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THE LEGAL UNCERTAINTIES OF SOCIOGENOMIC POLYGENIC SCORES

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ABSTRACT

Genomics may increasingly be used to predict associations with social traits through a new field called sociogenomics. This approach includes developing genetic 'scores' to identify associations with individuals' traits like educational attainment, feelings of loneliness, aggressive behavior, and criminality. Companies are already testing embryos to select for some of these traits, and these scores could be adopted by industries and settings beyond commercialized reproductive genetic testing services. The nature of the scores raises concerns about the potential dangers of a passive regulatory approach. Although supporters argue that sociogenomic polygenic scores could help mediate social inequality, there are worries that their implementation into society could be discriminatory and inequitable. Without adequate safeguards, it could have severe consequences for adults using IVF services, students, health insurance beneficiaries, employees, and others in the future. While existing legal structures are in place to regulate medical genetic information, these protections have their own flaws, and further, do not clearly extend to polygenic scores. Policy makers must therefore consider the potential harms of sociogenomic polygenic scores, and how to maximize any benefits.

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TABLE OF CONTENTS

I. INTRODUCTION

During their journey to become parents, a couple debates whether to prioritize implantation of an embryo that carries genetic variants correlated with success in school. Across town, a jury considers mitigating evidence suggesting that a man on trial carries genetic variants associated with an increased likelihood of engaging in aggressive behavior. At the same time, a high school implements standards for collecting, storing, and assessing applicants' genetic scores associated with educational attainment and risk-seeking behaviors. Depending on whom you ask, these are possible dystopic or utopic futures presented by a new ability to measure polygenic influences, or the combined effects of many genes, on conditions or traits through polygenic scores. Polygenic scores for social and behavioral traits ("PGSs")[1] are closely related to polygenic risk scores ("PRSs") — scores that measure associations with medical conditions and diseases — but raise unique legal and ethical challenges.

Polygenic risk scores for medical traits are currently available commercially[2] and backed by significant financial investments in medical

1. PGSs are also referred to as polygenic "indexes" in order to avoid giving "the impression of a value judgment where one is not intended." *See* Joel Becker, Casper A. P. Burik, Grant Goldman, Nancy Wang, Hariharan Jayashankar, Michael Bennett et al., *Resource Profile and User Guide of the Polygenic Index Repository*, 5 NATURE HUM. BEHAV. 1744 (2021), box 1.

2. *See* Anna C.F. Lewis & Robert C. Green, *Polygenic Risk Scores in the Clinic: New Perspectives Needed on Familiar Ethical Issues*, 13 GENOME MED. 1, 3 (2021) ("[Polygenic

research.[3] Recently, social scientists have begun utilizing score development methods beyond the medical context to measure associations with traits such as educational attainment, social mobility, well-being, and risk-seeking behavior.[4] PGSs help researchers elucidate, and when possible differentiate between, genetic and environmental influences on life outcomes and behavior.[5] Environmental influences could be physical, such as diet or pollution exposures, or social, such as the policies, people, and communities with whom and where individuals interact and live. For example, sociologists interested in the effects of gender discrimination on the educational attainment of women might include research on whether oppressive gender-based social practices and institutional policies inhibit the prospects of women with a high PGS for educational attainment.[6]

However, the potential to implement PGSs into policy and social science research is fraught with challenges. One widely expressed concern is the possibility that PGSs will become tools of eugenics and white supremacy.[7] In the United States, behavioral genomics gained ground during the eugenics era, a time that led to forced sterilization[8] (a practice that is still legal in some jurisdictions[9]), prohibitive

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risk scores] that are commercially available include those from Myriad Genetics for breast cancer risk, from Ambry Genetics for breast cancer and prostate cancer risk, and from 23andMe for type 2 diabetes risk." (citations omitted)).

3. *See, e.g.*, Prabarna Ganguly, *NIH Awards $38 Million to Improve Utility of Polygenic Risk Scores in Diverse Populations*, NAT'L HUM. GENOME RSCH. INST. (June 16, 2021), https://www.genome.gov/news/news-release/nih-awards-38-million-dollars-to-improve-utility-of-polygenic-risk-scores-in-diverse-populations [https://perma.cc/C9A3-VJ6N] ("The National Institutes of Health (NIH) will fund grants totaling $38 million over five years to develop methods that will improve the way that polygenic risk scores can be used to predict disease in diverse communities.").

4. *See* Melinda C. Mills & Felix C. Tropf, *Sociology, Genetics, and the Coming of Age of Sociogenomics*, 46 ANN. REV. SOCIO. 553 (2020) (discussing the growing use of genetic testing in social sciences).

5. *See, e.g.*, DALTON CONLEY & JASON FLETCHER, THE GENOME FACTOR: WHAT THE SOCIAL GENOMICS REVOLUTION REVEALS ABOUT OURSELVES, OUR HISTORY, AND THE FUTURE 3 (2017) ("By actively accounting for the portion of IQ, education, or income that is the result of genes, we can see more clearly the inequities in environmental inputs and their effects on individual's chances in the game of life."); *see also* Mills & Tropf, *supra* note 4, at 567.

6. Pamela Herd, Jeremy Freese, Kamil Sicinski, Benjamin W. Domingue, Kathleen Mullen Harris, Caiping Wei et al., *Genes, Gender Inequality, and Educational Attainment*, 84 AM. SOCIO. REV. 1069, 1070 (2019) (finding that, as historical constraints on gender declined, the predicted association between genetics and educational attainment grew).

7. *See, e.g.*, Aaron Panofsky, Kushan Dasgupta & Nicole Iturriaga, *How White Nationalists Mobilize Genetics: From Genetic Ancestry and Human Biodiversity to Counterscience and Metapolitics*, 175 AM. J. PHYSICAL ANTHROPOLOGY 387, 388 (2021).

8. Michelle N. Meyer, Paul S. Appelbaum, Daniel J. Benjamin, Shawneequa L. Callier, Nathaniel Comfort, Dalton Conley et al., *Wrestling with Social and Behavioral Genomics: Risks, Potential Benefits, and Ethical Responsibility*, 53 HASTINGS CTR. REP. S2, S9 (2023) (discussing the advent of the use of polygenic methodology for social and behavioral traits).

9. NAT'L WOMEN'S L. CTR., FORCED STERILIZATION LAWS IN EACH STATE AND TERRITORY (2022).

interracial marriage laws that were ruled unconstitutional only 60 years ago,[10] and 20th century eugenic immigration restrictions.[11] In May 2022, a gunman misappropriated and distorted research on genetics to serve his white supremacist ideologies and committed racially-targeted mass murder at a supermarket in Buffalo, New York.[12] Clearly, this act of hate and violence should be condemned in the strongest possible terms by lawmakers and scientists. Less clear is how the genomics field should respond to the weaponization of sociogenomic PGSs in white supremacy circles and the misappropriation of genomics research for nefarious purposes. To facilitate guidance in this area, there is now renewed attention to the need for strategies to mitigate the spread of misinformation and misleading representations of the field's findings.[13]

Still, there is another insidious danger raised by sociogenomic PGSs — the unchecked implementation of the scores in commercial, educational, criminal, and other nonmedical settings as well as their integration into reproductive services. Some uses of PGSs, such as to evaluate how a person's social environment promotes or constrains genetic influences, could be beneficial,[14] but widespread use of PGSs, especially without sufficient guardrails, may lead to increased disparities, discriminatory impacts, and unintended consequences.[15] The use of PGSs across society may, on the surface, appear less problematic than some of the concerns we articulated above (misappropriation, misinterpretation, weaponization), but could result in pernicious, long-lasting social and civil rights harms without adequate legal consideration or recourse.

Existing legal structures are in place within the medical realm to regulate how genetic information, including medical PRSs, are handled. While these existing legal structures have their own flaws,[16] novel harms due to the use of PGSs may fall outside even these established

10. *See* Loving v. Virginia, 388 U.S. 1,12 (1967) ("[T]he freedom to marry, or not marry, a person of another race resides with the individual, and cannot be infringed by the State.").

