Harvard Journal of Law & Technology
Volume 38, Number 2 Symposium 2024

DAMNED IF YOU DO OR DAMNED IF YOU DON'T: THE MEDICAL MALPRACTICE IMPLICATIONS OF CONSUMER-GENERATED POLYGENIC RISK SCORES

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ABSTRACT

Polygenic risk scores ("PRSs") calculate the genomic risk for complex conditions. While they have garnered significant attention, these assessments have unknown predictive value and clinical utility. Nonetheless, individuals can go online and obtain PRSs for a wide range of conditions. These patient-generated PRSs may show up in clinic if people share this information with their doctors. This paper uses PRSs to consider the medical malpractice implications for unsolicited, unverifiable consumer health data. Although doctors could be held liable both for acting on and for disregarding that information, we conclude that physicians confronted with medical and legal uncertainty are more likely to overtreat. We, therefore, advocate for (1) clinical practice guidelines to help discourage overtreatment when a custom has not yet developed and (2) physician immunity statutes to allow doctors to act with their best clinical judgment and not out of fear of liability.

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This work was supported in part by the National Institute of Mental Health and the National Human Genome Research Institute of the National Institutes of Health, grant R01MH128676. We are thankful for the very helpful comments of the participants of the 2024 JOLT Symposium: Medical and Legal Uncertainty in Emerging Technologies.

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I. INTRODUCTION

Thanks to the current explosion in technology, consumers have access to more tools than ever to help them assess their health. Some are dangerous and no better than the digital equivalent of snake oil.[1] Others begin as mere consumer wellness products but then gain the imprimatur of FDA approval.[2] However, where a particular innovation falls on the spectrum from quackery to confirmed validity may not be immediately apparent. This Article considers the medical malpractice implications of consumer-generated health data through the lens of polygenic risk scores ("PRSs").

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1. *See* Nathan Cortez, *The FDA Needs to Regulate "Digital Snake Oil,"* SLATE (Sept. 4, 2013), https://slate.com/technology/2013/09/mhealth-fda-needs-to-regulate-digital-snake-oil.html [https://perma.cc/9B3L-662D]; Leah R. Fowler, *Health App Lemons*, 74 ALA. L. REV. 65, 67 (2022).

2. *See, e.g.*, *FDA Allows Marketing of First Direct-to-Consumer Tests that Provide Genetic Risk Information for Certain Conditions*, FDA: PRESS ANNOUNCEMENTS (Apr. 6, 2017), https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-tests-provide-genetic-risk-information-certain-conditions [https://perma.cc/KT5D-ZHXF]; *FDA Allows Marketing of First Direct-to-Consumer App for Contraceptive Use to Prevent Pregnancy*, FDA: PRESS ANNOUNCEMENT (Aug. 10, 2018), https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-app-contraceptive-use-prevent-pregnancy [https://perma.cc/8GWC-KKPH].

PRSs assess a person's lifetime genomic risk of developing a particular condition using big data analytics.[3] PRSs offer an exciting opportunity to understand genetics' contribution to complex diseases.[4] But so far PRSs have primarily been limited to research settings. The actual predictive and clinical values of many PRSs remain unclear.[5] One recent article found that PRSs fared poorly both for individuals and across populations, concluding that the enthusiasm for them appears "disproportionate to their performance."[6] Moreover, because of the underrepresentation of people of color in biomedical research, PRSs are even less reliable for those populations.[7] For those reasons, most clinicians do not currently integrate PRS into their practices, although that may soon change.[8]

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3. *Polygenic Risk Scores*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/Health/Genomics-and-Medicine/Polygenic-risk-scores [https://perma.cc/P9JB-UTHS]. While we focus on health care, researchers have used PRS technology to calculate the probability of outcomes unrelated to disease risk, such as income, education, and job attainment. W. David Hill, Neil M. Davies, Stuart J. Ritchie, Nathan G. Skene, Julian Bryois, Steven Bell et al., *Genome-Wide Analysis Identifies Molecular Systems and 149 Genetic Loci Associated with Income*, 10 NATURE COMMC'NS, Dec. 16, 2019, at 1, 9; Emily Smith-Wooley, Saskia Selzam & Robert Plomin, *Polygenic Score for Educational Attainment Captures DNA Variants Shared Between Personality Traits and Educational Achievement*, 117 J. PERSONALITY & SOC. PSYCH. 1145, 1159 (2019); Zhaoli Song, Wen-Dong Li, Hengtong Li, Xin Zhang, Nan Wang & Qiao Fan, *Genetic Basis of Job Attainment Characteristics and the Genetic Sharing with Other SES Indices and Well-Being*, 12 SCI. REPS., May 26, 2022, at 1, 11; *see also* Shawneequa Callier & Anya E.R. Prince, *The Legal Uncertainties in Sociogenomic Polygenic Scores*, 38 HARV. J.L. & TECH. 553 (2024).

4. *See* I. Glenn Cohen & Jin K. Park, *The Regulation of Polygenic Risk Scores*, 38 HARV. J.L. & TECH. 377, 383 (2024).

5. *See* Edward Esplin, Comment to *Regulating Direct-to-Consumer Polygenic Risk Scores*, JAMA (Aug. 12, 2023), https://jamanetwork.com/journals/jama/article-abstract/2808229 [https://perma.cc/KBB2-JGRZ].

6. Aroon D. Hingorani, Jasmine Gratton, Chris Finan, A. Floriaan Schmidt, Riyaz Patel, Reecha Sofat et al., *Performance of Polygenic Risk Scores in Screening, Prediction, and Risk Stratification: Secondary Analysis of Data in the Polygenic Score Catalog*, 2 BMJ MED., Oct. 17, 2023, at 1, 2.

7. *See* Alicia R. Martin, Masahiro Kanai, Yoichiro Kamatani, Yukinori Okada, Benjamin M. Neale & Mark J. Daly, *Clinical Use of Current Polygenic Risk Scores May Exacerbate Health Disparities*, 51 NATURE GENETICS 584, 587 (2019); *see also* 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/88FY-HUFD].

8. Some studies show that PRSs have been well received by patients and physicians and, in borderline cases, led to changes in treatment plans. Ahmet Fuat, Ella Adlen, Mark Monane, Ruth Coll, Sarah Groves, Elizabeth Little et al., *A Polygenic Risk Score Added to a QRISK®2 Cardiovascular Disease Risk Calculator Demonstrated Robust Clinical Acceptance and Clinical Utility in the Primary Care Setting*, 31 EUR. J. PREVENTATIVE CARDIOLOGY 716, 720 (2024); *see also* Forest Ray, *Genomics Plc Shows Feasibility of Implementing Polygenic Risk Scores in Routine Clinical Care*, GENOMEWEB (Feb. 13, 2024), https://www.genomeweb.com/genetic-research/genomics-plc-shows-feasibility-implementing-polygenic-risk-scores-routine-clinical [https://perma.cc/DR9C-UVFW]. The company behind one of these studies noted that it is currently commercializing its PRS-inclusive risk assessment tool in the US as part of a wellness program administered by an undisclosed commercial partner. *See* Ray, *supra*.

