2021

To Fund or Not to Fund? Evaluating States' Current Funding of IVF and PGD, the Impact of the Lack of Funding, and Why One Round of Coverage is Better than None

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I. Introduction

The rapid evolution of both technology and modern medicine have presented the world with life-changing advancements. And depending on who you ask, these advancements have been made for the better—or worse. Additionally, when new technology presents citizens with medical options that were unimaginable years ago, the impact of utilizing, regulating, and funding such advancements is uncertain. One of these technological advancements, specifically, is preimplantation genetic diagnosis ("PGD"). Since its inception, this expensive procedure has raised many issues, both domestic and abroad, regarding access to the test, ethical uses of the test, and funding of the test.

Preimplantation Genetic Diagnosis is a procedure whereby in vitro fertilized embryos can be tested to determine the presence or absence of certain genes or chromosomes.[1] PGD testing requires in vitro fertilization ("IVF"), which substantially increases its cost.[2] Currently, in the United States, there are only a handful of states that require insurance coverage for IVF, however, none of them require coverage for PGD. This in turn, limits accessibility of the procedure to those of high socio-economic status.[3] This increases the disparity of fertility opportunities. In an effort to make IVF and PGD more accessible this article argues that each

[1] Thomas Lemke, *Social dimensions of preimplantation genetic diagnosis: a literature review*, 38 NEW GENETICS & SOC'Y 80, 80 (2018).
[2] Kathryn T. Drazba, Michele A. Kelley & Patricia E. Hershberger, *A qualitative inquiry of the financial concerns of couples opting to use preimplantation genetic diagnosis to prevent the transmission of known genetic disorders*, 23 J. GENETIC COUNSELING 202, 202 (2013).
[3] Michelle Bayefsky & Bruce Jennings, REGULATING PREIMPLANTATION GENETIC DIAGNOSIS IN THE UNITED STATES: THE LIMITS OF UNLIMITED SELECTION 90 (2015).

state should require insurance coverage for at least one round of IVF and PGD; and provide such coverage regardless of the purpose for its use.

Due to the lack of consistent funding for PGD combined with the ethnic prevalence of testable conditions, the United States' current approach to funding PGD is discriminatory, creates disparities, and therefore states should require insurances provide for the treatment for all purposes. Section II of this article will discuss the purpose, process, prevalence, and cost of PGD in the United States. Section III will discuss the current regulatory approaches implemented in foreign countries as well as those in the United States. Section IV will highlight private funding and focus on the minimal insurers that have provided coverage for PGD. And lastly, Section V will discuss the current and possible impacts of a lack of funding, and how those results may be mitigated.

II. The Practice of PGD

a. Purpose of PGD

While assisted reproductive technologies ("ART"), such as PGD, have advanced rapidly within the past few decades, PGD tests cannot be used to identify certain traits such as eye color, hair color, height, intelligence, artistic ability, etc.[4] Instead, PGD is limited to test for the presence, or absence, of certain genes and chromosomes.[5] PGD patients that undergo IVF and PGD testing do so for many different purposes and reasons. Some seek the procedures to ensure they have a child of a particular sex, while others undergo the procedures to give themselves the best chance in achieving a successful pregnancy or ensuring their child is not at risk for

[4] Jason Christopher Roberts, *Customizing Conception: A Survey of Preimplantation Genetic Diagnosis and the Resulting Social, Ethical, and Legal Dilemmas*, 2002 DUKE L. & TECH. REV. 12, 12 (2002).
[5] Arinze-Umobi Chinemelum Nelson, *An Appraisal of the Ethics of Genetic Modification of Embryos and Its Implications on the Dignity of Human Species*, 35 MED. & L. 509, 518 (2016).

developing certain genetic disorders. Generally, the tests for PGD have been characterized by medical and nonmedical,[6] or therapeutic and nontherapeutic.[7]

The therapeutic tests are commonly used to detect single gene disorders such as cystic fibrosis, Tay-Sachs disease, and sickle cell anemia, as well as chromosomal abnormalities such as Down syndrome and Turner syndrome.[8] The therapeutic use of PGD can test for numerous disorders, many of which are found predominately within certain ethnic groups.[9] For example, beta thalassemia and sickle cell anemia are prevalent in African ethnicities. [10] Cystic fibrosis and Tay-Sachs disease are more prevalent in people of Jewish descent from Eastern Europe (Ashkenazi).[11] And beta thalassemia is prevalent in Southeast Asian and Mediterranean ethnicities.[12] The prevalence of certain disorders among ethnic groups indicates that people of those ethnicities are more likely to have the genetic disorder, and thus would highly benefit from accessible genetic testing.[13]

The effect of these diseases on patients and their families highlights the importance of testing for therapeutic purposes. Infants born with cystic fibrosis in 2018 are predicted to live to be 47 years old.[14] Although the life expectancy has increased over the years, living with cystic fibrosis requires daily treatments and may result in frequent hospitalizations and complications such as cystic fibrosis-related diabetes and depression.[15] Additionally, children diagnosed with

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[6] JA Robertson, *Extending preimplantation genetic diagnosis: medical and non-medical uses*, 29 J. MED. ETHICS 213, 214 (2003).
[7] Jessica Knouse, *Reconciling Liberty and Equality in the Debate over Preimplantation Genetic Diagnosis*, 2013 UTAH L. REV. 107, 121 (2013).
[8] *Id*.
[9] 2 DAN JOSEPH TENNENHOUSE, ATTORNEYS MEDICAL DESKBOOK § 19:4 (4th ed. 2020).
[10] *Id*.
[11] *Id*.
[12] *Id*.
[13] *Id*.
[14] *Understanding Changes in Life Expectancy*, CYSTIC FIBROSIS FOUND., https://www.cff.org/Research/Researcher-Resources/Patient-Registry/Understanding-Changes-in-Life-Expectancy/ (last visited Dec. 16, 2020).
[15] *Id*.

