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THEORY OF GENETIC DIMENSIONS IN THE LAW, POLYGENIC RISK SCORES, AND REPRODUCTIVE DECISION-MAKING

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ABSTRACT

Genetics fits uneasily into the law. As judges, lawyers, and lawmakers endeavor to squeeze genetic phenomena into existing legal categories, they inevitably neglect important interests that individuals, families, and society have in the disposition of questions implicating genetics. This is particularly true in reproductive contexts, which are often the focal point of societal, political, and legal conflict.

In this essay, we focus on one such area: the growing use of genetic testing coupled with polygenic risk scores ("PRSs") in reproductive decision-making. In prior work, we proposed a conceptual framework for legally recognizing interests stemming from the multiple dimensions of genetic objects: A Theory of Genetic Dimensions in the Law ("ToGi," for short). We use ToGi as a framework for identifying the myriad genetic interests that should be taken into account by policymakers and judges when they decide matters involving genetic testing and PRSs in reproductive settings. We examine the available legal mechanisms for recognizing, addressing, and redressing these interests and suggest ways in which current legal frameworks fall short in accommodating the wider range of genetic interests that we have identified. Our goal is to assist policymakers in navigating the legal terrain as this technology, and other technologies like it, continue to develop and applications expand.

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I. INTRODUCTION

Genetics fits uneasily into existing legal categories. As judges and lawmakers endeavor to squeeze genetic phenomena into readily available legal categories, they inevitably fail to capture the full range of interests that individuals, families, and society have in genetics.[1] This is particularly true in reproductive contexts, which are often the sites of complex societal, political, and legal conflict.[2]

While the genetic engineering of embryos has received much public attention and consternation,[3] the reach of genetic technologies into reproductive decision-making through other avenues, such as for use in prenatal and preimplantation genetic testing, is expanding mostly out

1. For a fuller discussion of the disconnect between genetics and the law, *see, e.g.*, Yaniv Heled, Liza Vertinsky & Ana Santos Rutschman, *A Theory of Genetic Dimensions in the Law*, 99 IND. L.J. 1341 (2024).

2. For a broad look at some of the many issues that arise at the intersection of law, genetics and reproductive choices, see, e.g., JUDITH DAAR, I. GLENN COHEN, SEEMA MOHAPATRA & SONIA SUTER, REPRODUCTIVE TECHNOLOGIES AND THE LAW (3rd ed. 2022); *see also* HENRY GREELY, CRISPR PEOPLE: THE SCIENCE AND ETHICS OF EDITING HUMANS (2021).

3. *See, e.g.*, Edward Lanphier, Fyodor Urnov, Sarah Ehlen Haecker, Michael Werner & Joanna Smolenski, *Don't Edit the Human Germ Line*, 519 NATURE 410 (2015) (calling for a moratorium on modifying the DNA of human reproductive cells); Alice Park, *Experts Are Calling for a Ban on Gene Editing of Human Embryos. Here's Why They Are Worried*, TIME (March 13, 2019, 2:22 PM), https://time.com/5550654/crispr-gene-editing-human-embryos-ban/ [https://perma.cc/666X-7YLX].

of (legal) sight and in the absence of regulation.[4] At present, new applications of preimplantation genetic testing are increasing rapidly, moving quickly from research to clinical use and consumer markets.[5] These developments and the new reality of preimplantation genetic testing and screening of embryos carry profound implications for a broad range of different stakeholders with competing and sometimes conflicting interests.[6]

In this essay, we explore one such emerging technology with a potentially wide reach over reproductive decision-making: the use of polygenic risk scores as part of preimplantation genetic testing.[7] We focus on scenarios involving uses, decisions not to use, and even the prohibition of the use of this type of genetic testing. As far as we are aware, at the time of writing this Article, disputes connected to such uses (and

4. *See, e.g.*, Susan Klugman & Siobhan M. Dolan, *Expanded Genetic Testing in* Assisted *Reproduction: Lessons Learned from Prenatal Testing*, 16 AMA J. ETHICS 38, 39 (2014) (discussing questions raised by expansion of new genetic technologies in prenatal and preimplantation testing); Michelle Bayefsky, *Who Should Regulate Preimplantation Genetic Diagnosis in the United States?*, 20 AMA J. ETHICS 1160, 1161–63 (2018) [hereinafter Bayefsky, *Who Should Regulate*] (pointing out the lack of regulation of preimplantation genetic testing in the United States and arguing for future regulation despite federal and state barriers); Michelle Bayefsky, *The Regulatory Gap for Preimplantation Genetic Diagnosis*, 45 HASTINGS CTR. REP. 7 (2015) [hereinafter Bayefsky, *Regulatory Gap*] (same); Alex Polyakov, David J. Amor, Julian Savulescu, Christopher Gyngell, Ektoras X. Georgiou, Vanessa Ross et al., *Polygenic Risk Score for Embryo Selection — Not Ready for Prime Time*, 37 HUM. REPROD. 2229 (2022) (arguing that PRSs are being used in embryo selection in the minimally regulated U.S. market without adequate data to support its utility).

5. For a discussion of some of the ways in which preimplantation testing applications are expanding and proliferating in commercial markets, see, e.g., Dov Fox, Sonia M. Suter, Meghna Mukherjee, Stacey Pereira & Gabriel Lázaro-Muñoz, *Choosing Your "Healthiest" Embryo After* Dobbs*: Polygenic Screening and Distinctive Challenges for Truth in Advertising and Informed Consent*, 38 HARV. J.L. & TECH. 463 (2024); Jessica L. Roberts & Sonia M. Suter, *Damned If You Do or Damned If You Don't: The Medical Malpractice Implications of Consumer-Generated Polygenic Risk Scores*, 38 HARV. J.L. & TECH. 417 (2024).

6. *See, e.g.*, Gabriel Lázaro-Muñoz, Stacey Pereira, Shai Carmi & Todd Lencz, *Screening Embryos for Polygenic Conditions and Traits: Ethical Considerations for an Emerging Technology*, 23 GENETIC MED. 432 (2021) ("Polygenic embryo screening (PES) — the use of polygenic risk scores for complex phenotypes as a component of preimplantation genetic testing (PGT) — has emerged as a commercially available service, despite almost no public deliberation about its ethical, clinical, and societal implications."); 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 PERSP. MED., May 2020, at 5 (analyzing policy approaches to PGT and noting the permissive approach adopted in the United States).

7. *See, e.g.*, Patrick Turley, Michelle N. Meyer, Nancy Wang, David Cesarini, Evelynn Hammonds, Alicia R. Martin et al., *Problems with Using Polygenic Scores to Select Embryos*, 385 NEW ENG. J. MED. 78, 78 (2021) (discussing the emergence of embryo selection based on PRS in the marketplace and the risks associated with its use); Rémy A. Furrer, Dorit Barlevy, Stacey Pereira, Shai Carmi, Todd Lencz & Gabriel Lázaro-Muñoz, *Public Attitudes, Interests, and Concerns Regarding Polygenic Embryo Screening*, 7 JAMA Network Open., May 2024, at 1–2 (surveying U.S. adults to gauge attitudes, interests, and concerns regarding polygenic embryo screening, suggesting that "it is critical for health care professionals and medical societies to consider and understand the perspectives of diverse stakeholders (e.g., patients undergoing IVF, clinicians, and the general public), given the absence of regulation and the recent commercial availability of PES").

misuses) — to the extent that they have already emerged — appear to have remained largely unlitigated.[8] While this is likely to change, waiting for legal disputes to work their way through the courts and relying on ad hoc legal responses to specific legal disputes is unlikely to address, or even identify, all of the important interests implicated by these genetic technologies and their use in reproductive decisions. To prevent a siloed, incomplete response to the legal issues implicated by this form of genetic testing and screening, we offer legal decision-makers a framework for exploring and bridging the potential disconnect between applications of polygenic preimplantation genetic testing in reproductive decision-making and the law.