Despite limited medical adoption of PRSs, individuals can obtain genomic risk information through direct-to-consumer ("DTC") companies for a wide range of conditions and traits, including depression, type-2 diabetes, and athleticism.[9] Because PRSs calculate relative — not absolute — risk, companies report those results as compared to other users.[10] AncestryDNA, for example, reports its PRS traits across a spectrum of least likely, average, and most likely.[11] As of September 2023, the well-known DTC genetic testing company 23andMe offers over thirty PRS-based reports to consumers.[12] Depending on the product or service, curious users can send their sample to a lab or upload their existing genomic information for analysis.[13] The website or lab then uses the person's sequence data to produce a PRS for the desired condition or trait. Unfortunately, these products often go unregulated by the FDA because they are classified either as wellness products or as software.[14] Consumers can thus obtain unverified genomic risk information without the benefit of a physician intermediary.

As scholars have noted, DTC PRSs — like the earlier traditional DTC genetic tests — put users at risk of acting on unvalidated predictive data.[15] We argue, however, that physicians also face potential harm from these and other forms of widely available, yet largely unregulated, consumer-generated health data.

Perhaps to avoid liability, many consumer health companies encourage users to consult with a healthcare professional when purchasing their products and services.[16] While some companies recommend a certified genetic counselor,[17] consumers may find it easier or preferable to share their results with their doctors.

Currently there is no accepted practice regarding how to deal with unverifiable, unsolicited consumer health data. One author has strongly cautioned against any use of DTC PRSs without additional research, stating "DTC PRS represents significant risk without any conceivable

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9. Jacob S. Sherkow, Jin K. Park & Christine Y. Lu, *Regulating Direct to Consumer Polygenic Risk Scores*, 330 JAMA 691, 691 (2023).

10. Aaron Wolf, *Polygenic Risk Score (PRS) Traits*, ANCESTRY DNA, https://support.ancestry.com/s/article/PRS-traits?language=en_US [https://perma.cc/TE9H-N3ZH]. For a more detailed description of how PRSs are calculated, see *infra* Section III.A.

11. Wolf, *supra* note 10.

12. *See Understanding Polygenic Risk Scores (PRS)*, 23ANDME: BLOG (Sept. 25, 2023), https://blog.23andme.com/articles/better-polygenic-risk-prediction [https://perma.cc/D6L2-CLJZ]; *Reports Included in All Services*, 23ANDME, https://www.23andme.com/dna-reports-list/ [https://perma.cc/KH5U-BFJ6].

13. Sherkow et al., *supra* note 9, at 691.

14. *Id.*

15. For example, Sherkow et al. note that consumers might unwittingly conflate a high PRS with a diagnosis or use PRSs as a substitute for clinical care. *Id.* at 691–92.

16. *See* Fowler, *supra* note 1, at 76; *see also We Encourage You to Speak to a Genetic Counselor*, 23ANDME, https://www.23andme.com/test-info/genetic-health/ [https://perma.cc/6TLK-E2CA].

17. *See, e.g.*, 23ANDME, *supra* note 16.

clinical benefit to the consumers who may purchase them."[18] Yet once a patient has a potentially relevant PRS in hand, it may be difficult for a treating physician to disregard the information because of the possibility, however large or small, that the information could be clinically significant.

DTC PRSs also raise unique concerns for medical malpractice liability. When patients bring traditional DTC genetics into the clinic, their doctors can request testing to verify the findings. Consider a person whose results from an at-home testing kit indicate a heightened risk of breast or ovarian cancer.[19] If that individual shares the DTC information with their physician, the doctor can order a BRCA panel to confirm the result.[20] However, confirmation is not yet possible for many newer technologies until there have been studies to confirm their efficacy, accuracy, or clinical relevance. With the recent boom in health artificial intelligence ("AI"), it is likely that consumers will have access to even more information that has not been vetted for effectiveness or reliability since it will be difficult to verify the results of all AI findings. Thus, we can reasonably expect more patients to share unverifiable, unsolicited health data with their doctors.

As we discuss below, either disregarding or considering consumer-generated health data could result in malpractice liability. A physician who ignores a high DTC PRS could be sued for failing to act on the purported risk if the patient develops an avoidable medical condition. Likewise, a doctor who recommends treatment based on a DTC PRS could also be sued if the risk data turn out to be unreliable and the intervention proves unnecessary or even harmful. In short, physicians could be damned if they do or damned if they don't.

This Article responds to this dilemma in three parts. Part II offers a primer on medical malpractice, explaining how courts have held doctors liable both for disregarding information they did not ask for and for relying on unvalidated data in clinical decision-making. Part III introduces the PRS double-bind, explaining the science behind PRSs, PRSs' limitations, and the potential challenges consumer-generated PRSs present for clinicians. Although we acknowledge that greater regulation and oversight of consumer health technologies would be ideal, we are not optimistic about this solution given the limited meaningful regulatory action in this area.[21] Part IV, therefore, suggests professional guidance and technology-based physician immunity statutes as second-

18. Esplin, *supra* note 5.

19. For one such product, see *Comprehensive BRCA At-Home Test Kit with Expert Genetic Counseling Included*, APPLIED INGENUITY DIAGNOSITCS, https://applidx.com/product/brca-home-testing-with-counseling/ [https://perma.cc/NG89-SHMW].

20. *See BRCA Gene Test for Breast and Ovarian Cancer Risk*, MAYO CLINIC: TESTS & PROCEDURES, https://www.mayoclinic.org/tests-procedures/brca-gene-test/about/pac-20384815 [https://perma.cc/BN42-L9LJ].

21. *See* Sherkow et al., *supra* note 9, at 691.

best responses. Ultimately, we prefer the latter because it would allow doctors to use their professional judgment regarding the best decision for the patient based on currently available information without fear of liability.

II. PRIMER ON MEDICAL MALPRACTICE

In this Part, we consider the challenges that consumer health data create for medical malpractice law. To assess liability, courts look to the standard of care, frequently determined by professional custom. Consumer health data raise special issues regarding medical malpractice. First, the patients seek the health information. Second, the results often have unknown predictive value or clinical utility. And third, there is often no established custom in this area. The combination of these factors makes it hard for physicians to know whether to consider the information or to ignore it.

A. Standard of Care

Medical malpractice is a specialized type of tort that allows patients to recover damages for injuries caused by a health care providers' negligence.[22] Unlike in ordinary negligence claims where juries typically assess the defendant's actions based on their intuition of what "a hypothetical reasonably prudent person" would have done,[23] physicians — because of their "specialized knowledge and skill"[24] — must follow professional standards of care.[25] The standard of care for medical malpractice is, therefore, generally based on what "the average careful, diligent and skillful physician in the community or like communities, would do or not do in the care of similar cases."[26] In other words, the law essentially allows the medical profession to "set its own standards of reasonable conduct"[27] by treating professional custom as conclusive

22. Hall v. Hilbun, 466 So. 2d 856, 866 (Miss. 1985); BARRY R. FURROW, THOMAS L. GREANEY, SANDRA H. JOHNSON, TIMOTHY STOLTZFUS JOST & ROBERT L. SCHWARTZ, HEALTH LAW 264 (2d ed., 2000).

23. Robbins v. Footer, 553 F.2d 123, 126 (D.C. Cir. 1977); WILLIAM P. STATSKY, ESSENTIALS OF TORTS 131, 178–79 (3d ed. 2012).

24. *Robbins*, 553 F.2d. at 126.

25. *See* Phillip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 201 (2000); Allan H. McCoid, *The Care Required of Medical Practitioners*, 12 VAND. L. REV. 549, 558 (1959).