cystic fibrosis require a team of around six care takers, ranging from doctors to respiratory therapists, to properly treat the patient despite their inevitable early mortality.[16] Unlike cystic fibrosis, Tay-Sachs disease is a progressive neurodegenerative disease.[17] Despite the different pathophysiology of cystic fibrosis and Tay-Sachs disease, the emotional and financial impact on both the patient and family can be devastating. There is currently no cure for Tay-Sachs.[18] Treatment is available, however, which may include a number of prescription medications, various types of respiratory care, feeding tubes, and physical therapy.[19]

Sex selection, on the other hand, is an example of a use for a nontherapeutic test.[20] Sex selection, however, is difficult to define solely as a nontherapeutic test. It is important to note that although therapeutic and nontherapeutic tests seem distinct, one test may serve both therapeutic and nontherapeutic purposes. For example, testing for sex serves the nontherapeutic purpose for parents seeking a child of a certain sex, yet testing for sex may also serve the therapeutic purpose of identifying X-linked diseases for others.[21]

Another, technically medical, but highly controversial use of PGD is to create a "savior sibling."[22] Couples seek to create a savior sibling when they have a severely sick or dying child who needs a tissue or organ donation.[23] This couple will undergo IVF, and doctors will then use PGD to pick an embryo that will be the near-perfect genetic organ or tissue match for the sick

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[16] *Parent and Guardian Guidance*, CYSTIC FIBROSIS FOUND., https://www.cff.org/Life-With-CF/Caring-for-a-Child-With-CF/Parent-and-Guardian-Guidance/ (last visited Dec. 16, 2020).
[17] Guillaume Sillon, Pierre Allard, Stella Drury, Jean-Baptiste Rivière & Isabelle De Bie, *The incidence and carrier frequency of Tay-Sachs disease in the French-Canadian population of Quebec based on retrospective data from 24 years, 1992-2015*, 29 J. GENETIC COUNSELING 1173, 1173 (2020).
[18] *Tay-Sachs disease*, MAYO CLINIC (May 16, 2018), https://www.mayoclinic.org/diseases-conditions/tay-sachs-disease/diagnosis-treatment/drc-20378193 (last visited Dec. 16, 2020).
[19] *Id*.
[20] Knouse, *supra* note 7 at 121.
[21] *Id*.
[22] Nelson, *supra* note 5 at 518.
[23] Marley McClean, *Children's anatomy v. children's autonomy: a precarious balancing act with preimplantation genetic diagnosis and the creation of "savior siblings"*, 43 PEPP. L. REV. 837, 839 (2016).

sibling.[24] This use raises concern that the medical community will treat savior siblings as commodities, and thus lead to constant pressure [on the] savior siblings to donate whatever tissue was sought when creating the savior sibling in the first place.[25] Creating a "savior sibling," albeit controversial, is nonetheless a possibility with the use of PGD.

PGD can also help detect known genetic diseases or chromosomal abnormalities that, if undetected, could result in a failed pregnancy.[26] Therefore, good candidates for PGD include women who have had "repeated IVF failures, recurring miscarriages, or a history of genetically abnormal pregnancies,"[27] as well as women over the age of 37.[28] Women who are over the age of 37 are good candidates for PGD due to higher risk of abnormal embryo genetics with normal reproductive aging.[29] The PGD patients, here, differ from those mentioned above because these patients want better chances of a successful pregnancy of a child—rather than a successful pregnancy of a child of a certain sex, or with a desired genetic make-up.

b. Process of PGD

The process of PGD can only be done during a cycle of IVF, thus an individual that wishes to test their embryo through PGD must also go through a cycle of IVF.[30] So, taking into account both processes, the timeline for obtaining PGD includes: obtaining a full genetic work-up (for both IVF and PGD), consultation to discuss genetic information and genetic history of

[24] *Id*.
[25] *Id*. at 846.
[26] *Benefits & Risks of PGD/PGS (Preimplantation Genetic Testing)*, ADVANCED REPROD. MED. UNIV. COL., https://arm.coloradowomenshealth.com/services/ivf/pgd/risks (last visited Dec. 16, 2020).
[27] *Preimplantation Genetic Diagnosis & Screening*, N.Y.U. LANGONE MED. CTR., https://nyulangone.org/locations/fertility-center/preimplantation-genetic-testing (last visited Dec. 16, 2020).
[28] *Preimplantation Genetic Testing (PGD)*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/gynecology_obstetrics/specialty_areas/fertility-center/infertility-services/ART-procedures/preimplantation-genetic-testing.html (last visited Dec. 16, 2020).
[29] *Id*.
[30] *See* Drazba, *supra* note 2, at 202.

both individuals who provide the sperm and egg, beginning IVF, and then finally testing the embryo once it has been fertilized, but before it is implanted into the woman's uterus.[31]

The prescreening and genetic work-up that precede IVF requires extensive testing of both gamete donors (collectively these individuals will be referred to as the "PGD patients"). Prescreening and the genetic work-up includes chromosomal/DNA testing, pedigree analysis, an assessment of risk, gynecology and andrology assessments, hormone tests, ovarian response test, semen analysis, as well as an evaluation confirming the chromosomal or genetic abnormality sought to be avoided.[32] If needed, these tests may include analysis of family members' genetic makeup.[33] Once all of the preliminary screening and testing has been completed, the PGD patients may begin the first stages of the IVF procedure.

