, clinicians used PGT in the U.K. for two couples who faced X-linked genetic conditions and therefore chose female embryos,[25] which would be less affected or entirely unaffected since a female's dominant X chromosome may compensate for the defective recessive one.[26] Around this time, embryo abnormality was considered the leading cause of failure to implant.[27] By 1994, PGT was actively practiced in the United States.[28] Initially, patients and their doctors used PGT to screen embryos for a few serious genetic diseases with a high incidence in the sampled populations, such as Tay-Sachs and cystic fibrosis.[29] Over the decades, advanced techniques such as polymerase chain reaction (PCR) and fluorescent in situ hybridization (FISH) have permitted clinicians to identify with increasing accuracy embryos carrying an expanding range of genetic conditions.[30]

The medical process of PGT begins with the person who seeks to become pregnant undergoing an IVF cycle to retrieve eggs and create embryos, which are monitored in the laboratory. Approximately five to six days after fertilization, fertility clinic professionals perform a biopsy, meaning they remove a small number of cells from these blastocysts, as the embryos are termed at this stage.[31] The cells are sent to an outside laboratory for PGT.[32] During the week or two it takes for PGT results to arrive, fertility clinic professionals cryopreserve, or freeze, and store the

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PGT using the terms PGT-A, PGT-M, and PGT-SR. *See infra* notes 35-44 and accompanying text.

[24] Jamie Talan, IVF Used by Some to Avoid Passing on Genetic Diseases, WASHINGTON POST, Dec. 4, 2021.

[25] Ginoza & Isasi, *supra* note 5, at 2 (citation omitted).

[26] National Human Genome Research Institute, *X-Linked*, (July 10, 2023), https://www.genome.gov/genetics-glossary/X-Linked (noting that X-linked genetic conditions are more common in males, who have one X and one Y chromosome, because they have a single copy of the X chromosome that carries the disease-causing mutation).

[27] Gleicher et al., *supra* note 7, at 501.

[28] Ginoza & Isasi, *supra* note 5, at 5 (citation omitted).

[29] Yang et al., *supra* note 18, at 70.

[30] Ginoza & Isasi, *supra* note 5, at 2 (citations omitted).

[31] WASHINGTON UNIVERSITY PHYSICIANS FERTILITY & REPRODUCTIVE MEDICINE CENTER, *Preimplantation Testing (PGT)*, https://fertility.wustl.edu/treatments-services/genetic-counseling/preimplantation-genetic-testing-pgt/ (2023) [hereinafter Washington University PGT].

[32] *Id*.

blastocysts. If the PGT results indicate the embryo is likely to be free of the genetic disorders tested for and also viable, the patient is notified that it is time to schedule a frozen embryo transfer with their physician.[33] Embryos that are not used, if they are of good quality, can be stored for later use, donated to research, donated to another couple, or discarded. Poor quality embryos are typically discarded.[34]

There are several different types of PGT. PGT-A screens for aneuploid embryos, meaning embryos with an abnormal number of chromosomes, either because some are missing or there are extras. While embryos with aneuploidy are more likely to result in a failed IVF cycle or miscarriage, less often aneuploidy results in the birth of a child with a chromosome condition such as Down syndrome.[35] PGT-A can also be used for sex selection.[36] The second type of PGT, PGT-M, screens for specific monogenic diseases, meaning those that result from a variation in just a single gene, such as Marfan syndrome. One or both parents may themselves have a genetic condition that could be passed on to their children, or both members of the couple may carry a recessive genetic condition such as cystic fibrosis or sickle cell anemia. In other cases, families with certain blood disorders can use PGT-M to select an embryo that could be a match as a blood or bone marrow donor for a sibling or other family member in a process known as human leukocyte antigen (HLA) matching.[37] PGT-M was initially developed to identify IVF embryos that carried genes for serious, childhood-onset diseases, but the use of this technique has been

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[33] *Id.*

[34] Bayefsky, *supra* note 21, at 1162-63; Mara Simopoulou et al., *Discarding IVF Embryos: Reporting on Global Practices*, 36 J. ASSISTED REPROD. AND GENETICS 2447, 2448 (2019). *See also* Andrew Joseph, *If Roe Is Overturned, the Ripples Could Affect IVF and Genetic Testing of Embryos, Experts Warn*, STAT, https://www.statnews.com/2022/06/06/roe-v-wade-preimplantation-genetic-testing-ivf-clinics/ (June 6, 2022) (explaining that families "can pay to continue storing the embryos, donate them for use by other people, donate them for scientific and research purposes, or discard them").

[35] Washington University PGT, *supra* note 31. In contrast to the term aneuploid, the term euploid refers to an embryo having the correct number of chromosomes, which would be expected to develop normally. Genesis Fertility & Reproductive Medicine, *What Are Mosaic Embryos?*, https://www.genesisfertility.com/blog/what-are-mosaic-embryos/ (July 23, 2023).

[36] Harry J. Lieman & Andrzej K. Breborowicz, *Sex Selection for Family Balancing*, 16 AM. MED. ASS'N J. ETHICS 797, 797-98 (2014) (noting that medical professionals increasingly encounter requests for sex selection of embryos).

[37] Washington University PGT, *supra* note 31. For a discussion of the ethical issues raised by this process of human leukocyte antigen (HLA) matching between a donor and an intended transplant recipient, see Donna M. Gitter, *Am I My Brother's Keeper? The Use of Preimplantation Genetic Diagnosis to Create a Donor of Transplantable Stem Cells for an Older Sibling Suffering from a Genetic Disorder*, 13 GEO. MASON L. REV. 975 (2006).

growing rapidly to include screening for serious single-gene diseases that do not develop until adulthood, such as Huntington disease and early-onset Alzheimer disease; for cancer predisposition genes, such as BRCA mutations; and for non-fatal but potentially serious conditions that are apparent at birth, such as focal dermal hypoplasia.[38] A third type of PGT, PGT-SR, is used when a patient or their partner has a rearrangement of their own chromosomes, which increases their risk of producing embryos with missing or extra pieces of chromosomes.[39] Structural chromosomal rearrangements, though they affect less than one percent of the general population and about six percent of couples with recurrent pregnancy loss, have significant reproductive implications, such as infertility, miscarriages, stillbirths, and infants with chromosomal abnormalities.[40] A fourth use of PGT, called PGT-P, is newer and has not been proven to provide clinical utility.[41] It involves screening for polygenic conditions and can be used to determine a fetus's potential risk for development of late-onset disorders associated with polygenic traits, including diabetes, cardiovascular diseases, and some malignancies.[42] While PGT-P is not used in healthcare, some private companies market it to families seeking to choose healthy embryos.[43] Commentators note the "lack of specific regulatory guidance" surrounding PGT-P and emphasize that "guidelines and position papers on the ethical use of PGT-P are largely absent."[44]

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[38] Ethics Committee of the American Society of Reproductive Medicine, *Use of Preimplantation Genetic Testing for Monogenic Defects (PGT-M) for Adult-onset Conditions: An Ethics Committee Opinion*, 109 FERTILITY & STERILITY 989, 990 (2018) [hereinafter ASRM Ethics Committee Opinion on PGT for Monogenic Defects]. For a discussion of critiques of PGT-M testing, including the fact that the research into the use of this technology does not include enough people of non-European descent, and that PGT-M may be used to detect diseases that will not affect the embryo until well into its adulthood, *see The Alarming Rise of Complex Genetic Testing in Human Embryo Selection*, 603 NATURE 549, 549 (2022).

[39] Washington University PGT, *supra* note 31.

[40] Cagri Ogur et al., *PGT for Structural Chromosomal Rearrangements (PGT-SR) in 300 Couples Reveals Specific Risk Factors But an Interchromosomal Effect Is Unlikely*, 46 REPROD. BIOMED. ONLINE 713, 714 (2023).

[41] Theresa A. Grebe et al., *Clinical Utility of Polygenic Risk Scores for Embryo Selection: A Points to Consider Statement of the American College of Medical Genetics and Genomics (ACMG)*, 26 GENETICS MED. 1, 2 (2024).

[42] Marc R. Gualtieri et al., *The Promise and Challenges of Preimplantation Genetic Testing for IVF*, CONTEMPORARY OB/GYN. J. 7, 7 (2023), https://cdn.sanity.io/files/0vv8moc6/contobgyn/765af5b3d50c4a41b17cf9b89626cff6d19105a1.pdf/OBGYN0223_Obstetrics.pdf (Feb. 2023).

[43] Maria Siermann et al., *A Review of Normative Documents on Preimplantation Genetic Testing: Recommendations for PGT-P*, 24 GENETICS IN MED. 1165, 1166 (2022).

[44] *Id.*

The use of PGT has increased greatly in the last two decades, from approximately one thousand cycles in the mid-2000s, up to 19,000 by 2014, to over 54,000 cycles in 2017.[45] The available data shows that PGT-A is the most frequently used type.[46] In 2016, only 11.4 percent of U.S. IVF centers used PGT-A in more than half of their cycles, but by the following year, 21.4 percent of IVF centers did so. Currently, approximately half of all IVF cycles in the U.S. are performed in conjunction with PGT-A.[47]

Some critics of PGT-A criticize the fertility industry's marketing of PGT-A as a "mature technology and an established diagnostic test."[48] Nonetheless, some experts assert that prospective parents who use PGT-A to support their IVF cycles often achieve cost savings per live birth, shorter duration of treatment, fewer failed embryo transfers, and fewer clinical miscarriages.[49] According to these experts, by enabling IVF clinics to determine which embryo is chromosomally typical and thereby permitting the transfer of a single embryo, PGT-A can potentially reduce the multiple pregnancy rate. One study indicates that PGT-A has significantly reduced twin and higher order multiple births since 2014, in contrast with the annual increases in the preceding three decades.[50]

PGT has considerable limitations, however. The American College of Obstetricians and Gynecologists (ACOG) cautions that "a 'normal' or negative preimplantation genetic test result is not a guarantee of a newborn without genetic abnormalities," and recommends traditional diagnostic testing or screening as well.[51] During pregnancy, typical prenatal testing methods include chorionic villus sampling (CVS) and amniocentesis,[52] which are often used to confirm the results obtained with PGT, or

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[45] Gualtieri et al., *supra* note 42, at 7-8.

[46] *Id.* at 8.

[47] Gleicher et al., *supra* note 7, at 501. *See also* Norbert Gleicher et al., *Previously Reported and Here Added Cases Demonstrate Euploid Pregnancies Followed by PGT-A as "Mosaic" As Well As "Aneuploid" Designated Embryos*, 21 REPRODUCTIVE BIO. & ENDOCRINOLOGY 25, 28 (2023) (reporting that "approximately half of all U.S. IVF cycles are currently accompanied by PGT-A.").

[48] Christine Strauss, *PGT-A Under the Spotlight*, STANFORD LAW SCHOOL BLOGS, https://law.stanford.edu/2023/02/10/pgt-a-under-the-spotlight/ (Feb. 10, 2023) (citing Richard J. Paulson, *Hidden in Plain Sight: The Overstated Benefits and Underestimated Losses of Potential Implantations Associated With Advertised PGT-A Success Rates*, 35 HUMAN REPROD. 490 (2020)).

[49] Gualtieri et al., *supra* note 42, at 10.

[50] *Id.* at 8 (citing Joyce A. Martin, *Is Twin Childbearing on the Decline? Twin Births in the United States*, 2014-2018, U.S. Department of Health and Human Services, National Center for Health Statistics Data Brief No. 351, https://www.cdc.gov/nchs/data/databriefs/db351-h.pdf (Oct. 2019)).

[51] ACOG PGT Opinion, *supra* note 23, at e133.

[52] Giovanni Monni et al., *Invasive Diagnostic Procedures in Embryonic Period*, 15 DONALD SCH. J. ULTRASOUND OBSTETRICS AND GYNECOLOGY 169, 169 (2021).

even used as an alternative to PGT.[53] Both CVS and amniocentesis are performed after implantation of an embryo, however. CVS is typically available at ten to thirteen weeks' gestation, while amniocentesis is available at fifteen to eighteen weeks' gestation.[54]

PGT also introduces its own set of risks. While the American Society for Reproductive Medicine (ASRM) declared in 2018 that "to the best of current knowledge, embryo biopsy is not linked to fetal malformations or other identifiable problems in offspring,"[55] experts noted in 2023 that all types of PGT rely on an invasive procedure performed on the developing blastocyst, which involves surgically extracting five to seven cells with a pipelle for analysis.[56] According to one report, "[t]he fact that over thirty per cent of subsequently transferred euploid embryos do not yield a successful pregnancy and the significant variation in successful pregnancy rates among labs performing PGT strongly suggest potential harm of the procedure."[57] As emphasized by the ASRM in 2018, "much remains unknown about the long-term effects of embryo biopsy on a developing fetus" and, at least with respect to the use of PGT-M for adult-onset diseases of less serious or variable penetrance, patients should carefully weigh the potential risks and benefits of the procedure.[58] While the genetic testing industry is working on a non-invasive PGT (niPGT) process by testing cells in the fluids and media surrounding the embryos created via IVF,[59] this procedure has engendered lawsuits due to its inaccuracy.[60]

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[53] ACOG PGT Opinion, *supra* note 23, at e133 (stating that "[c]onfirmation of preimplantation testing-monogenic results with chorionic villus sampling (CVS) or amniocentesis should be offered."); ASRM Ethics Committee Opinion on PGT for Monogenic Defects, *supra* note 38, at 989 (describing the use of "[p]renatal diagnostic testing via chorionic villus sampling (CVS) or amniocentesis to confirm the results obtained with PGT-M, or as alternative to PGT-M").

[54] Society for Maternal-Fetal Medicine, *Risks of Chorionic Villus Sampling (CVS) and Amniocentesis*, https://www.contemporaryobgyn.net/view/pdf-smfm-patient-handout-risks-chorionic-villus-sampling-cvs-and-amniocentesis (Feb. 1, 2014).

[55] ASRM Ethics Committee Opinion on PGT for Monogenic Defects, *supra* note 38, at 990.

[56] Gualtieri et al., *supra* note 42, at 9.

[57] *Id. See also* Timothy Bracewell-Milnes et al., *A Systematic Review Exploring the Patient Decision-making Factors and Attitudes Towards Pre-implantation Genetic Testing for Aneuploidy and Gender Selection*, 100 ACTA OBSTETRICIA ET GYNECOLOGICA SCANDINAVICA 17, 18 (2021) ("As PGT-A is still not performed routinely in the majority of fertility clinics worldwide, patients should be informed that PGT-A may not be equally effective in all clinics, and, therefore, they should be made aware of the individual experiences of clinics using PGT-A prior to embarking on treatment.").