26. McCoid, *supra* note 25, at 558. A minority of courts, however, recognize a "'general reasonableness' standard." Ellen Wright Clayton, Paul S. Appelbaum, Wendy K. Chung, Gary E. Marchant, Jessica L. Roberts & Barbara J. Evans, *Does the Law Require Reinterpretation and Return of Revised Genomic Results?*, 23 GENETICS MED. 833, 833 (2021).

27. *Robbins*, 553 F.2d at 126.

in establishing reasonable care.[28] This is a notable deviation from the general rule that custom is *not* conclusive evidence of the standard of care.[29]

While custom may not always define the standard of care in medical malpractice cases,[30] most courts adopt a custom-based approach.[31] This general reliance on custom reflects a deference to the medical community because typical jurors do not have the training to assess whether a physician acted reasonably and because a "large measure of judgment" is at play in the practice of "'the healing art.'"[32] Thus, physicians are not treated as guarantors of good results,[33] "held to the standard of perfection[, or] evaluated with benefit of hindsight."[34]

Because the standard of care generally depends on the common practice, both sides often rely on expert witnesses to describe the professional standard.[35] Ideally, experts practice in the same field as the defendant physician,[36] although it may be sufficient for them to have expertise or experience with the procedure or treatment decision at issue.[37] Juries play a role in assessing whether the standard of care has been breached, but often their evaluation is based not on what would

28. Doe v. Am. Red Cross Blood Servs., 377 S.E.2d 323, 326 (S.C. 1989). Rarely, courts have deviated from that rule. *See* Helling v. Carey, 519 P.2d 981, 983 (Wash. 1974).

29. *See* Joseph King, *In Search of a Standard of Care of the Medical Profession: The "Accepted Practice" Formula*, 28 VAND. L. REV. 1213, 1236 (1975).

30. *See* Peters, *supra* note 25, at 186–87; *see also Helling*, 519 P.2d at 981. A tentative draft of the Restatement (Third) of Torts: Medical Malpractice defines the "standard of reasonable care" as "the care, skill, and knowledge regarded as competent among similar medical providers in the same or similar circumstance." RESTATEMENT (THIRD) OF TORTS: MEDICAL MALPRACTICE § 5 (AM. L. INST., Tenative Draft No. 2, 2024). It notes that this standard "is often reflected in prevailing professional practices" and is frequently referred to as "the 'customary' standard of care, the care 'ordinarily exercised,' the care 'ordinarily used,' or the care 'ordinarily practiced.'" *Id.*, cmt. c. But it emphasizes that, "while custom maintains currency, the governing standard" under this tentative draft of the Restatement is based on what is "*regarded as competent* among similar medical providers." *Id.*, Reporters' Note, cmt. c. In other words, if the "prevailing professional practice is deficient, cannot be ascertained, or does not exist, the ultimate question remains what similar professionals . . . believe *would be* competent to do in the same or similar circumstances." *Id.*, cmt. c.

31. Anna B. Laakmann, *When Should Physicians Be Liable for Innovation?*, 36 CARDOZO L. REV. 913, 926 (2015) (citing RICHARD A. EPSTEIN, TORTS, § 6.2, at 141 (1999)).

32. McCoid, *supra* note 25, at 608.

33. S. E. PEGALIS, AMERICAN LAW OF MEDICAL MALPRACTICE § 20:23 (2017).

34. Wainwright v. Leary, 623 So.2d 233, 235 (La. Ct. App. 1993).

35. FURROW ET AL., *supra* note 22, at 309, 311. Experts are not needed, however, when "the lack of care is so obvious as to be within the layman's common knowledge." Marshall v. Tomaselli, 372 A.2d 1280, 1283 (R.I. 1977).

36. FURROW ET AL., *supra* note 22, at 272–73.

37. *Id.* at 273; Sheeley v. Mem'l Hosp., 710 A.2d 161 (R.I. 1998); Monique C.M. Leahy, *Proof That Expert Witness in Medical Malpractice Litigation Practices in "Same Specialty" as Defendant Health Care Provider, or Is Otherwise Qualified to Testify as to Applicable Standard of Care*, 182 AM. JURIS. PROOF OF FACTS 289 § 9 (3d ed. 2020, updated February 2024).

be reasonable but on which expert they find credible.[38] In addition, jurisdictions differ as to whether national or local practices define the standard of care.[39] Where the defendant is a specialist or "board certified," states are more likely to impose a national standard of care.[40]

In some jurisdictions, the existence of "two schools of thought" may complicate determinations of the standard of care. In those cases, a physician may not be liable for failing to follow the custom, if her approach to care is "recognized by [a] reputable and respected, considerable number of medical experts [in the relevant field], even if in the minority . . . ."[41] In other words, the defendant can avoid liability by following either the majority or a "respectable minority."[42]

B. Special Concerns for Consumer Health Data

Assessing the standard of care becomes even more complicated with respect to the question of potential liability when physicians are presented with consumer health data. Should physicians use unsolicited information to make treatment decisions, or should they ignore it and rely only on the information they sought? Is there a risk in acting on the information if treatment ultimately proves unnecessary? Or is there also a risk in failing to act, if it later turns out that the information communicated actionable risk? And is one course of action any riskier than the other?

Unfortunately, there are few cases directly on point. The first thing to note, however, is that medical malpractice does not distinguish between acting and failing to act. If the provider's failure to meet the standard of care harms the patient, liability results regardless. Thus, physicians have been found liable for improperly performing procedures,[43] as well as for failing to act on clinically significant information, particularly when there is medical consensus regarding how to respond.[44]

As noted, consumer health data inevitably complicates assessing and applying the standard of care for at least three reasons: (1) it is

38. Coulter Boeschen & Stacy Barrett, *Medical Malpractice: Using Medical Expert Witnesses*, NOLO (Dec. 28, 2022), https://www.nolo.com/legal-encyclopedia/medical-malpractice-using-expert-witnesses-30087.html [https://perma.cc/XA5H-23AB].

39. *See* Leahy, *supra* note 37, §§ 13–14.

40. *See* Robbins v. Footer, 553 F.2d 123, 128–29 (D.C. Cir. 1977); FURROW ET AL., *supra* note 22, at 265.

41. Gala v. Hamilton, 715 A.2d 1108, 1110 (Pa. 1998) (quoting jury instructions for a medical malpractice verdict based on the two-schools-of-thought doctrine, which the court affirmed).

42. Borja v. Phx. Gen. Hosp., Inc., 727 P.2d 355, 357 (Ariz. Ct. App. 1986).

43. *See, e.g.*, Sheeley v. Mem'l Hosp., 10 A.2d 161 (R.I. 1998).

44. *See, e.g.*, Matsuyama v. Birnbaum, 890 N.E.2d 819 (Mass. 2008); Stafford-Fox v. Jenkins, 639 S.E.2d 610 (Ga. Ct. App. 2006); Dodge Cnty. Hosp. Auth. v. Seay, 880 S.E.2d 571 (Ga. Ct. App. 2022).

generated by third parties (not the physician); (2) it has unknown predictive value and clinical utility; and (3) because it is new, a clear custom for integrating (or not integrating) it into treatment does not yet exist.

