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CHOOSING YOUR "HEALTHIEST" EMBRYO AFTER *DOBBS*: POLYGENIC SCREENING AND DISTINCTIVE CHALLENGES FOR TRUTH IN ADVERTISING AND INFORMED CONSENT

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Polygenic embryo screening ("PES") analyzes embryos for hundreds or thousands of genomic loci to generate risk scores that estimate genetic susceptibility to conditions and traits compared to the general population. The technology is commercially marketed directly to consumers. Companies focus mostly on medical conditions, sometimes in ways that oversell its advantages and efficacy, encouraging fertility patients to "choose your healthiest embryo" and "protect your future child from genetic risks." The advertising of PES trades on norms of children's health and good parenting and reinforces those normative ideals. While it is easy to assume PES will be constrained in practice by its clinical limitations, high cost, and health burdens associated with in vitro fertilization, inflated marketing claims could exacerbate other legal and social forces to expand its use. Since the fall of Roe v. Wade, over a dozen states have banned abortion, forcing some people to give birth to children they would not otherwise have had. Others who are denied the abortion choice may seek to recover this lost sense of agency over their reproductive lives in other ways. This article examines the risks of decision fatigue and choice overload that PES may create in prospective parents, and the distinctive challenges that PES poses for legal liability over matters of truth in advertising and informed consent.

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There's nothing new about reproductive technology to test human embryos before selecting which to transfer. For decades, it's been limited, however, to "genetically simple" conditions like Down syndrome or Huntington's disease.[1] Suddenly, it is possible to screen embryos for estimated risks of developing characteristics whose causes are more complex — because they are influenced by multiple genes, hundreds or even thousands, often in combination with other contributory causes like lifestyle and environment.[2] These "polygenic" traits include some of the most common diseases, such as diabetes, heart disease, cancer, and arthritis, as well as height, skin/hair/eye color, and even a wide range of psychological and personality traits.[3]

Polygenic embryo screening ("PES") analyzes embryos for hundreds or thousands of genomic loci to generate risk scores that estimate genetic susceptibility compared to the general population.[4] It is marketed directly to consumers.[5] Companies focus mostly on medical conditions, sometimes in ways that over-sell the advantages and efficacy of screening, encouraging fertility patients to "choose your healthiest embryo"[6] and "protect your future child from genetic risks."[7] The advertising of PES trades on norms of children's health and good parenting and reinforces those normative ideals.[8] It is easy to assume PES will be constrained in practice by its clinical limitations and high cost, not to mention the medical risks of extracting eggs and the liability risks associated with handling embryos for screening and selection for transfer.[9]

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1. *See generally* Sonia M. Suter, *The Routinization of Prenatal Testing*, 28 AM. J.L. & MED. 233 (2002) (discussing the progression of testing methods).

2. Dorit Barlevy, Ilona Cenolli, T. Campbell, Rémy Furrer, Meghna Mukherjee, Kristin Kostick-Quenet et al., *Patient Interest in and Clinician Reservations on Polygenic Embryo Screening: Qualitative Study of Stakeholder Perspectives*, 41 J. ASSISTED REPROD. & GENETICS 1221, 1223, 1228 (2024); Rémy A. Furrer, Dorit Barlevy, Stacy Pereira, Shai Carmy, Todd Lencz & Gabriel Lázaro-Muñoz, *Public Attitudes, Interests, and Concerns Regarding Polygenic Embryo Screening*, 7 JAMA e2410832, e2410834 (2024); Gabriel Lázaro-Muñoz, Stacy Pereira, Shai Carmi & Todd Lencz, *Screening Embryos for Polygenic Conditions and Traits: Ethical Considerations for an Emerging Technology*, 23 GENETICS MED. 432, 432 (2021).

3. *See* 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).

4. *Id.*

5. *See id.*

6. *LifeView*, GENOMIC PREDICTION, https://lifeview.com [https://perma.cc/6V2Y-B5VG].

7. *Mitigate More Risks with the World's Most Advanced Whole Genome Screening for Embryos*, ORCHID, https://orchidhealth.com [https://perma.cc/E9RG-9YNE]. For discussion, see Turley et al., *supra* note 3.

8. *See* Suter, *supra* note 1, at 247–48; Janet Malek & Judith Daar, *The Case for a Parental Duty to Use Preimplantation Genetic Diagnosis for Medical Benefit*, 12 AM. J. BIOETHICS 3, 4 (2012).

9. *See* Azeen Ghorayshi & Sarah Kliff, *Accidents, Lax Rules and Abortion Laws Now Imperil Fertility Industry*, N.Y. TIMES (Feb. 22, 2024),

What this conventional wisdom overlooks is how inflated marketing claims could amplify existing legal and social pressures to expand its use. In June 2022, in *Dobbs v. Jackson Women's Health Organization*,[10] the U.S. Supreme Court overturned *Roe v. Wade*,[11] the case that for almost fifty years had afforded Americans the constitutional right to end a pregnancy before viability. Over a dozen states have since banned abortion, forcing some people to give birth to children they would not otherwise have had.[12] Others who are denied the abortion choice may seek to recover this lost sense of agency over their reproductive lives in other ways.[13]

Those with access to fertility care — the kind that lets them create embryos in a laboratory to screen — might try to learn as much as they can about a possible child, even before a pregnancy begins.[14] Using that information to help decide which among a number of embryos to transfer could offer an alternative way to rein in the uncertainties of reproduction for those already undergoing in vitro fertilization ("IVF") to treat infertility or who have the means to undertake it for the purposes of embryo screening. PES could be especially appealing because, compared with traditional forms of preimplantation genetic testing, it promises greater powers to screen embryos and select among them.[15]