[58] ASRM Ethics Committee Opinion on PGT for Monogenic Defects, *supra* note 38, at 989.

[59] Yang et al., *supra* note 18, at 70 (citation omitted).

[60] *See infra* notes 116-25 and accompanying text regarding niPGT and lawsuits relating to it.

Aside from the risks of the PGT procedure itself, PGT relies on the use of IVF, which is associated with an increased risk of multiple birth, particularly if more than one embryo is transferred. The ASRM has also noted that IVF gives rise to a small risk of ovarian hyperstimulation syndrome, potential complications associated with the retrieval of fertilized eggs, and an increased risk of adverse events during pregnancy and birth. Thus, the organization concluded that it cannot rule out the possibility of negative long-term consequences for the offspring born using IVF and PGT.[61]

In terms of expense, PGT typically increases the cost of an IVF cycle by $1,000 to $4,000, although technologies that permit many samples to be tested on a single microchip have significantly reduced costs.[62] While many experts view PGT-M and PGT-SR as cost-effective and reliable,[63] they caution against the use of PGT-A as a routine add-on to an already-planned IVF,[64] particularly for women under age thirty.[65]

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[61] ASRM Ethics Committee Opinion on PGT for Monogenic Defects, *supra* note 38, at 989.

[62] Gualtieri et al., *supra* note 42, at 10. *But cf.* Azeen Ghorayshi, *Study Raises Questions About Popular Genetic Test for 'Abnormal' Embryos*, N.Y. TIMES, Apr. 21, 2022 (stating that PGT costs from $4,000 to $10,000). Experts have noted that the high cost of IVF, which itself costs approximately $12,000, along with the additional cost of PGT, makes the technology available and affords choice only to those who can afford it. Ilana Löwy, *ART with PGD: Risky Heredity and Stratified Reproduction*, 11 REPROD. BIOMED. & SOC. ONLINE 48, 52 (2020) ("In countries where the couple has to pay for PGD out of pocket, the generous statement 'let parents decide' means, in practice, 'let parents who can afford PGD decide' — excluding the others."); *see also* Cohen, *supra* note 13, at 1024 (observing that because ART is not regulated there is an "inherent opportunity for inequitable treatment" because "reimbursement rather than prohibition becomes the key policy lever," permitting those who can afford to self-pay to receive services that those without means cannot access).

[63] *See supra* notes 35-44 and accompanying text regarding the different types of PGT.

[64] Ghorayshi, s*upra* note 62 (referring to PGT-A as a "standard add-on" to IVF); Yang et al., *supra* note 18, at 69 (critiquing the use of PGT-A as "a routine add-on for IVF") (citation omitted). *See infra* notes 66-85 and accompanying text regarding the high false-positive rates for PGT-A.

[65] Gualtieri et al., *supra* note 42, at 10 (stating the value of PGT-A for women under age thirty is "unproven"). *See also* Yang et al., *supra* note 18, at 71 (explaining that while PGT-A improved the live birth rate for women over thirty-five years old, it did not improve the outcomes of the general population). One large study screened over 15,000 embryos and found the aneuploid embryo rate was approximately 25 percent in young women (thirty years of age or younger), 58.2 per cent at age forty, 75.1 percent at forty-two, and 88.2 percent at age forty-four. Jason N. Franasiak et al., *The Nature of Aneuploidy with Increasing Age of the Female Partner: A Review of 15,169 Consecutive Trophectoderm Biopsies evaluated With Comprehensive Chromosomal Screening*, 101 FERTILITY & STERILITY 656, 658 (2014).

The most significant drawback associated with PGT-A is the high rate of false positive results arising from the lack of clinical validation,[66] meaning whether the test provides information relevant to health and disease in a patient.[67] PGT-A screens preimplantation embryos for aneuploidy, meaning an abnormally high or low number of chromosomes, as compared to euploidy, meaning a normal number of chromosomes.[68] Initially, embryos were characterized as either euploid or aneuploid. However, in 2015, two significant reports appeared in the scientific literature, claiming normal euploid births following transfer of embryos diagnosed as chromosomally abnormal through PGT-A, thereby calling into question the clinical validity of the procedure.[69]

In response to the 2015 reports, the Preimplantation Genetic Diagnosis International Society (PGDIS), a small organization consisting of under 320 members[70] mostly representing the genetic testing industry,[71] published in 2016 (on its website only) a practice guidance for PGT[72] for the first time ever.[73] Commentators note that "[r]emarkably, the new guidelines were unsigned, did not contain any references, and had not undergone peer review" and PGDIS "offered no explanation [as to] what thought process had led to their guidelines and who had authored them."[74]

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[66] Yang et al., *supra* note 18, at 69, 71 (stating that "the lack of clinical validation and high false-positive rate" of PGT-A are "extremely concerning" and criticizing the fact that "PGT-A was widely used in many IVF centers in the USA before clinicians realized the limitations of this technology"). *See also* Barad et al., *supra* note 18, at 1204 (finding that many embryos deemed abnormal through PGT resulted in healthy live births); Gleicher et al., *supra* note 18, at 731 (declaring that "[b]ecause of a high false-positive rate, PGT-A,[sic] actually reduces live IVF birth chances for many patients"); Norbert Gleicher et al., *The Uncertain Science of Preimplantation and Prenatal Genetic Testing*, 28 NATURE MED. 442, 444 (2022) ("All diagnostic tests should be validated prior to use, yet PGT-A has been used since the 1990s without such validation in four sequential versions.") (citation omitted).

[67] Gail H. Javitt & Kathy Hudson, *Federal Neglect: Regulation of Genetic Testing*, 22 ISSUES IN SCI. & TECH. (Spring 2006), https://issues.org/javitt/.

[68] *See* Lieman & Breborowicz, *supra* note 36, for the distinction between aneuploid and euploid embryos.

[69] Gleicher et al., *supra* note 18, at 733 (citations omitted).

[70] Preimplantation Genetic Diagnosis International Society, *PGDIS Members*, PGDIS, https://pgdis.org/pgd_members.html (last visited Dec. 15, 2024).

[71] Gleicher et al., *supra* note 18, at 733.

[72] Preimplantation Genetic Diagnosis International Society, *PGDIS Position Statement on Chromosome Mosaicism and Preimplantation Aneuploidy Testing at the Blastocyst Stage*, PGDIS (July 19, 2016), https://pgdis.org/docs/newsletter_071816.html [hereinafter PGDIS Statement].

[73] Gleicher et al., *supra* note 18, at 733; Gleicher et al., *supra* note 47, at 28 (citation omitted) (describing the PGDIS statement as an "unconventional 2016 guidance by a small society in an unreferenced and unsigned e-mail to membership (recently removed from the society's website)."

[74] Gleicher et al., *supra* note 18, at 733.

Nonetheless, these guidelines "radically changed" how laboratories conducted the analyses of biopsies and reported the results to IVF centers.[75] According to experts, "in order to explain delivery of healthy offspring following transfer of embryos with allegedly aneuploid biopsy results, embryos no longer were only classified in binary fashion as euploid or aneuploid" and the guidelines "for the first time added a new third category of mosaic embryos."[76]

The 2016 PGDIS statement suggested defining an embryo as mosaic if the amount of aneuploid DNA was between twenty to eighty percent, and the rest was euploid. The guidance stated that an embryo with less than twenty percent aneuploid DNA should be considered euploid (normal) and ready for transfer, while an embryo with more than eighty percent aneuploid DNA should be considered aneuploid, meaning abnormal, and should not be transferred. For an embryo within the twenty to eighty percent range of aneuploidy, the guidance suggested that transfer should be considered only if there were no euploid embryos, and after obtaining expert advice and genetic counseling.[77] According to critics, this standard has generally been followed by fertility clinics conducting PGT-A tests since 2016, without confirming the hypothesis that an embryo with twenty to eighty percent aneuploidy will be more likely to lead to chromosomal abnormalities and a lower possibility of a viable pregnancy.[78] Perhaps to avoid the difficult issue of how to handle mosaic embryos, some fertility clinics ask laboratories not to report mosaicism. One laboratory estimated that eighty percent of the two hundred clinics it serves classify mosaic embryos as abnormal.[79] Due to uncertainties surrounding mosaicism,

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[75] *Id.*

[76] *Id.* Gleicher et al. use the term "chromosome-abnormal," considering it only a temporary designation with very limited clinical significance, rather than differentiating between "mosaic" or "aneuploid" PGT-A diagnoses. Gleicher et al., *supra* note 47, at 27.

[77] PGDIS Statement, *supra* note 72. Experts have noted that PGDIS's definition of mosaic differs from the internationally accepted meaning of the term, which refers to findings in the entire organism (here the embryo) rather than a single biopsy of just a few cells. Barad et al., *supra* note 18, at 1195 (citation omitted); Gleicher et al., *supra* note 7, at 501; Gleicher et al., *supra* note 47, at 26 (noting that "[w]hile under uniform biological consensus, this term describes a single organism (in this case an embryo) that contains more than a single normal 46, XX, or 46, XY cell lineage, PGT-A laboratories describe an embryo incorrectly as 'mosaic' (and, therefore the use of quotation marks) if only a single [biopsy] of only approximately 5 cells contains more than a single normal 46, XX or 46, XY cell lineage").

[78] Barad et al., *supra* note 18, at 1195. *See also* Gleicher et al., *supra* note 18, at 733 (explaining that after 2016 PGT-A became a standard add-on, but "cannot reliably assess whether an embryo is normal euploid, mosaic, or abnormal aneuploid").

[79] Sonia M. Suter, *Legal Challenges in Reproductive Genetics*, 115 FERTILITY & STERILITY 282, 286 (2020).

increasing numbers of laboratories have, therefore, indeed returned to binary "euploid-aneuploid" reporting, with the cut-off between the two placed at either forty or fifty percent "aneuploid" lineage DNA.[80] The percentages used in different laboratories vary, resulting in embryos having different potential diagnoses depending on which PGT-A laboratory they use.[81]

The percentages are in any case invalid. Clinical results demonstrate that, in a significant number of cases, a mosaic embryo, when implanted, develops into a non-mosaic pregnancy, thereby contradicting PGT-A's validity. Indeed, hundreds of pregnancies worldwide have been reported without adverse outcomes following transfer of embryos previously diagnosed by PGT-A as "abnormal."[82] Despite these results, many, if not most, U.S. and international IVF centers continue to refuse to transfer mosaic or aneuploid embryos and require that patients consent to the automatic disposal of all embryos determined by PGT-A to be "chromosomal-abnormal."[83] Because of the recent scrutiny of PGT-A, many IVF centers have stopped automatic disposal of such "abnormal" embryos but usually still refuse their transfers.[84] Moreover, different genetics laboratories use dissimilar criteria in labeling an embryo mosaic. This lack of standardization further complicates interpretation of PGT-A reported results.[85] The ASRM encourages each IVF program to develop its own internal policy

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[80] Gleicher et al., *supra* note 47, at 27.

[81] *Id.*

[82] Barad et al., *supra* note 18, at 1195; Gleicher et al., *supra* note 47, at 26. *See also* Min Yang et al., *Depletion of Aneuploid Cells in Human Embryos and Gastruloids*, 23 NAT. CELL BIO. 314, 314 (2021) (declaring that "[o]ur findings challenge two current dogmas: that a single . . . biopsy at blastocyst stage to perform prenatal genetic testing can accurately determine the chromosomal make-up of a human embryo, and that aneuploid embryos should be withheld from embryo transfer in association with in vitro fertilization.")

[83] Barad et al., *supra* note 18, at 1195; Gleicher et al., *supra* note 47, at 28 ("a majority of IVF centers, still, do not transfer embryos unless signed out as "euploid."). *Cf.* Suter, *supra* note 79, at 286 (citation omitted) (citing a 2020 survey that reported that more than thirty-five percent of Society for Assisted Reproductive Technology members who were surveyed would not be comfortable transferring embryos with any level of mosaicism unless it involved monosomy X, and eleven per cent to fifteen percent were 'unsure' of what level of mosaicism would make them comfortable" and that "[m]ost providers were 'unsure' or uncomfortable with [mosaic embryo transfer], largely because of the uncertainty about its clinical implications").

[84] Barad et al., *supra* note 18, at 1195 (citation omitted).

[85] *Id.* at 1203. *See also* Suter, *supra* note 79, at 286 (citation omitted) (explaining that "[b]ecause the detection of mosaicism is influenced by the stage of the embryo biopsy, the method of analysis, and the classification scheme used, laboratories differ considerably in their detection rates").

addressing the transfer and storage of embryos diagnosed as mosaic and explain them to patients.[86]

Researchers posit several possible explanations for the healthy development of so-called "mosaic" embryos. First, such embryos may be able to self-correct during differentiation and proliferation. Therefore, the biopsied cell from PGT-A may not accurately represent the embryo and therefore lead to false-positive or false-negative results.[87] Second, a single embryo biopsy of five to six cells at the preimplantation stage may not reliably reflect the complete chromosomal makeup of the embryo. Mathematical modeling demonstrates that an average five- or six-cell biopsy cannot definitively characterize an embryo as either aneuploid or not aneuploid, even if one were to accept the questionable assumption that aneuploid cells are evenly distributed.[88] The ultimate consequence of such uncertainty may be false-negative and false-positive diagnoses of many embryos.[89] Third, an embryo's ploidy status does not necessarily represent a fetus's ultimate condition.[90] Biopsies are taken from the trophectoderm, which ultimately forms the placenta,[91] and chromosomal-normal pregnancies may have placentas that contain islands of aneuploid cells.[92] Further,

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[86] Ethics Committee of the American Society for Reproductive Medicine, *Transferring Embryos with Genetic Anomalies Detected in Preimplantation Testing: An Ethics Committee Opinion*, 107 FERTILITY & STERILITY 1130, 1135 (2017) [hereinafter ASRM Committee Opinion on Transferring Embryos with Anomalies].

[87] Barad et al., *supra* note 18, at 1195 (citations omitted) ("embryos can self-correct after embryo biopsies are taken during PGT-A); Gleicher et al., *supra* note 47, at 28 (same) (citation omitted); Gleicher et al., *supra* note 18, at 732 (citation omitted) (same); Yang et al., *supra* note 18, at 70 (citation omitted) (same). In contrast, mosaicism in a fetus or neonate is regarded as a genuine cause for concern. American Society for Reproductive Medicine, Practice Committee and Genetic Counseling Professional Group (GCPG) of the American Society for Reproductive Medicine, *Clinical Management of Mosaic Results from Preimplantation Genetic Testing for Aneuploidy (PGT-A) of Blastocysts: A Committee Opinion*, 114 FERTILITY & STERILITY 245, 247 (2020) [hereinafter ASRM Practice Committee and Genetic Counseling Professional Group].