1. Third-Party Generated Medical Data

While doctors have been held liable for failing to act on clinically relevant medical information,[45] the liability question becomes more complex when the physician disregards medical data requested by someone else. For example, in *Oraee v. Breeding*,[46] a doctor saw a patient after the patient presented with symptoms of a stroke.[47] The physician transferred her to another hospital for diagnostic imaging where another physician ordered further blood tests.[48] Those tests indicated that the patient's condition required anticoagulant medications.[49] Because the original doctor never sought or obtained the results, he prescribed antiplatelet medication, and days later the patient suffered another stroke and ultimately died.[50] Experts testified that had she been placed on anticoagulant medication, rather than platelet medication, she would not have suffered the second stroke that killed her.[51]

The doctor claimed immunity based on a Virginia statute insulating physicians "from civil liability for any failure to review, or to take any action in response to the receipt of, any report of the results of any laboratory test or other examination . . . which test or examination such physician neither requested nor authorized in writing . . . ."[52] Although the Virginia Supreme Court had granted immunity in an earlier, and factually similar, case,[53] it overruled that determination and concluded that the physician was not immune (and that the defendant in the earlier

45. For examples, see cases, *supra* note 44.
46. 621 S.E.2d 48 (Va. 2005).
47. *Id.* at 49.
48. *Id.*
49. *Id.* at 50.
50. *Id.*
51. *Id.*
52. VA. CODE ANN. § 8.01-581.18(B) (West 1993). The statute was amended in 2006, to provide more nuance to the immunity provision. It now provides immunity from liability

> for the failure to review or act on the results of laboratory tests or examinations of the physical or mental condition of any patient, which tests or examinations the physician neither requested nor authorized, unless (i) the report of such results is provided directly to the physician by the patient so examined or tested with a request for consultation; (ii) the physician assumes responsibility to review or act on the results; or (iii) the physician has reason to know that in order to manage the specific mental or physical condition of the patient, review of or action on the pending results is needed. VA. CODE ANN. § 8.01-581.18:1(A) (West 2025).

See *infra* Section IV.B for a discussion of other related physician immunity statutes.
53. Auer v. Miller, 613 S.E.2d 421, 423 (Va. 2005).

case should not have been either). In short, it interpreted the statute as granting immunity only when the test result that is not acted upon is "generated as a result of an individual's request, as opposed to *a physician's* request or written authorization . . . ."[54]

The consumer health industry is relatively young, leaving little time for case law to develop. Unfortunately, cases like *Oraee* are not directly on point because they do not address liability for physician action or inaction based on consumer health data; *Oraee* addresses physician action or inaction based on tests ordered by another physician. As the consumer health industry grows, case law will need to adapt to these data-based circumstances.

2. Unverified Predictive Value or Clinical Utility

Another analogous situation arises when there is a "lack of clinical data to evaluate predictive value and clinical utility for many genomic tests . . . ."[55] Professor Gary Merchant et al. describe potential scenarios where this situation could arise, again in the context of breast cancer. With the emergence of genomic tests that can assess the probabilities of cancer recurrence after tumor removal, physicians face uncertainties regarding whether to recommend testing. If they recommend recurrence testing, they may wonder whether to rely on the results to advise the patient either to pursue or forego chemotherapy, even though the chemotherapy may be unnecessary, or the cancer could recur. Similarly, if the physician does not order the test, they may fear liability if the test could have provided information about recurrence, and the patient did not or did pursue chemotherapy, depending on what the test results would have been.[56]

Merchant et al. describe a reported case in which a doctor treated a patient for cancer but did not offer recurrence testing, and the cancer ultimately returned.[57] The patient sued her physician for medical malpractice claiming that, had the testing been done, she would have received a score indicating chemotherapy was recommended, thus preventing the recurrence. The claim was ultimately settled.[58]

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54. *Oraee*, 621 S.E.2d at 52 (emphasis added). As we discuss in Part IV, a few other states have similar kinds of physician immunity legislation. *See infra* Section IV.B.

55. Gary Marchant, Mark Barnes, James P. Evans, Bonnie LeRoy & Susan M. Wolf, *From Genetics to Genomics: Facing the Liability Implications in Clinical Care*, 48 J.L. MED. & ETHICS 11, 22 (2020).

56. *Id.*

57. *Id.*

58. *Metastatic Cancer Originally Diagnosed as Non-Invasive*, VERDICTS & SETTLEMENTS (Va. Laws. Wkly.), Dec. 29, 2014, at 1.

3. Absence of Custom

With any new technology, there is no clear standard of care because the practice has not been around long enough for a custom to develop.[59] But, over time, as a technology is more widely used, common practices will necessarily emerge, and the decisions of providers will shape those standards. Of course, the difficulty is that physicians have little guidance while those customs begin to form.

In jurisdictions that recognize "two schools of thought," the risk of liability may be lower. With respect to consumer health data, the options are somewhat binary — consider the information or don't.[60] Thus, in theory, most physicians would likely be better protected from liability whatever they decide, if it could be shown that there are truly "two schools," with most physicians behaving one way and a "respectable minority" the other way. Being a mere outlier, however, would not likely protect against liability even in these jurisdictions.[61]

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To sum up, unsolicited and unverified consumer-generated health data raise special concerns for medical malpractice law, which recognizes liability for both action and inaction. Doctors do not seek the information, yet once they receive it, they must decide whether to incorporate it into their treatment decisions. And that choice is particularly difficult when the information does not have clear predictive value or established clinical utility, and there is no clear professional custom.

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59. For a discussion of similar issues related to variant reclassification, see generally Jessica L. Roberts & Alexandra L. Foulkes, *Genetic Duties*, 62 WM. & MARY L. REV. 143 (2020).

60. Of course, this construction is a bit oversimplified. Doctors could respond in various ways, ranging from seeking the guidance of a genetic counselor to preemptively prescribing medication. *See, e.g.*, Stacey Pereira, Katrina A. Muñoz, Brent J. Small, Takahiro Soda, Laura N. Torgerson, Clarissa E. Sanchez et al., *Psychiatric Polygenic Risk Scores: Child and Adolescent Psychiatrists' Knowledge, Attitudes, and Experiences*, 189 AM. J. MED. GENETICS 293 (2022).

61. Some scholars argue that physicians should not be liable when offering innovative treatment as long as the patient is fully informed about the conventional alternatives and the deviation from custom. *See* Gideon Parchomovsky & Alex Stein, *Torts and Innovation*, 107 MICH. L. REV. 285, 301–02 (2008). While they note that some courts have upheld those agreements, there are reasons to doubt whether this really protects physicians in most jurisdictions. First, some courts have suggested that consent is irrelevant to whether the physician followed the standard of care. Brady v. Urbas, 111 A.3d 1155, 1159 (Pa. 2015). But even more problematic, this theory is rooted in the idea that a patient can waive her right to sue for malpractice. Courts, however, are especially wary about upholding waivers against liability, particularly with respect to areas of social importance and necessity like medical care. *See, e.g.*, Tunkl v. Regents of Univ. of Cal., 383 P.2d 441 (Cal. 1963) (invalidating an exculpatory clause shielding a research hospital against liability); *see also* Laakmann, *supra* note 31, at 933.

Thus, doctors must decide how to proceed amid both medical and legal uncertainty regarding the consequences of their actions.