Background social pressures may operate to encourage prospective parents to use PES to choose against embryos with increased risk for diseases or genetic conditions.[16] In public health messaging, for example, early justifications for prenatal genetic testing claimed that aborting fetuses with Down and Edwards syndromes could save states up to 66,000 dollars per child annually.[17] Popular parenting books also

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https://www.nytimes.com/2024/02/22/health/fertility-clinics-embryos-alabama.html [https://perma.cc/6YFY-35BC] (discussing three lawsuits involving destroyed embryos at a fertility clinic, which led to the Alabama Supreme Court ruling that "the embryos . . . should be considered children under state law, a decision that sent shock waves through the fertility industry and raised urgent questions about how treatments could possibly proceed in the state").

10. 597 U.S. § 215 (2022).

11. 410 U.S. § 113 (1973).

12. Caroline Kitchener*, An Abortion Ban Made Them Teen Parents. This is Life Two Years Later.*, WASH. POST (Aug. 1, 2022), https://www.washingtonpost.com/politics/interactive/2023/texas-abortion-law-teen-parents/ [https://perma.cc/UH7N-LRVF].

13. *See* W. Connor Gibbs, Heejung S. Kim, Aaron C. Kay & David K. Sherman, *Who Needs Control? A Cultural Perspective on the Process of Compensatory Control*, 17 SOC. & PERSONALITY PSYCH. COMPASS 1, 4 (2023).

14. *See* Carey Goldberg, *The Pandora's Box of Embryo Testing is Officially Open*, BLOOMBERG (May 26, 2022, 5:00 AM EDT), https://www.bloomberg.com/news/features/2022-05-26/dna-testing-for-embryos-promises-to-predict-genetic-diseases?embedded-checkout=true [https://perma.cc/XB6B-LVTV].

15. *See* Dov Fox, *Selective Procreation in Public and Private Law*, 64 UCLA L. REV. DISCOURSE 294, 299–300 (2016).

16. *See* Dov Fox, *Silver Spoons and Golden Genes: Genetic Engineering and the Egalitarian Ethos*, 33 AM. J.L. & MED. 567, 571, 582, 606 (2007).

17. ALEXANDRA MINNA STERN, TELLING GENES: THE STORY OF GENETIC COUNSELING IN AMERICA 25 (2012).

describe prenatal testing as part of the natural course of good parenting and preparing for one's future child.[18] That prenatal testing has become so routinized only further heightens those pressures.[19]

All these messages contribute to a sense of individualized responsibility to use genetic information to manage self and family health, which can fuel disability stigma.[20] Health-related stigma (e.g., mental-illness stigma) further motivates decisions to select against polygenic conditions such as schizophrenia and depression.[21] Parents may be held unreasonably accountable for their children inheriting conditions because they did not (or could not) screen their embryos for some disease or another.[22] Social pressures to test are magnified and gendered for pregnant people; research shows that, in particular, women who opt out of testing or knowingly birth a disabled child tend to be characterized as "irresponsible" or "irrational."[23]

The law may also indirectly push providers to offer PES based on fear that the failure to do so could lead to potential liability.[24] Specifically, providers may worry about wrongful birth suits brought by parents for a provider's failure to identify and inform parents of health risks that would have impacted the parents' reproductive decisions.[25] In the PES context, parents might claim that they would have selected a different embryo if they had been offered PES and learned of a particular risk that manifested itself in the child they had. The success of such claims would depend on several factors, such as whether the standard of care in IVF is to offer PES. But even if PES testing is not yet the standard, fears of liability could ironically drive it to include PES. We have already seen instances where fears of malpractice shaped the standard of care in reproductive genetics.[26]

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18. Such books suggest that the quest for reproductive information through prenatal testing "constitutes good maternal behavior," HELENA MICHIE & NAOMI CAHN, CONFINEMENTS: FERTILITY AND INFERTILITY IN CONTEMPORARY CULTURE 84 (1997), and "conscientious parenting," Suter, *supra* note 1, at 247.

19. *See* Suter, *supra* note 1, at 241, 246, 248.

20. Carlos Novas & Nikolas Rose, *Genetic Risk and the Birth of the Somatic Individual*, 29 ECON. & SOC'Y 485, 496 (2000).

21. *See* Doron Dorfman, *Selecting for Disability: How an Anecdote Can Inspire Regulation of Genetic Reproductive Technologies*, 38 HARV. J.L. & TECH. 441 (2024).

22. *See* Dov Fox, *Interest Creep*, 82 GEO. WASH. L. REV. 273, 332 (2014).

23. JENNIFER M. DENBOW, GOVERNED THROUGH CHOICE: AUTONOMY, TECHNOLOGY, AND THE POLITICS OF REPRODUCTION 82, 84 (2015).

24. *See* 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, 424–27 (2024) (discussing the way in which fears of liability may drive physicians to use polygenic risks scores in medicine).

25. For discussion of why parents may bring such suits, see Cailin Harris, *Statutory Prohibitions on Wrongful Birth Claims and Their Dangerous Effects on Parents*, 34 B.C. J.L. & SOC. JUST. 365, 384–87 (2014).