11. TROY DUSTER, BACKDOOR TO EUGENICS 13–14 (2004).

12. Megan Molteni, *Buffalo Shooting Ignites a Debate over the Role of Genetics Researchers in White Supremacist Ideology*, STAT (May 23, 2022), https://www.statnews.com/2022/05/23/buffalo-shooting-ignites-debate-genetics-researchers-in-white-supremacist-ideology/ [https://perma.cc/TB2M-SD8L].

13. *See* Robbee Wedow, Daphne O. Martschenko & Sam Trejo, *Scientists Must Consider the Risk of Racist Misappropriation of Research*, SCI. AM. (May 26, 2022), https://www.scientificamerican.com/article/scientists-must-consider-the-risk-of-racist-misappropriation-of-research/ [https://perma.cc/QFS4-6YRA].

14. *See, e.g.*, Herd et al., *supra* note 6, at 1070 (helping to contextualize educational attainment scores across historical trends); *see also* Mills & Tropf, *supra* note 4, at 567 (mapping the history of merging genetics into social science and the benefits of this practice).

15. *See, e.g.*, CONLEY & FLETCHER, *supra* note 5, at 4 (arguing that a new type of inequality could emerge as those with power and resources selectively "breed themselves" based on knowledge of their genotype).

16. *See, e.g.*, 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) (discussing PRSs impact on medical malpractice).

legal guardrails.[17] Traditionally, many nonmedical genetic tests have been thinly regulated, in part because they are seen as posing little threat to individuals and society.[18] Yet, the same sparse regulatory framework may also be applied to PGSs, such as those related to intellect or aggression, despite the greater risks of harm.

This article illuminates the perils of a passive regulatory approach. Part II defines sociogenomic PGSs and describes their history, draw, and concerns. Part III describes the legal uncertainties around PGSs, including how the expansion of genetic testing into social and behavioral traits disturbs existing legal regimes. Part IV goes into depth about the potential social harms raised by PGSs, especially those outside the bounds of current laws. Part V concludes by highlighting where innovative legal and nonlegal approaches may be necessary to mitigate harms and maximize identifiable benefits. Regardless of whether regulators are prepared for sociogenomic PGSs, their use is likely to expand far beyond the reach of available commercialized genetic testing services and into nonmedical domains policy makers may not anticipate.

II. WHAT ARE SOCIOGENOMIC PGSS?

Sociogenomics refers to a growing field of genomics research focused on polygenic effects on social and behavioral phenotypes.[19] Genome-wide association studies ("GWASs"), studies that leverage genomic data from biobanks to identify correlations between genes and phenotypes, have identified thousands of genetic variations correlated with complex traits.[20] Taken alone, each variant accounts for a small proportion of observed variance in phenotype. By aggregating the genetic variants known to increase or decrease associations with a trait and weighting each variant based on estimated impact, scientists can calculate a PGS.[21] PGS reports typically stratify results and report

17. *See infra* Part III.

18. *See infra* Section III.D.

19. Mills & Tropf, *supra* note 4, at 558 (detailing the history of sociogenomics, including the rise of PGS and their limitations). It should be noted that all traits exist on a continuum, with some more squarely medical (such as cancer), and some more purely social (such as income). However, many exist in a blurry space between the two, such as a polygenic score for aggression or depression. In this Article, we tend to refer to social and behavioral traits as those that are not associated with a medical diagnosis. *See* Courtney Canter, Karen M. Meagher, R. Jean Cadigan, Amy M. Koopmann, Sara Watson, Matthew Kucmanic et al., *Scanning the Horizon of Sociogenomics* 12 (U. Iowa Legal Stud. Rsch. Paper No. 2024-34, 2024) (describing how to classify traits as "medical" and "social").

20. *See* Mills & Tropf, *supra* note 4, at 563; Linda Kachuri, Nilanjan Chatterjee, Jibril Hirbo, Daniel J. Schaid, Iman Martin, Iftikhar J. Kullo et al., *Principles and Methods for Transferring Polygenic Risk Scores Across Global Populations,* 25 NAT. REVS. GENETICS 8, 9 (2024).

21. *See* Kachuri et al., *supra* note 20, at 10; Eva Krapohl, Hamel Patel, Stephen Newhouse, Charles J. Curtis, Sophie von Stumm, Philip S. Dale et al., *Multi-Polygenic Score Approach*

whether an individual is more or less likely than others in the comparison group to have or develop the trait or behavior. However, the predictive power of PGSs applies to the group within which the score was developed (e.g., defined by demographic variables)[22] and lies at the group level; a single score may not align with whether any one individual is experiencing or manifesting the trait.[23] In other words, on average, those with high PGSs are more likely to have or develop the trait or behavior, but a specific individual may not develop the trait even with a high PGS score. Both medical PRSs and sociogenomic PGSs provide a breakthrough method for estimating genetic risk for, or presence of, complex traits and conditions in a way that is not possible using previous methodologies, like single-gene mutation testing.

A. The Current State of PGS Development

Even though development of PGSs in sociogenomics is relatively new, the field has rapidly progressed. Almost sixty traits have had PGSs developed and additional ones have been contemplated.[24] The traits range from subjective well-being to risk tolerance to reproductive behaviors (e.g., age at first birth) to income.[25] By far, the most studied social trait is educational attainment,[26] or completed years of schooling (this trait is often used to illustrate ethics and policy issues, as we do below). The largest study on educational attainment done so far has identified genetic variants that can account for about fourteen percent of the total observed variance, or differences in years of schooling across the population.[27] This contrasts with many other PGSs, which more commonly predict less than three percent of the variance in a trait.[28]

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to Trait Prediction, 23 MOLECULAR PSYCHIATRY 1368, 1368 (2018); *see also* Hakhamanesh Mostafavi, Arbel Harpak, Ipsita Agarwal, Dalton Conley, Jonathan K. Pritchard & Molly Przeworski, *Variable Prediction Accuracy of Polygenic Scores within an Ancestry Group*, 9 ELIFE, Jan. 30, 2020, at 1–2 (explaining that PGSs are most useful for predicting traits when the genetic influences are significant).

22. Kachuri et al., *supra* note 20, at 5–7.

23. Evan Charney, *The "Golden Age" of Behavior Genetics?*, 17 PERSPS. ON PSYCH. SCI. 1188, 1192 (2022) (noting that predictive value of polygenic scores is at the population level).

24. Canter et al., *supra* note 19, at 7.

25. *Id.* at 8.

26. *Id.*

27. Aysu Okbay, Yeda Wu, Nancy Wang, Hariharan Jayashankar, Michael Bennett, Seyed Moeen Nehzati et al., *Polygenic Prediction of Educational Attainment Within and Between Families From Genome-Wide Association Analyses in 3 Million Individuals*, 54 NAT. GENETICS 437, 440 (2022).

28. For example, a PGS developed for same-sex sexual behavior explains less than one percent of the variability. Andrea Ganna, Karin J. H. Verweij, Michel G. Nivard, Robert Maier, Robbee Wedow, Alexander S. Busch et al., *Large-Scale GWAS Reveals Insights into the Genetic Architecture of Same-Sex Sexual Behavior*, 365 SCIENCE 882, 886 (2019). The

Despite this limitation of predictive value compared to single-gene testing, for instance, PGSs have found growing interest among a wide variety of interdisciplinary fields. Researchers from sociology, economics, political science, demography, and psychology see promise in the ability of genes to help them better understand social science outcomes (and vice versa).[29]

B. PGS Applications

Proponents of PGS research believe that incorporating genomics into social science research could lead to more rigorous study, enable better understanding of gene-environment interactions, and eventually help create more equitable social policies.[30] For example, a sociogenomic researcher might use PGSs to assess when a discriminatory policy is suppressing members of a particular population's innate abilities to thrive. They may find, for instance, a high likelihood of educational attainment among a group of individuals within a given population (e.g., men in a particular zip code with primarily European ancestry) based on PGSs associated with success in school, but who are not succeeding. Identifying these individuals could reveal commonalities, such as membership in a particular socioeconomic class that could help to explain why this subgroup is failing to perform in line with their supposed genetic potential. According to one perspective, if PGSs are not used at all, that could result in social science research with an incomplete picture of the biological and environmental factors contributing to life outcomes.