III. THE PRS DOUBLE-BIND

The fact that PRSs are directly available to patients — yet have unknown predictive value and clinical utility — creates a double-bind for doctors. If they disregard a relevant PRS, they could potentially be held liable if the patient develops the condition. However, if they recommend treatment and the patient does not develop the condition, doctors could face liability for unnecessary treatment. This Part provides background on PRSs and their limitations in order to explain why these technologies present physicians with difficult choices, should patients share those unsolicited results with their doctors.

A. A Primer on PRS

As explained above, PRSs assess a person's genomic risk for developing a particular condition over the course of their lifetime.[62] While some health conditions are linked to a single gene,[63] others involve several different genes, as well as environmental factors.[64] These latter conditions are called "complex" or "polygenic" (which stands for many genes) diseases.[65] The number and distribution of the contributing genes make it challenging to study the genetic bases of those conditions because studies would need to know about and evaluate the role of each of those genes, some of which we have not yet uncovered. PRSs allow us to learn more about the genetics of complex diseases by comparing the genomes of people who have those conditions with the genomes of people who do not.

The entities generating PRSs tend to rely on preexisting datasets from other genomic studies,[66] often using the results of genome-wide association studies ("GWAS") as their source data.[67] GWAS rapidly scan the genomes of large numbers of people for variants that correlate

62. Importantly, PRSs can be calculated for many traits, not just medical risk. *See supra* note 3.

63. *Polygenic Risk Scores*, *supra* note 3.

64. *Id.*

65. *Id.*

66. *See Genomic Data Sharing: A Two-Part Series*, NAT'L INST. HEALTH: UNDER THE POLISCOPE (Aug. 17, 2015), https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/ [https://perma.cc/2ZKM-6938]; *Genomic Data Sharing Policy Overview*, NAT'L INST. HEALTH SCI. DATA SHARING, https://sharing.nih.gov/genomic-data-sharing-policy/about-genomic-data-sharing/gds-policy-overview [https://perma.cc/KQ5X-SJFT].

67. *See Genome-Wide Association Studies Fact Sheet*, NAT'L INST. HEALTH GENOME RSCH. INST. (Aug. 17, 2020), https://www.genome.gov/about-genomics/fact-sheets/Genome-Wide-Association-Studies-Fact-Sheet [https://perma.cc/8V77-7E5Y].

with a particular disease.[68] Researchers can then use big data analytics to compare the genomes of people with the relevant health condition to people without it. These associations can be used to calculate relative risks of developing a condition,[69] which is a PRS.

Importantly, PRSs have limitations. First, they only reflect relative — not absolute — risk.[70] Most people will find themselves in the middle of the bell curve.[71] Second, PRSs only show correlation, not causation.[72] While this quality is a strength because researchers do not have to identify every gene involved in a complex disease, it is also a weakness because we do not understand what is actually responsible for the health condition, which makes it harder to diagnose or treat. Third, PRSs do not provide a timeframe for disease onset or progression.[73] A person in their twenties and a person in their nineties, for example, could have the same PRSs yet different lifetime risks of developing the disease.[74] Finally, as noted, PRSs are not equally reliable for all populations because almost eighty percent of the individuals included in GWAS are of European descent.[75] One study found that the accuracy of PRSs based on European data was significantly lower for people from other ancestral populations.[76] Reliability decreased by factors of 1.6 for people of American and South Asian descent, 2.0 for people of East Asian descent, and a shocking 4.5 for people of African descent.[77]

PRSs are exciting because they help us understand how genetics contribute to complex diseases. But we still don't know how accurate they are, especially for underrepresented populations; nor do we know whether relying on them actually improves outcomes. While PRSs do not seem ready for clinical use, their commercial availability allows interested patients to obtain that information without the guidance of a doctor. If the patient then shares that data, the physician must decide what to do with information she never wanted in the first place.

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68. *Polygenic Risk Scores*, *supra* note 3; *What Are Genome-Wide Association Studies?*, MEDLINEPLUS (Mar. 22, 2022), https://medlineplus.gov/genetics/understanding/genomicresearch/gwastudies/ [https://perma.cc/35YC-XY6H].

69. *Polygenic Risk Scores*, *supra* note 3.

70. *Id.*

71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.*

75. Giorgio Sirugo, Scott M. Williams & Sarah A. Tishkoff, Commentary, *The Missing Diversity in Human Genetic Studies*, 177 CELL 26, 27–28 (2019); Martin et al., *supra* note 7, at 584, 585 fig.1.

76. Martin et al., *supra* note 7, at 586.

77. *Id.*

B. Challenges for Clinicians

Physicians face both medical and legal uncertainty when confronted with consumer health data. Although they potentially risk liability either for treating or failing to treat, we demonstrate below that the ambiguity in both areas threatens the same outcome: over-treatment.

1. Medical Uncertainty

Choosing whether to act on a PRS can be especially precarious if the PRS is the only available risk assessment tool. Recall the example of a patient who takes an at-home genetic test for breast and ovarian cancer risk. If that individual shares the DTC information with their physician, the doctor can order a BRCA panel to verify the result. However, the opportunity for confirmation is not available for many newer technologies.

In a UK study, for example, physicians were offered cardiovascular risk scores that include PRSs.[78] One commentator viewed cardiovascular disease as a best-case scenario because PRSs are "reasonably informative" for that condition, and absolute-risk models with associated professional guidelines already exist.[79] That is, physicians can verify their patients' risk apart from PRSs; they are not left to rely on PRSs alone. Unfortunately, most conditions don't have reliable alternative risk assessments, thus "the results [of this study are] not generalizable."[80] Even a representative of the company behind the study agreed that the clinical utility of PRSs must be determined on a case-by-case basis.[81] Chances are that if a patient brings a consumer-generated PRS into clinic, their doctor will be left with only the PRS.

Currently, physicians seem to err on the side of treatment. In the cardiovascular study, five percent of study participants were reclassified as high risk based on scores incorporating PRSs and five percent were reclassified as low risk.[82] These discrepancies appear to have influenced clinical decision-making. In about twenty-eight percent of the cases where the PRS-inclusive scores indicated heightened risk, physicians changed their management plans.[83] According to a representative of the company behind the research, doctors felt the risk assessment tool "made the conversation about starting treatment in otherwise

78. Fuat et al., *supra* note 8, at 717.
79. Ray, *supra* note 8.
80. *Id.*
81. *Id.*
82. Fuat et al., *supra* note 8, at 720; Ray, *supra* note 8.
83. Fuat et al., *supra* note 8, at 720; Ray, *supra* note 8.

healthy people much easier because it was more personalized."[84] The study did not report doctors opting *not* to treat individuals whose overall risk was downgraded.[85]

Another study found that, while thirty-five percent of the pediatric psychiatrists surveyed would not request a PRS, ten percent had a patient or family member share a PRS with them in clinic.[86] More than seventy percent of the respondents said they would take some clinical action based on a high psychiatric PRS even absent a diagnosis.[87] The study's authors note that some of those responses would be reasonable, such as requesting genetics consults or evaluating the child for symptoms. Others, however, raise red flags, like encouraging parents to alter their parenting or even preemptively prescribing medications.[88] Thus, the danger of prematurely integrating PRSs into clinical practice may well be over-, not under-, treatment.