26. *See* Suter, *supra* note 1, at 251–54 (describing how liability concerns led doctors to push maternal serum alpha-fetoprotein ("MSAFP") testing for all pregnant women, despite

The success of a wrongful birth claim regarding PES would also depend on whether parents could prove causation — that is whether they could show that, but for the PES results they received, they would have selected a different embryo. This is not a simple matter to prove, given that the PES information would likely have offered a complex set of tradeoffs; some embryos might have increased risks for one condition while other embryos might be at risk for another, each with different chances of presenting. Finally, the risk of liability depends on where IVF is offered. The majority of wrongful birth claims are claims that allege misconduct after a pregnancy has been started, for example, by distorting or withholding information that would have prompted an abortion. In contrast, a wrongful birth claim for PES would be a preconception claim, which some, but not all,[27] jurisdictions recognize. And while the majority of jurisdictions still allow wrongful birth claims generally,[28] an increasing number, which tend to be states that ban abortion, prohibit such claims.[29] How much the law will shape the use of PES remains to be seen, but one could imagine it playing a role in making PES more routine.

Routinization of reproductive genetic testing has led to dwindling numbers of people with certain disabilities. In Denmark, for example, ninety-five percent of pregnancies diagnosed with Down syndrome were terminated, resulting in only eighteen children born with the condition in 2019; the United States follows closely, with almost seventy percent of pregnancies identifying Down syndrome terminated.[30] While genetic testing enables important reproductive choices, social pressures to test and select particular outcomes may influence these decisions.[31] These pressures include media portrayals of people with disabilities that generate unfavorable perceptions about how they cause social inconvenience or struggle to engage in everyday activities that are poorly designed to accommodate them.[32]

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shortcomings like high false positive rates that the American College of Obstetricians and Gynecologists ("ACOG") warned could "increase cost and parental anxiety . . . and possibly lead to unnecessary abortions").

27. *See., e.g.*, Grossbaum v. Genesis Genetics Inst., No. 07-1359, 2011 WL 2462279 (D.N.J. June 10, 2011); Doolan v. IVF America (MA) Inc., No. 993476, 2000 WL 33170944 (Mass. Super. Ct. Nov. 20, 2000).

28. JUDITH DAAR, I. GLENN COHEN, SEEMA MOHAPATRA & SONIA SUTER, REPRODUCTIVE TECHNOLOGIES AND THE LAW 435 (3d ed. 2022).

29. Sonia M. Suter, *Why Reason-Based Abortion Bans Are Not a Remedy Against Eugenics: An Empirical Study*, 10 J.L. & Biosciences 1, 50–51 (2023).

30. Sarah Zhang, *The Last Children of Down Syndrome*, THE ATLANTIC (Dec. 2020), https://www.theatlantic.com/magazine/archive/2020/12/the-last-children-of-down-syndrome/616928/ [https://perma.cc/4M7Q-BKAW].

31. *See, e.g.*, Anthony F. Herzig, Françoise Clerget-Darpoux & Emmanuelle Génin, *The False Dawn of Polygenic Risk Scores for Human Disease Prediction*, 12 J. PERSONALIZED MED., July 31, 2022, at 7.

32. *See* Dov Fox, *Birth Rights and Wrongs: Reply to Critics*, 100 B.U. L. REV. ONLINE 159, 165–66 (2020).

With PES increasing the range of conditions that can be the basis for reproductive choices, it is essential that parents and providers recognize social pressures as they consider screening.[33] Others have already considered the ethics around whether and how parents ought to select for offspring traits.[34] Our focus in this paper is different. We examine how companies advertise and clinicians implement PES. We argue that these professionals should not overpromise the value or utility of such testing and must be clear to communicate with care about its meaning and significance.

Consumer-oriented testing products have long been prone to marketing claims that overstate a technology's capacities or obfuscate its limitations.[35] Research shows that genetic testing companies that market to consumers often fail to clarify the role of environmental factors and complex uncertainties that characterize risk estimates, as well as obscure the fact that other possible genetic variants associated with a condition are unknown or untested.[36] Testing embryos for multiple conditions can sometimes be less useful than selecting embryos based on just one, as we explain below.[37] For investors, the foray into common complex conditions presents an appealing expansion in the genetic testing market despite the more complex ethical questions that it raises compared with monogenetic testing, again discussed shortly. Finally, while clinicians keep the gates of emerging market-based fertility technologies, these fertility specialists may feel pressured to yield to patient requests for PES even before they consider it ready for routine clinical use.[38]

PES companies promise "actionable, clear results" on information about their embryos' future health.[39] But these results often come in the form of polygenic risk scores ("PRSs") that can be complicated and difficult to interpret, especially when they are generated for multiple

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33. *See* Dov Fox, *Reproducing Race in an Era of Reckoning*, 105 MINN. L. REV. HEADNOTES 233, 246 (2021); Dov Fox, *Racial Classification in Assisted Reproduction*, 118 YALE L.J. 1844, 1885–86 (2009).

34. *See, e.g.*, JONATHAN ANOMALY, CREATING FUTURE PEOPLE: THE SCIENCE AND ETHICS OF GENETIC ENHANCEMENT 122–24 (2d ed. 2024); DOV FOX, BIRTH RIGHTS AND WRONGS: HOW MEDICINE AND TECHNOLOGY ARE REMAKING REPRODUCTION AND THE LAW 162–64 (2019).

35. *See, e.g.*, Jessica Mozersky, Vardit Ravitsky, Rayna Rapp, Marsha Michie, Subhashini Chandrasekharan & Megan Allyse, *Toward an Ethically Sensitive Implementation of Noninvasive Prenatal Screening in the Global Context*, 47 HASTINGS CTR. REP. 41, 46 (2017).