The purpose of this essay is twofold. In prior work, we have proposed a conceptual framework for legally recognizing interests stemming from the multiple dimensions of genetics — a Theory of Genetic Dimensions in the Law ("ToGi," for short).[9] In this essay, we demonstrate how to use ToGi as a framework for analyzing the genetic interests that should be taken into account by legal decision-makers when polygenic risk scores are used in preimplantation genetic testing. We further use our framework to assist legal decision-makers — judges, legislators, regulators, and even lawyers — as they try to make sense of and resolve controversies, such as those described below, involving genetic testing and polygenic scoring in reproductive decision-making.

The rest of the essay proceeds as follows. In Part II, we offer a brief primer on the evolution and use of polygenic risk scores in preimplantation genetic testing. In Part III, we provide four hypothetical scenarios reflecting likely uses of these genetic testing and screening tools in reproductive decision-making. Each of the scenarios raises complex legal and ethical issues that lawmakers and courts will find challenging to confront. In Part IV, we describe the ToGi framework and demonstrate how decision-makers can use it to approach the questions raised in these four scenarios in a systematic, comprehensive way that takes into account the multitude of implicated stakeholder interests. Our proposed approach attempts to ensure that no legally cognizable interests of any relevant stakeholders are ignored, overlooked, or downplayed. It also provides a way of incorporating the bioethical issues implicated by the scenarios we describe into legal decision-making, thus serving as an organizing tool for investigating the ethical, legal, and social implications of these genetic technologies.

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8. *See generally* Jeremy Applebaum, Leigh Ann Humphries, Mary Ellen Nepps, Dara S. Berger & Kathleen O'Neill, *Malpractice Litigation Surrounding* In Vitro *Fertilization in the United States: A Legal Literature Review*, 119 FERTILITY & STERILITY 572 (2023) (cataloging in vitro malpractice cases, none of which raise issues with use of polygenic risk scores).

9. Heled et al., *supra* note 1.

II. EMERGING AREAS OF LEGAL UNCERTAINTY IN REPRODUCTIVE DECISIONS USING PGT-P

Prenatal and preimplantation genetic testing have been taking place for decades.[10] Until recently, most of this testing has focused on a small set of diseases or traits that map onto specific genes and chromosomal abnormalities, and much of it has taken place exclusively in a clinical context. Reproductive screening is now moving beyond monogenetic testing through the use of new techniques designed to test for diseases and other traits that are determined by a combination of multiple, often numerous, genes and the environment. This Part of the essay describes the evolution of polygenic preimplantation genetic testing, clarifying relevant terminology and laying the foundation for the scenarios described in Part III.

A. Evolution of PGT-P

Preimplantation genetic testing ("PGT") involves the testing of the genetic material of early-stage embryos created through in vitro fertilization ("IVF") before the embryo is implanted in the uterine wall (in a process called "transferring").[11] PGT was developed in the 1980s as an alternative to other methods of prenatal testing, such as amniocentesis, which involved increased risk to the embryo and could only occur later during pregnancy, potentially requiring the termination of the pregnancy in case of unfavorable test results. In PGT, a biopsy of the embryo is taken ex utero and is analyzed before implantation to detect genetic abnormalities and determine the embryo's suitability for transfer.[12]

PGT was initially used for embryo gender selection aimed at avoiding sex-chromosome linked genetic disorders, but its uses quickly proliferated to screening and selection in other monogenic diseases such as cystic fibrosis and sickle cell anemia and to chromosomal

10. *See, e.g.*, Firuza Rajesh Parikh Arundhati Sitaram Athalye, Nandkishor Jagannath Naik, Dattatray Jayaram Naik, Rupesh Ramesh Sanap & Prochi Fali Madon, *Preimplantation Genetic Testing: Its Evolution, Where Are We Today?*, 11 J. HUM. REPROD. SCI. 306, 306–10 (2018).

11. Nathalie Antonios, *Preimplantation Genetic Diagnosis*, ARIZ. STATE UNIV.: EMBRYO PROJECT ENCYCLOPEDIA (Mar. 24, 2011), https://embryo.asu.edu/pages/preimplantation-genetic-diagnosis [https://perma.cc/XN4H-TW86].

12. PGT is an umbrella term that includes all forms of genetic testing on embryos prior to implantation into the uterus. *See, e.g.*, Fernando Zegers-Hochschild, G. David Adamson, Silke Dyer, Catherine Racowsky, Jacques de Mouzon, Rebecca Sokol et al., *The International Glossary on Infertility and Fertility Care, 2017*, 108 FERTILITY & STERILITY 393 (2017) (defining PGT as a "test performed to analyze the DNA from oocytes (polar bodies) or embryos (cleavage stage or blastocyst) for HLA-typing or for determining genetic abnormalities. These include: PGT for aneuploidies (PGT-A); PGT for monogenic/single gene defects (PGT-M); and PGT for chromosomal structural rearrangements (PGT-SR)").

abnormalities such as Down syndrome.[13] However, most genetic traits, including those that impact morbidity and mortality through complex diseases like cancer, diabetes, schizophrenia, and asthma, involve an interaction of multiple, often numerous, genes and environmental factors.[14] While there is no foolproof diagnostic test for such complex genetic traits and diseases, the partial genetic basis for at least some of these traits can be estimated through the calculation of a polygenic risk score ("PRS").[15]

PRSs offer estimates of the probability of a specified complex disease or trait "obtained by aggregating the effects of dozens, thousands, and potentially millions of genetic variants associated with that specific trait into a single figure."[16] The PRS is a statistical calculation that is based on the presence or absence of multiple genomic variants in the specific individual compared to a genomic database comprised of a larger population, which is used to assess the risk of polygenic disease.[17]

Preimplantation genetic testing for polygenic disease risk, or PGT-P, is a form of PGT that uses PRSs to measure the risk of certain polygenic disorders.[18] In PGT-P, PRSs based on genetic materials from the embryo can be calculated for a variety of polygenic disorders, including cancer, cardiovascular disease, and schizophrenia.[19] It can also be used to calculate the probability of certain non-disease quantitative traits such as height.[20]

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13. Antonios, *supra* note 11.

14. Darren K. Griffin & Anthony T. Gordon, *Preimplantation Testing for Polygenic Disease (PGT-P): Brave New World or Mad Pursuit?*, 3 DNA 104, 104 (2023).

15. *See, e.g.*, Francesca Forzano, Olga Antonova, Angus Clarke, Guido de Wert, Sabine Hentze, Yalda Jamshidi et al., *The Use of Polygenic Risk Scores in Pre-Implantation Genetic Testing: An Unproven, Unethical Practice*, 30 EUR. J. HUM. GENETICS 493 , 493 (2022).

16. *Id.* For a discussion of the evolving legal landscape surrounding PRSs, see generally, Jin K. Park & I. Glenn Cohen, *The Regulation of Polygenic Risk Scores*, 38 HARV. J.L. & TECH. 377 (2024).