2. Legal Uncertainty

Recall that medical malpractice liability often turns on professional custom, which raises concerns in the context of consumer health data because case law has not yet had time to develop. The medical uncertainty described above can compound the legal uncertainty. For example, one could imagine a claim in which a patient shares results from DTC-genetic testing for BRCA mutations with her doctor and the doctor recommends a prophylactic mastectomy, only to discover that the result was a false positive.[89] The difference, however, between a PRS result and a result based on specific variants, like BRCA testing, is that the clinician could seek clinically validated testing for the variant test.[90] The failure to do so, therefore, could potentially subject a physician to liability. Yet as described at length above, a doctor cannot simply verify the PRS result. When faced with ambiguity, physicians have tended to

84. Ray, *supra* note 8.

85. *See* Fuat et al., *supra* note 8.

86. Pereira et al., *supra* note 60, at 299–300.

87. *Id.*

88. *Id.*

89. In at least one case, a woman who had a mastectomy based on results from a study of BRCA mutations discovered years later that her result was a false positive — she was not actually at an increased risk. It is not clear whether a physician had recommended the mastectomy or whether the patient acted on her own accord. *Woman Gets Double Mastectomy After Genetic Test — Then Learns of Misdiagnosis*, TODAY (May 14, 2019), https://www.today.com/video/woman-gets-double-mastectomy-after-genetic-test-then-learns-of-misdiagnosis-59588165887 [https://perma.cc/UH4A-GEVK]. Studies have shown that forty percent of variants described as BRCA mutations based on DTC testing were actually false positives. Stephany Tandy-Connor, Jenna Guiltinan, Kate Krempley, Holly LaDuca, Patrick Reineke, Stephanie Gutierrez et al., *False-Positive Results Released by Direct-to-Consumer Genetic Tests Highlight the Importance of Clinical Confirmation Testing for Appropriate Patient Care*, 20 GENETIC MED. 1515, 1515 (2018).

90. *Supra* notes 19–20 and accompanying text.

favor action over inaction, which can ironically result in the very liability doctors wish to avoid.

Consider the test for maternal serum alpha-fetoprotein ("AFP"), which was used to identify pregnancies at increased risk for Down syndrome. When the test was still new, the American College of Obstetrics and Gynecology ("ACOG") stated that "routine maternal serum AFP screening of all [pregnant women] is of uncertain value,"[91] making clear it should not yet become the standard of care.[92] But just a few years later, ACOG's Department of Liability issued an "Alert," called "Professional Liability Implications of APT Tests." Responding to the high risks of litigation in obstetrics, the Alert declared that it was "imperative that every prenatal patient be advised about the availability of this test and that discussion about the test and the patient's decision with respect to the test be documented in the patient's chart."[93] Thus, despite the uncertain value of routinely offering this test, fears of liability created a new standard of care.[94] In fact, this history influenced professional communities to be particularly cautious about carrier screening for cystic fibrosis ("CF") when those tests first became available. In the initial years, professional groups declared that carrier testing for CF should only be offered to those at increased risk.[95] After several years, when more information showed the validity of this screening, professional guidelines reflected the emerging view that such testing *should* be offered to all people planning pregnancies or currently pregnant.[96]

Scholars have raised the same concern about defensive medicine when reinterpreting genetic test results.[97] As we learn more about the clinical significance (or insignificance) of various genetic variants, those variants may be reclassified, for example from uncertain to

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91. AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, TECHNICAL BULLETIN NO. 68, PRENATAL DETECT OF NEURAL TUBE DEFECTS 6 (1982).

92. Sonia M. Suter, *The Routinization of Prenatal Testing*, 28 AM. J.L. & MED. 233, 252 (2002).

93. Sherman Elias, George J. Annas & Joe Leigh Simpson, *Carrier Screening for Cystic Fibrosis: A Case Study in Setting Standards of Medical Practice*, *in* GENE MAPPING: USING LAW AND ETHICS AS GUIDES 186, 197 (George J. Annas & Sherman Elias eds., 1992).

94. Suter*, supra* note 92, at 252–53.

95. Komal Bajal & Susan J. Gross, *Carrier Screening: Past, Present, and Future*, 3 J. CLINICAL MED. 1033, 1035 (2014).

96. *Carrier Screening for Genetic Conditions*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Mar. 2017), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/03/carrier-screening-for-genetic-conditions [https://perma.cc/44W7-8BJY].

97. *See* Marchant et al., *supra* note 55, at 16; Barbara J. Evans, *Minimizing Liability Risks Under the ACMG Recommendations for Reporting Incidental Findings in Clinical Exome and Genome Sequencing*, 15 GENETICS MED. 915, 919 (2013).

pathogenic or from uncertain to benign.[98] Reclassification raises questions as to whether clinicians and laboratories have legal obligations to reinterpret previously returned results.[99] Ellen Clayton et al. note that offering reinterpretation when the standard of care does not clearly require it increases the risk of liability because "[u]ndertaking duties the law does not strictly require can nevertheless influence the standard of care."[100]

The dangers of inadvertently creating a professional custom are particularly acute for consumer-generated PRSs because the physicians most likely to receive this data will not be geneticists. Without expertise in genetics, a doctor may not appreciate the complexities and limitations of these tests. Moreover, physicians untrained in genetics may be more likely to find the information valuable and clinically relevant.[101] In other contexts, a belief in the power and objectivity of genetics can distort perspectives about genetic information. For example, jurors and even investigators often attribute to forensic genetic information an infallibility that may not be present.[102] It would not be surprising therefore to see the allure of using PRSs to make clinical judgments in fields like cardiology and psychiatry. Undue faith in the value of this information might even heighten the fear of liability for *failing* to rely on PRSs, even if the standard of care does not demand that. In other words, physicians in these contexts might paradoxically create a standard of care where none initially existed.

Tort remedies also seem to support action over inaction when the standard of care is ambiguous. The potential damages for a wrongful death claim if a patient dies after a physician fails to recommend treatment are likely to be far greater than damages for unnecessary procedures or treatment protocols. Thus, a risk averse physician might tend

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98. *See* Nicola Walsh, Aislinn Cooper, Adrian Dockery & James J. O'Byrne, *Variant Reclassification and Clinical Implications*, 61 J. MED. GENETICS 207, 208 (2024). This review explores the medical and scientific literature available on variant reclassification, focusing on its clinical implications.

99. *See* Roberts & Foulkes, *supra* note 59, at 177.

100. Clayton et al., *supra* note 26, at 834.

101. Troublingly, Pereira et al, *supra* note 60, found that the respondents who "reported greater self-rated knowledge about PRS, and thus may feel more confident making clinical decisions based on PRS, were more likely to indicate they would recommend medications to decrease risk for children with no diagnosis but a high-psychiatric PRS. Interestingly, those who performed well on the PRS Graph Interpretation task were less likely to say they would prescribe medications." They conclude that their findings "suggest[] that these two groups — those with greater self-rated knowledge and those who interpreted the graph correctly — do not comprise the same people." *Id.* at 300. Thus, non-genetic specialists who have some familiarity with genetics may actually be more likely to overvalue PRS.

102. *See* John Alldredge, *The "CSI Effect" and Its Potential Impact on Juror Decisions*, 3 RSCH. J. JUST. STUD. & FORENSIC SCI. 113, 115 (2015) (describing the CSI effect as leading "jurors to have unrealistic expectations of forensic tests and possibly cause them to incorrectly weigh the importance of either the absence or presence of forensic evidence"); Sonia M. Suter, *All in the Family: Privacy and DNA Familial Searching*, 23 HARV. J.L. & TECH. 310, 386 (2010).

to err on the side of action as opposed to inaction.[103] Perhaps then it is not surprising that doctors in the United Kingdom[104] and pediatric psychiatry studies[105] indicated they were more likely to consider — and not disregard — PRSs.