36. *See* Melody Petersen, *A Startup Says It Helps Parents Pick Healthier Embryos. Experts Say It's Not That Simple*, L.A. TIMES (May 26, 2021), https://www.latimes.com/business/story/2021-05-26/a-startup-says-it-helps-parents-pick-healthier-embryos-experts-say-its-not-that-simple [https://perma.cc/X6U2-8KZE].

37. *See infra* text accompanying notes 61–63.

38. Stacey Pereira, Shai Carmi, Gheona Altarescu, Jehannine Austin, Dorit Barlevy, Avner Hershlag et al., *Polygenic Embryo Screening: Four Clinical Considerations Warrant Further Attention*, 37 HUM. REPROD. 1375, 1376 (2022).

39. *Have Healthy Babies*, ORCHID HEALTH, https://www.orchidhealth.com/couple-report [https://perma.cc/F3RR-4G4S].

conditions all at once. LifeView, for example, packages these insights through "Embryo Health Scores," which provide overall disease predispositions and degrees of healthiness.[40] The scores allow parents "to compare overall disease risks among embryos and make decisions about which embryo to prioritize for transfer."[41] Another company, Orchid, will quantify "each embryo's genetic risk" for particular conditions and inform a transfer plan by "prioritiz[ing] transferring embryos with the lowest genetic risk."[42] Prospective parents receive results that highlight embryos' relative risk for specific diseases, as well as a hierarchical ranking of the embryos available for transfer.[43]

40. LIFEVIEW, https://lifeview.com [https://perma.cc/EN2S-KPFS]; *see also* Max Kozlov, *The Controversial Embryo Tests that Promise a Better Baby*, 609 NATURE 668–671 (2022).

41. *Embryo Health Score Test*, LIFEVIEW, https://www.lifeview.com/tests_pgtp.html [https://perma.cc/8R6Y-GKN5].

42. *Why Orchid is Different than Other Genetic Tests*, ORCHID, https://guides.orchidhealth.com/post/5-things-that-only-orchid-can-do [https://perma.cc/CL3E-QVRS].

43. *See* Mohammed H. Albujja, Maher Al-Ghedan, Lakshmidevi Dakshnamoorthy & Josep Pla Victori, *Preimplantation Genetic Testing for Embryos Predisposed to Hereditary Cancer: Possibilities and Challenges*, 2 CANCER PATHOGENESIS & THERAPY, May 14, 2023, at 2.

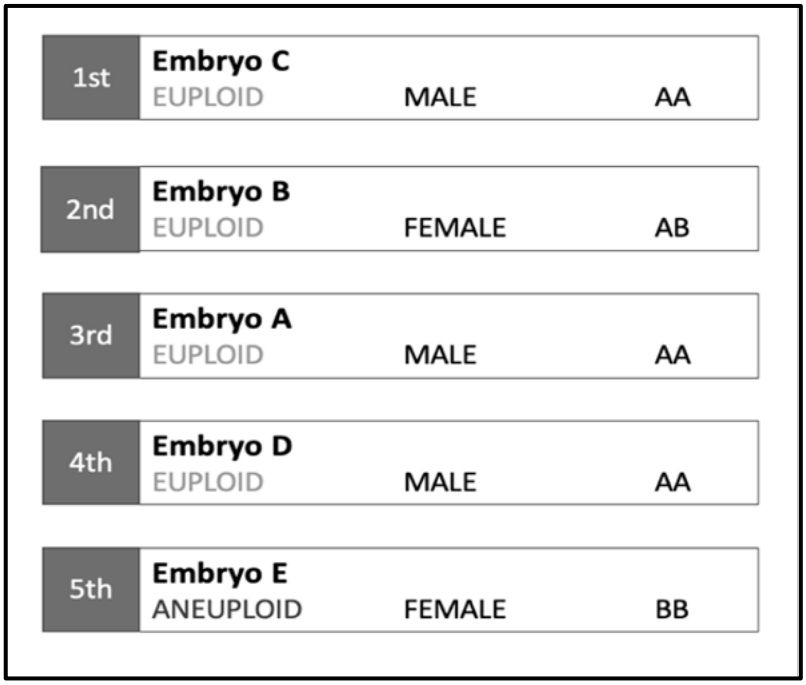
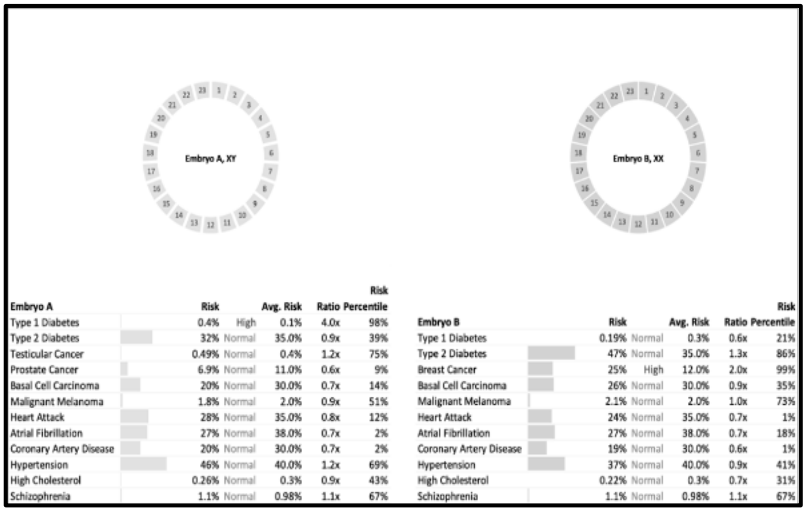


Figure 1: Sample Embryo Prioritization Report

Excluded from the figure above is any disclosure that indicates that it is based exclusively on the embryos' genetic information and that prospective parents looking to make reproductive decisions based on it should also discuss with their doctor which embryos they would recommend are most suitable for transfer.