[88] Barad et al., *supra* note 18, at 1195; Gleicher et al., *supra* note 18, at 732 (citation omitted). Mathematical certainty would require at least twenty cells, which is incompatible with the continued viability of the embryo. Gleicher et al., *supra* note 47, at 26 (2023); Gleicher et al., *supra* note 18, at 735.

[89] Barad et al., *supra* note 18, at 1195 (citation omitted).

[90] Gleicher et al., *supra* note 18, at 732 (citation omitted).

[91] Adam Mischler et al., *Two Distinct Trophectoderm Lineage Stem Cells from Human Pluripotent Stem Cells*, 296 J. BIO. CHEM. 1, 1 (2021) ("The trophectoderm layer of the blastocyst-stage embryo is the precursor for all trophoblast cells in the placenta").

[92] Barad et al., *supra* note 18, at 1195 ("A very recent study reconfirmed and further explored the known observation that term placentas are inherently mosaic, characterized by a substantial number of chromosomal abnormalities, even if the fetus is completely euploid."); Gleicher et al., *supra* note 18, at 732 (citation

due to the phenomenon of self-repair by cells, particularly embryonic as opposed to placental cells, "[d]ownstream self-correction renders upstream biopsy results irrelevant."[93] Fourth, the percentage of aneuploid DNA within a single biopsy does not accurately determine the degree of an embryo's mosaicism and, consequently, implantation, pregnancy, and live birth chances. PGT-A incorrectly associates clinical significance of mosaicism with increasing percentage of aneuploid DNA in a single biopsy, but PGT-A's cut-off value defining a euploid embryo as having eighty percent euploid DNA has no "biological, experimental, nor logical basis."[94] Determinations of percentages of aneuploid DNA require accurate nominators and denominators, but because biopsy damages individual cells, resulting in spillage of DNA and contamination of neighboring cells, it is impossible to assess during biopsy how many cells have been biopsied, and therefore to calculate a correct denominator.[95] Thus, "reported percentages of aneuploid DNA in PGT-A must be spurious."[96] Instead, researchers conclude that "current PGT-A practice greatly exaggerates diagnoses of euploidy and aneuploidy and greatly underestimates diagnoses of mosaicism."[97]

PGDIS ultimately replaced its 2016 position statement with a 2021 version,[98] recognizing that encouraging success rates in terms of viable pregnancies have been achieved after the transfer of "lower range" mosaic embryos.[99] Further, PGDIS noted that nearly all prenatal diagnoses of established pregnancies after a mosaic embryo transfer resulted in normal euploid fetuses, and all live births reported up to the time of publication of the statement showed no evidence of chromosome-based diseases.[100]

However, some experts have cautioned against using the term mosaic at all, which they call "misleading" because diagnosis of chromosomal

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omitted) ("Chromosomal-normal pregnancies may have placentas that contain islands of aneuploid cells."); Gleicher et al., *supra* note 47, at 26 (noting that "that chromosomally euploid and perfectly normal newborns still deliver with placentas with, often, considerable confined placental aneuploidy and an amalgam of genomic mutations").

[93] Gleicher et al., *supra* note 18, at 732 (citations omitted) (explaining that "[r]ecent studies convincingly demonstrated an efficient self-correction mechanism in the embryonic, but not to the same degree in the extraembryonic cell lineage in a mouse model and in human blastocyst stage embryos"); Yang et al., *supra* note 82, at 314 (noting that mouse models demonstrate the "innate ability" of the embryo, but not the placenta, to "select against aneuploid cells").

[94] Gleicher et al., *supra* note 18, at 732 (citation omitted).

[95] *Id.* at 732, 735.

[96] *Id.* at 732 (citation omitted).

[97] Gleicher et al., *supra* note 47, at 26.

[98] Preimplantation Genetic Diagnosis International Society, *PGDIS Position Statement on the Transfer of Mosaic Embryos 2021*, PGDIS (Aug. 19, 2021), https://pgdis.org/docs/PositionStatement.pdf.

[99] *Id.* at 4-5.

[100] *Id.* at 5.

mosaicism after blastocyst biopsy is not made by directly witnessing euploid and aneuploid individual cells.[101] Rather, the diagnosis is inferred from the presence of an intermediate chromosome copy number.[102] An intermediate chromosome copy number, revealed through genetic sequencing of embryonic cells, indicates that although the embryo does not have the normal two chromosome copies, referred to as disomy, neither does it present as having full monosomy, meaning a missing chromosome, nor full trisomy, meaning an extra chromosome.[103] In fact, for this reason, experts have called for the abandonment of the term mosaicism when referring to intermediate copy number.[104] Experts have noted that while such a change in terminology would recognize that mosaicism represents a much more common phenomenon than previously understood,[105] it is not likely to change clinical practice in the absence of understanding on the part of IVF clinics that embryos with "intermediate copy numbers" can still lead to viable euploid pregnancies.[106]

Even further, a team of researchers have rejected the use of PGT-A altogether, concluding that it "does not fulfill even minimal criteria for ethical clinical use in routine IVF practice" in terms of accuracy in serving as the diagnostic test that determines whether a human embryo can be transferred.[107] This team further emphasized that the clinical application of PGT-A "should be restricted to experimental investigations."[108] Noting

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[101] Richard R. Paulson & Nathan R. Treff, *Isn't It Time to Step Calling Preimplantation Embryos "Mosaic?"*, 1 FERTILITY & STERILITY REP. 164, 164 (2020).

[102] *Id.*

[103] *See* Bhavini Rana et al., *Identifying Parental and Cell-division Origins of Aneuploidy in the Human Blastocyst*, 110 AM. J. HUM. GENETICS 565, 565-66 (2023) (explaining that a mix of euploid and aneuploid cells produces intermediate chromosomal copy-number results that may be inaccurately interpreted as mosaicism).

[104] Paulson & Treff, *supra* note 101, at 164; Suter, *supra* note 79, at 286 (noting that some have suggested laboratories reporting results should replace the term "mosaic" with "consistent with possible mosaicism").

[105] Barad et al., *supra* note 18, at 1202 (noting that "[m]osaicism is not only common in human embryos," but also "represents a quite common phenomenon throughout human life"); Suter, *supra* note 79, at 286 (citation omitted) ("True mosaicism in embryos occurs at higher rates than have been reported through prenatal and postnatal analysis.").

[106] Barad et al., *supra* note 18, at 1203 (citation omitted) ("Several authors have reported that over 80% of embryos contain at least some aneuploid cells at preimplantation stages."); Gleicher et al., *supra* note 47, at 26 (noting "the reported prevalence of aneuploid cells in ca. 80% of embryos at blastocyst-stage.").

[107] Gleicher et al., *supra* note 18, at 731.

[108] *Id.* Many other researchers support the same conclusion. *See*, *e.g.*, Sebastiaan Mastenbroek et al., *The Imperative of Responsible Innovation in Reproductive Medicine*, 385 NEW ENG. J. MED. 2096, 2098 (2021) ("Given the lack of high-level evidence of the effectiveness for PGT-A and the potential for adverse consequences, the use of PGT-A is best limited at present to the research setting.");

the high incidence of false positive tests, they contended that PGT-A actually reduces pregnancy and live birth chances for women with small embryo numbers.[109] Arguing that continued use of PGT-A rests on "fundamental errors in understanding of basic human biology and embryology," including the mistaken conclusion that a single biopsy at blastocyst stage could reveal an embryo's ultimate chromosomal makeup with adequate clinical accuracy to determine its nonuse or even disposal,[110] they concluded by warning that "false-positive PGT-A diagnoses, therefore, lead to nonuse or disposal of large numbers of human embryos with normal pregnancy and delivery potential, representing a significant ethical as well as regulatory conundrum, demanding authoritative regulatory intervention."[111] PGT-A "not only raises serious ethical concerns but also calls into question the worldwide regulatory environment that pretends to extend special considerations to human embryos."[112]

Experts instead recommend, if no euploid embryos are available, using a hierarchy for transfer. They suggest favoring embryos with "mosaic" and segmental abnormalities,[113] followed by single monosomy or single selected trisomy.[114] Moreover, the more abnormal cell lineages are detected in a single biopsy sample, the poorer chances will be for

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Junhao Yan et al., *Live Birth with or Without Preimplantation Genetic Testing for Aneuploidy*, 385 NEW ENG. J. MED. 2047, 2047 (2021) (stating that PGT-A does not increase live birth rates for women with good quality blastocysts).

[109] Gleicher et al., *supra* note 18, at 731.

[110] *Id.*

[111] *Id.*; Barad, *supra* note 18, at 1203 ("Considering the increasing utilization of PGT-A worldwide, large numbers of human embryos with still reasonable pregnancy and live birth chances are regrettably disposed of or condemned to permanent cryopreservation."); Gleicher, *supra* note 47, at 27 ("[A]ny judgment of current PGT-A practice must conclude that restrictions of transferability of embryos based on current PGT-A definitions of 'euploid,' 'mosaic,' and 'aneuploid,' have no biological, mathematical, or ethical basis and, therefore, should be withdrawn."). *See also* Yang et al., *supra* note 18, at 72 (stating that the "current professional self-regulation system for PGT-A may not be sufficient" and "the FDA could provide oversight related to the accuracy of results and mosaicism, the indication of PGT-A as a medical necessity vs for personal and social reasons, and provide guidelines for developing and implementing patient education.").

[112] Gleicher et al., *supra* note 18, at 733.

[113] Ludovica Picchetta et al., *Investigating the Significance of Segmental Aneuploidy Findings in Preimplantation Embryos*, 4 F & S Sci. 17, 17 (May 2023) (explaining that segmental aneuploidies occur when a small region of a chromosome is lost or gained during cell division).

[114] Barad et al., *supra* note 18, at 1202 (citation omitted) (citing that a hierarchy for transfer favors "embryos with 'mosaic' and segmental abnormalities, followed by single monosomy or single selected trisomy"). Monosomy occurs when one member of a chromosome pair is missing and trisomy occurs when an extra chromosome is present, creating a triplet instead of a normal chromosome pair. Clare O'Connor, Chromosomal Abnormalities: Aneuploidies, 1 NATURE EDUC. 172, 172 (2008).

implantation. In one study, no embryo with more than two abnormal cell lineages detected by PGT-A led to live birth, suggesting that a PGT-A diagnosis could be useful in creating this hierarchy. It should be noted, however, that the relevant factor is the number of abnormal cell lineages, not the putative percentage of abnormal cells. Chromosomal 'abnormal' embryos with the best chances of implantation, therefore, do not appear defined by percentage of aneuploid DNA within a single biopsy, but instead by number of aneuploid cell lineages seen in a single biopsy. The more aneuploid cell lineages there are, the less likely the biopsy result represents a false-positive and, therefore, the less likely self-correction will occur.[115]

The latest iteration of PGT, called non-invasive PGT (niPGT), avoids embryo biopsy, relying instead on analysis of the free embryonic DNA (cfeD-NA) found in both embryonic fluid and in the medium where the embryo was grown.[116] The niPGT technique relies on the hypothesis that the embryos' cell-free DNA will reflect its status as either aneuploid or euploid.[117] NiPGT is not only less invasive, but is also potentially more affordable, as it obviates the need to train the provider of the biopsy. In addition, niPGT may in fact better represent the entire embryo, since the material analyzed is not drawn from just a single region of the blastocyst.[118]

However, niPGT-A has been described as diagnostically inferior to currently utilized PGT-A, though some IVF centers have started offering niPGT-A commercially.[119] niPGT has also been alleged to lead to the disposal of potentially healthy embryos. Commentators have critiqued niPGT based on what they believe is an erroneous view that the potential harm arising from embryo biopsy is the principal reason that PGT-A has failed to improve IVF outcomes during the last two decades.[120] These commentators criticize IVF centers for "prematurely and without proper prior validation studies" introducing niPGT-A into routine clinical practice.[121]

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[115] Barad et al., *supra* note 18, at 1202 (citation omitted). *See also* Gleicher et al., *supra* notes 94-95 and accompanying text, at 732, 735 (explaining why such percentages are inaccurate due to the absence of a meaningful denominator).

[116] Larissa Nogueira Sousa & Paula Bruno Monteiro, *Non-Invasive Preimplantation Genetic Testing: A Literature Review*, 26 JBRA ASSISTED REPROD. 554, 554 (2022).

[117] Gleicher et al., *supra* note 66, at 443 ("Most recently a fourth version of PGT-A, so-called niPGT-A (or PGS 4.0) . . . has been introduced to clinical practice under the hypothesis that the embryos' cell-free DNA in spent media must reflect embryo ploidy.").

[118] Sousa & Monteiro, *supra* note 116, at 554.

[119] Gleicher et al., *supra* note 66, at 443 (citation omitted).

[120] Gleicher et al., *supra* note 7, at 501–02 (citation omitted).

[121] Gleicher et al., *supra* note 18, at 734 (citation omitted). *See also* Rachael Brown, *Monash IVF Group's 'Inaccurate' Genetic Test Potentially Robbed These Women of Viable Embryos*, AUSTL. BD. CORP. (Apr. 20, 2022),

The first class-action lawsuit relating to PGT-A, which involved niPGT, arose in 2021 in Australia. Plaintiffs pursued a claim in the Supreme Court of Victoria state against Monash IVF in Melbourne, a leading IVF center, along with a second IVF center in Adelaide.[122] Claimants, who underwent IVF cycles with PGT-A between May 2019 and October 2020, sought damages for financial loss and psychiatric injury based on their claim that niPGT-A testing "should not have been provided by the defendants because there was a substantial risk, not disclosed to patients, that the niPGT-A testing might produce false positive results" and lead to an "erroneous determination that an embryo was aneuploidy [sic] and not suitable for transfer."[123] According to experts, all published studies, except for one,[124] indicate even more unreliable outcomes with niPGT-A than with standard PGT-A.[125]

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https://www.abc.net.au/news/2022-04-23/monash-ivf-group-faulty-genetic-test-class-action-compensation/101005352 (noting that the defendant Monash IVF Group suspended its new genetic test in October 2020, shortly after it realized the test was finding higher than expected numbers of embryos to be non-viable for implantation, and that the scientific consensus is that this technology is not ready for consumer use).