Others are less convinced that these possibilities are realistic.[31] Genetic research into human behavior cannot elucidate the most important reasons behind the diverse social outcomes experienced by individuals from varying environments, such as a history of structural racism or discriminatory policies.[32] As discussed more in depth below, there is also the worry that, paralleling the problematic history of genomics, PGSs will be implemented into society in discriminatory and inequitable ways.[33]

PGS for income explains only about two percent of population variation. W. David Hill, Neil M. Davies, Stuart J. Ritchie, Nathan G. Skene, Julien Bryois, Steven Bell et al., *Genome-Wide Analysis Identifies Molecular Systems and 149 Genetic Loci Associated with Income*, 10 NATURE COMMC'NS., Dec. 19, 2019, at 15.

29. Meyer et al., *supra* note 8, at S27.

30. *Id.* at S2, S23, S28; KATHRYN PAIGE HARDEN, THE GENETIC LOTTERY: WHY DNA MATTERS FOR SOCIAL EQUALITY 20, 188, 192 (2021).

31. *See generally* Daphne Oluwaseun Martschenko, *Social Equality in an Alternate World*, 51 HASTINGS CTR. REP. 54 (2021).

32. *Id.*

33. *See infra* Part III.

C. The Portability Problem

The demographics (e.g., sex and age), environments, and ancestries of the study population affect the performance of PGSs in other populations characterized by different demographic variables, ancestries, and geographic and social environments.[34] In genomics, this phenomenon is called a 'portability' or 'transferability' problem.[35] In the context of sociogenomics, these terms mean that PGSs do not transfer well to populations that are different from the populations included in the underlying research.[36] A separate but relevant problem is that geneticists develop PGSs almost exclusively based on data from people with primarily European ancestries due to limitations in available genomic data from, and methodologies designed for, populations with diverse ancestries.[37] Due to portability issues and inequities in representation of diverse ancestries, available PGSs are known to perform better in populations with European ancestries than those with other ancestries.[38] While the genomics field is exploring innovative solutions and approaches to overcome these barriers,[39] PGSs are currently developed in ways that are distant from, and unrepresentative of, real-world ancestral diversity.[40] These concerns increase the likelihood that any promised benefits of social PGSs or medical PRSs will disproportionately accrue to people with predominantly European ancestries.

The portability problem also creates a challenge regarding how to report and apply results that have differential predictive value across different ancestries.[41] For example, there is a risk that some will apply results to everyone regardless of the underlying ancestries included in the studies.[42] Depending on the ancestries included in the underlying

34. Alicia R. Martin, Christopher R. Gignoux, Raymond K. Walters, Genevieve L. Wojcik, Benjamin M. Neale, Simon Gravel et al., *Human Demographic History Impacts Genetic Risk Prediction across Diverse Populations*, 100 AM. J. HUM. GENETICS 635, 635–36 (2017); Kachuri et al., *supra* note 20, at 5.

35. Martin et al., *supra* note 34, 635–36; *see also* Kachuri et al., *supra* note 20, at 9.

36. *See* Martin et al., *supra* note 34, at 641.

37. *See, e.g.*, *id.* at 635–36 (finding that polygenic risk scores for eight traits were more accurate for the population in the original study than in other populations and highlighting the need to include diverse populations in genomic research).

38. *Id.*; *see also* Kachuri et al., *supra* note 20.

39. *See* Kachuri et al., *supra* note 20, at 1, 9, 16 (describing methodological innovations for polygenic risk score development for diverse ancestries).

40. Martin et al., *supra* note 34, at 636.

41. *See, e.g.*, Anna C.F. Lewis, Rex L. Chisholm, John J. Connolly, Edward D. Esplin, Joe Glessner, Adam Gordon et al., *Managing Differential Performance of Polygenic Risk Scores Across Groups: Real-World Experience of the eMERGE Network*, 111 AM. J. HUM. GENETICS 999 (2024) (outlining choices made in one large research study to report differential performances of medical polygenic risk scores across ancestry populations).

42. There is precedence for this possibility. In an oft-cited study of laboratory test reports, for instance, investigators found that individuals with African or unspecified ancestry received false positives of hypertrophic cardiomyopathy. Later simulations showed that

research and the way the scores are reported, PGS models can be more likely to lead to false positive results for most other ancestries.[43]

The challenges of interpreting results across ancestries are further compounded by society's common conflation of race and ancestry. This conflation is likely to extend to sociogenomic PGSs, further exacerbating the portability problem by reinforcing incorrect notions that race has a biological basis.[44] For example, PGS providers might discuss available scores developed for populations with European ancestries with those who identify as White, without taking into account their ancestries, which may not perfectly or fully align with their identified race.[45] While leading professional organizations have recently provided guidance on how to develop and better describe populations by taking into account diverse ancestries, ethnicities, and geography,[46] reported sociogenomic PGSs rely on broad continental and easily racialized labels (e.g., European, African, Asian) to describe differences.[47] There are few reasons to believe that sociogenomic PGSs will rely on race any less than biomedical research and medicine have for generations.[48]

Even if providers of results may understand the problems of portability across ancestry groups, they may fail to consider that PGSs are not portable even within groups of similar ancestries (e.g., ancestries from different regions of Europe).[49] To raise awareness about the potential low or high likelihood of accuracy of results, communicators of these results may provide caveats about the portability of PGSs based on one's racial identity without also carefully explaining that racial groups have diverse ancestries,[50] social environments, and other demographics that could impact score performance.

The problems of disproportionate benefit due to portability and limited research across diverse populations is compounded when those with predominantly European ancestries are most likely able to access

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misdiagnoses could have been prevented by the inclusion of even small numbers of Black Americans in control cohorts. Arjun K. Manrai, Birgit H. Funke, Heidi L. Rehm, Morton S. Olesen, Bradley A. Maron, Peter Szolovits et al., Genetic Misdiagnoses and the Potential for Health Disparities, 375 NEW ENG. J. MED. 655 (2016).

43. Martin et al., *supra* note 34, at 643.

44. CATHERINE BLISS, SOCIAL BY NATURE: THE PROMISE AND PERIL OF SOCIOGENOMICS 93 (2018).

45. For example, some patients who identify as White may have African ancestries that impact their genotype.

46. *See e.g.*, NAT'L ACADS. OF SCIS., ENG., & MED., USE OF RACE, ETHNICITY, AND ANCESTRY AS POPULATION DESCRIPTORS IN GENOMICS RESEARCH (2022).

47. Meyer et al., *supra* note 8, at S37–S38.

48. *See, e.g.*, Vence L. Bonham, Shawneequa L. Callier & Charmaine D. Royal, *Will Precision Medicine Move Us Beyond Race?*, 374 NEW ENG. J. MED. 2003 (2016).

49. Mostafavi et al., *supra* note 21, at 2 (finding that polygenic scores do not port across other factors, such as socioeconomic status).

50. *See, e.g.*, Kathryn Maxson Jones, Robert Cook Deegan, Charles N. Rotimi, Shawneequa L. Callier, Amy R. Bentley, Hallam Stevens et al., *Complicated Legacies: The Human Genome at 20*, 371 SCIENCE 564, 566 (noting that the African continent is highly diverse in terms of ancestry and contains the most genetic variation in the world).

testing and follow-up resources to maximize any benefits of using these scores.[51] Disproportionate access has already surfaced in commercial settings related to PRSs. Many genetic testing laboratories including Myriad Genomics and Ambry first marketed their tests to individuals of European ancestries because their PRS tests were developed in those populations.[52] This situation raises an ethics and policy question about the implications of investing resources into genomics research approaches that exacerbate inequity, but also, as discussed below, whether or how the law might promote equity.