Embryo A		Risk		Avg. Risk	Ratio	Risk Percentile
Type 1 Diabetes		0.4%	High	0.1%	4.0x	98%
Type 2 Diabetes		32%	Normal	35.0%	0.9x	39%
Testicular Cancer		0.49%	Normal	0.4%	1.2x	75%
Prostate Cancer		6.9%	Normal	11.0%	0.6x	9%
Basal Cell Carcinoma		20%	Normal	30.0%	0.7x	14%
Malignant Melanoma		1.8%	Normal	2.0%	0.9x	51%
Heart Attack		28%	Normal	35.0%	0.8x	12%
Atrial Fibrillation		27%	Normal	38.0%	0.7x	2%
Coronary Artery Disease		20%	Normal	30.0%	0.7x	2%
Hypertension		46%	Normal	40.0%	1.2x	69%
High Cholesterol		0.26%	Normal	0.3%	0.9x	43%
Schizophrenia		1.1%	Normal	0.98%	1.1x	67%

Embryo B		Risk		Avg. Risk	Ratio	Risk Percentile
Type 1 Diabetes		0.19%	Normal	0.3%	0.6x	21%
Type 2 Diabetes		47%	Normal	35.0%	1.3x	86%
Breast Cancer		25%	High	12.0%	2.0x	99%
Basal Cell Carcinoma		26%	Normal	30.0%	0.9x	35%
Malignant Melanoma		2.1%	Normal	2.0%	1.0x	73%
Heart Attack		24%	Normal	35.0%	0.7x	1%
Atrial Fibrillation		27%	Normal	38.0%	0.7x	18%
Coronary Artery Disease		19%	Normal	30.0%	0.6x	1%
Hypertension		37%	Normal	40.0%	0.9x	41%
High Cholesterol		0.22%	Normal	0.3%	0.7x	31%
Schizophrenia		1.1%	Normal	0.98%	1.1x	67%

Figure 2: Sample PES Results for Embryo A and B

The clinical value of PRSs in preimplantation settings is contested, which complicates the process through which embryo rankings and risk findings inform important reproductive decisions. There exists no reliable prospective data about the predictive power of these risk scores for adult diseases, so embryo screening predictions put their faith in models that have limited capacity to account for environmental factors.[44] Further, companies offer rankings that combine risk scores for multiple conditions, so an embryo with an increased risk for one condition but low risk for other conditions may be ranked higher than one that has an average risk for all conditions examined. Another challenge is that risk is probabilistic. Lower-risk embryos may still develop the condition and higher-risk ones may not.[45] Research also suggests that, when ranking embryos, the expected differences between embryos will be accompanied by wide confidence intervals.[46]

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44. Lázaro-Muñoz et al., *supra* note 2, at 432.

45. *See* Nathan R. Treff, Jennifer Eccles, Diego Marin, Edward Messick, Louis Lello, Jessalyn Gerber et al., *Preimplantation Genetic Testing for Polygenic Disease Relative Risk Reduction: Evaluation of Genomic Index Performance in 11,883 Adult Sibling Pairs*, 11 GENES, June 12, 2020, at 4.

46. Todd Lencz, Daniel Backenroth, Einat Granot-Hershkovitz, Adam Green, Kyle Gettler, Judy H. Cho et al., *Utility of Polygenic Embryo Screening for Disease Depends on the Selection Strategy*, 10 ELIFE, Oct. 12, 2021, at 13 ("[T]he accuracy of PRSs is sub-optimal when applied in non-European populations and across different socio-economic groups."); Turley et al., *supra* note 3, at 80 ("[T]he expected gains associated with ESPS are lower when the biologic parents have an ancestral background that is different from that of the study sample used to create the polygenic score. Almost all human genetics research to date has been conducted with research participants of European ancestries."); Ehud Karavani, Or Zuk, Danny Zeevi, Nir Barzilai, Nikos C. Stefanis, Alex Hatzimanolis et al., *Screening Human Embryos for Polygenic Traits Has Limited Utility*, 179 CELL 1424, 1431 (2019).

When applying PRS estimates for a specific disease, it is possible to achieve larger reductions in relative risk by comparing lots of embryos side by side. But this is unlikely to be feasible for people already using IVF because it may be difficult to generate sufficiently large numbers of embryos. In addition, PRSs are limited when the embryos come from the same egg and sperm because the significant overlap in their shared genes will diminish the genetic variability among them. Besides, restrictive legislation governing the creation and use of embryos might prevent people (directly or indirectly) from creating more than a few embryos,[47] making results about health risks less useful. Furthermore, for many conditions, large relative risk reductions translate into small absolute changes in the risk of developing the condition. For instance, reducing the chance of schizophrenia by half could constitute an absolute reduction of a fraction of a percent from 0.8 percent in the general population to 0.4 percent.[48] Finally, those of European ancestry see higher expected gains regarding risk insights because PRSs are based on mostly European data, while prospective parents of non-European ancestry would experience further reduced returns, especially if embryo use is limited.[49] PES companies must be pushed to better incorporate prospective parents' reproductive values around health and disability in an inclusive embryo ranking process alongside genetic counselors.[50]

These various risks associated with PES call for a regulatory response, at least to require providers of PES to refrain from making misleading claims or omissions likely to deceive consumers and materially affect their choices to use the resources offered to consumers. But regulatory alternatives are minimal at the federal level.[51] The Food and Drug Administration focuses narrowly on matters of safety and efficacy, thereby limiting its analysis to medical risks and benefits at the exclusion of moral values or other social consequences.[52] The single federal law that meaningfully regulates assisted reproduction — the Fertility Clinic Success Rate and Certification Act of 1992 — declines

47. Louisiana law states that "[a] viable in vitro fertilized human ovum is a juridical person which shall not be intentionally destroyed by any natural or other juridical person or through the actions of any other such person." LA. STAT. ANN. § 9:129 (2024).