[122] MONASH IVF CLASS ACTION, DANIELLE BOPPING V. IVF MONASH PTY LTD & ORS, SUPREME COURT OF VICTORIA CASE NO. S ECI 2020 04761, GROUP PROCEEDING SUMMARY STATEMENT (Apr. 3, 2021) [hereinafter Monash IVF Class Action].

[123] *Id.* Monash IVF settled the case in August 2024 for $56 million without admitting liability. *Monash IVF $56 Million Settlement Explored by Prof. Sonia Allen*, University of New England, https://www.une.edu.au/connect/news/2024/08/monash-ivf-$56-million-landmark-class-action-settlement-prof-sonia-allan (Aug. 28, 2024). Another class action relating to niPGT alleges negligent contamination of congenital defect tests that left families with no choice but to abandon what might well have been healthy, viable embryos. Sarah London, *Lieff Cabraser Files Negligence Lawsuit Against Natera, Inc. Over Faulty Embryo Viability Testing*, LIEFF, CABRASER, HEIMANN & BERNSTEIN (Nov. 19, 2021), https://www.lieffcabraser.com/2021/11/lieff-cabraser-files-negligence-lawsuit-against-natera-inc-over-faulty-embryo-viability-testing/. As noted by one expert, in the absence of federal or state legislation or regulation of ART in general and PGT in particular, plaintiffs seek redress through tort law. Cohen, *supra* note 13, at 1021 ("Outside of direct regulation and professional self-regulation, tort liability also plays some role in guiding ART practice, but it is hard to know how much.").

[124] *See* Akihiro Shitara, *Cell-free DNA in Spent Culture Medium Effectively Reflects the Chromosomal Status of Embryos Following Culturing Beyond Implantation Compared to Trophectoderm Biopsy*, 16 PLOS ONE 1, 2 (Feb. 11, 2021) (citations omitted), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0246438 (indicating that noninvasive PGT is as effective as some more invasive forms).

[125] Michelle Volovsky et al., *Non-invasive Preimplantation Genetic Testing for Aneuploidy: Is the Promise Real?*, 39 HUM. REPROD. 1899 (2024).

II. THE LACK OF FEDERAL REGULATION OF PGT IN THE U.S., IN CONTRAST WITH THE REST OF THE INDUSTRIALIZED WORLD, AND THE RESULTANT RISKS TO PATIENTS

PGT is but one technique of ART, which the U.S. Centers for Disease Control and Prevention (CDC) defines as any fertility treatment in which medical professionals handle or manipulate eggs or embryos.[126] ART has grown in popularity since the 1981 birth of the first infant conceived in the United States using this technology.[127] In 2019, approximately two percent of all infants born in the United States were conceived using ART.[128]

Notwithstanding its pervasiveness and medical and social significance, ART historically remained largely unregulated in the United States, which commentators to refer to as the "Wild West" of fertility treatments,[129] where "cash is king and informed consent is optional."[130] Commentators note that federal and state government reluctance to regulate ART stems from reproductive technology's proximity to the abortion debate, along with the self-funded nature of most reproductive care in the U.S.[131] Prior to recent efforts to secure state regulation, nearly the only regulation of ART technology appeared in professional guidelines published by organizations such as the ASRM and the American College of Obstetricians and Gynecologists (ACOG).[132] The only federal law that

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[126] *What Is Assisted Reproductive Technology?*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 8, 2019), https://www.cdc.gov/art/whatis.html.

[127] Saswati Sunderam et al., *Assisted Reproductive Technology Surveillance — United States, 2018*, 71 MORBIDITY & MORTALITY WKLY. REP. 1, 1 (Feb. 18, 2022).

[128] Caroline Hackley et al., *The Regulation of Assisted Reproduction*, REGUL. REV. (Aug. 13, 2022) https://www.theregreview.org/2022/08/13/saturday-seminar-the-regulation-of-assisted-reproduction/ (citing *State-Specific Assisted Reproductive Technology Surveillance* CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 27, 2021), https://www.cdc.gov/art/state-specific-surveillance/2021/index.html).

[129] Steve P. Calandrillo & Chryssa V. Deliganis, *In Vitro Fertilization and the Law: How Legal and Regulatory Neglect Compromised a Medical Breakthrough*, 57 ARIZ. L. REV. 311, 313 (2015). *See also* Ellen S. Fischer, *The 'Wild West' of Medicine: An Argument for Adopting the United Kingdom's 'HFEA' Framework, to Improve the Market for Assisted Reproduction in the United States*, 39 NW. J. INT'L LAW & BUS. 201, 202 (2019) (referring to the U.S. as the "the wild west of the fertility industry").

[130] Calandrillo & Deliganis, *supra* note 129, at 311.

[131] Bayefsky, *supra* note 21, at 1162-63. *See also supra* notes 8-16 and accompanying text (stating that prior to the *Dobbs* decision, states did not regulate PGT either for largely the same reasons that the federal government has declined to do so).

[132] Bayefsky, *supra* note 21, at 1164 (describing a dearth of PGD regulation and listing professional guidelines on PGD regulation published by a few medical associations); Cohen, *supra* note 13, at 1019 (citation omitted) ("The most

broadly regulates ART and IVF is the U.S. Fertility Clinic Success Rate and Certification Act of 1992.[133] This statute relates only to the certification of laboratories and the reporting of pregnancy success rates achieved by fertility clinics utilizing ART.[134] While most clinics comply, there is no legal consequence for failing to report. In fact, the only negative repercussion is the possibility of being listed as a non-responder in the annual report.[135] However, the CDC does not regulate the use of the technology.[136]

Another reason for the minimal regulation of PGT testing is its classification within the category of laboratory-developed tests (LDTs),[137] which the FDA has defined as "a type of in vitro diagnostic test that is designed, manufactured and used *within a single laboratory.*"[138] Labs typically devise LDTs to detect diseases that are changing rapidly, such as new strains of known infectious diseases; to detect diseases that are the subject of advancing scientific research, such as cancers that can be better diagnosed or treated through the use of genomic testing; and for genetic testing generally.[139] Although the FDA invokes the Food, Drug, and

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important such regulator is the American Society for Reproductive Medicine (ASRM), a membership organization founded in 1944 and made up of those work in reproductive medicine and ancillary professions."). *See infra* notes 197-210 and accompanying text for a discussion of the lack of firm guidelines for ART by U.S. professional organizations.

[133] Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (codified at 42 U.S.C. §§ 263a-1 to a-7).

[134] *See id.* (laying out the requirements for certification as a "laboratory"); 42 U.S.C. § 263a-1) (providing the standards for reporting pregnancy success rates to the CDC). *See also* Centers for Disease Control and Prevention, *Assisted Reproductive Technology (ART)*, National ART Surveillance, https://www.cdc.gov/art/nass/index.html (June 7, 2023) (setting forth the reporting system for ART clinics to submit data to the CDC).

[135] Cahn & Suter, *supra* note 4, at 40 n.55 (noting the noncomplying programs "will be identified as non-reporters in HHS/CDC's annual Assisted Reproductive Technology Fertility Clinic Success Rates Report"); Calandrillo & Deliganis, *supra* note 129, at 330 ("[T]he Fertility Clinic Success Rate and Certification Act provides some basic (but voluntary) reporting of clinics' advertising claims.").

[136] Bayefsky, *supra* note 21, at 1162.

[137] Gleicher et al., *supra* note 7, at 503 (defining PGT as an LDT).

[138] U.S. Food & Drug Administration, *Laboratory Developed Tests*, https://www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests (Apr. 29, 2024) (emphasis added). LDTs are also sometimes called in-house developed tests, or "home brew" tests. Centers for Medicare and Medicaid Services, *CLIA Overview*, https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/ldt-and-clia_faqs.pdf (Oct. 22, 2013).

[139] CONG. RSCH. SERV., FDA Regulation of Laboratory-Developed Tests (LDTs), https://crsreports.congress.gov/product/pdf/IF/IF11389 (Dec. 7, 2022) [hereinafter CONG. RSCH. SERV.]. *See also* THE PEW CHARITABLE TRUST, THE ROLE OF LAB-DEVELOPED TESTS IN THE IN VITRO DIAGNOSTICS MARKET 10, 12, https://www.pewtrusts.org/en/research-and-analysis/reports/2021/10/the-role-of-

Cosmetic Act (FD&C Act)[140] to regulate many in vitro diagnostic (IVD) tests, which use blood, saliva, and other human samples to detect the presence or risk of certain diseases,[141] the Agency has not in the past regulated the subset of IVD tests known as lab-developed tests (LDTs), meaning tests that are created and used in the same facility.[142]

The FDA has historically declined to regulate LDTs because it views them as presenting a lower risk as compared to mass-produced IVDs sold to labs.[143] When Congress granted the FDA oversight of medical devices in 1976, most LDTs were manufactured in small quantities and served a limited number of patients, typically those living in the vicinity of the labs that developed them.[144] The use of LDTs was typically limited to diagnosing rare diseases or serving the needs of the local patient population**.** In addition, LDTs typically involved manual techniques rather than automation and were used and interpreted by physicians in a single institution who were actively involved in patient care.[145] Currently, however, although some LDTs are limited in terms of the volume and geographical reach of their use, others are marketed in large quantities and used to test specimens from patients across the country, outside of the health care setting.[146] Today's LDTs are more often used to widely screen for common diseases or to predict personal risk of developing certain diseases, using complex algorithms that remain opaque to their users.[147] As noted by the

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lab-developed-tests-in-the-in-vitro-diagnostics-market (Oct 22, 2021) (noting that labs may prefer to use LDTs in genetic testing because "the test in question is evolving rapidly in response to emerging science, and developers might perceive FDA review as being too slow to keep pace" and because "some tests, such as those that rely on next-generation sequencing technology, may be highly complex to run and require specific training to interpret, both of which are factors that can make a test more difficult to standardize and produce at a commercial scale for use in many labs") [hereinafter PEW].

[140] 21 U.S.C. §§ 301-392 (Suppl. 5 1934). In 1976, the Medical Device Amendments of 1976 (the MDA) amended the FD&C Act to create a comprehensive system for the regulation of devices intended for human use. Public Law 94-295, 90 Stat. 539, 539 (May 28, 1976).

[141] Under Section 201(h)(1) of the FD&C Act, a device is defined to include, *inter alia*, "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article" that is "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals." 21 U.S.C. § 321(h)(1)).

[142] PEW, *supra* note 139, at 7, 12, 15 (noting that the FDA does not regulate LDTs).

[143] *Id.* at 3.

[144] *Id.* at 7; Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. 68006, 68009, (proposed Oct. 3, 2023) (to be codified at 21 C.F.R. pt. 809) [hereinafter Federal Register Proposed Rule].

[145] Federal Register Proposed Rule, *supra* note 144, at 68009.

[146] PEW, *supra* note 139, at 1-2; Federal Register Proposed Rule, *supra* note 144 at 68009.

[147] Federal Register Proposed Rule, *supra* note 144, at 68009.

FDA, "[t]he risks associated with most modern LDTs are therefore much greater today" than they were at the time the FDA began to regulate medical devices.[148]

LDTs are subject to minimal oversight by the Centers for Medicare & Medicaid Services (CMS) under separate regulations known as Clinical Laboratory Improvement Amendments (CLIA).[149] Congress enacted this legislation to strengthen federal oversight of clinical laboratories and to ensure accurate and reliable test results after observing the prevalence of low quality laboratory services. CLIA imposes basic requirements that address personnel qualifications, quality-control standards, and documentation and validation of tests and procedures.[150] Critics note that CLIA oversight presents several weaknesses, however. First, CLIA rules focus on specimen processing and results reporting, but do not regulate when medical professionals can order the tests,[151] nor assess the quality, reliability, or usefulness of LDTs, including whether patients have been harmed as a result of their use.[152] Second, because CLIA's regulatory system does not require a laboratory to demonstrate an LDT's clinical validity,[153] there is significant risk of false-positive and false-negative results.[154] Third, unlike FDA standards, CLIA regulations do not require makers of LDTs to publicly report adverse events that may stem from the use of their tests, nor is there a system in place to track these events.[155] Therefore, if an LDT is inaccurate and affects user outcomes, the number of people impacted and the extent of their loss remains unknown.[156] Finally, for most "high-

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[148] *Id. See also* PEW, *supra* note 139, at 3 ("LDTs have also become more complex, are used for a wider range of conditions that affect many more people, and are sometimes marketed nationwide.").

[149] The Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. § 263a (1988); *see also* Centers for Medicare and Medicaid Services, *Clinical Laboratory Improvement Amendments (CLIA)*, https://www.cms.gov/regulations-and-guidance/legislation/clia (May 11, 2023).

[150] Javitt & Hudson, *supra* note 67.

[151] Bayefsky, *supra* note 21, at 1162 (citation omitted); *see also* Javitt & Hudson, *supra* note 67 (explaining that CMS cannot "restrict when and for whom a test may be performed, meaning that it is up to the provider to determine whether a particular test is appropriate for a particular patient, without the help of specified indications for use (such as those provided for drugs and medical devices)").

[152] PEW, *supra* note 139, at 1; Javitt & Hudson, *supra* note 67.

[153] Javitt & Hudson, *supra* note 67 ("Currently, the government exercises only limited oversight of the analytic validity of genetic tests (whether they accurately identify a particular mutation) and virtually no oversight of the clinical validity of genetic tests (whether they provide information relevant to health and disease in a patient).").

[154] *See supra* note 66 and accompanying text.

[155] PEW, *supra* note 139, at 5; Javitt & Hudson, *supra* note 67 (stating that "CLIA does not permit CMS to be a 'gatekeeper' for home-brew tests, in that it authorizes neither prospective review nor pre- or postmarket approval of new tests by CMS.").