17. A PRS "uses genomic information alone to assess a person's chances of having or developing a particular medical condition. A person's PRS is a statistical calculation based on the presence or absence of multiple genomic variants, without taking environmental or other factors into account." Teri Manolio, *Polygenic Risk Score (PRS)*, NAT'L HUM. GENOME RSCH. INST.: TALKING GLOSSARY OF GENOMIC & GENETIC TERMS (Aug. 18, 2024), https://www.genome.gov/genetics-glossary/Polygenic-Risk-Score-PRS [https://perma.cc/D7GZ-DDCB]. A PRS for a person provides only a relative risk, as compared to the population used to calculate the score. *Polygenic Risk Scores*, NAT'L HUM. GENOME RSCH. INST. (Aug. 11, 2020), https://www.genome.gov/Health/Genomics-and-Medicine/Polygenic-risk-scores [https://perma.cc/A27S-PJWN].

18. PGT-P testing is used to determine the risk of complex multi-gene disorders. Griffin & Gordon, *supra* note 14, at 104 ("[M]ultiple genes are tested for with an associated polygenic risk score (PRS), usually established by a genome-wide association study (GWAS).").

19. *Id.* at 105.

20. Maria Siermann, Olga Tšuiko, Joris Robert Vermeesch, Taneli Raivio & Pascal Borry, *A Review of Normative Documents on Preimplantation Genetic Testing: Recommendations for PGT-P*, 24 GENETICS MED. 1165, 1165–66 (2022).

The expanding uses of PRSs in PGT have generated excitement, but also concern.[21] PRSs are imperfect measures of just the genetic component of a disease or trait. They depend heavily on a selection of risk variants and their weightings derived from GWAS, which are themselves limited by the scope and range of participants tested.[22] Additional complexities arise when trying to use these scores to determine the risk of diseases for an embryo.[23]

B. The Commercial and Regulatory Landscape in Which PGT-P is Taking Place

Although PRS calculations are imperfect, and the science and technology behind PRSs are still evolving, the private sector has forged ahead to develop commercial applications of this nascent technology, including expanded uses in PGT.[24] This is understandable, given the commercial realities of reproductive genetic testing. Carrier testing for single-gene diseases is now an industry worth more than $1.7 billion annually, and testing for more complex multi-gene diseases, which is still in its early stages, has the potential to grow this industry further by orders of magnitude.[25] New and established genetic testing companies are racing to develop and sell additional, more comprehensive genetic tests through the use of PRSs for more and more traits and diseases.[26]

In the reproductive setting, genetic testing companies are expanding their commercial offerings of PGT-P for prospective parents interested in selecting embryos for viability and the likelihood of certain kinds of diseases and even non-disease traits. The U.S.-based Genomic Prediction, Inc., for example, one of the first companies to offer

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21. *See, e.g.*, Theresa A. Grebe, George Khushf, John M. Greally, Patrick Turley, Nastaran Foyouzi, Sara Rabin-Havt 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 IN MED., Feb. 2024, at 2; Maria Siermann, Ophelia Valcke, Joris Robert Vermeesch, Taneli Raivio, Olga Tšuiko & Pascal Borry, *"Are We Not Going Too Far?": Socio-Ethical Consideration of Pre-Implantation Genetic Testing Using Polygenic Risk Scores According to Healthcare Professionals*, 343 SOC. SCI. & MED., Feb. 2024, at 2.

22. *See* Forzano et al., *supra* note 15, at 493–94.

23. *See, e.g.*, Fox et al., *supra* note 5; Roberts & Suter, *supra* note 5.

24. *See, e.g.*, Turley et al., *supra* note 7, at 78 (exploring the expansion of private sector applications for embryo selection based on polygenic scores); *see also* Grebe et al., *supra* note 21, at 2 ("We ultimately conclude that the use of PGT-P has not been proven to provide clinical utility — in short, the practice has moved too fast with too little evidence."); Leah R. Fowler, *The Appification of Genetic Risk*, 38 HARV. J.L. & TECH. 479 (2024); Fox et al., *supra* note; Roberts & Suter, *supra* note 5.

25. *See* Laura Hercher, *A New Era of Designer Babies May be Based on Overhyped Science*, SCI. AM. (July 12, 2021), https://www.scientificamerican.com/article/a-new-era-of-designer-babies-may-be-based-on-overhyped-science/ [https://perma.cc/E9XS-Q72E].

26. *See Preimplantation Genetic Testing Market*, GROWTH+ MKT. REPS. (Mar. 13, 2023), https://www.growthplusreports.com/report/preimplantation-genetic-testing-market/8402 [https://perma.cc/QM7P-RFU6].

polygenic risk scoring of embryos to consumers, has been marketing what it calls the LifeView PGT platform, which includes PGT-P as part of a suite of other PGT tests.[27] Orchid Health, another U.S.-based company, offers prospective parents genetic testing to calculate both their own risk of certain diseases, such as diabetes and schizophrenia, and the likelihood they will pass those risks to future children. Orchid also provides these tests in combination with preimplantation PRSs to assist parents in selecting their "healthiest" embryos for transfer.[28] Another company, MyOme, has offered embryo selection based on PRS for over 25 medical conditions and appears to have at least contemplated "providing patient participants with embryo polygenic scores for education, household income, cognitive ability, and subjective well-being as part of a research protocol . . . ."[29]

Once PGT is combined with the use of PRSs in this way, it becomes a method of screening embryos for a broadening range of traits. Commercial pressure is likely to drive further expansion in the scale and scope of this kind of testing, with new applications invariably outpacing an understanding of what the results mean and the implication of decision-making based on these results.[30] The growing use of PGT-P raises a host of complex ethical, social, and legal concerns in a largely unregulated environment.[31] There are questions about the accuracy of the scores; questions about whether those who use them — particularly parents — understand the limitations and inherent inaccuracies of the scores and of the information they do and do not provide; and broader questions about what types of traits can and should or should not be tested for.[32]

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27. Genomic Prediction, *Ovation Fertility Licenses LifeView PGT To Provide Patients With the Most Advanced Testing Available*, PR NEWSWIRE (Oct. 20, 2022, 1:00 PM), https://www.prnewswire.com/news-releases/ovation-fertility-licenses-genomic-predictions-lifeview-pgt-to-provide-patients-with-the-most-advanced-testing-available-301655186.html [https://perma.cc/9FWD-FEGM].

28. For a discussion of the commercial offerings for PGT-P testing, see Hercher, *supra* note 25.

29. Turley et al., *supra* note 7, at 78.

30. For a discussion of the ways in which commercial pressure will exacerbate existing challenges in managing the use of polygenic testing in embryo selection, see, e.g., Fox et al., *supra* note 5.

31. For a discussion of some of the legal, ethical, and social issues, see, e.g., Natalie Ram, *Polygenic Scoring and the Criminal Legal System*, 38 HARV. J.L. & TECH. 577 (2024) (analyzing legal, ethical and social implications of uses of polygenic risk scores in criminal justice); Shawneequa Callier & Anya E.R. Prince, *The Legal Uncertainties of Sociogenomic Polygenic Scores*, 38 HARV. J.L. & TECH. 553 (2024) (exploring concerns arising from expanding uses of PGS in many facets of society and argues for more direct role for regulation); Doron Dorfman, *Selecting for Disability: How an Anecdote Can Inspire Regulation of Genetic Reproductive Technologies*, 38 HARV. J.L. & TECH. 441 (2024) (exploring issues relating to selection for difference).

32. *See, e.g.*, Andrew Joseph, *A Baby with a Disease Gene or No Baby at All: Genetic Testing of Embryos Creates an Ethical Morass*, STAT (Oct. 23, 2017), https://www.stat

The United States — both on the state and federal level — has largely practiced a laissez-faire approach to the regulation of assisted reproductive technologies ("ART") in general, and the newly emerging area of PGT-P seems to be no exception.[33] This leaves the area of PGT-P to be regulated almost exclusively through the use of private law, primarily through traditional legal constructs under tort and contract law.[34] As uses of PGT-P expand, legal decision-makers can expect to confront cases such as those hypothesized in Part III and will face the need to fit the issues raised by these cases into existing legal categories. Their decisions will shape the governance of these technologies.