48. Simona Corina Trifu, Bianca Kohn, Andrei Vlasie & Bogden-Eduard Patrichi, *Genetics of Schizophrenia (Review)*, 20 EXPERIMENTAL & THERAPEUTIC MED. 3462 (2020).

49. Goldberg, *supra* note 14; Lázaro-Muñoz et al., *supra* note 2, at 432; Turley et al., *supra* note 3, at 79.

50. *See* Dov Fox, *Family Planning and Its Limits*, 23 J. CONTEMP. LEGAL ISSUES 87, 103–04 (2021).

51. Dov Fox, *Reproductive Negligence*, 117 COLUM. L. REV. 149, 163–64 (2017); Dov Fox, *Making Things Right When Reproductive Medicine Goes Wrong: Reply to Robert Rabin, Carol Sanger, and Gregory Keating*, 118 COLUM. L. REV. ONLINE 94, 95–96 (2018).

52. Dov Fox, *Safety, Efficacy, and Authenticity: The Gap Between Ethics and Law in FDA Decisionmaking*, 2005 MICH. ST. L. REV. 1135, 1160–64; Naomi Cahn & Sonia M. Suter, *The Art of Regulating ART*, 96 CHI.-KENT L. REV. 29, 66, 79 (2021).

to grant that agency the authority to regulate any reproductive technologies that do not manipulate human cells the way gene editing does.[53] That leaves the Federal Trade Commission and professional organizations to monitor the marketing of PES companies and impose consequences for misleading, exaggerated, or discriminatory messaging. The FTC has the authority to prohibit unfair and deceptive practices and the dissemination of misleading claims regarding services. It could require PES companies to substantiate or temper claims about choosing the "healthiest" embryo or that the embryo ranked first would indeed have better health than others. Alternatively, it could establish criteria for sufficient evidence to substantiate declarations regarding the expected benefits and the necessary information that should be disclosed, just as it did when addressing the embellished claims that clinics made about success rates of IVF in the early days.[54] The government could establish such authority through an independent body of patient advocates, scientists, clinicians, ethicists, and other stakeholders. This body could function similarly to the U.S. Preventive Services Task Force (or the U.K.'s Human Fertilisation & Embryology Authority ("HFEA"))[55] and would need to have a clear and transparent process for making recommendations about which conditions can be examined for matters of health or otherwise. Such an organization could also establish interdisciplinary working groups to foresee and address ongoing ethical concerns.[56]

In the meantime, professional medical organizations should formulate policy guidelines. Professional organizations such as the American Society for Reproductive Medicine or American College of Medical Genetics and Genomics ought to advance practice guidelines for which conditions and traits should be tested for within specific contexts.[57] They could also provide guidance on embryo rankings that reflect inclusive reproductive values, including greater emphasis on collaboration with genetic counselors before and after testing. Fertility clinics should adopt similarly thoughtful standards.[58]

Another possibility is that PES companies self-regulate by transparently integrating stakeholder perspectives and publicizing the criteria they use for conditions they screen. But financial pursuits could

53. Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. §§ 263a-1 to 263a-7 (2000); U.S. FOOD & DRUG ADMIN., FDA REGULATION OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/P'S) PRODUCT LIST (2018).

54. *See* Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. §§ 263a-1 to a-7 (2000).

55. Cahn & Suter, *supra* note 52, at 67, 80 (describing the value in the United States of a regulatory body modeled after the British HFEA that would regulate assisted reproductive technologies).

56. *Id.* at 74; Lázaro-Muñoz et al., *supra* note 2, at 433; Turley et al., *supra* note 3, at 78, 84.

57. Lázaro-Muñoz et al., *supra* note 2, at 434; Roberts & Suter, *supra* note 24, at 435–37.

58. *See* Pereira et al., *supra* note 38, at 1376–77.

create conflicts of interest that limit the effectiveness of self-regulation. Companies should demonstrate that the information provided to their customers is clinically validated and readily comprehensible despite the challenges of conveying such information accurately and communicating risk and uncertainty effectively. Companies must exercise care in their communications across platforms, including blogs, websites, advertising materials, and public statements about the potential benefits and risks of PES for a diverse consumer base. For example, healthcare providers and commercial entities should communicate estimated risks and gains in absolute and relative terms together with their relative uncertainty in the form of tables, figures, and other easy-to-understand materials.