[156] PEW, *supra* note 139, at 3.

complexity" tests, meaning those that demand considerable skill to perform or analyze, CLIA requires periodic "proficiency testing," mandating that laboratories demonstrate their ability to accurately perform the test and interpret the results. Genetic tests are high-complexity tests, but CMS has not established a genetic testing "specialty" for molecular and biological tests. Consequently, specific proficiency testing for these genetic tests is not mandated under CLIA, leaving laboratories to assess their proficiency for themselves. While some labs have implemented proficiency-testing programs established by professional organizations, CLIA does not require the use of these programs, and only a small number of genetic tests are subject to proficiency-testing programs by professional organizations.[157]

As early as 1995, the National Institutes of Health (NIH) and the U.S. Department of Energy jointly convened a government task force to review genetic testing in the United States and make recommendations to ensure the development of safe and effective genetic tests. Since that time, government advisory bodies have urged CMS to strengthen CLIA oversight for genetic tests by, among other things, establishing a specialty area for genetic testing. However, although Congress announced in 2000 that it would establish a genetics specialty area,[158] no specific requirements yet exist at the federal level for laboratories performing molecular genetic testing for heritable diseases and conditions.[159]

Currently, because LDTs are not centrally registered or tracked, no one knows precisely how many of them are on the market, when and why they are used, or how their performance compares with FDA-reviewed diagnostics. In 2014 the FDA estimated that there were 11,000 LDTs in use, developed in 650 labs. Yet by 2018 researchers studying the market for genetic tests estimated that 75,000 IVDs were in use, the overwhelming majority of which were classified as LDTs.[160]

While the debate over federal regulation of LDTs has continued for decades, the FDA, which has long maintained that it has regulatory authority over LDTs,[161] has traditionally exercised enforcement discretion

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[157] Javitt & Hudson, *supra* note 67.

[158] *Id.*

[159] Bin Chen et al., CTRS. FOR DISEASE CONTROL & PREVENTION, GOOD LABORATORY PRACTICES FOR MOLECULAR GENETIC TESTING FOR HERITABLE DISEASES AND CONDITIONS, 58 (RR-6):1-29, Morbidity & Mortality Weekly Rep. (June 12, 2009), https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5806a1.htm.

[160] PEW, *supra* note 139, at 14.

[161] Federal Register Proposed Rule, *supra* note 144, at 68015 (stating that the FDA "has made clear, on many occasions and over many years, that LDTs are devices under the FD&C [Federal Food, Drug and Cosmetic] Act"). As explained by a Congressional Research Service report, the federal agencies involved in the regulation of LDTs include the FDA and the Centers for Medicare & Medicaid Services (CMS). The FDA regulates the safety and effectiveness of the diagnostic test, as well as the quality of the design and manufacture of the diagnostic test, pursuant to the Federal, Food, Drug, and Cosmetic Act (FFDCA). CMS regulates

over them.[162] According to the Congressional Research Service, in practice, the FDA has chosen "not to enforce applicable statutory and regulatory requirements with respect to such tests," such that "most of these tests have neither undergone premarket review nor received FDA clearance, authorization or approval for marketing."[163]

It is only in the last decade that the FDA officially notified Congress of its intent to begin regulating LDTs through draft guidance.[164] In August 2023, the FDA took steps to establish its authority to regulate LDTs and published in the Federal Register its notice of proposed rulemaking with respect to LDTs.[165] The FDA is taking these actions after repeated Congressional failures to enact legislation explicitly extending the

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the quality of clinical laboratories and the clinical testing process pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CONG. RSCH. SERV., *supra* note 139.

[162] CONG. RSCH. SERV, *supra* note 139 (stating that "the FDA traditionally exercised enforcement discretion over LDTs"); Framework for Regulatory Oversight of Laboratory Developed Tests; Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories; Availability, 79 Fed. Reg. 59776, 59777 (Oct. 3, 2014) (explaining that the "FDA has exercised enforcement discretion so that the Agency has generally not enforced applicable provisions under the FD&C Act and FDA regulations with respect to laboratory developed tests (LDTs)") [hereinafter FDA Draft Guidance for Regulatory Oversight of LDTs].

[163] CONG. RSCH. SERV., *supra* note 139.

[164] *Id.* (stating that "In July 2014, FDA officially notified Congress of its intent to begin regulating LDTs through draft guidance"); FDA Draft Guidance for Regulatory Oversight of LDTs, *supra* note 162, at 59776 (proposing in 2014 a regulatory framework for LDTs); Food and Drug Administration Notification and Medical Device Reporting for Laboratory Developed Tests; Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories; Availability, 79 Fed. Reg. 59779, 59779 (Oct. 3, 2014) (explaining the process for clinical laboratories to notify the FDA of the LDTs they manufacture, and describing the Medical Device Reporting Requirements for clinical labs manufacturing LDTs).

[165] Office of Information and Regulatory Affairs, Office of Management and Budget, Notice of Proposed Rulemaking, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN=0910-AI85 (Spring 2023) (setting forth a proposed rule "to amend the Food and Drug Administration's regulations to make explicit that laboratory developed tests (LDTs) are devices under the Federal Food, Drug, and Cosmetic Act") [hereinafter Office of Information and Regulatory Affairs].

FDA's statutory authority to include LDTs.[166] The FDA faces industry challenges, however, to its assertion of regulatory authority over LDTs.[167]

The lack of PGT regulation in the U.S., which in addition to Mexico, has one of the "most permissive approaches" to PGT,[168] contrasts with robust PGT regulation in the rest of the world. As noted by one scholar, the U.S. "is the only industrialized country where PGT is widely tolerated but not regulated."[169] Before the *Dobbs* decision, there were essentially no legal limitations on the use of PGT. It could be employed "for any condition for which genetic testing is available at the discretion of fertility treatment clinicians and their patients,"[170] who are considered consumers.[171] By contrast, many European countries tightly regulate[172] or entirely prohibit PGT.[173] U.S. patients must weigh risks and benefits of PGT, presumably in consultation with their doctors or genetic counselors. These potential parents may wonder whether to test using PGT-A. Then, if their results show mosaicism, they must decide whether to transfer a mosaic embryo

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[166] *U.S. FDA Plans Laboratory-Developed Test Rulemaking and Launches Pilot Program*, SIDLEY (July 5, 2023), https://www.sidley.com/en/insights/newsupdates/2023/07/us-fda-plans-laboratory-developed-test-rulemaking-and-launches-pilot-program [hereinafter SIDLEY]. The most recent and comprehensive Congressional proposal to date is the bipartisan Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2021, introduced in the Senate, which would direct the FDA to regulate all diagnostics, including LDTs, based on their risk to patients if the tests gave the wrong result, regardless of where the tests were created and used. VALID Act of 2021, S. 2209, 117th Cong. (2021). Parties disagree, however, about whether the bill appropriately balances the dual goals of patient safety and rapid innovation. PEW, *supra* note 139.

[167] SIDLEY, *supra* note 166 (stating that the FDA's plan to regulate LDTs "is likely to be met with pushback in light of enduring questions about whether FDA's authorities extend to LDTs" and noting that, "[g]iven stakeholder interest, there will likely be a large number of public comments in the [notice of proposed rulemaking] docket); *see also* Gleicher et al., *supra* note 7, at 503 (declaring that "[a]s a so-called laboratory-developed test, PGT-A can be offered in the U.S. by reference laboratories without regulatory scrutiny from either federal or local state governments" and that the FDA "has no regulatory power over such tests"); Javitt & Hudson, *supra* note 67 ("Recently, the [FDA] has stated publicly that it lacks the statutory authority to regulate home-brew tests").

[168] Ginoza & Isasi, *supra* note 5, at 4.

[169] Löwy, *supra* note 62, at 50. *See also* Ginoza & Isasi, *supra* note 5, at 4 (noting that PGT is "actively practiced and commercially available" in the U.S., where it remains unregulated).

[170] Bayefsky, *supra* note 21, at 1160.

[171] Ginoza & Isasi, *supra* note 5, at 4 (noting the consumerist approach to PGT in the United States).

[172] *Id.* at 6, 8; Löwy, *supra* note 62, at 49 (explaining that PGT is allowed under specific conditions in the United Kingdom, France, Portugal, Spain, Norway, Sweden and Denmark and, recently, Germany).

[173] Löwy, *supra* note 62, at 49 (noting that PGT is explicitly prohibited in Austria, Ireland, Italy, Luxembourg, and Switzerland).

or instead abandon IVF and perhaps opt for adoption.[174] U.S. patients' decisions are complicated by the fact that many prospective parents act on inaccurate information from PGT testing labs.[175]

A primary reason for the lack of federal regulation of ART, including PGT, in the U.S., in contrast to other industrialized nations, is that the U.S. is the only industrialized country without universal health care.[176] One commentator noted that while it is possible for the U.S. government to regulate IVF and PGT without funding their use,[177] lack of government funding means a state is not required to provide recommendations for prudent allocation of public resources for PGT.[178] Experts have noted that Congress could pass a law establishing appropriate uses of PGT, but "it would be highly atypical for Congress to legislate when a particular medical treatment can be offered."[179] Many physicians contend that the government should not intervene in clinical practice, especially for procedures that the government does not fund.[180]

Unlike the U.S., most developed nations offer government-sponsored health care, and therefore implement legislation relating to whether and in which cases the government will fund PGT.[181] For example, in the UK, the National Health Service (NHS) funds approximately forty percent of

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[174] Yang et al., *supra* note 18, at 71.

[175] Gleicher et al., *supra* note 18, at 740.

[176] Bayefsky, *supra* note 21, at 1162 (describing the fact that "the US does not have a government-funded national health care system" as among the "challenges to federal or state regulation of PGD"); *see also* Chris Slaybaugh, *International Healthcare Systems: The U.S. Versus the World*, at 1, https://axenehp.com/international-healthcare-systems-us-versus-world/ (last visited Dec. 15, 2024) ("[t]he United States is the only industrialized country in the world that does not have Universal Health Coverage for all citizens").

[177] Bayefsky, *supra* note 21, at 1162. The U.S. federal government possesses the authority to regulate PGT, though it has rarely exercised its right to do so. Cohen, *supra* note 13, at 1016 (stating that given the "mass of federal law, it is curious how little directly pertains to reproductive technologies"). One example is the Fertility Clinic Success Rate and Certification Act, enacted by Congress in 1992, which mandates that all ART clinics report success rate data to the federal government in a standardized manner. Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (codified as amended in scattered sections of 42 U.S.C.). Moreover, President Obama signed into law in 2015 a Congressional appropriations rider that prohibits the FDA from considering "research in which a human embryo is intentionally created or modified to include heritable genetic modification" and thus essentially blocks U.S. approval of mitochondrial replacement therapy. Cohen, *supra* note 13, at 1016.

[178] Bayefsky, *supra* note 21, at 1162.

[179] *Id.* (citation omitted).

[180] *Id.*

[181] Ginoza & Isasi, *supra* note 5, at 3-4 (noting that the nations that legislate the availability of PGT often rely on policy statements and guidelines from national and professional organizations to supplement government statutes, particularly where the legislation is vague or outdated).

assisted reproductive technology but does not cover PGT-A.[182] In contrast, U.S patients seeking assisted reproductive technology in the U.S. must pay for it themselves, possibly with the help of their private insurance, and have until *Dobbs* remained free from regulatory oversight.[183] As of September 2024, while twenty-one states and the District of Columbia mandated some form of insurance coverage for fertility treatments, only fifteen of those laws required IVF coverage.[184] Research revealed no state that mandated coverage for PGT.[185] As noted by one expert, "one of the main tools for regulating medical practice in the United States—the regulation of insurance and reimbursement—is much less potent for reproductive technologies where (unlike for most medical procedures) most insurers do not cover it, so that patients are self-pay."[186]

Another reason for the historic lack of federal regulation of ART generally, including PGT-A, is its proximity to the abortion debate,[187] which leads to insufficiency in both funding for research and in the will to regulate.[188] As noted previously, embryos that are not selected for implantation, whether because they are predicted to be unhealthy or because they are in excess of a family's needs, may be donated to science, stored, donated to another family, or discarded.[189] Generally, federally funded medical researchers are subject to significant regulation and oversight by the Department of Health and Human Services ("DHHS"). As noted by experts, the U.S. government's reluctance to fund research on embryos and reproductive medicine has "seriously eroded any oversight or regulatory ability" that the DHHS might have had.[190] This dissociation of the federal government from reproductive medicine became pronounced in 1994, when President Clinton declared that federal funding should not be made available for research involving the creation or destruction of embryos.

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[182] Rachel Theobald et al., *The Status of Preimplantation Genetic Testing in the UK and USA*, 35 HUM. REPROD. 986, 989 (2020). *See also* HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY, *Frequently Asked Questions About Pre-Implantation Genetic Testing for Aneuploidy (PGT–A)*, https://www.hfea.gov.uk/treatments/explore-all-treatments/frequently-asked-questions-about-pre-implantation-genetic-testing-for-aneuploidy-pgt-a/ (last visited Dec. 15, 2024) (noting that "PGT-A is not currently funded by the NHS").

[183] Theobald, *supra* note 182, at 989-90.

[184] RESOLVE, THE NATIONAL INFERTILITY ASSOCIATION, *Insurance Coverage by State*, https://resolve.org/learn/financial-resources-for-family-building/insurance-coverage/insurance-coverage-by-state/ (last visited Dec. 15, 2024).

[185] Heidi Splete, *Insurance Mandates Drive Genetic Testing and Sex Selection in IVF*, MDEDGE (March 16, 2022), https://www.mdedge.com/obgyn/article/252825/reproductive-endocrinology/insurance-mandates-drive-genetic-testing-and-sex (declaring that "no states have mandates to cover PGT").

[186] Cohen, *supra* note 13, at 1021.

[187] Bayefsky, *supra* note 21, at 1161-62.

[188] Calandrillo & Deliganis, *supra* note 129, at 329.

[189] *See supra* note 34 and accompanying text.

[190] Calandrillo & Deliganis, *supra* note 129, at 329 (citation omitted).