III. LEGAL UNCERTAINTIES

Many proponents of sociogenomics contemplate the use of PGSs predominantly within medical and social science research settings.[53] However, as this part will show, there are currently few legal and policy guardrails that would cabin PGS findings within the research realm. Thus, despite the intention, and perhaps hope, that these scores will not be used for other purposes, it is likely that PGSs will be incorporated into broader policy discussions and practice. Two specific examples illustrate that this possibility is not just hypothetical. First, several sociogenomic researchers have advocated for the use PGSs to help improve the educational system, through learning plans personalized to a child's genetic profile.[54] While these recommendations remain controversial, they show interest by some in leveraging known genetic contributions to a social trait to influence public policy. Second, sociogenomic findings have already percolated into commercial spaces, including those offering in vitro fertilization ("IVF").[55]

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51. *See* Meyer et al., *supra* note 8, at S28 (describing concerns that patients will lack access to predictive PRS in medical settings). For an additional example, in education contexts, some warn that resources will not be allocated to disadvantaged students. Others doubt that any benefits will be worth the stigmatization that is likely to follow. *Id.*

52. Antonio Regalado, *White-People-Only DNA Tests Show How Unequal Science Has Become*, MIT TECH. REV. (Oct. 18, 2018), https://www.technologyreview.com/2018/10/18/1980/white-people-only-dna-tests-show-how-unequal-science-has-become/ [https://perma.cc/99P9-T7DX].

53. *See, e.g.*, Kathryn Paige Harden, *On Genetics and Justice: A Reply to Coop and Przeworski*, 76 EVOLUTION 2469, 2469 (2022) (arguing that "genetics is currently most useful to social policy when used as a tool for improving basic research").

54. *See infra* Section III.C. *See generally* KATHRYN ASBURY & ROBERT PLOMIN, G IS FOR GENES: THE IMPACT OF GENETICS ON EDUCATION AND ACHIEVEMENT (John Wiley & Sons eds., 2013) (arguing for the concept of "precision education"). *But see* Daphne Martschenko, Sam Trejo & Benjamin W. Domingue, *Genetics and Education: Recent Developments in the Context of an Ugly History and an Uncertain Future*, 5 AM. EDUC. RSCH. ASS'N OPEN, Feb. 19, 2019, at 1 (discussing challenges to incorporating genomics into education).

55. *See infra* Section III.A; Matthieu C. de Hemptinne & Danielle Posthuma, *Addressing the Ethical and Societal Challenges Posed by Genome-Wide Association Studies of Behavioral and Brain-Related Traits*, 26 NATURE NEUROSCIENCE 932, 934–35 (2023).

The potential for increasing incorporation of PGSs into society raises many legal and policy implications. The following sections survey the complex and uncertain ways that sociogenomic PGSs could interact with U.S. legal structures. The paper provides hypothetical examples of PGS uses in five areas covered by distinct legal regimes: IVF, anti-discrimination in insurance and corporate settings, antidiscrimination in education, direct-to-consumer ("DTC") testing, and criminal justice. Each section then discusses the current state of regulation and how PGSs may fit into this existing legal framework. The paper begins with a discussion of sociogenomics in IVF because this is one of the first areas where PGSs have begun to arrive in practice.[56] The remaining four examples represent areas where there has been the greatest discussion regarding the use of PGSs and the greatest probable societal harms.

A. Embryo Selection in IVF

A couple going through IVF reviews genetic profiles of their frozen embryos to determine the order they will transfer them. The profiles include genetic scores for intelligence and educational attainment.

Several companies recently have begun offering PGS genetic testing to those utilizing IVF.[57] The idea is that individuals and couples can select the embryo that has the "best" genetic profile.[58] Preimplantation genetic testing ("PGT") has traditionally been used to identify hereditary disease and other conditions, but the same methods could be used to identify non-medical traits as well.[59] Commercial genetic testing companies are beginning to sell sociogenomic PGT services, and their offerings could expand.[60] One company reportedly included PGSs for

56. *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 GENETICS MED. 432, 433 (2021); Courtney Canter, Kathleen Foley, Shawneequa L. Callier, Karen M. Meagher, Margaret Waltz, Aurora Washington et al., *The Slippery Slope of Prenatal Testing for Social Traits*, 23 AM. J. BIOETHICS 36 (2023).

57. de Hemptinne & Posthuma, *supra* note 55, at 934–35.

58. *See* Lázaro-Muñoz et al., *supra* note 56, at 433 (noting that genetic screening technologies could be used to select for "desirable" traits); Doron Dorfman, *Selecting for Disability: How an Anecdote Can Inspire Regulation of Genetic Reproductive Technologies*, 38 HARV. J.L. & TECH. 441, 448–49 (2024).

59. de Hemptinne & Posthuma, *supra* note 55, at 935 (noting that "using the same technology, embryonic selection in favor of desirable traits is also theoretically possible"). *See generally* Lázaro-Muñoz et al., *supra* note 56 (discussing the ethical questions raised by polygenic testing in IVF).

60. *See, e.g.*, *Genomic Prediction*, LIFEVIEW, https://www.lifeview.com/ [https://perma.cc/4CRT-BWJW]; REPROCARE CLINIC AND DIAGNOSTICS, https://reprocare.com.ng/ [https://perma.cc/X6CB-Z9WK]; ORCHID, https://www.orchidhealth.com/ [https://perma.cc/GHM6-U6B9]; MYOME, https://myome.com/ [https://perma.cc/C8H4-5A5A].

education, household income, cognitive ability, and subjective well-being in their services on an exploratory basis.[61] Another company has suggested that they may offer services in certain countries to screen for potential cognitive ability and skin color.[62] Another attempted to include in its testing package a test for intellectual disability that was based on a PGS for intelligence.[63] Given the problematic history of weaponizing the genetics of intelligence, this inclusion raised many alarm bells, and the company eventually decided to remove the trait from its test.[64] Yet, the idea of choosing embryos based on intelligence has not gone away.[65]

In the United States, few laws limit embryo selection or consider long-term harms stemming from such practices. Under federal unfair and deceptive practice law, companies must avoid misrepresentations or omissions likely to mislead consumers, especially if material to the decision to use their services.[66] Some have recommended that the Federal Trade Commission ("FTC") establish criteria to evaluate the evidence for informed disclosure related to embryo selection and PGS based on the FTC's history of providing guidance to curtail misleading communications about IVF clinics' success rates.[67] Apart from consumer disclosures, PGT and embryo selection are regulated in the United States only through clinical practice guidelines and standards.[68]

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61. 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). Although this was only one company and only a research protocol, it shows that there may be some interest from companies. Even if we regulate the company, consumers may choose to upload their data to a third-party website for further analysis. *See, e.g.*, Mary A. Majumder, Christi J. Guerrini & Amy L. McGuire, *Direct-to-Consumer Genetic Testing: Value and Risk*, 72 ANN. REV. MED. 151, 160 (2021) (describing the ability to download raw data from DTC test results and uploading them to third-party interpretation services).

62. Turley et. al*., supra* note 61, at 78.

63. de Hemptinne & Posthuma, *supra* note 55, at 934–35; *see also* Gabriel Lázaro-Muñoz, Stacey Pereira, Shai Carmi & Todd Lencz, *Screening Embryos for Polygenic Conditions and Traits: Ethical Considerations for an Emerging Technology*, 23 GENETICS MED. 432, 433 (2021).

64. *Id.*; Philip Ball, *Polygenic Screening of Embryos Is Here, but Is It Ethical?*, GUARDIAN (Oct. 17, 2021, 6:00 AM EDT), https://www.theguardian.com/science/2021/oct/17/polygenic-screening-of-embryos-is-here-but-is-it-ethical [https://perma.cc/ERH5-DLU6].

65. *See* Hannah Devlin, Tom Burgis, David Pegg & Jason Wilson, *US Startup Charging Couples to 'Screen Embryos for IQ,'* GUARDIAN (Oct. 18, 2024, 9:04 AM EDT), https://www.theguardian.com/science/2024/oct/18/us-startup-charging-couples-to-screen-embryos-for-iq [https://perma.cc/T524-7G78].