III. CAPTURING THE LEGAL COMPLEXITIES OF PGT-P: FOUR SCENARIOS

Although the challenges posed by the clinical and commercial use of PGT-P are the subject of growing debate,[35] there has been little discussion of how U.S. lawmakers and courts might or should approach and respond to the legal conflicts that are sure to arise.[36] We explore the potential challenges posed by PGT-P for legal decision-makers through a series of four hypothetical scenarios that capture different kinds of legal questions arising from the development and use of PGT-P.

The first scenario reflects questions that are already arising as PRSs enter clinical practice in conjunction with embryo selection.[37] The second scenario explores some of the implications of incorporating PGT-P as an established, or even required, part of clinical reproductive

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news.com/2017/10/23/ivf-embryo-genetic-testing/ [https://perma.cc/96XE-JD69]; Philip Ball, *Polygenic Screening of Embryos Is Here, But Is It Ethical?*, THE GUARDIAN (Oct. 17, 2021), https://www.theguardian.com/science/2021/oct/17/polygenic-screening-of-embryos-is-here-but-is-it-ethical [https://perma.cc/MR7R-CKG9].

33. *See* Bayefsky, *Who Should Regulate*, *supra* note 4, at 1162–63; Michelle J. Bayefsky, *Comparative Preimplantation Genetic Diagnosis Policy in Europe and the USA and Its Implications for Reproductive Tourism*, 3 REPROD. BIOMEDICINE & SOC'Y ONLINE 41, 42 (2016); Fox et al., *supra* note 5.

34. For an example of how tort law is used to fill in the gaps in this area, see, e.g., Roberts & Suter, *supra* note 5.

35. The other papers in this symposium tackle some of the most pressing legal, ethical, and social questions raised by the use of PRSs, both generally and within the context of PGT. *See also* Yasaman Lorkalantari, *PGT-P: Testing the Future*, ADVOCATE GENETICS (Mar. 28, 2022), https://www.advocategenetics.com/blog/553374-pgt-p-testing-the-future [https://perma.cc/B6HG-Q6E7] (exploring some of the social and ethical implications of PGT-P); Turley et al., *supra* note 7, at 84 (exploring limitations of polygenic scores for embryo selection and some of the potential negative consequences of using this technology).

36. *See* Ginoza & Isasi, *supra* note 6, at 5 (noting the permissive approach to PGT in the United States at both state and federal level).

37. For an analysis of the most immediate questions facing a doctor who is faced with decisions about whether, when and how to use PGT-P, see Roberts & Suter, *supra* note 5 (exploring how concerns about malpractice liability may drive physicians to use polygenic risks scores in medicine).

decision-making.[38] The third scenario explores ways in which the private sector may seek to use PGT-P, and even PRSs more broadly, in decisions concerning health insurance. The final scenario raises questions about how legislators and policymakers should approach regulating PGT-P.[39]

For each scenario, we consider the ways in which courts and lawmakers are likely to characterize the legal interests implicated in the dispute and utilize existing legal categories to handle the legal and policy questions they raise. We leave until Part IV the analysis of what is likely to be left out, and why it matters. We return to these scenarios in Part IV, applying the ToGi framework to show how the narrowing choices that legal decision-makers are likely to make, as described below, fall short in light of the broader range of individual, scientific, commercial, political, and social interests that the scenarios implicate.

Scenario 1: Clinic Refuses to Consider the Results of a PGT-P When Considering Embryo Transfer

A judge must decide a lawsuit filed by parents against a fertility clinic for not performing a PGT-P that would have identified an increased risk for schizophrenia — a polygenic disorder — in their embryo and for not informing the parents such a test was available. Rather, after conducting their customary, more limited PGT, the clinic recommended one of the embryos to the parents. The parents accepted the recommendation, the embryo was transferred, and a child was born who, later in their teenage years, was diagnosed with schizophrenia. The parents argue that a PGT-P would have dissuaded them from having that embryo chosen for implantation.[40]

This legal dispute is most likely to take the form of and be considered by the judge as a medical malpractice and, possibly, contractual dispute. In seeking to resolve the dispute, the judge will consider whether the clinicians' failure to perform PGT-P on the embryo was a violation of the standard of care and the clinic's contractual obligations

38. For a compelling discussion of how these tools may already be impacting healthcare professionals, see, e.g., Roberts & Suter, *supra* note 5 (exploring how concerns about malpractice liability may drive physicians to use PRSs in medicine).

39. For a discussion of alternative regulatory approaches, see, e.g., Sarah Munday & Julian Savulescu, *Three Models for the Regulation of Polygenic Scores in Reproduction*, 47 J. MED. ETHICS, Jan. 2021, at 4 (proposing a regulatory model for embryo selection using PRSs which limits embryo selection according to the impact of the predicted trait on well-being).

40. *See* Roberts & Suter, *supra* note 5, at 430–31. This scenario is also intentionally very similar to the scenario in *Atlanta Obstetrics & Gynecology Grp. v. Abelson*, 398 S.E.2d 557 (Ga. 1990), wherein the parents of a child born with Down syndrome sued a fertility clinic for failing to inform the parents of the availability of genetic tests that would have discovered the condition and given the parents the option to abort the pregnancy.

to the parents. The judge might go further to consider whether the clinic had a duty to inform and counsel the parents about the availability of polygenic tests, and whether the clinicians may be said to have "caused" the genetic condition in the child. The judge will also be faced with the difficult question of what might be appropriate remedies in the event of a breach or liability ruling.

Although the case is likely to be limited to determining whether the involved clinicians have satisfied their duty of care to the parents, and perhaps whether any contractual obligations to the parents were breached, the case raises a host of legal, ethical, and policy questions. Many of these questions do not fit easily into the malpractice and contract claims and analysis. Indeed, even the question of determining what the standard of care is in these contexts is complex and brings with it possible unintended consequences. A slew of additional legal and policy questions lurk in the background, including whether genetic tests should be offered, required, or prohibited, who should pay for them if provided, who is responsible for errors or inaccuracies in the test if given, how to deal with the uncertainty attached to the results, and who should be able to access the results. Underlying all of these issues are additional questions regarding how the technology might further develop and whether and how it ought to be regulated; what conditions may and ought to be screened for; what is the proper and acceptable level of scientific and technical validity of the testing method and specific tests available; and what would be the acceptable consequences of the court's decision at both an individual and population level.

The judge, who will inevitably rely heavily on the narrowing lens of existing legal categories to consider the interests involved in the dispute, will risk neglecting important stakeholder interests and inflicting problematic consequences on the parties to the dispute as well as ones who are not.

Scenario 2: Clinic Requires Prospective Parents to Obtain a PGT-P and Refuses to Transfer Embryos with a PGT-P Indicating High Risk For Certain Diseases Without Release from Liability

A fertility clinic institutes a policy of requiring PGT-P as part of providing IVF services and of not transferring embryos with PRSs indicating risk for certain diseases above a certain threshold without the intended parents first signing a release from liability. All the intended parents' embryos have a high PGT-P score for schizophrenia. Nonetheless, the parents want to have at least one of their embryos implanted. They sign the release required by the clinic, an embryo is transferred, and a child is born who, later in their teenage years, is

diagnosed with schizophrenia. Having reached the age of majority, the child now sues the fertility clinic for carrying out the implantation and for generating information from the PGT-P that the child wishes did not exist.