Shortly thereafter in 1996, Congress began attaching a rider to DHHS appropriations bills that implemented the presidential declaration. Because scientifically robust analysis of ART "would have involved the creation, destruction, and disposal of embryos, research involving this technology" was ineligible for federal funding and therefore proceeded not only without federal financial support, but also without the scientific scrutiny or human subjects' protections that accompany it.[191] At present, regulating PGT would require accounting for the fate of the embryos that are not selected, a particularly contentious issue in light of the *Dobbs* decision leaving regulation of abortion to the states, many of which may bar PGT altogether. This reluctance is exhibited not just by abortion opponents who wish to avoid the appearance of accepting technologies that result in discarded embryos, but also by progressives who wish to avoid the perception that they favor abortion restrictions.[192]

As a result of the lack of federal and state regulation of PGT, critics have described PGT-A as a case study in "how not to introduce a clinical test to routine medical practice" and enumerate several concerns with the testing process.[193] First, although in the U.S. fee-splitting in medicine is considered unethical and, in many states, even illegal,[194] PGT-A circumvented this concern, thereby allowing IVF centers to collect fees for embryo biopsy and genetic testing laboratories to earn fees for performing chromosomal analysis and generating reports. Second, the PGT-A test was "radically revised" on a few occasions due to inaccuracy and the resulting clinical consequences, but the testing industry does not acknowledge these shortcomings.[195] Third, the testing industry never properly validated PGT-A to determine whether it was able to reliably determine genetic abnormality and contribute accurately to embryo selection in a manner that improves implantation, pregnancy, and live birth rates for remaining euploid embryos. Fourth, critics contend that the testing industry ought to assume responsibility for validation of tests, but that it instead deflected this responsibility onto opponents of PGT-A. Fifth, proponents of PGT-A ignored new research about preimplantation-stage embryos that refuted the validity of the tests. Finally, whenever those opponents presented new

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[191] *Id.* at 330 (citation omitted); Isabella Cueto, *New Research Casts Fresh Doubt on a Common Procedure That Promises to Increase the Odds of IVF*, STAT (Nov. 26, 2021), https://www.statnews.com/2021/11/26/ivf-pregnancy-pgta-genetic-testing/ (noting the difficulty in studying PGT-A in the U.S. "given restrictions on federal funding for certain types of research involving embryos").

[192] Cohen, *supra* note 13, at 1021-22.

[193] Gleicher, *supra* note 7, at 502.

[194] Fee-splitting is when "a physician receives compensation for professional services and then divides or shares it with a person or party who did not render the service." Cheryl Miller, *Splitting Fees or Splitting Hairs?*, 11 AM. MED. ASS'N J. ETHICS 387, 387 (May 2009).

[195] Gleicher, *supra* note 7, at 502.

evidence, the rapidly evolving testing industry pivoted to offering IVF centers and patients later iterations of the tests.[196]

In the absence of federal or state regulation of PGT, the industry self-regulates via a bottom-up private ordering approach that relies on industry guidelines, such as position statements from professional organizations including the American College of Obstetricians and Gynecologists (ACOG) and the ASRM. Industry guidelines suggest best practices but typically do not have the power to enforce them or to impose sanctions on those who do not comply.[197] This system of professional self-regulation allows a fertility specialist to refer their patients to undergo any genetic testing available in the market.[198] Further, many reproductive healthcare professionals are themselves uninformed about IVF, due to biased and often inaccurate information from the medical professionals involved in genetic testing, the laboratory testing industry, and other economically interested parties.[199]

Several professional organizations warn of the limitations of PGT, especially the incidence of false-positive results with PGT-A. ACOG, in its 2020 guidelines, noted that there is a risk of false-positive and false-negative results with all PGT modalities, including PGT-A, PGT-M, and PGT-SR, and cautioned that "[p]atients and health care providers should be aware that a 'normal' or negative preimplantation genetic test result is not a guarantee of a newborn without genetic abnormalities."[200] With respect to PGT-A in particular, ACOG stated that there is "insufficient evidence" to use PGT-A routinely and emphasized that because embryo mosaicism is not well understood and transfer of mosaic embryos has resulted in term delivery of euploid fetuses, patients should receive detailed counseling from a specialist with genetic training before deciding whether to implant mosaic embryos.[201] Similarly, the Practice Committee of the American Society of Reproductive Medicine and the Society for Assisted Reproductive Technology advised that the value of the PGT-A as a "universal screening test" requires further investigation and emphasized that "[g]iven the uncertainty about self-correction, false positive PGT-A results, and/or accuracy of a mosaic diagnosis," the use of PGT-A may lead to "discarding embryos that may have resulted in healthy babies."[202]

Regarding the transfer of mosaic embryos, professional guidelines provide no clear directives in favor of or against mosaic embryo transfer.

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[196] *Id.*

[197] Ginoza & Isasi, *supra* note 5, at 3.

[198] Yang et al., *supra* note 18, at 72 (citation omitted).

[199] Gleicher et al., *supra* note 18, at 740.

[200] ACOG PGT Opinion, *supra* note 23, at e135.

[201] *Id.* at e135.

[202] Practice Comms. of the Am. Soc'y for Reprod. Med. and the Soc'y for Assisted Reprod. Tech., *The Use of Preimplantation Genetic Testing for Aneuploidy (PGT-A): A Comm. Op.*, 109 FERTILITY & STERILITY 429, 434 (2018) (citation omitted).

A 2017 ASRM Ethics Committee opinion, which predates much of the recent research in this area, stated that "it is ethically problematic" to transfer embryos when it is "highly likely" the child will have "a life-threatening condition that causes severe and early debility with no possibility of reasonable function."[203] By contrast, the Committee deemed it "ethically acceptable" to transfer or decline to transfer embryos positive for anomalies that are treatable or can be managed with medical interventions, as long as decisions are "made and applied in a nonarbitrary manner that does not discriminate against the patient on any basis."[204] With respect to conditions, such as mosaicism, that involve "variable phenotypes" and "uncertainty about" the health outcomes, the committee suggested that "uncertainty is an important factor that counsels in favor of individualized decision making."[205] While reiterating its Ethics Committee's view that it is acceptable to transfer or decline to transfer mosaic embryos, the ASRM Practice Committee and Genetic Counseling Professional Group (GCPG) stated that euploid embryos "should be preferentially transferred" and that mosaic embryo transfer is acceptable in combination with at least one euploid embryo or when patients have no euploid embryos available.[206] This group cautions that, given the "paucity of outcome data regarding the health of pregnancies and children after transfer of embryos with mosaic results,"[207] clinicians are uncertain about how to counsel patients who need to decide about embryo transfer.[208] The GCPG recommends that

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[203] ASRM Comm. Op. on Transferring Embryos with Anomalies, *supra* note 86, at 1130.

[204] *Id.*

[205] *Id.*

[206] ASRM Prac. Comm. and Genetic Couns. Pro. Grp., *supra* note 87, at 251.

[207] *Id.* at 247.

[208] *Id.* at 246 (stating that "clinicians are grappling with how to interpret such findings and how to counsel patients about embryo transfer decision-making"). The provision of genetic counseling is largely unregulated in the U.S., which does not require genetic counseling for all uses of PGT. Ginoza & Isasi, *supra* note 5, at 7. *See also* Yang et al., *supra* note 18, at 72 (2022) (noting the lack of professional guidelines results in "insufficient" genetic counseling in IVF clinics). However, it should be noted that, in the context of prenatal testing involving pregnant women, federal law and several state statutes require the provision of specific information following a prenatal diagnosis of Down syndrome or other prenatally diagnosed conditions, with the goal of discouraging patients from obtaining an abortion upon receiving prenatal test results. *See, e.g.*, Prenatally and Postnatally Diagnosed Conditions Awareness Act, Pub. Law No. 110-374 (2008) (providing for the receipt by new and expectant parents of "up-to-date information on the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes"). Proponents of such laws contend that they ensure that people electing PGT receive accurate information about living with Down syndrome and other genetic disorders. Critics argue that legislative mandates concerning the information provided to patients undergoing genetic testing violate the ethical norm of "strict neutrality" in genetic counseling. Ginoza & Isasi, *supra* note 5, at 7.

clinicians inform patients that there is currently "no evidence-based method available to determine which embryos with mosaic results have the best chance of resulting in a successful pregnancy."[209] GCPG recommends that the "field would greatly benefit from an improved effort to collect and publish the results of laboratory and clinical genetic follow-up evaluations."[210]

Evidence indicates that PGT-A does not lead to improved outcomes, and self-regulation of PGT-A has proved insufficient to protect patients. Barring intervention by the FDA or from professional organizations like the ASRM, a reversal of current practice patterns appears unlikely, considering the strong combined economic incentives for IVF centers and genetic testing laboratories that share in the fees the PGT-A procedure generates. Economic incentives are strengthened since fees for the procedure in the U.S. are not covered by insurance. Insurance companies correctly consider PGT-A an unvalidated procedure/test. Consequently, patients must pay for PGT-A out of pocket at undiscounted rates, even if their IVF cycle is covered by a medical insurance which pays IVF centers only at discounted rates.[211] These concerns have never given rise to federal or state consumer protection legislation relating to PGT. Pursuant to *Dobbs*, however, some states are beginning to regulate and limit — or prohibit altogether — some ART technologies including PGT.[212] These legislatures invoke legal theories based on the putative "personhood" of embryos, including preimplantation embryos.[213] As noted by one expert, theories of legal personhood seek "to normalize the idea that, from the moment of conception, developing embryos are entitled to the same rights and protections as living human beings."[214]

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[209] ASRM Prac. Comm. and Genetic Couns. Pro. Grp., *supra* note 87, at 249.

[210] *Id.* at 253.

[211] Gleicher et al., *supra* note 18, at 735.

[212] *See infra* Part III.

[213] Adam Edelman, *An Uptick in State Personhood Bills Fuels Growing Fears Over IVF Restrictions*, NBC News (Feb. 23, 2024) https://www.nbcnews.com/politics/personhood-bills-ivf-restrictions-alabama-rcna140228 (noting that fetal personhood bills have been introduced in at least fourteen state legislatures during their ongoing 2024 sessions); Wendy S. Heipt, *EMTALA in a Post-Dobbs World: The March Towards Fetal Personhood Continues*, 59 IDAHO L. REV. 369, 402 (2023) (describing *Dobbs* as a "a big advancement in the march toward fetal personhood").

[214] Heipt, *supra* note 213, at 399. Although personhood efforts have gained greater attention post-*Dobbs*, the concept has been championed for decades by the anti-reproductive freedom movement, which has proposed various forms of legislation to further its aims. Talia Curhan et al., *First Quarter 2024 State Policy Trends: An Evolving Focus of Attacks on Abortion, Youth Access, IVF and More*, GUTTMACHER INST. (May 2024), https://www.guttmacher.org/2024/05/first-quarter-2024-state-policy-trends.

III. POTENTIAL STATE BANS OF PGT PRE- AND POST-*DOBBS* AND ASSOCIATED THEORIES OF LEGAL PERSONHOOD

Even prior to *Dobbs*, government regulation of clinical practice was the province of the states. Some states had proposed or enacted laws related to abortion of fetuses with genetic or congenital anomalies.[215] For example, in 2013, North Dakota was the first state to prohibit abortions in cases of fetal abnormality, even in cases where the fetus has a condition that would impede live birth or lead to death soon after birth.[216] In February 2018, the Utah House passed a bill that prohibited physicians from performing abortions solely on the basis of fetal Down syndrome.[217] Legislators who restrict abortions intended to prevent the births of children with genetic abnormalities might well oppose employing PGT for the same purpose. While some legislators might distinguish between embryos in vitro and fetuses, and thus view PGT as a means of avoiding abortion, those who believe that life begins at conception might find creating and then rejecting (not selecting) affected embryos to be as ethically objectionable as abortion.[218] Indeed, a Louisiana statute dating from 1986 provides that "[a] viable in vitro fertilized human ovum is a juridical person which shall not be intentionally destroyed by any natural or other juridical person or through the actions of any other such person."[219] This means that in Louisiana if a couple declines to implant the embryo, it must be offered to others for donation.[220]

State legislatures may therefore interpret *Dobbs* in a way that leads them to restrict PGT itself, even though the Supreme Court decision does not explicitly mention IVF or PGT.[221] The Court explicitly stated that

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[215] Bayefsky, *supra* note 21, at 1163.

[216] *Abortion Bans in Cases of Sex or Race Selection or Genetic Anomaly*, GUTTMACHER INST. (Jan. 22, 2020), https://www.guttmacher.org/node/28382/printable/print.

[217] H.B. 166, 2019 Leg., Gen. Sess. (Utah 2019).

[218] Bayefsky, *supra* note 21, at 1163.

[219] LA. STAT. ANN. § 9:129 (1986)

[220] Jenna Casolo et al., *Assisted Reproductive Tech.*, 20 GEO. J. GENDER & L. 313, 320 (2019). One scholar has questioned whether this statute would be enacted today, given that it predated widespread use of and support for IVF. That same scholar noted, however, that while clinics in Louisiana do not destroy embryos but instead sometimes transfer them to more permissive states, this option might no longer be available post-*Dobbs*. I. Glenn Cohen, *Reproductive Tech. and Embryo Destruction After Dobbs* at 3 (Harv. Public L., Working Paper No. 23-03). Moreover, state courts have demonstrated a willingness to uphold centuries-old abortion laws, as demonstrated by the 2024 Arizona Supreme Court upholding a long-dormant 1864 law that bans nearly all abortions, expect if the mother's life is in danger. Planned Parenthood Arizona, Inc. v. Mayes, 545 P.3d 892 (2024).

[221] ASRM, The Supreme Court Overturns Right to Abortion, *supra* note 10 (explaining that in states where legislation "does not explicitly exempt IVF or IVF embryos" and/or includes "language to the effect that 'life begins at fertilization,' the potential impact on IVF and the ARTs may be problematic or

"potential life" and "unborn human being" are unique and uniquely deserving of protection,[222] raising concerns about the likelihood that states will restrict fertility treatments that involve the destruction or storage of preimplantation embryos.[223]

In one sense, those who subscribe to theories of fetal personhood may find it more appropriate to ban PGT than abortion. As one ASRM position paper notes in considering the impact of *Dobbs* on IVF, "Embryos also represent 'potential life,' and there are no bodily autonomy interests of a pregnant woman to balance against those that may be found for IVF embryos in a lab."[224] Therefore, according to the ASRM, "[i]n many ways, the court's embrace of protecting 'potential life' may not only be quite readily extended to embryos, but it may be easier than in the context of pregnancy."[225]

Perhaps counterintuitively, the *Dobbs* case also means that IVF and PGT may become more prevalent if patients have concerns about genetic anomalies and fear lack of access to abortion in such cases.[226] However,

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concerning at best"). The *Dobbs* dissent, however, did indeed raise concerns about IVF under the majority's decision. *Dobbs*, 597 U.S. at 393. (Breyer, Kagan, and Sotomayor, J.J., dissenting). Alternatively, of course, state legislatures could "explicitly exempt IVF from any anti-abortion law, or the language of a state's enacted law(s) could be interpreted not to apply to IVF or embryos, but only to termination of pregnancies." ASRM, The Supreme Court Overturns Right to Abortion, *supra* note 10.

[222] *Dobbs*, 597 U.S. at 218.