66. Federal Trade Commission Act, Pub. L. No. 63-203, 38 Stat. 717; 15 U.S.C. § 45(a)(1).

67. Turley et. al., *supra* note 61, at 84; 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, 473 (2024).

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

In this regulatory gap, companies are able to market PGSs for IVF despite the fact that the value of PGSs for embryo selection may be limited by low predictive power and complex interactions between genetics and the environment.[69] Further, selecting for one PGS (*e.g.*, educational attainment) could result in an unexpectedly higher risk for correlated traits (e.g., bipolar disorder).[70] If not adequately informed of these limitations, individuals and couples may choose embryos based on unclear associations, set unrealistic expectations, or, unbeknownst to them, select for traits that are undesirable to them.[71]

Thus, increased regulation to curb these harms in the IVF context may be warranted. However, regulations may be desirable even if PGSs are deemed beneficial to family planning. If enthusiasts are correct that PGS testing during IVF can lead to the selection of "better" embryos, uneven access could lead to deep inequities. There are already existing disparities in access to reproductive assistance.[72] For example, only a handful of states require private insurance companies to cover IVF and related services that would otherwise be prohibitively expensive for many.[73] In the long term, if only certain segments of the population are able to access reproductive technologies and accurately choose the "best" embryos, the aggregation of reproductive decisions over time can result in dramatic inequalities and the devaluation of certain traits.[74]

B. Anti-Discrimination in Insurance and Other Corporate Settings

During underwriting, a life insurer assesses an applicant's genetic profile to determine her risk tolerance. Applicants who are more likely to engage in risky behaviors are charged a higher premium.

There has long been a debate about whether life insurers should be allowed to consider an applicant's genetic test result during

69. *See* Turley, *supra* note 61, at 79 (discussing several reasons why the benefit of PGS screening in embryo selection may be limited).

70. Turley, *supra* note 61, at 79–81.

71. Although this potential for misunderstanding is a concern, there is also evidence that people remain interested in polygenic testing of embryos even when they understand the limitations. *See* Michelle N. Meyer, Tammy Tan, Daniel J. Benjamin, David Laibson & Patrick Turley, *Public Views on Polygenic Screening of Embryos*, 379 SCIENCE 541, 543 (finding that even after accurately explaining some limitations of testing, a substantial share of people in the study still expressed interest in the testing).

72. Naomi Cahn & Sonia M. Suter, *"Informal" Sperm Donation and Reproductive Justice*, *in* SPERM|HEALTH|POLITICS (Rene Almeling, Lisa Campo-Engelstein & Brian T. Nguyen eds., NYU Press forthcoming 2024) at 3 (on file with authors).

73. *Id.*

74. Turley et al., *supra* note 61, at 84 (noting that "the aggregation of many individual reproductive decisions over successive generations can have profound societal consequences, such as altering population demographics").

underwriting.[75] Most discussion regarding use of genetic information by life insurers relates to genomic predispositions and PRSs for medical conditions like cancer or heart conditions.[76] However, there could be future interest in sociogenomic PGSs, as in the hypothetical example above where a life insurer wishes, as part of comprehensive underwriting, to assess risk tolerance, currently measured by traits such as willingness to take risks, drive above the speed limit, or abuse alcohol.[77]

PGS use by life insurers is just one example of how a societal actor might utilize genomic information in discriminatory ways.[78] Different actors, such as employers, lenders, and other insurers, could also engage in discriminatory acts.[79] These possibilities mirror evergreen concerns of discrimination that have been present since scientists first began mapping human genetics.[80] It was to address these concerns that Congress passed the Genetic Information Nondiscrimination Act ("GINA")[81] in 2008. GINA bars covered health insurers and employers from discriminating based on individuals' genes.[82] Many states have

75. *See generally* Mark A. Rothstein, *Time to End the Use of Genetic Test Results in Life Insurance Underwriting*, 46 J.L. MED. & ETHICS 794 (2018); Patricia Born, *Genetic Testing in Underwriting: Implications for Life Insurance Markets*, 38 J. INS. REGUL. 1 (2019).

76. *See generally* Richard Karlsson Linnér & Philipp D. Koellinger, *Genetic Risk Scores in Life Insurance Underwriting*, 81 J. HEALTH ECON. 1 (2022). *See also* Jessye M. Maxwell, Richard A. Russell, Hei Man Wu, Natasha Sharapova, Peter Banthorpe, Paul F. O'Reilly et al., *Multifactorial Disorders and Polygenic Risk Scores: Predicting Common Diseases and the Possibility of Adverse Selection in Life and Protection Insurance*, 15 ANNALS ACTUARIAL SCI. 488 (2021) (exploring insurer utility for PRSs for breast cancer and coronary artery disease).

77. The PGS for risk tolerance has been associated with increased likelihood for speeding, making it particularly relevant to auto insurers. *See* Richard Karlsson Linnér, Pietro Biroli, Edward Kong, S. Fleur W. Meddens, Robbee Wedow, Mark Alan Fontana et al., *Genome-wide Association Analyses of Risk Tolerance and Risky Behaviors in over 1 Million Individuals Identify Hundreds of Loci and Shared Genetic Influences*, 51 NATURE GENETICS 245, 247 (developing a polygenic score for risk tolerance).

78. *See generally* Michelle N. Meyer, Nicholas W. Papageorge, Erik Parens, Alan Regenberg, Jeremy Sugarman & Kevin Thom, *Potential Corporate Uses of Polygenic Indexes: Starting a Conversation about the Associated Ethics and Policy Issues*, 11 AM. J. HUM. GENETICS 833 (2024).

79. Genetic Discrimination Observatory Working Group, *Proposal for an Inclusive Working Definition of Genetic Discrimination that Will Promote Comparative Research and a More Coherent Debate* (unpublished manuscript) (on file with author).

80. Louise Slaughter, *Genetic Information Non-Discrimination Act*, 50 HARV. J. ON LEGIS. 41, 41 (2013) (noting that evidence of genetic discrimination began even before the human genome was fully sequenced).

81. Genetic Information Nondiscrimination Act, Pub. L. No. 110-233, 122 Stat. 881 (2008) (codified as amended in scattered sections of 26, 29, and 42 U.S.C.); Slaughter, *supra* note 80, at 48–49 (noting that the author, Representative Slaughter, introduced GINA into Congress to address concerns of misuse of genetic information).

82. Genetic Information Nondiscrimination Act, Pub. L. No. 110-233, 122 Stat. 881 (2008).

expanded GINA's protections to also regulate life, disability, or long-term care insurers.[83]

State and federal genetic anti-discrimination laws are by no means comprehensive; many argue that the existing legal protections need to be bolstered. For example, state laws generally only weakly regulate life, long-term care, and disability insurers' use of genetic information,[84] leading to arguments that the use should be banned outright.[85] Yet PGSs could threaten even the limited existing legal structure. For example, in some cases, state laws regulating life insurer use of genetic information may not be able to be directly applied to PGSs because the state law definition of genetic information is limited to variants associated with disease or disorder.[86] Under these state laws, because a PGS, say for risk tolerance, does not predict a specific disease, it may not meet the legal definition of a genetic test. Therefore, even existing legal protections may not apply to PGSs.

Attention should also be paid to the sociogenomics of identity-based traits, such as the PGS for same-sex sexual behavior.[87] Although the authors of the study creating the score were careful to note that the trait only measured whether someone had reported engaging in same-sex sexual behavior, not their sexual identity, subsequent use of this score has conflated these concepts.[88] PGSs for other identity-based traits, like political traits and religion, have also been developed.[89] In states that bar discrimination based on religion but do not restrict discrimination based on genetic information, how might a genetic test result that predicts religious behaviors (*e.g.*, how often one goes to church) be viewed? It is currently unclear how courts and lawmakers would apply regulations to PGSs of identity-based traits, thus future interrogation of this issue is warranted.