To avoid misleading generalizations or clinical translations that lack practical significance, they should disclose ancestry and risk-specific estimates for each phenotype that is screened, including for multiple phenotypes simultaneously. European ancestry-skewed datasets make polygenic screening conspicuously less effective for individuals with non-European ancestry.[59] Commercial entities should also openly acknowledge expected gains for each ancestral group. For embryos that point to multiple ethnic backgrounds, they should use straightforward and specific language instead of technical or generalized disclaimers that are buried in fine print.[60]

The challenge of decision-making goes beyond making polygenic information intelligible. There is also the evaluative process of choosing which embryos to transfer based on the genomic profiles. Parents face the daunting task of evaluating and comparing the genomic profiles of these embryos, weighing each relative risk — of different medical conditions, non-medical traits, and the probabilities associated with each embryo — against the others. Parents would need to navigate the trade-offs between various genetic variants associated with different health risks and non-medical traits. For example, they might need to decide between embryos with a higher risk of certain diseases but a lower risk of others, or embryos with desirable physical traits but less desirable intellectual traits.[61] Decision-making could be further complicated due to pleiotropy, where genetic variations can influence multiple phenotypes. For example, higher educational attainment is associated

59. Goldberg, *supra* note 14; Lázaro-Muñoz et al., *supra* note 2, at 432; Turley et al., *supra* note 3, at 80, 81; *cf.* Dov Fox, *The Second Generation of Racial Profiling*, 38 AM. J. CRIM. L. 49, 61–65 (2010) (discussing geographically skewed databases from which forensic evidence is drawn about genetic ancestry and appearance).

60. Turley et al., *supra* note 3, at 85.

61. *See* Dov Fox, *The State's Interest in Potential Life*, 43 J.L. MED. & ETHICS, 345, 348–54 (2015).

with an increased risk of bipolar disorder.[62] When parents choose to select for or against a particular trait or condition in embryos, they might unintentionally influence the likelihood of another trait or condition.

This evaluation process is further complicated by the probabilistic nature of genetic information, making it challenging to predict the actual outcomes for each embryo. Then, there is the difficulty of comparing different genetic profiles to choose embryos that offer the preferred combination of health and non-medical traits for the future child in light of factors such as risks for diseases, traits, and potential interactions between genetic variants. Making these decisions for even a handful of embryos could tax would-be parents with decision fatigue and choice overload,[63] perhaps even to the point that it poses a problem for the ethical underpinnings of informed consent: self-determination, autonomy, and respect for persons.[64]

In practice, information and choice overload can create confusion, complicate decision-making, and diminish the meaningful weighing of risks and benefits for the many different probabilistic tradeoffs among medical and non-medical traits that can arise with PES. With such a wide range of probabilistic data, patients might become overwhelmed by the complexity and sheer volume of information. This overload of data could hinder their ability to fully comprehend the choices at hand and their respective implications. If information is too abundant or convoluted, patients might struggle to grasp its significance, which impairs their clear understanding of the information presented to them. These complications could compromise the quality of decision-making by misaligning a patient's choice with her preferences, values, and beliefs, forcing individuals to resort to simplifying strategies or biases, such as choosing a default option or an option influenced by external forces. This means that the ethical ideals of informed consent — a well-informed decision made possible through well-explained and thoroughly understood information — may not be realized, particularly with respect to complex information.

Informed consent doctrine fails to adequately protect patients from making ill-considered decisions about their care. The doctrine aims to ensure not only that patients have the capacity to make well-informed

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62. Aysu Okbay, Jonathan P. Beauchamp, Mark Alan Fontana, James J. Lee, Tune H. Pers, Cornelius A. Rietveld et al., *Genome-Wide Association Study Identifies 74 Loci Associated with Educational Attainment*, 533 NATURE 539, 540 (2016).

63. Sonia M. Suter, *The Tyranny of Choice: Reproductive Selection in the Future*, 5 J.L. & BIOSCIENCES 262, 276–78 (2018) (describing these challenges as "paralysing choices" that create the problem of "choice overload").

64. *See generally* Johan Bester, Cristie M. Cole & Eric Kodish, *The Limits of Informed Consent for an Overwhelmed Patient: Clinicians' Role in Protecting Patients and Preventing Overwhelm*, 18 AMA J. ETHICS 869 (2016) (discussing the limits of informed consent related to factors that can overwhelm decision-making capacity).

decisions but also that they can make educated and autonomous decisions about their healthcare and treatment options based on their understanding of risks, benefits, and alternative medical procedures.[65] Informed consent seeks to honor patients as self-governing agents to determine the best course of action in regard to medical treatment.[66] In theory, the doctrine ensures that consent is truly informed, but courts have understood the legal obligation to require *disclosure* of material information without a corresponding obligation to ensure that patients truly *comprehend* the disclosed information.[67] To truly promote such comprehension, complex medical data should be communicated in digestible chunks and incrementally. For example, the use of visual decision aids and graphs can improve patient understanding and information attainment.[68] Clinicians can also extend the decisional time frame to allow more flexibility for the patient, along with the opportunity to seek advice and support from various members of a care team with skills and expertise in translating the data and facilitating patient understanding.

Scholars have begun to explore potential remedies to address the decision-making challenges posed by the "tyranny of choice" when patients confront an overload of information in the context of reproductive testing.[69] Some have suggested categorizing genomic information based on characteristics including age of onset, medical relevance, severity, and likelihood of condition occurrence to provide clinicians and medical professionals with a structured framework to present information that acknowledges the limitations of patients' comprehension of medical and scientific data, while also aiding individuals in navigating the increasing range of choices available with preimplantation genetic testing ("PGT").[70] But this kind of classification can be difficult in practice.[71]

Algorithms may help prospective parents comprehend and navigate the overwhelming amount of information that could be obtained with expanded PGT, so they can make informed decisions. Algorithms

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65. *See* RUTH R. FADEN, TOM L. BEAUCHAMP & NANCY M. P. KING, A HISTORY AND THEORY OF INFORMED CONSENT 7–9 (1986).