One cycle of IFV can be broken down into several steps: "ovarian stimulation, egg retrieval, sperm retrieval, fertilization, and embryo transfer," and will normally take two to three weeks.[34] Throughout the course of this cycle, PGD patients may need different medications for particular issues, and will need to visit their doctor regularly.[35] Once the cells have been fertilized, but before the embryo is transferred to the uterus, the PGD process can begin.[36] Regardless of what gene or chromosome for which the PGD patients are testing, PGD "involves the biopsy of a single or few cells" from the harvested embryo.[37] Then, the collected cells will

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[31] PREIMPLANTATION GENETIC DIAGNOSIS 151 (Joyce Harper ed., 2d ed. 2009).
[32] *Id.*
[33] *Id*.
[34] *In vitro fertilization (IVF)*, MAYO CLINIC (Mar. 22, 2018), https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716 (last visited Dec. 16, 2020).
[35] *Id*.
[36] Martine De Rycke & Veerle Berckmoes, *Preimplantation Genetic Testing for Monogenic Disorders*, 11 Genes 871, 872 (2020).
[37] *Id*.

be tested for the presence or absence of the trait. Lastly, the desired embryos are transferred to the uterus with the hope of having a viable pregnancy.[38]

Retrieving the cells that will ultimately be tested, are extracted from the embryo through a biopsy procedure. This biopsy procedure is consistent, regardless of what gene or chromosome is being tested. Once the cells have been biopsied from the embryo, depending on the what the PGD patients wish to test for, the methods of testing may be either polymerase chain reaction ("PCR") or fluorescence in situ hybridization ("FISH").[39] PCR is mainly used for autosomal single gene mutations, X-linked single gene mutations, gender selection, and HLA matching, while FISH may be used for aneuploidy screening, structural chromosomal abnormalities, and gender selection.[40]

Specifically, the PCR method of PGD testing can identify conditions mainly linked to genes, including Tay-Sachs disease, Sickle cell anemia, Duchenne muscular dystrophy, cystic fibrosis, hemochromatosis, as well as Huntington disease.[41] Alternatively, the FISH method of PGD testing focuses more on evaluating the chromosomal makeup of a gene and can identify Down syndrome, Patau syndrome, Edwards syndrome (aka "Trisomy 18"), and Turner syndrome.[42] FISH can also identify structural chromosomal abnormalities, meaning "part of an

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[38] *Genetic Testing*, MAYO CLINIC (May 14, 2019), https://www.mayoclinic.org/tests-procedures/genetic-testing/about/pac-20384827 (last visited Dec. 16, 2020)
[39] Practice Comm., Soc'y for Assisted Reprod. Tech. & Practice Comm., Am. Soc'y for Reprod. Med., *Preimplantation Genetic Testing: A Practice Committee Opinion*, 90 FERTILITY & STERILITY S136, S138 (2008).
[40] *Id*.
[41] Genetic All., D.C. Dep't of Health, *Understanding Genetics: A District of Columbia Guide for Patients and Health Professionals*, (Feb. 17, 2010), https://www.ncbi.nlm.nih.gov/books/NBK132149/pdf/Bookshelf_NBK132149.pdf.
[42] Am. C. of Obstetricians and Gynecologists, *Genetic Disorders*, https://www.acog.org/womens-health/faqs/genetic-disorders (last visited Nov. 4, 2020).

individual chromosome is missing, extra, switched to another chromosome, or turned upside down."[43]

Overall, the requirement of IVF to obtain PGD, and the processes by which are undertaken can last approximately three weeks. Throughout this time, PGD patients are incurring medical expenses from costly medication and doctor's visits, all in the hope of a successful cycle that yields the desired PGD results.

c. Prevalence and Cost of PGD

The extensive scholarly commentary on the issues of PGD and IVF would lead a reader to believe that these processes were extremely popular. But in fact, only 1 to 2 percent of all U.S. births annually are via IVF.[44] Further, of the 1 to 2 percentage that undergo IVF, only approximately 4 to 6 percent of those procedures elect to use PGD.[45] Additionally, over 75 percent of fertility clinics in the United States offer preimplantation genetic diagnosis.[46] These low numbers may be attributable to the high costs associated with the procedures, paired with the lack of funding and insufficient insurance coverage.

Generally, throughout the United States, PGD and IVF are extremely expensive procedures. The combined cost, on average, of both the IVF and PGD procedures can range from $11,726 - $18,513 per cycle.[47] An individual IVF cycle can range from $9,226-12,513, while PGD testing can cost an additional $2,500-6,000 per cycle.[48] Undergoing IVF and PGD

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[43] Genetic All., *Understanding Genetics: A N.Y. – Mid-Atlantic Guide for Patients and Health Professionals*, https://www.ncbi.nlm.nih.gov/books/NBK115563/pdf/Bookshelf_NBK115563.pdf (Jul. 8, 2009).
[44] *IVF by the Numbers*, PENN MED.: FERTILITY BLOG (March 14, 2018), https://www.pennmedicine.org/updates/blogs/fertility-blog/2018/march/ivf-by-the-numbers#:~:text=The%20Centers%20for%20Disease%20Control,births%20annually%20are%20via%20IVF.
[45] William D. Winkelman, et. al, *Public perspectives on the use of preimplantation genetic diagnosis*, 32 J. ASSIST. REPROD. GENETICS 665, 665 (2005).
[46] *Id*.
[47] *See* Drazba, *supra* note 2, at 203.
[48] *Id*.

requires additional costs beyond the actual procedures as well. Pre-cycle screening fees, fertility medications, and early pregnancy monitoring are all fees that will need to be considered in the calculation as well.[49] These can add an additional expense of up to $20,000, on top of the cost of the PGD and IVF procedures.[50] The persuasive presence of fertility clinics that provide PGD in the United States and low percentages of resulting pregnancies, suggests that the high cost of the procedures is a barrier to access the procedures. As discussed in Section III, *infra*, some states have enacted laws that mandate insurance coverage for IVF, although not PGD. The laws are generally limited to individuals who have a family history of a genetic medical disease and if not, those who have shown infertility by one prescribed method or another. Further, most of the states that have mandated insurance coverage for PGD and IVF, are silent on the issue of savior siblings.