C. Anti-Discrimination in Education

An elementary school has divided classrooms into two tracks based upon the expected skill level of students. The hope is to provide targeted

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83. *See generally* Jarrod O. Anderson, Anna C. Lewis & Anya E.R. Prince, *The Problems with Patchwork: State Approaches to Regulating Insurer Use of Genetic Information*, 22 DEPAUL J. HEALTH CARE L. 1 (2021).

84. *Id.*

85. *See, e.g.*, Rothstein, *supra* note 75, at 794 (arguing that life insurers should be barred from using genetic test results).

86. Kayte Spector-Bagdady, Anya E. R. Prince, Joon-Ho Yu & Paul S. Appelbaum, *Analysis of State Laws on Informed Consent for Clinical Genetic Testing in the Era of Genomic Sequencing*, 178 AM. J. MED. GENETICS PART C, 81, 82 (2018).

87. *See generally* Ganna et al., *supra* note 28.

88. Melanie Goisauf, Kaya Akyüz & Gillian M. Martin, *Moving Back to the Future of Big Data-Driven Research: Reflecting on the Social in Genomics*, 7 HUMANITIES & SOC. SCIS. COMMC'NS 1, 3 (2020).

89. Canter et al., *supra* note 19, at 8.

resources to students based on PGSs associated with educational attainment.

Some sociogenomic researchers believe PGSs can enhance education systems by using genomic data to develop personalized learning plans.[90] For instance, educators could customize classroom interventions by combining a student's sociogenomic and neuropsychiatric profiles.[91] Ignoring scientific limitations and ethical concerns, however, may lead to flawed policies.

One California case, *Chadam v. Palo Alto Unified School District*,[92] highlights the complexities of incorporating genetic information into the educational setting. *Chadam* involved alleged genetic discrimination and privacy violations in schools based on a faulty response to cystic fibrosis ("CF").[93] In 2012, school officials moved a child, Cole Chadam, to another school because he carried genetic markers for CF.[94] Given that another student with the condition was enrolled, the school removed Chadam, even though he showed no signs of CF, in an attempt to follow guidance that two individuals with CF should limit interactions with each other.[95]

Currently, no federal law directly protects students against genetic discrimination.[96] Thus, absent any state law protections, education programs may have legal leeway to use genetics to inform students' trajectories in school as long as the students are not discriminated against on the basis of a protected class. Some states do provide additional protections.[97] For example, the California Genetic Information Nondiscrimination Act ("Cal-GINA") expands protections to the educational context.[98] The *Chadam* complaint, however, made no claims under Cal-GINA.[99] Instead, the complaint alleged violation of the federal Americans with Disabilities Act ("ADA").[100] The Ninth Circuit found that the

90. ASBURY & PLOMIN, *supra* note 54.

91. Maya Sabatello, *A Genomically Informed Education System? Challenges for Behavioral Genetics*, 46 J.L. MED. & ETHICS 130, 130 (2018).

92. 666 F. App'x 615 (9th Cir. 2016).

93. *Id.* at 616.

94. Sarah Zhang, *DNA Got a Kid Kicked out of School-and It Will Happen Again*, WIRED (Feb. 1, 2016, 7:00 AM), https://www.wired.com/2016/02/schools-kicked-boy-based-dna/ [https://perma.cc/5KBL-K8SL].

95. *Id.*; Although CF itself is not contagious, individuals with CF may have bacteria in their lungs that could be dangerous for another individual with CF. *See Cross-Infection at Events*, CYSTIC FIBROSIS TRUST, https://www.cysticfibrosis.org.uk/life-with-cystic-fibrosis/health-and-wellbeing/cross-infection/cross-infection-at-events [https://perma.cc/J5PX-V3XR].

96. Tyler Wood, *Genetic Information Discrimination in Public Schools: A Common-Sense Exception*, 49 U. PAC. L. REV. 309, 315–19 (2017).

97. *Id.*

98. 2011 Cal. Stat. 2774.

99. *Chadam*, 666 F. App'x at 618.

100. *Id.* at 616.

ADA applied and denied the school district's motion to dismiss.[101] No further public action occurred in this case, leaving it an open question of whether and how the ADA can be used to address instances of genetic discrimination in education.

Two important issues should be considered regarding the regulation of sociogenomic PGSs in education. First, most states lack laws extending genetic discrimination protections to students.[102] For those advocating for integrating PGSs into schools, the lack of overly proscriptive laws may be viewed as facilitating their beneficial use. However, the lack of regulation could be worrisome for those concerned that school use of PGSs could lead to discrimination or bias. Even though the lawyers argued that the genetic markers in *Chadam* could qualify as a disability under the ADA, it is unlikely that many sociogenomic PGSs would qualify.[103] For example, the ADA defines disability, in part, as "a physical or mental impairment that substantially limits one or more major life activities . . . ."[104] It is difficult to conceptualize a low educational attainment PGS as a physical or mental impairment. Therefore making classroom decisions based on an educational attainment PGS may not be considered discrimination on the basis of a disability as defined by the ADA. As a result, there could effectively be no anti-discrimination protections regarding PGS use in education at both the state or federal level in many places.

Second, *Chadam* highlights the perils of having school districts interpret genetic results. Although the case focuses on a monogenic example, it illustrates how difficult it may be for schools to interpret nuanced genetic test results. Ultimately, if educational attainment PGSs are deemed social goods that provide great benefits to society, law and policy would need to address barriers to access, appropriate use, and uptake.

D. Direct-to-Consumer PGS Testing

A Direct-to-Consumer company offers consumers genetic testing for ancestry and a handful of medical traits. They are considering adding testing for income, life satisfaction, and religious behaviors.

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101. *Id.* at 617–18. Chadam eventually returned to his school and the case settled out of court. Sue Dremann, *Palo Alto DNA-Privacy Case Could Have Wide Implications*, PALO ALTO ONLINE (Jan. 26, 2016, 2:35 PM), http://www.paloaltoonline.com/news/2016/01/24/palo-alto-dna-privacy-case-could-have-wide-implications [https://perma.cc/T4YZ-H2UD].

102. Wood, *supra* note 96, at 319.

103. Shanna Mason, *Privacy of Information and DNA Testing Kits*, 27 CATHOLIC U. J.L. & TECH 161, 178 (2018) (noting that much genetic information would not meet the statutory definition of disability under the ADA).

104. 42 U.S.C. § 12102.

DTC genetic testing, consumer-facing services that sell individuals access to genetic information without a physician's referral or counsel, emerged in the early 2000s.[105] With the launch of companies like 23andMe, deCODEme, Navigenics, and others, personalized genetic testing became commercially available.[106] At the time, such "lifestyle genomics companies" tested for nutritional, wellness, and "recreational" variants.[107] Obvious and readily apparent traits, such as ear wax, were reported, along with genes that seemed much more medically relevant, such as carrier status.[108] Given that DTC has long returned findings ranging from wellness to medical, it is not surprising that an expansion into sociogenomic PGSs is already occurring, raising questions about the sufficiency of the existing regulatory system to prevent harm in this area. Further, since many social traits cross medical, social, and behavioral boundaries,[109] companies could be incentivized to frame PGS testing as non-medical and related to wellness to avoid regulatory scrutiny. For example, companies reporting scores related to mental health conditions could classify them as social despite physiological contributors in order to minimize chances of regulatory review.[110]

The leading federal regulator of medical DTC testing is the FDA.[111] The FDA withheld scrutiny of early DTC tests, allowing DTC companies to spread.[112] Eventually, the FDA began to exercise jurisdiction, concerned that companies were marketing and selling services with medical implications alongside nonmedical tests and conflating

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105. *See* Catherine M. Sharkey, *Direct-to-Consumer Genetic Testing: The FDA's Dual Role as Safety and Health Information Regulator*, 68 DEPAUL L. REV. 343, 349 (2019).

106. *See generally* David Magnus, Mildred K. Cho & Robert Cook-Deegan, *Direct-to-consumer Genetic Tests: Beyond Medical Regulation?*, 1 GENOME MED., Feb. 2, 2009.