It is worth noting, however, that what constitutes overtreatment varies tremendously by situation. As we use the term here, we understand it as more healthcare than is needed to treat the patient appropriately. For example, if a patient chooses "watchful waiting" in response to a diagnosis,[106] then overtreatment could be as simple as requiring more testing during the waiting period than otherwise called for.

* * *

DTC PRSs provide a useful case study for understanding the dilemma that doctors face when there is a fair amount of uncertainty about the medical implications and the precise liability risk of responding to or ignoring this information, or any area of medical innovation. This uncertainty can push physicians to act in ways that actually create greater liability. The potential result is not only that doctors generate the very liability that they were hoping to avoid but that patients are at a real risk of overtreatment. The next Part explores how the law could help avoid these undesirable outcomes.

IV. SOLUTIONS

Unverified consumer health technologies put both patients and their doctors at risk. As explained above, doctors tend to err on the side of acting, which can harm both parties. Patients may experience time-consuming, stressful, and expensive, but potentially unnecessary, medical intervention. Physicians may create professional customs, and face potential legal liability, based not on their clinical best judgment but on risk aversion. We therefore propose solutions to mitigate liability and hopefully avoid these unwelcome consequences.

As noted, we recognize that our suggestions do not address the root of the problem: potentially dangerous consumer products and services that often escape regulation. Preventing ineffective or even harmful technology from going to market at all would be the best solution.

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103. *Cf.* Sonia M. Suter, *Genomic Medicine — New Norms Regarding Genetic Information*, 15 HOUS. J. HEALTH L. & POL'Y 83, 119–22 (2015).

104. *See supra* text accompanying notes 78–81.

105. *See supra* text accompanying notes 86–88.

106. Leslie Rittenmeyer, Dolores Huffman, Michael Alagna & Ellen Moore, *The Experience of Adults Who Choose Watchful Waiting or Active Surveillance as an Approach to Medical Treatment: A Qualitative Systematic Review*, 14 JBI DATABASE SYSTEMATIC REV. & IMPLEMENTATION REPS. 174, 174 (2016).

However, that outcome seems unlikely in the near-term, thus, we propose professional guidelines and physician immunity legislation.

A. Responding to Medical Uncertainty: Professional Guidance on PRS

Recall that the standard of care often relies on custom. While not decisive, clinical practice guidelines ("CPGs") influence how courts make that determination.[107] Some courts allow defendants to use CPGs to establish the standard of care or weigh them heavily when deciding what the standard is.[108] Others explicitly note that guidelines are "just guidelines" and therefore do not establish the standard of care.[109] Even if they do not define the standard of care, they influence the profession's behavior. Thus, CPGs could help doctors navigate the handling of consumer health data. Moreover, they may indirectly shape the standard of care by promoting or discouraging certain practices that influence professional custom.

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107. *See* Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 663 (2001); Carter L. Williams, *Evidence-Based Medicine in the Law Beyond Clinical Practice Guidelines: What Effect Will EBM Have on the Standard of Care?*, 61 WASH. & LEE L. REV. 479, 483 (2004); Conn v. United States, 880 F.Supp.2d 741, 745 (S.D. Miss. 2012).

108. Gerace v. United States, No. 03-CV-166, 2006 WL 2376696, at *24–25 (N.D.N.Y. Aug. 10, 2006); Dannenberg v. United States, No. 04-CV-4897, 2010 WL 4851341, at *6–7 (E.D.N.Y. Nov. 22, 2010); Lasser v. Reliance Standard Life Ins. Co., 130 F.Supp.2d 616, 622 (D.N.J. 2001). The Tentative Draft of the *Restatement (Third) of Torts: Medical Malpractice* includes a provision stating that "[p]roof that the provider complied with a practice guideline established by an authoritative body is sufficient to support, although not to compel, a finding that the provider did not breach the standard of care." RESTATEMENT (THIRD) OF TORTS: MEDICAL MALPRACTICE § 6(b) (AM. L. INST., Tentative Draft No. 2, 2024). The Draft acknowledges that "there is only limited case-law support" for this position, but it concludes that

> allowing the defendant-provider to rely on a relevant practice guideline established by an authoritative body is appropriate for three reasons. First, considering the results of an authoritative body's deliberations avoids the subjective elements that often characterize an individual expert's judgments about competent medical practice. Second, authoritative bodies generally can be expected to reflect collective professional opinion more reliably than experts hand-picked by a party's lawyer. Third, because such standards often aim to set an optimal level of care, compliance often reflects a margin of performance above merely competent care. *Id.*, cmt. f.

The Draft, however, describes its "endorsement of authoritative guidelines [as] asymmetric." In other words, it "permits authoritative practice guidelines to substitute for expert testimony only when the guidelines support compliance with, but not to establish a violation of, [the] standard of care." *Id.*

109. Estate of LaFarge *ex rel*. Blizzard v. Kyker, No. 08-CV-185, 2011 WL 6151595, at *3 (N.D. Miss. Dec. 12, 2011); *see also* Porter v. McHugh, 850 F.Supp.2d 264, 268 (D.D.C. 2012); Diaz v. N.Y. Downtown Hosp., 784 N.E.2d 68, 70 (N.Y. 2002); Levine v. Rosen, 616 A.2d 623, 628 (Pa. 1992); Greathouse v. Rhodes, 618 N.W.2d 106, 109 (Mich. Ct. App. 2000), *rev'd on other grounds*, 636 N.W.2d 138 (Mich. 2001).

Thankfully, some professional organizations have already issued guidance regarding PRSs, although some may not go far enough. The American Society of Human Genetics ("ASHG") made three key recommendations in December 2022:

(1) Develop diverse research cohorts and analyses.

(2) Foster robustness in scientific development, validation, application, and interpretation of PRSs.

(3) Accompany research products with communications materials for broad, non-specialist audiences.[110]

Of these three recommendations, the second and third are most relevant to this article. The insistence on developing validation and application for PRSs underscores the fact that these tests are largely not ready for widespread clinical use. In the full discussion of the third recommendation, the guidance emphasizes the importance of communication "to mitigate unintended consequences of research and *downstream application* of [PRSs]."[111] The focus on adequate communication is directed in part to prevent the public's misunderstanding of PRSs, but also to ensure that when PRSs are still in the research stage, communication "discourage[s] inappropriate or premature application of these metrics by, for example, direct-to-consumer genetic-testing companies."[112] Although these concerns imply that PRSs are not yet ready for use in treatment decisions, the guidance makes no such affirmative statement. Thus, to the extent that the guidance can be inferred to describe the appropriate standard of care for providers who receive these results from patients, it is far too indirect.

The American College of Medical Genetics and Genomics ("ACMG") has been more decisive. That organization focused on questions about PRS in the context of embryo selection,[113] pointing to many of the issues discussed by Dov Fox et al. in this issue.[114] The bottom line of this guidance is that the use of PRSs for embryo selection "to reduce disease burden remains 'unproven' and must be established through further research and longitudinal studies before the test can be

110. John Novembre, Catherine Stein, Samira Asgari, Claudia Gonazaga-Jauregui, Andrew Landstrom, Amy Lemke et al., *Addressing the Challenges of Polygenic Scores in Human Genetic Research*, 109 AM. J. HUM. GENETICS 2095, 2096 (2022).