Such a case will likely raise claims falling under both tort law and contract law, including questions of whether the child has standing to sue under either tort or contract law, limitations, causation, and measure of damages. Specific claims will include medical malpractice (e.g., whether requiring the PRS and then proceeding with the transfer despite the high score was a breach of the duty of care), wrongful life, tort claims grounded in privacy, and contract claims (including the validity of the release and its applicability for the child).

Many of these claims will be novel, and the judge will be faced with challenging questions of whether to allow them and, if so, how to evaluate them. Just like in the previous scenario, fitting this scenario into existing legal categories will likely exclude a broad range of interests arising from the decisions being made. These interests will implicate not just the individuals involved in the suit but also family members, individuals with shared genetic characteristics and groups of such individuals (including patient and disability rights groups), and the broader population. Questions about insurance coverage will also become important and will be sure to raise even further questions about whether PGT-P is medically necessary and how PRS results can and should be used and shared. Regardless of how such a case is decided, requiring or not requiring PGT-P as a "normal" part of reproductive decision-making would have far-reaching social implications that fall well outside of the confines of the specific case. Yet the judge facing this particular dispute will lack a framework for thinking about and weighing many of these issues.

Scenario 3: Healthcare Insurance Policy Requires PGT-P Reproductive Decision-Making as a Condition for IVF Coverage

Healthcare insurance providers institute a new policy requiring policyholders undergoing fertility treatments to obtain and consider PRS data before deciding which embryo(s) to have implanted. Under the policy, where a genetic condition is reasonably foreseeable and avoidable, proceeding with the embryo implantation despite the PRS data would result in a denial of coverage for the IVF treatment. Policyholder parents who are now seeking coverage for IVF treatments but who do not want to have a PGT-P testing of their embryos done

bring a lawsuit against the insurance company for wrongful denial of coverage.[41]

In this scenario, the issues are likely to be approached and addressed through the lens of the contractual relationship between the parties and insurance laws relevant to mandating (or not) insurance coverage for fertility treatments. Yet the determination of whether PGT-P testing should be a required part of covered fertility treatment raises a wide range of questions and implicates interests that fall well outside interpretation and proper scope of existing coverage. Approaching and addressing this type of scenario as a mere question of insurance coverage and contractual dispute runs the risk of leaving out pertinent stakeholder interests while deciding important policy questions that go well beyond the seemingly limited confines of the case. Yet the judge is left without a clear mandate for considering broader interests and a consistent, transparent way of doing so.

Scenario 4: Proposed State Law Would Prohibit Uses of PGT-P

State legislators are considering proposed legislation that would prohibit the use of PRSs in selecting embryos for non-disease traits (e.g., height, intelligence, athletic prowess).[42] *They face both opposition and support from various interest groups, including prospective parents, disability and patient rights groups, test providers, insurance companies, and fertility clinics.*

There has been much discussion of the implications of recent decisions concerning abortion, starting with the overturning of *Roe v. Wade,* for preimplantation genetic testing. The political climate and the change in law are likely to exacerbate the debates over and encourage interest in the use of PGT, while also complicating how it is used.[43] Against this backdrop, state legislators may begin to consider legal responses to the use of PGT and PRSs as part of PGT.

As part of this lawmaking exercise, legislators would need to consider both what interests are at stake and who should be given a seat at the table to inform any proposed legislation. Without a framework in place to identify the wide range of interests and stakeholders implicated

41. *See* Dorfman, *supra* note 31, at 448–49.

42. *Let's Talk About Muscle Composition & Genetics*, 23ANDME, https://www.23andme.com/topics/wellness/muscle-composition/ [https://perma.cc/574L-FGJT]; Furrer et al., *supra* note 7, at 8 (discussing public attitudes toward testing for complex genetic traits such as intelligence and height).

43. Fox et al., *supra* note 5.

by the use of PGT-P technologies, the debates over possible laws could easily be dominated by well-entrenched political interests closely tied to different views about reproduction (and abortion), disability rights, and commercial interests supporting the ability to develop, sell, and (for insurance providers) use the information from these tests. In Part IV, we discuss how such an outcome is not inevitable and may be avoided by approaching this and similar scenarios through the ToGi framework.

IV. A FRAMEWORK FOR GUIDING DECISION-MAKING IN MATTERS INVOLVING PRSS IN REPRODUCTIVE SETTINGS

In this Part, we first briefly describe the ToGi framework and then apply it to the four scenarios described above to show how the framework can be used to guide and inform different types of legal decision-making in the context of PGT-P. The framework can be viewed as a way of providing a consistent, transparent process for considering the full range of stakeholder interests attaching to questions of genetics and the law that can be deployed across different legal questions and forums.

A. The Theory of Genetic Dimensions in the Law (ToGi) Framework

When confronted with novel legal questions involving genetics, courts, lawmakers, and other jurists often struggle to fit genetics into existing legal categories.[44] However, forcing genetic phenomena into pre-existing legal categories inevitably leaves out critical aspects of these phenomena and, as a result, excludes consideration of important stakeholder interests.[45] That approach, which is typical for attempts to adapt new technology to old legal constructs, inhibits the ability of courts and lawmakers to tailor legal responses to problems involving genetics in ways that balance important stakeholder interests that stem from the multiple dimensions of genetics. This disconnect has grown in recent decades, as uses of genetics have permeated an increasingly larger number of legal fields — ranging from family law (e.g., parenthood determination) and criminal law (e.g., evidence collection) to intellectual property (e.g., the development of commercially valuable gene therapies and other genetic treatments) and health law (e.g., the popularization of direct-to-consumer genetic testing). In response to this disconnect, in earlier work, we developed the ToGi framework to guide legal decision-makers as they encounter issues involving

44. *See* Heled et al., *supra* note 1.

45. For a fuller discussion of why and how this happens and why it is particularly pernicious in matters involving genetic phenomena, see Heled et al., *supra* note 1, at 1343–52.

genetics.[46] The primary goal of this framework is to provide a systematic way for legal decision-makers to recognize the multiple dimensions of genetic phenomena, identify the plurality of stakeholder interests that may be implicated, and properly balance these interests in resolving legal questions involving genetics.

(1) Defining Genetic Objects for Legal Purposes

Under the ToGi framework, any legal treatment of issues involving genetics should start with identifying the foundational unit of analysis: the relevant "genetic object."[47] We define genetic objects as articles consisting of, or containing, the relevant sequence or chain of nucleotides — the building units of genetic material. In legal contexts, genetic objects may present themselves in different forms, ranging from, for example, blood evidence obtained by police officers at a crime scene to hair from a celebrity surreptitiously taken by genetic paparazzi or a genetic sample taken as part of a biopsy from a cancer patient.[48]

(2) Identifying the Relevant Dimensions of the Genetic Object

ToGi is based on the idea that genetic objects have multiple dimensions that may have varying legal and ethical significance depending on the context. In earlier work, we identified seven distinguishable dimensions of genetic objects with the understanding that this list may expand in the future as the frontiers of genetic science and the law expand.[49] The seven dimensions[50] are:

(1) *Physical-chemical*: this dimension relates to the structural aspects of genetic objects, which consist of chemical molecules and relevant articles containing these molecules.

(2) *Informational*: genetic objects generate multiple types of information, both direct (e.g., the sequence of nucleotides in the genetic object) and contextual (e.g., the location of the genetic object within a broader structure or the object's similarities to and dissimilarities from other genetic objects).