III. Regulatory Approaches

a. Foreign Approaches

PGD is largely outlawed around the globe, but there are a handful of countries, such as Italy, Switzerland, France, and the United Kingdom, that fund permitted uses of PGD.[51] Meaning, these countries fund PGD, but impose limitations as to who may use PGD and for what purposes.[52] Until 2015, Italian Law no. 40 of February 19, 2004, permitted access to ART, such as PGD, only in cases of certified and incurable sterility or infertility of a couple.[53] However, in 2015, the Corte Constituzionale found that provision of Law no. 40 of February 19, 2004 to be unconstitutional and held it unreasonable to prohibit fertile couples who were carriers of genetic

[49] Leslie Evans, *How Much Does PGD/PGT Cost?* ORM GENOMICS, https://ormgenomics.com/2018/09/13/pgd-pgt-cost/ (last visited Dec. 16, 2020).
[50] *Id*.
[51] *See generally*, Michelle J. Bayefsky, *Comparative preimplantation genetic diagnosis policy in Europe and the USA and its implications for reproductive tourism*, 3 REPROD. BIOMED. & SOC'Y ONLINE 41, 42-43 (2016).
[52] *Id*.
[53] Corte Cost., 14 maggio 2015, n. 96, Foro it. 2015, (It.).

diseases from having access to PGD.[54] Today, Italy allows PGD for purposes aimed at protecting the health and development of the embryo itself, but has banned the use for sex selection purposes.[55]

In 2017, Switzerland amended its reproductive laws allowing the use of assisted reproductive techniques, such as PGD, by infertile couples and couples that pose an unavoidable risk of transferring a serious disease to their offspring.[56] Switzerland also increased the amount of embryos that may be harvested in a single cycle from 3 embryos — when the article was approved — to now allowing 12 embryos per cycle.[57] In France, PGD used for HLA matching is generally permitted, while any other use of PGD must be approved by a Centre Pluridisciplinaire de Diagnostic Prenatal and is limited to selecting against a serious, incurable diseases.[58] Similarly, in the United Kingdom, the Human Fertilization and Embryology Acts of 1990 and 2008 authorized the Human Fertilization and Embryology Authority ("HEFA") to regulate ART.[59] This regulatory body regulated precisely the conditions for which PGD can be used and has concluded that PGD can be used to select against serious medical conditions or to select for an HLA match for a sick relative.[60]

The few foreign countries that permit PGD vary slightly in their regulations, but still impose strict limitations on who may access PGD and on what terms. The approaches taken by Italy, Switzerland, France, and the United Kingdom differ significantly from the United States' approach to PGD.

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[54] *Id*.
[55] Bavefsky, *supra* note 50 at 42.
[56] BUNDESVERFASSUNG [BV] [CONSTITUTION] Dec. 18, 1998, SR 810.11, art. 5 (Switz.).
[57] BUNDESVERFASSUNG [BV] [CONSTITUTION] Dec. 18, 1998, SR 810.11, art. 17 (Switz.).
[58] Bavefsky, *supra* note 50 at 43.
[59] Human Fertilisation and Embryology Act, 1990, c. 37, §§ 5, 8 (Eng).
[60] Bavefsky, *supra* note 50 at 42-43.

b. United States' Approach

In contrast to the foreign government regulation discussed above, the United States government has maintained a "hands-off" approach when it comes to PGD—there are currently no federal regulations or funding for the procedure. It further seems unlikely that the United States would adopt any of the approaches taken by Italy, Switzerland, France, or the United Kingdom, considering three, interrelated features of the United States: the lack of government sponsored healthcare, the independence of medical professionals, and the controversy surrounding embryos.[61]

First, Italy, France, and the United Kingdom for the most part, have government funded healthcare.[62] Because the government funds the healthcare, they can also determine what, and what not, to cover. To best demonstrate how this would not be possible in the United States, a few examples are illustrative. In France, "the government-sponsored insurance funds up to four IVF cycles, but only for heterosexual couples."[63] In the United Kingdom, the number of cycles funded by the government depends on the woman's age—women between the ages of 23 and 39 can receive up to three cycles, while women between the ages of 40 and 42 are limited to one cycle.[64] These approaches would not be sustainable in the United States. Although government funding would be helpful, it would come at the cost of sacrificing reproductive rights and limiting the autonomy Americans have when exercising their right to procreate and right to parent.

Second, absent government funding and regulation, assisted reproduction "is directed by market forces," which allows "physicians to offer the services they want to provide and charge

[61] *See generally id*. at 43-45
[62] *Id*. at 44.
[63] *Id*.
[64] Bavefsky, *supra* note 51 at 43-45.

the fees they deem appropriate."[65] As a result, many physicians have come to value their relative independence, including their financial independence, and therefore have a strong motivation to resist government regulation.[66] So, insisting that the United States fund PGD would lead to undesirable regulation of both consumers and healthcare providers.

Lastly, the United States government distanced themselves from issues surrounding embryonic politics when it enacted the 1995 Dickey-Wicker Amendment—prohibiting the use of federal funds for research that involves the creation or destruction of human embryos.[67] PGD escalates the controversy due to the fact that the practice often involves the destruction of excess embryos, and in the context of PGD, the discarded embryos contain an undesired genetic feature.[68] In addition to the close relationship of the destruction of embryos to the fierce domestic abortion debate, it seems nonsensical to suggest funding of PGD by the United States government.[69]

While government funding of PGD works in some foreign countries, their approaches would ultimately not translate into the United States' setting. As illustrated by Italy, France, and the United Kingdom, with funding comes invasive regulations; and insisting the United States government fund PGD in the States would give them leeway to begin regulating this assisted reproductive technology. Additionally, considering the independence of medical professionals and the issues surrounding embryo politics, a push for PGD funding by the United States government seems unrealistic.

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[65] *Id*.
[66] *Id*.
[67] Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, 110 Stat. 34 (1996).
[68] Bavefsky, *supra* note 51 at 44-45.
[69] Bavefsky, *supra* note 51 at 45.

Like the federal government, the States have generally kept hands-off in regulating PGD. However, there are a handful of states that have mandated coverage for IVF.[70] This may seem like a step in the right direction; however, the states[71] that mandate coverage for IVF have required the bare minimum coverage, subject to arbitrary qualifications.[72] Other states, such as California,[73] Louisiana,[74] and New York,[75] have done quite the opposite by explicitly excluding coverage for the IVF.