111. *Id.* at 2097 (emphasis added).

112. *Id.* at 2098.

113. Theresa A. Grebe, George Khushf, John M. Greally, Patrick Turley, Nastaran Foyouzi, Sara Rabin-Havt et al., *Clinical Utility of Polygenic Risk Scores for Embryo Selection: A Points to Consider Statement of the American College of Medical Genetics and Genomics (ACMG)*, 26 GENETICS MED., Apr. 2024, at 1.

114. Dov Fox, Sonia M. Suter, Meghna Mukherjee, Stacey Pereira & Gabriel Lázaro-Muñoz, *Choosing Your "Healthiest" Embryo After* Dobbs*: Polygenic Screening and Distinctive Challenges for Truth in Advertising and Informed Consent*, 38 HARV. J.L. & TECH. 463 (2024).

responsibly offered."[115] Further, it finds that "the risks outweigh the benefits" to the extent that there is "concern for individual harm to either the prospective parent or the future child."[116] Ultimately, it concludes quite directly that embryo selection "should not be offered as a clinical service."[117] While this statement alone does not necessarily reflect the actual custom within clinical medicine, its pointed conclusion cautions clinicians not to pursue these clinical uses. It may even provide some reassurance that they are not at great risk for liability should they forego the use of PRSs in this context.

And finally, the Electronic Medical Records and Genomics ("eMERGE") Network, funded by the National Human Genome Research Institute, developed frameworks and processes for returning PRS-based risk assessments to patients, designed "to inform the approach needed to implement PRS-based testing in diverse clinical settings."[118] While not a CPG per se, the eMERGE study, and others like it, could also influence clinical practice in this area.

CPGs could go a long way in deterring over-treatment based on DTC PRSs. When they are indirect as to what clinicians should do, as in the case of the ASHG guidance, they will not be helpful. However, more pointed guidance could assist clinicians in navigating uncertainty. Although even explicit statements like the ACMG guidance may not define the standard of care in all jurisdictions, its specific directive may help clinicians create a custom that aligns with the guidance. And thus, even if the guidance in those jurisdictions doesn't itself determine the standard, it will have shaped the custom that evolves. Thus, we encourage professional organizations to explicitly advise physicians against relying on unvalidated DTC PRSs and other unverifiable, consumer-generated health data to avoid over-treating patients.

B. Responding to Legal Uncertainty: Physician Immunity Statutes

Although we see great value in promulgating clear practice guidelines, we also recommend statutory protections for at least two reasons. First, courts may not find CPGs dispositive when deciding the standard of care, thus they only offer physicians limited protection. Second, CPGs must recommend a particular course of action. While we favor recommendations against using unvalidated PRSs in treatment decisions to offset the current incentives for over-treatment, this response

115. Grebe et al., *supra* note 113, at 11.

116. *Id.*

117. *Id.*

118. Niall J. Lennon, Leah C. Kottyan, Christopher Kachulis, Noura S. Abul-Husn, Josh Arias, Gillian Belbin et al., *Selection, Optimization and Validation of Ten Chronic Disease Polygenic Risk Scores for Clinical Implementation in Diverse U.S. Populations*, 30 NATURE MED. 480, 480 (2024).

may be too blunt an instrument. There may be certain instances where a PRS, even a consumer-generated one, might lead to better outcomes for the patient, such as early diagnosis and treatment or even preventing disease onset. Patients who seek DTC PRSs clearly find that information relevant, otherwise they would not share it with their physicians. Thus, foreclosing the option of considering it at all discounts the preferences of patients. As a result, we believe that physician immunity statutes, which would insulate doctors from liability for both action and inaction, are optimal. They allow doctors to act based on their medical judgment, not their fear of liability, while considering data deemed valuable by their patients.

A few states — Virginia,[119] California,[120] and Arizona[121] — have statutes that provide immunity from liability for physicians who fail to act on the results of tests they did not order. Recall that a doctor attempted to invoke the Virginia statute and failed.[122] Importantly, those statutes, which include a variety of exceptions, only protect doctors from *failing* to act. By contrast, the statute we envision would protect physicians from liability for both action and inaction based on unverifiable, consumer-generated health data as opposed to clinically accepted tests ordered by another doctor. Our goal is to allow physicians to do what they think is right under the specific circumstances without fear of liability in either direction. Moreover, once the health information in question has been validated or invalidated, the statute would no longer apply. Thus, if a PRS has clear predictive value and clinical utility, a physician could not simply ignore it. Alternatively, if a PRS is found to be junk science, a doctor could not rely on it to recommend treatment. Our proposed statute would only apply where the validity of consumer-generated health data is unknown.[123] Once information on predictive value and clinical validity is available, immunity would no longer apply.

Of course, this proposal may seem premature. Would it be a better long-term strategy to see how cases might play out, letting the tort system determine what conduct is acceptable and what should result in liability? Without the threat of liability, physicians might be tempted to take on risks that they might otherwise avoid, ultimately harming patients. Yet while those concerns might arise in other contexts, we're

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119. VA. CODE ANN. § 8.01-581.18:1(A) (West 2024) ("Immunity of physicians for laboratory results and examinations.").

120. CAL. CIVIL CODE § 43.9(c) (West 2024). The statute defines a "multiphasic screening unit" as "a facility which does not prescribe or treat patients but performs diagnostic testing only." *Id.* at § 43.9(d)(4).

121. ARIZ. REV. STAT. § 36-468(C). ("Laboratory testing without health care provider's order; results; report; duty of care; liability; definition.").

122. *See supra* notes 52–54 and accompanying text.

123. What constitutes "validation" will vary depending on the type of data and is outside the scope of this Article.

confident that our intervention is sufficiently narrow. The trigger for the immunity is patient — not physician — conduct. That is, a patient must bring consumer-generated health data to their provider for the immunity provision to apply. Next, that data must have unknown predictive value and clinical validity, thus presenting doctors with uncertainty. Only then could a doctor benefit from immunity. Because early evidence shows that physicians confronted with uncertainty err on the side of treatment because they fear liability, perhaps immunity provisions like these will prevent overtreatment. Our hope is that immunizing physicians will allow them to act based on their professional opinion, resulting in optimal outcomes for patients despite the current uncertainty.

V. CONCLUSION

PRSs offer a real-world opportunity to understand the risks that unverified, consumer-generated health data carry for both patients and doctors. While PRSs may help us better unpack the genetics of complex diseases, their analytic and clinical validity are still unknown, making it premature to bring them into the clinic. Yet while doctors do not regularly order PRSs for their patients, individuals can obtain those scores directly from companies and websites. Unfortunately, offering PRSs to consumers without the aid of a physician intermediary not only makes consumers vulnerable, but it could also subject doctors to malpractice liability. At present, physicians seem to respond to these medical and legal uncertainties by recommending treatment. Although the best response would be to prevent companies from hawking ineffective or even dangerous products and services, the current lack of regulation over consumer health technologies renders this solution unlikely. As a result, we advocate professional guidance and physician immunity statutes as possible second-order solutions when patients share consumer-generated health information with their doctors. Physician immunity statutes are particularly appealing, as they permit doctors to exercise discretion regarding whether to act in the given situation. Technology is outpacing our ability to assess its validity, and this trend will surely continue. As a society, we need to do more to protect patients and their doctors.