107. Justine Horne, Jason Gilliland, Janet Madill & Jacob Shelley, *A Critical Examination of Legal and Ethical Considerations for Nutrigenetic Testing with Recommendations for Improving Regulation in Canada: From Science to Consumer*, 7 J.L. & BIOSCIENCES 1, 1 (2020).

108. Amy L McGuire, Barbara J. Evans, Timothy Caulfield & Wylie Burke, *Regulating Direct-to-Consumer Personal Genome Testing*, 330 SCIENCE 181, 181 (2010); *see also* Kayte Spector-Bagdady & Elizabeth R. Pike, *Consuming Genomics: Regulating Direct-to-Consumer Genetic and Genomic Information*, 92 NEB. L. REV. 677, 689 (2014) (noting a variety of tests from mundane (such as excessive earwax), carrier status, probability of developing disease, or predictions of drug metabolism).

109. *See* Canter et al., *supra* note 56, at 37 (discussing the blurry continuum between medical and social traits).

110. Teneille R. Brown, *The Opposite of Empowering*, 38 HARV. J.L. & TECH. 501, 510 (2024) (noting that PRS for depression, anxiety, suicidality and addiction have been commercialized)*; see also* Meyer et al., *supra* note 8, at S6 (explaining how educational attainment, intelligence, and personality can be related to medical conditions such as schizophrenia, neurocognitive disorders, and other conditions, and how it is difficult to distinguish between medical and social phenotypes).

111. FDA regulates medical genetic tests sold in the market as *in vitro* devices. Jin K. Park & I. Glenn Cohen, *The Regulation of Polygenic Risk Scores*, 38 HARV. J.L. & TECH. 377, 384 (2024).

112. *See, e.g.*, Sharkey, *supra* note 105, at 350 (noting that 23andMe began operations mostly outside FDA regulation.

their qualities.[113] These authorities emphasized that laws regulating genetic testing laboratory standards required an authorized person to order or report results.[114] With these forceful actions, many DTC companies went out of business or changed their business models.[115] 23andMe was the first to return to the market, offering FDA-approved medical genetic tests and genetic ancestry testing services.[116] FDA continues to exercise enforcement discretion of medical laboratory developed tests and does not review nonmedical tests.[117]

Even if regulators increase oversight of nonmedical tests in the future, any regulatory action could be lacking, inconsistent, or have unpredictable effects. On the one hand, FDA regulation could provide trust in sociogenomic PGSs and take poor performers off the market. Conversely, there may be concern that FDA regulation could provide unwarranted legitimacy to tests, causing users to overlook their limitations. As discussed above, the current FDA approach to non-medical tests generally assumes that cautious buyers are the best able to decide when and how to utilize a technology. However, the unknown positive and negative effects of applying this "caveat emptor" approach may take decades to assess and could result in irreversible damage for future generations.

Additionally, bioethicists have raised concerns about consumers' rights to independently access personal genomic information, particularly without the assistance of a medical provider.[118] Consider the dual routes for procuring medical and social genetic tests. Medical PRSs fall under the practice of medicine, and healthcare providers are responsible for making decisions that are in patients' best interests. If providers are aware of PRSs' limitations, uses, benefits, and risks, they can guide patients. Meanwhile, commercial entities, clinical programs, and research institutions provide individuals unfettered access to their PGS information, providing web-based education models instead of

113. *Id.* at 351–54; s*ee also* James P. Evans & Robert C. Green, *Direct to Consumer Genetic Testing: Avoiding a Culture War*, 11 GENETICS IN MED. 568, 569 (2021) (recommending that DTC tests without medical implications be labeled as nonmedical and those of medical interest clearly labeled as a medical test).

114. Spector-Bagdady & Pike, *supra* note 108, at 720 (noting who qualifies as an authorized person depends on state law).

115. *Id.* at 728.

116. In February 2015, the FDA approved 23andMe's DTC carrier screening test for Bloom Syndrome. Sharkey, *supra* note 105, at 354.

117. *Direct-to-Consumer Tests*, US FOOD & DRUG ADMIN. (Dec. 20, 2019), https://www.fda.gov/medical-devices/in-vitro-diagnostics/direct-consumer-tests [https://perma.cc/9Q8K-GMTA] (noting that the FDA does not review "direct-to-consumer tests for non-medical, general wellness, or low risk medical purposes").

118. *See, e.g.*, McGuire et al., *supra* note 108, at 182 (noting consensus that genetic results should be returned by a health professional).

personalized counseling.[119] Current regulation does nothing to stop or discourage this practice.

E. Criminal Law

During a sentencing hearing, the defense seeks to bring in a genetic test showing that the defendant has a high PGS for aggression. They seek to introduce this evidence to argue that the defendant is not culpable for his actions and should receive a reduced sentence.

Over the decades, both prosecutors and defense counsel have sporadically attempted to introduce evidence related to genetic predispositions of defendants in criminal cases.[120] Depending on who is introducing the evidence, the goal is to deny responsibility, mitigate or enhance the sentence, or help prove the defendant's guilt.[121] A relatively common example is when defendants seek to introduce evidence regarding their monoamine oxidase A ("*MAOA*") gene.[122] Early genetic research linked the *MAOA* gene, also notoriously called the "warrior gene," to increased aggressive behaviors.[123] Defendants sought to introduce evidence of their predisposition to aggressive behavior to argue, among other things, that they were not culpable for a crime because their genes propelled them to act.[124] PGS findings, such as those related to aggression or substance use,[125] could be of similar interest within the criminal justice system.

Overall, courts have varied as to whether they allowed evidence related to the *MAOA* gene and how they factored the evidence into the case. For example, some judges imposed lighter sentences and some increased sentences based on the defendants' alleged genetic predispositions to violent behavior or criminal acts.[126]

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119. Hannah Wand, Sarah S. Kalia, Benjamin M. Helm, Sabrina A. Suckiel, Deanna Brockman, Natalie Vriesen et al., *Clinical Genetic Counseling and Translation Considerations for Polygenic Scores in Personalized Risk Assessments: A Practice Resource from the National Society of Genetic Counselors*, 32 J. GENETIC COUNSELING 558, 558 (2023); *see also* Lewis & Green, *supra* note 2, at 4 (noting one argument that individuals should be able to obtain genetic information without an "expert intermediary").

120. *See generally* Nita A. Farahany, *Neuroscience and Behavioral Genetics in U.S. Criminal Law: An Empirical Analysis*, 2 J.L. & BIOSCIENCES 485 (2015); Natalie Ram, *Polygenic Scoring and the Criminal Legal System*, 38 HARV. J.L. & TECH. 577 (2024).

121. *Id.* at 489.

122. *Id.* at 487

123. *Id.*

124. *See id.* at 489 & n.14.

125. *See* Canter et al., *supra* note 19, at 8 tbl.1 (identifying aggression and substance use as two traits for which PGS have been developed).

126. Farahany, *supra* note 120, at 504–06.

The science behind studies linking MAOA and aggression has since been shown to have significant flaws,[127] leading to questions about whether such evidence should be allowed at all.[128] For example, the New Mexico Supreme Court recently held "that evidence of mere genetic susceptibility to a given mental condition is not relevant on the issue of deliberate intent, at least in the absence of evidence that such susceptibility is so well understood and has such strong predictive value as to be clinically validated as an indicator of the mental condition."[129] The court focused on whether the genetic predisposition brought into evidence was scientifically valid, not whether such genetic evidence should be introduced at all.[130] Under this reasoning, the door remains open for "better" science regarding genetic predispositions to criminal traits to be introduced.[131] Thus, if sociogenomic PGS can overcome major methodological critiques, they may be of great interest in the criminal law realm.[132]

IV. THE LAW'S ROLE IN PREVENTING SOCIAL HARMS

Unlike prior researchers who used genetics in attempts to explain — and thereby justify — observed differences in social outcomes for people of different social statuses, races, and ethnicities, mainstream sociogenomics researchers have suggested that PGSs can be used to refute claims about innate inferiority and to show the enormous importance of environments in explaining observed differences.[133] Equally optimistically, some sociogenomics researchers believe that their careful attention to the role of genetics can help to refute stereotypes and reduce stigma.[134] In these ways, mainstream sociogenomics researchers today are distinct from any of their genetic determinist predecessors, and many of these researchers are actively pursuing research questions based on the premise that any serious science of social outcomes must attend carefully to environmental or social conditions.[135]

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127. Nita A. Farahany, Roderick T. Kennedy & Brandon L. Garrett, *Genetic Evidence,* MAOA*, and* State v. Yepez, 50 N.M. L. REV. 469, 482–83 (2020).