Massachusetts, although mandating coverage of IVF, does so with some of the least restrictive means to obtain coverage. Massachusetts requires coverage of diagnosis and treatment of infertility.[76] "Infertility" is defined as the "condition of an individual who is unable to conceive or produce conception during a period of one year if the female is age 35 or younger or during a period of six months if the female is over the age of 35;" the statute continues on to note the time periods commence "of the time she attempted to conceive prior to achieving that pregnancy."[77] Massachusetts also includes a clause prohibiting "exclusions, limitations or other restrictions on coverage for fertility-related drugs that are different from those imposed on any other prescription drugs."[78] So, to be eligible for required coverage in Massachusetts, PGD patients must provide proof of only one year—or six months—depending on age, of infertility. And the statute further provides protection of coverage for any fertility-related drugs required for the procedures.

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[70] *State Law Related to Insurance Coverage for Infertility Treatment*, NAT'L CONF. OF ST. LEGISLATURES (Jun. 12, 2019), https://www.ncsl.org/research/health/insurance-coverage-for-infertility-laws.aspx.
[71] Delaware, Arkansas, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, and New Jersey. *Id*.
[72] *Id*.
[73] CAL. INS. CODE § 10119.6(a) (Deering 2020); CAL. HEALTH & SAF. CODE § 1374.55(a) (Deering 2020).
[74] LA. STAT. ANN. § 22:1036(a)(1)(b) (2020).
[75] N.Y. INS. LAW § 3221 (Consol. 2020). (law explicitly excludes coverage, subject to limited circumstances)
[76] MASS. ANN. LAWS CH. 176G, § 4 (LexisNexis 2020)
[77] MASS. ANN. LAWS CH. 175, § 47H (LexisNexis 2020); MASS. ANN. LAWS CH. 176A, § 8K (LexisNexis 2020); MASS. ANN. LAWS CH. 176B, § 4J (LexisNexis 2020).
[78] 211. 37. MASS. CODE REGS. 37.06. (LexisNexis 2020).

Opposite from Massachusetts's least restrictive regulations for IVF and PGD is Hawaii. Within Hawaii's statutes, there is a section dedicated to in vitro fertilization procedure coverage.[79] This section defines the five requirements that, if satisfied, would trigger coverage, as well as limitations in quantity and scope.[80] This statute limits coverage to a one-time only benefit for all outpatient expenses arising from in vitro fertilization procedures.[81] The requirements that must be met include: the patient is the insured, the sperm that fertilizes the eggs must be the patient's spouse's sperm, the patient and patient's spouse must have a history of infertility of at least five years' duration (or infertility is associated with one or more of four listed medical conditions), other covered infertility treatments have proven unsuccessful for the patient, and the in vitro fertilization procedures are performed at medical facilities that conform to the American College of Obstetricians and Gynecologists ("ACOG") guidelines for in vitro fertilization clinics or to the American Society for Reproductive Medicine minimal standards for programs of in vitro fertilization.[82]

In contrast to Massachusetts, Hawaii mandates coverage for only one cycle of IVF (limited to the outpatient expenses), requires proof of five consecutive years of infertility, requires the patient's eggs are fertilized by the patient's spouse's sperm, and requires proof that all other covered infertility treatments have failed. The stark contrast between the Massachusetts and Hawaii statutes illustrates the inconsistent access to coverage among the states.

While some of the limitations may be attributable to the differences in culture across the United States, others seem to be selected and applied arbitrarily. For example, PGD patients seeking, at least, coverage of IVF in Hawaii must prove, absent four specified medical

[79] HAW. REV. STAT. ANN. § 431:10A-116.5 (LexisNexis 2020).
[80] *Id*.
[81] *Id*.
[82] *Id*.

conditions, infertility for a duration of five years.[83] Meanwhile, PGD patients in Massachusetts only have to prove infertility of, at most, one year to be eligible for coverage.[84] There seems to be some support for Massachusetts's one-years duration found in the Centers for Disease Control and Prevention's definition of "infertility" as "not being able to get pregnant (conceive) after one year (or longer) of unprotected sex."[85] While this definition seems to provide Massachusetts with slight justification, despite the lowered six-month duration of infertility, it does nothing to justify Hawaii's requirement of five years' duration. This amount of time, specifically, could be detrimental to a woman's goal of achieving a successful pregnancy, especially if she is over the age of 37.

In addition to Massachusetts and Hawaii, eleven other states also require insurance to cover IVF. These states include Arkansas,[86] Colorado,[87] Connecticut,[88] Delaware,[89] Illinois,[90] Maryland,[91] New Hampshire,[92] New Jersey,[93] New York,[94] Rhode Island,[95] and Utah.[96] As medical technologies continue to evolve, the number of women in the United States utilizing

[83] HAW. REV. STAT. ANN. § 431:10A-116.5 (LexisNexis 2020).
[84] MASS. ANN. LAWS CH. 175, § 47H (LexisNexis 2020); MASS. ANN. LAWS CH. 176A, § 8K (LexisNexis 2020); MASS. ANN. LAWS CH. 176B, § 4J (LexisNexis 2020).
[85] *Infertility FAQs*, CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/reproductivehealth/infertility/index.htm (last reviewed Jan. 16, 2019).
[86] ARK. CODE. ANN. § 23-85-137 (2011); ARK. CODE. ANN. § 23-86-118 (1987).
[87] COLO. REV. STAT. § 10-16-104(23) (2020). (applicable to health benefits issued or renewed in Colorado on or after Jan. 1, 2022)
[88] CONN. GEN. STAT. § 38a-509 (2017); CONN. GEN. STAT. § 38a-536 (2017).
[89] DEL. CODE. ANN. tit. 18, § 3342 (2018); DEL. CODE. ANN. tit. 18, § 3556 (2018).
[90] 215 ILL. COMP. STAT. ANN. 5 / 356m (LexisNexis 2015)
[91] MD. CODE ANN., INS. § 15-810 (LexisNexis 2020). (amendments effective Jan. 1, 2021)
[92] N.H. REV. STAT. ANN. § 417-G:1 (LexisNexis 2020).
[93] N.J. STAT. ANN. § 17:48-6x (West 2017); N.J. STAT. ANN. § 17:48A-7w (West 2017); N.J. STAT. ANN. § 17:48-35.22 (West 2017); N.J. STAT. ANN. § 17B:27-46.1x (West 2017).
[94] N.Y. INS. LAW § 3221 (Consol. 2020).
[95] 27. 18. R.I. GEN. LAWS § 27-18-30 (2020); 27. 19. R.I. GEN. LAWS § 27-19-23 (2020); 27. 20. R.I. GEN. LAWS § 27-20-20 (2020); 27. 41. R.I. GEN. LAWS § 27-41-33 (2020)
[96] UTAH CODE ANN. § 49-20-420 (LexisNexis 2020); UTAH CODE ANN. § 31A-22-654 (LexisNexis 2020)