[223] Cohen, *supra* note 220, at 2 (stating that if "a state were to prohibit entirely the destruction of embryos, the exact language Justice Alito uses to distinguish abortion from other constitutional rights directly applies — embryo destruction just as much as abortion 'destroys . . . 'potential life' and what such a potential state law 'regards as the life of an 'unborn human being'" and expressing the view that "[f]or reproductive technologies, the caller is already in the house."); Sigal Klipstein & Judith Daar, *Impact of Shifting Legal and Scientific Landscapes on In Vitro Fertilization Litigation*, 119 Fertility & Sterility 581, 581 (2023) (explaining that although the Supreme Court "did not address the legal status of reproductive technologies, including IVF, it did elevate the protection of 'potential life' and 'unborn human beings' over the interests of pregnant women, provoking concern about restrictions on fertility treatments in which preimplantation embryos are discarded or cryopreserved for later use"). *See also* Joseph, *supra* note 34 (noting that lawmakers' choice of language stating that life begins at implantation or at fertilization will impact IVF).

[224] ASRM, The Supreme Court Overturns Right to Abortion, *supra* note 10.

[225] *Id. See also* Cohen, *supra* note 220, at 8-9 (explaining that the argument for prohibiting embryo destruction in the context of IVF is "*stronger* (or if you prefer 'easier') than the argument for prohibiting abortion" because "prohibitions on embryo destruction do not involve forced gestation") (emphasis in original).

[226] ASRM, The Supreme Court Overturns Right to Abortion, *supra* note 10. *See also* Klipstein & Daar, *supra* note 223, at 581 (stating that "Interestingly, the utilization of PGT may increase because of the fear that restrictions on abortion would limit patient choice in the event of the fetus carrying a genetic anomaly.").

PGT itself raises two separate types of legal concerns post-*Dobbs*. First, some may fear that PGT testing itself harms embryos. This concern is unfounded in the face of scientific data establishing the safety of embryo biopsy techniques. The second legal concern, however, involves disposition of the tested embryos, "including whether all such embryos must be implanted (with open questions as to who might be recipients if the intended parents do not want to use them) or at a minimum stored indefinitely for that potential purpose (with open questions as to cost, responsibility, or liability in the event of future loss)."[227]

As noted previously, patients who have used IVF have four options with respect to their embryos that they do not transfer: either pay to continue storing the embryos, donate them for use by other people, grant them for scientific and research purposes, or discard them.[228] Experts note that laws that grant embryos personhood status will potentially criminalize discarding of embryos.[229] Currently, discarding embryos is quite common, whether because potential parents in need of IVF decide they no longer need the embryos, or because those using PGT detect genetic abnormalities in the embryos.[230] Moreover, courts have traditionally declined to confer personhood status on pre-implantation embryos in wrongful death cases brought by parents against medical facilities that accidentally destroyed their embryos.[231] Nonetheless, laws that criminalize discarding of embryos could even apply to those with genetic anomalies incompatible with successful pregnancies or with life.[232]

Some members of society may consider PGT morally preferable to prenatal screening, which involves testing during pregnancy and potential termination of that pregnancy, whereas successful PGT avoids pregnancy altogether if a genetic condition is detected. [233] However, many nonetheless object to PGT because it involves the destruction of a fertilized embryo. Moreover, PGT still raises the question of whether selecting against

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Of course, even if PGT is not barred, a state ban on abortion reduces its usefulness for families who wish to obtain follow-up prenatal testing before their state's abortion ban.

[227] ASRM, The Supreme Court Overturns Right to Abortion, *supra* note 10.

[228] *See supra* note 34.

[229] Joseph, *supra* note 34.

[230] Cohen, *supra* note 220, at 2.

[231] Suter, *supra* note 79, at 287 (citations omitted). *But see infra* notes 237-40 regarding the recent Alabama Supreme Court decision conferring personhood status on cryopreserved embryos.

[232] Joseph, *supra* note 34. One reproductive endocrinologist has noted that laws granting legal protections to IVF embryos might not eliminate IVF in those states but could make the process less efficient and more expensive. Clinicians might opt to fertilize one egg at a time, then wait to determine if it develops into an embryo suitable for implantations, and then wait more to see if it implants successfully. However, this commentator also observed that threats of legal action or prosecution might dissuade specialists from practicing at all in those states. *Id.*

[233] Ginoza & Isasi, *supra* note 5, at 7.

conditions such as Down syndrome is discriminatory toward people with disabilities.[234]

Theoretically, states could draft laws that require unused embryos to be cryopreserved indefinitely so that no embryos would be destroyed, though there would be significant challenges associated with this approach, including the costs of storage and the potential liability if harm were to befall the embryos. For some who view life as beginning at conception, perpetual storage might resolve the matter. For others, however, the concept of embryos remaining perpetually frozen is an anathema.[235] In fact, there is a movement for "snowflakes embryo adoption," the name given to the practice of arranging for families with remaining embryos in frozen storage to find a family to implant those embryos.[236]

A look at the post-*Dobbs* legislation related to IVF shows a complex picture of public support for IVF coupled with decreasing access due to reluctance by fertility clinics to expose themselves to legal liability. In February 2024, the Alabama Supreme Court ruled, in an unprecedented 7-2 decision relating to accidental destruction of cryopreserved IVF embryos, that embryos created through IVF are considered children under the state's Wrongful Death of a Minor law.[237] Consequently, many IVF clinics, including the University of Alabama, halted their services.[238] Although the next month Alabama's Republican-led legislature and Republican governor signed into law a narrow bill designed to protect doctors, clinics and other health care personnel who provide IVF treatment and services by offering such workers civil and criminal "immunity," the legislation does not actually clarify whether under state law frozen embryos created via IVF have the same rights as children.[239] Even with this law in place, some Alabama health care providers are ceasing IVF services.[240]

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[234] *Id.*

[235] Bayefsky, *supra* note 21, at 1163; Cohen, *supra* note 220, at 24 (stating that "It is difficult to argue" that indefinite freezing is better for an embryo than destruction and pointing out the risks of freezer failure and degradation of the embryo from being frozen so long). Another practice, called "compassionate transfer," involves transfer of the embryo to a woman's uterus during a non-fertile time in her cycle such that the embryo fails to implant rather than is destroyed. One could argue that this method is no different from embryo destruction, other than that it accords some recognition of the gravity of the occasion. Cohen, *supra* note 220, at 24-25.

[236] Bayefsky, *supra* note 21, at 1163. *See* Nightlights Christian Adoptions, Snowflakes Embryo Adoption Program, https://nightlight.org/snowflakes-embryo-adoption-donation/embryo-adoption/ (2022).

[237] LePage v. Ctr. for Reprod. Med., *supra* note 14.

[238] Julia Harte, *Alabama IVF Clinics Resuming Operations After Governor Signs Law Protecting Industry*, REUTERS (Mar. 7, 2024).

[239] Ala. S.B. 159 (2024).

[240] Sara Moniuszko, *Alabama Hospital to Stop IVF Services at End of Year Due to "Litigation Concerns,"* CBS NEWS, https://www.cbsnews.com/news/alabama-hospital-to-stop-ivf-embryos-mobile-infirmary/ (Apr. 4, 2024) (noting that

Like Alabama, at least ten other states, most of which either severely restrict or entirely ban abortion, have introduced bills that either protect IVF providers from criminal or civil liability or establish that fertilized embryos outside of a human body are not human beings.[241] For example, West Virginia's restrictive new abortion law, HB302, enacted in September 2022, explicitly excludes IVF from its definition of abortion.[242] Tennessee's post-*Dobbs* abortion law, notwithstanding its broad definition of "unborn child" that includes stages from "fertilization until birth,"[243] limits the definition of abortion to include only the termination of a pregnancy, defined as the "condition of having a living unborn child within [the] body.[244] On the other hand, in Virginia, a proposed bill currently pending would establish that life begins at conception, and does not contain language that exempts embryos created through IVF.[245] Even before *Dobbs*, those opposed to abortion have aimed to restrict IVF. In 2021, South Dakota lawmakers considered a bill that would have required health providers to track how many embryos were created in infertility treatments and report them to the state.[246]

In many states, the law relating to IVF is still in a state of flux, creating uncertainty as to the availability of PGT. In 2021, the Arizona Legislature passed a personhood statute directing that Arizona laws must be construed to acknowledge that "an unborn child at every stage of development" has the same "rights, privileges and immunities available to other persons."[247] As explained on the website of the Arizona Attorney General (AG), "[a]lthough this bears some similarity to Alabama laws . . . the Arizona statute also says it does not create a right to sue a person who lawfully performs IVF procedures."[248] The Arizona AG noted that the statute is on hold pending litigation, and explained the "[b]ottom line" as follows: "IVF is legal right now, but the law in this area could change depending

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an Alabama hospital declared its intention to cease IVF treatments at the end of 2024, "in light of litigation concerns surrounding IVF therapy").

[241] Curhan et al., *supra* note 214.

[242] HB-302, W. VA. Code §16-2R-4(5) (2022), https://www.wvlegislature.gov/Bill_Status/bills_text.cfm?billdoc=HB302%20ENG.htm&yr=2022&sesstype=3X&i=302.

[243] TENN. CODE ANN. § 39-15-213(a)(4) (2022)

[244] *Id.* at § (a)(3).

[245] VA HB 1395, https://lis.virginia.gov/cgi-bin/legp604.exe?231+sum+HB1395 (Nov. 30, 2022).

[246] SD HB 1248, https://sdlegislature.gov/Session/Bill/22432/216201 (2021).

[247] ARIZ. REV. STAT. ANN. § 1-219 (2021).

[248] Arizona Attorney General, *Consumer Alert, Understanding Arizona Law Regarding In Vitro Fertilization*, https://www.azag.gov/sites/default/files/2024-03/consumer%20alert_IVF.pdf (Mar. 2024).

on litigation about current Arizona law and any additional laws the Arizona Legislature or Congress might pass."[249]

Some Congresspeople have proposed federal legislation to protect the right to assisted reproductive technology. In early 2024, a group of Democratic senators introduced the Right to Build Families Act,[250] and Democratic representatives introduced companion legislation in the House of Representatives.[251] These proposed bills face slim odds of enactment, however, in a divided Congress.[252]

Indeed, it is difficult to imagine our divided Congress collaborating on legislative solutions to the challenges posed by PGT, even though the interests of both those who propound legal personhood theories and those who support continued use of IVF and PGT converge in some instances. Both groups wish to avoid misconstruing viable embryos as aneuploid, thereby leading in many cases to their destruction. Despite the deeply opposing views of these groups, FDA regulation of PGT could advance their interests and offer a solution that could benefit both camps.

IV. A PROPOSAL FOR FDA AND FTC REGULATION OF PGT

While many experts have emphasized that self-regulation by the PGT industry is insufficient to protect consumers and therefore advocate for FDA regulation,[253] Bayefsky advocates for professional self-regulation, achieved through rigorous professional guidelines, rather than individual clinician discretion. She contends that health professionals are more likely

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[249] *Id.* Separately, it should be noted that in April 2024, the Arizona Supreme Court approved the enforcement of a long-dormant 1864 law that bans nearly all abortions. Jacques Billeaud & Morgan Lee, *What to Know About Abortion in Arizona Under the Near-total 1864 Ban*, Associated Press, https://apnews.com/article/arizona-abortion-ban-what-to-know-797a4bbbc738497fe2284d6870c5be24 (Apr. 10, 2024).

[250] Right to Build Families Act, S.5276, 117th Cong., § 2 (2021). This legislation would prohibit states from limiting any individual's access to assisted reproductive technology as well as any individual's ability to retain their "reproductive genetic materials." *Id.* at § 3(a).

[251] Congresswoman Susan Wild, *ICYMI: Rep. Wild Introduces Legislation to Protect IVF Access*, https://wild.house.gov/media/press-releases/icymi-rep-wild-introduces-legislation-protect-ivf-access#:~:text=Susan%20Wild%20introduced%20the%20Access%20to%20Family%20Building%20Act%2C%20which,are%20used%20during%20such%20treatments (Feb. 1, 2024).

[252] González, *supra* note 13.

[253] Javitt & Hudson, *supra* note 67 (stating, with respect to genetic testing in general, that "[i]n order to protect consumers, and to help advance the potential benefits offered by genetic testing, government action is urgently needed"); Yang et al., *supra* note 18, at 72 (stating that "it is critical to establish regulation in the USA to assure proper preclinical evaluation and continuous quality assessment of PGT-A services" and that "[t]he current professional self-regulation system for PGT-A may not be sufficient.").

than legislators to understand patients' needs and genetic testing technology. She also argues that although professional guidelines are not legally binding, if physicians fail to meet prevailing standards of care, they risk litigation and possible revocation of their licenses.[254]

Cohen emphasizes, however, the lack of empirical evidence relating to the effectiveness of self-regulation by organizations such as the ASRM in ensuring ethical and quality reproductive health care. Although legal and medical scholars have examined the issue, high-quality empirical research design is challenging because the ASRM's Practice Guidelines and Ethics Committee opinions are national. According to Cohen, "thus empirical scholars cannot make use of statewide variation or differences in the timing of introduction" and absent "deep empirical knowledge, there is disagreement among legal scholars on how effective ASRM has been."[255]

When considering self-regulation with respect to the rate of multiple births, for example, critics have charged that neither the ASRM nor the Society for Assisted Reproductive Technology has done enough to reduce twin rates in the U.S. The high U.S. rate of twin births contrasts with the rate in Western Europe, where professional societies issue embryo transfer guidelines intended to reduce the rate of twin births, which present health, psychological, and financial burdens for twins and their families.[256] Some experts do believe, however, that the ASRM has reduced multiple births to some extent, noting that ASRM self-regulation "may have contributed" to a decline in the higher-order multiple birth rate (triplets or greater) which fell from five percent in 1999 to two percent in 2008.[257] Such reductions tend not to last, however, occurring immediately and for a limited period after the ASRM issues guidelines decreasing transfer rates.[258]

Arguments for self-regulation fall short, however, given that IVF is a multibillion-dollar industry that has advanced many techniques without proper clinical validation, and that optimal patient care requires rigorous clinical validation. Critics note that clinicians have performed PGT-A on thousands of IVF patients, and yet several professional committees believe that the value of PGT-A testing remains to be determined. IVF patients are particularly vulnerable in that they face barriers to achieving a healthy pregnancy, and therefore may be willing to try new methods without fully understanding the costs and benefits. Even health professionals may not understand, or may hold differing views, as to the risks and benefits of PGT.[259] Furthermore, if some clinicians offer PGT for any reason

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[254] Bayefsky, *supra* note 21, at 1164.

[255] Cohen, *supra* note 13, at 1020.

[256] *Id.* (citation omitted).

[257] *Id.* at 1021 (citation omitted).