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46. *Id.* at 1344–45.

47. *Id.* at 1352–53.

48. *Id.* For scientists obtaining tissue samples, the genetic object may be the tissue sample itself, the cell line they develop from it, a specific gene of interest within the cell line, or the promoter sequence preceding the gene that controls the gene's expression, depending on the legal scenario. *See id.* at 1370 (describing the mischaracterization by the California Supreme Court of the genetic object in the case of *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990)).

49. *Id.* at 1353.

50. *Id.* at 1361–62, tbl.1.

(3) *Functional*: relates to the biological functions performed by the genetic object, such as coding for a protein, assisting in initiating or terminating transcription, etc.

(4) *Taxonomic*: relating to the object's connection to a biological species.

(5) *Group-identity-conferring*: relating to the object's conferral of membership in subgroups within a species.

(6) *Individual-identity-conferring*: similarly relating to the object's conferral and determination of individual characteristics of the organism from which the genetic object had originated.

(7) *Reproductive*: relating to genetic objects' ability to replicate, bearing a crucial role in the formation of other organisms beyond the original genetic object and its carrier.

B. A Framework for Identifying Stakeholder Interests

After determining the dimensions that are implicated by a specific genetic object (or set of genetic objects) in a given legal scenario, the ToGi framework requires legal decision-makers to take the additional step of exploring the legal significance of interests that various stakeholders might have in the object, which stem from each of these dimensions.[51] Legal decision-makers are then left with the task of deciding whether to legally recognize, and how to balance, potentially competing interests. This balancing might take place as part of internal guidance by research institutions, agency rulemaking, judicial decision-making, legislation (or deciding not to legislate), or in some other formal or informal form of legal policymaking and adjudication.

The ToGi framework[52] is, essentially, a multi-step process for identifying the interests attached to a genetic object and then balancing those interests as follows:

(1) **Step 1:** Identify the genetic object (or objects) that are relevant in the specific legal context;

(2) **Step 2:** For each genetic object, identify the relevant dimensions of the genetic object within the context of the given legal issue(s);

51. *Id.* at 1364–65.
52. *Id.* at 1365.

(3) **Step 3:** For each dimension, identify the potentially legally cognizable interests stemming from each dimension for each stakeholder; and

(4) **Step 4:** Search for a legal solution that provides an equitable balancing of the interests identified in the previous step.

We contend that legal decision-makers who consider scenarios involving the use of PRSs in reproduction will be better positioned to properly identify and balance competing interests in such scenarios if they follow the above process.[53]

C. Application of the ToGi Framework to Analyze the Four Scenarios

The ToGi framework begins by identifying the relevant genetic subject, which becomes the "genetic object" of the analysis. In the context of preimplantation genetic testing, the object might be the donor egg and sperm, the test sample, the sample as amplified by the testing lab, or the embryo itself, depending on the scenario. The most relevant genetic object in each of the four scenarios we developed in Part III is the embryo that is being subjected to PGT-P and that is meant to be transferred.

The accurate definition of the genetic object is crucial for the analysis because it shapes how we think about the dimensions implicated by the legal scenario and, consequently, how we incorporate the stakeholder interests attaching to these dimensions. The legally relevant dimensions of an unimplanted embryo, for example, will be different from those of an embryo that has been implanted. Similarly, an embryo biopsy will likely invoke genetic dimensions that are very different from the embryo from which it was taken, even if the embryo itself consists of only a handful of cells that are just starting to replicate. Considering the explicit and implicit assumptions and implications that go along with the choice of genetic object for the legal analysis is an important part of this first step, and frames the subsequent analysis.

With that in mind, the relevant genetic object for a ToGi analysis of the four scenarios described earlier is the embryo or embryos that undergo or are meant to undergo PGT-P prior to being transferred.

The second step of the ToGi framework requires considering the relevant dimensions of the genetic object for the given legal context, with the goal of identifying and organizing the different types of interests and stakeholders that will be implicated by a legal decision that impacts the genetic object. All four of our scenarios involve legal questions about PGT-P and its use in decisions concerning the genetic object

53. For examples of how the ToGi framework may be applied in other areas of the law, such as criminal law, patent law, and tort law, see *id.* at 1366–92.

(the embryo), and so the relevant dimensions are the same or similar across the four scenarios.

Starting with the embryo as the genetic object, the relevant genetic dimensions[54] of the genetic object(s) implicated by the four scenarios we describe, and what these dimensions mean within the context of the scenarios, are as follows:

(1) *Physical-chemical:* The physical entity that is the embryo itself, including its entire genetic makeup.

(2) *Informational:* The results of the genetic tests conducted on the embryo's DNA and the PRS calculations for schizophrenia based on these results.[55]

(3) *Functional:* The potential functional implications of the embryo's genetics on the expression of the trait and the developmental ramifications for the resulting individual should the embryo be implanted and come to term.

(4) *Group-identity-conferring*: Membership in identity groups in which the relevant trait is implicated. For example, the expression of schizophrenia will determine the child's membership in the group of individuals who have schizophrenia, the larger group of individuals struggling with mental health conditions, and the even larger groups of individuals with disabilities.

(5) *Individual-identity-conferring:* The individual's own trait and identity as informed and affected by the expression of that trait. For example, the expression of schizophrenia will determine the teenager's identity as "schizophrenic," "mentally ill," "disabled," etc.

(6) *Reproductive:* Perhaps the most foregrounded aspect of the four scenarios concerns the choice of the embryo for implantation and, thus, for being allowed to develop into a child (who — in turn — may themselves later choose to reproduce).

The third step under the ToGi framework — and the one that pulls the dimensions into legal decision-making — is to identify the specific stakeholder interests stemming from each dimension within the given legal context. This step makes the navigation and balancing of interests

54. *See supra* note 50 and accompanying text.

55. Notably, this information may be relevant to the individuals involved in the scenarios and, potentially, also to the broader public and research community. *Cf.* Jorge L. Contreras, *Genetic Property*, 105 GEO. L.J. 1, 6–7 (2016) (criticizing and warning against the negative effects of property regimes in genetic data on scientific research).

explicit for the legal decision-maker, and it enables them to approach the fourth step — equitable balancing of the interests — with a fuller understanding and appreciation of the stakeholders and the stakes of any decision.

Rather than starting with the particular claims as fashioned by litigants or legislation as fashioned by a particular interest group, the legal decision-maker in this third step begins with a broad consideration of stakeholders and their interests and then attempts to weigh all the interests identified as they reach a decision.

The first three scenarios involve litigants in court and the judge as decision-maker. The fourth scenario involves legislation that might evolve from these disputes. Still, because all four scenarios involve overlapping questions about how to legally respond to PGT-P that impacts reproductive decision-making, the identification and enumeration of stakeholders and their interests are, therefore, largely similar across all four scenarios.

In practical terms, the legal decision-maker can go party by party and consider their interests under each of the dimensions, systematically moving through the dimensions and the stakeholders. The parties most immediately implicated in the first three scenarios, and most directly impacted in the fourth, are the parents, the child born from the embryo, and the fertility clinic, making them a natural starting point.

In the case of the intended parents, the judge ought to consider the property interest the parents have in the embryo stemming from the *physical-chemical dimension* of the embryo. The judge should similarly consider what interest the parents might have in the PGT-P results and PRS data based on the results (stemming from the *informational dimension* of the embryo); the parents' interest in the desired development of the embryo during gestation and child after birth and throughout its life (stemming from the *functional dimension*)[56]; their interest in negative affiliation with groups of individuals who have schizophrenia and their family members (stemming from the *group-identity-conferring dimension*); and their interest in having the ability to make an informed decision and determine whether to implant the embryo in the first place (stemming from the *reproductive dimension*).