medical technologies to overcome infertility also increases.[97] Insurance coverage, however, is slow to keep up with the need for treatments due to the fact that infertility treatments have been deemed not to be a medical necessity.[98] As more states have mandated such coverage, opponents argue that these mandates may do more harm than good by forcing insurers to offer benefits for services that people might not want.[99] This, they argue, would lead to harmful side effects, such as increased costs, while not adequately providing coverage for everyone. These thirteen states are the firsts to mandate coverage of IVF, notwithstanding the fact they have done so reluctantly. Their limitations and restrictions in mandating IVF coverage are reflective of the United States' hesitant approach regarding PGD.

IV. Private Funding and Focus on the Insurances

Despite the United States keeping a hands-off approach towards PGD, there are two major, private health insurance providers that include coverage for PGD—Aetna ("Aetna") and United Healthcare ("United").[100] Aetna and United took it upon themselves to include the coverage for PGD, however, the terms impose great restrictions and limitations for available coverage.

Aetna's coverage of IVF and PGD is severely limited. As an initial matter, "the IVF procedure . . . is covered only for persons with ART benefits who meet medical necessity criteria for IVF."[101] PGD is covered only when "medically necessary" to identify single gene mutations

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[97] Sheree L. Boulet, Jennifer Kawwass, Donna Session, Denise J. Jamieson, Dmitry M. Kissin & Scott D. Grosse, *US state-level infertility insurance mandates and health plan expenditures on infertility treatments*, 23 MATERAL AND CHILD HEALTH J. 623, 624 (2019).
[98] *Id*.
[99] Marianne P. Bitler & Lucie Schmidt, *Utilization of Infertility Treatments: The Effects of Insurance Mandates*, 49 DEMOGRAPHY 125, 126 (2012).
[100] *See* Bayefsky, et. al., *supra* note 3, at 90.
[101] *Invasive Prenatal Diagnosis of Genetic Diseases*, AETNA (Nov. 9, 1999), http://www.aetna.com/cpb/medical/data/300_399/0358.html.

or X-related conditions.[102] PGD is further limited by requiring that the "genetic disease [to be detected] is associated with clinically significant morbidity or disability."[103] Aetna also notes in their PGD policy, that the use of PGD to determine the human leukocyte antigen (HLA) — to create a "savior sibling"— is considered "experimental and investigational", and is therefore not covered.[104] Essentially, Aetna requires consumers to purchase their ART coverage plan, which *may* cover IVF, and even if it does, the coverage of PGD is limited to the detection of genetic diseases that result in *significant* risk of suffering from a disease or disability. What is considered a disease that would result in *significant* risk of suffering from a disease or disability is unspecified and unclear. Aetna further explicitly excludes PGD for testing of HLA. So, if a couple wishes to undergo IVF and PGD to create a savior sibling, coverage for that purpose will not be provided, regardless of whether the couple has purchased the ART coverage plan.

Similar to Aetna, United's coverage for PGD delineates when the PGD procedure is medically necessary for the following, qualifying risks:

> the embryo is at increased risk of a recognized inherited disorder with both of the following:
> - The increased risk of a recognized inherited disorder is due to one of the following:
>   - The parents are carriers of an autosomal recessive disease
>   - At least one parent is a carrier of an autosomal dominant, sex-linked, or mitochondrial condition
>   - At least one parent is a carrier of a balanced structural chromosome rearrangement
> - The medical condition being prevented must result in Significant Health Problems or Severe Disability and be caused by a single gene (PGT-M) or structural changes of a parents' chromosome (PGT-SR).[105]

[102] *Id*.
[103] *Id*.
[104] *Id*.
[105] *Preimplantation Genetic Testing*, UNITED HEALTHCARE COM. MED. POL'Y (July 1, 2020), https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/preimplantation-genetic-testing.pdf.

This is similar to Aetna's coverage in limiting the uses, as well as requiring that the condition result in health problems or disability. However, under United's plan, human leukocyte antigen (HLA) typing on an embryo in order for the future child to provide bone marrow or blood to treat an affected sibling is considered a medical necessity.[106] This provision does allow PGD to create a "savior sibling," however, the policy limits the type of tissue the savior sibling can donate by permitting the donation of only bone marrow and blood. This clause is far more permissive than Aetna's ban on providing coverage to create a savior sibling. However, it's still restrictive. In one of the more extreme cases, an individual may seek to create a savior sibling for the purpose of providing an organ, such as a kidney, to a sick family member. This case would not be covered under United's plan because it exceeds the scope of permissible donative tissues.[107]

The policies provided by Aetna and United seem fairly permissive on their face. However, a closer look into both policies shows the strict requirements and limitations placed on what tests will actually be covered. These insurers provide coverage to single genetic disorders (subject to other qualifications), only one provides coverage to the limited use of PGD to produce a "savior sibling," and neither cover testing for sex selection. It is a step in the right direction for PGD coverage to be listed on an insurance plan, however, the vast limitations and qualifications effectively deem these plans useless in trying to provide equal access to the testing.