128. State v. Yepez, 483 P.3d 576, 584–89 (N.M. 2021) (determining whether evidence of the MAOA gene should be allowable in court).

129. *Id.* at 589.

130. *Id.*

131. *Id.*

132. *See generally* Farahany, *supra* note 120; Ram, *supra* note 120.

133. *See* Conley & Fletcher, *supra* note 5, at 3 (arguing that by actively accounting for genes that influence IQ, income, and education, "we can see more clearly the inequities in environmental inputs"). For an overview of the proposed benefits of PGS research, including limiting emphasis on genomics and disputing discriminatory claims based on genomics see Meyer et al. *supra* note 8, at S23.

134. *See* HARDEN, *supra* note 30, at 20, 195; Meyer et al., *supra* note 8, at S23 (arguing that discriminatory claims may be able to be refuted based on GWAS evidence).

135. HARDEN, *supra* note 30, at 21 (arguing that resistance to the role of genetics has "hobbled" scientific progress); Meyer et al., *supra* note 8, at S23.

Even as scientific methods improve, however, entrenched social, political, and scientific barriers to the equitable distribution of resources threaten to increase stigmatization, stereotyping, and other harms to groups of individuals on the wrong end of a PGS.[136] Further, it is exceedingly difficult to imagine a world in which identifying people by where they sit on numerical scales does not lead to inequitable and unfair treatment of those at the wrong end of the scales. Since human biases are difficult to detect or prove, the social risks of PGSs may be exceedingly difficult to mitigate.

Still, the law may have a role to play in helping to prevent flawed science from influencing policy. First, policy makers should consider the history of those behavioral geneticists who have made deeply erroneous arguments on behalf of various eugenic and racist claims, such as those averring "[B]lacks' intellectual genetic inferiority."[137] Such claims were made despite attempts by the field's mainstream to distance itself from them,[138] but lawmakers sided with eugenicists under the guise of supporting the public's interest, and courts upheld these unjust state statutes in the past.[139] Contemporary mainstream sociogenomics researchers, too, distance themselves from eugenics claims.[140] However, history shows that genetic research can be weaponized and used to violate civil rights despite mainstream opposition to weaponization and eugenics.[141]

Second, scientific problems associated with inadequate understanding of the role of the environment on social traits and life outcomes could lead to the very genetic deterministic and discriminative policies mainstream researchers believe their work should prevent.[142] As explained in the section on the portability problem, there is still a gap between the aspiration and the ability of sociogenomics researchers to study the interplay between genetics and environmental influences. Further, as of today, the biobanks that these researchers rely on do not have sufficiently large numbers of samples to make it possible to conduct robust research on people from most of the world's populations.[143]

Third, the ethical problems regarding the just distribution of any benefits that grow out of sociogenomic research could undermine those very benefits. Despite difficulties in measuring the role of the

136. Meyer et al., *supra* note 8, at S21.

137. AARON PANOFSKY, MISBEHAVING SCIENCE: CONTROVERSY AND THE DEVELOPMENT OF BEHAVIOR GENETICS 100 (2014).

138. *Id.* at 14.

139. Buck v. Bell, 274 U.S. 200, 205 (1927) (upholding a statute passed by the Virginia legislature that stated that "the health of the patient and the welfare of society may be promoted in certain cases by the sterilization of mental defectives").

140. *See, e.g.*, HARDEN, *supra* note 30, at 19–20; Meyer et al., *supra* note 8, at S21.

141. Meyer et al., *supra* note 8, at S9.

142. *Id.*

143. *See supra* Section II.C.

environment,[144] if these scores are interpreted in a deterministic way and widely adopted in society, they could create stigmatization and a self-fulfilling prophecy for users. Consider, again, the example of genome-based personalized learning plans related to educational attainment. Advocates for these plans frame them as an innovative and scientific approach to helping children maximize their natural potential, yet they do so without fully considering the impact of finite resources.[145] Finite resources, however, have long created inequities when attempting to differentiate students by achievement or skill. For example, historically, school tracking programs differentiated students designated as gifted.[146] Yet "[t]hese practices didn't just mirror societal inequities; they institutionalized them when finite educational resources were distributed to the different groups/levels/tracks."[147] The students labeled as poor performers generally received insufficient resources, less qualified teachers, and less engaging instruction.[148] Marking such students, often from low-resource backgrounds, could have the effect of reinforcing their positions in society, making it even harder for them to succeed and resulting in lower academic performance and discouragement from completing their education.[149] This reinforcement fits into a consistent pattern that emerges when genetics and policy meet: "the more privileged strata have at each juncture raised genetic questions about those at the lower end of the socioeconomic ladder."[150]

While proponents of sociogenomic PGS adamantly distinguish themselves from the eugenics researchers of the past,[151] without adequate safeguards, such as increased regulation or increased self-governance of researchers in the field, the consequences of sociogenomic PGSs could be dire for society, affecting various areas of the law related to reproductive genomics, education, insurance, employment and criminal law.

V. CONCLUSION

As explained above, sociogenomics researchers argue that integrating PGSs into social science research can lead to more robust studies

144. *See supra* Section II.C.

145. JAMES TABERY, TYRANNY OF THE GENE 159 (2023) (noting, for example, that those envisioning a future of personalized education often admittedly "fantasized" all these problems away and that some have admitted it was a utopian vision).

146. JEANNIE OAKES, KEEPING TRACK: HOW SCHOOLS STRUCTURE INEQUALITY 221 (2d ed., 2005).

147. TABERY, *supra* note 145, at 158.

148. *Id.*

149. *Id.* at 157–59.

150. DUSTER, *supra* note 11, at 10.

151. *See, e.g.*, HARDEN, *supra* note 30, at 19–20 (pointing out eugenicists' "scientific and ideological errors" and describing her alternative anti-eugenic approach).

and improved understandings of interactions between genes and the environment. This integration into research could lead to what they understand to be more just social policies. However, the scientific results to date are arguably not robust enough for use in policymaking or practice, and the social harms may be too great with an unprepared regulatory system. For those who believe fairness requires that beneficial technologies be accessible to all populations regardless of ancestry and resources, we have underscored where and how sociogenomic PGSs fall short.

While concerns about eugenics and the ongoing misinterpretation of genomics research by white supremacists have received significant attention,[152] this manuscript draws attention to the potential pernicious group and individual harms stemming from the use of sociogenomic PGSs that may fly under the radar. The nascent, but rapidly growing, field of PGSs creates many legal uncertainties if, and when, the scores are incorporated into society. Current legal frameworks may not be enough to prevent flawed scientific data from being applied to nonmedical scenarios across industries.[153] Yet, commercial availability may make use and implementation of PGSs feasible in many sectors beyond medicine. Ongoing attention to the limitations and progress in sociogenomic PGS research is needed. History also reminds us of the importance of providing adequate resources and investment in a society that too often lacks a commitment to low-tech social interventions.[154]

Innovative, legal and non-legal approaches are necessary to inform public discourse, law, and policy. These must be developed thoughtfully and deliberately depending on how the technology and its use in society morphs. Potential solutions, such as updating existing regulation to cover non-medical genetic testing, modifying governance structures of the underlying research, and reconceptualizing current legal frameworks or, in some instances, barring the use of sociogenomic PGSs in certain segments of society, should all be carefully considered. Only with thoughtful attention to how PGSs are used can we maximize the benefits and minimize the harms of the scores across our population and society.

152. *See generally* Wedow et al., *supra* note 13.
153. *See supra* Part III.
154. Brown, *supra* note 110; TABERY, *supra* note 145, at 230.