Turning to the interests of the child born from the embryo, the judge ought to consider their interest in knowing (or, in some cases, not knowing) the PGT-P results for schizophrenia (*informational*); the child's interest in healthy and minimally painful development and existence throughout their childhood and life (*functional*); their interest in

56. *See* Julian Savulescu, *Procreative Beneficence: Why We Should Select the Best Children*, 15 BIOETHICS 413, 413 (2001) (making the case for parental selection of embryos and fetuses "most likely to have the best life, based on available genetic information, including information about non-disease genes").

non-affiliation[57] with the group of individuals who have high PRSs for schizophrenia or the condition itself (*group-identity-conferring*); and the child's interest in being or assuming an identity of a person having the genetic condition (*individual-identity-conferring*).

In the case of the fertility clinic and its providers, the judge ought to consider both their interests and, possibly, obligations stemming from the identified dimensions, including their interests and obligations pertaining to the physical custody of the embryo (*physical-chemical*); their interest in knowing, or not knowing, the PGT-P test results for schizophrenia (*informational*); and their interest, and possible obligation, attached to the development of the embryo during gestation and child after birth and throughout its life (*functional*).

When looking at the full range of dimensions attached to the embryo, it becomes clear that other stakeholders have interests that may be affected by the outcome of the court's decision. Such other stakeholders might include a surrogate carrier, a sperm and egg donor, a sperm bank and egg provider or clinic, additional clinicians and genetic counselors operating outside the clinic that provided the fertility services, groups of patients and individuals affected by the genetic condition, or public health authorities who may also be acting as stewards of the interests of the larger public.

In the case of groups of patients and individuals affected by the genetic condition — regardless of whether they join the suit as amici or otherwise — the judge may wish to consider these groups and individuals' interests stemming from their affiliation with the child and parents (*group-identity-conferring*). For example, controversially, the judge should at least be aware of such groups and individuals' possible interest in having the PGT testing and PRS results *not* affect the decision of whether to implant embryos (*informational; reproductive*).

Finally, and again, regardless of whether public health authorities are part of the lawsuit, the judge should consider such entities' interests in the PGT-P results and PRS data based on the results (*informational*); their interest — as stewards of the public health — in the healthy development of the embryo during gestation and the child after birth and throughout its childhood and life (*functional*); and, possibly, their interest in limiting the proliferation of alleles that are potentially responsible for schizophrenia in the population (*reproductive*).

The above analysis plays an important role in identifying the broader range of stakeholders and interests implicated in any legal decision. It also suggests at least three things the judge should consider that might have been missed or downplayed if the focus were

57. Sometimes, individuals may have an interest in affiliation with what others might consider a disability group (e.g., deafness, dwarfism), but it is highly unlikely the parents or child in this case would consider having schizophrenia or affiliation with groups of individuals afflicted with the disease as desirable.

exclusively on the parents' interest in obtaining and using the PGT-P information to inform a reproductive choice. First, the parents and the child may have potentially conflicting interests, including in obtaining and using PGT-P test results. Second, the clinic has an interest in clarifying its obligations vis-à-vis obtaining and using this PGT-P information and with potential liability implications. Third, the outcome of the case will have an almost inevitable impact on family members, members of other groups of individuals with similar genetic conditions, and other parties, as well as on public health, which is potentially far-reaching but that would otherwise likely be left unconsidered under the limited legal frame of the negligence and contract suit.

While sharing a similar starting point, the analysis across scenarios diverges where the framework highlights the limitations of existing legal categories in each case and identifies and organizes the types of interests that require a legal response within the particular scenario. Thus, in returning to the scenarios, we explore the varying stakeholder interests that are implicated in each scenario and highlight issues, and interests, that would likely have been overlooked or ignored by the judge in the absence of the ToGi framework.

Scenario 1: Clinic Refuses to Use PGT-P to Inform Embryo Transfer

In the first scenario, the parents sue the clinic, likely arguing that they should have been informed about all testing options, that having a PGT-P should be considered part of the standard of care, and that having a PGT-P would have dissuaded them from having that embryo chosen for implantation.[58] The parents seek compensation for the extra medical costs involved in managing their child's schizophrenia and, possibly, other losses resulting from the need to provide care for their child. The judge (or jury) is tasked with deciding whether the clinic should have informed the parents about the option of getting a PGT-P and should have used the results to inform its recommendation to the parents regarding embryo transfer.

In approaching this matter, it is most likely that the court's focus would be on whether PGT-P is, or should be, part of the standard of care and whether, even if it was not, the parents should have been given notice of the option to obtain this additional test, including possibly under any contractual obligations the clinic may have had to the

58. In a recent presentation, Prof. Evelyn Tenebaum proposed a novel cause of action of "wrongful selection" as an alternative to the traditional wrongful birth claim in such cases. Evelyn Tenenbaum, Professor, Albany Sch. of L., Presentation at the 2024 Health Law Professors Conference: Wrongful Selection as an Alternative to Wrongful Birth in Cases Involving Late Onset Genetic Conditions (June 6, 2024).

parents. Yet narrowing the focus of legal inquiry in this manner leaves out important interests that the judge should at least consider and perhaps incorporate into the analysis. For instance, forcing the case into the bucket of medical malpractice highlights the informational and reproductive dimensions and foregrounds the interests of the parents in having (or not having) the test information and using that information to impact reproductive decisions. Yet a decision in this case will impact a broader range of stakeholder interests, including the interests of the child, the interest of physicians and other healthcare workers who will be involved in these kinds of tests and decisions based upon them, and broader social and economic interests attaching to the uses of PGT-P. At the very least, the judge should be aware of the limits, and potential consequences, of any decision that excludes this broader range of interests.

Scenario 2: Clinic Requires Prospective Parents to Obtain a PGT-P and Refuses to Transfer Embryos With a PGT-P Indicating High Risk Without Release from Liability

In this scenario, the fertility clinic institutes a policy of requiring prospective parents to obtain a PGT-P and of not transferring embryos with a PGT-P indicating risk for certain diseases above a certain threshold without the parents first signing a release from liability. We can imagine a scenario in which the parents refuse to obtain a PGT-P, highlighting the tension between the interests of at least some parents and those clinics insisting on its use. Here, the parents allow the PGT-P and want to proceed with the transfer regardless of the results. The parents sign a release and have an embryo with a high PGT-P score for schizophrenia implanted. The child, now diagnosed with schizophrenia, having reached the age of majority, sues the fertility clinic for carrying out the testing *and* for transferring the child's high-PRS embryo despite the genetic risk in the first place.

The ToGi framework analysis of this scenario highlights how at least some stakeholder interests — particularly those of the child — might be left out of the analysis under existing tort and contract law constructs. A court approaching the child's lawsuit against the clinic in this current scenario will inevitably struggle to fit the child's (and, possibly, the parents') claims within the confines and limitations of existing tort and contract laws. In particular, the court would need to traverse a messy terrain of archaic legal doctrines pertaining to the child's

ability to file the suit against the clinic in the first place[59] and the parents' ability to participate in the lawsuit.[60] And, as before, it would need to contend with momentous questions of ethics and public policy, including whether a child should be able to sue their (literal) makers for creating them with a known and, at least in some cases, avoidable flaw or disability (and, if so, what constitutes a flaw or disability sufficiently significant to allow such a suit); what might be a proper remedy in such a suit; how to overcome the nonidentity problem[61] in crafting the proper remedy in the case; and whether the clinic should be allowed to crossclaim the parents, and if so, under what legal theory. The current legal doctrines that limit wrongful life lawsuits[62] and lawsuits by children against their parents[63] would make it very difficult, if not impossible, for the court even to acknowledge, let alone redress, the child's interests in filing the lawsuit.[64]

The ToGi framework itself does not (and cannot) provide answers to many of the above questions or provide ways around the many archaic constructs that might hamper the child's suit. Still, it would ensure that any decision by the court would at least take under advice and perhaps even reflect and respond to the relevant interests and concerns of the child and all other implicated parties — whether they are part of the case or not — making the ultimate decision more legally sound and just (or, at the very least, transparent as to its limits).