V. Impact of Lack of Funding

The lack of state mandated insurance coverage for PGD and IVF has resulted in unequal access to both procedures. ART, in general, "is deeply divided on race and class lines given the

[106] *Id*.
[107] Alejandra Zúñiga-Fajuri, *Born to donate: Proposals for "savior sibling" regulation in Latin America*, 49 Colombia Médica 228, 228 (2018).

expense of accessing ART services. This inequality of access is furthered by the high cost, and lack of insurance coverage for these services."[108] This inequality is further perpetrated by the fact that a majority of states limit coverage of IVF,[109] which is the most expensive fertility treatment, [110] and provide no guidance on PGD coverage.[111]

Looking more broadly at restricted access to ART, minority women are less likely to access ART due to cost, education, and cultural beliefs.[112] Further, in narrowing the scope to evaluate the diseases detectable by PGD, there are multiple diseases that are more common amongst certain ethnic groups that can be discovered through PGD. For example, Edwards syndrome (aka "Trisomy 18") has a much higher occurrence in non-Hispanic American Indian/Alaskan Natives.[113] Sickle Cell Disease ("SCD") occurs among about 1 out of every 365 Black or African American births versus 1 out of every 16,300 Hispanic-American births.[114] Tay-Sachs disease, although rare in the general population, is more common in people of Ashkenazi (eastern and central European) Jewish heritage than in those with other backgrounds.[115] And beta thalassemia is prevalent in Southeast Asian and Mediterranean ethnicities. The fact that these genetic disorders are "found predominately within certain ethnic groups [sic] raises the degree of suspicion that a genetic disorder is present and may mandate

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[108] Aziza Ahmed, *Race and assisted reproduction: implications for population health*, 86 FORDHAM L. REV. 2801, 2806 (2018).
[109] *See* Section III(b), *supra*.
[110] *See* Ahmed, *supra* note 108.
[111] *See* Section III(b), *supra*.
[112] Alicia Armstrong & Torie C. Plowden, *Ethnicity and Assisted Reproductive Technologies*, 9 CLINICAL PRAC. 651, 652 (2012).
[113] *Racial and Ethnic Differences in the Occurrence of Major Birth Defects*, CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/ncbddd/birthdefects/features/racialethnicdifferences.html (last visited Dec. 16, 2020).
[114] *Data & Statistics on Sickle Cell Disease*, CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/ncbddd/sicklecell/data.html (last visited Dec. 16, 2020).
[115] Medline Plus, *Tay-Sachs disease*, https://medlineplus.gov/genetics/condition/tay-sachs-disease/#frequency (last visited Dec. 16, 2020).

genetic testing if available."[116] Further, in the United States, "it is the racial minorities, particularly Black, Latino, and immigrant communities, that bear the adverse consequences of ill health due to poverty, lack of insurance, and, in turn, lack of access to health serviced and technologies."[117] This supports the push for equal access to PGD testing through state mandated coverage.

Even in the several states that do provide coverage for IVF through state law mandates,[118] there is not equal access to the procedure for everyone.[119]

> Mandates do not apply to those who obtain health coverage through governmental programs (such as Medicaid), and are uninsured, or obtain health coverage from self-insured employers. As a result, even in mandates states, infertility care has been accessed disproportionately by non-Hispanic white women with higher educational training and socioeconomic status.[120]

This point illustrates that, although it's not likely to happen anytime soon, the United States government should continue to consider the lack of equal access to IVF and PGD and the possibility of regulating the procedure. As new technologies develop, the lack of access to these technologies may further inequalities of illness and worsen the burden of disease for particular communities.[121] Although state mandated insurance coverage for PGD may not provide every single person with access to PGD, the need to start moving toward better accessibility and closing the disparate gap is a pressing matter.

Opponents of the issues of equality — ensuring that everyone has equal access to the IVF and PGD — argue that perhaps "any proposal to fund PGD use to screen out genetic illness or

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[116] 2 DAN JOSEPH TENNENHOUSE, ATTORNEYS MEDICAL DESKBOOK § 19:4 (4th ed. 2020).
[117] Ahmed, *supra* note 108 at 2810.
[118] *See* Section III(b), *supra*.
[119] Molly Quinn & Victor Fujimoto, *Racial and Ethnic Disparities in Assisted Reproductive Technology Access and Outcomes*, 105 FERTILITY & STERILITY 1119, 1120 (2016).
[120] *Id*. at 1120-21.
[121] Ahmed, *supra* note 108 at 2810.

chromosomal abnormalities impacts the disabled."[122] When PGD patients elect to undergo the test, there is an understanding that a possibility exists where an embryo may hold an "undesirable trait," which may result in its disposal. In doing so, "efforts to deselect embryos for disabilities can be seen as a failure to understand the value of the lives of the disabled."[123] It is further argued that "funding for therapeutic PGD may create pressure to deselect embryos because doing so is what the government and society believe is right."[124] The idea behind this argument is that because the test is funded by the government, there is a pressure to conform to what the government and society deem is "right" or "correct."[125] And as such pressure continues and grows, society will feel the need to conform to and receive the test to ensure they do not have a "disabled child."[126] Its further argued that this societal pressure would in turn reduce the number of disabled people, while the social stigma of being different is likely to increase.[127]

This argument, however, is based on two very important premises: 1) that the PGD testing would be funded directly by the government; and 2) that individuals who wish to have a child with traits that others would consider to be undesirable would not utilize PGD.[128] State mandates that require insurance companies to cover at least one round of PGD and IVF are not based on government funding.[129] Additionally, there is no requirement that all insured PGD patients go through the process of IVF or PGD. Couples insured in the states that have mandated coverage will not be prevented from conceiving a child naturally, or by any other fertility

[122] Lauren R. Roth, *Reproductive Selection Bias*, 27 HEALTH MATRIX 263, 280 (2017).
[123] *Id*.
[124] *Id*. at 281.
[125] *Id*.
[126] *Id*.
[127] *Id*.
[128] Roth, *supra* note 122 at 281.
[129] *See* Section III(b), *supra*

treatment. The state mandate coverage simply is in place for those who wish to utilize PGD and IVF, who would otherwise not have the means or option to do so.