[258] *Id.* (citation omitted).

[259] Yang et al., *supra* note 18, at 71 (citations omitted) (describing a "lack of understanding and/or consensus among health professionals" regarding PGT).

requested by the patient, others could feel pressured to do so to avoid losing patients to colleagues with more permissive policies.[260]

Options for regulation of PGT, and other forms of ART, include either establishing a new body, such as the Human Fertilisation and Embryology Authority (HFEA), a statutory authority in the United Kingdom, [261] or regulation by the FDA. The HFEA maintains a list of conditions for which PGT-M has been approved, now numbering over 1,400. These conditions include having the BRCA1 or 2 gene, which increase susceptibility to breast cancer; sickle cell anemia; and even an adult-onset disease that causes progressive vision loss called vitelliform macular dystrophy.[262] For conditions not already on the list, the HFEA requires a licensed PGT-M clinic to apply on behalf of the patient and considers numerous factors in reviewing the application, including "how serious the condition is, the likelihood of it being inherited and the testimony of people affected by the condition before deciding whether to approve it for PGD testing."[263] As for PGT-A, the HFEA does not fund it,[264] questions its efficacy absent further evidence,[265] and prohibits it for non-medical sex selection of embryos.[266]

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[260] Bayefsky, *supra* note 21, at 1164 (explaining that "physicians face pressure to conform their practices to the standard of case"); Löwy, *supra* note 62, at 50 (stating that "physicians in the highly competitive — and highly lucrative — field of reproductive medicine may feel pressured to offer PGD in order not to lose patients to colleagues with more liberal practices").

[261] Bayefsky, *supra* note 21, at 1161.

[262] Human Fertilisation and Embryology Authority, *Approved PGT-M and PTT Conditions*, https://www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/approved-pgt-m-and-ptt-conditions/ (last visited Dec. 15, 2024).

[263] *Id.*

[264] Human Fertilisation & Embryology Authority, *Frequently Asked Questions About Pre-implantation Genetic Testing for Aneuploidy (PGT-A)*, https://www.hfea.gov.uk/treatments/explore-all-treatments/frequently-asked-questions-about-pre-implantation-genetic-testing-for-aneuploidy-pgt-a/ (last visited Dec. 15, 2024).

[265] *Id.*

[266] Human Fertilisation & Embryology Authority, *HFEA Statement into Daily Mail Investigation About Sex Selection*, https://www.hfea.gov.uk/about-us/news-and-press-releases/2018/hfea-statement-into-daily-mail-investigation-about-sex-selection/ (Dec. 20. 2020) ("UK law is very clear that selecting the sex of your child for any reason other than preventing serious inherited illness is strictly prohibited."). Media reports reveal that some HFEA-licensed fertility clinics in the UK are nonetheless performing and sending patients abroad for PGT for gender selection without a medical reason. Hannah Mays, *UK Doctors Accused of Helping Couples Choose the Sex of Their Babies*, THE GUARDIAN (Oct. 18, 2018), https://www.theguardian.com/society/2018/oct/08/uk-doctors-accused-helping-couples-choose-baby-sex-fertility. *See also Gender Selection Via IVF*, GENDERCHOICE.CO.UK, https://genderchoice.co.uk (last visited Dec. 15, 2024) (offering services to help UK families conduct sex selection for reasons

The advantage of an entity such as the HFEA that is solely devoted to the regulation of ART is that it is led by professionals with scientific, clinical, and bioethics expertise in reproductive technologies. These professionals can best assess the safety, efficacy, and societal impact of ART.[267] An HFEA authority is unlikely to gain acceptance in U.S., however, largely because of the precedent for individual choice in making PGT decisions, not to mention most healthcare choices. Even the *Dobbs* decision, which challenges precedent recognizing a zone of reproductive privacy, instead entrusts such decisions to the states rather than the federal government.

PGT remains within the remit of the FDA as a lab-developed test, however. Despite past controversy regarding the ability of the FDA to regulate PGT,[268] the FDA published in October 2023 its proposed rule "to amend the Food and Drug Administration's regulations to make explicit that laboratory developed tests (LDTs) are devices under the Federal Food, Drug, and Cosmetic Act," including "when the manufacturer of the IVD is a laboratory."[269] The FDA is also proposing to phase out the FDA's general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs. In other words, the identity or location of the manufacturer would not be relevant in deciding whether an IVD is a device subject to FDA regulation.[270] Public comments on the proposed rule were accepted until December 4, 2023.[271]

Some experts critique FDA regulation on several grounds. First, they warn of the FDA's increasing lack of independence from presidential oversight and related politics.[272] Second, the FDA's approach to regulation is deliberate and lacks transparency, leading to charges that it impedes innovation.[273] For example, during the 2020 Covid-19 pandemic, the FDA was

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that include "genetic disease prevention," "family balancing," and "personal reasons").

[267] Cahn & Suter, *supra* note 4, at 80.

[268] *See supra* notes 161-63 and accompanying text.

[269] Office of Information and Regulatory Affairs, *supra* note 165. *See supra* note 165 and accompanying text.

[270] Federal Register Proposed Rule, *supra* note 144, at 68017.

[271] *Id.*

[272] *See* Eli Adashi et al., *When Science and Politics Collide: Enhancing the FDA*, 364 SCI. 628, 628 (2019) (arguing that "partisan political interposition has grown increasingly worrisome" at the FDA and advocating for policies to bolster the independence of the agency from political pressures); Myrisha S. Lewis, *Innovating Federalism in the Life Sciences*, 92 TEMP. L. REV. 383, 388 (2020) (stating that the FDA "does include political and social considerations in its decision-making process, which are outside of its statutory mandate and contrary to administrative law's goals of transparency and accountability").

[273] Cahn & Suter, *supra* note 4, at 65 (citations omitted); Federal Register Proposed Rule, *supra* note 144, at 68013 (acknowledging the critique that ending

frequently faulted for its slow response.[274] Third, the FDA has numerous other priorities and does not focus on reproductive technology.[275] Fourth, some critics contend federal regulation could obstruct the doctor/patient relationship by imposing inflexible rules that impinge on reproductive freedom and limit patients' ability to access innovative techniques,[276] a somewhat paradoxical concern post-*Dobbs.* Finally, some experts express concern that the FDA, while attending to safety and efficacy of the products it regulates, does not adequately consider the social or ethical implications raised by the technologies.[277]

The benefit of regulation by the FDA is that the agency already exists and has developed a protocol to assess devices from the research phase to the marketing stage.[278] For effective regulation of PGT, however, the FDA must revise its procedures. First, the agency needs to develop robust data collection methods to better assess the efficacy of PGT. Second, it must gain expertise in the rapidly changing field of reproductive genetics, a particular challenge because the FDA's remit is so broad.[279] Third, given the FDA's responsibility to provide accurate, science-based health information to the public,"[280] the FDA should be transparent in providing

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the general enforcement discretion approach for LDTs would interfere with test innovation).

[274] *See, e.g.*, Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA's Role in America's COVID-testing Debacle*, 130 YALE L.J. 78, 78-79 (July 29, 2020) (arguing that the FDA's delayed rollout of tests for COVID-19 in the United States in early 2020 "potentially foreclosed opportunities to arrest widespread community transmission of the disease").

[275] Cahn & Suter, *supra* note 4, at 65.

[276] *Id.* at 65-66.

[277] *Id.* at 66. While this article takes a consumer protection approach to PGT, there are several ethical reasons to regulate PGT. Experts express concern that PGT will be used to select embryos with the goal of creating offspring with desired traits, such as intelligence or a particular gender; that PGT will exacerbate the effects of income inequality since the technology will not be available to lower income families; that selection via PGT devalues and fosters discrimination against people with disabilities; and that the technology presents unknown threats to the gene pool. *See* Ido Alon et al., *Mapping Ethical, Legal, and Social Implications (ELSI) of Preimplantation Genetic Testing (PGT)*, 41 J. ASSISTED REPRODUCTION & GENETICS 1153 (Mar. 21, 2024) (reviewing recent literature relating to the ethical, legal and social implications of PGT).

[278] Cahn & Suter, *supra* note 4, at 78.

[279] *Id.* at 79 (citations omitted); Pew, *supra* note 139 ("Any new regulatory approach for diagnostics must be flexible enough to allow developers to modify tests or develop new ones in order to meet patient need without undue delay."). The FDA describes its role as "protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation." *Food and Drug Administration (FDA)*, USA.GOV, https://www.usa.gov/agencies/food-and-drug-administration (last visited Dec. 15, 2024) [hereinafter FDA].

[280] FDA, *supra* note 279.

information about PGT to the public and educating potential users of this technology.[281] Fourth, the FDA must either regulate advertising, which it currently does only with respect to prescription drugs, some medical devices, and procedures, or coordinate with the FTC to implement advertising rules for PGT.[282]

For the FDA to collect data on PGT testing, it must require that developers of PGT tests register all such products with the agency, report adverse events related to these tests, and gather and publish information regarding the performance of these products.[283] As noted by experts, evidence-based data is needed to evaluate the risks and benefits for patients,[284] with an emphasis on the development of a classification system that accurately selects embryos for implantation.[285] In addition, prospective studies are needed to track the long-term results for children born using PGT testing,[286] given that abnormal characteristics may not present immediately in those born using PGT.[287]

To develop expertise necessary to evaluate the PGT data it gathers, the FDA requires increased funding. The agency notes that "[w]hen funding is available," the FDA sends its employees to scientific conferences, meetings and courses, as well as site visits to companies to learn about manufacturing and clinical research.[288] In May 2024, the Alliance for a Stronger FDA, which represents over 150 patient and consumer advocacy organizations, called on Congress to increase the FDA's budget by $377 million.[289] The Alliance emphasized that the agency's duties have become more complex and "require greater sophistication and expertise,"[290] including with respect to medical products.[291]

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[281] Cahn & Suter, *supra* note 4, at 78 (citation omitted).

[282] *Id.* at 79 (citations omitted).

[283] Pew, *supra* note 139.

[284] Yang et al., *supra* note 18, at 72.

[285] *Id.* at 70.

[286] *Id.*

[287] Barad et al., *supra* note 18, at 1194 (declaring that "[n]ot all abnormal phenotypes present in the immediate postnatal period so it will be important to continue to follow the development" of children born using PGT-A).

[288] *Training and Development Initiatives*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/science-research/fda-stem-outreach-education-and-engagement/training-and-development-initiatives (last visited Dec. 15, 2024).

[289] Chad Van Alstin, *Advocacy Group Asks Congress for $377M Increase in Funds for the FDA*, HEALTHEXEC (May 17, 2024), https://healthexec.com/topics/healthcare-management/healthcare-policy/alliance-stronger-fda-asks-congress-377m-increase-funds.

[290] *Id.*

[291] *Virtual Hill Days Next Week, Following House and Senate Meetings the Last Two Weeks*, ALLIANCE FOR A STRONG FDA, https://www.strengthenfda.org/friday-updates-list/afarqcysv5khn4grk2ehwoshyogc3u (May 17, 2024) (noting the "need for additional resources to adequately fund FDA's growing

The FDA must also share with the public the expertise that it develops. The FDA ought to establish guidelines for PGT testing companies directing their creation and implementation of patient education.[292]

In addition, the information shared by the PGT testing industry with patients should be mediated through regulation of advertising. The FTC requires advertisements concerning health and safety claims to be supported by "'competent and reliable scientific evidence,'" including "tests, studies or other scientific evidence that has been evaluated by people qualified to review it."[293] The lack of FDA regulation of LDTs, however, precludes review of advertising claims concerning those tests, because FTC enforcement of laws against false and misleading advertising rests upon FDA labeling requirements that establish appropriate limits for advertising claims. Since the FDA does not regulate LDTs, the FTC lacks any basis to assess whether advertisements appropriately disclose all relevant information to consumers.[294] The FDA should collaborate with the FTC to ensure that PGT advertisements are "truthful, not misleading, and . . . backed by scientific evidence."[295]

Even if the FTC were to proceed with proper authority to regulate advertising of PGT, critiques may be leveled against such regulation. Advertising laws could be viewed as unduly paternalistic. In addition, advertising regulation could face legal challenges to the extent that the FTC purports to prohibit advertising claims that are not clearly false or misleading, since the First Amendment provides broad protection for commercial speech.[296] Ultimately, regulation of advertising of PGT, while important, would not resolve fundamental concerns regarding the analytic and clinical validity of PGT genetic tests.[297] Notwithstanding the importance of providing patients with adequate information about PGT, the goal is not simply to limit access to unreliable tests, but rather to offer tests of high quality that reduce the unnecessary waste of viable embryos.

Many in the clinical laboratory industry and in academic medical centers oppose recent efforts to strengthen FDA oversight, warning that it would stymie innovation and disrupt patient care. Nonetheless, a Pew Center report based on interviews with lab managers revealed their widespread belief that appropriately designed FDA oversight could improve patient safety and enhance the quality of LDTs.[298]

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responsibilities," especially in the fields of medical devices and medtech innovation).

[292] Yang et al., *supra* note 18, at 72.

[293] *Advertising FAQ's: A Guide for Small Business*, FEDERAL TRADE COMMISSION, https://www.ftc.gov/business-guidance/resources/advertising-faqs-guide-small-business (Apr. 2001).

[294] Javitt & Hudson, *supra* note 67.

[295] Cahn & Suter, *supra* note 4, at 76 (citation omitted).

[296] Javitt & Hudson, *supra* note 67.

[297] *Id.*

[298] PEW, *supra* note 139.

CONCLUSION

Pre-implantation genetic testing is plagued by scientific inaccuracy and an excess of false positive results, which leads users of this technology to discard embryos unnecessarily. The absence of regulation of PGT in the U.S. stands in stark contrast to most other developed nations. At the same time, states have begun to limit PGT and other assisted reproductive technologies pursuant to *Dobbs* and theories of fetal personhood. Those opposed to ART and those who believe PGT must remain available disagree on a great deal. Yet, they can reach agreement on the importance of regulation that reduces false positive results and the resultant loss of embryos. This moment in history presents an opportunity to implement FDA regulation of PGT that fosters robust data collection methods to better assess the efficacy of PGT; enhanced FDA expertise in the rapidly changing field of reproductive genetics; the provision of accurate, science-based health information to the public; and oversight by the FDA and FTC, acting in concert, of PGT advertising rules. Federal regulation of PGT will give birth to an improved process that protects consumers and may encourage dialogue among those on opposing sides of the debates concerning assisted reproductive technologies.

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