Scenario 3: Healthcare Insurance Policy Requires PGT-P Reproductive Decision-Making as a Condition for IVF Coverage

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59. Notably, the law in virtually all states forecloses children from filing wrongful life suits. *See* James A. Henderson, Jr., *Things of Which We Dare Not Speak: An Essay on Wrongful Life*, 86 GEO. WASH. L. REV. 689, 690–91 (2018); Barbara Pfeffer Billauer, Wrongful Life *in the Age of Crispr-Cas: Using the Legal Fiction of "The Conceptual Being" to Redress Wrongful Gamete Manipulation*, 124 PENN ST. L. REV. 435, 438 (2020).

60. The parents are also estopped from bringing a claim against the clinic under the release they have signed and, thus, cannot join the child's suit as plaintiffs. The only way the parents might become involved in this lawsuit, it seems, is if the clinic is somehow allowed to file a crossclaim against them, seeking reimbursement for the clinic's legal expenses and whatever damages might be ruled for the plaintiff-child against the clinic. Regardless of whether the parents are excluded from the case, the court ought to remain cognizant of their status as stakeholders and of their interests, which remain much the same as those mentioned in the discussion of the first scenario.

61. *See* Billauer, *supra* note 59, at 478–82.

62. *See id.* at 463–78.

63. *See* RESTATEMENT (THIRD) OF TORTS: CONCLUDING PROVISIONS § 2 cmts. a, c (AM. L. INST., Tentative Draft No. 1, 2022) (discussing the doctrine of parental immunity in the United States).

64. Some of the child's interests, teased out using the ToGi framework, may include, for example, being unencumbered by their schizophrenia (functional, individual-identity-conferring, group-identity-conferring) and not knowing the PGT-P test results.

In this scenario, the court must consider whether the insurance company can require PGT-P testing as a precondition for covering IVF and whether it can deny coverage of IVF in cases of transfer of embryos that have PGT-P test results indicating a high likelihood of certain diseases. As part of this analysis, the judge must consider whether the insurance company adheres to the Affordable Care Act's prohibition on exclusion from coverage due to preexisting conditions, as well as consider which types of services must be covered.[65] Resolving the question of permissibility of the requirement to obtain a screening test, as well as the requirement to use the results to determine coverage of the procedure, necessitates careful consideration of the meaning of "pre-existing condition," which in turn hangs on an understanding of the full range of stakeholder interests.

Interests of particular importance in this scenario are the parents' interests in knowing their embryos' PGT results and PRS data (*informational*) and in being able to act on this knowledge in making their reproductive decisions (*reproductive*); the child's interest in healthy and minimally painful development and existence throughout their childhood and life (*functional*); patient and disability groups' possible interest in having the PGT testing and PRS results not affect the decision of whether to implant embryos (*informational*; *reproductive*); and public health authorities' interest in avoiding preventable diseases — genetic or otherwise — in the population (functional) but also in making sure that those suffering from such diseases are not stigmatized (*group-identity-conferring*) and are able to obtain and pay for treatment for their genetic conditions (which is not a genetic interest per se, but is within their purview).

In this scenario, the ToGi framework emphasizes the importance of considering interests of stakeholders that are not parties to this lawsuit. Doing so would offer the court insight into a range of highly variable perspectives on what, at first blush, might seem like a very specific, almost technical, contractual dispute but is, in fact, an amalgam of many legal, ethical, and public policy issues that go to the heart of using genetic technologies in reproductive settings.

Scenario 4: Proposed State Law Would Prohibit PGT-P

In the fourth scenario, state legislators are considering a legal prohibition on the use of PRSs in selecting embryos either for non-disease traits or for any use at all. This scenario is different in that the legal decision-maker is not a judge but rather a legislator or group of

65. 42 U.S.C. § 300gg-3(a) ("A group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion with respect to such plan or coverage.").

legislators considering a general rule that would regulate the use of PRS in reproductive settings to achieve certain public policy goals. To be sure, such goals may vary dramatically from one state to another and even from one election cycle to another within the same state. Regardless, the legal, ethical, and policy questions faced by such legislators are equally significant to those faced by the judges in the previous scenarios. As a starting point, the legislator needs to consider which stakeholders and interests should be considered in deliberations about what the law should be.

Employing the ToGi framework in this scenario would be most helpful not just because it would ensure that the legislation is considered from the perspectives of more than just one or two bodies of law, such as torts and contract law, but also that consideration is given to the interests of parties and groups beyond just the most well-entrenched, deep-pocketed, and vociferous.

Evidently, once we open the door to holistic considerations of how PGT-P ought to be used, this can raise an overwhelming array of legal, ethical, and policy questions implicating a seemingly unmanageable number of conflicting interests of numerous stakeholders, some of whom are not even parties to the matter at hand. Yet, the third step in the ToGi framework provides a way for the legal decision-maker to take proper notice of and consider all relevant stakeholder interests while explicitly acknowledging tensions and tradeoffs in the weighing and adjudication of rights. While this approach will not make the legal decision easier, it increases the likelihood that whatever decision the decision-maker ends up making is based on a sufficiently comprehensive understanding and consideration of the full gamut of stakeholder interests. The analysis also highlights areas in which there are important interests that the law in its current form is unable to accommodate, suggesting the need for a less formalistic judicial response or even legislative response.

V. CONCLUSION

Decisions involving genetics in reproductive contexts are particularly fraught with ethical, legal, and social concerns. Within this area, concerns arising from the implications of human germline editing have tended to dominate the public imagination and debate. Yet the expanding availability and use of less "visible" genetic technologies, particularly in reproductive contexts, can have a significant impact. These issues will be compounded by the blurring lines between research,

clinical use, and commercial availability of increasingly advanced methods of embryo testing, screening, and selection.[66]

In this essay, we have offered a framework designed to help legal decision-makers who are confronted by complex legal issues at the intersection of genetics and the law and suggested how it might be used to navigate new questions arising from polygenic testing. Our framework offers a systematic way for legal decision-makers to recognize the multiple dimensions of genetic phenomena, identify the plurality of stakeholder interests that may be implicated, and properly balance these interests in resolving legal questions involving genetics. We have employed this framework to analyze potential legal disputes involving the expanding uses of PGT-P, illustrating the role that it can play in ensuring reasoned treatment of the full range of stakeholder interests implicated by expanding uses of polygenic testing in reproduction. Although for this essay, we have focused on specific scenarios involving the use of PGT-P, many of the legal and bioethical issues uncovered by our discussion are relevant to the broader range of reproductive decisions that rely on genetic testing and scoring both inside and outside of the context of clinical care.

66. *See, e.g.*, Cathryn M. Lewis & Evangelos Vassos, *Polygenic Risk Scores: From Research Tools to Clinical Instruments*, GENOME MED., May 2020, at 9 (discussing the need for more research in PRS before clinical implementation); Forzano et al., *supra* note 15, at 494.