This approach eliminates the idea that the government, through funding, will be able to influence what is "correct" or "right" in our society. Further, individuals who are seeking a certain trait and those that are seeking to avoid that same certain trait would both have equal access to undergo PGD to obtain their respective desired results. Individuals who seek to have a child with a certain trait that others may deem "undesirable," would not prohibit the individual from otherwise undergoing PGD to ensure the child had that specific trait.

Moreover, the potentially negative social stigma attributable to the use of PGD would require widespread and persuasive use of PGD to affect that result. A study published in 2019 sought to examine the extent to which health plan expenditures for infertility services differed by whether women resided in states with mandates requiring coverage of such services and by whether coverage was provided through a self-insured plan subject to state mandates versus fully insured health plans. subject only to federal regulations.[130] The study included a little over six million women, 19-45 years of age.[131] The study observed the women, continuously enrolled in different insurance plans for 2011, and tracked whether the women sought certain fertility treatments including IVF, intrauterine insemination, or ovulation-inducing medications.[132] Of the 6,006,017 women enrolled in the study, only 9,199 women — or 0.15% — had one or more IVF claims.[133] And less than 65% of those 9,199 women lived in a state with an infertility insurance mandate.[134] This study indicates that even where fertility treatments are accessible to many

[130] Boulet, et. al., *supra* note 97 at 623.
[131] *Id*. at 623-24
[132] *Id*.
[133] *Id*. at 625-26.
[134] *Id*. at 626.

women, a majority most likely will not receive the treatment for one reason or another. These numbers, in turn, are not large enough to persuasively suggest a negative social stigma arising from accessible IVF and PGD testing.

There has also been a slippery slope argument that has been made against providing insurance coverage for PGD and IVF. There is a concern that once PGD and IVF have become so prevalent in society, or society begins to feel the pressure of electing to undergo PGD, insurance providers will eventually stop providing coverage for conditions that are "preventable." Meaning, those conditions that could be detected through PGD, should be detected through PGD. Furthermore, there is a fear that once insurance coverage becomes widely accessible, insurance providers will begin to tack on extra costs and fees for individuals who choose to procreate without using PGD.[135] Opposite from the social stigma argument, the fear that insurance providers could eventually punish carriers for not utilizing PGD and IVF doesn't rely on the number of individuals who actually undergo the procedures. When insurance companies provide coverage for certain treatments, there is the possibility that the cost of the coverage plan will increase. To offset that increase in costs caused by providing coverage for PGD and IVF, insurance companies could charge carriers who do not utilize the service. However, this would be a far overreach by the insurance companies due to the invasive nature and requirements of the IVF and PGD procedures.

Considering the unworkable foreign approaches to funding PGD and the United States' unwillingness to become involved in any domestic approach, the states[136] seem to be in the best

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[135] Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past-Present, and Future?*, 36 CONN. L. REV. 125, 211 (2003).

[136] As a note relevant to insurance coverage mandates, it has been suggested that the Affordable Care Act ("ACA") "presents an opportunity to expand access to therapeutic PGD and other ARTs." Lauren R. Roth, *Reproductive Selection Bias*, 27 HEALTH MATRIX 263, 296 (2017). While I agree this suggestion could very well be a good though, the uncertainty of the ACA's future makes it a hard sell. *See generally* California v. Texas, oral arguments scheduled Nov. 10, 2020).

position to mandate insurance coverage of at least one cycle of IVF and PGD — regardless of the purpose or reason for utilizing the procedures. The states thus far have placed arbitrary requirements on proving infertility, which would only then trigger coverage for IVF. These arbitrary requirements include the length of time one must be unable to have a child to be deemed "infertile," and how many failed cycles of IVF one must endure before coverage activates.

The coverage suggested in this Article requires at least one cycle of PGD and IVF, even if it is the first attempt for a couple to become pregnant, and regardless of what gene or chromosome the patients are seeking to test. After, the states may regulate subsequent cycles as they please, subject to constitutional restraints. Mandating at least one covered cycle of PGD and IVF, rather than mandating blanket coverage, will provide equal access to the procedures regardless of the reason of testing, while mitigating any stigmatizing effect on individuals with conditions deemed undesirable that could be detected through PGD.

The issues with the current state mandates are that they are scarce and extremely restrictive — only a few states have them, and only a few uses of IVF are covered. Additionally, the statutes leave out any possibility of coverage in the event PGD patients want to produce a "savior sibling," so, PGD patients who want HLA testing do not even have a chance for coverage under the current mandates. The statutes limit the uses to particular genetic disorders, rather than all, and require other arbitrary limitations. In doing so, the states have gone into unnecessary hair-splitting detail with their legislation. This ultimately indicates the state's approval for some uses, while showing disapproval for other uses. However, it is not for the state to decide what the good uses are for PGD versus the bad uses and what tests should be allowed versus those that should not be allowed.

VI. Conclusion

In conclusion, states should require insurance providers to cover at least one cycle of IVF with PGD. Further, the coverage should be provided absent a showing of infertility or familial history of genetic disorders. The few states that do require health insurers to cover these procedures, and the existing coverage by Aetna and United, limit the access to coverage with arbitrary bounds.

This unequal access to ART, generally, has a disparate impact against various minority groups. Further, because PGD can detect the presence of specific diseases that are more common among certain ethnic groups, it would be prejudicial to restrict access to the testing. Where individuals have access to PGD and IVF, patients will have the opportunity to potentially rid their child of the common disease.

Government involvement in regulating PGD, as it stands today does not seem like a feasible option, without impeding a family's right to reproduce and family plan. Regulatory framework abroad cannot translate to practice in the United States, as the foreign countries placed heavy restrictions on, what in the United States are, developed fundamental rights. Regulations coming from the federal government and delineating when coverage for PGD is acceptable would eventually lead to a separation of "acceptable" uses and "nonacceptable" uses—determined by the government. With the growing number of uses for PGD, not calling for blanket coverage for at least one cycle of treatment would compartmentalize the ethical status of testing, and at the same time prevent a family to have a child they want to have, as in the case of the savior sibling. While equal access to PGD testing is important, it cannot be limited to those families with existing genetic disorders, it must be accessible for at least one cycle—regardless of purpose, or not at all.