66. *See* Dov Fox, *Medical Disobedience*, 136 HARV. L. REV. 1030, 1066, 1085–86 (2023).

67. Sonia M. Suter, *The Politics of Information: Informed Consent in Abortion and End-of-Life Decision Making*, 39 AM. J.L. & MED. 7, 14 (2013).

68. Suter, *supra* note 63, at 282.

69. *Id.* at 287–300 (discussing algorithms as a potential remedy for paralyzing choices).

70. Eline M. Bunnik, A. Cecile J.W. Janssens & Maartje H.N. Schermer, *A Tiered-Layered-Staged Model for Informed Consent in Personal Genome Testing*, 21 EUR. J. HUM. GENETICS 596, 597–98 (2013); Jonathan S. Berg, Muin J. Khoury & James P. Evans, *Deploying Whole Genome Sequencing in Clinical Practice and Public Health: Meeting the Challenge One Bin at a Time*, 13 GENETICS MED. 499, 501–03 (2011).

71. Leila Jamal, Jill O. Robinson, Kurt D. Christensen, Jennifer Blumenthal-Barby, Melody J. Slashinski, Denise Lautenbach Perry et al., *When Bins Blur: Patient Perspectives on Categories of Results from Clinical Whole Genome Sequencing*, 8 AJOB EMPIRICAL BIOETHICS 82, 86–87 (2017).

could use computational methods to help parents select embryos for transfer based on specific criteria that have been generated using an individualized or generic algorithm.[72] Individualized algorithms could be developed based on questionnaires that first evaluate the genomic characteristics parents desire; the algorithms would then score embryos according to the parents' responses and preferences. In contrast, generic algorithms would provide a more standardized method to select embryos by awarding points to genotypes associated with diseases, taking into account severity, impairment, and age of onset. Different categories would be weighted differently, and scores would be adjusted based on the probabilistic association between traits and genetic variants. Generic algorithms might universally select against conditions due to their gravity, while other algorithms might include some variation based on personal preferences for less serious characteristics. Both types of algorithms could theoretically incorporate variants associated with nonmedical traits, but the inclusion of such traits would probably depend on factors like professional guidelines and the creators who developed the algorithms. Ultimately, providers and clinics would likely determine the extent to which patients could choose attributes to select for or against.

While in theory these algorithms would be created to maximize informed decision-making, they are fraught with problems.[73] First, they could be developed by professional societies, healthcare providers, or commercial entities, each of which may have its own set of social biases around race, disability, or other factors that could be reflected in the algorithms.[74] Moreover, the biases are likely to be hidden, making it harder to respond to them directly. If the algorithms push many people towards the same types of choices, they could lead to a reduction of diversity and have potential eugenic implications. Routine use of algorithms could also challenge the traditional role of healthcare professionals and shift decision-making power from the patient to the physician. All of these risks seem to conflict with important bioethics principles.

Determining the appropriate professional and policy response to the enormous decisional challenges associated with PES will be a daunting task. The current polarization surrounding abortion and reproduction only intensifies the issues in this space. The *Dobbs* decision makes patently clear that states have a broad range of authority to regulate and even ban abortion. As scholars have noted, the reasoning of *Dobbs* also grants states authority to regulate or ban IVF and PGT.[75] Indeed, the decision explicitly declares that states have a legitimate

72. Suter, *supra* note 63, at 288.

73. Suter, *supra* note 63, at 293–300.

74. *Id.* at 297–99; *see also supra* text accompanying notes 32.

75. *See* Gerard Letterie & Dov Fox, *Legal Personhood and Frozen Embryos: Implications for Fertility Patients and Providers in Post-*Roe *America*, 10 J.L. & BIOSCIENCES 1, 2 (2023).

interest in protecting prenatal life at "all stages of development,"[76] which could include IVF-created embryos. Recently, the Alabama Supreme Court determined that frozen embryos are persons for purposes of the state's wrongful death statute.[77] Attributions of in vitro personhood raise the prospect that much of this technology would be difficult, if not impossible, to access in states that follow suit.[78]

The current state of science and politics creates a deep paradox at this moment. On the one hand, technologies are expanding reproductive options so vastly that they are complicating decision-making. On the other hand, the Supreme Court's interpretation of the Constitution allows states to thwart reproductive choice more broadly than ever. How states respond to the complex tensions at work is bound to shape social attitudes about reproduction in significant ways.[79]

76. Dobbs v. Jackson Women's Health Org., 597 U.S. 215, 301 (2022).

77. *See* LePage v. Ctr. for Reprod. Med., No. CV-21-901607, 2024 WL 656591, at *3, *7 (Ala. Feb. 20, 2024).

78. *See* Mary Ziegler, Naomi Cahn & Sonia Suter, *The Massive Legal Fallout from Alabama's IVF Ruling Is Just the Beginning*, MSNBC (Feb. 22, 2024, 2:32 PM EST), https://www.msnbc.com/opinion/msnbc-opinion/alabama-ivf-supreme-court-consequences-rcna140004 [https://perma.cc/WUR8-FFT3]; Janice H. Tanne, University in Alabama Halts IVF Treatments after Court Rules Embryos Are Children, 384 BMJ, Feb. 22, 2024.

79. *See* Dov Fox & Christopher L. Griffin, Jr., *Disability-Selective Abortion and the Americans with Disabilities Act*, 2009 UTAH L. REV. 845, 866, 870.